

Terms and AI Act Articles

0 Acceptability

0 Acceptance criteria

33 Access (See also: *Accessibility*)

- Art. 3. (44):** 'publicly accessible space' means any publicly or privately owned physical place accessible to an undetermined number of natural persons, regardless of whether certain conditions for access may apply, and regardless of the potential capacity restrictions;
- Art. 10. 5(c):** the special categories of personal data are subject to measures to ensure that the personal data processed are secured, protected, subject to suitable safeguards, including strict controls and documentation of the access, to avoid misuse and ensure that only authorised persons have access to those personal data with appropriate confidentiality obligations;
- Art. 17. (j):** the handling of communication with national competent authorities, other relevant authorities, including those providing or supporting the access to data, notified bodies, other operators, customers or other interested parties;
- Art. 21. 2:** Upon a reasoned request by a competent authority, providers shall also give the requesting competent authority, as applicable, access to the automatically generated logs of the high-risk AI system referred to in Article 12(1), to the extent such logs are under their control.
- Art. 22. 3(c):** provide a competent authority upon a reasoned request, with all the information and documentation, including that referred to in point (b) of this subparagraph, necessary to demonstrate the conformity of a high-risk AI system with the requirements set out in Section 2, including access to the logs, as referred to in Article 12(1), automatically generated by the high-risk AI system, to the extent such logs are under the control of the provider;
- Art. 25. 2:** Where the circumstances referred to in paragraph 1 occur, the provider that initially placed the AI system on the market or put it into service shall no longer be considered to be a provider of that specific AI system for the purposes of this Regulation. That initial provider shall closely cooperate with new providers and shall be available the necessary information and the reasonable expected technical access and other assistance that are required for the fulfilment of the obligations set out in this Regulation, in particular regarding the compliance with the conformity assessment of high-risk AI systems. This paragraph shall not apply in cases where the initial provider has clearly specified that its AI system is not to be changed into a high-risk AI system and therefore does not fall under the obligation to hand over the documentation.
- Art. 25. 4:** The provider of a high-risk AI system and the third party that supplies an AI system, tools, services, components, or processes that are used or integrated in a high-risk AI system shall, by written agreement, specify the necessary information, capabilities, technical access and other assistance based on the generally acknowledged state of the art, in order to enable the provider of the high-risk AI system to fully comply with the obligations set out in this Regulation. This paragraph shall not apply to third parties making accessible to the public tools, services, processes, or components, other than general-purpose AI models, under a free and open-source licence. The AI Office may develop and recommend voluntary model terms for contracts between providers of high-risk AI systems and third parties that supply tools, services, components or processes that are used for or integrated into high-risk AI systems. When developing those voluntary model terms, the AI Office shall take into account possible contractual requirements applicable in specific sectors or business cases. The voluntary model terms shall be published and be available free of charge in an easily usable electronic format.
- Art. 49. 4(d):** points 1, 2, 3 and 5, of Annex IX. Only the Commission and national authorities referred to in Article 74(8) shall have access to the respective restricted sections of the EU database listed in the first subparagraph of this paragraph.
- Art. 53. 2:** The obligations set out in paragraph 1, points (a) and (b), shall not apply to providers of AI models that are released under a free and open-source licence that allows for the access, usage, modification, and distribution of the model, and whose parameters, including the weights, the information on the model architecture, and the information on model usage, are made publicly available. This exception shall not apply to general-purpose AI models with systemic risks.
- Art. 54. 6:** The obligation set out in this Article shall not apply to providers of general-purpose AI models that are released under a free and open-source licence that allows for the access, usage, modification, and distribution of the model, and whose parameters, including the weights, the information on the model architecture, and the information on model usage, are made publicly available, unless the general-purpose AI models present systemic risks.
- Art. 57. 8:** Subject to the confidentiality provisions in Article 78, and with the agreement of the provider or prospective provider, the Commission and the Board shall be authorised to access the exit reports and shall take them into account, as appropriate, when exercising their tasks under this Regulation. If both the provider or prospective provider and the national competent authority explicitly agree, the exit report may be made publicly available through the single information platform referred to in this Article.
- Art. 57. 9(a):** facilitating and accelerating access to the Union market for AI systems, in particular when provided by SMEs; including start-ups.
- Art. 57. 10:** National competent authorities shall ensure that, to the extent the innovative AI systems involve the processing of personal data or otherwise fall under the supervisory remit of other national authorities or competent authorities providing or supporting access to data, the national data protection authorities and those other national or competent authorities are associated with the operation of the AI regulatory sandbox and involved in the supervision of those aspects to the extent of their respective tasks and powers.
- Art. 58. 2(b):** that AI regulatory sandboxes also broad and equal access and keep up with demand for participation; providers and prospective providers may also submit applications in partnerships with deployers and other relevant third parties;
- Art. 58. 2(c):** that access to the AI regulatory sandboxes is free of charge for SMEs, including start-ups, without prejudice to exceptional costs that national competent authorities may recover in a fair and proportionate manner.
- Art. 59. 1(d):** any personal data to be processed in the context of the sandbox are in a functionally separate, isolated and protected data processing environment under the control of the prospective provider and only authorised persons have access to those data;
- Art. 62. 1(a):** provide SMEs, including start-ups, having a registered office or a branch in the Union, with priority access to the AI regulatory sandboxes, to the extent that they fulfil the eligibility conditions and selection criteria; the priority access shall not preclude other SMEs, including start-ups, other than those referred to in this paragraph from access to the AI regulatory sandbox, provided that they also fulfil the eligibility conditions and selection criteria;
- Art. 69:** Access to the pool of experts by the Member States
- Art. 69. 2:** The Member States may be required to pay fees for the advice and support provided by the experts. The structure and the level of fees as well as the scale and structure of recoverable costs shall be set out in the implementing act referred to in Article 68(1), taking into account the objectives of the adequate implementation of this Regulation, cost-effectiveness and the necessity of ensuring effective access to experts for all Member States.
- Art. 69. 3:** The Commission shall facilitate timely access to the experts by the Member States, as needed, and ensure that the combination of support activities carried out by Union AI testing support pursuant to Article 84 and experts pursuant to this Article is efficiently organised and provides the best possible added value.
- Art. 74. 12:** Without prejudice to the powers provided for under Regulation (EU) 2019/1020, and where relevant and limited to what is necessary to fulfil their tasks, the market surveillance authorities shall be granted full access by providers to the documentation as well as the training, validation and testing data sets used for the development of high-risk AI systems, including, where appropriate and subject to security safeguards, through application programming interfaces (API) or other relevant technical means and tools enabling remote access.
- Art. 74. 13:** Market surveillance authorities shall be granted access to the source code of the high-risk AI system upon a reasoned request and only when both of the following conditions are fulfilled:
- Art. 74. 13(a):** access to source code is necessary to assess the conformity of a high-risk AI system with the requirements set out in Chapter III, Section 2; and
- Art. 75. 3:** Where a market surveillance authority is unable to conclude its investigation of the high-risk AI system because of its inability to access certain information related to the general-purpose AI model despite having made all appropriate efforts to obtain that information, it may submit a reasoned request to the AI Office, by which access to that information shall be enforced. In that case, the AI Office shall supply to the applicant authority without delay, and in any event within 30 days, any information that the AI Office considers to be relevant in order to establish whether a high-risk AI system is non-compliant. Market surveillance authorities shall safeguard the confidentiality of the information that they obtain in accordance with Article 78 of this Regulation. The procedure provided for in Chapter VI of Regulation (EU) 2019/1020 shall apply mutatis mutandis.
- Art. 77. 1:** National public authorities or bodies which supervise or enforce the respect of obligations under Union law protecting fundamental rights, including the right to non-discrimination, in relation to the use of high-risk AI systems referred to in Annex III shall have the power to request and access any documentation created or maintained under this Regulation in accessible language and format when access to that documentation is necessary for effectively fulfilling their mandates within the limits of their jurisdiction. The relevant public authority or body shall inform the market surveillance authority of the Member State concerned of any such request.
- Art. 78. 3:** Without prejudice to paragraphs 1 and 2, information exchanged on a confidential basis between the national competent authorities or between national competent authorities and the Commission shall not be disclosed without prior consultation of the originating national competent authority and the deployer when high-risk AI systems referred to in point 1, 6 or 7 of Annex III are used by law enforcement, border control, immigration or asylum authorities and when such disclosure would jeopardise public and national security interests. This exchange of information shall not cover sensitive operational data in relation to the activities of law enforcement, border control, immigration or asylum authorities. When the law enforcement, immigration or asylum authorities are providers of high-risk AI systems referred to in point 1, 6 or 7 of Annex III, the technical documentation referred to in Annex IV shall remain within the premises of those authorities. Those authorities shall ensure that the market surveillance authorities referred to in Article 74(8) and (9), as applicable, can, upon request, immediately access the documentation or obtain a copy thereof. Only staff of the market surveillance authority holding the appropriate level of security clearance shall be allowed to access that documentation or any copy thereof.
- Art. 91. 3:** Upon a duly substantiated request from the scientific panel, the Commission may issue a request for information to a provider of a general-purpose AI model, where the access to information is necessary and proportionate for the fulfilment of the tasks of the scientific panel under Article 68(2).
- Art. 92. 3:** For the purposes of paragraph 1, the Commission may request access to the general-purpose AI model concerned through APIs or further appropriate technical means and tools, including source code.
- Art. 92. 4:** The request for access shall state the legal basis, the purpose and reasons of the request and set the period within which the access is to be provided, and the fines provided for in Article 101 for failure to provide access.
- Art. 92. 5:** The provider of a general-purpose AI model or its representative shall submit the information requested. In the case of legal persons, companies or firms, or where the provider has no legal personality, the persons authorised to represent them by law or by their statutes, shall provide the access requested on behalf of the provider of the general-purpose AI model concerned.
- Art. 92. 7:** Prior to requesting access to the general-purpose AI model concerned, the AI Office may initiate a structured dialogue with the provider of the general-purpose AI model to gather more information on the internal testing of the model, internal safeguards for preventing systemic risks, and other internal procedures and measures the provider has taken to mitigate such risks.
- Art. 100. 5:** The rights of defence of the parties concerned shall be fully respected in the proceedings. They shall be entitled to have access to the European Data Protection Supervisor's file, subject to the legitimate interest of individuals or undertakings in the protection of their personal data or business secrets.
- Art. 101. 1(d):** failed to make available to the Commission access to the general-purpose AI model or general-purpose AI model with systemic risk with a view to conducting an evaluation pursuant to Article 92. In fixing the amount of the fine or periodic penalty payment, regard shall be had to the nature, gravity and duration of the infringement, taking due account of the principles of proportionality and appropriateness. The Commission shall also take into account commitments made in accordance with Article 93(3) or made in relevant codes of practice in accordance with Article 56.

0 Access control

4 Accessibility (See also: *Access*)

- Art. 16. (f):** ensure that the high-risk AI system complies with accessibility requirements in accordance with Directives (EU) 2016/2102 and (EU) 2019/882.
- Art. 50. 5:** The information referred to in paragraphs 1 to 4 shall be provided to the natural persons concerned in a clear and distinguishable manner at the latest at the time of the first interaction or exposure. The information shall conform to the applicable accessibility requirements.
- Art. 50. 6:** The Commission shall be responsible for the design and implementation of the programme of measures referred to in Article 50(5) and shall be supported by the administrative and administrative support. The EU database shall comply with the applicable accessibility requirements.
- Art. 95. 2(a):** assessing and preventing the negative impact of AI systems on vulnerable persons or groups of vulnerable persons, including as regards accessibility for persons with a disability, as well as on gender equality.

2 Accountability

- Art. 17. 1(m):** an accountability framework setting out the responsibilities of the management and other staff with regard to all the aspects listed in this paragraph.
- Art. 66. (e)(vi):** trends on the evolving typology of AI value chains, in particular on the resulting implications in terms of accountability;

6 Accuracy (See also: *Free of errors*)

- Art. 13. 3(b)(ii):** the level of accuracy, including its metrics, robustness and cybersecurity referred to in Article 15 against which the high-risk AI system has been tested and validated and which can be expected, and any known and foreseeable circumstances that may have an impact on that expected level of accuracy, robustness and cybersecurity;
- Art. 15:** Accuracy, robustness and cybersecurity
- Art. 15. 1:** High-risk AI systems shall be designed and developed in such a way that they achieve an appropriate level of accuracy, robustness, and cybersecurity, and that they perform consistently in those respects throughout their lifecycle.
- Art. 15. 2:** To address the technical aspects of how to measure the appropriate levels of accuracy and robustness set out in paragraph 1 and any other relevant performance metrics, the Commission shall, in cooperation with relevant stakeholders and organisations such as metrology and benchmarking authorities, encourage, as appropriate, the development of benchmarks and measurement methodologies.
- Art. 15. 3:** The levels of accuracy and the relevant accuracy metrics of high-risk AI systems shall be declared in the accompanying instructions of use.
- Art. 56. 2(a):** the means to ensure that the information referred to in Article 53(1), points (a) and (b), is kept up to date in light of market and technological developments;

1 Acquisition

- Art. 17. 1(f):** systems and procedures for data management, including data acquisition, data collection, data analysis, data labelling, data storage, data filtration, data mining, data aggregation, data retention and any other operation regarding the data that is performed before and for the purpose of the placing on the market or the putting into service of high-risk AI systems;

16 Administrative fine

- Art. 57. 12:** Providers and prospective providers participating in the AI regulatory sandbox shall remain liable under applicable Union and national liability law for any damage inflicted on third parties as a result of the experimentation taking place in the sandbox. However, provided that the prospective providers observe the specific plan and the terms and conditions for their participation and follow in good faith the guidance given by the national competent authority, no administrative fines shall be imposed by the authorities for infringements of this Regulation. Where other competent authorities responsible for other Union and national law were actively involved in the supervision of the AI system in the sandbox and provided guidance for compliance, no administrative fines shall be imposed regarding that law.
- Art. 99. 3:** Non-compliance with the prohibition of the AI practices referred to in Article 5 shall be subject to administrative fines of up to EUR 35 000 000 or, if the offender is an undertaking, up to 7 % of its total worldwide annual turnover for the preceding financial year, whichever is higher.
- Art. 99. 4:** Non-compliance with any of the following provisions related to operators or notified bodies, other than those laid down in Articles 5, shall be subject to administrative fines of up to EUR 15 000 000 or, if the offender is an undertaking, up to 3 % of its total worldwide annual turnover for the preceding financial year, whichever is higher:
- Art. 99. 5:** The supply of false or misleading information to notified bodies or national competent authorities in reply to a request shall be subject to administrative fines of up to EUR 7 500 000 or, if the offender is an undertaking, up to 1 % of its total worldwide annual turnover for the preceding financial year, whichever is higher.
- Art. 99. 7:** When deciding whether to impose an administrative fine and when deciding on the amount of the administrative fine in each individual case, all relevant circumstances of the specific situation shall be taken into account and, as appropriate, regard shall be given to the following:
- Art. 99. 7(b):** whether administrative fines have already been applied by other market surveillance authorities to the same operator for the same infringement;
- Art. 99. 7(c):** whether administrative fines have already been applied by other authorities to the same operator for infringements of other Union or national law, when such infringements result from the same activity or omission constituting a relevant infringement of this Regulation;
- Art. 99. 8:** Each Member State shall lay down rules on to what extent administrative fines may be imposed on public authorities and bodies established in that Member State.
- Art. 99. 9:** Depending on the legal system of the Member States, the rules on administrative fines may be applied in such a manner that the fines are imposed by competent national courts or by other bodies, as applicable in those Member States. The application of such rules in those Member States shall have an equivalent effect.
- Art. 99. 11:** Member States shall, on an annual basis, report to the Commission about the administrative fines they have issued during that year, in accordance with this Article, and about any related litigation or judicial proceedings.
- Art. 100:** Administrative fines on Union institutions, bodies, offices and agencies
- Art. 100. 1:** The European Data Protection Supervisor may impose administrative fines on Union institutions, bodies, offices and agencies falling within the scope of this Regulation. When deciding whether to impose an administrative fine and when deciding on the amount of the administrative fine in each individual case, all relevant circumstances of the specific situation shall be taken into account and due regard shall be given to the following:
- Art. 100. 2:** Non-compliance with the prohibition of the AI practices referred to in Article 5 shall be subject to administrative fines of up to EUR 1 500 000.
- Art. 100. 3:** The non-compliance of the AI system with any requirements or obligations under this Regulation, other than those laid down in Article 5, shall be subject to administrative fines of up to EUR 750 000.
- Art. 100. 7:** The European Data Protection Supervisor shall, on an annual basis, notify the Commission of the administrative fines it has imposed pursuant to this Article and of any litigation or judicial proceedings it has initiated.
- Art. 112. 4(b):** the state of penalties, in particular administrative fines as referred to in Article 99(1), applied by Member States for infringements of this Regulation;

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14 Advisory forum

Art. 40, 2: In accordance with Article 10 of Regulation (EU) No 1025/2012, the Commission shall issue, without undue delay, standardisation requests covering all requirements set out in Section 2 of this Chapter and, as applicable, standardisation requests covering obligations set out in Chapter V, Sections 2 and 3, of this Regulation. The standardisation request shall also ask for deliverables on reporting and documentation processes to improve AI systems' resource performance, such as reducing the high-risk AI system's consumption of energy and of other resources during its lifecycle, and on the energy-efficient development of general-purpose AI models. When preparing a standardisation request, the Commission shall consult the Board and relevant stakeholders, including the advisory forum. When issuing a standardisation request to European standardisation organisations, the Commission shall specify that standards have to be clear, consistent, including with the standards developed in the various sectors for products covered by the existing Union harmonisation legislation listed in Annex I, and aiming to ensure that high-risk AI systems or general-purpose AI models placed on the market or put into service in the Union meet the relevant requirements or obligations laid down in this Regulation. The Commission shall request the European standardisation organisations to provide evidence of their best efforts to fulfil the objectives referred to in the first and the second subparagraph of this paragraph in accordance with Article 24 of Regulation (EU) No 1025/2012.

Art. 41, 1(b): no reference to harmonised standards covering the requirements referred to in Section 2 of this Chapter or, as applicable, the obligations referred to in Sections 2 and 3 of Chapter V has been published in the Official Journal of the European Union in accordance with Regulation (EU) No 1025/2012, and no such reference is expected to be published within a reasonable period. When drafting the common specifications, the Commission shall consult the advisory forum referred to in Article 67. The implementing acts referred to in the first subparagraph of this paragraph shall be adopted in accordance with the examination procedure referred to in Article 98(2).

Art. 65, 6: The Board shall establish two standing sub-groups to provide a platform for cooperation and exchange among market surveillance authorities and notifying authorities about issues related to market surveillance and notified bodies respectively. The standing sub-group for market surveillance should act as the administrative cooperation group (ADCO) for this Regulation within the meaning of Article 30 of Regulation (EU) 2019/1020. The Board may establish other standing or temporary sub-groups as appropriate for the purpose of examining specific issues. Where appropriate, representatives of the advisory forum referred to in Article 67 may be invited to such sub-groups or to specific meetings of those subgroups as observers.

Art. 67: Advisory forum

Art. 67, 1: An advisory forum shall be established to provide technical expertise and advise the Board and the Commission, and to contribute to their tasks under this Regulation.

Art. 67, 2: The membership of the advisory forum shall represent a balanced selection of stakeholders, including industry, start-ups, SMEs, civil society and academia. The membership of the advisory forum shall be balanced with regard to commercial and non-commercial interests and, within the category of commercial interests, with regard to SMEs and other undertakings.

Art. 67, 3: The Commission shall appoint the members of the advisory forum, in accordance with the criteria set out in paragraph 2, from amongst stakeholders with recognised expertise in the field of AI.

Art. 67, 4: The term of office of the members of the advisory forum shall be two years, which may be extended by up to no more than four years.

Art. 67, 5: The Fundamental Rights Agency, CNISA, the European Committee for Standardization (CEN), the European Committee for Electrotechnical Standardization (CENELEC), and the European Telecommunications Standards Institute (ETSI) shall be permanent members of the advisory forum.

Art. 67, 6: The advisory forum shall draw up its rules of procedure. It shall elect two co-chairs from among its members, in accordance with criteria set out in paragraph 2. The term of office of the co-chairs shall be two years, renewable once.

Art. 67, 7: The advisory forum shall hold meetings at least twice a year. The advisory forum may invite experts and other stakeholders to its meetings.

Art. 67, 8: The advisory forum may prepare opinions, recommendations and written contributions at the request of the Board or the Commission.

Art. 67, 9: The advisory forum may establish standing or temporary sub-groups as appropriate for the purpose of examining specific questions related to the objectives of this Regulation.

Art. 67, 10: The advisory forum shall prepare an annual report on its activities. That report shall be made publicly available.

2 Aggregation

Art. 10, 2(c): relevant data-preparation processing operations, such as annotation, labelling, cleaning, updating, enrichment and aggregation;

Art. 17, 1(f): systems and procedures for data management, including data acquisition, data collection, data analysis, data labelling, data storage, data filtration, data mining, data aggregation, data retention and any other operation regarding the data that is performed before and for the purpose of the placing on the market or the putting into service of high-risk AI systems;

0 AI application

3 AI Ecosystem

Art. 57, 4: Member States shall ensure that the competent authorities referred to in paragraphs 1 and 2 allocate sufficient resources to comply with this Article effectively and in a timely manner. Where appropriate, national competent authorities shall cooperate with other relevant authorities, and may allow for the involvement of other actors within the AI ecosystem. This Article shall not affect other regulatory sandboxes established under Union or national law. Member States shall ensure an appropriate level of cooperation between the authorities supervising those other sandboxes and the national competent authorities.

Art. 57, 5(c): fostering innovation and competitiveness and facilitating the development of an AI ecosystem;

Art. 58, 2(f): that AI regulatory sandboxes facilitate the involvement of other relevant actors within the AI ecosystem, such as notified bodies and standardisation organisations, SMEs, including start-ups, enterprises, innovators, testing and experimentation facilities, research and experimentation labs and European Digital Innovation Hubs, centres of excellence, individual researchers, in order to allow and facilitate cooperation with the public and private sectors;

5 AI literacy

Art. 3, (56): 'AI literacy' means skills, knowledge and understanding that allow providers, deployers and affected persons, taking into account their respective rights and obligations in the context of this Regulation, to make an informed deployment of AI systems, as well as to gain awareness about the opportunities and risks of AI and possible harm it can cause;

Art. 4: AI literacy

Art. 4: Providers and deployers of AI systems shall take measures to ensure, to their best extent, a sufficient level of AI literacy of their staff and other persons dealing with the operation and use of AI systems on their behalf, taking into account their technical knowledge, experience, education and training and the context the AI systems are to be used in, and considering the persons or groups of persons on whom the AI systems are to be used.

Art. 66, (f): support the Commission in promoting AI literacy, public awareness and understanding of the benefits, risks, safeguards and rights and obligations in relation to the use of AI systems;

Art. 95, 2(c): promoting AI literacy, in particular that of persons dealing with the development, operation and use of AI;

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93 AI model

- Art. 1 (2)(e):** harmonised rules for the placing on the market of general-purpose AI models;
- Art. 2 (1a):** provides placing on the market or putting into service AI systems or placing on the market general-purpose AI models in the Union, irrespective of whether those providers are established or located within the Union or in a third country;
- Art. 2 (6):** This Regulation does not apply to AI systems or AI models, including their output, specifically developed and put into service for the sole purpose of scientific research and development.
- Art. 2 (7):** This Regulation applies to research, testing or development activity regarding AI systems or AI models prior to their being placed on the market or put into service. Such activities shall be conducted in accordance with applicable Union law. Testing in real world conditions shall not be covered by this exclusion.
- Art. 3 (3):** 'provider' means a natural or legal person, public authority, agency or other body that develops an AI system or a general-purpose AI model or that has an AI system or a general-purpose AI model developed and places it on the market or puts the AI system into service under its name or trademark, whether for payment or free of charge;
- Art. 3 (5):** 'authorised representative' means a natural or legal person located or established in the Union who has received and accepted a written mandate from a provider of an AI system or a general-purpose AI model to, respectively, perform and carry out on its behalf the obligations and procedures established by this Regulation;
- Art. 3 (9):** 'placing on the market' means the first making available of an AI system or a general-purpose AI model on the Union market;
- Art. 3 (10):** 'making available on the market' means the supply of an AI system or a general-purpose AI model for distribution or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge;
- Art. 3 (47):** 'AI Office' means the Commission's function of contributing to the implementation, monitoring and supervision of AI systems and general-purpose AI models, and AI governance, provided for in Commission Decision of 24 January 2024; references in this Regulation to the AI Office shall be construed as references to the Commission;
- Art. 3 (63):** 'general-purpose AI model' means an AI model, including where such an AI model is trained with a large amount of data using self-supervision at scale, that displays significant generality and is capable of competently performing a wide range of distinct tasks regardless of the way the model is placed on the market and that can be integrated into a variety of downstream systems or applications, except AI models that are used for research, development of prototyping activities before they are placed on the market;
- Art. 3 (64):** 'high-impact capabilities' means capabilities that match or exceed the capabilities recorded in the most advanced general-purpose AI models;
- Art. 3 (65):** 'systemic risk' means a risk that is specific to the high-impact capabilities of general-purpose AI models, having a significant impact on the Union market due to their reach, or due to actual or reasonably foreseeable negative effects on public health, safety, public security, fundamental rights, or the society as a whole, that can be propagated at scale across the value chain;
- Art. 3 (66):** 'general-purpose AI system' means an AI system which is based on a general-purpose AI model and which has the capability to serve a variety of purposes, both for direct use as well as for integration in other AI systems;
- Art. 3 (68):** 'downstream provider' means a provider of an AI system, including a general-purpose AI system, which integrates an AI model, regardless of whether the AI model is provided by themselves and vertically integrated or provided by another entity based on contractual relations.
- Art. 10:** High-risk AI systems which make use of techniques involving the training of AI models with data shall be developed on the basis of training, validation and testing data sets that meet the quality criteria referred to in paragraphs 2 to 5 whenever such data sets are used.
- Art. 15 (5):** For the development of high-risk systems not using techniques involving the training of AI models, paragraphs 2 to 5 apply only to the testing data sets.
- Art. 15, 8:** High-risk AI systems shall be resilient against attempts by unauthorised third parties to alter their use, outputs or performance by exploiting system vulnerabilities. The technical solutions aiming to ensure the cybersecurity of high-risk AI systems shall be appropriate to the relevant circumstances and the risks. The technical solutions to address AI specific vulnerabilities shall include, where appropriate, measures to prevent, detect, respond to, resolve and control for attacks trying to manipulate the training data set (data poisoning), or pre-trained components or training (model poisoning), inputs designed to cause the AI model to make a mistake (adversarial examples or model evasion), confidentiality attacks or model flaws.
- Art. 25, 4:** The provider of a high-risk AI system and the third party that supplies an AI system, tools, services, components, or processes that are used or integrated in a high-risk AI system shall, by written agreement, specify the necessary information, capabilities, technical access and other assistance based on the generally acknowledged state of the art, in order to enable the provider of the high-risk AI system to fully comply with the obligations set out in this Regulation. This paragraph shall not apply to third parties making accessible to the public tools, services, components, or processes that are used for or integrated into high-risk AI systems. When developing those voluntary model terms, the AI Office shall take into account possible contractual requirements applicable in specific sectors or business cases. The voluntary model terms shall be published and be available free of charge in an easily usable electronic format.
- Art. 25, 5:** High-risk AI systems and general-purpose AI models which are in conformity with harmonised standards or parts thereof the references of which have been published in the Official Journal of the European Union in accordance with Regulation (EU) No 1025/2012 shall be presumed to be in conformity with the requirements set out in Section 2 of this Chapter or, as applicable, with the obligations set out in of Chapter V, Sections 2 and 3, of this Regulation, to the extent that those standards cover those requirements or obligations.
- Art. 40, 2:** In accordance with Article 10 of Regulation (EU) No 1025/2012, the Commission shall issue, without undue delay, standardisation requests covering all requirements set out in Section 2 of this Chapter and, as applicable, standardisation requests covering obligations set out in Chapter V, Sections 2 and 3, of this Regulation. The standardisation request shall also ask for deliverables on reporting and documentation processes to improve AI systems' resource performance, such as reducing the high-risk AI system's consumption of energy and of other resources during its lifecycle, and on the energy-efficient development of general-purpose AI models. When preparing a standardisation request, the Commission shall consult the Board and relevant stakeholders, including the advisory forum. When issuing a standardisation request to European standardisation organisations, the Commission shall specify that standards have to be clear, consistent, including with the standards developed in the various sectors for products covered by the existing Union harmonisation legislation listed in Annex I, and aiming to ensure that high-risk AI systems or general-purpose AI models placed on the market or put into service in the Union meet the relevant requirements or obligations laid down in this Regulation. The Commission shall request the European standardisation organisations to provide evidence of their best efforts to fulfil the objectives referred to in the first and the second subparagraph of this paragraph in accordance with Article 24 of Regulation (EU) No 1025/2012.
- Art. 40, 3:** High-risk AI systems or general-purpose AI models which are in conformity with the common specifications referred to in paragraph 1, or parts of those specifications, shall be presumed to be in conformity with the requirements set out in Section 2 of this Chapter or, as applicable, to comply with the obligations referred to in Section 2 and 3 of Chapter V, to the extent those common specifications cover those requirements or those obligations.
- Art. 41, 5:** Where providers of high-risk AI systems or general-purpose AI models do not comply with the common specifications referred to in paragraph 1, they shall duly justify that they have adopted technical solutions that meet the requirements referred to in Section 2 of this Chapter or, as applicable, to comply with the obligations referred to in Section 2 and 3 of Chapter V to a level at least equivalent thereto.
- CHAPTER V: GENERAL-PURPOSE AI MODELS**
- Art. 51:** Classification of general-purpose AI models as general-purpose AI models with systemic risk
- Art. 51, 1:** A general-purpose AI model shall be classified as a general-purpose AI model with systemic risk if it meets any of the following conditions:
- Art. 52, 1:** A general-purpose AI model shall be presumed to have high impact capabilities pursuant to paragraph 1, point (a), when the cumulative amount of computation used for its training measured in floating point operations is greater than 1025.
- Art. 52, 1:** Where a general-purpose AI model meets the condition referred to in Article 51(1), point (a), the relevant provider shall notify the Commission without delay and in any event within two weeks after that requirement is met or it becomes known that it will be met. That notification shall include the information that the Commission becomes aware of a general-purpose AI model presenting systemic risks of which it has not been notified, it may decide to designate it as a model with systemic risk.
- Art. 52, 2:** The provider of a general-purpose AI model that meets the condition referred to in Article 51(1), point (a), may present, with its notification, sufficiently substantiated arguments to demonstrate that, exceptionally, although it meets that requirement, the general-purpose AI model does not present, due to its specific characteristics, systemic risks and therefore should not be classified as a general-purpose AI model with systemic risk.
- Art. 52, 3:** Where the Commission is notified pursuant to paragraph 1 that a general-purpose AI model with systemic risk is not sufficient substantiated and the relevant provider was not able to demonstrate that the general-purpose AI model does not present, due to its specific characteristics, systemic risks, it shall reject those arguments, and the general-purpose AI model shall be considered to be a general-purpose AI model with systemic risk.
- Art. 52, 4:** The Commission may designate a general-purpose AI model as presenting systemic risks, ex officio or following a qualified alert from the scientific panel pursuant to Article 90(1), point (a), on the basis of criteria set out in Annex XIII. The Commission is empowered to adopt the measures set out in accordance with the Commission's powers under Annex XIII by specifying and updating the criteria set out in that annex.
- Art. 52, 5:** Upon a reasoned request of a provider whose model has been designated as a general-purpose AI model with systemic risk pursuant to paragraph 4, the Commission shall take the request into account and may decide to reassess whether the general-purpose AI model can still be considered to present systemic risks on the basis of the criteria set out in Annex XIII. Such a request shall contain objective, detailed and new reasons that have arisen since the designation decision. Providers may request reassessment at the earliest six months after that decision.
- Art. 52, 6:** The Commission shall ensure that a list of general-purpose AI models with systemic risk is published and shall keep that list up to date, without prejudice to the need to observe and protect intellectual property rights and confidential business information or trade secrets in accordance with Union and national law.
- SECTION 2: Obligations for providers of general-purpose AI models**
- Art. 53: Obligations for providers of general-purpose AI models**
- Art. 53, 1:** Providers of general-purpose AI models shall:
- Art. 53, 1(a):** draw up, keep up to date and make available information and documentation to providers of AI systems who intend to integrate the general-purpose AI model into their AI systems. Without prejudice to the need to observe and protect intellectual property rights and confidential business information or trade secrets in accordance with Union and national law, the information and documentation shall:
- Art. 53, 1(b):** enable providers of AI systems to have a good understanding of the capabilities and limitations of the general-purpose AI model and to comply with their obligations pursuant to this Regulation; and
- Art. 53, 1(c):** draw up and make available a summary of the content used for training of the general-purpose AI model, according to a template provided by the AI Office.
- Art. 53, 2:** The obligations set out in paragraph 1, points (a) and (b), shall not apply to providers of AI models that are released under a free and open-source licence that allows for the access, usage, modification, and distribution of the model, and whose parameters, including the weights, the information on the model architecture, and the information on model usage, are made publicly available. This exception shall not apply to general-purpose AI models with systemic risks.
- Art. 53, 3:** Providers of general-purpose AI models shall cooperate with the Commission and the national competent authorities in the exercise of their competences and powers pursuant to this Regulation.
- Art. 53, 4:** Providers of general-purpose AI models may rely on codes of practice within the meaning of Article 56 to demonstrate compliance with the obligations set out in paragraph 1 of this Article, until a harmonised standard is published. Compliance with European harmonised standards grants providers the presumption of conformity to the extent that those standards cover those obligations. Providers of general-purpose AI models who do not adhere to an approved code of practice or do not comply with a European harmonised standard shall demonstrate or provide adequate means of compliance for assessment by the Commission.
- Art. 54:** Authorised representatives of providers of general-purpose AI models
- Art. 54, 1:** Prior to placing a general-purpose AI model on the Union market, the provider of a general-purpose AI model shall designate an authorised representative who is established in the Union.
- Art. 54, 3(a):** keep a copy of the designation specified in Annex XI at the disposal of the AI Office and national competent authorities, for a period of 10 years after the general-purpose AI model has been placed on the market, and the contact details of the provider that appointed the authorised representative;
- Art. 54, 3(b):** cooperate with the AI Office and competent authorities, upon a reasoned request, in any action they take in relation to the general-purpose AI model, including when the model is integrated into AI systems placed on the market or put into service in the Union.
- Art. 54, 6:** The information set out in this Article shall not apply to providers of general-purpose AI models that are released under a free and open-source licence that allows for the access, usage, modification, and distribution of the model, and whose parameters, including the weights, the information on the model architecture, and the information on model usage, are made publicly available, unless the general-purpose AI models present systemic risks.
- SECTION 3: Obligations of providers of general-purpose AI models with systemic risk**
- Art. 55: Obligations of providers of general-purpose AI models with systemic risk**
- Art. 55, 1:** In addition to the obligations listed in Articles 53 and 54, providers of general-purpose AI models with systemic risk shall:
- Art. 55, 1(a):** assess and mitigate possible systemic risks at Union level, including the sources that may stem from the development, the placing on the market, or the use of general-purpose AI models with systemic risk;
- Art. 55, 1(b):** ensure an adequate level of cybersecurity protection for the general-purpose AI model with systemic risk and the physical infrastructure of the model;
- Art. 55, 2:** Providers of general-purpose AI models with systemic risk may rely on codes of practice within the meaning of Article 56 to demonstrate compliance with the obligations set out in paragraph 1 of this Article, until a harmonised standard is published. Compliance with European harmonised standards grants providers the presumption of conformity to the extent that those standards cover those obligations. Providers of general-purpose AI models with systemic risks who do not adhere to an approved code of practice or do not comply with a European harmonised standard shall demonstrate alternative adequate means of compliance for assessment by the Commission.
- Art. 56, 3:** The AI Office may invite all providers of general-purpose AI models, as well as relevant national competent authorities, to participate in the drawing-up of codes of practice. Civil society organisations, industry, academia and other relevant stakeholders, such as downstream providers, may also support the drawing-up of codes of practice.
- Art. 56, 7:** The AI Office may invite all providers of general-purpose AI models to adhere to the codes of practice. For providers of general-purpose AI models not presenting systemic risks this adherence may be limited to the obligations provided for in Article 53, unless they declare explicitly their interest to join the full code.
- Art. 65:** (c) provide advice on the implementation of this Regulation, in particular as regards the enforcement of rules on general-purpose AI models;
- Art. 66:** (n) provide opinions to the Commission on the qualified alerts regarding general-purpose AI models;
- Art. 66:** (o) receive opinions by the Member States on qualified alerts regarding general-purpose AI models, and on national experiences and practices on the monitoring and enforcement of AI systems, in particular systems integrating the general-purpose AI models.
- Art. 68:** (i) independence from the provider of the general-purpose AI model;
- Art. 68:** (j) supporting the implementation and enforcement of this Regulation as regards general-purpose AI models and systems, in particular by:
- Art. 68:** (j)(i): alerting the AI Office of possible systemic risks at Union level of general-purpose AI models, in accordance with Article 90;
- Art. 68:** (j)(ii): contributing to the development of tools and methodologies for evaluating the capabilities of general-purpose AI models and systems, including through benchmarks;
- Art. 68:** (j)(iii): providing advice on the classification of general-purpose AI models with systemic risk;
- Art. 68:** (j)(iv): providing advice on the classification of various general-purpose AI models and systems;
- Art. 75, 1:** Where an AI system is based on a general-purpose AI model, and the model and the system are developed by the same provider, the AI Office shall have powers to monitor and supervise compliance of that AI system with obligations under this Regulation. To carry out its monitoring and supervision tasks, the AI Office shall have all the powers of a market surveillance authority provided for in this Section and Regulation (EU) 2019/1020.
- Art. 75, 3:** Where a market surveillance authority is unable to conclude its investigation of the high-risk AI system because of its inability to access certain information related to the general-purpose AI model despite having made all appropriate efforts to obtain that information, it may submit a reasoned request to the AI Office, by which access to that information shall be enforced. In that case, the AI Office shall supply to the applicant authority without delay, and in any event within 30 days, any information that the AI Office considers to be relevant in order to establish whether a high-risk AI system is non-compliant. Market surveillance authorities shall safeguard the confidentiality of the information that they obtain in accordance with Article 78 of this Regulation. The procedure provided for in Chapter VI of Regulation (EU) 2019/1020 shall apply mutatis mutandis.
- SECTION 5: Supervision, investigation, enforcement and monitoring in respect of providers of general-purpose AI models**
- Art. 88: Enforcement of the obligations of providers of general-purpose AI models**
- Art. 89, 1:** For the purpose of carrying out the tasks assigned to it under this Section, the AI Office may take the necessary actions to monitor the effective implementation and compliance with this Regulation by providers of general-purpose AI models, including their adherence to approved codes of practice.
- Art. 89, 2(a):** the point of contact of the provider of the general-purpose AI model concerned;
- Art. 89, 2(b):** a description of the relevant facts, the provisions of this Regulation concerned, and the reason why the downstream provider considers that the provider of the general-purpose AI model concerned infringed this Regulation;
- Art. 90, 1(a):** a general-purpose AI model poses concrete identifiable risk at Union level; or
- Art. 90, 1(b):** a general-purpose AI model meets the conditions referred to in Article 51.
- Art. 90, 3(a):** the point of contact of the provider of the general-purpose AI model with systemic risk concerned;
- Art. 90, 4:** The Commission may request the provider of the general-purpose AI model concerned to provide the documentation drawn up by the provider in accordance with Articles 53 and 55, or any additional information that is necessary for the purpose of assessing compliance of the provider with this Regulation.
- Art. 91, 2:** Before sending the request for information, the AI Office may initiate a structured dialogue with the provider of the general-purpose AI model.
- Art. 91, 3:** Upon a duly substantiated request from the scientific panel, the Commission may issue a request for information to a provider of a general-purpose AI model, where the access to information is necessary and proportionate for the fulfilment of the tasks of the scientific panel under Article 68(2).
- Art. 91, 5:** The provider of the general-purpose AI model concerned, or its representative shall supply the information requested. In the case of legal persons, companies or firms, or where the provider has no legal personality, the persons authorised to represent them by law or by their statutes, shall supply the information requested on behalf of the provider of the general-purpose AI model concerned. Lawyers duly authorised to act may supply information on behalf of their clients. The clients shall nevertheless remain fully responsible if the information supplied is incomplete, incorrect or misleading.
- Art. 92, 1:** The AI Office, after consulting the Board, may conduct evaluations of the general-purpose AI model concerned:
- Art. 92, 1(b):** to investigate systemic risks at Union level of general-purpose AI models with systemic risk, in particular following a qualified alert from the scientific panel in accordance with Article 90(1), point (a).
- Art. 92, 2:** For the purposes of paragraph 1, the Commission may request access to the general-purpose AI model concerned through APIs or further appropriate technical means and tools, including source code.
- Art. 92, 5:** The providers of the general-purpose AI model concerned or its representative shall supply the information requested. In the case of legal persons, companies or firms, or where the provider has no legal personality, the persons authorised to represent them by law or by their statutes, shall provide the access requested on behalf of the provider of the general-purpose AI model concerned.
- Art. 92, 7:** Prior to requesting access to the general-purpose AI model concerned, the AI Office may initiate a structured dialogue with the provider of the general-purpose AI model to gather more information on the internal testing of the model, internal safeguards for preventing systemic risks, and other internal procedures and measures the provider has taken to mitigate such risks.
- Art. 93, 2:** Before a measure is requested, the AI Office may initiate a structured dialogue with the provider of the general-purpose AI model.
- Art. 93, 3:** If, during the structured dialogue referred to in paragraph 2, the provider of the general-purpose AI model with systemic risk offers commitments to implement mitigation measures to address a systemic risk at Union level, the Commission may, by decision, make those commitments binding and declare that there are no further grounds for action.
- Art. 94: Procedural rights of economic operators of the general-purpose AI model**
- Art. 94, Article 18 of Regulation (EU) 2019/1020 shall apply mutatis mutandis to the providers of the general-purpose AI model, without prejudice to more specific procedural rights provided for in this Regulation.**
- Art. 101: Fines for providers of general-purpose AI models**
- Art. 101, 1:** The Commission may impose on providers of general-purpose AI models fines not exceeding 3 % of their annual total worldwide turnover in the preceding financial year or EUR 15 000 000, whichever is higher., when the Commission finds that the provider intentionally or negligently:
- Art. 101, 1(d):** failed to make available to the Commission access to the general-purpose AI model or general-purpose AI model with systemic risk with a view to conducting an evaluation pursuant to Article 92. In fixing the amount of the fine or periodic penalty payment, regard shall be had to the nature, gravity and duration of the infringement, taking due account of the principles of proportionality and appropriateness. The Commission shall also take into account commitments made in accordance with Article 93(3) or made in relevant codes of practice in accordance with Article 56.
- Art. 110, 2:** Before adopting the decision pursuant to paragraph 1, the Commission shall communicate its preliminary findings to the provider of the general-purpose AI model and give it an opportunity to be heard.
- Art. 111:** AI systems already placed on the market or put into service and general-purpose AI models already placed on the market
- Art. 111, 3:** Providers of general-purpose AI models that have been placed on the market before 2 August 2025 shall take the necessary steps in order to comply with the obligations laid down in this Regulation by 2 August 2027.
- Art. 112, 6:** By 2 August 2028 and every four years thereafter, the Commission shall submit a report on the progress on the development of standardisation deliverables on the energy-efficient development of general-purpose AI models, and assess the need for further measures or actions, including binding measures or actions. The report shall be submitted to the European Parliament and to the Council, and it shall be made public.

Terms and AI Act Articles

55 AI Office

- Art. 3, (47):** 'AI Office' means the Commission's function of contributing to the implementation, monitoring and supervision of AI systems and general-purpose AI models, and AI governance, provided for in Commission Decision of 24 January 2024; references in this Regulation to the AI Office shall be construed as references to the Commission;
- Art. 25, 4:** The provider of a high-risk AI system and the third party that supplies an AI system, tools, services, components, or processes that are used or integrated in a high-risk AI system shall, by written agreement, specify the necessary information, capabilities, technical access and other assistance to the generally acknowledged state of the art, in order to enable the provider of the high-risk AI system to fully comply with the obligations set out in this Regulation. This paragraph shall not apply to third parties making accessible to the public tools, services, processes, or components, other than general-purpose AI models, under a free and open-source licence. The AI Office may develop and recommend voluntary model terms for contracts between providers of high-risk AI systems and third parties that supply tools, services, components or processes that are used for or integrated into high-risk AI systems. When developing those voluntary model terms, the AI Office shall take into account possible contractual requirements applicable in specific sectors or business cases. The voluntary model terms shall be published and be available for use in an easily accessible and electronic format.
- Art. 27, 5:** The AI Office shall develop a template for a questionnaire, including through an automated tool, to facilitate deployers in complying with their obligations under this Article in a simplified manner.
- Art. 50, 7:** The AI Office shall encourage and facilitate the drawing up of codes of practice at Union level to facilitate the effective implementation of the obligations regarding the detection and labelling of artificially generated or manipulated content. The Commission may adopt implementing acts to approve codes of practice in accordance with the procedure laid down in Article 56 (6). If it deems the code is not adequate, the Commission may adopt an implementing act specifying common rules for the implementation of those obligations in accordance with the examination procedure laid down in Article 98(2).
- Art. 53, (1a):** draw up and keep up-to-date the technical documentation of the model, including its training and testing process and the results of its evaluation, which shall contain, at a minimum, the information set out in Annex XI for the purpose of providing it, upon request, to the AI Office and the national competent authorities;
- Art. 53, (1d):** draw up and make publicly available a sufficiently detailed summary about the content used for training of the general-purpose AI model, according to a template provided by the AI Office.
- Art. 54, 3:** The authorised representative shall perform the tasks specified in the mandate received from the provider. It shall provide a copy of the mandate to the AI Office upon request, in one of the official languages of the institutions of the Union. For the purposes of this Regulation, the mandate shall empower the authorised representative to carry out the following tasks:
- Art. 54, (3b):** keep a copy of the technical documentation specified in Annex XI at the disposal of the AI Office and national competent authorities, for a period of 10 years after the general-purpose AI model has been placed on the market, and the contact details of the provider that appointed the authorised representative;
- Art. 54, (3c):** provide the AI Office, upon a reasoned request, with all the information and documentation, including that referred to in point (b), necessary to demonstrate compliance with the obligations in this Chapter;
- Art. 54, (3d):** cooperate with the AI Office and competent authorities, upon a reasoned request, in any action they take in relation to the general-purpose AI model, including when the model is integrated into AI systems placed on the market or put into service in the Union.
- Art. 54, 4:** The mandate shall empower the authorised representative to be addressed, in addition to or instead of the provider, by the AI Office or the competent authorities, on all issues related to ensuring compliance with this Regulation.
- Art. 54, 5:** The authorised representative shall terminate the mandate if it considers or has reason to consider the provider to be acting contrary to its obligations pursuant to this Regulation. In such a case, it shall also immediately inform the AI Office about the termination of the mandate and the reasons therefor.
- Art. 55, (1c):** keep track of, document, and report, without undue delay, to the AI Office and, as appropriate, to national competent authorities, relevant information about serious incidents and possible corrective measures to address them;
- Art. 56, 1:** The AI Office shall facilitate the drawing up of codes of practice at Union level in order to contribute to the proper application of this Regulation, taking into account international approaches.
- Art. 56, 2:** The AI Office and the Board shall aim to ensure that the codes of practice cover at least the obligations provided for in Articles 53 and 55, including the following issues:
- Art. 56, 3:** The AI Office may invite all providers of general-purpose AI models, as well as relevant national competent authorities, to participate in the drawing-up of codes of practice. Civil society organisations, industry, academia and other relevant stakeholders, such as downstream exporters and independent experts, may support the process.
- Art. 56, 4:** The AI Office and the Board shall aim to ensure that the codes of practice clearly set out their specific objectives and contain commitments or measures, including key performance indicators as appropriate, to ensure the achievement of those objectives, and that they take due account of the needs and interests of all interested parties, including affected persons, at Union level.
- Art. 56, 5:** The AI Office shall ensure that participants to the codes of practice report regularly to the AI Office on the implementation of the commitments and the measures taken and their outcomes, including as measured against the key performance indicators as appropriate. Key performance indicators and reporting commitments shall reflect differences in size and capacity between various participants.
- Art. 56, 6:** The AI Office and the Board shall regularly monitor and evaluate the achievement of the objectives of the codes of practice by the participants and their contribution to the proper application of this Regulation. The AI Office and the Board shall assess whether the codes of practice cover the obligations provided for in Articles 53 and 55, and shall regularly monitor and evaluate the achievement of their objectives. They shall publish their assessment of the adequacy of the codes of practice. The Commission may, by way of an implementing act, approve a code of practice and give it a general validity within the Union. That implementing act shall be adopted in accordance with the examination procedure referred to in Article 98(2).
- Art. 56, 7:** The AI Office may invite all providers of general-purpose AI models to adhere to the codes of practice. For providers of general-purpose AI models not presenting systemic risks this adherence may be limited to the obligations provided for in Article 53, unless they declare explicitly their interest to join the full code.
- Art. 56, 8:** The AI Office shall, as appropriate, also encourage and facilitate the review and adaptation of the codes of practice, in particular in light of emerging standards. The AI Office shall assist in the assessment of available standards.
- Art. 56, 9:** Codes of practice shall be ready at the latest by 2 May 2025. The AI Office shall take the necessary steps, including inviting providers pursuant to paragraph 7, if, by 2 August 2025, a code of practice cannot be finalised, or if the AI Office deems it is not adequate following its assessment under paragraph 6 of this Article, the Commission may provide, by means of implementing acts, common rules for the implementation of the obligations provided for in Articles 53 and 55, including the issues set out in paragraph 2 of this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 98(2).
- Art. 57, 11:** The AI regulatory sandboxes shall not affect the supervisory or corrective powers of the competent authorities supervising the sandboxes, including at regional or local level. Any significant risks to health and safety and fundamental rights identified during the development and testing of such AI systems shall result in an adequate mitigation. National competent authorities shall have the power to temporarily or permanently suspend the testing process, or the participation in the sandbox if no effective mitigation is possible, and shall inform the AI Office of such decision. National competent authorities shall exercise their supervisory powers within the limits of the relevant law, using their discretionary powers when implementing legal provisions in respect of a specific AI regulatory sandbox project, with the objective of supporting innovation in AI in the Union.
- Art. 57, 15:** National competent authorities shall inform the AI Office and the Board of the establishment of a sandbox, and may ask them for support and guidance. The AI Office shall make publicly available a list of planned and existing sandboxes and keep it up to date in order to encourage more interaction in the AI regulatory sandboxes and cross-border cooperation.
- Art. 57, 16:** National competent authorities shall submit annual reports to the AI Office and to the Board, from one year after the establishment of the AI regulatory sandbox and every year thereafter until its termination, and a final report. Those reports shall provide information on the progress and results of the implementation of those sandboxes, including best practices, incidents, lessons learnt and recommendations on their setup and, where relevant, on the application and possible revision of this Regulation, including its delegated and implementing acts, and on the application of other Union law supervised by the competent authorities within the sandbox. The national competent authorities shall make those annual reports or abstracts thereof available to the public, online. The Commission shall, where appropriate, take the annual reports into account when exercising its tasks under this Regulation.
- Art. 62, 3:** The AI Office shall undertake the following actions:
- Art. 64:** AI Office
- Art. 64, 1:** The Commission shall develop Union expertise and capabilities in the field of AI through the AI Office.
- Art. 64, 2:** Member States shall facilitate the tasks entrusted to the AI Office, as reflected in this Regulation.
- Art. 65, 2:** The Board shall be composed of one representative per Member State. The European Data Protection Supervisor shall participate as observer. The AI Office shall also attend the Board's meetings, without taking part in the votes. Other national and Union authorities, bodies or experts may be invited to the meetings by the Board on a case by case basis, where the issues discussed are of relevance for them.
- Art. 65, 8:** The Board shall be chaired by one of the representatives of the Member States. The AI Office shall provide the secretariat for the Board, convene the meetings upon request of the Chair, and prepare the agenda in accordance with the tasks of the Board pursuant to this Regulation and its rules of procedure.
- Art. 66, (1):** assist the AI Office in supporting national competent authorities in the establishment and development of AI regulatory sandboxes, and facilitate cooperation and information-sharing among AI regulatory sandboxes;
- Art. 68, 3:** The scientific panel shall advise and support the AI Office, in particular with regard to the following tasks:
- Art. 68, (3a)(i):** alerting the AI Office of possible systemic risks at Union level of general-purpose AI models, in accordance with Article 90;
- Art. 68, (3d):** supporting the AI Office in carrying out its duties in the context of the Union safeguard procedure pursuant to Article 81.
- Art. 68, 4:** The experts on the scientific panel shall perform their tasks with impartiality and objectivity, and shall ensure the confidentiality of information and data obtained in carrying out their tasks and activities. They shall neither seek nor take instructions from anyone when exercising their tasks under paragraph 3. Each expert shall draw up a declaration of interests, which shall be made publicly available. The AI Office shall establish systems and procedures to actively manage and prevent potential conflicts of interest.
- Art. 68, 5:** The implementing act referred to in paragraph 1 shall include provisions on the conditions, procedures and detailed arrangements for the scientific panel and its members to issue alerts, and to request the assistance of the AI Office for the performance of the tasks of the scientific panel.
- Art. 74, 11:** Market surveillance authorities and the Commission shall be able to propose joint activities, including joint investigations, to be conducted by either market surveillance authorities or market surveillance authorities jointly with the Commission, that have the aim of promoting compliance, identifying non-compliance, raising awareness or providing guidance in relation to this Regulation with respect to specific categories of high-risk AI systems that are found to present a serious risk across two or more Member States in accordance with Article 9 of Regulation (EU) 2019/1020. The AI Office shall provide coordination support for joint investigations.
- Art. 75, 1:** Where an AI system is based on a general-purpose AI model, and the model and the system are developed by the same provider, the AI Office shall have powers to monitor and supervise compliance of that AI system with obligations under this Regulation. To carry out its monitoring and supervision tasks, the AI Office shall have all the powers of a market surveillance authority provided for in this Section and Regulation (EU) 2019/1020.
- Art. 75, 2:** Where the relevant market surveillance authorities have sufficient reason to consider general-purpose AI systems that can be used directly by deployers for at least one purpose that is classified as high-risk pursuant to this Regulation to be non-compliant with the requirements laid down in this Regulation, they shall cooperate with the AI Office to carry out compliance evaluations, and shall inform the Board and other market surveillance authorities accordingly.
- Art. 75, 3:** Where a market surveillance authority is unable to conclude its investigation of the high-risk AI system because of its inability to access certain information related to the general-purpose AI model despite having made all appropriate efforts to obtain that information, it may submit a reasoned request to the AI Office, by which access to that information shall be enforced. In that case, the AI Office shall supply to the applicant authority without delay, and in any event within 30 days, any information that the AI Office considers to be relevant in order to establish whether a high-risk AI system is non-compliant. Market surveillance authorities shall safeguard the confidentiality of the information that they obtain in accordance with Article 78 of this Regulation. The procedure provided for in Chapter VI of Regulation (EU) 2019/1020 shall apply mutatis mutandis.
- Art. 88, 1:** The Commission shall have exclusive powers to supervise and enforce Chapter V, taking into account the procedural guarantees under Article 94. The Commission shall entrust the implementation of these tasks to the AI Office, without prejudice to the powers of organisation of the Commission and the division of competences between Member States and the Union based on the Treaties.
- Art. 89, 1:** For the purpose of carrying out the tasks assigned to it under this Section, the AI Office may take the necessary actions to monitor the effective implementation and compliance with this Regulation by providers of general-purpose AI models, including their adherence to approved codes of practice.
- Art. 90, 1:** The scientific panel may provide a qualified alert to the AI Office where it has reason to suspect that:
- Art. 90, 2:** Upon such qualified alert, the Commission, through the AI Office and after having informed the Board, may exercise the powers laid down in this Section for the purpose of assessing the matter. The AI Office shall inform the Board of any measure according to Articles 91 to 94.
- Art. 91, 2:** Before sending the request for information, the AI Office may initiate a structured dialogue with the provider of the general-purpose AI model.
- Art. 92, 1:** The AI Office, after consulting the Board, may conduct evaluations of the general-purpose AI model concerned.
- Art. 92, 7:** Prior to requesting access to the general-purpose AI model concerned, the AI Office may initiate a structured dialogue with the provider of the general-purpose AI model to gather more information on the internal testing of the model, internal safeguards for preventing systemic risks, and other internal procedures and measures the provider has taken to mitigate such risks.
- Art. 93, 2:** Before a measure is requested, the AI Office may initiate a structured dialogue with the provider of the general-purpose AI model.
- Art. 95, 1:** The AI Office and the Member States shall encourage and facilitate the drawing up of codes of conduct, including related governance mechanisms, intended to foster the voluntary application to AI systems, other than high-risk AI systems, of some or all of the requirements set out in Chapter III, Section 2 taking into account the available technical solutions and industry best practices allowing for the application of such requirements.
- Art. 95, 2:** The AI Office and the Member States shall facilitate the drawing up of codes of conduct concerning the voluntary application, including by deployers, of specific requirements to all AI systems, on the basis of clear objectives and key performance indicators to measure the achievement of those objectives, including elements such as, but not limited to:
- Art. 95, 4:** The AI Office and the Member States shall take into account the specific interests and needs of SMEs, including start-ups, when encouraging and facilitating the drawing up of codes of conduct.
- Art. 95, 5:** At the request of the Member States or the AI Office, or on its own initiative, the Commission shall update guidelines previously adopted when deemed necessary.
- Art. 112, 5:** By 2 August 2028, the Commission shall evaluate the functioning of the AI Office, whether the AI Office has been given sufficient powers and competences to fulfil its tasks, and whether it would be relevant and needed for the proper implementation and enforcement of this Regulation to upgrade the AI Office and its enforcement competences and to increase its resources. The Commission shall submit a report on its evaluation to the European Parliament and to the Council.
- Art. 112, 11:** To guide the evaluations and reviews referred to in paragraphs 1 to 7 of this Article, the AI Office shall undertake to develop an objective and participative methodology for the evaluation of risk levels based on the criteria outlined in the relevant Articles and the inclusion of new systems in:

0 AI practitioner

0 AI professional

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390 AI system

Art. 1. 1. The purpose of this Regulation is to improve the functioning of the internal market and promote the uptake of human-centric and trustworthy artificial intelligence (AI), while ensuring a high level of protection of health, safety, fundamental rights enshrined in the Charter, including democracy, the rule of law and environmental protection, against the harmful effects of AI systems in the Union and supporting innovation.
Art. 1. 2(a): harmonised rules for the placing on the market, the putting into service, and the use of AI systems in the Union;
Art. 1. 2(b): specific requirements for high-risk AI systems and obligations for operators of such systems;
Art. 1. 2(c): harmonised transparency rules for certain AI systems;
Art. 1. 3(a): providers placing on the market or putting into service AI systems or placing on the market general-purpose AI models in the Union, irrespective of whether those providers are established or located within the Union or in a third country;
Art. 2. 1(a): deployers of AI systems or placing on the market or putting into service AI systems in the Union, where those authorities or organisations use AI systems in the framework of international cooperation or agreements for law enforcement and judicial cooperation with the Union or with one or more Member States, provided that such a third country or international organisation provides adequate safeguards with respect to the protection of fundamental rights and freedoms of individuals.
Art. 2. 6: This Regulation does not apply to AI systems or AI models, including their output, specifically developed and put into service for the sole purpose of scientific research and development.
Art. 2. 8: This Regulation does not apply to research, testing or development activity regarding AI systems or AI models prior to their being placed on the market or put into service. Such activities shall be conducted in accordance with applicable Union law. Testing in real world conditions shall not be covered by this exclusion.
Art. 2. 10: This Regulation does not apply to obligations of deployers who are natural persons using AI systems in the course of a purely personal non-professional activity.
Art. 2. 11: This Regulation does not apply to areas outside the scope of Union law, and shall not, in any event, affect the competences of the Member States concerning national law, regulations or administrative provisions which are favourable to workers in terms of protecting their rights in respect of the use of AI systems by employers, or from encouraging or allowing the application of collective agreements which are more favourable to workers.
Art. 2. 12: This Regulation does not apply to AI systems released under free and open-source licences, unless they are placed on the market or put into service as high-risk AI systems or as an AI system that falls under Article 5 or 50.
Art. 3. (1): AI system means any system that is designed to operate with varying levels of autonomy and that may exhibit adaptiveness after deployment, and that, for explicit or implicit objectives, infers, from the input it receives, how to generate outputs such as predictions, content, recommendations, or decisions that can influence physical or virtual environments;
Art. 3. (3): 'provider' means a natural or legal person, public authority, agency or other body that develops an AI system or a general-purpose AI model or that has an AI system or a general-purpose AI model developed and places it on the market or puts the AI system into service under its own trademark;
Art. 3. (4): 'importer' means a natural or legal person, public authority, agency or other body using an AI system under its authority except where the AI system is used in the course of a personal non-professional activity;
Art. 3. (5): 'authorised representative' means a natural or legal person located or established in the Union who has received and accepted a written mandate from a provider of an AI system or a general-purpose AI model to, respectively, perform and carry out on its behalf the obligations set out in this Regulation;
Art. 3. (6): 'distributor' means a natural or legal person located or established in the Union that places on the market an AI system that bears the name or trademark of a natural or legal person established in a third country;
Art. 3. (7): 'distributor' means a natural or legal person in the supply chain, other than the provider or the importer, that makes an AI system available on the Union market;
Art. 3. (8): 'making available on the market' means the supply of an AI system or a general-purpose AI model for distribution or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge;
Art. 3. (9): 'putting into service' means the supply of an AI system for first use directly to the deployer or for own use in the Union, for its intended purpose;
Art. 3. (10): 'intended purpose' means the use which an AI system is intended by the provider, including the specific context and conditions of use, as specified in the information supplied by the provider in the instructions for use, promotional or sales materials and statements, as well as in the technical documentation;
Art. 3. (11): 'reasonably foreseeable misuse' means the use of an AI system in a way that is not in accordance with its intended purpose, but which may result from reasonably foreseeable human behaviour or interaction with other systems, including other AI systems;
Art. 3. (12): 'safety component' means a component of a product or of an AI system which fulfils a safety function for that product or AI system, or the failure or malfunctioning of which endangers the health and safety of persons or property;
Art. 3. (13): 'instructions for use' means the information provided by the provider to inform the deployer of, in particular, an AI system's intended purpose and proper use;
Art. 3. (14): 'recall' means the return to the provider or importer or taking out of service or disabling of an AI system made available to deployers;
Art. 3. (15): 'withdrawal of an AI system' means any measure aiming to prevent an AI system in the supply chain being made available on the market;
Art. 3. (16): 'performance of an AI system' means the ability of an AI system to achieve its intended purpose;
Art. 3. (17): 'conformity assessment' means the process of demonstrating that the requirements set out in Chapter III, Section 2 relating to a high-risk AI system have been fulfilled;
Art. 3. (18): 'substantial modification' means a change to an AI system after its placing on the market or putting into service which is not foreseen or planned in the initial conformity assessment carried out by the provider and as a result of which the compliance of the AI system with the requirements set out in Chapter III, Section 2 is affected or results in a modification to the intended purpose for which the AI system has been assessed;
Art. 3. (19): 'CE marking by system' means conformity with the requirements set out in Chapter III, Section 2 and other applicable Union harmonisation legislation providing for its affixing;
Art. 3. (20): 'post-market monitoring system' means all activities carried out by providers of AI systems to collect and review experience gained from the use of AI systems they place on the market or put into service for the purpose of identifying any need to immediately apply any necessary corrective or preventive actions;
Art. 3. (21): 'training data' means data used for training an AI system through fitting its learnable parameters;
Art. 3. (22): 'validation data' means data used for providing an evaluation of the trained AI system and for tuning its non-learnable parameters and its learning process in order, inter alia, to prevent underfitting or overfitting;
Art. 3. (23): 'testing data' means data used for providing an independent evaluation of the AI system in order to confirm the expected performance of that system before its placing on the market or putting into service;
Art. 3. (24): 'input data' means data used by an AI system on the basis of which the system produces an output;
Art. 3. (25): 'emotion recognition system' means an AI system for the purpose of identifying or inferring emotions or intentions of natural persons on the basis of their biometric data;
Art. 3. (26): 'biometric categorisation system' means an AI system for the purpose of assigning natural persons to specific categories on the basis of their biometric data, unless it is ancillary to another commercial service and strictly necessary for objective technical reasons;
Art. 3. (27): 'remote identification system' means an AI system for the purpose of identifying or classifying natural persons or groups of persons on the basis of their biometric data contained in a reference database;
Art. 3. (28): 'AI Office' means the Commission's function of contributing to the implementation, monitoring and supervision of AI systems and general-purpose AI models, and AI governance, provided for in Commission Decision of 24 January 2024; references in this Regulation to the AI Office shall be construed as references to the Commission;
Art. 3. (29): 'national competent authority or a market surveillance authority, as regards AI systems put into service or used by Union institutions, agencies, offices and bodies, references to national competent authorities or market surveillance authorities in this Regulation shall be construed as references to the European Data Protection Supervisor;
Art. 3. (30): 'serious incident' means an incident or malfunctioning of an AI system that directly or indirectly leads to any of the following:
Art. 3. (31): AI regulation system means a control framework set up by a competent authority which offers providers or prospective providers of AI systems the possibility to develop, train, validate and test, where appropriate in real-world conditions, an innovative AI system, pursuant to a sandbox plan for a limited time under regulatory supervision;
Art. 3. (32): 'AI testing' means skills, knowledge and understanding that allow providers, deployers and affected persons, taking into account their respective rights and obligations in the context of this Regulation, to make an informed deployment of AI systems, as well as to gain an awareness about the opportunities and risks of such systems;
Art. 3. (33): 'testing in real-world conditions' means the temporary testing of an AI system for its intended purpose in real-world conditions outside a laboratory or otherwise simulated environment, with a view to gathering reliable and robust data and to assessing and verifying the conformity of the AI system with the requirements of this Regulation and it does not qualify as placing the AI system on the market or putting it into service within the meaning of this Regulation, provided that all the conditions laid down in Article 57 or 60 are fulfilled;
Art. 3. (34): 'general-purpose AI system' means an AI system which has the capability to serve a variety of purposes, both for direct use as well as for integration in other AI systems;
Art. 3. (35): 'downstream provider' means a provider of an AI system, including a general-purpose AI system, which integrates an AI model, regardless of whether the AI model is provided by themselves and vertically integrated or provided by another entity based on contractual relations;
Art. 4. Providers and deployers of AI systems shall take measures to ensure, to their best extent, a sufficient level of AI literacy of their staff and other persons dealing with the operation and use of AI systems on their behalf, taking into account their technical knowledge, experience, education and training needs, and the specific context and conditions of use of the AI systems;
Art. 5. 1(a): the placing on the market, the putting into service or the use of an AI system that deploys subliminal techniques beyond a person's consciousness or purposefully manipulative or deceptive techniques, with the objective, or the effect of materially distorting the behaviour of a person or a group of persons by appreciably impairing their ability to make an informed decision, thereby causing them to take a decision that they would not have otherwise taken in a manner that causes or is reasonably likely to cause that person, another person or group of persons significant harm;
Art. 5. 1(b): the placing on the market, the putting into service or the use of an AI system that exploits any of the vulnerabilities of a natural person or a specific group of persons due to their age, disability or a specific social or economic situation, with the objective, or the effect, of distorting the behaviour of that person or directing them to that group in a manner that causes or is reasonably likely to cause that person or another person significant harm;
Art. 5. 1(c): the placing on the market, the putting into service or the use of an AI system the evaluation or classification of natural persons or groups of persons on the basis of their social behaviour or known, inferred or predicted personal or personality characteristics, with the social score leading to either or both of the following:
Art. 5. 1(d): the placing on the market, the putting into service or the use of an AI system for making risk assessments of natural persons in order to assess or predict the risk of a natural person committing a criminal offence, based solely on the profiling of a natural person or on assessing their personality traits and characteristics; this prohibition shall not apply to AI systems used to support the human assessment of the involvement of a person in a criminal activity, which is already based on objective and verifiable facts directly linked to a criminal activity;
Art. 5. 1(e): the placing on the market, the putting into service for this specific purpose, or the use of AI systems that create or expand facial recognition databases through the untargeted scraping of facial images from the internet or CCTV footage;
Art. 5. 1(f): the placing on the market, the putting into service for this specific purpose, or the use of AI systems to infer emotions of a natural person in the areas of workplace and education institutions, except where the use of the AI system is intended to be put in place or into the market for medical or safety reasons;
CHAPTER III: HIGH-RISK AI SYSTEMS
SECTION 1: Classification of AI systems as high-risk
Art. 6. Classification rules for high-risk AI systems
Art. 6. 1. Irrespective of whether placed on the market or put into service independently of the products referred to in points (a) and (b), that AI system shall be considered to be high-risk where both of the following conditions are fulfilled:
Art. 6. 1(a): the AI system is intended to be used as a safety component of a product, or the AI system is itself a product, covered by the Union harmonisation legislation listed in Annex I;
Art. 6. 1(b): the product whose safety component pursuant to point (a) is the AI system, or the AI system itself as a product, is required to undergo a third-party conformity assessment, with a view to the placing on the market or the putting into service of that product pursuant to the Union harmonisation legislation listed in Annex I;
Art. 6. 2. In addition to the high-risk AI systems referred to in paragraph 1, AI systems referred to in Annex III shall be considered to be high-risk.
Art. 6. 3. By derogation from paragraph 2, an AI system referred to in Annex III shall not be considered to be high-risk where it does not pose a significant risk of harm to the health, safety or fundamental rights of natural persons, including by not materially influencing the outcome of decision-making. The first subparagraph of the following paragraphs shall apply where this condition is fulfilled:
Art. 6. 3(a): the AI system is intended to perform a narrow procedural task;
Art. 6. 3(b): the AI system is intended to improve the result of a previously completed human activity;
Art. 6. 3(c): the AI system is intended to inform or assist a person in their decision-making patterns and is not meant to replace or influence the previously completed human assessment, without proper human review; or
Art. 6. 3(d): the AI system is intended to perform a preparatory task to an assessment relevant for the purposes of the use cases listed in Annex II. Notwithstanding the first subparagraph, an AI system referred to in Annex III shall always be considered to be high-risk where the AI system performs profiling of natural persons.
Art. 6. 4. A provider who considers that an AI system referred to in Annex III is not high-risk shall document its assessment before that system is placed on the market or put into service. Such provider shall be subject to the registration obligation set out in Article 49(2). Upon request of national competent authorities, the provider shall provide the documentation of the assessment.
Art. 6. 5. The Commission shall, after consulting the European Artificial Intelligence Board (the 'Board'), and no later than 2 February 2026, provide guidelines specifying the practical implementation of this Article in line with Article 96 together with a comprehensive list of practical examples of use cases or scenarios that are not high-risk.
Art. 6. 6. The Commission is empowered to adopt delegated acts in accordance with Article 97 in order to amend paragraph 3, second subparagraph, of this Article by adding new conditions to those laid down therein, or by modifying them, where there is concrete and reliable evidence of the existence of AI systems that fall under the scope of Annex III, but do not pose a significant risk of harm to the health, safety or fundamental rights of natural persons.
Art. 7. 1. The Commission is empowered to adopt delegated acts in accordance with Article 97 to amend Annex III by adding or modifying use-cases of high-risk AI systems where both of the following conditions are fulfilled:
Art. 7. 1(a): the AI systems are intended to be used in any of the areas listed in Annex III;
Art. 7. 1(b): the AI systems pose a risk of harm to health and safety, or an adverse impact on fundamental rights, and that risk is equivalent to, or greater than, the risk of harm or of adverse impact posed by the high-risk AI systems already referred to in Annex III.
Art. 7. 2(a): the intended purpose;
Art. 7. 2(b): the extent to which the AI system has been used or is likely to be used;
Art. 7. 2(c): the nature and amount of the data processed and used by the AI system, in particular whether special categories of personal data are processed;
Art. 7. 2(d): the extent to which the AI system acts autonomously and the possibility for a human to override a decision or recommendation that may lead to potential harm;
Art. 7. 2(e): the extent to which the use of an AI system has already caused harm to health and safety, has had an adverse impact on fundamental rights or has given rise to significant concerns in relation to the likelihood of such harm or adverse impact, as demonstrated, for example, by reports or documented allegations submitted to national competent authorities or by other reports, as appropriate;
Art. 7. 2(f): the extent to which the use of an AI system has caused harm to health and safety, has had an adverse impact on fundamental rights or has given rise to significant concerns in relation to the likelihood of such harm or adverse impact, as demonstrated, for example, by reports or documented allegations submitted to national competent authorities or by other reports, as appropriate;
Art. 7. 2(g): the extent to which there is an imbalance of power, or the persons who are potentially harmed or suffer an adverse impact are in a vulnerable position in relation to the provider of an AI system, in particular due to status, authority, knowledge, economic or social inequalities, or age;
Art. 7. 2(h): the extent to which the outcome produced involving an AI system is easily corrigible or reversible, taking into account the technical solutions available to correct or reverse it, whereby outcomes having an adverse impact on health, safety or fundamental rights, shall not be considered to be easily corrigible or reversible;
Art. 7. 2(i): the magnitude and benefit of the deployment of the AI system for individuals, groups, society at large, including possible improvements in product safety;
Art. 7. 2(j): effective measures of redress in relation to the risks posed by an AI system, with the exclusion of claims for damages;
Art. 7. 3. The Commission is empowered to adopt delegated acts in accordance with Article 97 to amend the list in Annex III by removing high-risk AI systems where both of the following conditions are fulfilled:
Art. 7. 3(a): the high-risk AI system no longer poses any significant risks to fundamental rights, health or safety, taking into account the criteria listed in paragraph 2;
SECTION 2: Requirements for high-risk AI systems
Art. 8. 1. High-risk AI systems shall comply with the requirements laid down in this Section, taking into account their intended purpose as well as the generally acknowledged state of the art on AI and AI-related technologies. The risk management system referred to in Article 9 shall take into account the intended purpose of the high-risk AI system.
Art. 8. 2. Where a product contains an AI system, to which the requirements of this Regulation as well as requirements of the Union harmonisation legislation listed in Section A of Annex I apply, providers shall be responsible for ensuring that their product is fully compliant with all applicable requirements under applicable Union harmonisation legislation. In ensuring the compliance of high-risk AI systems referred to in paragraph 1 with the requirements set out in this Section, and in order to ensure consistency, avoid duplication and minimise additional burdens, providers shall have a choice of compliance, as appropriate, the necessary testing and reporting processes, information and documentation they provide with regard to their product into documentation and procedures that already exist and are required under the Union harmonisation legislation listed in Section A of Annex I.
Art. 9. 1. A risk management system shall be established, implemented, documented and maintained in relation to high-risk AI systems.
Art. 9. 2. The risk management system shall be run throughout the entire lifecycle of a high-risk AI system, requiring regular systematic review and updating. It shall comprise the following steps:
Art. 9. 2(a): the identification and analysis of the known and the reasonably foreseeable risks that the high-risk AI system can pose to health, safety or fundamental rights when the high-risk AI system is used in accordance with its intended purpose;
Art. 9. 2(b): the estimation and evaluation of the risks that may emerge when the high-risk AI system is used in accordance with its intended purpose, and under conditions of reasonably foreseeable misuse;
Art. 9. 2(c): the risks referred to in paragraph 2(a) shall be analysed in relation to the specific geographical, contextual, behavioural or functional setting within which the high-risk AI system is used;
Art. 9. 5. The risk management measures referred to in paragraph 2, point (d), shall be such that the relevant residual risk associated with each hazard, as well as the overall residual risk of the high-risk AI systems is judged to be acceptable. In identifying the most appropriate risk management measures, the following shall be ensured:
Art. 9. 5(a): elimination or reduction of risks identified and evaluated pursuant to paragraph 2 in as far as technically feasible through adequate design and development of the high-risk AI system;
Art. 9. 5(b): provision of information required pursuant to Article 13 and, where appropriate, training to deployers. With a view to eliminating or reducing risks related to the use of the high-risk AI system, due consideration shall be given to the technical knowledge, experience, education, the training to be expected by the deployer, and the presumable context in which the system is intended to be used.
Art. 9. 6. High-risk AI systems shall be tested for the purpose of identifying the most appropriate and targeted risk management measures. Testing shall ensure that high-risk AI systems perform consistently for their intended purpose and that they are in compliance with the requirements set out in this Section.
Art. 9. 8. The testing of high-risk AI systems shall be performed, as appropriate, at any time throughout the development process, and, in any event, prior to their being placed on the market or put into service. Testing shall be carried out against prior defined metrics and probabilistic thresholds that are appropriate to the intended purpose of the high-risk AI system.
Art. 9. 9. When implementing the risk management system as provided for in paragraphs 1 to 7, providers shall give consideration to whether in view of its intended purpose the high-risk AI system is likely to have an adverse impact on persons under the age of 18 and, as appropriate, other vulnerable groups.
Art. 9. 10. For providers of high-risk AI systems that are subject to requirements regarding internal risk management processes under other relevant provisions of Union law, the aspects provided in paragraphs 1 to 9 may be part of, or combined with, the risk management procedures established pursuant to that law.
Art. 10. 1. High-risk AI systems which make use of techniques involving the training of AI models with data sets shall be developed on the basis of training, validation and testing data sets that meet the quality criteria referred to in paragraphs 2 to 5 whenever such data sets are used.
Art. 10. 2. Training, validation and testing data sets shall be subject to data governance and management practices appropriate for the intended purpose of the high-risk AI system. Those practices shall concern in particular:
Art. 10. 3. Training, validation and testing data sets shall be relevant, sufficiently representative, and to the best extent possible, free of errors and complete in view of the intended purpose. They shall have the appropriate statistical properties, including, where applicable, as regards the persons or groups of persons in relation to whom the high-risk AI system is intended to be used. Those characteristics of the data sets may be met at the level of individual data sets or at the level of a combination thereof.
Art. 10. 4. Data sets shall be relevant and complete in view of the intended purpose of the high-risk AI system, in particular by ensuring that the data sets are representative of the specific geographical, contextual, behavioural or functional setting within which the high-risk AI system is intended to be used.
Art. 10. 5. To the extent that it is strictly necessary for the purpose of ensuring bias detection and correction in relation to the high-risk AI systems in accordance with paragraph 2, points (f) and (g) of this Article, the providers of such systems may exceptionally process special categories of personal data, subject to appropriate safeguards for the fundamental rights and freedoms of natural persons. In addition to the provisions set out in Regulations (EU) 2016/679 and (EU) 2018/1725 and Directive (EU) 2016/680, all the following conditions must be met in order for such processing to occur:
Art. 10. 6. For the development of high-risk AI systems not using techniques involving the training of AI models, paragraphs 2 to 5 apply only to the testing data sets.
Art. 10. 7. The technical documentation of high-risk AI systems shall be drawn up before the system is placed on the market or put into service and shall be kept up-to-date. The technical documentation shall be drawn up in such a way as to demonstrate that the high-risk AI system complies with the requirements set out in this Section and to provide national competent authority and notified bodies with the necessary information in a clear and comprehensive form to assess the compliance of the AI system with those requirements. It shall contain, at a minimum, the elements set out in Annex IV. SMEs, including start-ups, may provide the elements of the technical documentation specified in Annex IV in a simplified manner. To that end, the Commission shall establish a simplified technical documentation form targeted at the needs of small and medium-sized enterprises.
Art. 11. 2. Where a high-risk AI system related to a product covered by the Union harmonisation legislation listed in Section A of Annex I is placed on the market or put into service, a single set of technical documentation shall be drawn up containing all the information set out in paragraph 1, as well as the information required under those legal acts.
Art. 12. High-risk AI systems shall be subject to the automatic recording of events (logs) over the lifetime of the system.
Art. 12. 2. In order to ensure a level of traceability of the functioning of a high-risk AI system that is appropriate to the intended purpose of the system, logging capabilities shall enable the recording of events relevant for:
Art. 12. 2(a): identifying situations that may result in the high-risk AI system presenting a risk within the meaning of Article 79(1) or in a substantial modification;
Art. 12. 2(b): monitoring the operation of high-risk AI systems referred to in Article 26(2);
Art. 12. 3. For high-risk AI systems referred to in point 1 (a), of Annex III, the logging capabilities shall provide, at a minimum:
Art. 13. 1. High-risk AI systems shall be designed and developed in such a way as to ensure that their operation is sufficiently transparent to enable deployers to interpret a system's output and use it appropriately. An appropriate type and degree of transparency shall be ensured with a view to achieving consistent and reliable results.
Art. 13. 2. High-risk AI systems shall be accompanied by instructions for use in an appropriate digital format or otherwise that include concise, complete, correct and clear information that is relevant, accessible and comprehensible to deployers.
Art. 13. 3(b): the characteristics, capabilities and limitations of performance of the high-risk AI system, including:
Art. 13. 3(b)(i): the level of accuracy, robustness and cybersecurity referred to in Article 15 against which the high-risk AI system has been tested and validated and which can be expected, and any known and foreseeable circumstances that may have an impact on that expected level of accuracy, robustness and cybersecurity;
Art. 13. 3(b)(ii): any known or foreseeable circumstance, related to the use of the high-risk AI system in accordance with its intended purpose or under conditions of reasonably foreseeable misuse, which may lead to risks to the health and safety or fundamental rights referred to in Article 5;
Art. 13. 3(b)(iv): where applicable, the technical capabilities and characteristics of the high-risk AI system to provide information that is relevant to explain its output;
Art. 13. 3(b)(v): when appropriate, specifications for the input data, or any other relevant information in terms of the training, validation and testing data sets used, taking into account the intended purpose of the high-risk AI system;
Art. 13. 3(c): the changes to the high-risk AI system and its performance which have been pre-determined by the provider at the moment of the initial conformity assessment, if any;
Art. 13. 3(d): the human oversight measures referred to in Article 14, including the technical measures set in place to facilitate the interpretation of the outputs of the high-risk AI systems by the deployers;
Art. 13. 3(e): the combination of the technical measures referred to in paragraph 1, and any necessary measures, such as the provision of training, validation and testing data sets, to ensure the proper functioning of that AI system, including as regards software updates;
Art. 13. 3(f): where relevant, a description of the mechanisms included within the high-risk AI system that allows deployers to properly collect, store and interpret the logs in accordance with Article 12.
Art. 14. 1. High-risk AI systems shall be designed and developed in such a way, including with appropriate human-machine interface tools, that they can be effectively overseen by natural persons during the period in which they are in use.
Art. 14. 2. Human oversight shall aim to prevent or minimise the risks to health, safety or fundamental rights that may emerge when a high-risk AI system is used in accordance with its intended purpose or under conditions of reasonably foreseeable misuse, in particular where such risks

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- Art. 77, 3: Where the documentation referred to in paragraph 1 is insufficient to ascertain whether an infringement of obligations under Union law protecting fundamental rights has occurred, the public authority or body referred to in paragraph 1 may make a reasoned request to the market surveillance authority in order to request the high-risk AI system to undergo technical measures.
Art. 78, 2: The authorities involved in the application of this Regulation pursuant to paragraph 1 shall request only data that is strictly necessary for the assessment of the risk posed by AI systems and for the exercise of their powers in accordance with this Regulation and with Regulation (EU) 2019/1020. They shall put in place adequate and effective cybersecurity measures to protect the security and confidentiality of the information and data obtained, and shall delete the data collected as soon as it is no longer needed for the purpose for which it was obtained, in accordance with applicable law.
Art. 78, 3: Without prejudice to paragraphs 1 and 2, information exchanged on a confidential basis between the national competent authorities or between national competent authorities and the Commission shall not be disclosed without prior consultation of the originating national competent authority and the deployer when high-risk AI systems referred to in point 1, 6 or 7 of Annex III are used by law enforcement, border control, immigration or asylum authorities and when such disclosure would jeopardise public and national security interests.
Art. 79, 4: The operator shall ensure that appropriate corrective action is taken in respect of all AI systems concerned that it has made available on the Union market.
Art. 79, 5: Where the operator of an AI system does not take adequate corrective action within the period referred to in paragraph 2, the market surveillance authority shall take all appropriate provisional measures to prohibit or restrict the AI system's being made available on its national market or put into service, to withdraw the product or the standalone AI system from that market or to recall it.
Art. 79, 6: The notified authority shall include all available details, in particular the information necessary for the identification of the non-compliant AI system, the origin of the AI system and the supply chain, the nature of the non-compliance alleged and the risk involved, the nature and duration of the national measures taken and the arguments put forward by the relevant operator.
Art. 79, 7: The market surveillance authorities other than the market surveillance authority of the Member State initiating the procedure shall, without undue delay, inform the Commission and the other Member States of any measures adopted and of any additional information at their disposal relating to the non-compliance of the AI system concerned, and, in the event of disagreement with the notified national measure, of their objections.
Art. 80, 3: Where the market surveillance authority considers that the use of the AI system concerned is not restricted to its national territory, it shall inform the Commission and the other Member States without undue delay of the results of the evaluation and of the actions which it has required the provider to take.
Art. 80, 4: The provider shall ensure that all necessary action is taken to bring the AI system into compliance with the requirements and obligations laid down in this Regulation.
Art. 80, 5: Where the provider of the AI system concerned does not take adequate corrective action within the period referred to in paragraph 2 of this Article, the provider shall be subject to fines in accordance with Article 99.
Art. 80, 6: Where the provider of the AI system concerned does not take adequate corrective action within the period referred to in paragraph 2 of this Article, the market surveillance authority shall carry out an evaluation of the AI system concerned in respect of its classification as a high-risk AI system based on the conditions set out in Article 6(3) and the Commission guidelines.
Art. 80, 7: Where, in the course of the evaluation, the market surveillance authority finds that the high-risk AI system does not comply with the requirements and obligations laid down in this Regulation, as well as take appropriate corrective action within a period the market surveillance authority may prescribe.
Art. 80, 8: Where the market surveillance authority considers that the use of the AI system concerned is not restricted to its national territory, it shall inform the Commission and the other Member States without undue delay of the results of the evaluation and of the actions which it has required the provider to take.
Art. 80, 9: Where the national measure referred to in paragraph 2 and the non-compliance of the AI system is attributed to shortcomings in the harmonised standards or common specifications referred to in Articles 40 and 41 of this Regulation, the Commission shall apply the procedure provided for in Article 11 of Regulation (EU) No 1025/2012.
Art. 82: Compliant AI systems which present a risk
Art. 95, 1: The AI Office and the Member States shall encourage and facilitate the drawing up of codes of conduct, including related governance mechanisms, intended to foster the voluntary application to AI systems, other than high-risk AI systems, of some or all of the requirements set out in Chapter III, Section 2, of this Regulation.
Art. 95, 2: The AI Office and the Member States shall facilitate the drawing up of codes of conduct concerning the voluntary application, including by deployers, of specific requirements to all AI systems, on the basis of clear objectives and key performance indicators to measure the achievement of those objectives, including elements such as, but not limited to:
Art. 95, 2(a): assessing and minimising the impact of AI systems on environmental sustainability, including as regards energy-efficient programming and techniques for the efficient design, training and use of AI;
Art. 95, 2(b): facilitating an inclusive and diverse design of AI systems, including through the establishment of inclusive and diverse development teams and the promotion of stakeholders' participation in that process;
Art. 95, 2(c): assessing and preventing the negative impact of AI systems on vulnerable persons or groups of vulnerable persons, including as regards accessibility for persons with a disability, as well as on gender equality.
Art. 95, 3: Codes of conduct may be drawn up by individual providers or deployers of AI systems or by organisations representing them or by both, including with the involvement of any interested stakeholders and their representative organisations, including civil society organisations and academia. Codes of conduct may cover one or more AI systems taking into account the similarity of the relevant systems.
Art. 96, 1(f): the application of the definition of an AI system as set out in Article 3, point (1). When issuing such guidelines, the Commission shall pay particular attention to the needs of SMEs including start-ups, of local public authorities and of the sectors most likely to be affected by this Regulation. The guidelines referred to in the first subparagraph of this paragraph shall take due account of the generally acknowledged state of the art on AI, as well as of relevant harmonised standards and common specifications that are referred to in Articles 40 and 41, or of those harmonised standards or technical specifications that are set out pursuant to Union harmonisation law.
Art. 99, 7(a): the nature, gravity and duration of the infringement and of its consequences, taking into account the purpose of the AI system, as well as, where appropriate, the number of affected persons and the level of damage suffered by them;
Art. 100, 1(a): the duration of the infringement and of its consequences, taking into account the purpose of the AI system concerned, as well as, where appropriate, the number of affected persons and the level of damage suffered by them;
Art. 100, 3: The non-compliance of the AI system with any requirements or obligations under this Regulation, other than those laid down in Article 5, shall be subject to administrative fines of up to EUR 750 000.
Art. 102: In Article 4(3) of Regulation (EC) No 300/2008, the following subparagraph is added: 'When adopting detailed measures related to technical specifications and procedures for approval and use of security equipment concerning Artificial Intelligence systems within the meaning of Regulation (EU) 2024/1689 of the European Parliament and of the Council (*1), the requirements set out in Chapter III, Section 2, of that Regulation shall be taken into account.'
Art. 103: In Article 17(5) of Regulation (EU) No 167/2013, the following subparagraph is added: 'When adopting delegated acts pursuant to the first subparagraph concerning artificial intelligence systems which are safety components within the meaning of Regulation (EU) 2024/1689 of the European Parliament and of the Council (*2), the requirements set out in Chapter III, Section 2, of that Regulation shall be taken into account.'
Art. 104: In Article 22(5) of Regulation (EU) No 168/2013, the following subparagraph is added: 'When adopting delegated acts pursuant to the first subparagraph concerning Artificial Intelligence systems which are safety components within the meaning of Regulation (EU) 2024/1689 of the European Parliament and of the Council (*3), the requirements set out in Chapter III, Section 2, of that Regulation shall be taken into account.'
Art. 105: In Article 8 of Directive 2014/90/EU, the following paragraph is added: '5. For Artificial Intelligence systems which are safety components within the meaning of Regulation (EU) 2024/1689 of the European Parliament and of the Council (*4), when carrying out its activities pursuant to paragraph 1 and when adopting technical specifications and testing standards in accordance with paragraphs 2 and 3, the Commission shall take into account the requirements set out in Chapter III, Section 2, of that Regulation.'
Art. 106: In Article 5 of Directive (EU) 2016/797, the following paragraph is added: '12. When adopting delegated acts pursuant to paragraph 1 and implementing acts pursuant to paragraph 11 concerning Artificial Intelligence systems which are safety components within the meaning of Regulation (EU) 2024/1689 of the European Parliament and of the Council (*5), the requirements set out in Chapter III, Section 2, of that Regulation shall be taken into account.'
Art. 107: In Article 5 of Directive (EU) 2016/953, the following paragraph is added: '4. When adopting delegated acts pursuant to paragraph 3 concerning Artificial Intelligence systems which are safety components within the meaning of Regulation (EU) 2024/1689 of the European Parliament and of the Council (*6), the requirements set out in Chapter III, Section 2, of that Regulation shall be taken into account.'
Art. 108(1): in Article 17, the following paragraph is added: '3. Without prejudice to paragraph 2, when adopting implementing acts pursuant to paragraph 1 concerning Artificial Intelligence systems which are safety components within the meaning of Regulation (EU) 2024/1689 of the European Parliament and of the Council (*7), the requirements set out in Chapter III, Section 2, of that Regulation shall be taken into account.'
Art. 108(2): in Article 19, the following paragraph is added: '4. When adopting delegated acts pursuant to paragraphs 1 and 2 concerning Artificial Intelligence systems which are safety components within the meaning of Regulation (EU) 2024/1689, the requirements set out in Chapter III, Section 2, of that Regulation shall be taken into account.'
Art. 108(3): in Article 43, the following paragraph is added: '4. When adopting implementing acts pursuant to paragraph 1 concerning Artificial Intelligence systems which are safety components within the meaning of Regulation (EU) 2024/1689, the requirements set out in Chapter III, Section 2, of that Regulation shall be taken into account.'
Art. 108(4): in Article 47, the following paragraph is added: '3. When adopting delegated acts pursuant to paragraphs 1 and 2 concerning Artificial Intelligence systems which are safety components within the meaning of Regulation (EU) 2024/1689, the requirements set out in Chapter III, Section 2, of that Regulation shall be taken into account.'
Art. 108(5): in Article 57, the following paragraph is added: 'When adopting those implementing acts concerning Artificial Intelligence systems which are safety components within the meaning of Regulation (EU) 2024/1689, the requirements set out in Chapter III, Section 2, of that Regulation shall be taken into account.'
Art. 108(6): in Article 58, the following paragraph is added: '3. When adopting delegated acts pursuant to paragraphs 1 and 2 concerning Artificial Intelligence systems which are safety components within the meaning of Regulation (EU) 2024/1689, the requirements set out in Chapter III, Section 2, of that Regulation shall be taken into account.'
Art. 109: In Article 11 of Regulation (EU) 2019/12144, the following paragraph is added: '3. When adopting the implementing acts pursuant to paragraph 2, concerning artificial intelligence systems which are safety components within the meaning of Regulation (EU) 2024/1689 of the European Parliament and of the Council (*8), the requirements set out in Chapter III, Section 2, of that Regulation shall be taken into account.'
Art. 111: AI systems already placed on the market or put into service and general-purpose AI models already placed on the market
Art. 111, 1: Without prejudice to the application of Article 5 as referred to in Article 113(9), point (a), AI systems which are components of the large-scale IT systems established by the legal acts listed in Annex X that have been placed on the market or put into service before 2 August 2027 shall be brought into compliance with this Regulation by 31 December 2030. The requirements laid down in this Regulation shall be taken into account in the evaluation of each large-scale IT system established by the legal acts listed in Annex X to be undertaken as provided for in those legal acts and where those legal acts are replaced or amended.
Art. 111, 2: Without prejudice to the application of Article 5 as referred to in Article 113(3), point (a), this Regulation shall apply to operators of high-risk AI systems, other than the systems referred to in paragraph 1 of this Article, that have been placed on the market or put into service before 2 August 2026, only if, as from that date, those systems are subject to significant changes in their designs. In any case, the providers and deployers of high-risk AI systems intended to be used by public authorities shall take the necessary steps to comply with the requirements and obligations of this Regulation by 2 August 2030.
Art. 112, 2(b): amendments to the list of AI systems requiring additional transparency measures in Article 50;
Art. 112, 7: By 2 August 2028 and every three years thereafter, the Commission shall evaluate the impact and effectiveness of voluntary codes of conduct to foster the application of the requirements set out in Chapter III, Section 2 for AI systems other than high-risk AI systems and possibly other additional requirements for AI systems other than high-risk AI systems, including as regards environmental sustainability.
Art. 112, 10: The Commission shall, if necessary, submit appropriate proposals to amend this Regulation, in particular taking into account developments in technology, the effect of AI systems on health and safety, and on fundamental rights, and in light of the state of progress in the information society.
Art. 112, 11(c): the list of AI systems requiring additional transparency measures pursuant to Article 50.

0 AI system lifecycle

12 Alert

- Art. 51, 1(b): based on a decision of the Commission, ex officio or following a qualified alert from the scientific panel, it has capabilities or an impact equivalent to those set out in point (a) having regard to the criteria set out in Annex XIII.
Art. 52, 4: The Commission may designate a general-purpose AI model as presenting systemic risks, ex officio or following a qualified alert from the scientific panel pursuant to Article 90(1), point (a), on the basis of criteria set out in Annex XIII. The Commission is empowered to adopt delegated acts in accordance with Article 97 in order to amend Annex XIII by specifying and updating the criteria set out in that Annex.
Art. 65, (n): provide opinions to the Commission on the qualified alerts regarding general-purpose AI models.
Art. 66, (o): receive opinions by the Member States on qualified alerts regarding general-purpose AI models, and on national experiences and practices on the monitoring and enforcement of AI systems, in particular systems integrating the general-purpose AI models.
Art. 68, 3(a)(i): alerting the AI Office of possible systemic risks at Union level of general-purpose AI models, in accordance with Article 90.
Art. 68, 5: The implementing act referred to in paragraph 1 shall include provisions on the conditions, procedures and detailed arrangements for the scientific panel and its members to issue alerts, and to request the assistance of the AI Office for the performance of the tasks of the scientific panel.
Art. 90: Alerts of systemic risks by the scientific panel
Art. 90, 1: The scientific panel may provide a qualified alert to the AI Office where it has reason to suspect that:
Art. 90, 2: Upon such qualified alert, the Commission, through the AI Office and after having informed the Board, may exercise the powers laid down in this Section for the purpose of assessing the matter. The AI Office shall inform the Board of any measure according to Articles 91 to 94.
Art. 90, 3: A qualified alert shall be duly reasoned and indicate at least:
Art. 90, 3(a): a description of the relevant risks and the reasons for the alert by the scientific panel;
Art. 92, 1(b): to investigate systemic risks at Union level of general-purpose AI models with systemic risk, in particular following a qualified alert from the scientific panel in accordance with Article 90(1), point (a).

0 Algorithm

0 Algorithmic Bias

Terms and AI Act Articles

20 Amendment

Art. 6, 8: Any amendment to the conditions laid down in paragraph 3, second subparagraph, adopted in accordance with paragraphs 6 and 7 of this Article shall not decrease the overall level of protection of health, safety and fundamental rights provided for by this Regulation and shall ensure consistency with the delegated acts adopted pursuant to Article 7(1), and take account of market and technological developments.

Art. 7: Amendments to Annex III

Art. 66, (e)(iv): on the potential need for amendment to Annex III in accordance with Article 7, and on the potential need for possible revision of Article 5 pursuant to Article 112, taking into account relevant available evidence and the latest developments in technology;

Art. 99, 2: The Member States shall, without delay and at the latest by the date of entry into application, notify the Commission of the rules on penalties and of other enforcement measures referred to in paragraph 1, and shall notify it, without delay, of any subsequent amendment to them.

Art. 102: Amendment to Regulation (EC) No 300/2008

Art. 103: Amendment to Regulation (EU) No 167/2013

Art. 104: Amendment to Regulation (EU) No 168/2013

Art. 105: Amendment to Directive 2014/90/EU

Art. 106: Amendment to Regulation (EU) 2016/797

Art. 107: Amendment to Regulation (EU) 2018/858

Art. 108: Amendments to Regulation (EU) 2018/1139

Art. 109: Amendment to Regulation (EU) 2019/2144

Art. 110: Amendment to Directive (EU) 2020/1828

Art. 112, 1: The Commission shall assess the need for amendment of the list set out in Annex III and of the list of prohibited AI practices laid down in Article 5, once a year following the entry into force of this Regulation, and until the end of the period of the delegation of power laid down in Article 97. The Commission shall submit the findings of that assessment to the European Parliament and the Council.

Art. 112, 2(a): the need for amendments extending existing area headings or adding new area headings in Annex III;

Art. 112, 2(b): amendments to the list of AI systems requiring additional transparency measures in Article 50;

Art. 112, 2(c): amendments enhancing the effectiveness of the supervision and governance system.

Art. 112, 3: By 2 August 2029 and every four years thereafter, the Commission shall submit a report on the evaluation and review of this Regulation to the European Parliament and to the Council. The report shall include an assessment with regard to the structure of enforcement and the possible need for a Union agency to resolve any identified shortcomings. On the basis of the findings, that report shall, where appropriate, be accompanied by a proposal for amendment of this Regulation. The reports shall be made public.

Art. 112, 12: Any amendment to this Regulation pursuant to paragraph 10, or relevant delegated or implementing acts, which concerns sectoral Union harmonisation legislation listed in Section 5 of Annex I shall take into account the regulatory specificities of each sector, and the existing governance, conformity assessment and enforcement mechanisms and authorities established therein.

Art. 112, 13: By 2 August 2031, the Commission shall carry out an assessment of the enforcement of this Regulation and shall report on it to the European Parliament, the Council and the European Economic and Social Committee, taking into account the first years of application of this Regulation. On the basis of the findings, that report shall, where appropriate, be accompanied by a proposal for amendment of this Regulation with regard to the structure of enforcement and the need for a Union agency to resolve any identified shortcomings.

0 Analytics

1 Annotation

Art. 10, 2(c): relevant data-preparation processing operations, such as annotation, labelling, cleaning, updating, enrichment and aggregation;

1 Anonymised data (See also: *Synthetic*)

Art. 10, 5(a): the bias detection and correction cannot be effectively fulfilled by processing other data, including synthetic or anonymised data;

1 Applicable, as regards the persons or groups

Art. 10, 3: Training, validation and testing data sets shall be relevant, sufficiently representative, and to the best extent possible, free of errors and complete in view of the intended purpose. They shall have the appropriate statistical properties, including, where applicable, as regards the persons or groups of persons in relation to whom the high-risk AI system is intended to be used. Those characteristics of the data sets may be met at the level of individual data sets or at the level of a combination thereof.

1 Appropriate confidentiality

Art. 10, 5(c): the special categories of personal data are subject to measures to ensure that the personal data processed are secured, protected, subject to suitable safeguards, including strict controls and documentation of the access, to avoid misuse and ensure that only authorised persons have access to those personal data with appropriate confidentiality obligations;

1 Appropriate statistical properties

Art. 10, 3: Training, validation and testing data sets shall be relevant, sufficiently representative, and to the best extent possible, free of errors and complete in view of the intended purpose. They shall have the appropriate statistical properties, including, where applicable, as regards the persons or groups of persons in relation to whom the high-risk AI system is intended to be used. Those characteristics of the data sets may be met at the level of individual data sets or at the level of a combination thereof.

2 Architecture

Art. 53, 2: The obligations set out in paragraph 1, points (a) and (b), shall not apply to providers of AI models that are released under a free and open-source licence that allows for the access, usage, modification, and distribution of the model, and whose parameters, including the weights, and the information on the model architecture, and the information on model usage, are made publicly available. This exception shall not apply to general-purpose AI models with systemic risks.

Art. 54, 6: The obligation set out in this Article shall not apply to providers of general-purpose AI models that are released under a free and open-source licence that allows for the access, usage, modification, and distribution of the model, and whose parameters, including the weights, the information on the model architecture, and the information on model usage, are made publicly available, unless the general-purpose AI models present systemic risks.

19 Artificial intelligence

Art. 1, 1: The purpose of this Regulation is to improve the functioning of the internal market and promote the uptake of human-centric and trustworthy artificial intelligence (AI), while ensuring a high level of protection of health, safety, fundamental rights enshrined in the Charter, including democracy, the rule of law and environmental protection, against the harmful effects of AI systems in the Union and supporting innovation.

Art. 6, 5: The Commission shall, after consulting the European Artificial Intelligence Board (the Board), and no later than 2 February 2026, provide guidelines specifying the practical implementation of this Article in line with Article 96 together with a comprehensive list of practical examples of use cases of AI systems that are high-risk and not high-risk.

Art. 65: Establishment and structure of the European Artificial Intelligence Board

Art. 65, 1: A European Artificial Intelligence Board (the Board) is hereby established.

Art. 102: In Article 4(3) of Regulation (EC) No 300/2008, the following subparagraph is added: "When adopting detailed measures related to technical specifications and procedures for approval and use of security equipment concerning Artificial Intelligence systems within the meaning of Regulation (EU) 2024/1689 of the European Parliament and of the Council (*)1, the requirements set out in Chapter III, Section 2, of that Regulation shall be taken into account."

Art. 103: In Article 17(5) of Regulation (EU) No 167/2013, the following subparagraph is added: "When adopting delegated acts pursuant to the first subparagraph concerning artificial intelligence systems which are safety components within the meaning of Regulation (EU) 2024/1689 of the European Parliament and of the Council (*), the requirements set out in Chapter III, Section 2, of that Regulation shall be taken into account."

Art. 104: In Article 22(5) of Regulation (EU) No 168/2013, the following subparagraph is added: "When adopting delegated acts pursuant to the first subparagraph concerning Artificial Intelligence systems which are safety components within the meaning of Regulation (EU) 2024/1689 of the European Parliament and of the Council (*), the requirements set out in Chapter III, Section 2, of that Regulation shall be taken into account."

Art. 105: In Article 8 of Directive 2014/90/EU, the following paragraph is added: "5. For Artificial Intelligence systems which are safety components within the meaning of Regulation (EU) 2024/1689 of the European Parliament and of the Council (*), when carrying out its activities pursuant to paragraph 1 and when adopting technical specifications and testing standards in accordance with paragraphs 2 and 3, the Commission shall take into account the requirements set out in Chapter III, Section 2, of that Regulation."

Art. 106: In Article 5 of Regulation (EU) 2018/858 the following paragraph is added: "12. When adopting delegated acts pursuant to paragraph 1 and implementing acts pursuant to paragraph 11 concerning Artificial Intelligence systems which are safety components within the meaning of Regulation (EU) 2024/1689 of the European Parliament and of the Council (*), the requirements set out in Chapter III, Section 2, of that Regulation shall be taken into account."

Art. 108(1): In Article 17, the following paragraph is added: "3. Without prejudice to paragraph 2, when adopting implementing acts pursuant to paragraph 1 concerning Artificial Intelligence systems which are safety components within the meaning of Regulation (EU) 2024/1689 of the European Parliament and of the Council (*), the requirements set out in Chapter III, Section 2, of that Regulation shall be taken into account."

Art. 108(7): Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence and amending Regulations (EC) No 300/2008, (EU) No 167/2013, (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1139 and (EU) 2019/2144 and Directives 2014/90/EU, (EU) 2016/797 and (EU) 2020/1828 (Artificial Intelligence Act) (OJ L, 2024/1689, 12.7.2024, ELI: <http://data.europa.eu/eli/reg/2024/1689/oj>).

Art. 108(2): In Article 19, the following paragraph is added: "4. When adopting delegated acts pursuant to paragraphs 1 and 2 concerning Artificial Intelligence systems which are safety components within the meaning of Regulation (EU) 2024/1689, the requirements set out in Chapter III, Section 2, of that Regulation shall be taken into account."

Art. 108(3): In Article 43, the following paragraph is added: "4. When adopting implementing acts pursuant to paragraph 1 concerning Artificial Intelligence systems which are safety components within the meaning of Regulation (EU) 2024/1689, the requirements set out in Chapter III, Section 2, of that Regulation shall be taken into account."

Art. 108(4): In Article 47, the following paragraph is added: "3. When adopting delegated acts pursuant to paragraphs 1 and 2 concerning Artificial Intelligence systems which are safety components within the meaning of Regulation (EU) 2024/1689, the requirements set out in Chapter III, Section 2, of that Regulation shall be taken into account."

Art. 108(5): In Article 57, the following subparagraph is added: "When adopting those implementing acts concerning Artificial Intelligence systems which are safety components within the meaning of Regulation (EU) 2024/1689, the requirements set out in Chapter III, Section 2, of that Regulation shall be taken into account."

Art. 108(6): In Article 58, the following paragraph is added: "3. When adopting delegated acts pursuant to paragraphs 1 and 2 concerning Artificial Intelligence systems which are safety components within the meaning of Regulation (EU) 2024/1689, the requirements set out in Chapter III, Section 2, of that Regulation shall be taken into account."

Art. 109: In Article 11 of Regulation (EU) 2019/2144, the following paragraph is added: "3. When adopting the implementing acts pursuant to paragraph 2, concerning artificial intelligence systems which are safety components within the meaning of Regulation (EU) 2024/1689 of the European Parliament and of the Council (*), the requirements set out in Chapter III, Section 2, of that Regulation shall be taken into account."

Art. 110: In Annex I to Directive (EU) 2020/1828 of the European Parliament and of the Council (58), the following point is added: "(68) Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence and amending Regulations (EC) No 300/2008, (EU) No 167/2013, (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1139 and (EU) 2019/2144 and Directives 2014/90/EU, (EU) 2016/797 and (EU) 2020/1828 (Artificial Intelligence Act) (OJ L, 2024/1689, 12.7.2024, ELI: <http://data.europa.eu/eli/reg/2024/1689/oj>))."

0 Artificial neural network

Terms and AI Act Articles

1 Assessment of the availability

Art. 10, 2(e): an assessment of the availability, quantity and suitability of the data sets that are needed;

9 Assessment procedures

Art. 17, 1(a): a strategy for regulatory compliance, including compliance with conformity assessment procedures and procedures for the management of modifications to the high-risk AI system;

Art. 34, 1: Notified bodies shall verify the conformity of high-risk AI systems in accordance with the conformity assessment procedures set out in Article 43.

Art. 38, 1: The Commission shall ensure that, with regard to high-risk AI systems, appropriate coordination and cooperation between notified bodies active in the conformity assessment procedures pursuant to this Regulation are put in place and properly operated in the form of a sectoral group of notified bodies.

Art. 43, 1: For high-risk AI systems listed in point 1 of Annex III, where, in demonstrating the compliance of a high-risk AI system with the requirements set out in Section 2, the provider has applied harmonised standards referred to in Article 40, or, where applicable, common specifications referred to in Article 41, the provider shall opt for one of the following conformity assessment procedures based on:

Art. 44, 2: Certificates shall be valid for the period they indicate, which shall not exceed five years for AI systems covered by Annex I, and four years for AI systems covered by Annex III. At the request of the provider, the validity of a certificate may be extended for further periods, each not exceeding five years for AI systems covered by Annex I, and four years for AI systems covered by Annex III, based on a re-assessment in accordance with the applicable conformity assessment procedures. Any supplement to a certificate shall remain valid, provided that the certificate which it supplements is valid.

Art. 46, 1: By way of derogation from Article 43 and upon a duly justified request, any market surveillance authority may authorise the placing on the market or the putting into service of specific high-risk AI systems within the territory of the Member State concerned, for exceptional reasons of public security or the protection of life and health of persons, environmental protection or the protection of key industrial and infrastructural assets. That authorisation shall be for a limited period while the necessary conformity assessment procedures are being carried out, taking into account the exceptional reasons justifying the derogation. The completion of those procedures shall be undertaken without undue delay.

Art. 48, 4: Where applicable, the CE marking shall be followed by the identification number of the notified body responsible for the conformity assessment procedures set out in Article 43. The identification number of the notified body shall be affixed by the body itself or, under its instructions, by the provider or by the provider's authorised representative. The identification number shall also be indicated in any promotional material which mentions that the high-risk AI system fulfils the requirements for CE marking.

Art. 57, 7: Competent authorities shall provide providers and prospective providers participating in the AI regulatory sandbox with guidance on regulatory expectations and how to fulfil the requirements and obligations set out in this Regulation. Upon request of the provider or prospective provider of the AI system, the competent authority shall provide a written proof of the activities successfully carried out in the sandbox. The competent authority shall also provide an exit report detailing the activities carried out in the sandbox and the related results and learning outcomes. Providers may use such documentation to demonstrate their compliance with this Regulation through the conformity assessment process or relevant market surveillance activities. In this regard, the exit reports and the written proof provided by the national competent authority shall be taken positively into account by market surveillance authorities and notified bodies, with a view to accelerating conformity assessment procedures to a reasonable extent.

Art. 66, (d): contribute to the harmonisation of administrative practices in the Member States, including in relation to the derogation from the conformity assessment procedures referred to in Article 46, the functioning of AI regulatory sandboxes, and testing in real world conditions referred to in Articles 57, 59 and 60;

1 Attack

Art. 5, 1(h)(ii): the prevention of a specific, substantial and imminent threat to the life or physical safety of natural persons or a genuine and present or genuine and foreseeable threat of a terrorist attack;

0 Auditability

1 Authentication

Art. 3, (36): 'biometric verification' means the automated, one-to-one verification, including authentication, of the identity of natural persons by comparing their biometric data to previously provided biometric data;

0 Authenticity

Terms and AI Act Articles

(EU) 2019/1020. They shall put in place adequate and effective cybersecurity measures to protect the security and confidentiality of the information and data obtained, and shall delete the data collected as soon as it is no longer needed for the purpose for which it was obtained, in accordance with applicable Union or national law.

Art. 78. 3. Without prejudice to paragraphs 1 and 2, information exchanged on a confidential basis between the national competent authorities or between national competent authorities and the Commission shall not be disclosed without prior consultation of the originating national competent authority and the deployer when high-risk AI systems referred to in point 1, 6 or 7 of Annex III are used by law enforcement, border control, immigration or asylum authorities. When the law enforcement, immigration or asylum authorities are providers of high-risk AI systems referred to in point 1, 6 or 7 of Annex III, the technical documentation referred to in Annex IV shall remain within the premises of those authorities. Those authorities shall ensure that the market surveillance authorities referred to in Article 74(8) and (9), as applicable, can, upon request, immediately access the documentation or obtain a copy thereof. Only staff of the market surveillance authority holding the appropriate level of security clearance shall be allowed to access that documentation or any copy thereof.

Art. 78. 4. Paragraphs 1, 2 and 3 shall not affect the rights or obligations of the Commission, Member States and their relevant authorities, as well as those of notified bodies, with regard to the exchange of information and the dissemination of warnings, including in the context of cross-border cooperation, nor shall they affect the obligations of the parties concerned to provide information under criminal law of the Member States.

Art. 78. 5. The Commission and Member States may exchange, where necessary and in accordance with relevant provisions of international and trade agreements, confidential information with regulatory authorities of third countries with which they have concluded bilateral or multilateral confidentiality arrangements guaranteeing an adequate level of confidentiality.

Art. 79. 2. Where the market surveillance authority of a Member State has sufficient reason to consider an AI system to present a risk as referred to in paragraph 1 of this Article, it shall carry out an evaluation of the AI system concerned in respect of its compliance with all the requirements and obligations laid down in this Regulation. Particular attention shall be given to AI systems presenting a risk to vulnerable groups. Where risks to fundamental rights are identified, the market surveillance authority shall also inform and fully cooperate with the relevant national public authorities referred to in Article 77(1). The relevant operators shall cooperate with the market surveillance authority and with the other national public authorities or bodies referred to in Article 77(1). Where, in the course of that evaluation, the market surveillance authority or, where applicable the market surveillance authority in cooperation with the national public authority referred to in Article 77(1), finds that the AI system does not comply with the requirements and obligations laid down in this Regulation, it shall without undue delay require the relevant operator to take all appropriate corrective actions to bring the AI system into compliance, to withdraw the AI system from the market, or to recall it within a period the market surveillance authority may prescribe, and in any event within the shorter of 15 working days, or as provided for in the relevant Union harmonisation legislation. The market surveillance authority shall inform the relevant notified body accordingly. Article 18 of Regulation (EU) 2019/1020 shall apply to the measures referred to in the second subparagraph of this paragraph.

Art. 79. 3. Where the market surveillance authority considers that the non-compliance is not restricted to its national territory, it shall inform the Commission and the other Member States without undue delay of the results of the evaluation and of the actions which it has required the operator to take.

Art. 79. 5. Where the operator of an AI system does not take adequate corrective action within the period referred to in paragraph 2, the market surveillance authority shall take all appropriate provisional measures to prohibit or restrict the AI system's being made available on its national market or put into service, to withdraw the product or the standalone AI system from that market or to recall it. That authority shall without undue delay notify the Commission and the other Member States of those measures.

Art. 79. 6. The notification referred to in paragraph 5 shall include all available details, in particular the information necessary for the identification of the non-compliant AI system, the origin of the AI system and the supply chain, the nature of the non-compliance alleged and the risk involved, the nature and duration of the national measures taken and the arguments put forward by the relevant operator. In particular, the market surveillance authorities shall indicate whether the non-compliance is due to one or more of the following:

Art. 79. 7. The market surveillance authorities other than the market surveillance authority of the Member State initiating the procedure shall, without undue delay, inform the Commission and the other Member States of any measures adopted and of any additional information at their disposal relating to the non-compliance of the AI system concerned, and, in the event of disagreement with the notified national measure, of their objections.

Art. 79. 8. Where, within three months of receipt of the notification referred to in paragraph 5 of this Article, no objection has been raised by either a market surveillance authority of a Member State or by the Commission in respect of a provisional measure taken by a market surveillance authority of another Member State, that measure shall be deemed justified. This shall be without prejudice to the procedural rights of the concerned operator in accordance with Article 18 of Regulation (EU) 2019/1020. The three-month period referred to in this paragraph shall be reduced to 30 days in the event of non-compliance with the prohibition of the AI practices referred to in Article 5 of this Regulation.

Art. 79. 9. The market surveillance authorities shall ensure that appropriate restrictive measures are taken in respect of the product or the AI system concerned, such as withdrawal of the AI system from their market, without undue delay.

Art. 80. 1. Where a market surveillance authority has sufficient reason to consider that an AI system classified by the provider as non-high-risk pursuant to Article 6(3) is indeed high-risk, the market surveillance authority shall carry out an evaluation of the AI system concerned in respect of its classification as a high-risk AI system based on the conditions set out in Article 6(3) and the Commission guidelines.

Art. 80. 2. Where, in the course of that evaluation, the market surveillance authority finds that the AI system concerned is high-risk, it shall without undue delay require the relevant provider to take all necessary actions to bring the AI system into compliance with the requirements and obligations laid down in this Regulation, as well as take appropriate corrective action within a period the market surveillance authority may prescribe.

Art. 80. 3. Where the market surveillance authority considers that the use of the AI system concerned is not restricted to its national territory, it shall inform the Commission and the other Member States without undue delay of the results of the evaluation and of the actions which it has required the provider to take.

Art. 80. 7. Where, in the course of the evaluation pursuant to paragraph 1 of this Article, the market surveillance authority establishes that the AI system was misclassified by the provider as non-high-risk in order to circumvent the application of requirements in Chapter III, Section 2, the subject to which this Article shall be subject shall be the AI system concerned.

Art. 80. 8. In exercising their power to monitor the application of this Article, and in accordance with Article 11 of Regulation (EU) 2019/1020, market surveillance authorities may perform appropriate checks, taking into account in particular information stored in the EU database referred to in Article 71 of this Regulation.

Art. 81. 1. Where, within three months of receipt of the notification referred to in Article 79(5), or within 30 days in the case of non-compliance with the prohibition of the AI practices referred to in Article 5, objections are raised by the market surveillance authority of a Member State to a measure taken by another market surveillance authority, or where the Commission considers the measure to be contrary to Union law, the Commission shall without undue delay enter into consultation with the market surveillance authority of the relevant Member State and the operator or operators, and shall evaluate the national measure. On the basis of the results of that evaluation, the Commission shall, within six months, or within 60 days in the case of non-compliance with the prohibition of the AI practices referred to in Article 5, starting from the notification referred to in Article 79(5), decide whether the national measure is justified and shall notify its decision to the market surveillance authority of the Member State concerned. The Commission shall also inform all other market surveillance authorities of its decision.

Art. 82. 1. Where, having performed an evaluation under Article 79, after consulting the relevant national public authority referred to in Article 77(1), the market surveillance authority of a Member State finds that although a high-risk AI system complies with this Regulation, it nevertheless presents a risk to the health or safety of persons, to fundamental rights, or to other aspects of public interest protection, it shall require the relevant operator to take all appropriate measures to ensure that the AI system concerned, when placed on the market or put into service, no longer presents that risk without undue delay, within a period it may prescribe.

Art. 82. 2. The provider or other relevant operator shall ensure that corrective action is taken in respect of all the AI systems concerned that it has made available on the Union market within the timeline prescribed by the market surveillance authority of the Member State referred to in paragraph 1.

Art. 83. 1. Where the market surveillance authority of a Member State makes one of the following findings, it shall require the relevant provider to put an end to the non-compliance concerned, within a period it may prescribe:

Art. 83. 2. Where the non-compliance referred to in paragraph 1 persists, the market surveillance authority of the Member State concerned shall take appropriate and proportionate measures to restrict or prohibit the high-risk AI system being made available on the market or to ensure that it is recalled or withdrawn from the market without delay.

Art. 84. 2. Without prejudice to the tasks referred to in paragraph 1, Union AI testing support structures shall also provide independent technical or scientific advice at the request of the Board, the Commission, or of market surveillance authorities.

Art. 85. Right to lodge a complaint with a market surveillance authority

Art. 85. Without prejudice to other administrative or judicial remedies, any natural or legal person having grounds to consider that there has been an infringement of the provisions of this Regulation may submit complaints to the relevant market surveillance authority. In accordance with Regulation (EU) 2019/1020, such complaints shall be taken into account for the purpose of conducting market surveillance activities, and shall be handled in line with the dedicated procedures established therefor by the market surveillance authorities.

Art. 86. 2. Without prejudice to Article 75(3), market surveillance authorities may request the Commission to exercise the powers laid down in this Section, where that is necessary and proportionate to assist with the fulfilment of their tasks under this Regulation.

Art. 86. 1(f) the application of the definition of an AI system as set out in Article 3, point (1). When issuing such guidelines, the Commission shall pay particular attention to the needs of SMEs including start-ups, of local public authorities and of the sectors most likely to be affected by this Regulation. The guidelines referred to in the first subparagraph of this paragraph shall take due account of the generally acknowledged state of the art on AI, as well as of relevant harmonised standards and common specifications that are referred to in Articles 40 and 41, or of those harmonised standards or technical specifications that are set out pursuant to Union harmonisation law.

Art. 89. 5. The supply of incorrect, incomplete or misleading information to notified bodies or national competent authorities in reply to a request shall be subject to administrative fines of up to EUR 7 500 000 or, if the offender is an undertaking, up to 1 % of its total worldwide annual turnover for the preceding financial year, whichever is higher.

Art. 90. 7(b). whether administrative fines have already been applied by other market surveillance authorities to the same operator for the same infringement;

Art. 90. 7(c). whether administrative fines have already been applied by other authorities to the same operator for infringements of other Union or national law, when such infringements result from the same activity or omission constituting a relevant infringement of this Regulation;

Art. 90. 7(f). the degree of cooperation with the national competent authorities, in order to remedy the infringement and mitigate the possible adverse effects of the infringement;

Art. 90. 7(h). the manner in which the infringement became known to the national competent authorities, in particular whether, and if so to what extent, the operator notified the infringement;

Art. 90. 8. Each Member State shall lay down rules on to what extent administrative fines may be imposed on public authorities and bodies established in that Member State.

Art. 111. 2. Without prejudice to the application of Article 5 as referred to in Article 113(3), point (a), this Regulation shall apply to operators of high-risk AI systems, other than the systems referred to in paragraph 1 of this Article, that have been placed on the market or put into service before 2 August 2026, only if, as from that date, those systems are subject to significant changes in their designs. In any case, the providers and deployers of high-risk AI systems intended to be used by public authorities shall take the necessary steps to comply with the requirements and obligations of this Regulation from 2 August 2026.

Art. 112. 4(a): the status of the financial, technical and human resources of the national competent authorities in order to effectively perform the tasks assigned to them under this Regulation;

Art. 112. 8: For the purposes of paragraphs 1 to 7, the Board, the Member States and national competent authorities shall provide the Commission with information upon its request and without undue delay.

Art. 112. 12: Any amendment to this Regulation pursuant to paragraph 10, or relevant delegated or implementing acts, which concerns sectoral Union harmonisation legislation listed in Section B of Annex I shall take into account the regulatory specificities of each sector, and the existing governance, conformity assessment and enforcement mechanisms and authorities established therein.

2 Autonomy

Art. 3. (1): 'AI system' means a machine-based system that is designed to operate with varying levels of autonomy and that may exhibit adaptiveness after deployment, and that, for explicit or implicit objectives, infers, from the input it receives, how to generate outputs such as predictions, content, recommendations, or decisions that can influence physical or virtual environments.

Art. 14. 3: The oversight measures shall be commensurate with the risks, level of autonomy and context of use of the high-risk AI system, and shall be ensured through either one or both of the following types of measures:

3 Availability

Art. 10. 2(e): an assessment of the availability, quantity and suitability of the data sets that are needed;

Art. 10. 2(f): Notified bodies shall have sufficient internal competences to be able effectively to evaluate the tasks conducted by external parties on their behalf. The notified body shall have permanent availability of sufficient administrative, technical, legal and scientific personnel who possess experience and knowledge relating to the relevant types of AI systems, data and data computing, and relating to the requirements set out in Section 2.

Art. 43. 6: The Commission is empowered to adopt delegated acts in accordance with Article 97 in order to amend paragraphs 1 and 2 of this Article in order to subject high-risk AI systems referred to in points 2 to 8 of Annex III to the conformity assessment procedure referred to in Annex VII, or parts thereof. The Commission shall adopt such delegated acts taking into account the effectiveness of the conformity assessment procedure based on internal control referred to in Annex VI in preventing or minimising the risks to health and safety and protection of fundamental rights posed by such systems, as well as the availability of adequate capacities and resources among notified bodies.

1 Balance

Art. 9. 4: The risk management measures referred to in paragraph 2, point (d), shall give due consideration to the effects and possible interaction resulting from the combined application of the requirements set out in this Section, with a view to minimising risks more effectively while achieving an appropriate balance in implementing the measures to fulfil those requirements.

0 Beneficial (See also: Beneficialness)

0 Beneficialness (See also: Benefit)

1 Benefit

Art. 7. 2(j): the magnitude and likelihood of benefit of the deployment of the AI system for individuals, groups, or society at large, including possible improvements in product safety;

8 Bias

Art. 10. 2(f): examination in view of possible biases that are likely to affect the health and safety of persons, have a negative impact on fundamental rights or lead to discrimination prohibited under Union law, especially where data outputs influence inputs for future operations;

Art. 10. 2(g): appropriate measures to detect, prevent and mitigate possible biases identified according to point (f);

Art. 10. 5: to the extent that it is strictly necessary for the purpose of ensuring bias detection and correction in relation to the high-risk AI systems in accordance with paragraph (2), points (f) and (g) of this Article, the providers of such systems may exceptionally process special categories of personal data, subject to appropriate safeguards for the fundamental rights and freedoms of natural persons. In addition to the provisions set out in Regulations (EU) 2016/679 and (EU) 2018/1725 and Directive (EU) 2016/680, all the following conditions must be met in order for such processing to occur:

Art. 10. 5(a): the bias detection and correction cannot be effectively fulfilled by processing other data, including synthetic or anonymised data;

Art. 10. 5(b): the special categories of personal data are deleted once the bias has been corrected or the personal data has reached the end of its retention period, whichever comes first;

Art. 10. 5(f): the records of processing activities pursuant to Regulations (EU) 2016/679 and (EU) 2018/1725 and Directive (EU) 2016/680 include the reasons why the processing of special categories of personal data was strictly necessary to detect and correct biases, and why that objective could not be achieved by processing other data;

Art. 14. 4(b): to remain aware of the possible tendency of automatically relying on or over-relying on the output produced by a high-risk AI system (automation bias), in particular for high-risk AI systems used to provide information or recommendations for decisions to be taken by natural persons;

Art. 15. 1: Each Member State shall establish or designate as national competent authorities at least one notifying authority and at least one market surveillance authority for the purposes of this Regulation. Those national competent authorities shall exercise their powers independently, impartially and without bias so as to safeguard the objectivity of their activities and tasks, and to ensure the application and implementation of this Regulation. The members of those authorities shall refrain from any action incompatible with their duties. Provided that those principles are observed, such activities and tasks may be performed by one or more designated authorities, in accordance with the organisational needs of the Member State.

2 Bias detection and correction (See also: Dataset, File)

Art. 10. 5: To the extent that it is strictly necessary for the purpose of ensuring bias detection and correction in relation to the high-risk AI systems in accordance with paragraph (2), points (f) and (g) of this Article, the providers of such systems may exceptionally process special categories of personal data, subject to appropriate safeguards for the fundamental rights and freedoms of natural persons. In addition to the provisions set out in Regulations (EU) 2016/679 and (EU) 2018/1725 and Directive (EU) 2016/680, all the following conditions must be met in order for such processing to occur:

Art. 10. 5(a): the bias detection and correction cannot be effectively fulfilled by processing other data, including synthetic or anonymised data;

0 Bias in AI system

0 Biometric characteristic

Terms and AI Act Articles

10 Biometric data

- Art. 3. (34):** 'biometric data' means personal data resulting from specific technical processing relating to the physical, physiological or behavioural characteristics of a natural person, such as facial images or dactyloscopic data;
- Art. 3. (35):** 'biometric identification' means the automated recognition of physical, physiological, behavioural, or psychological human features for the purpose of establishing the identity of a natural person by comparing biometric data of that individual to biometric data of individuals stored in a database;
- Art. 3. (36):** 'biometric verification' means the automated, one-to-one verification, including authentication, of the identity of natural persons by comparing their biometric data to previously provided biometric data;
- Art. 3. (39):** 'emotion recognition system' means an AI system for the purpose of identifying or inferring emotions or intentions of natural persons on the basis of their biometric data;
- Art. 3. (40):** 'biometric categorisation system' means an AI system for the purpose of assigning natural persons to specific categories on the basis of their biometric data, unless it is ancillary to another commercial service and strictly necessary for objective technical reasons;
- Art. 3. (41):** 'remote biometric identification system' means an AI system for the purpose of identifying natural persons, without their active involvement, typically at a distance through the comparison of a person's biometric data with the biometric data contained in a reference database;
- Art. 3. (42):** 'real-time remote biometric identification system' means a remote biometric identification system, whereby the capturing of biometric data, the comparison and the identification all occur without a significant delay, comprising not only instant identification, but also limited short delays in order to avoid circumvention;
- Art. 3. (1g):** the placing on the market, the putting into service for its specific purpose, or the use of biometric categorisation systems that categorise individually natural persons based on their biometric data to deduce or infer their race, political opinions, trade union membership, religious or philosophical beliefs, sex life or sexual orientation; this prohibition does not cover any labelling or filtering of lawfully acquired biometric datasets, such as images, based on biometric data or categorizing of biometric data in the area of law enforcement;
- Art. 5. 1(b)(iii):** the localisation or identification of a person suspected of having committed a criminal offence, for the purpose of conducting a criminal investigation or prosecution or executing a criminal penalty for offences referred to in Annex II and punishable in the Member State concerned by a custodial sentence for a maximum period of at least four years. Point (h) of the first subparagraph is without prejudice to Article 9 of Regulation (EU) 2016/679 for the processing of biometric data for purposes other than law enforcement.
- Art. 26. 10:** Without prejudice to Directive (EU) 2016/680, in the framework of an investigation for the targeted search of a person suspected or convicted of having committed a criminal offence, the deployer of a high-risk AI system for post-remote biometric identification shall request an authorisation, ex ante, or without undue delay and no later than 48 hours, by a judicial authority or an administrative authority whose decision is binding and subject to judicial review, for the use of that system, except when it is used for the initial identification of a potential suspect based on objective and verifiable facts directly linked to the offence. Each use shall be limited to what is strictly necessary for the investigation of a specific criminal offence. If the authorisation requested pursuant to the first subparagraph is rejected, the use of the post-remote biometric identification system linked to that requested authorisation shall be stopped with immediate effect and the personal data linked to the use of the high-risk AI system for which the authorisation was requested shall be deleted. In no case shall such high-risk AI system for post-remote biometric identification be used for law enforcement purposes in an untargeted way, without any link to a criminal offence, a criminal proceeding, a genuine and present or genuine and foreseeable threat of a criminal offence, or the search for a specific missing person. It shall be ensured that no decision that produces an adverse legal effect on a person may be taken by the law enforcement authorities based solely on the output of such post-remote biometric identification systems. This paragraph is without prejudice to Article 9 of Regulation (EU) 2016/679 and Article 10 of Directive (EU) 2016/680 for the processing of biometric data. Regardless of the purpose or deployer, each use of such high-risk AI systems shall be documented in the relevant police file and shall be made available to the relevant market surveillance authority and the national data protection authority upon request, including the disclosure of sensitive operational data related to law enforcement. This subparagraph shall be without prejudice to the powers conferred by Directive (EU) 2016/680 on supervisory authorities. Deployers shall submit annual reports to the relevant market surveillance and national data protection authorities on their use of post-remote biometric identification systems, excluding the disclosure of sensitive operational data related to law enforcement. The reports may be aggregated to cover more than one deployment. Member States may introduce, in accordance with Union law, more restrictive laws on the use of post-remote biometric identification systems.

13 Biometric identification

- Art. 3. (35):** 'biometric identification' means the automated recognition of physical, physiological, behavioural, or psychological human features for the purpose of establishing the identity of a natural person by comparing biometric data of that individual to biometric data of individuals stored in a database;
- Art. 3. (41):** 'remote biometric identification system' means an AI system for the purpose of identifying natural persons, without their active involvement, typically at a distance through the comparison of a person's biometric data with the biometric data contained in a reference database;
- Art. 3. (42):** 'real-time remote biometric identification system' means a remote biometric identification system, whereby the capturing of biometric data, the comparison and the identification all occur without a significant delay, comprising not only instant identification, but also limited short delays in order to avoid circumvention;
- Art. 3. (43):** 'post-remote biometric identification system' means a remote biometric identification system other than a real-time remote biometric identification system;
- Art. 5. 1(h):** the use of 'real-time' remote biometric identification systems in publicly accessible spaces for the purposes of law enforcement, unless and in so far as such use is strictly necessary for one of the following objectives:
- Art. 5. 2:** The use of 'real-time' remote biometric identification systems in publicly accessible spaces for the purposes of law enforcement for any of the objectives referred to in paragraph 1, first subparagraph, point (h), of this Article shall comply with necessary and proportionate safeguards and conditions in relation to the use in accordance with the national law authorising the use thereof, in particular as regards the temporal, geographic and personal limitations. The use of the 'real-time' remote biometric identification system in publicly accessible spaces shall be authorised only if the law enforcement authority has completed a fundamental rights impact assessment as provided for in Article 27 and has registered the system in the EU database according to Article 49. However, in duly justified cases of urgency, the use of such systems may be commenced without the registration in the EU database, provided that such registration is completed without undue delay.
- Art. 5. 3:** For the purposes of paragraph 1, first subparagraph, point (h) and paragraph 2, each use for the purposes of law enforcement of a 'real-time' remote biometric identification system in publicly accessible spaces shall be subject to a prior authorisation granted by a judicial authority or an independent administrative authority whose decision is binding on the Member State in which the use is to take place, issued upon a reasoned request and in accordance with the detailed rules of national law referred to in paragraph 5. However, in a duly justified situation of urgency, the use of such system may be commenced without an authorisation provided that such authorisation is requested without undue delay, at the latest within 24 hours. If such authorisation is rejected, the use shall be stopped with immediate effect and all the data, as well as the results and outputs of that use shall be immediately discarded and deleted. The competent judicial authority or an independent administrative authority whose decision is binding shall grant the authorisation only where it is satisfied, on the basis of objective evidence and clear indications presented to it, that the use of the 'real-time' remote biometric identification system concerned is necessary for, and proportionate to, achieving one of the objectives specified in paragraph 1, first subparagraph, point (h), as identified in the request and, in particular, remains limited to what is strictly necessary concerning the period of time as well as the geographic and personal scope. In deciding on the request, that authority shall take into account the elements referred to in paragraph 2. No decision that produces an adverse legal effect on a person may be taken based solely on the output of the 'real-time' remote biometric identification system.
- Art. 5. 4:** Without prejudice to paragraph 5, each use of a 'real-time' remote biometric identification system in publicly accessible spaces for law enforcement purposes shall be notified to the relevant market surveillance authority and the national data protection authority in accordance with the national rules referred to in paragraph 5. The notification shall, as a minimum, contain the information specified under paragraph 6 and shall not include sensitive operational data.
- Art. 5. 5:** A Member State may decide to provide for the possibility to fully or partially authorise the use of 'real-time' remote biometric identification systems in publicly accessible spaces for the purposes of law enforcement within the limits and under the conditions listed in paragraph 1, first subparagraph, point (h), and paragraphs 2 and 3. Member States concerned shall lay down in their national law the necessary detailed rules for the request, issuance and exercise of, as well as supervision and reporting relating to, the authorisations referred to in paragraph 5. Those rules shall also specify in respect of which of the objectives listed in paragraph 1, first subparagraph, point (h), including which of the criminal offences referred to in point (h)(ii) thereof, the competent authorities may be authorised to use those systems for the purposes of law enforcement. Member States shall notify those rules to the Commission at the latest 30 days following the adoption thereof. Member States may introduce, in accordance with Union law, more restrictive laws on the use of remote biometric identification systems.
- Art. 5. 6:** National market surveillance authorities and the national data protection authorities of Member States that have been notified of the use of 'real-time' remote biometric identification systems in publicly accessible spaces for law enforcement purposes pursuant to paragraph 4 shall submit to the Commission annual reports on such use. For that purpose, the Commission shall provide Member States and national market surveillance and data protection authorities with a template, including information on the number of the decisions taken by competent judicial authorities or an independent administrative authority whose decision is binding upon requests for authorisations in accordance with paragraph 3 and their result.
- Art. 5. 7:** The Commission shall publish annual reports on the use of real-time remote biometric identification systems in publicly accessible spaces for law enforcement purposes, based on aggregated data in Member States on the basis of the annual reports referred to in paragraph 6. Those annual reports shall not include sensitive operational data of the related law enforcement activities.
- Art. 26. 10:** Without prejudice to Directive (EU) 2016/680, in the framework of an investigation for the targeted search of a person suspected or convicted of having committed a criminal offence, the deployer of a high-risk AI system for post-remote biometric identification shall request an authorisation, ex ante, or without undue delay and no later than 48 hours, by a judicial authority or an administrative authority whose decision is binding and subject to judicial review, for the use of that system, except when it is used for the initial identification of a potential suspect based on objective and verifiable facts directly linked to the offence. Each use shall be limited to what is strictly necessary for the investigation of a specific criminal offence. If the authorisation requested pursuant to the first subparagraph is rejected, the use of the post-remote biometric identification system linked to that requested authorisation shall be stopped with immediate effect and the personal data linked to the use of the high-risk AI system for which the authorisation was requested shall be deleted. In no case shall such high-risk AI system for post-remote biometric identification be used for law enforcement purposes in an untargeted way, without any link to a criminal offence, a criminal proceeding, a genuine and present or genuine and foreseeable threat of a criminal offence, or the search for a specific missing person. It shall be ensured that no decision that produces an adverse legal effect on a person may be taken by the law enforcement authorities based solely on the output of such post-remote biometric identification systems. This paragraph is without prejudice to Article 9 of Regulation (EU) 2016/679 and Article 10 of Directive (EU) 2016/680 for the processing of biometric data. Regardless of the purpose or deployer, each use of such high-risk AI systems shall be documented in the relevant police file and shall be made available to the relevant market surveillance authority and the national data protection authority upon request, including the disclosure of sensitive operational data related to law enforcement. This subparagraph shall be without prejudice to the powers conferred by Directive (EU) 2016/680 on supervisory authorities. Deployers shall submit annual reports to the relevant market surveillance and national data protection authorities on their use of post-remote biometric identification systems, excluding the disclosure of sensitive operational data related to law enforcement. The reports may be aggregated to cover more than one deployment. Member States may introduce, in accordance with Union law, more restrictive laws on the use of post-remote biometric identification systems.

0 Biometric verification

1 Biometric verification

- Art. 3. (36):** 'biometric verification' means the automated, one-to-one verification, including authentication, of the identity of natural persons by comparing their biometric data to previously provided biometric data;

0 Bounded domain

8 Categorization (See also: Classification)

- Art. 16. (h):** the placing on the market, the putting into service or the use of AI systems for the evaluation or classification of natural persons or groups of persons over a certain period of time based on their social behaviour or known, inferred or predicted personal or personality characteristics, with the social score leading to either or both of the following:

SECTION 1: Classification of AI systems as high-risk

Art. 6: Classification rules for high-risk AI systems

SECTION 1: Classification rules

Art. 51: Classification of general-purpose AI models as general-purpose AI models with systemic risk.

Art. 68. 3(a)(iii): providing advice on the classification of general-purpose AI models with systemic risk;

Art. 68. 3(a)(iv): providing advice on the classification of various general-purpose AI models and systems;

Art. 80. 1: Where a market surveillance authority has sufficient reason to consider that an AI system classified by the provider as non-high-risk pursuant to Article 6(3) is indeed high-risk, the market surveillance authority shall carry out an evaluation of the AI system concerned in respect of its classification as a high-risk AI system based on the conditions set out in Article 6(3) and the Commission guidelines.

12 CE marking

- Art. 3. (24):** 'CE marking' means a marking by which a provider indicates that an AI system is in conformity with the requirements set out in Chapter III, Section 2 and other applicable Union harmonisation legislation providing for its affixing;
- Art. 16. (h):** affix the CE marking to the high-risk AI system or, where that is not possible, on its packaging or its accompanying documentation, to indicate conformity with this Regulation, in accordance with Article 48;
- Art. 23. (1c):** the system bears the required CE marking and is accompanied by the EU declaration of conformity referred to in Article 47 and instructions for use;
- Art. 24. 1:** Before making a high-risk AI system available on the market, distributors shall verify that it bears the required CE marking, that it is accompanied by a copy of the EU declaration of conformity referred to in Article 47 and instructions for use, and that the provider and the importer of that system, as applicable, have complied with their respective obligations as laid down in Article 16, points (b) and (c) and Article 23(5).
- Art. 48:** CE marking
- Art. 48. 1:** The CE marking shall be subject to the general principles set out in Article 30 of Regulation (EC) No 765/2008.
- Art. 48. 2:** For high-risk AI systems provided digitally, a digital CE marking shall be used, if it can easily be accessed via the interface from which that system is accessed or via an easily accessible machine-readable code or other electronic means.
- Art. 48. 3:** The CE marking shall be affixed visibly, legibly and indelibly for high-risk AI systems. Where that is not possible or not warranted on account of the nature of the high-risk AI system, it shall be affixed to the packaging or to the accompanying documentation, as appropriate.
- Art. 48. 4:** Where applicable, the CE marking shall be followed by the identification number of the notified body responsible for the conformity assessment procedures set out in Article 43. The identification number of the notified body shall be affixed by the body itself or, under its instructions, by the provider or the provider's authorised representative. The identification number shall also be indicated in any promotional material which mentions that the high-risk AI system fulfils the requirements for CE marking.
- Art. 48. 5:** Where high-risk AI systems are subject to other Union law which also provides for the affixing of the CE marking, the CE marking shall indicate that the high-risk AI system also fulfil the requirements of that other law.
- Art. 83. (1a):** the CE marking has been affixed in violation of Article 48;
- Art. 83. (1b):** the CE marking has not been affixed;

Terms and AI Act Articles

28 Certificate

Art. 20, 2: Where the high-risk AI system presents a risk within the meaning of Article 79(1) and the provider becomes aware of that risk, it shall immediately investigate the causes, in collaboration with the reporting deployer, where applicable, and inform the market surveillance authorities competent for the high-risk AI system concerned and, where applicable, the notified body that issued a certificate for that high-risk AI system in accordance with Article 44, in particular, of the nature of the non-compliance and of any relevant corrective action taken.
Art. 22, 3(b): keep at the disposal of the competent authorities and national authorities or bodies referred to in Article 74(10), for a period of 10 years after the high-risk AI system has been placed on the market or put into service, the contact details of the provider that appointed the authorised representative and a copy of the EU declaration of conformity referred to in Article 47, the technical documentation and, if applicable, the certificate issued by the notified body.
Art. 23, 5: Importers shall keep, for a period of 10 years after the high-risk AI system has been placed on the market or put into service, a copy of the certificate issued by the notified body, where applicable, of the instructions for use, and of the EU declaration of conformity referred to in Article 47.
Art. 29, 2: The application for notification shall be accompanied by a description of the conformity assessment activities, the conformity assessment module or modules and the types of AI systems for which the conformity assessment body claims to be competent, as well as by an accreditation certificate, where one exists, issued by a national accreditation body attesting that the conformity assessment body fulfils the requirements laid down in Article 31. Any valid document related to existing designations of the applicant notified body under any other Union harmonisation legislation shall be added.
Art. 29, 3: Where the conformity assessment body concerned cannot provide an accreditation certificate, it shall provide the notifying authority with all the documentary evidence necessary for the verification, recognition and regular monitoring of its compliance with the requirements laid down in Article 31.
Art. 29, 4: For notified bodies which are designated under any other Union harmonisation legislation, all documents and certificates linked to those designations may be used to support their designation procedure under this Regulation, as appropriate. The notified body shall update the documentation referred to in paragraphs 2 and 3 of this Article whenever relevant changes occur, in order to enable the authority responsible for notified bodies to monitor and verify continuous compliance with all the requirements laid down in Article 31.
Art. 30, 3: The notification referred to in paragraph 2 of this Article shall include full details of the conformity assessment activities, the conformity assessment module or modules, the types of AI systems concerned, and the relevant attestation of competence. Where a notification is not based on an accreditation certificate as referred to in Article 29(2), the notifying authority shall provide the Commission and the other Member States with documentary evidence which attests to the competence of the conformity assessment body and to the arrangements in place to ensure that that body will be monitored regularly and will continue to satisfy the requirements in Article 31.
Art. 30, 4: The conformity assessment body concerned may perform the activities of a notified body only where no objections are raised by the Commission or the other Member States within two weeks of a notification by a notifying authority where it includes an accreditation certificate referred to in Article 29(2), or within two months of a notification by the notifying authority where it includes documentary evidence referred to in Article 29(3).
Art. 35, 3: Where a notified body decides to cease its conformity assessment activities, it shall inform the notifying authority and the providers concerned as soon as possible and, in the case of a planned cessation, at least one year before ceasing its activities. The certificates of the notified body may remain valid for a period of nine months after cessation of the notified body's activities, on condition that another notified body has confirmed in writing that it will assume responsibilities for the high-risk AI systems covered by those certificates. The latter notified body shall complete a full assessment of the high-risk AI systems affected by the end of that nine-month-period before issuing new certificates for those systems. Where the notified body has ceased its activity, the notifying authority shall withdraw the designation.
Art. 36, 1(a): assess the impact on the certificates issued by the notified body.
Art. 36, 1(c): require the notified body to suspend or withdraw, within a reasonable period of time determined by the authority, any certificates which were unduly issued, in order to ensure the continuing conformity of high-risk AI systems on the market.
Art. 36, 2: inform the Commission and the Member States about certificates the suspension or withdrawal of which it has required;
Art. 36, 3: (a) provide the national competent authorities of the Member State in which the provider has its registered place of business with all relevant information about the certificates of which it has required the suspension or withdrawal; that authority shall take the appropriate measures, where necessary, to avoid a potential risk to health, safety or fundamental rights.
Art. 36, 8: With the exception of certificates unduly issued, and where a designation has been suspended or restricted, the certificates shall remain valid in one of the following circumstances:
Art. 36, 8(a): the notifying authority has confirmed, within one month of the suspension or restriction, that there is no risk to health, safety or fundamental rights in relation to certificates affected by the suspension or restriction, and the notifying authority has outlined a timeline for actions to remedy the suspension or restriction; or
Art. 36, 8(b): the notifying authority has confirmed that no certificates relevant to the suspension will be issued, amended or re-issued during the course of the suspension or restriction, and states whether the notified body has the capability of continuing to monitor and remain responsible for existing certificates issued for the period of the suspension or restriction; in the event that the notifying authority determines that the notified body does not have the capability to support existing certificates issued, the provider of the system covered by the certificate shall confirm in writing to the national competent authorities of the Member State in which it has its registered place of business, within three months of the suspension or restriction, that another qualified notified body is temporarily assuming the functions of the notified body to monitor and remain responsible for the certificates during the period of suspension or restriction.
Art. 36, 9: With the exception of certificates unduly issued, and where a designation has been withdrawn, the certificates shall remain valid for a period of nine months under the following circumstances:
Art. 36, 9(a): the national competent authority of the Member State in which the provider of the high-risk AI system covered by the certificate has its registered place of business has confirmed that there is no risk to health, safety or fundamental rights associated with the high-risk AI systems concerned; and
Art. 36, 9(b): another notified body has confirmed in writing that it will assume immediate responsibility for those AI systems and completes its assessment within 12 months of the withdrawal of the designation. In the circumstances referred to in the first subparagraph, the national competent authority of the Member State in which the provider of the system covered by the certificate has its place of business may extend the provisional validity of the certificates for additional periods of three months, which shall not exceed 12 months in total. The national competent authority of the notified body assuming the functions of the notified body affected by the change of designation shall immediately inform the Commission, the other Member States and the other notified bodies thereof.
SECTION 5: Standards, conformity assessment, certificates, registration
Art. 42, 2: High-risk AI systems that have been certified or for which a statement of conformity has been issued under a cybersecurity scheme pursuant to Regulation (EU) 2019/881 and the references of which have been published in the Official Journal of the European Union shall be presumed to comply with the cybersecurity requirements set out in Article 15 of this Regulation in so far as the cybersecurity certificate or statement of conformity or parts thereof cover those requirements.
Art. 44: Certificates
Art. 44, 1: Certificates issued by notified bodies in accordance with Annex VII shall be drawn-up in a language which can be easily understood by the relevant authorities in the Member State in which the notified body is established.
Art. 44, 2: Certificates shall be valid for the period they indicate, which shall not exceed five years for AI systems covered by Annex I, and four years for AI systems covered by Annex III. At the request of the provider, the validity of a certificate may be extended for further periods, each not exceeding five years for AI systems covered by Annex I, and four years for AI systems covered by Annex III, based on a re-assessment in accordance with the applicable conformity assessment procedures. Any supplement to a certificate shall remain valid, provided that the certificate which it supplements is valid.
Art. 44, 3: Where a notified body finds that an AI system no longer meets the requirements set out in Section 2, it shall, taking account of the principle of proportionality, suspend or withdraw the certificate issued or impose restrictions on it, unless compliance with those requirements is ensured by appropriate corrective action taken by the provider of the system within an appropriate deadline set by the notified body. The notified body shall give reasons for its decision. An appeal procedure against decisions of the notified bodies, including on conformity certificates issued, shall be available.
Art. 45, 1(a): any Union technical documentation assessment certificates, any supplements to those certificates, and any quality management system approvals issued in accordance with the requirements of Annex VII;
Art. 45, 1(b): any refusal, restriction, suspension or withdrawal of a Union technical documentation assessment certificate or a quality management system approval issued in accordance with the requirements of Annex VII;
Art. 45, 2(b): Union technical documentation assessment certificates or any supplements thereto which it has refused, withdrawn, suspended or otherwise restricted, and, upon request, of the certificates and/or supplements thereto which it has issued.

8 Chain

Art. 3, 7): 'distributor' means a natural or legal person in the supply chain, other than the provider or the importer, that makes an AI system available on the Union market;
Art. 3, 17): 'withdrawal of an AI system' means any measure aiming to prevent an AI system in the supply chain being made available on the market;
Art. 45, 1(c): 'systemic risk' means a risk that is specific to the high-impact capabilities of general-purpose AI models, having a significant impact on the Union market due to their reach, or due to actual or reasonably foreseeable negative effects on public health, safety, public security, fundamental rights, or the society as a whole, that can be propagated at scale across the value chain;
Art. 56, 2(d): the measures, procedures and modalities for the assessment and management of the systemic risks at Union level, including the documentation thereof, which shall be proportionate to the risks, take into consideration their severity and probability and take into account the specific challenges of tackling those risks in light of the possible ways in which such risks may emerge and materialise along the AI value chain.
Art. 66, 6(a)(iv): trends on the evolving typology of value chains, in particular on the resulting implications in terms of accountability;
Art. 75, 6: The notification referred to in paragraph 5 shall include all available details, in particular the information necessary for the identification of the non-compliant AI system, the origin of the AI system and the supply chain, the nature of the non-compliance alleged and the risk involved, the nature and duration of the national measures taken and the arguments put forward by the relevant operator. In particular, the market surveillance authorities shall indicate whether the non-compliance is due to one or more of the following:
Art. 82, 3: The Member States shall immediately inform the Commission and the other Member States of a finding under paragraph 1. That information shall include all available details, in particular the data necessary for the identification of the AI system concerned, the origin and the supply chain of the AI system, the nature of the risk involved and the nature and duration of the national measures taken.

8 Classification (See also: Categorization)

Art. 5, 1(c): the placing on the market, the putting into service or the use of AI systems for the evaluation or classification of natural persons or groups of persons over a certain period of time based on their social behaviour or known, inferred or predicted personal or personality characteristics, with the social score leading to either or both of the following:
SECTION 1: Classification of AI systems as high-risk
Art. 6: Classification rules for high-risk AI systems
SECTION 1: Classification rules
Art. 51: Classification of general-purpose AI models as general-purpose AI models with systemic risk
Art. 56, 2: The AI Office shall aim to ensure that the codes of practice cover at least the obligations provided for in Articles 53 and 55, including the following issues:
Art. 56, 3: The AI Office may invite all providers of general-purpose AI models, as well as relevant national competent authorities, to participate in the drawing-up of codes of practice. Civil society organisations, industry, academia and other relevant stakeholders, such as downstream providers and independent experts, may support the process.
Art. 56, 4: The AI Office and the Board shall aim to ensure that the codes of practice clearly set out their specific objectives and contain commitments or measures, including key performance indicators as appropriate, to ensure the achievement of those objectives, and that they take due account of the needs and interests of all interested parties, including affected persons, at Union level.
Art. 56, 5: The AI Office shall aim to ensure that participants to the codes of practice report regularly to the AI Office on the implementation of the commitments and the measures taken and their outcomes, including as measured against the key performance indicators as appropriate. Key performance indicators and commitments shall reflect differences in size and capacity between various participants.
Art. 56, 6: The AI Office and the Board shall regularly monitor and evaluate the achievement of the objectives of the codes of practice by the participants and their contribution to the proper application of this Regulation. The AI Office and the Board shall assess whether the codes of practice cover the obligations provided for in Articles 53 and 55, and shall regularly monitor and evaluate the achievement of their objectives. They shall publish their assessment of the adequacy of the codes of practice. The Commission may, by way of an implementing act, approve a code of practice and give it general effect within the Union, that implementing act shall be adopted in accordance with the examination procedure referred to in Article 98(2).
Art. 80, 7: The AI Office may invite all providers of general-purpose AI models to adhere to the codes of practice. For providers of general-purpose AI models not presenting systemic risks this adherence may be limited to the obligations provided for in Article 53, unless they declare their interest to go beyond that.

1 Cleaning

Art. 10, 2(c): relevant data-preparation processing operations, such as annotation, labelling, cleaning, updating, enrichment and aggregation;

0 Cloud service

0 Clustering

17 Code of practice

Art. 50, 7: The AI Office shall encourage and facilitate the drawing up of codes of practice at Union level to facilitate the effective implementation of the obligations regarding the detection and labelling of artificially generated or manipulated content. The Commission may adopt implementing acts to approve those codes of practice in accordance with the procedure laid down in Article 56 (6). If it deems the code is not adequate, the Commission may adopt an implementing act specifying common rules for the implementation of those obligations in accordance with the examination procedure laid down in Article 98(2).
Art. 53, 4: Providers of general-purpose AI models may rely on codes of practice within the meaning of Article 56 to demonstrate compliance with the obligations set out in paragraph 1 of this Article, until a harmonised standard is published. Compliance with European harmonised standards grants providers the presumption of conformity to the extent that those standards cover those obligations. Providers of general-purpose AI models who do not adhere to an approved code of practice or do not comply with a European harmonised standard shall demonstrate alternative adequate means of compliance for assessment by the Commission.
Art. 55, 2: Providers of general-purpose AI models with systemic risk may rely on codes of practice within the meaning of Article 56 to demonstrate compliance with the obligations set out in paragraph 1 of this Article, until a harmonised standard is published. Compliance with European harmonised standards grants providers the presumption of conformity to the extent that those standards cover those obligations. Providers of general-purpose AI models with systemic risks who do not adhere to an approved code of practice or do not comply with a European harmonised standard shall demonstrate alternative adequate means of compliance for assessment by the Commission.
SECTION 4: Codes of practice
Art. 56: Codes of practice
Art. 56, 1: The AI Office shall encourage and facilitate the drawing up of codes of practice at Union level in order to contribute to the proper application of this Regulation, taking into account international approaches.
Art. 56, 2: The AI Office and the Board shall aim to ensure that the codes of practice cover at least the obligations provided for in Articles 53 and 55, including the following issues:
Art. 56, 3: The AI Office may invite all providers of general-purpose AI models, as well as relevant national competent authorities, to participate in the drawing-up of codes of practice. Civil society organisations, industry, academia and other relevant stakeholders, such as downstream providers and independent experts, may support the process.
Art. 56, 4: The AI Office and the Board shall aim to ensure that the codes of practice clearly set out their specific objectives and contain commitments or measures, including key performance indicators as appropriate, to ensure the achievement of those objectives, and that they take due account of the needs and interests of all interested parties, including affected persons, at Union level.
Art. 56, 5: The AI Office shall aim to ensure that participants to the codes of practice report regularly to the AI Office on the implementation of the commitments and the measures taken and their outcomes, including as measured against the key performance indicators as appropriate. Key performance indicators and commitments shall reflect differences in size and capacity between various participants.
Art. 56, 6: The AI Office and the Board shall regularly monitor and evaluate the achievement of the objectives of the codes of practice by the participants and their contribution to the proper application of this Regulation. The AI Office and the Board shall assess whether the codes of practice cover the obligations provided for in Articles 53 and 55, and shall regularly monitor and evaluate the achievement of their objectives. They shall publish their assessment of the adequacy of the codes of practice. The Commission may, by way of an implementing act, approve a code of practice and give it general effect within the Union, that implementing act shall be adopted in accordance with the examination procedure referred to in Article 98(2).
Art. 80, 7: The AI Office may invite all providers of general-purpose AI models to adhere to the codes of practice. For providers of general-purpose AI models not presenting systemic risks this adherence may be limited to the obligations provided for in Article 53, unless they declare their interest to go beyond that.
Art. 56, 8: The AI Office shall, as appropriate, also encourage and facilitate the review and adaptation of the codes of practice, in particular in light of emerging standards. The AI Office shall assist in the assessment of available standards.
Art. 56, 9: Codes of practice shall be ready at the latest by 2 May 2025. The AI Office shall take the necessary steps, including inviting providers pursuant to paragraph 7. If, by 2 August 2025, a code of practice cannot be finalised, or if the AI Office deems it is not adequate following its assessment under paragraph 6 of this Article, the Commission may provide, by means of implementing acts, common rules for the implementation of the obligations provided for in Articles 53 and 55, including the issues set out in paragraph 2 of this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 98(2).
Art. 66, 6(e)(i): on the development and application of codes of conduct and codes of practice pursuant to this Regulation, as well as of the Commission's guidelines;
Art. 66, 6(e)(ii): For the purpose of carrying out the tasks assigned to it under this Section, the AI Office may take the necessary actions to monitor the effective implementation and compliance with this Regulation by providers of general-purpose AI models, including their adherence to approved codes of practice.
Art. 101, 1(d): failed to make available to the Commission access to the general-purpose AI model or general-purpose AI model with systemic risk with a view to conducting an evaluation pursuant to Article 92. In fixing the amount of the fine or periodic penalty payment, regard shall be had to the nature, gravity and duration of the infringement, taking due account of the principles of proportionality and appropriateness. The Commission shall also take into account commitments made in accordance with Article 93(3) or made in relevant codes of practice in accordance with Article 56.

0 Compatibility

Terms and AI Act Articles

9 Competence

Art. 14, 5: For high-risk AI systems referred to in point 1(a) of Annex III, the measures referred to in paragraph 3 of this Article shall be such as to ensure that, in addition, no action or decision is taken by the deployer on the basis of the identification resulting from the system unless that identification has been separately verified and confirmed by at least two natural persons with the necessary competence, training and authority. The requirement for a separate verification by at least two natural persons shall not apply to high-risk AI systems used for the purposes of law enforcement, migration, border control or asylum, where Union or national law considers the application of this requirement to be disproportionate.

Art. 26, 2: Deployers shall assign human oversight to natural persons who have the necessary competence, training and authority, as well as the necessary support.

Art. 30, 3: The notification referred to in paragraph 2 of this Article shall include full details of the conformity assessment activities, the conformity assessment module or modules, the types of AI systems concerned, and the relevant attestation of competence. Where a notification is not based on an accreditation certificate as referred to in Article 29(2), the notifying authority shall provide the Commission and the other Member States with documentary evidence which attests to the competence of the conformity assessment body and to the arrangements in place to ensure that that body will be monitored regularly and will continue to satisfy the requirements laid down in Article 31.

Art. 31, 10: Notified bodies shall be capable of carrying out all their tasks under this Regulation with the highest degree of professional integrity and the requisite competence in the specific field, whether those tasks are carried out by notified bodies themselves or on their behalf and under their responsibility.

Art. 37: Challenges to the competence of notified bodies

Art. 37, 1: The Commission shall, where necessary, investigate all cases where there are reasons to doubt the competence of a notified body or the continued fulfilment by a notified body of the requirements laid down in Article 31 and of its applicable responsibilities.

Art. 37, 2: The notifying authority shall provide the Commission, on request, with all relevant information relating to the notification or the maintenance of the competence of the notified body concerned.

Art. 68, 2(a): having particular expertise and competence and scientific or technical expertise in the field of AI;

Art. 70, 3: Member States shall ensure that their national competent authorities are provided with adequate technical, financial and human resources, and with infrastructure to fulfil their tasks effectively under this Regulation. In particular, the national competent authorities shall have a sufficient number of personnel permanently available whose competences and expertise shall include an in-depth understanding of AI technologies, data and data computing, personal data protection, cybersecurity, fundamental rights, health and safety risks and knowledge of existing standards and legal requirements. Member States shall assess and, if necessary, update competence and resource requirements referred to in this paragraph on an annual basis.

5 Complete (See also: [Completeness](#))

Art. 10, 3: Training, validation and testing data sets shall be relevant, sufficiently representative, and to the best extent possible, free of errors and complete in view of the intended purpose. They shall have the appropriate statistical properties, including, where applicable, as regards the persons or groups of persons in relation to whom the high-risk AI system is intended to be used. Those characteristics of the data sets may be met at the level of individual data sets or at the level of a combination thereof.

Art. 13, 2: High-risk AI systems shall be accompanied by instructions for use in an appropriate digital format or otherwise that include concise, complete, correct and clear information that is relevant, accessible and comprehensible to deployers.

Art. 36, 5: Where a notified body decides to cease its conformity assessment activities, it shall inform the notifying authority and the providers concerned as soon as possible and, in the case of a planned cessation, at least one year before ceasing its activities. The certificates of the notified body may remain valid for a period of nine months after cessation of the notified body's activities, on condition that another notified body has confirmed in writing that it will assume responsibilities for the high-risk AI systems covered by those certificates. The latter notified body shall complete a full assessment of the high-risk AI systems affected by the end of that nine-month-period before issuing new certificates for those systems. Where the notified body has ceased its activity, the notifying authority shall withdraw the designation.

Art. 59, 1(i): a complete and detailed description of the process and rationale behind the training, testing and validation of the AI system is kept together with the testing results as part of the technical documentation referred to in Annex IV;

Art. 73, 5: Where necessary to ensure timely reporting, the provider or, where applicable, the deployer, may submit an initial report that is incomplete, followed by a complete report.

5 Completeness (See also: [Complete](#))

Art. 10, 3: Training, validation and testing data sets shall be relevant, sufficiently representative, and to the best extent possible, free of errors and complete in view of the intended purpose. They shall have the appropriate statistical properties, including, where applicable, as regards the persons or groups of persons in relation to whom the high-risk AI system is intended to be used. Those characteristics of the data sets may be met at the level of individual data sets or at the level of a combination thereof.

Art. 13, 2: High-risk AI systems shall be accompanied by instructions for use in an appropriate digital format or otherwise that include concise, complete, correct and clear information that is relevant, accessible and comprehensible to deployers.

Art. 36, 5: Where a notified body decides to cease its conformity assessment activities, it shall inform the notifying authority and the providers concerned as soon as possible and, in the case of a planned cessation, at least one year before ceasing its activities. The certificates of the notified body may remain valid for a period of nine months after cessation of the notified body's activities, on condition that another notified body has confirmed in writing that it will assume responsibilities for the high-risk AI systems covered by those certificates. The latter notified body shall complete a full assessment of the high-risk AI systems affected by the end of that nine-month-period before issuing new certificates for those systems. Where the notified body has ceased its activity, the notifying authority shall withdraw the designation.

Art. 59, 1(i): a complete and detailed description of the process and rationale behind the training, testing and validation of the AI system is kept together with the testing results as part of the technical documentation referred to in Annex IV;

Art. 73, 5: Where necessary to ensure timely reporting, the provider or, where applicable, the deployer, may submit an initial report that is incomplete, followed by a complete report.

Terms and AI Act Articles

6 Compliant

Art. 8, 2: Where a product contains an AI system, to which the requirements of this Regulation as well as requirements of the Union harmonisation legislation listed in Section A of Annex I apply, providers shall be responsible for ensuring that their product is fully compliant with all applicable requirements under applicable Union harmonisation legislation. In ensuring the compliance of high-risk AI systems referred to in paragraph 1 with the requirements set out in this Section, and in order to ensure consistency, avoid duplication and minimise additional burdens, providers shall have a choice of integrating, as appropriate, the necessary testing and reporting processes, information and documentation they provide with regard to their product into documentation and procedures that already exist and are required under the Union harmonisation legislation listed in Section A of Annex I.

Art. 16, (a): ensure that their high-risk AI systems are compliant with the requirements set out in Section 2;

Art. 75, 2: Where the relevant market surveillance authorities have sufficient reason to consider general-purpose AI systems that can be used directly by deployers for at least one purpose that is classified as high-risk pursuant to this Regulation to be non-compliant with the requirements laid down in this Regulation, they shall cooperate with the AI Office to carry out compliance evaluations, and shall inform the Board and other market surveillance authorities accordingly.

Art. 75, 3: Where a market surveillance authority is unable to conclude its investigation of the high-risk AI system because of its inability to access certain information related to the general-purpose AI model despite having made all appropriate efforts to obtain that information, it may submit a reasoned request to the AI Office, by which access to that information shall be enforced. In that case, the AI Office shall supply to the applicant authority without delay, and in any event within 30 days, any information that the AI Office considers to be relevant in order to establish whether a high-risk AI system is non-compliant. Market surveillance authorities shall safeguard the confidentiality of the information that they obtain in accordance with Article 78 of this Regulation. The procedure provided for in Chapter VI of Regulation (EU) 2019/1020 shall apply mutatis mutandis.

Art. 79, 8: The notification referred to in paragraph 5 shall include all available details, in particular the information necessary for the identification of the non-compliant AI system, the origin of the AI system and the supply chain, the nature of the non-compliance alleged and the risk involved, the nature and duration of the national measures taken and the arguments put forward by the relevant operator. In particular, the market surveillance authorities shall indicate whether the non-compliance is due to one or more of the following:

Art. 82: Compliant AI systems which present a risk

25 Confidential

Art. 2, 7: Union law on the protection of personal data, privacy and the confidentiality of communications applies to personal data processed in connection with the rights and obligations laid down in this Regulation. This Regulation shall not affect Regulation (EU) 2016/679 or (EU) 2018/1725, or Directive 2002/58/EC or (EU) 2016/680, without prejudice to Article 10(5) and Article 59 of this Regulation.

Art. 10, 5(c): the special categories of personal data are subject to measures to ensure that the personal data processed are secured, protected, subject to suitable safeguards, including strict controls and documentation of the access, to avoid misuse and ensure that only authorised persons have access to those personal data with appropriate confidentiality obligations.

Art. 15, 5: High-risk AI systems shall be resilient against attempts by unauthorised third parties to alter their use, outputs or performance by exploiting system vulnerabilities. The technical solutions aiming to ensure the cybersecurity of high-risk AI systems shall be appropriate to the relevant circumstances and the risks. The technical solutions to address AI specific vulnerabilities shall include, where appropriate, measures to prevent, detect, respond to, resolve and control for attacks trying to manipulate the training data set (data poisoning), or pre-trained components used in training (model poisoning), inputs designed to cause the AI model to make a mistake (adversarial examples or model evasion), confidentiality attacks or model flaws.

Art. 21, 3: Any information obtained by a competent authority pursuant to this Article shall be treated in accordance with the confidentiality obligations set out in Article 78.

Art. 25, 5: Paragraphs 2 and 3 are without prejudice to the need to observe and protect intellectual property rights, confidential business information and trade secrets in accordance with Article 78.

Art. 28, 6: Notifying authorities shall safeguard the confidentiality of the information that they obtain, in accordance with Article 78.

Art. 31, 7: Notified bodies shall have documented procedures in place ensuring that their personnel, committees, subsidiaries, subcontractors and any associated body or personnel of external bodies maintain, in accordance with Article 78, the confidentiality of the information which comes into their possession during the performance of conformity assessment activities, except when its disclosure is required by law. The staff of notified bodies shall be bound to observe professional secrecy with regard to all information obtained in carrying out their tasks under this Regulation, except in relation to the notifying authorities of the Member State in which their activities are carried out.

Art. 37, 3: The Commission shall ensure that all sensitive information obtained in the course of its investigations pursuant to this Article is treated confidentially in accordance with Article 78.

Art. 45, 4: Notified bodies shall safeguard the confidentiality of the information that they obtain, in accordance with Article 78.

Art. 52, 6: The Commission shall ensure that a list of general-purpose AI models with systemic risk is published and shall keep that list up to date, without prejudice to the need to observe and protect intellectual property rights and confidential business information or trade secrets in accordance with Union and national law.

Art. 53, 1(b): draw up, keep up-to-date and make available information and documentation to providers of AI systems who intend to integrate the general-purpose AI model into their AI systems. Without prejudice to the need to observe and protect intellectual property rights and confidential business information or trade secrets in accordance with Union and national law, the information and documentation shall:

Art. 53, 7: Any information or documentation obtained pursuant to this Article, including trade secrets, shall be treated in accordance with the confidentiality obligations set out in Article 78.

Art. 55, 3: Any information or documentation obtained pursuant to this Article, including trade secrets, shall be treated in accordance with the confidentiality obligations set out in Article 78.

Art. 57, 8: Subject to the confidentiality provisions in Article 78, and with the agreement of the provider or prospective provider, the Commission and the Board shall be authorised to access the exit reports and shall take them into account, as appropriate, when exercising their tasks under this Regulation. If both the provider or prospective provider and the national competent authority explicitly agree, the exit report may be made publicly available through the single information platform referred to in this Article.

Art. 68, 4: The experts on the scientific panel shall perform their tasks with impartiality and objectivity, and shall ensure the confidentiality of information and data obtained in carrying out their tasks and activities. They shall neither seek nor take instructions from anyone when exercising their tasks under paragraph 3. Each expert shall draw up a declaration of interests, which shall be made publicly available. The AI Office shall establish systems and procedures to actively manage and prevent potential conflicts of interest.

Art. 70, 5: When performing their tasks, the national competent authorities shall act in accordance with the confidentiality obligations set out in Article 78.

Art. 74, 14: Any information or documentation obtained by market surveillance authorities shall be treated in accordance with the confidentiality obligations set out in Article 78.

Art. 75, 3: Where a market surveillance authority is unable to conclude its investigation of the high-risk AI system because of its inability to access certain information related to the general-purpose AI model despite having made all appropriate efforts to obtain that information, it may submit a reasoned request to the AI Office, by which access to that information shall be enforced. In that case, the AI Office shall supply to the applicant authority without delay, and in any event within 30 days, any information that the AI Office considers to be relevant in order to establish whether a high-risk AI system is non-compliant. Market surveillance authorities shall safeguard the confidentiality of the information that they obtain in accordance with Article 78 of this Regulation. The procedure provided for in Chapter VI of Regulation (EU) 2019/1020 shall apply mutatis mutandis.

Art. 77, 4: Any information or documentation obtained by the national public authorities or bodies referred to in paragraph 1 of this Article pursuant to this Article shall be treated in accordance with the confidentiality obligations set out in Article 78.

Art. 78: Confidentiality

Art. 78, 1: The Commission, market surveillance authorities and notified bodies and any other natural or legal person involved in the application of this Regulation shall, in accordance with Union or national law, respect the confidentiality of information and data obtained in carrying out their tasks and activities in such a manner as to protect, in particular:

Art. 78, 1(a): the intellectual property rights and confidential business information or trade secrets of a natural or legal person, including source code, except in the cases referred to in Article 5 of Directive (EU) 2016/943 of the European Parliament and of the Council (57);

Art. 78, 2: The authorities involved in the application of this Regulation pursuant to paragraph 1 shall request only data that is strictly necessary for the assessment of the risk posed by AI systems and for the exercise of their powers in accordance with this Regulation and with Regulation (EU) 2019/1020. They shall put in place adequate and effective cybersecurity measures to protect the security and confidentiality of the information and data obtained, and shall delete the data collected as soon as it is no longer needed for the purpose for which it was obtained, in accordance with applicable Union or national law.

Art. 78, 3: Without prejudice to paragraphs 1 and 2, information exchanged on a confidential basis between the national competent authorities or between national competent authorities and the Commission shall not be disclosed without prior consultation of the originating national competent authority and the deployer when high-risk AI systems referred to in point 1, 6 or 7 of Annex III are used by law enforcement, border control, immigration or asylum authorities and when such disclosure would jeopardise public and national security interests. This exchange of information shall not cover sensitive operational data in relation to the activities of law enforcement, border control, immigration or asylum authorities. When the law enforcement, immigration or asylum authorities are providers of high-risk AI systems referred to in point 1, 6 or 7 of Annex III, the technical documentation referred to in Annex IV shall remain within the premises of those authorities. Those authorities shall ensure that the market surveillance authorities referred to in Article 74(8) and (9), as applicable, can, upon request, immediately access the documentation or obtain a copy thereof. Only staff of the market surveillance authority holding the appropriate level of security clearance shall be allowed to access that documentation or any copy thereof.

Art. 78, 5: The Commission and Member States may exchange, where necessary and in accordance with relevant provisions of international and trade agreements, confidential information with regulatory authorities of third countries with which they have concluded bilateral or multilateral confidentiality arrangements guaranteeing an adequate level of confidentiality.

0 Confidential data

Terms and AI Act Articles

52 Confidentiality (See also: [Personal data](#), [Identifiability](#))

- Art. 2, 7.** Union law on the protection of personal data, privacy and the confidentiality of communications applies to personal data processed in connection with the rights and obligations laid down in this Regulation. This Regulation shall not affect Regulation (EU) 2016/679 or (EU) 2018/1725, or Directive 2002/58/EC or (EU) 2016/680, without prejudice to Article 10(5) and Article 58 of this Regulation.
- Art. 3, (34).** 'biometric data' means personal data resulting from specific technical processing relating to the physical, physiological or behavioural characteristics of a natural person, such as facial images or dactyloscopic data.
- Art. 3, (37).** 'special categories of personal data' means the categories of personal data referred to in Article 9(1) of Regulation (EU) 2016/679, Article 10 of Directive (EU) 2016/680 and Article 10(1) of Regulation (EU) 2018/1725;
- Art. 3, (50).** 'personal data' means personal data as defined in Article 4, point (1), of Regulation (EU) 2016/679.
- Art. 3, (51).** 'non-personal data' means data other than personal data as defined in Article 4, point (1), of Regulation (EU) 2016/679.
- Art. 3, (52).** In addition, the use of 'real-time' remote biometric identification systems in publicly accessible spaces for the purposes of law enforcement for any of the objectives referred to in paragraph 1, first subparagraph, point (h), of this Article shall comply with necessary and proportionate safeguards and conditions in relation to the use in accordance with the national law authorising the use thereof, in particular as regards the temporal, geographic and personal limitations. The use of the 'real-time' remote biometric identification system in publicly accessible spaces shall be authorised only if the law enforcement authority has completed a fundamental rights impact assessment as provided for in Article 27 and has registered the system in the EU database according to Article 49. However, in duly justified cases of urgency, the use of such systems may be commenced without an authorisation provided that such authorisation is requested without undue delay, at the latest within 24 hours, if the authorisation is rejected, the use shall be stopped with immediate effect and all the data, as well as the results and outputs of that use shall be immediately discarded and deleted. The competent judicial authority or an independent administrative authority whose decision is binding shall grant the authorisation only where it is satisfied, on the basis of objective evidence or clear indications presented to it, that the use of the 'real-time' remote biometric identification system concerned is necessary for, and proportionate to, achieving one of the objectives specified in paragraph 1, first subparagraph, point (h), as identified in the request and, in particular, remains limited to what is strictly necessary for the purposes of law enforcement for any of the objectives referred to in paragraph 2. No decision that produces an adverse legal effect on a person may be taken based solely on the output of the 'real-time' remote biometric identification system.
- Art. 10, 2(a).** data collection processes and the original data in the case of personal data, the original purpose of the data collection;
- Art. 10, 2.** To the extent that it is strictly necessary for the purpose of ensuring bias detection and correction in relation to the high-risk AI systems in accordance with paragraph (2), points (f) and (g) of this Article, the providers of such systems may exceptionally process special categories of personal data, subject to appropriate safeguards for the fundamental rights and freedoms of natural persons. In addition to the provisions set out in Regulations (EU) 2016/679 and (EU) 2018/1725 and Directive (EU) 2016/680, all the following conditions must be met in order for such processing to occur:
- Art. 10, 5(b).** the special categories of personal data are subject to technical limitations on the re-use of the personal data, and state-of-the-art security and privacy-preserving measures, including pseudonymisation;
- Art. 10, 5(c).** the special categories of personal data are subject to measures to ensure that the personal data processed are secured, protected, subject to suitable safeguards, including strict controls and documentation of the access, to avoid misuse and ensure that only authorised persons have access to these personal data with appropriate confidentiality obligations;
- Art. 10, 5(d).** the special categories of personal data are not to be transmitted, transferred or otherwise accessed by other parties;
- Art. 10, 5(e).** the special categories of personal data are deleted once the bias has been corrected or the personal data has reached the end of its retention period, whichever comes first;
- Art. 10, 5(f).** the records of processing activities pursuant to Regulations (EU) 2016/679 and (EU) 2018/1725 and Directive (EU) 2016/680 include the reasons why the processing of special categories of personal data was strictly necessary to detect and correct biases, and why that objective could not be achieved by processing other data.
- Art. 15, 5.** High-risk AI systems shall be resilient against attempts by unauthorised third parties to alter their use, outputs or performance by exploiting system vulnerabilities. The technical solutions aiming to ensure the cybersecurity of high-risk AI systems shall be appropriate to the relevant circumstances and the risks. The technical solutions to address AI specific vulnerabilities shall include, where appropriate, measures to prevent, detect, respond to, resolve and control for attacks trying to manipulate the training data set (data poisoning), or pre-trained components used in training (model poisoning), inputs designed to cause the AI model to make a mistake (adversarial examples or model evasion), confidentiality attacks or model flaws.
- Art. 19, 4.** Providers of high-risk AI systems shall keep the logs referred to in Article 12(1), automatically generated by their high-risk AI systems, to the extent such logs are under their control. Without prejudice to applicable Union or national law, the logs shall be kept for a period appropriate to the intended purpose of the high-risk AI system, of at least six months, unless provided otherwise in the applicable Union or national law, in particular in Union law on the protection of personal data.
- Art. 21, 3.** Any information obtained by a competent authority pursuant to this Article shall be treated in accordance with the confidentiality obligations set out in Article 78.
- Art. 25, 5.** Deployers of high-risk AI systems shall keep the logs automatically generated by that high-risk AI system to the extent such logs are under their control, for a period appropriate to the intended purpose of the high-risk AI system, of at least six months, unless provided otherwise in applicable Union or national law, in particular in Union law on the protection of personal data. Deployers that are financial institutions subject to requirements regarding their internal governance, arrangements or processes under Union financial services law shall maintain the logs as part of the documentation kept pursuant to the relevant Union financial service law.
- Art. 26, 10.** Without prejudice to Directive (EU) 2016/680, in the framework of an investigation for the targeted search of a person suspected or convicted of having committed a criminal offence, the deployer of a high-risk AI system for post-remote biometric identification shall request an authorisation, ex ante, without undue delay and no later than 48 hours, by a judicial authority or an administrative authority whose decision is binding and subject to judicial review, for the use of that system, except when it is used for the initial identification of a potential suspect based on objective and verifiable facts directly linked to the offence. Each use shall be limited to what is strictly necessary for the investigation of a specific criminal offence. If the authorisation requested pursuant to the first subparagraph is rejected, the use of the post-remote biometric identification system linked to that requested authorisation shall be stopped with immediate effect and the personal data linked to the use of the high-risk AI system for which the authorisation was requested shall be deleted. In no case shall such high-risk AI system for post-remote biometric identification be used for law enforcement purposes in an untargeted way, without any link to a criminal offence, a criminal proceeding, a genuine and present or genuine and foreseeable threat of a criminal offence, or the search for a specific missing person. It shall be ensured that no decision that produces an adverse legal effect on a person may be taken by the law enforcement authorities based solely on the output of such post-remote biometric identification systems. This paragraph is without prejudice to Article 9 of Regulation (EU) 2016/679 and Article 10 of Directive (EU) 2016/680 for the processing of biometric data. Regardless of the purpose or deployer, each use of such high-risk AI systems shall be documented in the relevant police file and shall be made available to the relevant market surveillance authority and the national data protection authority upon request, excluding the disclosure of sensitive operational data related to law enforcement. This subparagraph shall be without prejudice to the powers conferred by Directive (EU) 2016/680 on supervisory authorities. Deployers shall submit annual reports to the relevant market surveillance and national data protection authorities on their use of post-remote biometric identification systems, excluding the disclosure of sensitive operational data related to law enforcement. The reports may be aggregated to cover more than one deployment. Member States may introduce national law, more restrictive laws on the use of post-remote biometric identification systems.
- Art. 28, 6.** Notifying authorities shall safeguard the confidentiality of the information that they obtain, in accordance with Article 78.
- Art. 31, 7.** Notified bodies shall have documented procedures in place ensuring that their personnel, committees, subsidiaries, subcontractors and any associated body or personnel of external bodies maintain, in accordance with Article 78, the confidentiality of the information which comes into their possession during the performance of conformity assessment activities, except when its disclosure is required by law. The staff of notified bodies shall be bound to observe professional secrecy with regard to all information obtained in carrying out their tasks under this Regulation, except in relation to the notifying authorities of the Member State in which their activities are carried out.
- Art. 45, 4.** Notified bodies shall safeguard the confidentiality of the information that they obtain, in accordance with Article 78.
- Art. 46, 3.** Deployers of innovative AI systems shall inform the natural persons exposed thereto of the operation of the system, and shall process the personal data in accordance with Regulations (EU) 2016/679 and (EU) 2018/1725 and Directive (EU) 2016/680, as applicable. This obligation shall not apply to AI systems used for biometric categorisation and emotion recognition, which are permitted by law to detect, prevent or investigate criminal offences, subject to appropriate safeguards for the rights and freedoms of third parties, and in accordance with Union law.
- Art. 53, 7.** Any information or documentation obtained pursuant to this Article, including trade secrets, shall be treated in accordance with the confidentiality obligations set out in Article 78.
- Art. 55, 3.** Any information or documentation obtained pursuant to this Article, including trade secrets, shall be treated in accordance with the confidentiality obligations set out in Article 78.
- Art. 57, 8.** Subject to the confidentiality provisions in Article 78, and with the agreement of the provider or prospective provider, the Commission and the Board shall be authorised to access the exit reports and shall take them into account, as appropriate, when exercising their tasks under this Regulation. If both the provider or prospective provider and the national competent authority explicitly agree, the exit report may be made publicly available through the single information platform referred to in this Article.
- Art. 57, 10.** National competent authorities shall ensure that, to the extent the innovative AI systems involve the processing of personal data or otherwise fall under the supervisory remit of other national authorities or competent authorities providing or supporting access to data, the national data protection authorities and those other national or competent authorities are associated with the operation of the AI regulatory sandbox and involved in the supervision of those aspects to the extent of their respective tasks and powers.
- Art. 59.** Further processing of personal data for developing certain AI systems in the public interest in the AI regulatory sandbox
- Art. 59, 1.** In the AI regulatory sandbox, personal data lawfully collected for other purposes may be processed solely for the purpose of developing, training and testing certain AI systems in the sandbox when all of the following conditions are met:
- Art. 59, 1(a).** the data processed are necessary for complying with one or more of the requirements referred to in Chapter III, Section 2 where those requirements cannot effectively be fulfilled by processing anonymised, synthetic or other non-personal data;
- Art. 59, 1(b).** any personal data to be processed in the context of the sandbox are in a functionally separate, isolated and protected data processing environment under the control of the prospective provider and only authorised persons have access to those data;
- Art. 59, 1(c).** providers can further share the originally collected data only in accordance with Union data protection law; any personal data created in the sandbox cannot be shared outside the sandbox;
- Art. 59, 1(d).** any processing of personal data in the context of the sandbox neither leads to measures or decisions affecting the data subjects nor does it affect the application of their rights laid down in Union law on the protection of personal data;
- Art. 59, 1(e).** any personal data processed in the context of the sandbox are protected by means of appropriate technical and organisational measures and deleted once the participation in the sandbox has terminated or the personal data has reached the end of its retention period;
- Art. 59, 1(f).** the logs of the processing of personal data in the context of the sandbox are kept for the duration of the participation in the sandbox, unless provided otherwise by Union or national law;
- Art. 59, 2.** For the purposes of the prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, including safeguarding against and preventing threats to public security, under the control and responsibility of law enforcement authorities, the processing of personal data in AI regulatory sandboxes shall be based on a specific Union or national law and subject to the same cumulative conditions as referred to in paragraph 1.
- Art. 59, 3.** Paragraph 1 is without prejudice to Union or national law which excludes processing of personal data for other purposes than those explicitly mentioned in that law, as well as to Union or national law laying down the basis for the processing of personal data which is necessary for the purpose of developing, testing or training of innovative AI systems or any other legal basis, in compliance with Union law on the protection of personal data.
- Art. 60, 4(f).** the subjects of the testing in real world conditions have given informed consent in accordance with Article 61, or in the case of law enforcement, where the seeking of informed consent would prevent the AI system from being tested, the testing itself and the outcome of the testing in the real world conditions shall not have any negative effect on the subjects, and their personal data shall be deleted after the test is performed;
- Art. 60, 5.** Any subjects of the testing in real world conditions, or their legally designated representative, as appropriate, may, without any resulting detriment and without having to provide any justification, withdraw from the testing at any time by revoking their informed consent and may request the immediate and permanent deletion of their personal data. The withdrawal of the informed consent shall not affect the activities already carried out.
- Art. 68, 4.** The experts on the scientific panel shall perform their tasks with impartiality and objectivity, and shall ensure the confidentiality of information and data obtained in carrying out their tasks and activities. They shall neither seek nor take instructions from anyone when exercising their tasks under paragraph 3. Each expert shall draw up a declaration of interests, which shall be made publicly available. The AI Office shall establish systems and procedures to actively manage and prevent potential conflicts of interest.
- Art. 70, 3.** Member States shall ensure that their national competent authorities are provided with adequate technical, financial and human resources, and with infrastructure to fulfil their tasks effectively under this Regulation. In particular, the national competent authorities shall have a sufficient number of personnel permanently available whose competences and expertise shall include an in-depth understanding of AI technologies, data and data computing, personal data protection, cybersecurity, fundamental rights, health and safety risks and knowledge of existing standards and legal requirements. Member States shall assess and, if necessary, update competence and resource requirements referred to in this paragraph on an annual basis.
- Art. 71, 5.** When performing their tasks, the national competent authorities shall act in accordance with the confidentiality obligations set out in Article 78.
- Art. 71, 5.** The EU database shall contain personal data only in so far as necessary for collecting and processing information in accordance with this Regulation. That information shall include the names and contact details of natural persons who are responsible for registering the system and have the legal authority to represent the provider or the deployer, as applicable.
- Art. 74, 14.** Any information or documentation obtained by market surveillance authorities shall be treated in accordance with the confidentiality obligations set out in Article 78.
- Art. 75, 3.** Where a market surveillance authority is unable to conclude its investigation of the high-risk AI system because of its inability to access certain information related to the general-purpose AI model despite having made all appropriate efforts to obtain that information, it may submit a reasoned request to the AI Office, by which access to that information shall be enforced. In that case, the AI Office shall supply to the applicant authority without delay, and in any event within 30 days, any information that the AI Office considers to be relevant in order to establish whether a high-risk AI system is non-compliant. Market surveillance authorities shall safeguard the confidentiality of the information that they obtain in accordance with Article 78 of this Regulation. The procedure provided for in Chapter VI of Regulation (EU) 2019/1020 shall apply mutatis mutandis.
- Art. 77, 4.** Any information or documentation obtained by the national public authorities or bodies referred to in paragraph 1 of this Article pursuant to this Article shall be treated in accordance with the confidentiality obligations set out in Article 78.
- Art. 78:** Confidentiality
- Art. 78, 1.** The Commission, market surveillance authorities and notified bodies and any other natural or legal person involved in the application of this Regulation shall, in accordance with Union or national law, respect the confidentiality of information and data obtained in carrying out their tasks and activities in such a manner as to protect, in particular:
- Art. 78, 2.** the authorities involved in the application of this Regulation pursuant to paragraph 1 shall request only data that is strictly necessary for the assessment of the risk posed by AI systems and for the exercise of their powers in accordance with this Regulation and with Regulation (EU) 2019/1020. They shall put in place adequate and effective cybersecurity measures to protect the security and confidentiality of the information and data obtained, and shall delete the data collected as soon as it is no longer needed for the purpose for which it was obtained, in accordance with applicable Union or national law.
- Art. 78, 5.** The Commission and Member States may exchange, where necessary and in accordance with relevant provisions of international and trade agreements, confidential information with regulatory authorities of third countries with which they have concluded bilateral or multilateral confidentiality arrangements guaranteeing an adequate level of confidentiality.
- Art. 100, 5.** The rights of defence of the parties concerned shall be fully respected in the proceedings. They shall be entitled to have access to the European Data Protection Supervisor's file, subject to the legitimate interest of individuals or undertakings in the protection of their personal data or business secrets.

Terms and AI Act Articles

60 Conformity assessment

Art. 3. (19): notifying authority means the national authority responsible for setting up and carrying out the necessary procedures for the assessment, designation and notification of conformity assessment bodies and for their monitoring;

Art. 3. (20): conformity assessment means the process of demonstrating whether the requirements set out in Chapter III, Section 2 relating to a high-risk AI system have been fulfilled;

Art. 3. (21): conformity assessment body means a body that performs third-party conformity assessment activities, including testing, certification and inspection;

Art. 3. (22): notified body means a conformity assessment body notified in accordance with this Regulation and other relevant Union harmonisation legislation;

Art. 3. (23): substantial modification means a change to an AI system after its placing on the market or putting into service which is not foreseen or planned in the initial conformity assessment carried out by the provider and as a result of which the compliance of the AI system with the requirements set out in Chapter III, Section 2 is affected or results in a modification to the intended purpose for which the AI system has been assessed;

Art. 3. (b): the product without prejudice pursuant to point (a) is the AI system, or the AI system itself as a product, is required to undergo a third-party conformity assessment, with a view to the placing on the market or the putting into service of that product pursuant to the Union harmonisation legislation listed in Annex I.

Art. 11. 1: The technical documentation of a high-risk AI system shall be drawn up before that system is placed on the market or put into service and shall be kept up-to-date. The technical documentation shall be drawn up in such a way as to demonstrate that the high-risk AI system complies with the requirements set out in this Section and to prohibit competent authorities and the necessary information in a clear and accessible manner to assess the compliance of the AI system with those requirements. It shall contain, at a minimum, the elements set out in Annex IV. SMEs, including start-ups, may provide the elements of the technical documentation specified in Annex IV in a simplified manner. To that end, the Commission shall establish a simplified technical documentation form targeted at the needs of small and microenterprises. Where an SME, including a start-up, opts to provide the information required in Annex IV in a simplified manner, it shall use the form referred to in this paragraph. Notified bodies shall accept the form for the purposes of the conformity assessment.

Art. 13. 3(a): the change to the high-risk AI system and its performance which have been pre-determined by the provider at the moment of the initial conformity assessment, if any;

Art. 16. (f): ensure that the high-risk AI system undergoes the relevant conformity assessment procedure as referred to in Article 43, prior to its being placed on the market or put into service;

Art. 17. 1(a): a strategy for regulatory compliance, including compliance with conformity assessment procedures and procedures for the management of modifications to the high-risk AI system;

Art. 20. 2(a): verify that the EU declaration of conformity referred to in Article 47 and the technical documentation referred to in Article 11 have been drawn up and that an appropriate conformity assessment procedure has been carried out by the provider;

Art. 23. 1(a): the relevant conformity assessment procedure referred to in Article 43 has been carried out by the provider of the high-risk AI system;

Art. 25. 2: Where the circumstances referred to in paragraph 1 occur, the provider that initially placed the AI system on the market or put it into service shall no longer be considered to be a provider of that specific AI system for the purposes of this Regulation. That initial provider shall closely cooperate with the notified body to evaluate the necessary information provided by the provider to ensure the reasonably expected technical access and other assistance that are required for the fulfilment of the obligations set out in this Regulation, in particular regarding the compliance with the conformity assessment of high-risk AI systems. This paragraph shall not apply in cases where the initial provider has clearly specified that its AI system is not to be changed into a high-risk AI system and therefore does not fall under the obligation to hand over the documentation.

Art. 26. 1: Each Member State shall designate or establish at least one notifying authority responsible for setting up and carrying out the necessary procedures for the assessment, designation and notification of conformity assessment bodies and for their monitoring. Those procedures shall be developed in cooperation between the notifying authorities of the Member States.

Art. 28. 3: Notifying authorities shall be established, organised and operated in such a way that no conflict of interest arises with conformity assessment bodies, and that the objectivity and impartiality of their activities are safeguarded.

Art. 28. 4: Notifying authorities shall be organised in such a way that decisions relating to the notification of conformity assessment bodies are taken by competent persons different from those who carried out the assessment of those bodies.

Art. 29. 3: Notifying authorities shall not provide either any activities that conformity assessment bodies perform, nor any consultancy services on a commercial or competitive basis.

Art. 29. 4: Application of a conformity assessment body for notification

Art. 29. 5: Conformity assessment bodies shall submit an application for notification to the notifying authority of the Member State in which they are established.

Art. 29. 6: The application for notification shall contain information on the scope of the conformity assessment activities, the modules and the types of AI systems for which the conformity assessment body claims to be competent, as well as by an accreditation certificate, where one exists, issued by a national accreditation body attesting that the conformity assessment body fulfils the requirements laid down in Article 31. Any valid document related to existing designations of the applicant notified body under any other Union harmonisation legislation shall be added.

Art. 30. 3: Where the conformity assessment body concerned cannot provide an accreditation certificate, it shall provide the notifying authority with all the documentary evidence necessary for the verification, recognition and regular monitoring of its compliance with the requirements laid down in Article 31.

Art. 30. 4: Notifying authorities may notify only conformity assessment bodies which have satisfied the requirements laid down in Article 31.

Art. 30. 5: Notifying authorities shall notify the Commission and the other Member States, using the electronic notification tool developed and managed by the Commission, of each conformity assessment body referred to in paragraph 1.

Art. 30. 6: The notification referred to in paragraph 2 of this Article shall include full details of the conformity assessment activities, the conformity assessment module or modules, the types of AI systems concerned, and the relevant attestation of competence. Where a notification is not based on an accreditation certificate as referred to in Article 29(2), the notifying authority shall provide the Commission and the other Member States with documentary evidence which attests to the competence of the conformity assessment body and to the arrangements in place to ensure that that body will be monitored regularly and will continue to satisfy the requirements laid down in Article 31.

Art. 30. 7: The conformity assessment body concerned may perform the activities of a notified body only where no objections are raised by the Commission or the other Member States within two weeks of a notification by a notifying authority where it includes an accreditation certificate as referred to in Article 29(2), or within two weeks of a notification by the notifying authority where it does not include documentary evidence referred to in Article 29(3).

Art. 30. 8: Where objections are raised, the Commission shall, without delay, enter into consultations with the relevant Member States and the conformity assessment body. In view thereof, the Commission shall decide whether the authorisation is justified. The Commission shall address its decision to the Member State concerned and to the relevant conformity assessment body.

Art. 31. 1: The organisational and operational separation of notified bodies shall ensure confidence in their performance, and in the results of the conformity assessment activities that the notified bodies conduct.

Art. 31. 4: Notified bodies shall be independent of the provider of a high-risk AI system in relation to which they perform conformity assessment activities. Notified bodies shall also be independent of any other operator having an economic interest in high-risk AI systems assessed, as well as of any competitors of the provider. This shall not preclude the use of assessed high-risk AI systems that are necessary for the operations of the conformity assessment body, or the use of such high-risk AI systems for personal purposes.

Art. 31. 5: Neither the notifying authority nor the provider shall be directly involved in the design, development, marketing or use of high-risk AI systems, nor shall they represent the parties engaged in those activities. They shall not engage in any activity that might conflict with their independence of judgment or integrity in relation to conformity assessment activities for which they are notified. This shall, in particular, apply to consultancy services.

Art. 31. 7: Notified bodies shall have documented procedures in place ensuring that their personnel, committees, subsidiaries, subcontractors and any associated body or personnel of external bodies maintain, in accordance with Article 76, the confidentiality of the information which comes into their possession in providing the performance of conformity assessment activities, except where its disclosure is required by law. The staff of notified bodies shall be bound to observe professional secrecy with regard to all information obtained in carrying out their tasks under this Regulation, except in relation to the notifying authorities of the Member State in which their activities are carried out.

Art. 31. 8: Notified bodies shall take out appropriate liability insurance for their conformity assessment activities, unless liability is assumed by the Member State in which they are established in accordance with national law or that Member State is itself directly responsible for the conformity assessment.

Art. 32: Where a conformity assessment body demonstrates its conformity with the criteria laid down in the relevant harmonised standards or parts thereof, the references of which have been published in the Official Journal of the European Union, it shall be presumed to comply with the requirements set out in Article 31 in so far as the applicable harmonised standards cover those requirements.

Art. 32. 1: Where a notified body subcontract specific tasks connected with the conformity assessment or has recourse to a subsidiary, it shall ensure that the subcontractor or the subsidiary meets the requirements laid down in Article 31, and shall inform the notifying authority accordingly.

Art. 34. 1: Notified bodies shall verify the conformity of high-risk AI systems in accordance with the conformity assessment procedures set out in Article 43.

Art. 34. 2: Where a notified body decides to cease its conformity assessment activities, it shall inform the notifying authority and the providers concerned as soon as possible and, in the case of a planned cessation, at least one year before ceasing its activities. The certificates of the notified body may remain valid for a period of nine months after cessation of the notified body's activities, on condition that another notified body has confirmed in writing that it will assume responsibilities for the high-risk AI systems covered by those certificates. The latter notified body shall complete a full assessment of the high-risk AI systems affected by the end of that nine-month-period before issuing new certificates for those systems. Where the notified body has ceased its activity, the notifying authority shall withdraw the designation.

Art. 35. 1: The Commission shall ensure that, with regard to high-risk AI systems, appropriate coordination and cooperation between notified bodies active in the conformity assessment procedures pursuant to this Regulation are put in place and properly operated in the form of a sectoral group of notified bodies.

Art. 39: Conformity assessment bodies of third countries

Art. 39: Conformity assessment bodies established under the law of a third country with which the Union has concluded an agreement may be authorised to carry out the activities of notified bodies under this Regulation, provided that they meet the requirements laid down in Article 31 or they ensure an equivalent level of compliance.

SECTION 5. Standards, conformity assessment, certificates, registration

Art. 43: Conformity assessment

Art. 43. 1: For high-risk AI systems listed in point 1 of Annex III, where, in demonstrating the compliance of a high-risk AI system with the requirements set out in Section 2, the provider has applied harmonised standards referred to in Article 40, or, where applicable, common specifications referred to in Article 41, the provider shall opt for one of the following conformity assessment procedures based on:

Art. 43. (b): the assessment of the quality management system and the assessment of the technical documentation, with the involvement of a notified body, referred to in Annex VII. In demonstrating the compliance of a high-risk AI system with the requirements set out in Section 2, the provider shall follow the conformity assessment procedure set out in Annex VII where:

Art. 43. (d): one or more of the harmonised standards referred to in point (a) has been published with a restriction, and only on the part of the standard that was restricted. For the purposes of the conformity assessment procedure referred to in Annex VII, the provider may choose any of the notified bodies. However, where the high-risk AI system is intended to be put into service by law enforcement, immigration or asylum authorities or by Union institutions, bodies, offices or agencies, the market surveillance authority referred to in Article 74(8) or (9), as applicable, shall act as a notified body.

Art. 43. 2: For high-risk AI systems referred to in points 2 to 8 of Annex III, providers shall follow the conformity assessment procedure based on internal control as referred to in Annex VI, which does not provide for the involvement of a notified body.

Art. 43. 3: For high-risk AI systems covered by the Union harmonisation legislation listed in Section A of Annex I, the provider shall follow the relevant conformity assessment procedure as required under those legal acts. The requirements set out in Section 2 of this Chapter shall apply to those high-risk AI systems and shall be part of that assessment. Points 4.3., 4.4., 4.5. and the fifth paragraph of point 4.6 of Annex VII shall also apply. For the purposes of that assessment, notified bodies which have been notified under those legal acts shall be entitled to control the conformity of the high-risk AI systems with the requirements set out in Section 2, provided that the compliance of those notified bodies with requirements laid down in Article 31(4), (5), (10) and (11) has been assessed in the context of the notification procedure under those legal acts.

Art. 43. 4: Where a legal act in Section 2 of Annex I enables the product manufacturer to opt for a third-party conformity assessment, provided that that manufacturer has applied all harmonised standards covering all the relevant requirements, that manufacturer may use that option only if it has also applied harmonised standards or, where applicable, common specifications referred to in Article 41, covering all requirements set out in Section 2 of this Chapter.

Art. 43. 5: High-risk AI systems covered by the Union harmonisation legislation referred to in Section 2 of Annex I shall not constitute a substantial modification, regardless of whether the modified system is intended to be further distributed or continues to be used by the current deployer. For high-risk AI systems that continue to learn after being placed on the market or put into service, changes to the high-risk AI system and its performance that have been pre-determined by the provider at the moment of the initial conformity assessment and are part of the information contained in the technical documentation referred to in point 2(f) of Annex IV, shall not constitute a substantial modification.

Art. 43. 6: The Commission shall ensure that the conformity assessment procedure based on internal control referred to in Annex VI in preventing or minimising the risks to health and safety and protection of fundamental rights posed by such systems, as well as the availability of adequate capacities and resources among notified bodies.

Art. 43. 7: High-risk AI systems covered by the Union harmonisation legislation referred to in Section 2 of Annex I and four years for AI systems covered by Annex III. At the request of the provider, the validity of a certificate may be extended for further periods, each not exceeding five years for AI systems covered by Annex I, and four years for AI systems covered by Annex III, based on a re-assessment in accordance with the applicable conformity assessment procedures. Any supplement to a certificate shall remain valid, provided that the certificate which it supplements is valid.

Art. 45. 1(d): any request for information which they have received from market surveillance authorities regarding conformity assessment activities;

Art. 45. 1(e): on request, conformity assessment activities performed within the scope of their notification and any other activity performed, including cross-border activities and subcontracting.

Art. 45. 3: Each notified body shall provide the other notified bodies carrying out similar conformity assessment activities covering the same types of AI systems with relevant information on issues relating to negative and, on request, positive conformity assessment results.

Art. 46: Derogation from conformity assessment procedure

Art. 46. 1: By way of derogation from Article 43 and upon a duly justified request, any market surveillance authority may authorise the placing on the market or the putting into service of specific high-risk AI systems within the territory of the Member State concerned, for exceptional reasons of public security or the protection of life and health of persons, environmental protection or the protection of key industrial and infrastructural assets. That authorisation shall be for a limited period while the necessary conformity assessment procedures are being carried out, taking into account the exceptional circumstances justifying the derogation and the completion of those procedures for AI systems undertaken without undue delay.

Art. 46. 2: For high-risk AI systems related to products covered by Union harmonisation legislation listed in Section A of Annex I, only the derogations from the conformity assessment established in that Union harmonisation legislation shall apply.

Art. 46. 4: Where applicable, the CE marking shall be followed by the identification number of the notified body responsible for the conformity assessment procedures set out in Article 43. The identification number of the notified body shall be affixed by the body itself or, under its instructions, by the provider or by the provider's authorised representative. The identification number shall also be indicated in any promotional material which mentions that the high-risk AI system fulfils the requirements for CE marking.

Art. 57. 7: Competent authorities shall provide providers and prospective providers participating in the AI regulatory sandbox with guidance on regulatory expectations and how to fulfil the requirements and obligations set out in this Regulation. Upon request of the provider or prospective provider of the AI system, the competent authority shall provide a written proof of the activities successfully carried out in the sandbox. The competent authority shall also provide an exit report detailing the activities carried out in the sandbox and the related results and learning outcomes. Providers may use such information to demonstrate their conformity assessment process or relevant market surveillance activities. In this regard, the exit reports and the written proof provided by the national competent authority shall be taken into account by market surveillance authorities and notified bodies, with a view to accelerating conformity assessment procedures to a reasonable extent.

Art. 58. 2(a): that they facilitate providers and prospective providers, by means of the learning outcomes of the AI regulatory sandboxes, in complying with conformity assessment obligations under this Regulation and the voluntary application of the codes of conduct referred to in Article 35.

Art. 62. 2: The specific interests and needs of the SME providers, including start-ups, shall be taken into account when setting the fees for conformity assessment under Article 43, reducing those fees proportionately to their size, market size and other relevant indicators.

Art. 66. 1(d): contribute to the harmonisation of administrative practices in the Member States, including in relation to the derogation from the conformity assessment procedures referred to in Article 46, the functioning of AI regulatory sandboxes, and testing in real world conditions referred to in Articles 57, 58 and 60.

Art. 112. 12: Any amendment to this Regulation pursuant to paragraph 10, or relevant delegated or implementing acts, which concerns sectoral Union harmonisation legislation listed in Section B of Annex I shall take into account the regulatory specificities of each sector, and the existing governance, conformity assessment and enforcement mechanisms and authorities established therein.

0 Consequence

5 Consistency

Art. 6. 8: Any amendment to the conditions laid down in paragraph 3, second subparagraph, adopted in accordance with paragraphs 6 and 7 of this Article shall not decrease the overall level of protection of health, safety and fundamental rights provided for by this Regulation and shall ensure consistency with the delegated acts adopted pursuant to Article 7(1), and take account of market and technological developments.

Art. 9. 2: Where a product contains an AI system, to which the requirements of this Regulation as well as requirements of the Union harmonisation legislation listed in Section A of Annex I apply, providers shall be responsible for ensuring that their product is fully compliant with all applicable requirements under applicable Union harmonisation legislation. In ensuring the compliance of high-risk AI systems referred to in paragraph 1 with the requirements set out in this Section, and in order to ensure consistency, avoid duplication and minimise additional burdens, providers shall have a choice of integrating, as appropriate, the necessary testing and reporting processes, information and documentation they provide with regard to their product into documentation and procedures that already exist and are required under the Union harmonisation legislation listed in Section A of Annex I.

Art. 65. 2(c): are empowered to facilitate consistency and coordination between national competent authorities in their Member State as regards the implementation of this Regulation, including through the collection of relevant data and information for the purpose of fulfilling their tasks on the Board.

Art. 72. 4: For high-risk AI systems covered by the Union harmonisation legislation listed in Section A of Annex I, where a post-market monitoring system and plan are already established under that legislation, in order to ensure consistency, avoid duplications and minimise additional burdens, providers shall have a choice of integrating, as appropriate, the necessary elements described in paragraphs 1, 2 and 3 using the template referred to in paragraph 3 into systems and plans already existing under that legislation, provided that it achieves an equivalent level of governance, arrangements or processes.

Art. 96. 1(e): detailed information on the relationship of this Regulation with the Union harmonisation legislation listed in Annex I, as well as with other relevant Union law, including as regards consistency in their enforcement;

10 Contact

Art. 13. 3(a): the identity and the contact details of the provider and, where applicable, of its authorised representative;

Art. 22. 2(b): keep at the disposal of the competent authorities and national authorities or bodies referred to in Article 74(10), for a period of 10 years after the high-risk AI system has been placed on the market or put into service, the contact details of the provider that appointed the authorised representative, a copy of the EU declaration of conformity referred to in Article 47, the technical documentation and, if applicable, the certificate issued by the notified body;

Art. 24. 3(b): keep a copy of the technical documentation specified in Annex XI at the disposal of the AI Act and national competent authorities, for a period of 10 years after the general-purpose AI model has been placed on the market, and the contact details of the provider that appointed the authorised representative;

Art. 61. 1(e): the Union-wide unique single identification number of the testing in real world conditions in accordance with Article 60(4) point (c), and the contact details of the provider or its legal representative from whom further information can be obtained.

Art. 63. 4(b): as are designated as a single contact point vis-à-vis the Board and, where appropriate, taking into account Member States' needs, as a single contact point for stakeholders.

Art. 70: Designation of national competent authorities and single points of contact

Art. 70. 2: Member States shall designate, in consultation with the notifying authorities and the market surveillance authorities and the tasks of those authorities, as well as any subsequent changes thereto. Member States shall make publicly available information on how competent authorities and single points of contact can be contacted, through electronic communication means by 2 August 2025. Member States shall designate a market surveillance authority to act as the single point of contact for this Regulation, and shall notify the Commission of the identity of the single point of contact. The Commission shall make a list of the single points of contact publicly available.

Art. 71. 5: The EU database shall contain information on the identity of the notifying authorities and the market surveillance authorities for collecting and processing information in accordance with this Regulation. That information shall include the names and contact details of natural persons who are responsible for registering the system and have the legal authority to represent the provider or the deployer, as applicable.

Art. 89. 2(a): the point of contact of the provider of the general-purpose AI model concerned;

Art. 90. 3(a): the point of contact of the provider of the general-purpose AI model with systemic risk concerned;

2. Context of use

Art. 14. 3: The oversight measures shall be commensurate with the risks, level of autonomy and context of use of the high-risk AI system, and shall be ensured through either one or both of the following types of measures:

Art. 15. 2: Providers shall ensure that natural persons who are directly or indirectly affected in such a way that the natural persons concerned are informed that they are interacting with an AI system, unless this is obvious from the point of view of a natural person who is reasonably well-informed, observant and circumspect, taking into account the circumstances and the context of use. This obligation shall not apply to AI systems authorised by law to detect, prevent, investigate or prosecute criminal offences, subject to appropriate safeguards for the rights and freedoms of third parties, unless those systems are available for the public to report a criminal offence.

Terms and AI Act Articles

0 Controllability

1 Controller

Art. 71. 6: The Commission shall be the controller of the EU database. It shall make available to providers, prospective providers and deployers adequate technical and administrative support. The EU database shall comply with the applicable accessibility requirements.

20 Cooperation

Art. 2. 4: This Regulation applies neither to public authorities in a third country nor to international organisations falling within the scope of this Regulation pursuant to paragraph 1, where those authorities or organisations use AI systems in the framework of international cooperation or agreements for law enforcement and judicial cooperation with the Union or with one or more Member States, provided that such a third country or international organisation provides adequate safeguards with respect to the protection of fundamental rights and freedoms of individuals.

Art. 15. 2: To address the technical aspects of how to measure the appropriate levels of accuracy and robustness set out in paragraph 1 and any other relevant performance metrics, the Commission shall, in cooperation with relevant stakeholders and organisations such as metrology and benchmarking authorities, encourage, as appropriate, the development of benchmarks and measurement methodologies.

Art. 21: Cooperation with competent authorities

Art. 26. 1: Each Member State shall designate or establish at least one notifying authority responsible for setting up and carrying out the necessary procedures for the assessment, designation and notification of conformity assessment bodies and for their monitoring. Those procedures shall be developed in cooperation between the notifying authorities of all Member States.

Art. 38. 1: The Commission shall ensure that, with regard to high-risk AI systems, appropriate coordination and cooperation between notified bodies active in the conformity assessment procedures pursuant to this Regulation are put in place and properly operated in the form of a sectoral group of notified bodies.

Art. 40. 3: The participants in the standardisation process shall seek to promote investment and innovation in AI, including through increasing legal certainty, as well as the competitiveness and growth of the Union market, to contribute to strengthening global cooperation on standardisation and taking into account existing international standards in the field of AI that are consistent with Union values, fundamental rights and interests, and to enhance multi-stakeholder governance ensuring a balanced representation of interests and the effective participation of all relevant stakeholders in accordance with Articles 5, 6, and 7 of Regulation (EU) No 1025/2012.

Art. 57. 4: Member States shall ensure that the competent authorities referred to in paragraphs 1 and 2 allocate sufficient resources to comply with this Article effectively and in a timely manner. Where appropriate, national competent authorities shall cooperate with other relevant authorities, and may allow for the involvement of other actors within the AI ecosystem. This Article shall not affect other regulatory sandboxes established under Union or national law. Member States shall ensure an appropriate level of cooperation between the authorities supervising those other sandboxes and the national competent authorities.

Art. 57. 5(b): supporting the sharing of best practices through cooperation with the authorities involved in the AI regulatory sandbox;

Art. 57. 13: The AI regulatory sandboxes facilitate the involvement of other relevant actors within the AI ecosystem, such as notified bodies and standardisation organisations, SMEs, including start-ups, enterprises, innovators, testing and experimentation facilities, research and experimentation labs and European Digital Innovation Hubs, centres of excellence, individual researchers, in order to allow and facilitate cooperation with the public and private sectors;

Art. 60. 4(h): where a provider or prospective provider organises the testing in real world conditions in cooperation with one or more employers or prospective employers, the latter have been informed of all aspects of the testing that are relevant to their decision to participate, and given the relevant instructions for use of the AI system referred to in Article 13; the provider or prospective provider and the employer or prospective employer shall conclude an agreement specifying their roles and responsibilities with a view to ensuring compliance with the provisions for testing in real world conditions under this Regulation and under other applicable Union and national law;

Art. 65. 6: The Board shall establish two standing sub-groups to provide a platform for cooperation and exchange among market surveillance authorities and notifying authorities about issues related to market surveillance and notified bodies respectively. The standing sub-group for market surveillance should act as the administrative cooperation group (ADCO) for this Regulation within the meaning of Article 30 of Regulation (EU) 2019/1020. The Board may establish other standing or temporary sub-groups as appropriate for the purpose of examining specific issues. Where appropriate, representatives of the advisory forum referred to in Article 67 may be invited to such sub-groups or to specific meetings of those sub-groups as observers.

Art. 66. (c): contribute to the coordination among national competent authorities responsible for the application of this Regulation and, in cooperation with and subject to the agreement of the market surveillance authorities concerned, support joint activities of market surveillance authorities referred to in Article 77(1);

Art. 66. (i): contribute to effective cooperation with the competent authorities of third countries and with international organisations;

Art. 66. (k): assist the AI Office in supporting national competent authorities in the establishment and development of AI regulatory sandboxes, and facilitate cooperation and information-sharing among AI regulatory sandboxes;

Art. 66. 4: Paragraphs 1, 2 and 3 shall not affect the rights or obligations of the Commission, Member States and their relevant authorities, as well as those of notified bodies, with regard to the exchange of information and the dissemination of warnings, including in the context of cross-border cooperation, nor shall they affect the obligations of the parties concerned to provide information under criminal law of the Member States.

Art. 79. 2: Where the market surveillance authority of a Member State has sufficient reason to consider an AI system to present a risk as referred to in paragraph 1 of this Article, it shall carry out an evaluation of the AI system concerned in respect of its compliance with all the requirements and obligations laid down in this Regulation. Particular attention shall be given to AI systems presenting a risk to vulnerable groups. Where risks to fundamental rights are identified, the market surveillance authority shall also inform and fully cooperate with the relevant national public authorities or bodies referred to in Article 77(1). The relevant operators shall cooperate as necessary with the market surveillance authority and with the other national public authorities or bodies referred to in Article 77(1). Where, in the course of that evaluation, the market surveillance authority or, where applicable the market surveillance authority in cooperation with the national public authority referred to in Article 77(1), finds that the AI system does not comply with the requirements and obligations laid down in this Regulation, it shall without undue delay require the relevant operator to take all appropriate corrective actions to bring the AI system into compliance, to withdraw the AI system from the market, or to recall it within a period the market surveillance authority may prescribe, and in any event within the shorter of 15 working days, or as provided for in the relevant Union harmonisation legislation. The market surveillance authority shall inform the relevant notified body accordingly. Article 18 of Regulation (EU) 2019/1020 shall apply to the measures referred to in the second subparagraph of this paragraph.

Art. 99. 7(f): the degree of cooperation with the national competent authorities, in order to remedy the infringement and mitigate the possible adverse effects of the infringement;

Art. 100. 1(d): the degree of cooperation with the European Data Protection Supervisor in order to remedy the infringement and mitigate the possible adverse effects of the infringement, including compliance with any of the measures previously ordered by the European Data Protection Supervisor against the Union institution, body, office or agency concerned with regard to the same subject matter;

9 Coordination

Art. 31. 12: Notified bodies shall participate in coordination activities as referred to in Article 38. They shall also take part directly, or be represented in, European standardisation organisations, or ensure that they are aware and up to date in respect of relevant standards.

Art. 38: Coordination of notified bodies

Art. 39. 1: The Commission shall ensure that, with regard to high-risk AI systems, appropriate coordination and cooperation between notified bodies active in the conformity assessment procedures pursuant to this Regulation are put in place and properly operated in the form of a sectoral group of notified bodies.

Art. 65. (c): are empowered to facilitate consistency and coordination between national competent authorities in their Member State as regards the implementation of this Regulation, including through the collection of relevant data and information for the purpose of fulfilling their tasks on the ground;

Art. 66. (e): contribute to the coordination among national competent authorities responsible for the application of this Regulation and, in cooperation with and subject to the agreement of the market surveillance authorities concerned, support joint activities of market surveillance authorities referred to in Article 74(11);

Art. 74. 7: For high-risk AI systems related to products covered by the Union harmonisation legislation listed in Section A of Annex I, the market surveillance authority for the purposes of this Regulation shall be the authority responsible for market surveillance activities designated under those legal acts. By derogation from the first subparagraph, and in appropriate circumstances, Member States may designate another relevant authority to act as a market surveillance authority, provided they ensure coordination with the relevant sectoral market surveillance authorities responsible for the enforcement of the Union harmonisation legislation listed in Annex I.

Art. 74. 7: By way of derogation from paragraph 6, in appropriate circumstances, and provided that coordination is ensured, another relevant authority may be identified by the Member State as market surveillance authority for the purposes of this Regulation. National market surveillance authorities supervising regulated credit institutions regulated under Directive 2013/36/EU, which are participating in the Single Supervisory Mechanism established by Regulation (EU) No 1024/2013, should report, without delay, to the European Central Bank any information identified in the course of their market surveillance activities that may be of potential interest for the prudential supervisory tasks of the European Central Bank specified in that Regulation.

Art. 74. 10: Member States shall facilitate coordination between market surveillance authorities designated under this Regulation and other relevant national authorities or bodies which supervise the application of Union harmonisation legislation listed in Annex I, or in other Union law, that might be relevant for the high-risk AI systems referred to in Annex III.

Art. 74. 11: Market surveillance authorities and the Commission shall be able to propose joint activities, including joint investigations, to be conducted by either market surveillance authorities or market surveillance authorities jointly with the Commission, that have the aim of promoting compliance, identifying non-compliance, raising awareness or providing guidance in relation to this Regulation with respect to specific categories of high-risk AI systems that are found to present a serious risk across two or more Member States in accordance with Article 9 of Regulation (EU) 2019/1020. The AI Office shall provide coordination support for joint investigations.

14 Corrective action

Art. 16. (i): take the necessary corrective actions and provide information as required in Article 20;

Art. 20: Corrective actions and duty of information

Art. 20. 1: Providers of high-risk AI systems which consider or have reason to consider that a high-risk AI system that they have placed on the market or put into service is not in conformity with this Regulation shall immediately take the necessary corrective actions to bring that system into conformity, to withdraw it, to disable it, or to recall it, as appropriate. They shall inform the distributors of the high-risk AI system concerned and, where applicable, the deployers, the authorised representative and importers accordingly.

Art. 20. 2: Where the high-risk AI system presents a risk within the meaning of Article 79(1) and the provider becomes aware of that risk, it shall immediately investigate the causes, in collaboration with the reporting deployer, where applicable, and inform the market surveillance authorities competent for the high-risk AI system concerned and, where applicable, the notified body that issued a certificate for that high-risk AI system in accordance with Article 44, in particular, of the nature of the non-compliance and of any relevant corrective action taken.

Art. 24. 4: A distributor that considers or has reason to consider, on the basis of the information in its possession, a high-risk AI system which it has made available on the market not to be in conformity with the requirements set out in Section 2, shall take the corrective actions necessary to bring that system into conformity with those requirements, to withdraw it or recall it, or shall ensure that the provider, the importer or any relevant operator, as appropriate, takes those corrective actions. Where the high-risk AI system presents a risk within the meaning of Article 79(1), the distributor shall immediately inform the provider or importer of the system and the authorities competent for the high-risk AI system concerned, giving details, in particular, of the non-compliance and of any corrective actions taken.

Art. 44. 3: Where a notified body finds that an AI system no longer meets the requirements set out in Section 2, it shall, taking account of the principle of proportionality, suspend or withdraw the certificate issued or impose restrictions on it, unless compliance with those requirements is ensured by appropriate corrective action taken by the provider of the system within an appropriate deadline set by the notified body. The notified body shall give reasons for its decision. An appeal procedure against decisions of the notified bodies, including on conformity certificates issued, shall be available.

Art. 73. 6: Following the reporting of a serious incident pursuant to paragraph 1, the provider shall, without delay, perform the necessary investigations in relation to the serious incident and the AI system concerned. This shall include a risk assessment of the incident, and corrective action. The provider shall cooperate with the competent authorities, and where relevant with the notified body concerned, during the investigations referred to in the first subparagraph, and shall not perform any investigation which involves altering the AI system concerned in a way which may affect any subsequent evaluation of the causes of the incident, prior to informing the competent authorities of such action.

Art. 79. 2: Where the market surveillance authority of a Member State has sufficient reason to consider an AI system to present a risk as referred to in paragraph 1 of this Article, it shall carry out an evaluation of the AI system concerned in respect of its compliance with all the requirements and obligations laid down in this Regulation. Particular attention shall be given to AI systems presenting a risk to vulnerable groups. Where risks to fundamental rights are identified, the market surveillance authority shall also inform and fully cooperate with the relevant national public authorities or bodies referred to in Article 77(1). The relevant operators shall cooperate as necessary with the market surveillance authority and with the other national public authorities or bodies referred to in Article 77(1). Where, in the course of that evaluation, the market surveillance authority or, where applicable the market surveillance authority in cooperation with the national public authority referred to in Article 77(1), finds that the AI system does not comply with the requirements and obligations laid down in this Regulation, it shall without undue delay require the relevant operator to take all appropriate corrective actions to bring the AI system into compliance, to withdraw the AI system from the market, or to recall it within a period the market surveillance authority may prescribe, and in any event within the shorter of 15 working days, or as provided for in the relevant Union harmonisation legislation. The market surveillance authority shall inform the relevant notified body accordingly. Article 18 of Regulation (EU) 2019/1020 shall apply to the measures referred to in the second subparagraph of this paragraph.

Art. 79. 4: The operator shall ensure that all appropriate corrective action is taken in respect of all the AI systems concerned that it has made available on the Union market.

Art. 79. 5: Where the operator of an AI system does not take adequate corrective action within the period referred to in paragraph 2, the market surveillance authority shall take all appropriate provisional measures to prohibit or restrict the AI system's being made available on its national market or put into service, to withdraw the product or the standalone AI system from that market or to recall it. That authority shall without undue delay notify the Commission and the other Member States of those measures.

Art. 80. 2: Where, in the course of that evaluation, the market surveillance authority finds that the AI system concerned is high-risk, it shall without undue delay require the relevant provider to take all necessary actions to bring the AI system into compliance with the requirements and obligations laid down in this Regulation, as well as take appropriate corrective action within a period the market surveillance authority may prescribe.

Art. 80. 5: The provider shall ensure that all appropriate corrective action is taken in respect of all the AI systems concerned that it has made available on the Union market.

Art. 80. 6: Where the provider of the AI system concerned does not take adequate corrective action within the period referred to in paragraph 2 of this Article, Article 79(5) to (9) shall apply.

Art. 82. 2: The provider or other relevant operator shall ensure that corrective action is taken in respect of all the AI systems concerned that it has made available on the Union market within the timeline prescribed by the market surveillance authority of the Member State referred to in paragraph 1.

0 Credibility

0 Currentness

0 Customer

12 Cybersecurity (See also: Security)

Art. 13. 3(b)(ii): the level of accuracy, including its metrics, robustness and cybersecurity referred to in Article 15 against which the high-risk AI system has been tested and validated and which can be expected, and any known and foreseeable circumstances that may have an impact on that expected level of accuracy, robustness and cybersecurity;

Art. 15: Accuracy, robustness and cybersecurity

Art. 15. 1: High-risk AI systems shall be designed and developed in such a way that they achieve an appropriate level of accuracy, robustness, and cybersecurity, and that they perform consistently in those respects throughout their lifecycle.

Art. 15. 5: High-risk AI systems shall be designed and developed in such a way that they are resilient to unauthorised third parties to alter their use, outputs or performance by exploiting system vulnerabilities. The technical solutions aiming to ensure the cybersecurity of high-risk AI systems shall be appropriate to the relevant circumstances and the risks. The technical solutions to address AI specific vulnerabilities shall include, where appropriate, measures to prevent, detect, respond to, resolve and control for attacks trying to manipulate the training data set (data poisoning), or pre-trained components used in training (model poisoning), inputs designed to cause the AI model to make a mistake (adversarial examples or model evasion), confidentiality attacks or model flaws.

Art. 31. 2: Notified bodies shall ensure that the organisational, quality management, resources and process requirements that are necessary to fulfil their tasks, as well as suitable cybersecurity requirements.

Art. 42. 2: High-risk AI systems that have been certified or for which a statement of conformity has been issued under a cybersecurity scheme pursuant to Regulation (EU) 2019/881 and the references of which have been published in the Official Journal of the European Union shall be presumed to comply with the cybersecurity requirements set out in Article 15 of this Regulation in so far as the cybersecurity certificate or statement of conformity or parts thereof cover those requirements.

Art. 55. 1(d): ensure an adequate level of cybersecurity protection for the general-purpose AI model with systemic risk and the physical infrastructure of the model;

Art. 58. 2(i): that AI regulatory sandboxes facilitate the development of tools and infrastructure for testing, benchmarking, assessing and explaining dimensions of AI systems relevant for regulatory learning, such as accuracy, robustness and cybersecurity, as well as measures to mitigate risks to fundamental rights and society at large;

Art. 66. (h): cooperate, as appropriate, with other Union institutions, bodies, offices and agencies, as well as relevant Union expert groups and networks, in particular in the fields of product safety, cybersecurity, competition, digital and media services, financial services, consumer protection, data and fundamental rights protection;

Art. 70. 3: Member States shall ensure that their national competent authorities are provided with adequate technical, financial and human resources, and with infrastructure to fulfil their tasks effectively under this Regulation. In particular, the national competent authorities shall have a sufficient number of personnel permanently available whose competences and expertise shall include an in-depth understanding of AI technologies, data and data computing, personal data protection, cybersecurity, fundamental rights, health and safety risks and knowledge of existing standards and legal requirements. Member States shall assess and, if necessary, update competence and resource requirements referred to in this paragraph on an annual basis.

Art. 70. 4: National competent authorities shall ensure that their national competent authorities are provided with adequate technical, financial and human resources, and with infrastructure to fulfil their tasks effectively under this Regulation. In particular, the national competent authorities shall have a sufficient number of personnel permanently available whose competences and expertise shall include an in-depth understanding of AI technologies, data and data computing, personal data protection, cybersecurity, fundamental rights, health and safety risks and knowledge of existing standards and legal requirements. Member States shall assess and, if necessary, update competence and resource requirements referred to in this paragraph on an annual basis.

Art. 78. 2: The authorities involved in the application of this Regulation pursuant to paragraph 1 shall request only data that is strictly necessary for the assessment of the risk posed by AI systems and for the exercise of their powers in accordance with this Regulation and with Regulation (EU) 2019/1020. They shall put in place adequate and effective cybersecurity measures to protect the security and confidentiality of the information and data obtained, and shall delete the data collected as soon as it is no longer needed for the purpose for which it was obtained, in accordance with applicable Union or national law.

Terms and AI Act Articles

108 Data

- Art. 2: Union law on the protection of personal data, privacy and the confidentiality of communications applies to personal data processed in connection with the rights and obligations laid down in this Regulation... Art. 3: (29) 'training data' means data used for training an AI system through fitting its learnable parameters... Art. 10: Data sets shall be collected and processed for the purposes of developing, training and testing certain AI systems... Art. 11: The Board shall have the authority to suspend, suspend the powers conferred by Article 49... Art. 78: The Commission and the Member States shall be empowered to take appropriate measures to prevent the occurrence of criminal offences...

Terms and AI Act Articles

Art. 100, 1(f): the manner in which the infringement became known to the European Data Protection Supervisor, in particular whether, and if so to what extent, the Union institution, body, office or agency notified the infringement;
Art. 100, 4: Before taking decisions pursuant to this Article, the European Data Protection Supervisor shall give the Union institution, body, office or agency which is the subject of the proceedings conducted by the European Data Protection Supervisor the opportunity of being heard on the matter regarding the possible infringement. The European Data Protection Supervisor shall base his or her decisions only on elements and circumstances on which the parties concerned have been able to comment. Complainants, if any, shall be associated closely with the proceedings.
Art. 100, 5: The rights of defence of the parties concerned shall be fully respected in the proceedings. They shall be entitled to have access to the European Data Protection Supervisor's file, subject to the legitimate interest of individuals or undertakings in the protection of their personal data or business secrets.
Art. 100, 7: The European Data Protection Supervisor shall, on an annual basis, notify the Commission of the administrative fines it has imposed pursuant to this Article and of any litigation or judicial proceedings it has initiated.

1 Data acquisition

Art. 17, 1(f): systems and procedures for data management, including data acquisition, data collection, data analysis, data labelling, data storage, data filtration, data mining, data aggregation, data retention and any other operation regarding the data that is performed before and for the purpose of the placing on the market or the putting into service of high-risk AI systems;

1 Data aggregation

Art. 17, 1(f): systems and procedures for data management, including data acquisition, data collection, data analysis, data labelling, data storage, data filtration, data mining, data aggregation, data retention and any other operation regarding the data that is performed before and for the purpose of the placing on the market or the putting into service of high-risk AI systems;

1 Data analysis

Art. 17, 1(f): systems and procedures for data management, including data acquisition, data collection, data analysis, data labelling, data storage, data filtration, data mining, data aggregation, data retention and any other operation regarding the data that is performed before and for the purpose of the placing on the market or the putting into service of high-risk AI systems;

0 Data bias

1 Data collection processes

Art. 10, 2(b): data collection processes and the origin of data, and in the case of personal data, the original purpose of the data collection;

0 Data decommissioning

1 Data filtration

Art. 17, 1(f): systems and procedures for data management, including data acquisition, data collection, data analysis, data labelling, data storage, data filtration, data mining, data aggregation, data retention and any other operation regarding the data that is performed before and for the purpose of the placing on the market or the putting into service of high-risk AI systems;

0 Data format

2 Data governance

Art. 10: Data and data governance
Art. 10, 2: Training, validation and testing data sets shall be subject to data governance and management practices appropriate for the intended purpose of the high-risk AI system. Those practices shall concern in particular:

0 Data holder

1 Data labelling

Art. 17, 1(f): systems and procedures for data management, including data acquisition, data collection, data analysis, data labelling, data storage, data filtration, data mining, data aggregation, data retention and any other operation regarding the data that is performed before and for the purpose of the placing on the market or the putting into service of high-risk AI systems;

0 Data life cycle

1 Data management

Art. 17, 1(f): systems and procedures for data management, including data acquisition, data collection, data analysis, data labelling, data storage, data filtration, data mining, data aggregation, data retention and any other operation regarding the data that is performed before and for the purpose of the placing on the market or the putting into service of high-risk AI systems;

1 Data mining

Art. 17, 1(f): systems and procedures for data management, including data acquisition, data collection, data analysis, data labelling, data storage, data filtration, data mining, data aggregation, data retention and any other operation regarding the data that is performed before and for the purpose of the placing on the market or the putting into service of high-risk AI systems;

5 Data processed

Art. 2, 7: Union law on the protection of personal data, privacy and the confidentiality of communications applies to personal data processed in connection with the rights and obligations laid down in this Regulation. This Regulation shall not affect Regulation (EU) 2016/679 or (EU) 2018/1725, or Directive 2002/58/EC or (EU) 2016/680, without prejudice to Article 10(5) and Article 59 of this Regulation.

Art. 7, 2(c): the nature and amount of the data processed and used by the AI system, in particular whether special categories of personal data are processed;

Art. 10, 5(c): the special categories of personal data are subject to measures to ensure that the personal data processed are secured, protected, subject to suitable safeguards, including strict controls and documentation of the access, to avoid misuse and ensure that only authorised persons have access to those personal data with appropriate confidentiality obligations;

Art. 59, 1(b): the data processed are necessary for complying with one or more of the requirements referred to in Chapter III, Section 2 where those requirements cannot effectively be fulfilled by processing anonymised, synthetic or other non-personal data;

Art. 59, 1(g): any personal data processed in the context of the sandbox are protected by means of appropriate technical and organisational measures and deleted once the participation in the sandbox has terminated or the personal data has reached the end of its retention period;

Terms and AI Act Articles

21 Data protection (See also: [Privacy](#))

Art. 3. (48): 'national competent authority' means a notifying authority or a market surveillance authority; as regards AI systems put into service or used by Union institutions, agencies, offices and bodies, references to national competent authorities or market surveillance authorities in this Regulation shall be construed as references to the European Data Protection Supervisor;

Art. 5. 4: Without prejudice to paragraph 3, each use of a 'real-time' remote biometric identification system in publicly accessible spaces for law enforcement purposes shall be notified to the relevant market surveillance authority and the national data protection authority in accordance with the national rules referred to in paragraph 5. The notification shall, as a minimum, contain the information specified under paragraph 6 and shall not include sensitive operational data.

Art. 5. 6: National market surveillance authorities and the national data protection authorities of Member States that have been notified of the use of 'real-time' remote biometric identification systems in publicly accessible spaces for law enforcement purposes pursuant to paragraph 4 shall submit to the Commission annual reports on such use. For that purpose, the Commission shall provide Member States and national market surveillance and data protection authorities with a template, including information on the number of the decisions taken by competent judicial authorities or an independent body on the basis of a binding upon requests for authorisations in accordance with paragraph 3 and their result.

Art. 26. 9: Where applicable, deployers of high-risk AI systems shall use the information provided under Article 13 of this Regulation to comply with their obligation to carry out a data protection impact assessment under Article 35 of Regulation (EU) 2016/679 or Article 27 of Directive (EU) 2016/680.

Art. 26. 10: Without prejudice to Directive (EU) 2016/680, in the framework of an investigation for the targeted search of a person suspected or convicted of having committed a criminal offence, the deployer of a high-risk AI system for post-remote biometric identification shall request an authorisation, ex ante, or without undue delay and no later than 48 hours, by a judicial authority or an administrative authority whose decision is binding and subject to judicial review, for the use of that system, except when it is used for the initial identification of a potential suspect based on objective and verifiable facts directly linked to the offence. Each use shall be limited to what is strictly necessary for the investigation of a specific criminal offence. If the authorisation requested pursuant to the first subparagraph is rejected, the use of the post-remote biometric identification system linked to that requested authorisation shall be stopped with immediate effect and the personal data linked to the use of the high-risk AI system for which the authorisation was requested shall be deleted. In no case shall such high-risk AI system for post-remote biometric identification be used for law enforcement purposes in an untargeted way, without any link to a criminal offence, a criminal proceeding, a genuine and present or genuine and foreseeable threat of a criminal offence, or the search for a specific missing person. It shall be ensured that no decision that produces an adverse legal effect on a person may be taken by the law enforcement authorities based solely on the output of such post-remote biometric identification systems. This paragraph is without prejudice to Article 9 of Regulation (EU) 2016/679 and Article 10 of Directive (EU) 2016/680 for the processing of biometric data. Regardless of the purpose or deployer, each use of such high-risk AI systems shall be documented in the relevant police file and shall be made available to the relevant market surveillance authority and the national data protection authority upon request, excluding the disclosure of sensitive operational data related to law enforcement. This subparagraph shall be without prejudice to the powers conferred by Directive (EU) 2016/680 on supervisory authorities. Deployers shall submit annual reports to the relevant market surveillance and national data protection authorities on their use of post-remote biometric identification systems, excluding the disclosure of sensitive operational data related to law enforcement. The reports may be aggregated to cover more than one deployment. Member States may introduce, in accordance with Union law, more restrictive laws on the use of post-remote biometric identification systems.

Art. 27. 4: If any of the obligations laid down in this Article is already met through the data protection impact assessment conducted pursuant to Article 35 of Regulation (EU) 2016/679 or Article 27 of Directive (EU) 2016/680, the fundamental rights impact assessment referred to in paragraph 1 of this Article shall complement that data protection impact assessment.

Art. 57. 3: The European Data Protection Supervisor may also establish an AI regulatory sandbox for Union institutions, bodies, offices and agencies, and may exercise the roles and the tasks of national competent authorities in accordance with this Chapter.

Art. 57. 10: National competent authorities shall ensure that, to the extent the innovative AI systems involve the processing of personal data or otherwise fall under the supervisory remit of other national authorities or competent authorities providing or supporting access to data, the national data protection authorities and those other national or competent authorities are associated with the operation of the AI regulatory sandbox and involved in the supervision of those aspects to the extent of their respective tasks and powers.

Art. 58. 2(g): that procedures, processes and administrative requirements for application, selection, participation and exiting the AI regulatory sandbox are simple, easily intelligible, and clearly communicated in order to facilitate the participation of SMEs, including start-ups, with limited legal and administrative capacities and are streamlined across the Union, in order to avoid fragmentation and that participation in an AI regulatory sandbox established by a Member State, or by the European Data Protection Supervisor is mutually and uniformly recognised and carries the same legal effects across the Union;

Art. 59. 1(e): providers can further share the originally collected data only in accordance with Union data protection law; any personal data created in the sandbox cannot be shared outside the sandbox;

Art. 65. 2: The Board shall be composed of one representative per Member State. The European Data Protection Supervisor shall participate as observer. The AI Office shall also attend the Board's meetings, without taking part in the votes. Other national and Union authorities, bodies or experts may be invited to the meetings by the Board on a case by case basis, where the issues discussed are of relevance for them.

Art. 70. 3: Member States shall ensure that their national competent authorities are provided with adequate technical, financial and human resources, and with infrastructure to fulfil their tasks effectively under this Regulation. In particular, the national competent authorities shall have a sufficient number of personnel permanently available whose competences and expertise shall include an in-depth understanding of AI technologies, data and data computing, personal data protection, cybersecurity, fundamental rights, health and safety risks and knowledge of existing standards and legal requirements. Member States shall assess and, if necessary, update competence and resource requirements referred to in this paragraph on an annual basis.

Art. 74. 8: For high-risk AI systems listed in point 1 of Annex III to this Regulation, in so far as the systems are used for law enforcement purposes, border management and justice and democracy, and for high-risk AI systems listed in points 6, 7 and 8 of Annex III to this Regulation, Member States shall designate as market surveillance authorities for the purposes of this Regulation either the competent data protection supervisory authorities under Regulation (EU) 2016/679 or Directive (EU) 2016/680, or any other authority designated pursuant to the same conditions laid down in Articles 41 to 44 of Directive (EU) 2016/680. Market surveillance activities shall in no way affect the independence of judicial authorities, or otherwise interfere with their activities when acting in their judicial capacity.

Art. 74. 9: Where Union institutions, bodies, offices or agencies fall within the scope of this Regulation, the European Data Protection Supervisor shall act as their market surveillance authority, except in relation to the Court of Justice of the European Union acting in its judicial capacity.

Art. 100. 1: The European Data Protection Supervisor may impose administrative fines on Union institutions, bodies, offices and agencies falling within the scope of this Regulation. When deciding whether to impose an administrative fine and when deciding on the amount of the administrative fine in each individual case, all relevant circumstances of the specific situation shall be taken into account and due regard shall be given to the following:

Art. 100. 1(d): the degree of cooperation with the European Data Protection Supervisor in order to remedy the infringement and mitigate the possible adverse effects of the infringement, including compliance with any of the measures previously ordered by the European Data Protection Supervisor against the Union institution, body, office or agency concerned with regard to the same subject matter;

Art. 100. 1(f): the manner in which the infringement became known to the European Data Protection Supervisor, in particular whether, and if so to what extent, the Union institution, body, office or agency notified the infringement;

Art. 100. 4: Before taking decisions pursuant to this Article, the European Data Protection Supervisor shall give the Union institution, body, office or agency which is the subject of the proceedings conducted by the European Data Protection Supervisor the opportunity of being heard on the matter regarding the possible infringement. The European Data Protection Supervisor shall base his or her decisions only on elements and circumstances on which the parties concerned have been able to comment. Complainants, if any, shall be associated closely with the proceedings.

Art. 100. 5: The rights of defence of the parties concerned shall be fully respected in the proceedings. They shall be entitled to have access to the European Data Protection Supervisor's file, subject to the legitimate interest of individuals or undertakings in the protection of their personal data or business secrets.

Art. 100. 7: The European Data Protection Supervisor shall, on an annual basis, notify the Commission of the administrative fines it has imposed pursuant to this Article and of any litigation or judicial proceedings it has initiated.

0 Data provenance (See also: [Origin of data](#))

0 Data quality (See also: [Quality criteria](#), [Data quality model](#), [Data requirements](#))

0 Data quality assessment

0 Data quality management

0 Data quality management lifecycle

0 Data quality model (See also: [Data requirements](#), [Data quality model](#), [Data quality requirements](#), [Quality criteria](#), [Quality model](#), [Quality assurance](#))

0 Data quality requirements (See also: [Data quality model](#), [Data requirements](#), [Quality criteria](#), [Quality model](#), [Quality assurance](#))

0 Data recoverability (See also: [Data storage](#), [Data retention](#))

0 Data requirements (See also: [Data quality model](#), [Data quality requirements](#), [Quality criteria](#), [Quality model](#), [Quality assurance](#))

1 Data retention (See also: [Data recoverability](#), [Data storage](#))

Art. 17. 1(f): systems and procedures for data management, including data acquisition, data collection, data analysis, data labelling, data storage, data filtration, data mining, data aggregation, data retention and any other operation regarding the data that is performed before and for the purpose of the placing on the market or the putting into service of high-risk AI systems;

1 Data storage (See also: [Data recoverability](#), [Data retention](#))

Art. 17. 1(f): systems and procedures for data management, including data acquisition, data collection, data analysis, data labelling, data storage, data filtration, data mining, data aggregation, data retention and any other operation regarding the data that is performed before and for the purpose of the placing on the market or the putting into service of high-risk AI systems;

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22 Database

Art. 3. (35): 'biometric identification' means the automated recognition of physical, physiological, behavioural, or psychological human features for the purpose of establishing the identity of a natural person by comparing biometric data of that individual to biometric data of individuals stored in a database;

Art. 3. (41): 'remote biometric identification system' means an AI system for the purpose of identifying natural persons, without their active involvement, typically at a distance through the comparison of a person's biometric data with the biometric data contained in a reference database;

Art. 12. (3): 'reference database' means a database containing biometric data for the purpose of identifying natural persons, without their active involvement, typically at a distance through the comparison of a person's biometric data with the biometric data contained in a reference database; such a database shall be established and maintained by the competent authorities referred to in paragraph 1, first subparagraph, point (b), of this Article shall comply with necessary and proportionate safeguards and conditions in relation to the use in accordance with the national law authorising the use thereof, in particular as regards the temporal, geographic and personal limitations. The use of the real-time remote biometric identification system in publicly accessible spaces shall be authorised only if the law enforcement authority has completed a fundamental rights impact assessment as provided for in Article 27 and has registered the system in the EU database according to Article 49. However, in duly justified cases of urgency, the use of such systems may be commenced without the registration in the EU database, provided that such registration is completed without undue delay.

Art. 12. (3b): the reference database against which input data has been checked by the system;

Art. 26. 8: Deployers of high-risk AI systems that are public authorities, or Union institutions, bodies, offices or agencies shall comply with the registration obligations referred to in Article 49. When such deployers find that the high-risk AI system that they envisage using has not been registered in the EU database referred to in Article 71, they shall not use that system and inform the provider or the distributor;

Art. 49. 1: Before placing on the market or putting into service a high-risk AI system listed in Annex III, with the exception of high-risk AI systems referred to in point 2 of Annex III, the provider or, where applicable, the authorised representative shall register themselves and their system in the EU database referred to in Article 71.

Art. 49. 2: Before placing on the market or putting into service an AI system for which the provider has concluded that it is not high-risk according to Article 6(3), that provider or, where applicable, the authorised representative shall register themselves and that system in the EU database referred to in Article 71.

Art. 49. 3: Before putting into service or using a high-risk AI system listed in Annex III, with the exception of high-risk AI systems listed in point 2 of Annex III, deployers that are public authorities, Union institutions, bodies, offices or agencies or persons acting on their behalf shall register themselves, select the system and register its use in the EU database referred to in Article 71.

Art. 49. 4: For high-risk AI systems referred to in points 1, 6 and 7 of Annex III, in the areas of law enforcement, migration, asylum and border control management, the registration referred to in paragraphs 1, 2 and 3 of this Article shall be in a secure non-public section of the EU database referred to in Article 71 and shall include only the following information, as applicable, referred to in:

Art. 49. 4(a): points 1, 2, 3 and 5 of Annex III. Only the Commission and national authorities referred to in Article 74(8) shall have access to the respective restricted sections of the EU database listed in the first subparagraph of this paragraph.

Art. 60. 4(c): the provider or prospective provider, with the exception of providers or prospective providers of high-risk AI systems referred to in points 1, 6 and 7 of Annex III in the areas of law enforcement, migration, asylum and border control management, and high-risk AI systems referred to in point 2 of Annex III in the areas of law enforcement, migration, asylum and border control management, has registered the testing in real-world conditions in the secure non-public section of the EU database according to Article 49(4), point (c), with a Union-wide unique single identification number and with the information specified therein; the provider or prospective provider of high-risk AI systems referred to in point 2 of Annex III has registered the testing in real-world conditions in accordance with Article 49(5);

Art. 66. (e)(ii): the evaluation and review of this Regulation pursuant to Article 12, including as regards the serious incident reports referred to in Article 73, and the functioning of the EU database referred to in Article 71, the preparation of the delegated or implementing acts, and as regards possible alignments of this Regulation with the Union harmonisation legislation listed in Annex I;

CHAPTER VIII. EU DATABASE FOR HIGH-RISK AI SYSTEMS

Art. 71. EU database for high-risk AI systems listed in Annex III

Art. 71. 1: The Commission shall, in collaboration with the Member States, set up and maintain an EU database containing information referred to in paragraphs 2 and 3 of this Article concerning high-risk AI systems referred to in Article 6(2) which are registered in accordance with Articles 49 and 60 and AI systems that are not considered as high-risk pursuant to Article 6(3) and which are registered in accordance with Article 6(4) and Article 49. When setting the functional specifications of such database, the Commission shall consult the relevant experts, and when updating the functional specifications of such database, the Commission shall consult the Board.

Art. 71. 2: The data listed in Section A of Annex VIII shall be entered into the EU database by the provider or, where applicable, by the authorised representative.

Art. 71. 3: The data listed in Section C of Annex VIII shall be entered into the EU database by the deployer who is, or who acts on behalf of, a public authority, agency or body, in accordance with Article 49(3) and (4).

Art. 71. 4: With the exception of the section referred to in Article 49(4) and Article 60(4), point (c), the information contained in the EU database registered in accordance with Article 49 shall be accessible and publicly available in a user-friendly manner. The information should be easily retrievable and machine-readable. The information registered in accordance with Article 60 shall be accessible only to market surveillance authorities and the Commission, unless the prospective provider or provider has given consent for also making the information accessible to the public.

Art. 71. 5: The EU database shall contain personal data only in so far as necessary for collecting and processing information in accordance with this Regulation. That information shall include the names and contact details of natural persons who are responsible for registering the system and have the legal authority to represent the provider or the deployer, as applicable.

Art. 71. 6: The Commission shall be the controller of the EU database. It shall make available to providers, prospective providers and deployers adequate technical and administrative support. The EU database shall comply with the applicable accessibility requirements.

Art. 80. 8: In exercising their power to monitor the application of this Article, and in accordance with Article 11 of Regulation (EU) 2019/1020, market surveillance authorities may perform appropriate checks, taking into account in particular information stored in the EU database referred to in Article 71 of this Regulation.

Art. 83. (1e): the registration in the EU database referred to in Article 71 has not been carried out;

16 Dataset (See also: [File, Bias detection and correction](#))

Art. 3. (31): 'validation data set' means a separate data set or part of the training data set, either as a fixed or variable split;

Art. 5. 1(g): the placing on the market, the putting into service for this specific purpose, or the use of biometric categorisation systems that categorise individually natural persons based on their biometric data to deduce or infer their race, political opinions, trade union membership, religious or philosophical beliefs, sex life or sexual orientation; this prohibition does not cover any labelling or filtering of lawfully acquired biometric datasets, such as images, based on biometric data or categorizing of biometric data in the area of law enforcement;

Art. 10. 1: High-risk AI systems which make use of techniques involving the training of AI models with data shall be developed on the basis of training, validation and testing data sets that meet the quality criteria referred to in paragraphs 2 to 5, whenever such data sets are used.

Art. 10. 2: Training, validation and testing data sets shall be subject to data governance and management practices appropriate for the intended purpose of the high-risk AI system. Those practices shall concern in particular:

Art. 10. 2(a): an assessment of the availability, quantity and suitability of the data sets that are needed;

Art. 10. 3: training, validation and testing data sets shall be relevant, sufficiently representative, and to the best extent possible, free of errors and complete in view of the intended purpose. They shall have the appropriate statistical properties, including, where applicable, as regards the persons or groups of persons in relation to whom the high-risk AI system is intended to be used. Those characteristics of the data sets may be met at the level of individual data sets or at the level of a combination thereof.

Art. 10. 4: Data sets shall take into account, to the extent required by the intended purpose, the characteristics or elements that are particular to the specific geographical, contextual, behavioural or functional setting within which the high-risk AI system is intended to be used.

Art. 10. 5: To the extent that it is strictly necessary for the purpose of ensuring bias detection and correction in relation to the high-risk AI systems in accordance with paragraph (2), points (f) and (g) of this Article, the providers of such systems may exceptionally process special categories of personal data, subject to appropriate safeguards for the fundamental rights and freedoms of natural persons. In addition to the provisions set out in Regulations (EU) 2016/679 and (EU) 2018/1725 and Directive (EU) 2016/680, all the following conditions must be met in order for such processing to occur:

Art. 10. 6: For the development of high-risk AI systems not using techniques involving the training of AI models, paragraphs 2 to 5 apply only to the testing data sets.

Art. 13. (3)(vi): when appropriate, specifications for the input data, or any other relevant information in terms of the training, validation and testing data sets used, taking into account the intended purpose of the high-risk AI system;

Art. 15. 3: High-risk AI systems shall be resilient against attempts by unauthorised third parties to alter their use, outputs or performance by exploiting system vulnerabilities. The technical solutions aiming to ensure the cybersecurity of high-risk AI systems shall be appropriate to the relevant circumstances and the risks. The technical solutions to address AI specific vulnerabilities shall include, where appropriate, measures to prevent, detect, respond to, resolve and control for attacks trying to manipulate the training data set (data poisoning), or pre-trained components used in training (model poisoning), inputs designed to cause the AI model to make a mistake (adversarial examples or model evasion), confidentiality attacks or model flaws.

Art. 26. 5: Deployers shall monitor the operation of the high-risk AI system on the basis of the instructions for use and, where relevant, inform providers in accordance with Article 72. Where deployers have reason to consider that the use of the high-risk AI system in accordance with the instructions may result in that AI system presenting a risk within the meaning of Article 73(1), they shall, without undue delay, inform the provider or distributor and the relevant market surveillance authorities, and shall suspend the use of that system. Where deployers have identified a serious incident, they shall also immediately inform first the provider, and then the importer or distributor and the relevant market surveillance authorities of that incident. If the deployer is not able to reach the provider, Article 73 shall apply mutatis mutandis. This obligation shall not cover sensitive operational data of deployers of AI systems which are law enforcement authorities. For deployers that are financial institutions subject to requirements regarding their internal governance, arrangements or processes under Union financial services law, the monitoring obligation set out in the first subparagraph shall be deemed to be fulfilled by complying with the rules on internal governance arrangements, processes and mechanisms pursuant to the relevant financial service law.

Art. 31. 11: Notified bodies shall have sufficient internal competences to be able effectively to evaluate the tasks conducted by external parties on their behalf. The notified body shall have permanent availability of sufficient administrative, technical, legal and scientific personnel who possess experience and knowledge relating to the relevant types of AI systems, data and data computing, and relating to the requirements set out in Section 2.

Art. 42. 1: High-risk AI systems that have been trained and tested on data reflecting the specific geographical, behavioural, contextual or functional setting within which they are intended to be used shall be presumed to comply with the relevant requirements laid down in Article 10(4).

Art. 72. 2: The post-market monitoring system shall actively and systematically collect, document and analyse relevant data which may be provided by deployers or which may be collected through other sources on the performance of high-risk AI systems throughout their lifetime, and which allow the provider to evaluate the continuous compliance of AI systems with the requirements set out in Chapter II, Section 2. Where relevant, post-market monitoring shall include an analysis of the interaction with other AI systems. This obligation shall not cover sensitive operational data of deployers which are law-enforcement authorities.

Art. 74. 12: Without prejudice to the powers provided for under Regulation (EU) 2019/1020, and where relevant and limited to what is necessary to fulfil their tasks, the market surveillance authorities shall be granted full access by providers to the documentation as well as the training, validation and testing data sets used for the development of high-risk AI systems, including, where appropriate and subject to security safeguards, through application programming interfaces (API) or other relevant technical means and tools enabling remote access.

4 Decision-making

Art. 6. 3: By derogation from paragraph 2, an AI system referred to in Annex III shall not be considered to be high-risk where it does not pose a significant risk of harm to the health, safety or fundamental rights of natural persons, including by not materially influencing the outcome of decision making. The first subparagraph shall apply where any of the following conditions is fulfilled:

Art. 6. 3(c): the AI system is intended to detect decision-making patterns or deviations from prior decision-making patterns and is not meant to replace or influence the previously completed human assessment, without proper human review; or

Art. 86: Right to explanation of individual decision-making

Art. 96. 1: Any affected person subject to a decision which is taken by the deployer on the basis of the output from a high-risk AI system listed in Annex III, with the exception of systems listed under point 2 thereof, and which produces legal effects or similarly significantly affects that person in a way that they consider to have an adverse impact on their health, safety or fundamental rights shall have the right to obtain from the deployer clear and meaningful explanations of the role of the AI system in the decision-making procedure and the main elements of the decision taken.

16 Declaration

Art. 16. (g): draw up an EU declaration of conformity in accordance with Article 47;

Art. 18. 1(e): the EU declaration of conformity referred to in Article 47;

Art. 19. 3(a): verify that the EU declaration of conformity referred to in Article 47 and the technical documentation referred to in Article 11 have been drawn up and that an appropriate conformity assessment procedure has been carried out by the provider;

Art. 22. (2)(b): keep at the disposal of the competent authorities and national authorities or bodies referred to in Article 74(10), for a period of 10 years after the high-risk AI system has been placed on the market or put into service, the contact details of the provider that appointed the authorised representative, a copy of the EU declaration of conformity referred to in Article 47, the technical documentation and, if applicable, the certificate issued by the notified body;

Art. 23. 1(c): the system bears the required CE marking and is accompanied by the EU declaration of conformity referred to in Article 47 and instructions for use;

Art. 23. 5: Importers shall keep, for a period of 10 years after the high-risk AI system has been placed on the market or put into service, a copy of the certificate issued by the notified body, where applicable, of the instructions for use, and of the EU declaration of conformity referred to in Article 47;

Art. 24. 1: Before making a high-risk AI system available on the market, distributors shall verify that it bears the required CE marking, that it is accompanied by a copy of the EU declaration of conformity referred to in Article 47 and instructions for use, and that the provider and the importer of that system, as applicable, have complied with their respective obligations as laid down in Article 16, points (b) and (c) and Article 23(3).

Art. 47. 1: The provider shall draw up a written machine readable, physical or electronically signed EU declaration of conformity for each high-risk AI system, and keep it at the disposal of the national competent authorities for 10 years after the high-risk AI system has been placed on the market or put into service. The EU declaration of conformity shall identify the high-risk AI system for which it has been drawn up. A copy of the EU declaration of conformity shall be submitted to the relevant national competent authorities upon request.

Art. 47. 2: The EU declaration of conformity shall be drawn up in the language of the Member State in which the high-risk AI system is placed on the market or made available. The EU declaration of conformity shall contain the information set out in Annex V, and shall be translated into a language that can be easily understood by the national competent authorities of the Member States in which the high-risk AI system is placed on the market or made available.

Art. 47. 3: Where high-risk AI systems are subject to other Union harmonisation legislation which also requires an EU declaration of conformity, a single EU declaration of conformity shall be drawn up in respect of all Union law applicable to the high-risk AI system. The declaration shall contain all the information required to identify the system and the declaration referred to in Article 47 and instructions for use;

Art. 47. 4: By drawing up the EU declaration of conformity, the provider shall assume responsibility for compliance with the requirements set out in Section 2. The provider shall keep the EU declaration of conformity up-to-date as appropriate.

Art. 47. 5: The Commission is empowered to adopt delegated acts in accordance with Article 97 in order to amend Annex V by updating the content of the EU declaration of conformity set out in that Annex, in order to introduce elements that become necessary in light of technical progress.

Art. 68. 4: The experts on the scientific panel shall perform their tasks with impartiality and objectivity, and shall ensure the confidentiality of information and data obtained in carrying out their tasks and activities. They shall neither seek nor take instructions from anyone when exercising their tasks under paragraph 3. Each expert shall draw up a declaration of interests, which shall be made publicly available. The AI Office shall establish systems and procedures to actively manage and prevent potential conflicts of interest.

Art. 83. 1(f): the EU declaration of conformity referred to in Article 47 has not been drawn up;

Art. 83. 1(d): the EU declaration of conformity referred to in Article 47 has not been drawn up correctly;

0 Decommissioning

0 Deep learning

3 Definition

Art. 3: Definitions

Art. 3: For the purposes of this Regulation, the following definitions apply:

Art. 3. (61)(a): has harmed or is likely to harm the collective interests of individuals residing in at least two Member States other than the Member State in which:

2 Democracy

Art. 1. 1: The purpose of this Regulation is to improve the functioning of the internal market and promote the uptake of human-centric and trustworthy artificial intelligence (AI), while ensuring a high level of protection of health, safety, fundamental rights enshrined in the Charter, including democracy, the rule of law and environmental protection, against the harmful effects of AI systems in the Union and supporting innovation.

Art. 74. 8: For high-risk AI systems listed in point 1 of Annex III to this Regulation, in so far as the systems are used for law enforcement purposes, border management and justice and democracy, and for high-risk AI systems listed in points 6, 7 and 8 of Annex III to this Regulation, Member States shall designate a supervisory authority for the purposes of this Regulation, either the competent data protection supervisory authorities under Regulation (EU) 2016/679 or Directive (EU) 2016/680, or any other authority designated pursuant to the same conditions laid down in Articles 41 to 44 of Directive (EU) 2016/680. Market surveillance activities shall in no way affect the independence of judicial authorities, or otherwise interfere with their activities when acting in their judicial capacity.

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7 Design

Art. 9. 3: The risks referred to in this Article shall concern only those which may be reasonably mitigated or eliminated through the development or design of the high-risk AI system, or the provision of adequate technical information.
Art. 9. 5(a): elimination or reduction of risks identified and evaluated pursuant to paragraph 2 in as far as technically feasible through adequate design and development of the high-risk AI system;
Art. 10. 2(a): the relevant design choices;
Art. 17. 1(b): technical procedures referred to in Article 18;

3 Disability

Art. 5. 1(b): the placing on the market, the putting into service or the use of an AI system that exploits any of the vulnerabilities of a natural person or a specific group of persons due to their age, disability or a specific social or economic situation, with the objective, or the effect, of materially distorting the behaviour of that person or a person belonging to that group in a manner that causes or is reasonably likely to cause that person or another person significant harm;
Art. 60. 4(a): the subjects of the testing in real world conditions who are persons belonging to vulnerable groups due to their age or disability, are appropriately protected;
Art. 95. 2(a): assessing and preventing the negative impact of AI systems on vulnerable persons or groups of vulnerable persons, including as regards accessibility for persons with a disability, as well as on gender equality.

7 Distributor

Art. 3. 7: 'distributor' means a natural or legal person in the supply chain, other than the provider or the importer, that makes an AI system available on the Union market;
Art. 3. 8: 'operator' means a provider, product manufacturer, deployer, authorised representative, importer or distributor;
Art. 24. 2: Where a distributor considers or has reason to consider, on the basis of the information in its possession, that a high-risk AI system is not in conformity with the requirements set out in Section 2, it shall not make the high-risk AI system available on the market until the system has been brought into conformity with the requirements set out in Article 24(2);
Art. 24. 4: A distributor that considers or has reason to consider, on the basis of the information in its possession, a high-risk AI system which it has made available on the market but is not in conformity with the requirements set out in Section 2, shall take the corrective actions necessary to bring that system into conformity with those requirements, to withdraw it or recall it, or shall ensure that the provider, the importer or any relevant operator, as appropriate, takes those corrective actions. Where the high-risk AI system presents a risk within the meaning of Article 79(1), the distributor shall ensure that the provider, the importer or any relevant operator, as appropriate, takes those corrective actions, giving details, in particular, of the non-compliance and of any corrective actions taken;
Art. 25. 1: Any distributor, importer, deployer or other third-party shall be considered to be a provider of a high-risk AI system for the purposes of this Regulation and shall be subject to the obligations of the provider under Article 16, in any of the following circumstances:
Art. 26. 5: Deployers shall monitor the operation of the high-risk AI system on the basis of the instructions for use and, where relevant, inform providers in accordance with Article 72. Where deployers have reason to consider that the use of the high-risk AI system in accordance with the instructions may result in that AI system presenting a risk within the meaning of Article 79(1), they shall, without undue delay, inform the provider or distributor and the relevant market surveillance authority, and shall suspend the use of that system. Where deployers have identified a serious incident, they shall also immediately inform first the provider, and then the importer or distributor and the relevant market surveillance authorities of that incident. If the deployer is not able to reach the provider, Article 73 shall apply mutatis mutandis. This obligation shall not cover sensitive operational data of deployers of AI systems which are law enforcement authorities. For deployers that are financial institutions subject to requirements regarding their internal governance, arrangements or processes under Union financial services law, the monitoring obligation set out in the first subparagraph shall be deemed to be fulfilled by complying with the rules on internal governance arrangements, processes and mechanisms pursuant to the relevant financial service law.
Art. 26. 8: Deployers of high-risk AI systems that are public authorities, or Union institutions, bodies, offices or agencies shall comply with the registration obligations referred to in Article 49. When such deployers find that the high-risk AI system that they envisage using has not been registered in the EU database referred to in Article 71, they shall not use that system and shall inform the provider or the distributor.

0 Diversity

61 Documentation

Art. 3. 12: 'intended purpose' means the use for which an AI system is intended by the provider, including the specific context and conditions of use, as specified in the information supplied by the provider in the instructions for use, promotional or sales materials and statements, as well as in the technical documentation;
Art. 6. 4: A provider who considers that an AI system referred to in Annex III is not high-risk shall document its assessment before that system is placed on the market or put into service. Such provider shall be subject to the registration obligation set out in Article 49(2). Upon request of the relevant competent authority, the provider shall provide the documentation referred to in Article 6(4);
Art. 8. 2: Where a product contains an AI system, to which the requirements of this Regulation as well as requirements of the Union harmonisation legislation listed in Section A of Annex I apply, providers shall be responsible for ensuring that their product is fully compliant with all applicable requirements under applicable Union harmonisation legislation. In ensuring the compliance of high-risk AI systems referred to in paragraph 1 with the requirements set out in this Section, and in order to ensure consistency, avoid duplication and minimise additional burdens, providers shall have a choice of integrating, as appropriate, the necessary testing and reporting processes, information and documentation they provide with regard to their product into documentation and procedures that already exist and are required under the Union harmonisation legislation listed in Section A of Annex I;
Art. 10. 5(c): the special categories of personal data are subject to measures to ensure that the personal data processed are secured, protected, subject to suitable safeguards, including strict controls and documentation of the access, to avoid misuse and ensure that only authorised persons have access to data with appropriate confidentiality obligations;
Art. 11: Technical documentation
Art. 11. 1: The technical documentation of a high-risk AI system shall be drawn up before that system is placed on the market or put into service and shall be kept up-to-date. The technical documentation shall be drawn up in such a way as to demonstrate that the high-risk AI system complies with the requirements set out in this Section and to provide national competent authorities and notified bodies with the necessary information in a clear and comprehensive form to assess the compliance of the AI system with those requirements. It shall contain, at a minimum, the elements set out in Annex IV. SMEs, including start-ups, may provide the elements of the technical documentation specified in Annex IV in a simplified manner. To that end, the Commission shall establish a simplified technical documentation form targeted at the needs of small and microenterprises, where an SME, including a start-up, opts to provide the information required in Annex IV in a simplified manner, it shall use the form referred to in this paragraph. Notified bodies shall accept the form for the purposes of the conformity assessment;
Art. 11. 2: Where a high-risk AI system related to a product covered by the Union harmonisation legislation listed in Section A of Annex I is placed on the market or put into service, a single set of technical documentation shall be drawn up containing all the information set out in paragraph 1, as well as the information required under those legal acts;
Art. 11. 3: The Commission is empowered to adopt delegated acts in accordance with Article 97 in order to amend Annex IV, where necessary, to ensure that, in light of technical progress, the technical documentation provides all the information necessary to assess the compliance of the system with the requirements set out in this Section;
Art. 16. 1(b): indicate on the high-risk AI system or, where that is not possible, on its packaging or its accompanying documentation, as applicable, their name, registered trade name or registered trade mark, the address at which they can be contacted;
Art. 16. 1(d): keep the documentation referred to in Article 11 up-to-date;
Art. 16. 1(h): affix the CE marking to the high-risk AI system or, where that is not possible, on its packaging or its accompanying documentation, to indicate conformity with this Regulation, in accordance with Article 48;
Art. 17. 1(k): systems and procedures for record-keeping of all relevant documentation and information;
Art. 18: Documentation
Art. 18. 1(a): the technical documentation referred to in Article 11;
Art. 18. 1(b): the documentation concerning the quality management system referred to in Article 17;
Art. 18. 2: The documentation shall be available to the relevant authority responsible for setting bodies and the relevant market surveillance authority with all the requirements set out in Article 79(1);
Art. 18. 2: Each Member State shall determine conditions under which the documentation referred to in paragraph 1 remains at the disposal of the national competent authorities for the period indicated in that paragraph for the cases when a provider or its authorised representative established on its territory goes bankrupt or ceases its activity prior to the end of that period;
Art. 19: Providers that are financial institutions subject to requirements regarding their internal governance, arrangements or processes under Union financial services law shall maintain the technical documentation as part of the documentation kept under the relevant Union financial services law;
Art. 19. 2: Providers that are financial institutions subject to requirements regarding their internal governance, arrangements or processes under Union financial services law shall maintain the logs automatically generated by their high-risk AI systems as part of the documentation kept under the relevant Union financial services law;
Art. 21. 1: Providers of high-risk AI systems shall, upon a reasoned request by a competent authority, provide that authority all the information and documentation necessary to demonstrate the conformity of the high-risk AI system with the requirements set out in Section 2, in a language which can be easily understood by the authority in one of the official languages of the institutions of the Union as indicated by the Member State concerned;
Art. 22. 3(a): verify that the technical documentation referred to in Article 11 has been drawn up and that an appropriate conformity assessment procedure has been carried out by the provider;
Art. 22. 3(b): keep at the disposal of the competent authorities and national authorities or bodies referred to in Article 74(10), for a period of 10 years after the high-risk AI system has been placed on the market or put into service, the contact details of the provider that appointed the authorised representative, a copy of the EU declaration of conformity referred to in Article 47, the technical documentation and, if applicable, the certificate issued by the notified body;
Art. 22. 3(c): provide a copy of the information and documentation, including that referred to in paragraph 2, to demonstrate the conformity of a high-risk AI system with the requirements set out in Section 2, including access to the logs, as referred to in Article 12(1), automatically generated by the high-risk AI system, to the extent such logs are under the control of the provider;
Art. 23. 1(b): the provider has drawn up the technical documentation in accordance with Article 11 and Annex IV;
Art. 23. 1(c): Where an importer, as defined in Article 23(1), is not in conformity with this Regulation, or is falsified, or accompanied by falsified documentation, it shall not place the system on the market until it has been brought into conformity. Where the high-risk AI system presents a risk within the meaning of Article 79(1), the importer shall inform the provider of the system, the authorised representative and the market surveillance authorities to that effect;
Art. 23. 3: Importers shall indicate their name, registered trade name or registered trade mark, and the address at which they can be contacted on the high-risk AI system and on its packaging or its accompanying documentation, where applicable;
Art. 23. 4: Importers shall provide the relevant competent authorities, upon a reasoned request, with all the necessary information and documentation, including that referred to in paragraph 2, to demonstrate the conformity of a high-risk AI system with the requirements set out in Section 2 in a language which can be easily understood by them. For this purpose, they shall also ensure that the technical documentation can be made available to those authorities;
Art. 24. 5: Upon a reasoned request from a relevant competent authority, distributors of a high-risk AI system shall provide that authority with all the information and documentation regarding their actions pursuant to paragraphs 1 to 4 necessary to demonstrate the conformity of that system with the requirements set out in this Section;
Art. 25. 2: Where the circumstances referred to in paragraph 1 occur, the provider that initially placed the AI system on the market or put it into service shall no longer be considered to be a provider of that specific AI system for the purposes of this Regulation. That initial provider shall closely cooperate with new providers and make available the necessary information and provide the reasonably expected technical assistance and other assistance that are required for the fulfilment of the obligations set out in this Regulation, in particular regarding the compliance with the conformity assessment of high-risk AI systems. This paragraph shall not apply in cases where the initial provider has clearly specified that its AI system is not to be changed into a high-risk AI system and therefore does not fall under the obligation to hand over the documentation;
Art. 26. 6: Deployers of high-risk AI systems shall keep the logs automatically generated by that high-risk AI system to the extent such logs are under their control, for a period appropriate to the intended purpose of the high-risk AI system, of at least six months, unless provided otherwise in applicable Union or national law, in particular in Union law on the protection of personal data. Deployers that are financial institutions subject to requirements regarding their internal governance, arrangements or processes under Union financial services law shall maintain the logs as part of the documentation kept pursuant to the relevant Union financial services law;
Art. 29. 4: For notified bodies which are designated under any other Union harmonisation legislation, all documents and certificates linked to those designations may be used to support their designation procedure under this Regulation, as appropriate. The notified body shall update the documentation referred to in this Article with the assessment of the technical documentation, with the involvement of a notified body, referred to in Annex VII. In demonstrating the compliance of a high-risk AI system with the requirements set out in Section 2, the provider shall follow the conformity assessment procedure set out in Annex VII where:
Art. 30. 2: In accordance with Regulation (EU) No 1025/2012, the Commission shall issue, without undue delay, standardisation requests covering all requirements set out in Section 2 of this Chapter and, as applicable, standardisation requests covering obligations set out in Chapter V, Sections 2 and 3, of this Regulation. The standardisation request shall also ask for deliverables on reporting and documentation processes to improve AI systems' resource performance, such as reducing the high-risk AI system's consumption of energy and of other resources during its lifecycle, and on the energy-efficient development of general-purpose AI models. When preparing a standardisation request, the Commission shall consult the Board and relevant stakeholders, including the advisory forum. When issuing a standardisation request to European standardisation organisations, the Commission shall ensure that the request is consistent with the existing Union harmonisation legislation listed in Annex I, and aiming to ensure that high-risk AI systems or general-purpose AI models placed on the market or put into service in the Union meet the relevant requirements or obligations laid down in this Regulation. The Commission shall request the European standardisation organisations to provide evidence of their best efforts to fulfil the objectives referred to in the first and the second subparagraph of this paragraph in accordance with Article 24 of Regulation (EU) No 1025/2012;
Art. 31. 1(b): the assessment of the technical documentation, with the involvement of a notified body, referred to in Annex VII. In demonstrating the compliance of a high-risk AI system with the requirements set out in Section 2, the provider shall follow the conformity assessment procedure set out in Annex VII where:
Art. 43. 4: High-risk AI systems that have already been subject to a conformity assessment procedure shall undergo a new conformity assessment procedure in the event of a substantial modification, regardless of whether the modified system is intended to be further distributed or continues to be used by the current deployer. For high-risk AI systems that continue to learn after being placed on the market or put into service, changes to the high-risk AI system and its performance that have been pre-determined by the provider at the moment of the initial conformity assessment and are part of the information contained in the technical documentation referred to in point 2(f) of Annex IV, shall not constitute a substantial modification;
Art. 45. 1(a): any Union technical documentation assessment certificates, any supplements to those certificates, and any quality management system approvals issued in accordance with the requirements of Annex VII;
Art. 45. 1(b): any refusal, restriction, suspension or withdrawal of a Union technical documentation assessment certificate or a quality management system approval issued in accordance with the requirements of Annex VII;
Art. 45. 2(b): Union technical documentation assessment certificates or any supplements thereto which it has refused, withdrawn, suspended or otherwise restricted, and, upon request, of the certificates and/or supplements thereto which it has issued;
Art. 48. 3: The CE marking shall be affixed visibly, legibly and indelibly for high-risk AI systems. Where that is not possible or not warranted on account of the nature of the high-risk AI system, it shall be affixed to the packaging or to the accompanying documentation, as appropriate;
Art. 53. 1(a): draw up and keep up-to-date the technical documentation of the model, including its training and testing process and the results of its evaluation, which shall contain, at a minimum, the information set out in Annex XI for the purpose of providing it, upon request, to the AI Office and the national competent authorities;
Art. 53. 1(b): draw up, keep up-to-date and make available information and documentation to providers of AI systems who intend to integrate the general-purpose AI model into their AI systems. Without prejudice to the need to observe and protect intellectual property rights and confidential business information or trade secrets in accordance with Union and national law, the information and documentation shall:
Art. 53. 5: For the purpose of facilitating compliance with Annex XI, in particular points 2 (d) and (e) thereof, the Commission is empowered to adopt delegated acts in accordance with Article 97 to detail measurement and calculation methodologies with a view to allowing for comparable and verifiable documentation;
Art. 53. 7: Any information or documentation obtained pursuant to this Article, including trade secrets, shall be treated in accordance with the confidentiality obligations set out in Article 78;
Art. 54. 3(a): verify that the technical documentation specified in Annex XI has been drawn up and all obligations referred to in Article 53 and, where applicable, Article 55 have been fulfilled by the provider;
Art. 54. 3(b): keep a copy of the technical documentation specified in Annex XI at the disposal of the AI Office and national competent authorities, for a period of 10 years after the general-purpose AI model has been placed on the market, and the contact details of the provider that appointed the authorised representative;
Art. 54. 3(c): provide the AI Office, upon a reasoned request, with all the information and documentation, including that referred to in point (b), necessary to demonstrate compliance with the obligations in this Chapter;
Art. 55. 2: Any information or documentation obtained pursuant to this Article, including trade secrets, shall be treated in accordance with the confidentiality obligations set out in Article 78;
Art. 55. 3: the measures, procedures and modalities for the assessment and management of the systemic risks at Union level, including the documentation thereof, which shall be proportionate to the risks, take into consideration their severity and probability and take into account the specific challenges of tackling those risks in light of the possible ways in which such risks may emerge and materialise along the AI value chain;
Art. 57. 1: Competent authorities shall coordinate and cooperate with providers participating in the AI regulatory sandbox with a view to ensuring that the providers' testing and reporting processes, information and documentation they provide with regard to their product into documentation and procedures that already exist and are required under the Union harmonisation legislation listed in Section A of Annex I, and aiming to ensure that high-risk AI systems or general-purpose AI models placed on the market or put into service in the Union meet the relevant requirements or obligations laid down in this Regulation. The Commission shall request the European standardisation organisations to provide evidence of their best efforts to fulfil the objectives referred to in the first and the second subparagraph of this paragraph in accordance with Article 24 of Regulation (EU) No 1025/2012;
Art. 59. 1(a): a complete and detailed description of the process and rationale behind the training, testing and validation of the AI system is kept together with the testing results as part of the technical documentation referred to in Annex IV;
Art. 72. 3: The post-market monitoring plan shall be based on a post-market monitoring plan. The post-market monitoring plan shall be part of the technical documentation referred to in Annex IV. The Commission shall adopt an implementing act laying down detailed provisions establishing a template for the post-market monitoring plan and the list of elements to be included in the plan by 2 February 2026. That implementing act shall be adopted in accordance with the examination procedure referred to in Article 98(2);
Art. 74. 12: Without prejudice to the powers provided for under Regulation (EU) 2019/1020, and where relevant and limited to what is necessary to fulfil their tasks, the market surveillance authorities shall be granted full access by providers to the documentation as well as the training, validation and testing data sets used for the development of high-risk AI systems, including, where appropriate and subject to security safeguards, through application programming interfaces (API) or other relevant technical means and tools enabling remote access;
Art. 74. 13(b): testing or auditing data sets used for the development of high-risk AI systems, including, where appropriate and subject to security safeguards, through application programming interfaces (API) or other relevant technical means and tools enabling remote access;
Art. 74. 14: Any information or documentation obtained by market surveillance authorities shall be treated in accordance with the confidentiality obligations set out in Article 78;
Art. 77. 1: National public authorities or bodies which supervise or enforce the respect of obligations under Union law protecting fundamental rights, including the right to non-discrimination, in relation to the use of high-risk AI systems referred to in Annex III shall have the power to request and access any documentation created or held by the provider, in any accessible language and format when access to that documentation is necessary for effectively fulfilling their mandates within the limits of their jurisdiction. The relevant public authority or body shall inform the market surveillance authority of the Member State concerned of any such request;
Art. 77. 3: Where the documentation referred to in paragraph 1 is insufficient to ascertain whether an infringement of obligations under Union law protecting fundamental rights has occurred, the public authority or body referred to in paragraph 1 may make a reasoned request to the market surveillance authority to conduct a further investigation;
Art. 77. 4: Any information or documentation obtained by the national public authorities or bodies referred to in paragraph 1 of this Article pursuant to this Article shall be treated in accordance with the confidentiality obligations set out in Article 78;
Art. 78. 3: Without prejudice to paragraphs 1 and 2, information exchanged on a confidential basis between the national competent authorities or between national competent authorities and the Commission shall not be disclosed without prior consultation of the originating national competent authority and the originating national public authority or body referred to in paragraph 1 of this Article, unless the disclosure is necessary for the purposes of the Union harmonisation legislation listed in Section A of Annex I, and aiming to ensure that high-risk AI systems or general-purpose AI models placed on the market or put into service in the Union meet the relevant requirements or obligations laid down in this Regulation. When the law enforcement, immigration or asylum authorities are providers of high-risk AI systems referred to in point 1, 6 or 7 of Annex III, the technical documentation referred to in Annex IV shall remain within the premises of those authorities. Those authorities shall ensure that the market surveillance authorities referred to in Article 74(8) and (9), as applicable, can, upon request, immediately access the documentation or obtain a copy thereof from the market surveillance authority holding the appropriate level of security clearance shall be allowed to access that documentation or any copy thereof;
Art. 83. 1(g): technical documentation is not available;
Art. 91: Power to request documentation and information
Art. 91. 1: The Commission may request the provider of the general-purpose AI model concerned to provide the documentation drawn up by the provider in accordance with Articles 53 and 55, or any additional information that is necessary for the purpose of assessing compliance of the provider with this Regulation.

Terms and AI Act Articles

1 Documentation of the access

Art. 10, 5(c): the special categories of personal data are subject to measures to ensure that the personal data processed are secured, protected, subject to suitable safeguards, including strict controls and documentation of the access, to avoid misuse and ensure that only authorised persons have access to those personal data with appropriate confidentiality obligations;

0 Documented information

0 Domains (See also: *Sectors*)

0 Economical risk

3 Education

Art. 4: Providers and deployers of AI systems shall take measures to ensure, to their best extent, a sufficient level of AI literacy of their staff and other persons dealing with the operation and use of AI systems on their behalf, taking into account their technical knowledge, experience, education and training and the context the AI systems are to be used in, and considering the persons or groups of persons on whom the AI systems are to be used.
Art. 5, 1(f): the placing on the market, the putting into service for this specific purpose, or the use of AI systems to infer emotions of a natural person in the areas of workplace and education institutions, except where the use of the AI system is intended to be put in place or into the market for medical or safety reasons.
Art. 9, 5(c): provision of information required pursuant to Article 13 and, where appropriate, training to deployers. With a view to eliminating or reducing risks related to the use of the high-risk AI system, due consideration shall be given to the technical knowledge, experience, education, the training to be expected by the deployer, and the presumable context in which the system is intended to be used.

5 Effectiveness

Art. 43, 6: The Commission is empowered to adopt delegated acts in accordance with Article 97 in order to amend paragraphs 1 and 2 of this Article in order to subject high-risk AI systems referred to in points 2 to 8 of Annex III to the conformity assessment procedure referred to in Annex VII or parts thereof. The Commission shall adopt such delegated acts taking into account the effectiveness of the conformity assessment procedure based on internal control referred to in Annex VI in preventing or minimising the risks to health and safety and protection of fundamental rights posed by such systems, as well as the availability of adequate capacities and resources among notified bodies.
Art. 57, 6: Competent authorities shall provide, as appropriate, guidance, supervision and support within the AI regulatory sandbox with a view to identifying risks, in particular to fundamental rights, health and safety, testing, mitigation measures, and their effectiveness in relation to the obligations and requirements of this Regulation and, where relevant, other Union and national law supervised within the sandbox.
Art. 69, 2: The Member States may be required to pay fees for the advice and support provided by the experts. The structure and the level of fees as well as the scale and structure of recoverable costs shall be set out in the implementing act referred to in Article 68(1), taking into account the objectives of the adequate implementation of this Regulation, cost-effectiveness and the necessity of ensuring effective access to experts for all Member States.
Art. 112, 2(c): amendments enhancing the effectiveness of the supervision and governance system.
Art. 112, 7: By 2 August 2028 and every three years thereafter, the Commission shall evaluate the impact and effectiveness of voluntary codes of conduct to foster the application of the requirements set out in Chapter III, Section 2 for AI systems other than high-risk AI systems and possibly other additional requirements for AI systems other than high-risk AI systems, including as regards environmental sustainability.

2 Efficiency

Art. 51, 3: The Commission shall adopt delegated acts in accordance with Article 97 to amend the thresholds listed in paragraphs 1 and 2 of this Article, as well as to supplement benchmarks and indicators in light of evolving technological developments, such as algorithmic improvements or increased hardware efficiency, when necessary, for these thresholds to reflect the state of the art.
Art. 53, 1(a)(v): efficiency and quality of public administration and public services;

1 Enrichment

Art. 10, 2(c): relevant data-preparation processing operations, such as annotation, labelling, cleaning, updating, enrichment and aggregation;

2 Environmental protection

Art. 1, 1: The purpose of this Regulation is to improve the functioning of the internal market and promote the uptake of human-centric and trustworthy artificial intelligence (AI), while ensuring a high level of protection of health, safety, fundamental rights enshrined in the Charter, including democracy, the rule of law and environmental protection, against the harmful effects of AI systems in the Union and supporting innovation.
Art. 46, 1: By way of derogation from Article 43 and upon a duly justified request, any market surveillance authority may authorise the placing on the market or the putting into service of specific high-risk AI systems within the territory of the Member State concerned, for exceptional reasons of public security or the protection of life and health of persons, environmental protection or the protection of key industrial and infrastructural assets. That authorisation shall be for a limited period while the necessary conformity assessment procedures are being carried out, taking into account the exceptional reasons justifying the derogation. The completion of those procedures shall be undertaken without undue delay.

0 Environmental risk

0 Ethical concerns

0 Ethical framework

1 Ethical review

Art. 60, 3: The testing of high-risk AI systems in real world conditions under this Article shall be without prejudice to any ethical review that is required by Union or national law.

0 Ethical risk

19 EU database

Art. 5, 2: In addition, the use of 'real-time' remote biometric identification systems in publicly accessible spaces for the purposes of law enforcement for any of the objectives referred to in paragraph 1, first subparagraph, point (h), of this Article shall comply with necessary and proportionate safeguards and conditions in relation to the use in accordance with the national law authorising the use thereof, in particular as regards the temporal, geographic and personal limitations. The use of the 'real-time' remote biometric identification system in publicly accessible spaces shall be authorised only if the law enforcement authority has completed a fundamental rights impact assessment as provided for in Article 27 and has registered the system in the EU database according to Article 49. However, in duly justified cases of urgency, the use of such systems may be commenced without the registration in the EU database, provided that such registration is completed without undue delay.
Art. 26, 8: Deployers of high-risk AI systems that are public authorities, or Union institutions, bodies, offices or agencies shall comply with the registration obligations referred to in Article 49. When such deployers find that the high-risk AI system that they envisage using has not been registered in the EU database referred to in Article 71, they shall not use that system and shall inform the provider or the distributor.
Art. 49, 1: Before placing on the market or putting into service a high-risk AI system listed in Annex III, with the exception of high-risk AI systems referred to in point 2 of Annex III, the provider or, where applicable, the authorised representative shall register themselves and their system in the EU database referred to in Article 71.
Art. 49, 2: Before placing on the market or putting into service an AI system for which the provider has concluded that it is not high-risk according to Article 6(3), that provider or, where applicable, the authorised representative shall register themselves and that system in the EU database referred to in Article 71.
Art. 49, 3: Before putting into service or using a high-risk AI system listed in Annex III, with the exception of high-risk AI systems listed in point 2 of Annex III, deployers that are public authorities, Union institutions, bodies, offices or agencies or persons acting on their behalf shall register themselves, select the system and register its use in the EU database referred to in Article 71.
Art. 49, 4: For high-risk AI systems referred to in points 1, 6 and 7 of Annex III, in the areas of law enforcement, migration, asylum and border control management, the registration referred to in paragraphs 1, 2 and 3 of this Article shall be in a secure non-public section of the EU database referred to in Article 71 and shall include only the following information, as applicable, referred to in:
Art. 49, 4(d): points 1, 2, 3 and 5, of Annex IX. Only the Commission and national authorities referred to in Article 74(8) shall have access to the respective restricted sections of the EU database listed in the first subparagraph of this paragraph.
Art. 60, 4(c): the provider or prospective provider, with the exception of providers or prospective providers of high-risk AI systems referred to in points 1, 6 and 7 of Annex III in the areas of law enforcement, migration, asylum and border control management, and high-risk AI systems referred to in point 2 of Annex III has registered the testing in real world conditions in accordance with Article 71(4) with a Union-wide unique single identification number and with the information specified in Annex IX; the provider or prospective provider of high-risk AI systems referred to in points 1, 6 and 7 of Annex III in the areas of law enforcement, migration, asylum and border control management, has registered the testing in real-world conditions in the secure non-public section of the EU database according to Article 49(4), point (d), with a Union-wide unique single identification number and with the information specified therein; the provider or prospective provider of high-risk AI systems referred to in point 2 of Annex III has registered the testing in real-world conditions in accordance with Article 49(5);
Art. 66, 1(e)(ii): the evaluation and review of this Regulation pursuant to Article 112, including as regards the serious incident reports referred to in Article 73, and the functioning of the EU database referred to in Article 71, the preparation of the delegated or implementing acts, and as regards possible alignments of this Regulation with the Union harmonisation legislation listed in Annex I.
CHAPTER VIII: EU DATABASE FOR HIGH-RISK AI SYSTEMS
Art. 71: EU database for high-risk AI systems listed in Annex III
Art. 71, 1: The Commission shall, in collaboration with the Member States, set up and maintain an EU database containing information referred to in paragraphs 2 and 3 of this Article concerning high-risk AI systems referred to in Article 6(2) which are registered in accordance with Articles 49 and 60 and AI systems that are not considered as high-risk pursuant to Article 6(3) and which are registered in accordance with Article 6(4) and Article 49. When setting the functional specifications of such database, the Commission shall consult the Board.
Art. 71, 2: The data listed in Sections A and B of Annex VIII shall be entered into the EU database by the provider or, where applicable, by the authorised representative.
Art. 71, 3: The data listed in Section C of Annex VIII shall be entered into the EU database by the deployer who is, or who acts on behalf of, a public authority, agency or body, in accordance with Article 49(3) and (4).
Art. 71, 4: With the exception of the section referred to in Article 49(4) and Article 60(4), point (c), the information contained in the EU database registered in accordance with Article 49 shall be accessible and publicly available in a user-friendly manner. The information should be easily navigable and machine-readable. The information registered in accordance with Article 60 shall be accessible only to market surveillance authorities and the Commission, unless the prospective provider or provider has given consent for also making the information accessible to the public.
Art. 71, 5: The EU database shall contain personal data only in so far as necessary for collecting and processing information in accordance with this Regulation. That information shall include the names and contact details of natural persons who are responsible for registering the system and have the legal authority to represent the provider or the deployer, as applicable.
Art. 71, 6: The Commission shall be the controller of the EU database. It shall make available to providers, prospective providers and deployers adequate technical and administrative support. The EU database shall comply with the applicable accessibility requirements.
Art. 80, 8: In exercising their power to monitor the application of this Article, and in accordance with Article 11 of Regulation (EU) 2019/1020, market surveillance authorities may perform appropriate checks, taking into account in particular information stored in the EU database referred to in Article 71 of this Regulation.
Art. 83, 1(e): the registration in the EU database referred to in Article 71 has not been carried out;

Terms and AI Act Articles

1 Evaluating

Art. 68, 3(a)(ii): contributing to the development of tools and methodologies for evaluating capabilities of general-purpose AI models and systems, including through benchmarks;

25 Evaluation (See also: Evaluating)

Art. 3 (30): 'validation data' means data used for providing an evaluation of the trained AI system and for tuning its non-learnable parameters and its learning process in order, inter alia, to prevent underfitting or overfitting;
Art. 3 (32): 'testing data' means data used for providing an independent evaluation of the AI system in order to confirm the expected performance of that system before its placing on the market or putting into service;
Art. 5, 1(c): the placing on the market, the putting into service or the use of AI systems for the evaluation or classification of natural persons or groups of persons over a certain period of time based on their social behaviour or known, inferred or predicted personal or personality characteristics, with the social score leading to either or both of the following;
Art. 9, 2(b): the estimation and evaluation of the risks that may emerge when the high-risk AI system is used in accordance with its intended purpose, and under conditions of reasonably foreseeable misuse;
Art. 9, 2(c): the evaluation of other risks possibly arising, based on the analysis of data gathered from the post-market monitoring system referred to in Article 72;
Art. 53, 1(a): draw up and keep up-to-date the technical documentation of the model, including its training and testing process and the results of its evaluation, which shall contain, at a minimum, the information set out in Annex XI for the purpose of providing it, upon request, to the AI Office and the national competent authorities;
Art. 55, 1(a): perform model evaluation in accordance with standardised protocols and tools reflecting the state of the art, including conducting and documenting adversarial testing of the model with the view to identifying and mitigating systemic risks;
Art. 66, 6(e)(ii): the evaluation and review of this Regulation pursuant to Article 112, including as regards the serious incident reports referred to in Article 73, and the functioning of the EU database referred to in Article 71, the preparation of the delegated or implementing acts, and as regards possible alignments of this Regulation with the Union harmonisation legislation listed in Annex I;
Art. 73, 6: Following the reporting of a serious incident pursuant to paragraph 1, the provider shall, without delay, perform the necessary investigations in relation to the serious incident and the AI system concerned. This shall include a risk assessment of the incident, and corrective action. The provider shall cooperate with the competent authorities, and where relevant with the notified body concerned, during the investigations referred to in the first subparagraph, and shall not perform any investigation which involves altering the AI system concerned in a way which may affect any subsequent evaluation of the causes of the incident, prior to informing the competent authorities of such action;
Art. 79, 2: Where the market surveillance authority of a Member State has sufficient reason to consider an AI system to present a risk as referred to in paragraph 1 of this Article, it shall carry out an evaluation of the AI system concerned in respect of its compliance with all the requirements and obligations laid down in this Regulation. Particular attention shall be given to AI systems presenting a risk to vulnerable groups. Where risks to fundamental rights are identified, the market surveillance authority shall also inform and fully cooperate with the relevant national public authorities or bodies referred to in Article 77(1). The relevant operators shall cooperate as necessary with the market surveillance authority and with the other national public authorities or bodies referred to in Article 77(1). Where, in the course of that evaluation, the market surveillance authority or, where applicable the market surveillance authority in cooperation with the national public authority referred to in Article 77(1), finds that the AI system does not comply with the requirements and obligations laid down in this Regulation, it shall without undue delay require the relevant operator to take all appropriate corrective actions to bring the AI system into compliance, to withdraw the AI system from the market, or to recall it within a period the market surveillance authority may prescribe, and in any event within the shorter of 15 working days, or as provided for in the relevant Union harmonisation legislation. The market surveillance authority shall inform the relevant notified body accordingly. Article 18 of Regulation (EU) 2019/1020 shall apply to the measures referred to in the second subparagraph of this paragraph;
Art. 79, 3: Where the market surveillance authority considers that the non-compliance is not restricted to its national territory, it shall inform the Commission and the other Member States without undue delay of the results of the evaluation and of the actions which it has required the operator to take;
Art. 80, 1: Where a market surveillance authority has sufficient reason to consider that an AI system classified by the provider as non-high-risk pursuant to Article 6(3) is indeed high-risk, the market surveillance authority shall carry out an evaluation of the AI system concerned in respect of its classification as a high-risk AI system based on the conditions set out in Article 6(3) and the Commission guidelines;
Art. 80, 2: Where, in the course of that evaluation, the market surveillance authority finds that the AI system concerned is high-risk, it shall without undue delay require the relevant provider to take all necessary actions to bring the AI system into compliance with the requirements and obligations laid down in this Regulation, as well as take appropriate corrective action within a period the market surveillance authority may prescribe;
Art. 80, 3: Where the market surveillance authority considers that the use of the AI system concerned is not restricted to its national territory, it shall inform the Commission and the other Member States without undue delay of the results of the evaluation and of the actions which it has required the provider to take;
Art. 80, 7: Where, in the course of the evaluation pursuant to paragraph 1 of this Article, the market surveillance authority establishes that the AI system was misclassified by the provider as non-high-risk in order to circumvent the application of requirements in Chapter III, Section 2, the provider shall be subject to fines in accordance with Article 99;
Art. 81, 1: Where, within three months of receipt of the notification referred to in Article 79(5), or within 30 days in the case of non-compliance with the prohibition of the AI practices referred to in Article 5, objections are raised by the market surveillance authority of a Member State to a measure taken by another market surveillance authority, or where the Commission considers the measure to be contrary to Union law, the Commission shall without undue delay enter into consultation with the market surveillance authority of the relevant Member State and the operator or operators, and shall evaluate the national measure. On the basis of the results of that evaluation, the Commission shall, within six months, or within 60 days in the case of non-compliance with the prohibition of the AI practices referred to in Article 5, starting from the notification referred to in Article 79(5), decide whether the national measure is justified and shall notify its decision to the market surveillance authority of the Member State concerned. The Commission shall also inform all other market surveillance authorities of its decision;
Art. 82, 1: Where, having performed an evaluation under Article 79, after consulting the relevant national public authority referred to in Article 77(1), the market surveillance authority of a Member State finds that although a high-risk AI system complies with this Regulation, it nevertheless presents a risk to the health or safety of persons, to fundamental rights, or to other aspects of public interest protection, it shall require the relevant operator to take all appropriate measures to ensure that the AI system concerned, when placed on the market or put into service, no longer presents that risk without undue delay, within a period it may prescribe;
Art. 82, 4: The Commission shall without undue delay enter into consultation with the Member States concerned and the relevant operators, and shall evaluate the national measures taken. On the basis of the results of that evaluation, the Commission shall decide whether the measure is justified and, where necessary, propose other appropriate measures;
Art. 93, 1(b): implement mitigation measures, where the evaluation carried out in accordance with Article 92 has given rise to serious and substantiated concern of a systemic risk at Union level;
Art. 101, 1(b): failed to make available to the Commission access to the general-purpose AI model or general-purpose AI model with systemic risk with a view to conducting an evaluation pursuant to Article 92. In fixing the amount of the fine or periodic penalty payment, regard shall be had to the nature, gravity and duration of the infringement, taking due account of the principles of proportionality and appropriateness. The Commission shall also take into account commitments made in accordance with Article 93(3) or made in relevant codes of practice in accordance with Article 112;
Art. 111, 1: Without prejudice to the application of Article 5 as referred to in Article 113(3), point (a), AI systems which are components of the large-scale IT systems established by the legal acts listed in Annex X that have been placed on the market or put into service before 2 August 2027 shall be brought into compliance with this Regulation by 31 December 2030. The requirements laid down in this Regulation shall be taken into account in the evaluation of each large-scale IT system established by the legal acts listed in Annex X to be undertaken as provided for in the relevant acts and where those legal acts so provide;
Art. 112: Evaluation and review;
Art. 112, 3: By 2 August 2029 and every four years thereafter, the Commission shall submit a report on the evaluation and review of this Regulation to the European Parliament and to the Council. The report shall include an assessment with regard to the structure of enforcement and the need for a Union agency to resolve any identified shortcomings. On the basis of the findings that may be made, where appropriate, accompanied by a proposal for amendment of this Regulation, the reports shall be made public;
Art. 112, 5: By 2 August 2028, the Commission shall evaluate the functioning of the AI Office, whether the AI Office has been given sufficient powers and competences to fulfil its tasks, and whether it would be relevant and needed for the proper implementation and enforcement of this Regulation to upgrade the AI Office and its enforcement competences and to increase its resources. The Commission shall submit a report on its evaluation to the European Parliament and to the Council;
Art. 112, 11: To guide the evaluations and reviews referred to in paragraphs 1 to 7 of this Article, the AI Office shall undertake to develop an objective and participative methodology for the evaluation of risk levels based on the criteria outlined in the relevant Articles and the inclusion of new systems in:

15 Event

Art. 2, 3: This Regulation does not apply to areas outside the scope of Union law, and shall not, in any event, affect the competences of the Member States concerning national security, regardless of the type of entity entrusted by the Member States with carrying out tasks in relation to those competences. This Regulation does not apply to AI systems where and in so far they are placed on the market, put into service, or used with or without modification exclusively for military, defence or national security purposes, regardless of the type of entity carrying out those activities. This Regulation does not apply to AI systems which are not placed on the market or put into service in the Union, where the output is used in the Union exclusively for military, defence or national security purposes, regardless of the type of entity carrying out those activities;
Art. 9, 8: The testing of high-risk AI systems shall be performed, as appropriate, at any time throughout the development process, and, in any event, prior to their being placed on the market or put into service. Testing shall be carried out against prior defined metrics and probabilistic thresholds that are appropriate to the intended purpose of the high-risk AI system;
Art. 12, 2: The implementation of the aspects referred to in paragraph 1 shall be proportionate to the size of the provider's organisation. Providers shall, in any event, respect the degree of rigour and the level of protection required to ensure the compliance of their high-risk AI systems with this Regulation;
Art. 36, 6: In the event of the restriction, suspension or withdrawal of a designation, the notifying authority shall take appropriate steps to ensure that the files of the notified body concerned are kept, and to make them available to notifying authorities in other Member States and to market surveillance authorities at their request;
Art. 36, 7: In the event of the restriction, suspension or withdrawal of a designation, the notifying authority shall:
Art. 36, 8(b): the notifying authority has confirmed that no certificates relevant to the suspension will be issued, amended or re-issued during the course of the suspension or restriction, and states whether the notified body has the capability of continuing to monitor and remain responsible for existing certificates issued for the period of the suspension or restriction; in the event that the notifying authority determines that the notified body does not have the capability to support existing certificates issued, the provider of the system covered by the certificate shall confirm in writing to the national competent authorities of the Member State in which it has its registered place of business, within three months of the suspension or restriction, that another qualified notified body is temporarily assuming the functions of the notified body to monitor and remain responsible for the certificates during the period of suspension or restriction;
Art. 4, 4: High-risk AI systems that have already been subject to a conformity assessment procedure shall undergo a new conformity assessment procedure in the event of a substantial modification, regardless of whether the modified system is intended to be further distributed or continues to be used by the current deployer. For high-risk AI systems that continue to learn after being placed on the market or put into service, changes to the high-risk AI system and its performance that have been pre-determined by the provider at the moment of the initial conformity assessment and are part of the information contained in the technical documentation referred to in point 2(f) of Annex IV, shall not constitute a substantial modification;
Art. 52, 1: Where a general-purpose AI model meets the condition referred to in Article 5(1)(1), point (a), the relevant provider shall notify the Commission without delay and in any event within two weeks after that requirement is met or it becomes known that it will be met. That notification shall include the information necessary to demonstrate that the relevant requirement has been met. If the Commission becomes aware of a general-purpose AI model presenting systemic risks of which it has not been notified, it may decide to designate it as a model with systemic risk;
Art. 73, 2: The report referred to in paragraph 1 shall be made immediately after the provider has established a causal link between the AI system and the serious incident or the reasonable likelihood of such a link, and, in any event, not later than 15 days after the provider or, where applicable, the deployer, becomes aware of the serious incident. The period for the reporting referred to in the first subparagraph shall take account of the severity of the serious incident;
Art. 73, 3: Notwithstanding paragraph 2 of this Article, in the event of a widespread infringement or a serious incident as defined in Article 3, point (49)(b), the report referred to in paragraph 1 of this Article shall be provided immediately, and not later than two days after the provider or, where applicable, the deployer becomes aware of that incident;
Art. 74, 4: Notwithstanding paragraph 2, in the event of the death of a person, the report shall be provided immediately after the provider or the deployer has established, or as soon as it suspects, a causal relationship between the high-risk AI system and the serious incident, but not later than 10 days after the date on which the provider or, where applicable, the deployer becomes aware of the serious incident;
Art. 75, 3: Where a market surveillance authority is unable to conclude its investigation of the high-risk AI system because of its inability to access certain information related to the general-purpose AI model despite having made all appropriate efforts to obtain that information, it may submit a reasoned request to the AI Office, by which access to that information shall be enforced. In that case, the AI Office shall supply to the applicant authority without delay, and in any event within 30 days, any information that the AI Office considers to be relevant in order to establish whether a high-risk AI system is non-compliant. Market surveillance authorities shall safeguard the confidentiality of the information that they obtain in accordance with Article 78 of this Regulation. The procedure provided for in Chapter VI of Regulation (EU) 2019/1020 shall apply mutatis mutandis;
Art. 79, 2: Where the market surveillance authority of a Member State has sufficient reason to consider an AI system to present a risk as referred to in paragraph 1 of this Article, it shall carry out an evaluation of the AI system concerned in respect of its compliance with all the requirements and obligations laid down in this Regulation. Particular attention shall be given to AI systems presenting a risk to vulnerable groups. Where risks to fundamental rights are identified, the market surveillance authority shall also inform and fully cooperate with the relevant national public authorities or bodies referred to in Article 77(1). The relevant operators shall cooperate as necessary with the market surveillance authority and with the other national public authorities or bodies referred to in Article 77(1). Where, in the course of that evaluation, the market surveillance authority or, where applicable the market surveillance authority in cooperation with the national public authority referred to in Article 77(1), finds that the AI system does not comply with the requirements and obligations laid down in this Regulation, it shall without undue delay require the relevant operator to take all appropriate corrective actions to bring the AI system into compliance, to withdraw the AI system from the market, or to recall it within a period the market surveillance authority may prescribe, and in any event within the shorter of 15 working days, or as provided for in the relevant Union harmonisation legislation. The market surveillance authority shall inform the relevant notified body accordingly. Article 18 of Regulation (EU) 2019/1020 shall apply to the measures referred to in the second subparagraph of this paragraph;
Art. 79, 7: The market surveillance authorities other than the market surveillance authority of the Member State initiating the procedure shall, without undue delay, inform the Commission and the other Member States of any measures adopted and of any additional information at their disposal relating to the non-compliance of the AI system concerned, and, in the event of disagreement with the notified national measure, of their objections;
Art. 79, 8: Where, within three months of receipt of the notification referred to in paragraph 1 of this Article, no objection has been raised by either a market surveillance authority of a Member State or by the Commission in respect of a provisional measure taken by a market surveillance authority of another Member State, that measure shall be deemed justified. This shall be without prejudice to the procedural rights of the concerned operator in accordance with Article 18 of Regulation (EU) 2019/1020. The three-month period referred to in this paragraph shall be reduced to 30 days in the event of non-compliance with the prohibition of the AI practices referred to in Article 5 of this Regulation.

0 Examination of biases (See also: Health, Safety)

5 Experience

Art. 3, (25): 'post-market monitoring system' means all activities carried out by providers of AI systems to collect and review experience gained from the use of AI systems they place on the market or put into service for the purpose of identifying any need to immediately apply any necessary corrective or preventive actions;
Art. 4: Providers and deployers of AI systems shall take measures to ensure, to their best extent, a sufficient level of AI literacy of their staff and other persons dealing with the operation and use of AI systems on their behalf, taking into account their technical knowledge, experience, education and training and the context the AI systems are to be used in, and considering the persons or groups of persons on whom the AI systems are to be used;
Art. 9, 5(c): provision of information required pursuant to Article 13 and, where appropriate, training to deployers. With a view to eliminating or reducing risks related to the use of the high-risk AI system, due consideration shall be given to the technical knowledge, experience, education, the training to be expected by the deployer, and the presumable context in which the system is intended to be used;
Art. 31, 1f: Notified bodies shall have sufficient internal competences to be able effectively to evaluate the tasks conducted by external parties on their behalf. The notified body shall have permanent availability of sufficient administrative, technical, legal and scientific personnel who possess experience and knowledge relating to the relevant types of AI systems, data and data computing, and relating to the requirements set out in Section 2;
Art. 70, 7: The Commission shall facilitate the exchange of experience between national competent authorities.

0 Explainability

Terms and AI Act Articles

28 Fine

Art. 57, 12: Providers and prospective providers participating in the AI regulatory sandbox shall remain liable under applicable Union and national liability law for any damage inflicted on third parties as a result of the experimentation taking place in the sandbox. However, provided that the prospective providers observe the specific plan and the terms and conditions for their participation and follow in good faith the guidance given by the national competent authority, no administrative fines shall be imposed by the authorities for infringements of this Regulation. Where other competent authorities responsible for other Union and national law were actively involved in the supervision of the AI system in the sandbox and provided guidance for compliance, no administrative fines shall be imposed regarding that law.

Art. 80, 4: The provider shall ensure that all necessary action is taken to bring the AI system into compliance with the requirements and obligations laid down in this Regulation. Where the provider of an AI system concerned does not bring the AI system into compliance with those requirements and obligations within the period referred to in paragraph 2 of this Article, the provider shall be subject to fines in accordance with Article 99.

Art. 80, 7: Where, in the course of the evaluation pursuant to paragraph 1 of this Article, the market surveillance authority establishes that the AI system was misclassified by the provider as non-high-risk in order to circumvent the application of requirements in Chapter III, Section 2, the provider shall be subject to fines in accordance with Article 99.

Art. 91, 4: The request for information shall state the legal basis and the purpose of the request, specify what information is required, set a period within which the information is to be provided, and indicate the fines provided for in Article 101 for supplying incorrect, incomplete or misleading information.

Art. 92, 4: The request for access shall state the legal basis, the purpose and reasons of the request and set the period within which the access is to be provided, and the fines provided for in Article 101 for failure to provide access.

Art. 99, 3: Non-compliance with the prohibition of the AI practices referred to in Article 5 shall be subject to administrative fines of up to EUR 35 000 000 or, if the offender is an undertaking, up to 7 % of its total worldwide annual turnover for the preceding financial year, whichever is higher.

Art. 99, 4: Non-compliance with any of the following provisions related to operators or notified bodies, other than those laid down in Articles 5, shall be subject to administrative fines of up to EUR 15 000 000 or, if the offender is an undertaking, up to 3 % of its total worldwide annual turnover for the preceding financial year, whichever is higher:

Art. 99, 5: The supply of incorrect, incomplete or misleading information to notified bodies or national competent authorities in reply to a request shall be subject to administrative fines of up to EUR 7 500 000 or, if the offender is an undertaking, up to 1 % of its total worldwide annual turnover for the preceding financial year, whichever is higher.

Art. 99, 6: In the case of SMEs, including start-ups, each fine referred to in this Article shall be up to the percentages or amount referred to in paragraphs 3, 4 and 5, whichever thereof is lower.

Art. 99, 7: When deciding whether to impose an administrative fine and when deciding on the amount of the administrative fine in each individual case, all relevant circumstances of the specific situation shall be taken into account and, as appropriate, regard shall be given to the following:

Art. 99, 7(b): whether administrative fines have already been applied by other market surveillance authorities to the same operator for the same infringement;

Art. 99, 7(c): whether administrative fines have already been applied by other authorities to the same operator for infringements of other Union or national law, when such infringements result from the same activity or omission constituting a relevant infringement of this Regulation;

Art. 99, 8: Each Member State shall lay down rules on to what extent administrative fines may be imposed on public authorities and bodies established in that Member State.

Art. 99, 9: Depending on the legal system of the Member States, the rules on administrative fines may be applied in such a manner that the fines are imposed by competent national courts or by other bodies, as applicable in those Member States. The application of such rules in those Member States shall have an equivalent effect.

Art. 99, 11: Member States shall, on an annual basis, report to the Commission about the administrative fines they have issued during that year, in accordance with this Article, and about any related litigation or judicial proceedings.

Art. 100: Administrative fines on Union institutions, bodies, offices and agencies

Art. 100, 1: The European Data Protection Supervisor may impose administrative fines on Union institutions, bodies, offices and agencies falling within the scope of this Regulation. When deciding whether to impose an administrative fine and when deciding on the amount of the administrative fine in each individual case, all relevant circumstances of the specific situation shall be taken into account and due regard shall be given to the following:

Art. 100, 2: Non-compliance with the prohibition of the AI practices referred to in Article 5 shall be subject to administrative fines of up to EUR 1 500 000.

Art. 100, 3: The non-compliance of the AI system with any requirements or obligations under this Regulation, other than those laid down in Article 5, shall be subject to administrative fines of up to EUR 750 000.

Art. 100, 6: Funds collected by imposition of fines in this Article shall contribute to the general budget of the Union. The fines shall not affect the effective operation of the Union institution, body, office or agency fined.

Art. 100, 7: The European Data Protection Supervisor shall, on an annual basis, notify the Commission of the administrative fines it has imposed pursuant to this Article and of any litigation or judicial proceedings it has initiated.

Art. 101: Fines for providers of general-purpose AI models

Art. 101, 1: The Commission may impose on providers of general-purpose AI models fines not exceeding 3 % of their annual total worldwide turnover in the preceding financial year or EUR 15 000 000, whichever is higher., when the Commission finds that the provider intentionally or negligently:

Art. 101, 1(d): failed to make available to the Commission access to the general-purpose AI model or general-purpose AI model with systemic risk with a view to conducting an evaluation pursuant to Article 92. In fixing the amount of the fine or periodic penalty payment, regard shall be had to the nature, gravity and duration of the infringement, taking account of the principles of proportionality and appropriateness. The Commission shall also into account commitments made in accordance with Article 93(3) or made in relevant codes of practice in accordance with Article 95.

Art. 101, 3: Fines imposed in accordance with this Article shall be effective, proportionate and dissuasive.

Art. 101, 4: Information on fines imposed under this Article shall also be communicated to the Board as appropriate.

Art. 101, 5: The Court of Justice of the European Union shall have unlimited jurisdiction to review decisions of the Commission fixing a fine under this Article. It may cancel, reduce or increase the fine imposed.

Art. 112, 4(b): the state of penalties, in particular administrative fines as referred to in Article 99(1), applied by Member States for infringements of this Regulation;

1 Flexibility

Art. 58, 2(c): that the detailed arrangements for, and conditions concerning AI regulatory sandboxes support, to the best extent possible, flexibility for national competent authorities to establish and operate their AI regulatory sandboxes;

0 Formal method

1 Free of errors (See also: [Accuracy](#))

Art. 10, 3: Training, validation and testing data sets shall be relevant, sufficiently representative, and to the best extent possible, free of errors and complete in view of the intended purpose. They shall have the appropriate statistical properties, including, where applicable, as regards the persons or groups of persons in relation to whom the high-risk AI system is intended to be used. Those characteristics of the data sets may be met at the level of individual data sets or at the level of a combination thereof.

0 Freedom from risk

0 Functional adaptability

0 Functional appropriateness

0 Functional completeness

0 Functional correctness

0 Functional safety

2 Functional setting

Art. 10, 4: Data sets shall take into account, to the extent required by the intended purpose, the characteristics or elements that are particular to the specific geographical, contextual, behavioural or functional setting within which the high-risk AI system is intended to be used.

Art. 42, 1: High-risk AI systems that have been trained and tested on data reflecting the specific geographical, behavioural, contextual or functional setting within which they are intended to be used shall be presumed to comply with the relevant requirements laid down in Article 10(4).

0 Functional suitability

Terms and AI Act Articles

45 Fundamental right

- Art. 1, 1.** The purpose of this Regulation is to improve the functioning of the internal market and promote the uptake of human-centric and trustworthy artificial intelligence (AI), while ensuring a high level of protection of health, safety, fundamental rights enshrined in the Charter, including democracy, the rule of law and environmental protection, against the harmful effects of AI systems in the Union and supporting innovation.
- Art. 2, 4.** This Regulation applies neither to public authorities in a third country nor to international organisations falling within the scope of this Regulation pursuant to paragraph 1, where those authorities or organisations use AI systems in the framework of international cooperation or agreements for law enforcement or judicial cooperation with the Union or with one or more Member States, provided that such a third country or international organisation provides adequate safeguards with respect to the protection of fundamental rights and freedoms of individuals.
- Art. 3, (49)(c).** the infringement of obligations under Union law intended to protect fundamental rights;
- Art. 3, (65)** 'systemic risk' means a risk that is specific to the high-impact capabilities of general-purpose AI models, having a significant impact on the Union market due to their reach, or due to actual or reasonably foreseeable negative effects on public health, safety, public security, fundamental rights, or the society as a whole, that can be propagated at scale across the value chain;
- Art. 5, 2.** In addition, the use of 'real-time' remote biometric identification systems in publicly accessible spaces for the purposes of law enforcement for any of the objectives referred to in paragraph 1, first subparagraph, point (h), of this Article shall comply with necessary and proportionate safeguards and conditions in relation to the use in accordance with the national law authorising the use thereof, in particular as regards the temporal, geographic and personal limitations. The use of the 'real-time' remote biometric identification system in publicly accessible spaces shall be authorised only if the law enforcement authority has completed a fundamental rights impact assessment as provided for in Article 27 and has registered the system in the EU database according to Article 49. However, in duly justified cases of urgency, the use of such systems may be commenced without the registration in the EU database, provided that such registration is completed without undue delay.
- Art. 6, 3.** By derogation from paragraph 2, an AI system referred to in Annex III shall not be considered to be high-risk where it does not pose a significant risk of harm to the health, safety or fundamental rights of natural persons, including by not materially influencing the outcome of decision making. The first subparagraph shall apply where any of the following conditions is fulfilled:
- Art. 6, 6.** The Commission is empowered to adopt delegated acts in accordance with Article 97 in order to amend paragraph 3, second subparagraph, of this Article by adding new conditions to those laid down therein, or by modifying them, where there is concrete and reliable evidence of the existence of AI systems that fall under the scope of Annex III, but do not pose a significant risk of harm to the health, safety or fundamental rights of natural persons.
- Art. 6, 7.** The Commission shall adopt delegated acts in accordance with Article 97 in order to amend paragraph 3, second subparagraph, of this Article by deleting any of the conditions laid down therein, where there is concrete and reliable evidence that this is necessary to maintain the level of protection of health, safety and fundamental rights provided for by this Regulation.
- Art. 6, 8.** Any amendment to the conditions laid down in paragraph 3, second subparagraph, adopted in accordance with paragraphs 6 and 7 of this Article shall not decrease the overall level of protection of health, safety and fundamental rights provided for by this Regulation and shall ensure consistency with the delegated acts adopted pursuant to Article 7(1), and take account of market and technological developments.
- Art. 7, 1(b):** the AI systems pose a risk of harm to health and safety, or an adverse impact on fundamental rights, and that risk is equivalent to, or greater than, the risk of harm or of adverse impact posed by the high-risk AI systems already referred to in Annex III.
- Art. 7, 2(a):** the extent to which the use of an AI system has already caused harm to health and safety, has had an adverse impact on fundamental rights or has given rise to significant concerns in relation to the likelihood of such harm or adverse impact, as demonstrated, for example, by reports of documented allegations submitted to national competent authorities or by other reports, as appropriate;
- Art. 7, 2(i):** the extent to which the outcome produced involving an AI system is easily corrigible or reversible, taking into account the technical solutions available to correct or reverse it, whereby outcomes having an adverse impact on health, safety or fundamental rights, shall not be considered to be easily corrigible or reversible;
- Art. 7, 3(a):** the high-risk AI system concerned no longer poses any significant risks to fundamental rights, health or safety, taking into account the criteria listed in paragraph 2;
- Art. 7, 3(b):** the deletion does not decrease the overall level of protection of health, safety and fundamental rights under Union law.
- Art. 9, 2(a):** the identification and analysis of the known and the reasonably foreseeable risks that the high-risk AI system can pose to health, safety or fundamental rights when the high-risk AI system is used in accordance with its intended purpose;
- Art. 10, 2(a):** examination in view of possible biases that are likely to affect the health and safety of persons, have a negative impact on fundamental rights or lead to discrimination prohibited under Union law, especially where data outputs influence inputs for future operations;
- Art. 10, 5:** To the extent that it is strictly necessary for the purpose of ensuring bias detection and correction in relation to the high-risk AI systems in accordance with paragraph (2), points (f) and (g) of this Article, the providers of such systems may exceptionally process special categories of personal data, subject to appropriate safeguards for the fundamental rights and freedoms of natural persons. In addition to the provisions set out in Regulations (EU) 2016/679 and (EU) 2018/1725 and Directive (EU) 2016/680, all the following conditions must be met in order for such processing to occur:
- Art. 13, 3(b)(iii):** any known or foreseeable circumstance, related to the use of the high-risk AI system in accordance with its intended purpose or under conditions of reasonably foreseeable misuse, which may lead to risks to the health and safety or fundamental rights referred to in Article 2(a);
- Art. 14, 2.** Human oversight shall aim to prevent or minimise the risks to health, safety or fundamental rights that may emerge when a high-risk AI system is used in accordance with its intended purpose or under conditions of reasonably foreseeable misuse, in particular where such risks persist despite the application of other requirements set out in this Section.
- Art. 27.** Fundamental rights impact assessment for high-risk AI systems
- Art. 27, 1.** Prior to deploying a high-risk AI system referred to in Article 6(2), with the exception of high-risk AI systems intended to be used in the area listed in point 2 of Annex III, deployers that are bodies governed by public law, or are private entities providing public services, and deployers of high-risk AI systems referred to in points 5, (b) and (c) of Annex III, shall perform an assessment of the impact on fundamental rights that the use of such system may produce. For that purpose, deployers shall perform an assessment consisting of:
- Art. 27, 2.** The obligation laid down in paragraph 1 applies to the first use of the high-risk AI system. The deployer may, in similar cases, rely on previously conducted fundamental rights impact assessments or existing impact assessments carried out by provider. If, during the use of the high-risk AI system, the deployer considers that any of the elements listed in paragraph 1 has changed or is no longer up to date, the deployer shall take the necessary steps to update the information.
- Art. 27, 4.** If any of the obligations laid down in this Article is already met through the data protection impact assessment conducted pursuant to Article 35 of Regulation (EU) 2016/679 or Article 27 of Directive (EU) 2016/680, the fundamental rights impact assessment referred to in paragraph 1 of this Article shall complement that data protection impact assessment.
- Art. 28, 7.** Notifying authorities shall have an adequate number of competent personnel at their disposal for the proper performance of their tasks. Competent personnel shall have the necessary expertise, where applicable, for their function, in fields such as information technologies, AI and law, including the supervision of fundamental rights.
- Art. 30, 1(a):** providing the national competent authorities of the Member State in which the provider has its registered place of business with all relevant information about the certificates of which it has required the suspension or withdrawal; that authority shall take the appropriate measures, where necessary, to avoid a potential risk to health, safety or fundamental rights.
- Art. 36, 9(a):** the notifying authority has confirmed, within one month of the suspension or restriction, that there is no risk to health, safety or fundamental rights in relation to certificates affected by the suspension or restriction, and the notifying authority has outlined a timeline for actions to lift the suspension or restriction; or
- Art. 36, 9(a):** the national competent authority of the Member State in which the provider of the high-risk AI system covered by the certificate has its registered place of business has confirmed that there is no risk to health, safety or fundamental rights associated with the high-risk AI systems concerned; and
- Art. 40, 3.** The participants in the standardisation process shall seek to promote investment and innovation in AI, including through increasing legal certainty, as well as the competitiveness and growth of the Union market, to contribute to strengthening global cooperation on standardisation and taking into account existing international standards in the field of AI that are consistent with Union values, fundamental rights and interests, and to enhance multi-stakeholder governance ensuring a balanced representation of interests and the effective participation of all relevant stakeholders in accordance with Articles 5, 6, and 7 of Regulation (EU) No 1025/2012.
- Art. 41, 1(a)(iii):** the relevant harmonised standards insufficiently address fundamental rights concerns; or
- Art. 43, 6.** The Commission is empowered to adopt delegated acts in accordance with Article 97 in order to amend paragraphs 1 and 2 of this Article in order to subject high-risk AI systems referred to in points 2 to 8 of Annex III to the conformity assessment procedure referred to in Annex VII or parts thereof. The Commission shall adopt such delegated acts taking into account the effectiveness of the conformity assessment procedure based on internal control referred to in Annex VI in preventing or minimising the risks to health and safety and protection of fundamental rights posed by such systems, as well as the availability of adequate capacities and resources among notified bodies.
- Art. 57, 6.** Competent authorities shall provide, as appropriate, guidance, supervision and support within the AI regulatory sandbox with a view to identifying risks, in particular to fundamental rights, health and safety, testing, mitigation measures, and their effectiveness in relation to the obligations and requirements of this Regulation and, where relevant, other Union and national law supervised within the sandbox.
- Art. 57, 11.** The AI regulatory sandboxes shall not affect the supervisory or corrective powers of the competent authorities supervising the sandboxes, including at regional or local level. Any significant risks to health and safety and fundamental rights identified during the development and testing of such AI systems shall result in an adequate mitigation. National competent authorities shall have the power to temporarily or permanently suspend the testing process, or the participation in the sandbox if no effective mitigation is possible, and shall inform the AI Office of such decision. National competent authorities shall exercise their supervisory powers within the limits of the relevant law, using their discretionary powers when implementing legal provisions in respect of a specific AI regulatory sandbox project, with the objective of supporting innovation in AI in the Union.
- Art. 58, 2(i):** that AI regulatory sandboxes facilitate the development of tools and infrastructure for testing, benchmarking, assessing and explaining dimensions of AI systems relevant for regulatory learning, such as accuracy, robustness and cybersecurity, as well as measures to mitigate risks to fundamental rights and society at large.
- Art. 58, 4.** Where national competent authorities consider authorising testing in real world conditions supervised within the framework of an AI regulatory sandbox to be established under this Article, they shall specifically agree the terms and conditions of such testing and, in particular, the appropriate safeguards with the participants, with a view to protecting fundamental rights, health and safety. Where appropriate, they shall cooperate with other national competent authorities with a view to ensuring consistent practices across the Union.
- Art. 65, (h):** cooperate, as appropriate, with other Union institutions, bodies, offices and agencies, as well as relevant Union expert groups and networks, in particular in the fields of product safety, cybersecurity, competition, digital and media services, financial services, consumer protection, data and fundamental rights protection;
- Art. 67, 5.** The Fundamental Rights Agency, ENISA, the European Committee for Standardization (CEN), the European Committee for Electrotechnical Standardization (CENELEC), and the European Telecommunications Standards Institute (ETSI) shall be permanent members of the advisory forum.
- Art. 70, 3.** Member States shall ensure that their national competent authorities are provided with adequate technical, financial and human resources, and with infrastructure to fulfil their tasks effectively under this Regulation. In particular, the national competent authorities shall have a sufficient number of personnel permanently available whose competences and expertise shall include an in-depth understanding of AI technologies, data and data computing, personal data protection, cybersecurity, fundamental rights, health and safety risks and knowledge of existing standards and legal requirements. Member States shall assess and, if necessary, update competence and resource requirements referred to in this paragraph on an annual basis.
- Art. 77.** Powers of authorities protecting fundamental rights
- Art. 77, 1.** National public authorities or bodies which supervise or enforce the respect of obligations under Union law protecting fundamental rights, including the right to non-discrimination, in relation to the use of high-risk AI systems referred to in Annex III shall have the power to request and access any documentation created or maintained under this Regulation in accessible language and format when access to that documentation is necessary for effectively fulfilling their mandates within the limits of their jurisdiction. The relevant public authority or body shall inform the market surveillance authority of the Member State concerned of any such request.
- Art. 77, 3.** Where the documentation referred to in paragraph 1 is insufficient to ascertain whether an infringement of obligations under Union law protecting fundamental rights has occurred, the public authority or body referred to in paragraph 1 may make a reasoned request to the market surveillance authority to organise testing of the high-risk AI system through technical means. The market surveillance authority shall organise the testing with the close involvement of the requesting public authority or body within a reasonable time following the request.
- Art. 79, 1.** AI systems presenting a risk shall be understood as a 'product presenting a risk' as defined in Article 3, point 19 of Regulation (EU) 2019/1020, in so far as they present risks to the health or safety, or to fundamental rights, of persons.
- Art. 79, 2.** Where the market surveillance authority of a Member State has sufficient reason to consider an AI system to present a risk as referred to in paragraph 1 of this Article, it shall carry out an evaluation of the AI system concerned in respect of its compliance with all the requirements and obligations laid down in this Regulation. Particular attention shall be given to AI systems presenting a risk to vulnerable groups. Where risks to fundamental rights are identified, the market surveillance authority shall also inform and fully cooperate with the relevant national public authorities or bodies referred to in Article 77(1). The relevant operators shall cooperate as necessary with the market surveillance authority and with the other national public authorities or bodies referred to in Article 77(1). Where, in the course of that evaluation, the market surveillance authority or, where applicable the market surveillance authority in cooperation with the national public authority referred to in Article 77(1), finds that the AI system does not comply with the requirements and obligations laid down in this Regulation, it shall without undue delay require the relevant operator to take all appropriate corrective actions to bring the AI system into compliance, to withdraw the AI system from the market, or to recall it within a period the market surveillance authority may prescribe, and in any event within the shorter of 15 working days, or as provided for in the relevant Union harmonisation legislation. The market surveillance authority shall inform the relevant notified body accordingly. Article 18 of Regulation (EU) 2019/1020 shall apply to the measures referred to in the second subparagraph of this paragraph.
- Art. 82, 1.** Where, having performed an evaluation under Article 79, after consulting the relevant national public authority referred to in Article 77(1), the market surveillance authority of a Member State finds that although a high-risk AI system complies with this Regulation, it nevertheless presents a risk to the health or safety of persons, to fundamental rights, or to other aspects of public interest protection, it shall require the relevant operator to take all appropriate measures to ensure that the AI system concerned, when placed on the market or put into service, no longer presents that risk without undue delay, within a period it may prescribe.
- Art. 86, 1.** Any affected person subject to a decision which is taken by the deployer on the basis of the output from a high-risk AI system listed in Annex III, with the exception of systems listed under point 2 thereof, and which produces legal effects or similarly significantly affects that person in a way that they consider to have an adverse impact on their health, safety or fundamental rights shall have the right to obtain from the deployer clear and meaningful explanations of the role of the AI system in the decision-making procedure and the main elements of the decision taken.
- Art. 112, 10.** The Commission shall, if necessary, submit appropriate proposals to amend this Regulation, in particular taking into account developments in technology, the effect of AI systems on health and safety, and on fundamental rights, and in light of the state of progress in the information society.

Terms and AI Act Articles

87 General-purpose AI model

- Art. 1. 2(e):** harmonised rules for the placing on the market of general-purpose AI models;
- Art. 2. 1(a):** providers placing on the market or putting into service AI systems or placing on the market general-purpose AI models in the Union, irrespective of whether those providers are established or located within the Union or in a third country;
- Art. 3. (3):** 'provider' means a natural or legal person, public authority, agency or other body that develops an AI system or a general-purpose AI model or that has an AI system or a general-purpose AI model developed and places it on the market or puts the AI system into service under its own name or trademark, or pays or receives payment for the placing on the market or putting into service of the AI system;
- Art. 3. (5):** 'authorised representative' means a natural or legal person located or established in the Union who has received and accepted a written mandate from a provider of an AI system or a general-purpose AI model to, respectively, perform and carry out on its behalf the obligations and procedures established by this Regulation;
- Art. 3. (6):** 'placing on the market' means the first making available of an AI system or a general-purpose AI model on the Union market;
- Art. 3. (7):** 'making available on the market' means the supply of an AI system or a general-purpose AI model for distribution or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge;
- Art. 3. (47):** 'AI Office' means the Commission's function of contributing to the implementation, monitoring and supervision of AI systems and general-purpose AI models, and AI governance, provided for in Commission Decision of 24 January 2024; references in this Regulation to the AI Office shall be construed as references to the Commission;
- Art. 3. (63):** 'general-purpose AI model' means an AI model, including where such an AI model is trained with a large amount of data using self-supervision at scale, that displays significant generality and is capable of competently performing a wide range of distinct tasks regardless of the way the model is placed on the market and that can be integrated into a variety of downstream systems or applications, except AI models that are used for research, development or prototyping activities before they are placed on the market;
- Art. 3. (64):** 'high-risk AI system' means a general-purpose AI model placed on the market or put into service in the Union that meets the relevant requirements or obligations laid down in this Regulation. The Commission shall request the European standardisation organisations to provide evidence of their best efforts to fulfil the objectives referred to in the first and the second subparagraph of this paragraph in accordance with Article 24 of Regulation (EU) No 1025/2012.
- Art. 3. (65):** 'systemic risk' means a risk that is specific to the high-impact capabilities of general-purpose AI models, having a significant impact on the Union market due to their reach, or due to actual or reasonably foreseeable negative effects on public health, safety, public security, fundamental rights, or the society as a whole, that can be propagated at scale across the value chain.
- Art. 3. (66):** 'general-purpose AI model' means a general-purpose AI model and which has the capability to serve a variety of purposes, both for direct use as well as for integration in other AI systems;
- Art. 25. 4.** The provider of a high-risk AI system and the third party that supplies an AI system, tools, services, components, or processes that are used or integrated in a high-risk AI system shall, by written agreement, specify the necessary information, capabilities, technical access and other assistance based on the generally acknowledged state of the art, in order to enable the provider of the high-risk AI system to fully comply with the obligations set out in this Regulation. This paragraph shall not apply to third parties making accessible to the public tools, services, components or processes that are used for or integrated into high-risk AI systems. When developing those voluntary model terms, the AI Office shall take into account possible contractual requirements applicable in specific sectors or business cases. The voluntary model terms shall be published and be available free of charge in an easily usable electronic format.
- Art. 40. 1.** High-risk AI systems of general-purpose AI models which are in conformity with harmonised standards or parts thereof the references of which have been published in the Official Journal of the European Union in accordance with Regulation (EU) No 1025/2012 shall be presumed to be in conformity with the requirements set out in Section 2 of this Chapter or, as applicable, with the obligations set out in Chapter V, Sections 2 and 3, of this Regulation, to the extent that those standards cover those requirements or obligations.
- Art. 40. 2.** In accordance with Article 10 of Regulation (EU) No 1025/2012, the Commission shall issue, without undue delay, standardisation requests covering obligations set out in Chapter V, Sections 2 and 3 of this Regulation. The standardisation request shall also ask for deliverables on reporting and documentation processes to improve AI systems' resource performance, such as reducing the high-risk AI system's consumption of energy and of other resources during its lifecycle, and on the energy-efficient development of general-purpose AI models. When preparing a standardisation request, the Commission shall consult the Board and relevant stakeholders, including the advisory forum. When issuing a standardisation request to European standardisation organisations, the Commission shall specify that standards have to be clear, consistent, including with the standards developed in the various sectors for products covered by the existing Union harmonisation legislation listed in Annex I, and aiming to ensure that high-risk AI systems or general-purpose AI models placed on the market or put into service in the Union meet the relevant requirements or obligations laid down in this Regulation. The Commission shall request the European standardisation organisations to provide evidence of their best efforts to fulfil the objectives referred to in the first and the second subparagraph of this paragraph in accordance with Article 24 of Regulation (EU) No 1025/2012.
- Art. 41. 3.** High-risk AI systems or general-purpose AI models which are in conformity with the common specifications referred to in paragraph 1, or parts of those specifications, shall be presumed to be in conformity with the requirements set out in Section 2 of this Chapter or, as applicable, to comply with the obligations referred to in Sections 2 and 3 of Chapter V, to the extent those common specifications cover those requirements or those obligations.
- Art. 41. 5.** Where providers of high-risk AI systems or general-purpose AI models do not comply with the common specifications referred to in paragraph 1, they shall duly justify that they have adopted technical solutions that meet the requirements referred to in Section 2 of this Chapter
- CHAPTER V: GENERAL PURPOSE AI MODELS**
- Art. 51:** Classification of general-purpose AI models as general-purpose AI models with systemic risk
- Art. 51. 1.** A general-purpose AI model shall be classified as a general-purpose AI model with systemic risk if it meets any of the following conditions:
- Art. 51. 2.** A general-purpose AI model shall be presumed to have high impact capabilities pursuant to paragraph 1, point (a), when the cumulative amount of computation used for its training measured in floating point operations is greater than 1025.
- Art. 52. 1.** Where a general-purpose AI model meets the condition referred to in Article 51(1), point (a), the relevant provider shall notify the Commission without delay and in any event within two weeks after that requirement is met or it becomes known that it will be met. That notification shall include the necessary information to demonstrate that the model does not present systemic risks.
- Art. 52. 2.** The provider of a general-purpose AI model that meets the condition referred to in Article 51(1), point (a), may present with its notification, sufficiently substantiated arguments to demonstrate that, exceptionally, although it meets that requirement, the general-purpose AI model does not present, due to its specific characteristics, systemic risks and therefore should not be classified as a general-purpose AI model with systemic risk.
- Art. 52. 3.** Where the Commission considers that the provider of a general-purpose AI model does not present, due to its specific characteristics, systemic risks, it shall reject those arguments, and the general-purpose AI model shall be considered to be a general-purpose AI model with systemic risk.
- Art. 52. 4.** The Commission may designate a general-purpose AI model as presenting systemic risks, ex officio or following a qualified alert from the scientific panel pursuant to Article 90(1), point (a), on the basis of criteria set out in Annex XIII. The Commission is empowered to adopt Chapter V, Sections 2 and 3 of this Regulation. The standardisation request shall also ask for deliverables on reporting and documentation processes to improve AI systems' resource performance, such as reducing the high-risk AI system's consumption of energy and of other resources during its lifecycle, and on the energy-efficient development of general-purpose AI models. When preparing a standardisation request, the Commission shall consult the Board and relevant stakeholders, including the advisory forum. When issuing a standardisation request to European standardisation organisations, the Commission shall specify that standards have to be clear, consistent, including with the standards developed in the various sectors for products covered by the existing Union harmonisation legislation listed in Annex I, and aiming to ensure that high-risk AI systems or general-purpose AI models placed on the market or put into service in the Union meet the relevant requirements or obligations laid down in this Regulation. The Commission shall request the European standardisation organisations to provide evidence of their best efforts to fulfil the objectives referred to in the first and the second subparagraph of this paragraph in accordance with Article 24 of Regulation (EU) No 1025/2012.
- Art. 52. 5.** Upon a reasoned request of a provider whose model has been designated as a general-purpose AI model with systemic risk pursuant to paragraph 4, the Commission shall take the request into account and may decide to reassess whether the general-purpose AI model can still be considered to present systemic risks on the basis of the criteria set out in Annex XIII. Such a request shall contain objective, detailed and new reasons that have arisen since the designation decision. Providers may request reassessment at the earliest six months after the decision of the Commission. Where the Commission follows its reassessment, it decides to maintain the designation as a general-purpose AI model with systemic risk, providers may request reassessment at the earliest six months after that decision.
- Art. 52. 6.** The Commission shall ensure that a list of general-purpose AI models with systemic risk is published and shall keep that list up to date, without prejudice to the need to observe and protect intellectual property rights and confidential business information or trade secrets in accordance with Union and national law.
- SECTION 2: Obligations for providers of general-purpose AI models**
- Art. 53: Obligations for providers of general-purpose AI models**
- Art. 53. 1:** Providers of general-purpose AI models shall:
- Art. 53. 1(a):** draw up, keep up-to-date and make available to providers of AI systems who intend to integrate the general-purpose AI model into their AI systems, without prejudice to the need to observe and protect intellectual property rights and confidential business information or trade secrets in accordance with Union and national law, the information and documentation shall:
- Art. 53. 1(b):** enable providers of AI systems to have a good understanding of the capabilities and limitations of the general-purpose AI model and to comply with their obligations pursuant to this Regulation; and
- Art. 53. 1(c):** draw up and make available to providers of AI systems a sufficiently detailed summary about the content used for training of the general-purpose AI model, according to a template provided by the AI Office.
- Art. 53. 2:** The obligations set out in paragraph 1, points (a) and (b), shall not apply to providers of AI models that are released under a free and open-source licence that allows for the access, usage, modification, and distribution of the model, and whose parameters, including the weights, the information on the model architecture, and the information on model usage, are made publicly available. This exception shall not apply to general-purpose AI models with systemic risks.
- Art. 53. 3:** Providers of general-purpose AI models may rely on codes of practice within the meaning of Article 56 to demonstrate compliance with the obligations set out in paragraph 1 of this Article, until a harmonised standard is published. Compliance with European harmonised standards grants providers the presumption of conformity to the extent that those standards cover those obligations. Providers of general-purpose AI models with systemic risks who do not adhere to an approved code of practice or do not comply with a European harmonised standard shall demonstrate alternative adequate means of compliance for assessment by the Commission.
- Art. 53. 4:** Authorised representatives of providers of general-purpose AI models
- Art. 54. 1:** Prior to placing a general-purpose AI model on the Union market, providers established in third countries shall, by written mandate, appoint an authorised representative which is established in the Union.
- Art. 54. 2:** Providers shall keep a copy of the information specified in Annex XI at the disposal of the AI Office and national competent authorities, for a period of 10 years after the general-purpose AI model has been placed on the market, and the contact details of the provider that appointed the authorised representative;
- Art. 54. 3(a):** cooperate with the AI Office and competent authorities, upon a reasoned request, in any action they take in relation to the general-purpose AI model, including when the model is integrated into AI systems placed on the market or put into service in the Union.
- Art. 54. 3:** The obligation to keep a copy of the information specified in Annex XI at the disposal of the AI Office and national competent authorities, for a period of 10 years after the general-purpose AI model has been placed on the market, and whose parameters, including the weights, the information on the model architecture, and the information on model usage, are made publicly available, unless the general-purpose AI models present systemic risks.
- SECTION 3: Obligations of providers of general-purpose AI models with systemic risk**
- Art. 55: Obligations of providers of general-purpose AI models with systemic risk**
- Art. 55. 1:** In addition to the obligations listed in Articles 53 and 54, providers of general-purpose AI models with systemic risk shall:
- Art. 55. 1(a):** assess and mitigate possible systemic risks at Union level, including the outcomes, that may stem from the development, the placing on the market, or the use of general-purpose AI models with systemic risk;
- Art. 55. 1(b):** ensure an adequate technical description of the general-purpose AI model with systemic risk and the physical infrastructure of the model;
- Art. 55. 2:** Providers of general-purpose AI models with systemic risk may rely on codes of practice within the meaning of Article 56 to demonstrate compliance with the obligations set out in paragraph 1 of this Article, until a harmonised standard is published. Compliance with European harmonised standards grants providers the presumption of conformity to the extent that those standards cover those obligations. Providers of general-purpose AI models with systemic risks who do not adhere to an approved code of practice or do not comply with a European harmonised standard shall demonstrate alternative adequate means of compliance for assessment by the Commission.
- Art. 56. 3:** The AI Office may invite all providers of general-purpose AI models, as well as relevant national competent authorities, to participate in the drawing-up of codes of practice. Civil society organisations, industry, academia and other relevant stakeholders, such as downstream providers and independent experts, may support the process.
- Art. 56. 7:** The AI Office may invite all providers of general-purpose AI models to adhere to the codes of practice. For providers of general-purpose AI models not presenting systemic risks this adherence may be limited to the obligations provided for in Article 53, unless they declare explicitly their interest to join the full code.
- Art. 66. (c):** provide advice on the implementation of this Regulation, in particular as regards the enforcement of rules on general-purpose AI models;
- Art. 66. (d):** provide opinions to the Commission on the qualified alerts regarding general-purpose AI models;
- Art. 66. (e):** receive opinions by the Member States on qualified alerts regarding general-purpose AI models, and on national experiences and practices on the monitoring and enforcement of AI systems, in particular systems integrating the general-purpose AI models.
- Art. 68. (a):** independence from any provider of AI systems or general-purpose AI models;
- Art. 68. 3(a):** supporting the implementation and enforcement of this Regulation as regards general-purpose AI models and systems, in particular by:
- Art. 68. 3(a)(i):** alerting the AI Office of possible systemic risks at Union level of general-purpose AI models, in accordance with Article 90;
- Art. 68. 3(a)(ii):** contributing to the development of tools and methodologies for evaluations of the capabilities of general-purpose AI models and systems, including through benchmarks;
- Art. 68. 3(a)(iii):** providing advice on the classification of general-purpose AI models with systemic risk;
- Art. 68. 3(a)(iv):** providing advice on the classification of various general-purpose AI models and systems;
- Art. 75. 1:** Where an AI system is based on a general-purpose AI model, and the model and the system are developed by the same provider, the AI Office shall have powers to monitor and supervise compliance of that AI system with obligations under this Regulation. To carry out its monitoring and supervision tasks, the AI Office shall have all the powers of a market surveillance authority provided for in this Section and Regulation (EU) 2019/1020.
- Art. 75. 3:** Where a market surveillance authority is unable to conclude its investigation of the high-risk AI system because of its inability to access certain information related to the general-purpose AI model despite having made all appropriate efforts to obtain that information, it may submit a reasoned request to the AI Office, by which access to that information shall be enforced. In that case, the AI Office shall supply to the applicant authority without delay, and in any event within 30 days, any information that the AI Office considers to be relevant in order to establish whether a high-risk AI system is non-compliant. Market surveillance authorities shall safeguard the confidentiality of the information that they obtain in accordance with Article 78 of this Regulation. The procedure provided for in Chapter VI of Regulation (EU) 2019/1020 shall apply mutatis mutandis.
- SECTION 5: Supervision, investigation, enforcement and monitoring in respect of providers of general-purpose AI models**
- Art. 88: Enforcement of the obligations of providers of general-purpose AI models**
- Art. 89. 1:** For the purpose of carrying out the tasks assigned to it under this Section, the AI Office may take the necessary actions to monitor the effective implementation and compliance with this Regulation by providers of general-purpose AI models, including their adherence to approved codes of practice.
- Art. 89. 2(a):** the point of contact of the provider of the general-purpose AI model concerned;
- Art. 89. 2(b):** a description of the relevant facts, the provisions of this Regulation concerned, and the reason why the downstream provider considers that the provider of the general-purpose AI model concerned infringed this Regulation;
- Art. 90. 1(a):** a general-purpose AI model poses concrete identifiable risk at Union level; or
- Art. 90. 1(b):** a general-purpose AI model meets the conditions referred to in Article 51.
- Art. 90. 3(a):** the point of contact of the provider of the general-purpose AI model with systemic risk concerned;
- Art. 91. 1:** The Commission may request the provider of the general-purpose AI model concerned to provide the documentation drawn up by the provider in accordance with Articles 53 and 55, or any additional information that is necessary for the purpose of assessing compliance of the provider with this Regulation.
- Art. 91. 2:** Before sending the request for information, the AI Office may initiate a structured dialogue with the provider of the general-purpose AI model.
- Art. 91. 3:** Upon a duly substantiated request from the scientific panel, the Commission may issue a request for information to a provider of a general-purpose AI model, where the access to information is necessary and proportionate for the fulfilment of the tasks of the scientific panel under Article 68(2).
- Art. 91. 5:** The provider of the general-purpose AI model concerned, or its representative shall supply the information requested. In the case of legal persons, companies or firms, or where the provider has no legal personality, the persons authorised to represent them by law or by their statutes, shall supply the information requested on behalf of the provider of the general-purpose AI model concerned. Lawyers duly authorised to act may supply information on behalf of their clients. The clients shall nevertheless remain fully responsible if the information supplied is incomplete, incorrect or misleading.
- Art. 92. 1:** The AI Office, after consulting the Board, may conduct evaluations of the general-purpose AI model concerned;
- Art. 92. 1(b):** to investigate systemic risks at Union level of general-purpose AI models with systemic risk, in particular following a qualified alert from the scientific panel in accordance with Article 90(1), point (a).
- Art. 92. 3:** For the purposes of paragraph 1, the Commission may request access to the general-purpose AI model concerned through APIs or further appropriate technical means and tools, including source code.
- Art. 92. 5:** The providers of the general-purpose AI model concerned or its representative shall supply the information requested. In the case of legal persons, companies or firms, or where the provider has no legal personality, the persons authorised to represent them by law or by their statutes, shall provide the access requested on behalf of the provider of the general-purpose AI model concerned.
- Art. 92. 7:** Prior to requesting access to the general-purpose AI model concerned, the AI Office may initiate a structured dialogue with the provider of the general-purpose AI model to gather more information on the internal testing of the model, internal safeguards for preventing systemic risks, and other internal procedures and measures the provider has taken to mitigate such risks.
- Art. 93. 2:** Before a measure is requested, the AI Office may initiate a structured dialogue with the provider of the general-purpose AI model.
- Art. 93. 3:** If, during the structured dialogue referred to in paragraph 2, the provider of the general-purpose AI model with systemic risk offers commitments to implement mitigation measures to address a systemic risk at Union level, the Commission may, by decision, make those commitments binding and enforceable if there is no further ground for action.
- Art. 94:** Procedural rights of economic operators of the general-purpose AI model
- Art. 94:** Article 18 of Regulation (EU) 2019/1020 shall apply mutatis mutandis to the providers of the general-purpose AI model, without prejudice to more specific procedural rights provided for in this Regulation.
- Art. 101:** Fines for providers of general-purpose AI models
- Art. 101. 1:** The Commission may impose on providers of general-purpose AI models fines not exceeding 3 % of their annual total worldwide turnover in the preceding financial year or EUR 15 000 000, whichever is higher., when the Commission finds that the provider intentionally or negligently:
- Art. 101. 1(d):** failed to make available to the Commission access to the general-purpose AI model or general-purpose AI model with systemic risk with a view to conducting an evaluation pursuant to Article 92. In fixing the amount of the fine or periodic penalty payment, regard shall be had to the nature, gravity and duration of the infringement, taking due account of the principles of proportionality and appropriateness. The Commission shall also take into account commitments made in accordance with Article 93(3) or made in relevant codes of practice in accordance with Article 56.
- Art. 101. 2:** Before adopting the decision pursuant to paragraph 1, the Commission shall communicate its preliminary findings to the provider of the general-purpose AI model and give it an opportunity to be heard.
- Art. 111:** AI systems already placed on the market or put into service and general-purpose AI models already placed on the market
- Art. 111. 3:** Providers of general-purpose AI models that have been placed on the market before 2 August 2025 shall take the necessary steps in order to comply with the obligations laid down in this Regulation by 2 August 2027.
- Art. 111. 6:** By 2 August 2025 and every two years thereafter, the Commission shall submit a report on the review of the progress on the development of standardisation deliverables on the energy-efficient development of general-purpose AI models, and assess the need for further measures or actions, including binding measures or actions. The report shall be submitted to the European Parliament and to the Council, and it shall be made public.

0 Generative AI

Terms and AI Act Articles

17 Governance

Art. 1, 2(f): rules on market monitoring, market surveillance, governance and enforcement;
Art. 3, (47): 'AI Office' means the Commission's function of contributing to the implementation, monitoring and supervision of AI systems and general-purpose AI models, and AI governance, provided for in Commission Decision of 24 January 2024; references in this Regulation to the AI Office shall be construed as references to the Commission;
Art. 10: Data and data governance
Art. 10, 2: Training, validation and testing data sets shall be subject to data governance and management practices appropriate for the intended purpose of the high-risk AI system. Those practices shall concern in particular:
Art. 17, 4: For providers that are financial institutions subject to requirements regarding their internal governance, arrangements or processes under Union financial services law, the obligation to put in place a quality management system, with the exception of paragraph 1, points (g), (h) and (i) of this Article, shall be deemed to be fulfilled by complying with the rules on internal governance arrangements or processes pursuant to the relevant Union financial services law. To that end, any harmonised standards referred to in Article 40 shall be taken into account.
Art. 18, 3: Providers that are financial institutions subject to requirements regarding their internal governance, arrangements or processes under Union financial services law shall maintain the technical documentation as part of the documentation kept under the relevant Union financial services law.
Art. 18, 4: Providers that are financial institutions subject to requirements regarding their internal governance, arrangements or processes under Union financial services law shall maintain the logs automatically generated by their high-risk AI systems as part of the documentation kept under the relevant financial services law.
Art. 26, 5: Deployers shall monitor the operation of the high-risk AI system on the basis of the instructions for use and, where relevant, inform providers in accordance with Article 72. Where deployers have reason to consider that the use of the high-risk AI system in accordance with the instructions may result in that AI system presenting a risk within the meaning of Article 73(1), they shall, without undue delay, inform the provider or distributor and the relevant market surveillance authority, and shall suspend the use of that system. Where deployers have identified a serious incident, they shall also immediately inform first the provider, and then the importer or distributor and the relevant market surveillance authorities of that incident. If the deployer is not able to reach the provider, Article 73 shall apply mutatis mutandis. This obligation shall not cover sensitive operational data of deployers of AI systems which are law enforcement authorities. For deployers that are financial institutions subject to requirements regarding their internal governance, arrangements or processes under Union financial services law, the monitoring obligation set out in the first subparagraph shall be deemed to be fulfilled by complying with the rules on internal governance arrangements or processes pursuant to the relevant financial services law.
Art. 26, 6: Deployers of high-risk AI systems shall keep the logs automatically generated by that high-risk AI system to the extent such logs are under their control, for a period appropriate to the intended purpose of the high-risk AI system, of at least six months, unless provided otherwise in applicable Union or national law, in particular in Union law on the protection of personal data. Deployers that are financial institutions subject to requirements regarding their internal governance, arrangements or processes under Union financial services law shall maintain the logs as part of the documentation kept pursuant to the relevant Union financial services law.
Art. 27, 1(f): the measures to be taken in the case of the materialisation of those risks, including the arrangements for internal governance and complaint mechanisms.
Art. 40, 3: The participants in the standardisation process shall seek to promote investment and innovation in AI, including through increasing legal certainty, as well as the competitiveness and growth of the Union market, to contribute to strengthening global cooperation on standardisation and taking into account existing international standards in the field of AI that are consistent with Union values, fundamental rights and interests, and to enhance multi-stakeholder governance ensuring a balanced representation of interests and the effective participation of all relevant stakeholders in accordance with Articles 5, 6, and 7 of Regulation (EU) No 1025/2012.
SECTION VII: GOVERNANCE
SECTION 1: Governance at Union level
Art. 72, 4: For high-risk AI systems covered by the Union harmonisation legislation listed in Section A of Annex I, where a post-market monitoring system and plan are already established under that legislation, in order to ensure consistency, avoid duplications and minimise additional burdens, providers shall have a choice of integrating, as appropriate, the necessary elements described in paragraphs 1, 2, and 3 using the template referred in paragraph 3 into systems and plans already existing under that legislation, provided that it achieves an equivalent level of protection. The first subparagraph of this paragraph shall also apply to high-risk AI systems referred to in point 5 of Annex III placed on the market or put into service by financial institutions that are subject to requirements under Union financial services law regarding their internal governance, arrangements or processes.
Art. 95, 1: The AI Office and the Member States shall encourage and facilitate the drawing up of codes of conduct, including related governance mechanisms, intended to foster the voluntary application to AI systems, other than high-risk AI systems, of some or all of the requirements set out in Chapter III, Section 2, taking into account the availability of such instruments for the application of such requirements.
Art. 112, 2(c): amendments enhancing the effectiveness of the supervision and governance system.
Art. 112, 10: Any amendment to this Regulation pursuant to paragraph 10, or relevant delegated or implementing acts, which concerns sectoral Union harmonisation legislation listed in Section B of Annex I shall take into account the regulatory specificities of each sector, and the existing governance, conformity assessment and enforcement mechanisms and authorities established therein.

0 Governing body

1 Harmful effect

Art. 1, 1: The purpose of this Regulation is to improve the functioning of the internal market and promote the uptake of human-centric and trustworthy artificial intelligence (AI), while ensuring a high level of protection of health, safety, fundamental rights enshrined in the Charter, including democracy, the rule of law and environmental protection, against the harmful effects of AI systems in the Union and supporting innovation.

24 Harmonised standard

Art. 3, (27): 'harmonised standard' means a harmonised standard as defined in Article 2(1), point (c), of Regulation (EU) No 1025/2012;
Art. 17, 1(e): technical specifications, standards, or applied codes, where the harmonised standard are not applied in full or do not cover all of the relevant requirements set out in Section 2, the means to be used to ensure that the high-risk AI system complies with those requirements;
Art. 17, 4: For providers that are financial institutions subject to requirements regarding their internal governance, arrangements or processes under Union financial services law, the obligation to put in place a quality management system, with the exception of paragraph 1, points (g), (h) and (i) of this Article, shall be deemed to be fulfilled by complying with the rules on internal governance arrangements or processes pursuant to the relevant Union financial services law. To that end, any harmonised standards referred to in Article 40 shall be taken into account.
Art. 32: Where a conformity assessment body demonstrates its conformity with the criteria laid down in the relevant harmonised standards or parts thereof, the references of which have been published in the Official Journal of the European Union, it shall be presumed to comply with the requirements set out in Article 31 in so far as the applicable harmonised standards cover those requirements.
Art. 40, 1: High-risk AI systems or general-purpose AI models which are in conformity with harmonised standards or parts thereof the references of which have been published in the Official Journal of the European Union in accordance with Regulation (EU) No 1025/2012 shall be deemed to be in conformity with the requirements set out in Section 2 of this Chapter, or, as applicable, with the obligations set out in Chapter V, Sections 2 and 3, of this Regulation, to the extent that those standards cover those requirements or obligations.
Art. 41, 1(a): the Commission has requested, pursuant to Article 10(1), Regulation (EU) No 1025/2012, one or more European standardisation organisations to draft a harmonised standard for the requirements set out in Section 2 of this Chapter, or, as applicable, for the obligations set out in Sections 2 and 3 of Chapter V, and:
Art. 41, 1(a)(i): the harmonised standards addressing that request are not delivered within the deadline set in accordance with Article 10(1) of Regulation (EU) No 1025/2012; or
Art. 41, 1(a)(ii): the relevant harmonised standards insufficiently address fundamental rights concerns; or
Art. 41, 1(a)(iii): the harmonised standards do not comply with the request; and
Art. 41, 1(b): no reference to harmonised standards covering the requirements referred to in Section 2 of this Chapter or, as applicable, the obligations referred to in Sections 2 and 3 of Chapter V has been published in the Official Journal of the European Union in accordance with Regulation (EU) No 1025/2012, and no such reference is expected to be published within a reasonable period. When drafting the common specifications, the Commission shall consult the advisory forum referred to in Article 67. The implementing acts referred to in the first subparagraph of this paragraph shall be adopted in accordance with the examination procedure referred to in Article 98(2).
Art. 41, 4: Where a harmonised standard is adopted by a European standardisation organisation and proposed to the Commission for the publication of its reference in the Official Journal of the European Union, the Commission shall assess the harmonised standard in accordance with Regulation (EU) No 1025/2012. When reference to a harmonised standard is published in the Official Journal of the European Union, the Commission shall repeal the implementing acts referred to in paragraph 1, or parts thereof which cover the same requirements set out in Section 2 of this Chapter or, as applicable, the same obligations set out in Sections 2 and 3 of Chapter V.
Art. 43, 1: For high-risk AI systems or general-purpose AI models which rely on the compliance of a high-risk AI system with the requirements set out in Section 2, the provider has applied harmonised standards referred to in Article 40, or, where applicable, common specifications referred to in Article 41, the provider shall opt for one of the following conformity assessment procedures based on:
Art. 43, 1(a): harmonised standards referred to in Article 40 do not exist, and common specifications referred to in Article 41 are not available;
Art. 43, 1(b): the provider has not applied, or has applied only part of, the harmonised standard;
Art. 43, 1(c): one or more of the harmonised standards referred to in point (a) has been published with a restriction, and only on the part of the standard that was restricted. For the purposes of the conformity assessment procedure referred to in Annex VII, the provider may choose any of the notified bodies. However, where the high-risk AI system is intended to be put into service by law enforcement, immigration or asylum authorities or by Union institutions, bodies, offices or agencies, the market surveillance authority referred to in Article 74(8) or (9), as applicable, shall act as a notified body.
Art. 43, 2: For high-risk AI systems covered by the Union harmonisation legislation listed in Section A of Annex I, the provider shall follow the relevant conformity assessment procedure as required under those legal acts. The requirements set out in Section 2 of this Chapter shall apply to those high-risk AI systems and shall be part of that assessment. Points 4.3., 4.4., 4.5. and the fifth paragraph of point 4.6 of Annex VII shall also apply. For the purposes of that assessment, notified bodies which have been notified under those legal acts shall be entitled to control the level of protection of health, safety and fundamental rights conferred by a product or of a system with the meaning of Article 31(4), (5), (10) and (11) has been assessed in the context of the notification procedure under those legal acts. Where a legal act listed in Section A of Annex I enables the product manufacturer to opt out from a third-party conformity assessment, provided that that manufacturer has applied all harmonised standards covering all the relevant requirements, that manufacturer may use that option only if it has also applied harmonised standards or, where applicable, common specifications referred to in Article 41, covering all requirements set out in Section 2 of this Chapter.
Art. 43, 3: Providers of general-purpose AI models may rely on codes of practice with the meaning of Article 56 to demonstrate compliance with the obligations set out in paragraph 1 of this Article, until a harmonised standard is published. Compliance with European harmonised standards grants providers the presumption of conformity to the extent that those standards cover those obligations. Providers of general-purpose AI models who do not adhere to an approved code of practice or do not comply with a European harmonised standard shall demonstrate alternative adequate means of compliance for assessment by the Commission.
Art. 43, 4: Providers of general-purpose AI models who do not adhere to an approved code of practice with the meaning of Article 56 to demonstrate compliance with the obligations set out in paragraph 1 of this Article, until a harmonised standard is published. Compliance with European harmonised standards grants providers the presumption of conformity to the extent that those standards cover those obligations. Providers of general-purpose AI models with systemic risks who do not adhere to an approved code of practice or do not comply with a European harmonised standard shall demonstrate alternative adequate means of compliance for assessment by the Commission.
Art. 65, 6(a)(v): on the use of harmonised standards or common specifications referred to in Articles 40 and 41;
Art. 79, 8(c): shortcomings in the harmonised standards or common specifications referred to in Articles 40 and 41 conferring a presumption of conformity;
Art. 81, 3: Where the natural measure is considered justified and the non-compliance of the AI system is attributed to shortcomings in the harmonised standards or common specifications referred to in Articles 40 and 41 of this Regulation, the Commission shall apply the procedure provided for in Article 11 of Regulation (EU) No 1025/2012;
Art. 96, 1(f): the application of the definition of an AI system as set out in Article 3, point (1). When issuing such guidelines, the Commission shall pay particular attention to the needs of SMEs including start-ups, of local public authorities and of the sectors most likely to be affected by this Regulation. The guidelines referred to in the first subparagraph of this paragraph shall take due account of the generally acknowledged state of the art on AI, as well as of relevant harmonised standards and common specifications that are referred to in Articles 40 and 41, or of those harmonised standards or technical specifications that are set out pursuant to Union harmonisation law.
Art. 112, 4(c): adopted harmonised standards and common specifications developed to support this Regulation;

31 Health (See also: Examination of biases, health and safety of persons, Safety)

Art. 1, 1: The purpose of this Regulation is to improve the functioning of the internal market and promote the uptake of human-centric and trustworthy artificial intelligence (AI), while ensuring a high level of protection of health, safety, fundamental rights enshrined in the Charter, including democracy, the rule of law and environmental protection, against the harmful effects of AI systems in the Union and supporting innovation.
Art. 3, (14): 'safety components' means any part of a product or of a system which fulfils a safety function for that product or AI system, or the failure or malfunctioning of which endangers the health and safety of persons or property;
Art. 3, (49a): the death of a person, or serious harm to a person's health;
Art. 3, (65): 'systemic risk' means a risk that is specific to the high-impact capabilities of general-purpose AI models, having a significant impact on the Union market due to their reach, or due to actual or reasonably foreseeable negative effects on public health, safety, public security, fundamental rights, or the society as a whole, that can be propagated at scale across the value chain.
Art. 6, 3: By derogation from paragraph 2, an AI system referred to in Annex III shall not be considered to be high-risk where it does not pose a significant risk of harm to the health, safety or fundamental rights of natural persons, including by not materially influencing the outcome of decision making. The first subparagraph shall apply where any of the following conditions is fulfilled:
Art. 6, 3, (a): The Commission shall adopt delegated acts in accordance with Article 97 in order to amend paragraph 3, second subparagraph, of this Article by adding new conditions to those laid down therein, or by modifying them, where there is concrete and reliable evidence of the existence of AI systems that fall under the scope of Annex III, but do not pose a significant risk of harm to the health, safety or fundamental rights of natural persons.
Art. 6, 7: The Commission shall adopt delegated acts in accordance with Article 97 in order to amend paragraph 3, second subparagraph, of this Article by deleting any of the conditions laid down therein, where there is concrete and reliable evidence that this is necessary to maintain the level of protection of health, safety and fundamental rights provided for by this Regulation.
Art. 6, 8: Any amendment to the conditions laid down in paragraph 3, second subparagraph, adopted in accordance with paragraphs 6 and 7 of this Article shall not decrease the overall level of protection of health, safety and fundamental rights provided for by this Regulation and shall ensure consistency with the delegated acts adopted pursuant to Article 71(1), and take account of market and technological developments.
Art. 7, 1(b): the AI systems pose a risk of harm to health and safety, or an adverse impact on fundamental rights, and that risk is equivalent to, or greater than, the risk of harm or of adverse impact posed by the high-risk AI systems already referred to in Annex III.
Art. 7, 2(e): the extent to which the use of an AI system has already caused harm to health and safety, has had an adverse impact on fundamental rights or has given rise to significant concerns in relation to the likelihood of such harm or adverse impact, as demonstrated, for example, by reports or documented allegations submitted to national competent authorities or by other reports, as appropriate.
Art. 7, 2(i): the extent to which the outcomes produced involving an AI system is easily corrigible or reversible, taking into account the technical solutions available to correct or reverse it, whereby outcomes having an adverse impact on health, safety or fundamental rights, shall not be considered to be easily corrigible or reversible;
Art. 7, 3(a): the high-risk AI system concerned no longer poses any significant risks to fundamental rights, health or safety, taking into account the criteria listed in paragraph 2;
Art. 7, 3(b): the deletion does not decrease the overall level of protection of health, safety and fundamental rights under Union law.
Art. 9, 2(a): the identification and analysis of the known and the reasonably foreseeable risks that the high-risk AI system can pose to health, safety or fundamental rights when the high-risk AI system is used in accordance with its intended purpose;
Art. 10, 3(b): examination in view of possible biases that are likely to affect the health and safety of persons, have a negative impact on fundamental rights or lead to discrimination prohibited under Union law, especially where data outputs influence inputs for future operations;
Art. 13, 3(a)(iii): any known or foreseeable circumstance, related to the use of the high-risk AI system in accordance with its intended purpose or under conditions of reasonably foreseeable misuse, which may lead to risks to the health and safety or fundamental rights referred to in Article 9(2);
Art. 14, 2: Human oversight shall aim to prevent or minimise the risks to health, safety or fundamental rights that may emerge when a high-risk AI system is used in accordance with its intended purpose or under conditions of reasonably foreseeable misuse, in particular where such risks persist despite the application of other requirements set out in this Section.
Art. 36, 7(e): provide the national competent authorities of the Member State in which the provider has its registered place of business with all relevant information about the certificates of which it has required the suspension or withdrawal; that authority shall take the appropriate measures, where necessary, to avoid a potential risk to health, safety or fundamental rights.
Art. 36, 8(a): the notifying authority has confirmed, within one month of the suspension or restriction, that there is no risk to health, safety or fundamental rights in relation to certificates affected by the suspension or restriction, and the notifying authority has outlined a timeline for actions to remedy the suspension or restriction; or
Art. 36, 8(b): the national competent authority of the Member State in which the provider of the high-risk AI system covered by the certificate has its registered place of business has confirmed that there is no risk to health, safety or fundamental rights associated with the high-risk AI systems concerned; and
Art. 43, 6: The Commission is empowered to adopt delegated acts in accordance with Article 97 in order to amend paragraphs 1 and 2 of this Article in order to subject high-risk AI systems referred to in points 2 to 8 of Annex III to the conformity assessment procedure referred to in Annex VI in preventing or minimising the risks to health and safety and protection of fundamental rights posed by such systems, as well as the availability of adequate capacities and resources among notified bodies.
Art. 46, 1: By way of derogation from Article 43 and upon a duly justified request, any market surveillance authority may authorise the placing on the market or the putting into service of specific high-risk AI systems within the territory of the Member State concerned, for exceptional cases of public security or safety, where necessary, to include an in-depth understanding of AI technologies, data and data computing, personal data protection, cybersecurity, fundamental rights, health and safety risks and knowledge of existing standards and legal requirements. Member States shall assess and, if necessary, update competence and resource requirements referred to in this paragraph on an annual basis.
Art. 75, 1: AI systems presenting a risk shall be understood as a 'product presenting a risk' as defined in Article 3, point 19 of Regulation (EU) 2019/1020, in so far as they present risks to the health or safety, or to fundamental rights, of persons.
Art. 82, 1: Where, having performed an evaluation under Article 79, after consulting the relevant national public authority referred to in Article 77(1), the market surveillance authority of a Member State finds that although a high-risk AI system complies with this Regulation, it nevertheless presents a risk to the health or safety of persons, to fundamental rights, or to other aspects of public interest protection, it shall require the relevant operator to take all appropriate measures to ensure that the AI system concerned, when placed on the market or put into service, no longer presents that risk without undue delay, within a period it may prescribe.
Art. 85, 1: Any affected person subject to a decision which is taken by the deployer on the basis of the output from a high-risk AI system listed in Annex III, with the exception of systems listed under point 2 thereof, and which produces legal effects or similarly significantly affects that person in a way that they consider to have an adverse impact on their health, safety or fundamental rights shall have the right to obtain from the deployer clear and meaningful explanations of the role of the AI system in the decision-making procedure and the main elements of the decision taken.
Art. 112, 10: The Commission shall, if necessary, submit appropriate proposals to amend this Regulation, in particular taking into account developments in technology, the effect of AI systems on health and safety, and on fundamental rights, and in light of the state of progress in the information society.

New

MAPPING & TERMINOLOGY

Standard

AI Act

AI Act sub-articles

Whereas

Annexes

Mapping & Terminology

The data presented have a value for research and not a legal value.

Alphabetical

ID



Technical Committee
533 AI



Hosting and developing

Terms and AI Act Articles

0 [Health risk](#)

0 [Healthcare](#)

Terms and AI Act Articles

Art. 80, 2: Where, in the course of that evaluation, the market surveillance authority finds that the AI system concerned is high-risk, it shall without undue delay require the relevant provider to take all necessary actions to bring the AI system into compliance with the requirements and obligations laid down in this Regulation, as well as take appropriate corrective action within a period the market surveillance authority may prescribe.

Art. 80, 7: Where, in the course of the evaluation pursuant to paragraph 1 of this Article, the market surveillance authority establishes that the AI system was misclassified by the provider as non-high-risk in order to circumvent the application of requirements in Chapter III, Section 2, the provider shall be subject to fines in accordance with Article 95.

Art. 82, 1: Where, having performed an evaluation under Article 79, after consulting the relevant national public authority referred to in Article 77(1), the market surveillance authority of a Member State finds that although a high-risk AI system complies with this Regulation, it nevertheless presents a risk to the health or safety of persons, to fundamental rights, or to other aspects of public interest protection, it shall require the relevant operator to take all appropriate measures to ensure that the AI system concerned, when placed on the market or put into service, no longer presents that risk without undue delay, within a period it may prescribe.

Art. 83, 2: Where non-compliance referred to in paragraph 1 persists, the market surveillance authority of the Member State concerned shall take appropriate and proportionate measures to restrict or prohibit the high-risk AI system being made available on the market or to ensure that it is recalled or withdrawn from the market without delay.

Art. 86, 2: Any affected person subject to a decision which is taken by the deployer on the basis of the output from a high-risk AI system listed in Annex III, with the exception of systems listed under point 2 thereof, and which produces legal effects or similarly significantly affects that person in a way that they consider to have an adverse impact on their health, safety or fundamental rights shall have the right to obtain from the deployer clear and meaningful explanations of the role of the AI system in the decision-making procedure and the main elements of the decision taken.

Art. 95, 1: The AI Office and the Member States shall encourage and facilitate the drawing up of codes of conduct, including related governance mechanisms, intended to foster the voluntary application to AI systems, other than high-risk AI systems, of some or all of the requirements set out in Chapter III, Section 2 taking into account the available technical solutions and industry best practices allowing for the application of such requirements.

Art. 111, 2: Without prejudice to the application of Article 5 as referred to in Article 113(3), point (a), this Regulation shall apply to operators of high-risk AI systems, other than the systems referred to in paragraph 1 of this Article, that have been placed on the market or put into service before 2 August 2026, only if, as from that date, those systems are subject to significant changes in their designs. In any case, the providers and deployers of high-risk AI systems intended to be used by public authorities shall take the necessary steps to comply with the requirements and obligations of this Regulation by 2 August 2030.

Art. 112, 7: By 2 August 2028 and every three years thereafter, the Commission shall evaluate the impact and effectiveness of voluntary codes of conduct to foster the application of the requirements set out in Chapter III, Section 2 for AI systems other than high-risk AI systems and possibly other additional requirements for AI systems other than high-risk AI systems, including as regards environmental sustainability.

20 Human

Art. 1, 1: The purpose of this Regulation is to improve the functioning of the internal market and promote the uptake of human-centric and trustworthy artificial intelligence (AI), while ensuring a high level of protection of health, safety, fundamental rights enshrined in the Charter, including democracy, the rule of law and environmental protection, against the harmful effects of AI systems in the Union and supporting innovation.

Art. 3, 13(1): 'reasonably foreseeable misuse' means the use of an AI system in a way that is not in accordance with its intended purpose, but which may result from reasonably foreseeable human behaviour or interaction with other systems, including other AI systems;

Art. 3, 35(1): 'biometric identification' means the automated recognition of physical, physiological, behavioural, or psychological human features for the purpose of establishing the identity of a natural person by comparing biometric data of that individual to biometric data of individuals stored in a database;

Art. 5, 1(d): the placing on the market, the putting into service for this specific purpose, or the use of an AI system for making risk assessments of natural persons in order to assess or predict the risk of a natural person committing a criminal offence, based solely on the profiling of a natural person or on assessing their personality traits and characteristics; this prohibition shall not apply to AI systems used to support the human assessment of the involvement of a person in a criminal activity, which is already based on objective and verifiable facts directly linked to a criminal activity;

Art. 5, 1(h)(i): the targeted search for specific victims of abduction, trafficking in human beings or sexual exploitation of human beings, as well as the search for missing persons;

Art. 6, 3(b): the AI system is intended to improve the result of a previously completed human activity;

Art. 6, 3(c): the AI system is intended to detect decision-making patterns or deviations from prior decision-making patterns and is not meant to replace or influence the previously completed human assessment, without proper human review; or

Art. 7, 2(d): the extent to which the AI system acts autonomously and the possibility for a human to override a decision or recommendations that may lead to potential harm;

Art. 13, 3(d): the human oversight measures referred to in Article 14, including the technical measures put in place to facilitate the interpretation of the outputs of the high-risk AI systems by the deployers;

Art. 14: Human oversight

Art. 14, 1: High-risk AI systems shall be designed and developed in such a way, including with appropriate human-machine interface tools, that they can be effectively overseen by natural persons during the period in which they are in use.

Art. 14, 2: Human oversight shall aim to prevent or minimise the risks to health, safety or fundamental rights that may emerge when a high-risk AI system is used in accordance with its intended purpose or under conditions of reasonably foreseeable misuse, in particular where such risks persist despite the application of other requirements set out in this Section.

Art. 14, 4: For the purpose of implementing paragraphs 1, 2 and 3, the high-risk AI system shall be provided to the deployer in such a way that natural persons to whom human oversight is assigned are enabled, as appropriate and proportionate:

Art. 26, 2: Deployers shall assign human oversight to natural persons who have the necessary competence, training and authority, as well as the necessary support.

Art. 27, 4: If any of the obligations laid down in paragraphs 1 and 2, are without prejudice to other deployer obligations under Union or national law and to the deployer's freedom to organise its own resources and activities for the purpose of implementing the human oversight measures indicated by the provider.

Art. 27, 1(e): a description of the implementation of human oversight measures, according to the instructions for use;

Art. 50, 4: Deployers of an AI system that generates or manipulates image, audio or video content constituting a deep fake, shall disclose that the content has been artificially generated or manipulated. This obligation shall not apply where the use is authorised by law to detect, prevent, investigate or prosecute criminal offence. Where the content forms part of an evidentiary artistic, creative, satirical, fictional or analogous work or programme, the transparency obligations set out in this paragraph are limited to disclosure of the existence of such generated or manipulated content in an appropriate manner that does not hamper the display or enjoyment of the work. Deployers of an AI system that generates or manipulates text which is published with the purpose of informing the public on matters of public interest shall disclose that the text has been artificially generated or manipulated. This obligation shall not apply where the use is authorised by law to detect, prevent, investigate or prosecute criminal offences or where the AI-generated content has undergone a process of human review or editorial control and where a natural or legal person holds editorial responsibility for the publication of the content.

Art. 70, 3: Member States shall ensure that their national competent authorities are provided with adequate technical, financial and human resources, and with infrastructure to fulfil their tasks effectively under this Regulation. In particular, the national competent authorities shall have a sufficient number of personnel permanently available whose competences and expertise shall include an in-depth understanding of AI technologies, data and data computing, personal data protection, cybersecurity, fundamental rights, health and safety risks and knowledge of existing standards and legal requirements. Member States shall assess and, if necessary, update competence and resource requirements referred to in this paragraph on an annual basis.

Art. 112, 6: By 2 August 2025, and once every two years thereafter, Member States shall report to the Commission on the status of the financial and human resources of the national competent authorities, with an assessment of their adequacy. The Commission shall transmit that information to the Board for discussion and possible recommendations.

Art. 112, 4(a): the status of the financial, technical and human resources of the national competent authorities in order to effectively perform the tasks assigned to them under this Regulation;

0 Human life risk

7 Human oversight

Art. 13, 3(d): the human oversight measures referred to in Article 14, including the technical measures put in place to facilitate the interpretation of the outputs of the high-risk AI systems by the deployers;

Art. 14: Human oversight

Art. 14, 2: Human oversight shall aim to prevent or minimise the risks to health, safety or fundamental rights that may emerge when a high-risk AI system is used in accordance with its intended purpose or under conditions of reasonably foreseeable misuse, in particular where such risks persist despite the application of other requirements set out in this Section.

Art. 14, 4: For the purpose of implementing paragraphs 1, 2 and 3, the high-risk AI system shall be provided to the deployer in such a way that natural persons to whom human oversight is assigned are enabled, as appropriate and proportionate:

Art. 26, 2: Deployers shall assign human oversight to natural persons who have the necessary competence, training and authority, as well as the necessary support.

Art. 27, 4: If any of the obligations laid down in paragraphs 1 and 2, are without prejudice to other deployer obligations under Union or national law and to the deployer's freedom to organise its own resources and activities for the purpose of implementing the human oversight measures indicated by the provider.

Art. 27, 1(e): a description of the implementation of human oversight measures, according to the instructions for use;

1 Human-centric

Art. 1, 1: The purpose of this Regulation is to improve the functioning of the internal market and promote the uptake of human-centric and trustworthy artificial intelligence (AI), while ensuring a high level of protection of health, safety, fundamental rights enshrined in the Charter, including democracy, the rule of law and environmental protection, against the harmful effects of AI systems in the Union and supporting innovation.

0 Human-Machine teaming

0 Identifiability (See also: Confidentiality, Personal data)

5 Impact assessment

Art. 5, 2: In addition, the use of 'real-time' remote biometric identification systems in publicly accessible spaces for the purposes of law enforcement for any of the objectives referred to in paragraph 1, first subparagraph, point (h), of this Article shall comply with necessary and proportionate safeguards and conditions in relation to the use in accordance with the national law authorising the use thereof, in particular as regards the temporal, geographic and personal limitations. The use of the 'real-time' remote biometric identification system in publicly accessible spaces shall be authorised only if the law enforcement authority has completed a fundamental rights impact assessment as provided for in Article 27 and has registered the system in the EU database according to Article 49. However, in duly justified cases of urgency, the use of such systems may be commenced without the registration in the EU database, provided that such registration is completed without undue delay.

Art. 26, 9: Where applicable, deployers of high-risk AI systems shall use the information provided under Article 13 of this Regulation to comply with their obligation to carry out a data protection impact assessment under Article 35 of Regulation (EU) 2016/679 or Article 27 of Directive (EU) 2016/680.

Art. 27: Fundamental rights impact assessment for high-risk AI systems

Art. 27, 2: The obligation laid down in paragraph 1 applies to the first use of the high-risk AI system. The deployer may, in similar cases, rely on previously conducted fundamental rights impact assessments or existing impact assessments carried out by provider. If, during the use of the high-risk AI system, the deployer considers that any of the elements listed in paragraph 1 has changed or is no longer up to date, the deployer shall take the necessary steps to update the information.

Art. 27, 4: If any of the obligations laid down in this Article is already met through the data protection impact assessment conducted pursuant to Article 35 of Regulation (EU) 2016/679 or Article 27 of Directive (EU) 2016/680, the fundamental rights impact assessment referred to in paragraph 1 of this Article shall complement that data protection impact assessment.

10 Importer

Art. 2, 1(d): importers and distributors of AI systems;

Art. 20, 1: Providers of high-risk AI systems which consider or have reason to consider that a high-risk AI system that they have placed on the market or put into service is not in conformity with this Regulation shall immediately take the necessary corrective actions to bring that system into conformity, to withdraw it, to disable it, or to recall it, as appropriate. They shall inform the distributors of the high-risk AI system concerned and, where applicable, the deployers, the authorised representative and importers accordingly.

Art. 23: Obligations of importers

Art. 23, 1: Before placing a high-risk AI system on the market, importers shall ensure that the system is in conformity with this Regulation by verifying that:

Art. 23, 3: Importers shall indicate their name, registered trade name or registered trade mark, and the address at which they can be contacted on the high-risk AI system and on its packaging or its accompanying documentation, where applicable.

Art. 23, 4: Importers shall ensure that, while a high-risk AI system is under their responsibility, storage or transport conditions, where applicable, do not jeopardise its compliance with the requirements set out in Section 2.

Art. 23, 5: Importers shall keep, for a period of 10 years after the high-risk AI system has been placed on the market or put into service, a copy of the certificate issued by the notified body, where applicable, of the instructions for use, and of the EU declaration of conformity referred to in Article 20.

Art. 23, 6: Importers shall provide the relevant competent authorities, upon a reasoned request, with all the necessary information and documentation, including that referred to in paragraph 5, to demonstrate the conformity of a high-risk AI system with the requirements set out in Section 2 in a language which can be easily understood by them. For this purpose, they shall also ensure that the technical documentation can be made available to those authorities.

Art. 23, 7: Importers shall cooperate with the relevant competent authorities in any action those authorities take in relation to a high-risk AI system placed on the market by the importers, in particular to reduce and mitigate the risks posed by it.

Art. 99, 4(c): obligations of importers pursuant to Article 23;

2 Improvement

Art. 59, 1(a)(i): public safety and public health, including disease detection, diagnosis prevention, control and treatment and improvement of health care systems;

Art. 59, 1(a)(ii): a high level of protection and improvement of the quality of the environment, protection of biodiversity, protection against pollution, green transition measures, climate change mitigation and adaptation measures;

Terms and AI Act Articles

14 Incident

Art. 3. (49): 'serious incident' means an incident or malfunctioning of an AI system that directly or indirectly leads to any of the following:

Art. 17. (1): procedures related to the reporting of a serious incident in accordance with Article 73;

Art. 26. 5: Deployers shall monitor the operation of the high-risk AI system on the basis of the instructions for use and, where relevant, inform providers in accordance with Article 72. Where deployers have reason to consider that the use of the high-risk AI system in accordance with the instructions may result in that AI system presenting a risk within the meaning of Article 73(1), they shall, without undue delay, inform the provider or distributor and the relevant market surveillance authority, and shall suspend the use of that system. Where deployers have identified a serious incident, they shall also immediately inform first the provider, and then the importer or distributor and the relevant market surveillance authorities of that incident. If the deployer is not able to reach the provider, Article 73 shall apply mutatis mutandis. This obligation shall not cover sensitive operational data of deployers of AI systems which are law enforcement authorities. For deployers that are financial institutions subject to requirements regarding their internal governance, arrangements or processes under Union financial services law, the monitoring obligation set out in the first subparagraph shall be deemed to be fulfilled by complying with the rules on internal governance arrangements, processes and mechanisms pursuant to the relevant financial service law.

Art. 60. 7: Any serious incident identified in the course of the testing in real world conditions shall be reported to the national market surveillance authority in accordance with Article 73. The provider or prospective provider shall adopt immediate mitigation measures or, failing that, shall suspend the testing in real world conditions until such mitigation takes place, or otherwise terminate it. The provider or prospective provider shall establish a procedure for the prompt recall of the AI system upon such termination of the testing in real world conditions.

Art. 65. (e)(ii): the evaluation and review of this Regulation pursuant to Article 112, including as regards the serious incident reports referred to in Article 73, and the functioning of the EU database referred to in Article 71, the preparation of the delegated or implementing acts, and as regards possible alignments of this Regulation with the Union harmonisation legislation listed in Annex I.

Art. 73. 1: Providers of high-risk AI systems placed on the Union market shall report any serious incident to the market surveillance authorities of the Member States where that incident occurred.

Art. 73. 2: The report referred to in paragraph 1 shall be made immediately after the provider has established a causal link between the AI system and the serious incident or the reasonable likelihood of such a link, and, in any event, not later than 15 days after the provider or, where applicable, the deployer, becomes aware of the serious incident. The period for the reporting referred to in the first subparagraph shall take account of the severity of the serious incident.

Art. 73. 3: Notwithstanding paragraph 2 of this Article, in the event of a widespread infringement or a serious incident as defined in Article 3, point (49)(b), the report referred to in paragraph 1 of this Article shall be provided immediately, and not later than two days after the provider or, where applicable, the deployer becomes aware of that incident.

Art. 73. 4: Notwithstanding paragraph 2, in the event of the death of a person, the report shall be provided immediately after the provider or the deployer has established, or as soon as it suspects, a causal relationship between the high-risk AI system and the serious incident, but not later than 10 days after the date on which the provider or, where applicable, the deployer becomes aware of the serious incident.

Art. 73. 5: Following the reporting of a serious incident pursuant to paragraph 1, the provider shall, without delay, perform the necessary investigations in relation to the serious incident and the AI system concerned. This shall include a risk assessment of the incident, and corrective action. The provider shall cooperate with the competent authorities, and where relevant with the notified body concerned, during the investigations referred to in the first subparagraph, and shall not perform any investigation which involves altering the AI system concerned in a way which may affect any subsequent evaluation of the causes of the incident, prior to informing the competent authorities of such action.

Art. 73. 7: Upon receiving a notification related to a serious incident referred to in Article 3, point (49)(c), the relevant market surveillance authority shall inform the national public authorities or bodies referred to in Article 77(1). The Commission shall develop dedicated guidance to facilitate compliance with the obligations set out in paragraph 1 of this Article. That guidance shall be issued by 2 August 2025, and shall be assessed regularly.

Art. 73. 10: For high-risk AI systems which are safety components of devices, or are themselves devices, covered by Regulations (EU) 2017/745 and (EU) 2017/746, the notification of serious incidents shall be limited to those referred to in Article 3, point (49)(c) of this Regulation, and shall be made to the national competent authority chosen for that purpose by the Member States where the incident occurred.

Art. 73. 11: National competent authorities shall immediately notify the Commission of any serious incident, whether or not they have taken action on it, in accordance with Article 20 of Regulation (EU) 2019/1020.

Art. 76. 3: Where a market surveillance authority has been informed by the prospective provider, the provider or any third party of a serious incident or has other grounds for considering that the conditions set out in Articles 60 and 61 are not met, it may take either of the following decisions on its territory, as appropriate:

5 Independent expert

Art. 56. 3: The AI Office may invite all providers of general-purpose AI models, as well as relevant national competent authorities, to participate in the drawing-up of codes of practice. Civil society organisations, industry, academia and other relevant stakeholders, such as downstream providers and independent experts, may support the process.

Art. 68: Scientific panel of independent experts

Art. 68. 1: The Commission shall, by means of an implementing act, make provisions on the establishment of a scientific panel of independent experts (the 'scientific panel') intended to support the enforcement activities under this Regulation. That implementing act shall be adopted in accordance with the examination procedure referred to in Article 98(2).

Art. 92. 2: The Commission may decide to appoint independent experts to carry out evaluations on its behalf, including from the scientific panel established pursuant to Article 68. Independent experts appointed for this task shall meet the criteria outlined in Article 68(2).

Art. 92. 5: The Commission shall adopt implementing acts setting out the detailed arrangements and the conditions for the evaluations, including the detailed arrangements for involving independent experts, and the procedure for the selection thereof. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 98(2).

0 Industrial data

Terms and AI Act Articles

Art. 91: Power to request documentation and information

Art. 91, 1: The Commission may request the provider of the general-purpose AI model concerned to provide the documentation drawn up by the provider in accordance with Articles 53 and 55, or any additional information that is necessary for the purpose of assessing compliance of the provider with this Regulation.

Art. 91, 2: Before sending the request for information, the AI Office may initiate a structured dialogue with the provider of the general-purpose AI model.

Art. 91, 3: Upon a duly substantiated request, the Commission may issue a request for information to a provider of a general-purpose AI model, where the access to information is necessary and proportionate for the fulfilment of the tasks of the scientific panel under Article 68(2).

Art. 91, 4: The request for information shall state the legal basis and the purpose of the request, specify what information is required, set a period within which the information is to be provided, and indicate the fines provided for in Article 101 for supplying incorrect, incomplete or misleading information.

Art. 91, 5: The provider of the general-purpose AI model concerned, or its representative shall supply the information requested. In the case of legal persons, companies or firms, or where the provider has no legal personality, the persons authorised to represent them by law or by their statutes, shall provide the access requested on behalf of the provider of the general-purpose AI model concerned. Lawyers duly authorised to act may supply information on behalf of their clients. The clients shall nevertheless remain fully responsible if the information supplied is incomplete, incorrect or misleading.

Art. 92, 1(a): to assess compliance of the provider with obligations under this Regulation, where the information gathered pursuant to Article 91 is insufficient; or

Art. 92, 2: The providers of the general-purpose AI model concerned or its representative shall supply the information requested. In the case of legal persons, companies or firms, or where the provider has no legal personality, the persons authorised to represent them by law or by their statutes, shall provide the access requested on behalf of the provider of the general-purpose AI model concerned.

Art. 92, 7: Prior to requesting access to the general-purpose AI model concerned, the AI Office may initiate a structured dialogue with the provider of the general-purpose AI model to gather more information on the internal testing of the model, internal safeguards for preventing systemic risks, and other internal procedures and measures the provider has taken to mitigate such risks.

Art. 96, 1(a): detailed information on the relationship of this Regulation with the Union harmonisation legislation listed in Annex I, as well as with other relevant Union law, including as regards consistency in their enforcement;

Art. 99, 8: the supply of incorrect, incomplete or misleading information to notified bodies or national competent authorities in reply to a request shall be subject to administrative fines of up to EUR 7 500 000 or, if the offender is an undertaking, up to 1 % of its total worldwide annual turnover for the preceding financial year, whichever is higher.

Art. 101, 1(b): failed to comply with a request for document or for information pursuant to Article 91, or supplied incorrect, incomplete or misleading information;

Art. 101, 4: information on fines imposed under this Article shall also be communicated to the Board as appropriate.

Art. 112, 8: For the purposes of paragraphs 1 to 7, the Board, the Member States and national competent authorities shall provide the Commission with information upon its request and without undue delay.

Art. 112, 10: The Commission shall, if necessary, submit appropriate proposals to amend this Regulation, in particular taking into account developments in technology, the effect of AI systems on health and safety, and on fundamental rights, and in light of the state of progress in the information society.

0 Information quality

0 Information security

0 Information system

26 Infringement

Art. 3, (49)(c): the infringement of obligations under Union law intended to protect fundamental rights;

Art. 3, (61): "widespread infringement" means any act or omission contrary to Union law protecting the interest of individuals, which:

Art. 3, (61)(iii): the deployer is established in the Member State in which the infringement is committed by the deployer;

Art. 57, 12: Providers and prospective providers participating in the AI regulatory sandbox shall remain liable under applicable Union and national liability law for any damage inflicted on third parties as a result of the experimentation taking place in the sandbox. However, provided that the prospective providers observe the specific plan and the terms and conditions for their participation and follow in good faith the guidance given by the national competent authority, no administrative fines shall be imposed by the authorities for infringements of this Regulation. Where other competent authorities responsible for other Union and national law were actively involved in the supervision of the AI system in the sandbox and provided guidance for compliance, no administrative fines shall be imposed regarding that law.

Art. 73, 3: Notwithstanding paragraph 2 of this Article, in the event of a widespread infringement or a serious incident as defined in Article 3, point (49)(b), the report referred to in paragraph 1 of this Article shall be provided immediately, and not later than two days after the provider or, where applicable, the deployer becomes aware of that incident.

Art. 77, 3: Where the documentation referred to in paragraph 1 is insufficient to ascertain whether an infringement of obligations under Union law protecting fundamental rights has occurred, the public authority or body referred to in paragraph 1 may make a reasoned request to the market surveillance authority, to organise testing of the high-risk AI system through technical means. The market surveillance authority shall organise the testing with the close involvement of the requesting public authority or body within a reasonable time following the request.

Art. 85: Without prejudice to other administrative or judicial remedies, any natural or legal person having grounds to consider that there has been an infringement of the provisions of this Regulation may submit complaints to the relevant market surveillance authority. In accordance with Regulation (EU) 2019/1020, such complaints shall be taken into account for the purpose of conducting market surveillance activities, and shall be handled in line with the dedicated procedures established therefor by the market surveillance authorities.

Art. 87: Reporting of infringements and protection of reporting persons

Art. 87, Directive (EU) 2019/1937 shall apply to the reporting of infringements of this Regulation and the protection of persons reporting such infringements.

Art. 89, 2: Downstream providers shall have the right to lodge a complaint alleging an infringement of this Regulation. A complaint shall be duly reasoned and indicate at least:

Art. 99, 1: in accordance with the terms and conditions laid down in this Regulation, Member States shall lay down the rules on penalties and other enforcement measures, which may also include warnings and non-monetary measures, applicable to infringements of this Regulation by operators, and shall take all measures necessary to ensure that they are properly and effectively implemented, thereby taking into account the guidelines issued by the Commission pursuant to Article 96. The penalties provided for shall be effective, proportionate and dissuasive. They shall take into account the interests of SMEs, including start-ups, and their economic viability.

Art. 99, 7(a): the nature, gravity and duration of the infringement and of its consequences, taking into account the purpose of the AI system, as well as, where appropriate, the number of affected persons and the level of damage suffered by them;

Art. 99, 7(b): whether administrative fines have already been applied by other market surveillance authorities to the same operator for the same infringement;

Art. 99, 7(c): whether administrative fines have already been applied by other authorities to the same operator for infringements of other Union or national law, when such infringements result from the same activity or omission constituting a relevant infringement of this Regulation;

Art. 99, 7(d): the size, the annual turnover and market share of the operator committing the infringement;

Art. 99, 7(e): any other aggravating or mitigating factor applicable to the circumstances of the case, such as financial benefits gained, or losses avoided, directly or indirectly, from the infringement;

Art. 99, 7(f): the degree of cooperation with the national competent authorities, in order to remedy the infringement and mitigate the possible adverse effects of the infringement;

Art. 99, 7(h): the manner in which the infringement became known to the national competent authorities, in particular whether, and if so to what extent, the operator notified the infringement;

Art. 99, 7(i): the intentional or negligent character of the infringement;

Art. 100, 1(a): the nature, gravity and duration of the infringement and of its consequences, taking into account the purpose of the AI system concerned, as well as, where appropriate, the number of affected persons and the level of damage suffered by them;

Art. 100, 1(d): the degree of cooperation with the European Data Protection Supervisor in order to remedy the infringement and mitigate the possible adverse effects of the infringement, including compliance with any of the measures previously ordered by the European Data Protection Supervisor against the Union institution, body, office or agency concerned with regard to the same subject matter;

Art. 100, 1(e): any similar previous infringements by the Union institution, body, office or agency;

Art. 100, 1(f): the manner in which the infringement became known to the European Data Protection Supervisor, in particular whether, and if so to what extent, the Union institution, body, office or agency notified the infringement;

Art. 100, 4: Before taking decisions pursuant to this Article, the European Data Protection Supervisor shall give the Union institution, body, office or agency which is the subject of the proceedings conducted by the European Data Protection Supervisor the opportunity of being heard on the matter regarding the possible infringement. The European Data Protection Supervisor shall base his or her decisions only on elements and circumstances on which the parties concerned have been able to comment. Complainants, if any, shall be associated closely with the proceedings.

Art. 101, 1(d): failed to make available to the Commission access to the general-purpose AI model or general-purpose AI model with systemic risk with a view to conducting an evaluation pursuant to Article 92. In fixing the amount of the fine or periodic penalty payment, regard shall be had to the nature, gravity and duration of the infringement, taking due account of the principles of proportionality and appropriateness. The Commission shall also take into account commitments made in accordance with Article 93(3) or made in relevant codes of practice in accordance with Article 56.

Art. 112, 4(b): the state of penalties, in particular administrative fines as referred to in Article 99(1), applied by Member States for infringements of this Regulation;

9 Innovation

Art. 1, 1: The purpose of this Regulation is to improve the functioning of the internal market and promote the uptake of human-centric and trustworthy artificial intelligence (AI), while ensuring a high level of protection of health, safety, fundamental rights enshrined in the Charter, including democracy, the rule of law and environmental protection, against the harmful effects of AI systems in the Union and supporting innovation.

Art. 1, 2(a): measures to support innovation, with a particular focus on SMEs, including start-ups.

Art. 40, 2: The participants in the standardisation process shall seek to promote investment and innovation in AI, including through increasing legal certainty, as well as the competitiveness and growth of the Union market, to contribute to strengthening global cooperation on standardisation and taking into account existing international standards in the field of AI that are consistent with Union values, fundamental rights and interests, and to enhance multi-stakeholder governance ensuring a balanced representation of interests and the effective participation of all relevant stakeholders in accordance with Articles 5, 6, and 7 of Regulation (EU) No 1025/2012.

CHAPTER VI: MEASURES IN SUPPORT OF INNOVATION

Art. 57, 5: AI regulatory sandboxes established under paragraph 1 shall provide for a controlled environment that fosters innovation and facilitates the development, training, testing and validation of innovative AI systems for a limited time before their being placed on the market or put into service pursuant to a specific sandbox plan agreed between the providers or prospective providers and the competent authority. Such sandboxes may include testing in real world conditions supervised therein.

Art. 57, 9(c): fostering innovation and competitiveness and facilitating the development of an AI ecosystem.

Art. 57, 11: The AI regulatory sandboxes shall not affect the supervisory or corrective powers of the competent authorities supervising the sandboxes, including at regional or local level. Any significant risks to health and safety and fundamental rights identified during the development and testing of such AI systems shall result in an adequate mitigator. National competent authorities shall have the power to temporarily or permanently suspend the testing process, or the participation in the sandbox if no effective mitigation is possible, and shall inform the AI Office of such decision. National competent authorities shall exercise their supervisory powers within the limits of the relevant law, using their discretionary powers when implementing legal provisions in respect of a specific AI regulatory sandbox project, with the objective of supporting innovation in AI in the Union.

Art. 58, 2(f): that AI regulatory sandboxes facilitate the involvement of other relevant actors within the AI ecosystem, such as notified bodies and standardisation organisations, SMEs, including start-ups, enterprises, innovators, testing and experimentation facilities, research and experimentation labs and European Digital Innovation Hubs, centres of excellence, individual researchers, in order to allow and facilitate cooperation with the public and private sectors.

Art. 58, 3: Prospective providers in the AI regulatory sandboxes, in particular SMEs and start-ups, shall be directed, where relevant, to pre-deployment services such as guidance on the implementation of this Regulation, to other value-adding services such as help with standardisation documents and certification, testing and experimentation facilities, European Digital Innovation Hubs and centres of excellence.

6 Input data

Art. 3, (33): "input data" means data provided to or directly acquired by an AI system on the basis of which the system produces an output;

Art. 12, 3(b): the reference database against which input data has been checked by the system;

Art. 12, 3(c): the input data for which the search has led to a match;

Art. 13, 3(b)(vi): when appropriate, specifications for the input data, or any other relevant information in terms of the training, validation and testing data sets used, taking into account the intended purpose of the high-risk AI system;

Art. 26, 4: Without prejudice to paragraphs 1 and 2, to the extent the deployer exercises control over the input data, that deployer shall ensure that input data is relevant and sufficiently representative in view of the intended purpose of the high-risk AI system.

Art. 50, 2: Providers of AI systems, including general-purpose AI systems, generating synthetic audio, image, video or text content, shall ensure that the outputs of the AI system are marked in a machine-readable format and detectable as artificially generated or manipulated. Providers shall ensure their technical solutions are effective, interoperable, robust and reliable as far as this is technically feasible, taking into account the specificities and limitations of various types of content, the costs of implementation and the generally acknowledged state of the art, as may be reflected in relevant technical standards. This obligation shall not apply to the extent the AI systems perform an assistive function for standard editing or do not substantially alter the input data provided by the deployer or the semantics thereof, or where authorised by law to detect, prevent, investigate or prosecute criminal offences.

Terms and AI Act Articles

28 Intended purpose

Art. 3. (11): 'putting into service' means the supply of an AI system for first use directly to the deployer or for own use in the Union for its intended purpose;

Art. 3. (12): 'intended purpose' means the use for which an AI system is intended by the provider, including the specific context and conditions of use, as specified in the information supplied by the provider in the instructions for use, promotional or sales materials and statements, as well as in the technical documentation;

Art. 3. (13): 'reasonably foreseeable misuse' means the use of an AI system in a way that is not in accordance with its intended purpose, but which may result from reasonably foreseeable human behaviour or interaction with other systems, including other AI systems;

Art. 3. (15): 'instructions for use' means the information provided by the provider to inform the deployer of, in particular, an AI system's intended purpose and proper use;

Art. 3. (18): 'performance of an AI system' means the ability of an AI system to achieve its intended purpose;

Art. 3. (23): 'substantial modification' means a change to an AI system after its placing on the market or putting into service which is not foreseen or planned in the initial conformity assessment carried out by the provider and as a result of which the compliance of the AI system with the requirements set out in Chapter III, Section 2 is affected or results in a modification to the intended purpose for which the AI system has been assessed;

Art. 3. (57): 'testing in real-world conditions' means the temporary testing of an AI system for its intended purpose in real-world conditions outside a laboratory or otherwise simulated environment, with a view to gathering reliable and robust data and to assessing and verifying the conformity of the system with the requirements of this Regulation and it does not qualify as placing the AI system on the market or putting it into service within the meaning of this Regulation, provided that all the conditions laid down in Article 57 or 60 are fulfilled;

Art. 7. 2(a): the intended purpose of the AI system;

Art. 8. 1: High-risk AI systems shall comply with the requirements laid down in this Section, taking into account their intended purpose as well as the generally acknowledged state of the art on AI and AI-related technologies. The risk management system referred to in Article 9 shall be taken into account when assessing compliance with the requirements of this Section;

Art. 9. 2(a): the identification and analysis of the known and the reasonably foreseeable risks that the high-risk AI system can pose to health, safety or fundamental rights when the high-risk AI system is used in accordance with its intended purpose;

Art. 9. 2(b): the estimation and evaluation of the risks that may emerge when the high-risk AI system is used in accordance with its intended purpose, and under conditions of reasonably foreseeable misuse;

Art. 9. 6: High-risk AI systems shall be tested for the purpose of identifying the most appropriate and targeted risk management measures. Testing shall ensure that high-risk AI systems perform consistently for their intended purpose and that they are in compliance with the requirements set out in this Section.

Art. 9. 8: The testing of high-risk AI systems shall be performed, as appropriate, at any time throughout the development process, and, in any event, prior to their being placed on the market or put into service. Testing shall be carried out against prior defined metrics and probabilistic thresholds that are appropriate to the intended purpose of the high-risk AI system.

Art. 9. 9: When implementing the risk management system as provided for in paragraphs 1 to 7, providers shall give consideration to whether in view of its intended purpose the high-risk AI system is likely to have an adverse impact on persons under the age of 18 and, as appropriate, other vulnerable groups.

Art. 10. 2: Training, validation and testing data sets shall be subject to data governance and management practices appropriate for the intended purpose of the high-risk AI system. Those practices shall concern in particular:

Art. 10. 3: Training, validation and testing data sets shall be relevant, sufficiently representative, and to the best extent possible, free of errors and complete in view of the intended purpose. They shall have the appropriate statistical properties, including, where applicable, as regards the persons or groups of persons in relation to whom the high-risk AI system is intended to be used. Those characteristics of the data sets may be met at the level of individual data sets or at the level of a combination thereof.

Art. 10. 4: Data sets shall take into account, to the extent required by the intended purpose, the characteristics or elements that are particular to the specific geographical, contextual, behavioural or functional setting within which the high-risk AI system is intended to be used.

Art. 12. 2: In order to ensure a level of traceability of the functioning of a high-risk AI system that is appropriate to the intended purpose of the system, logging capabilities shall enable the recording of events relevant for:

Art. 13. 3(b)(i): its intended purpose;

Art. 13. 3(b)(ii): any known or foreseeable circumstance, related to the use of the high-risk AI system in accordance with its intended purpose or under conditions of reasonably foreseeable misuse, which may lead to risks to the health and safety or fundamental rights referred to in Article 9(2);

Art. 13. 3(b)(vi): when appropriate, specifications for the input data, or any other relevant information in terms of the training, validation and testing data sets used, taking into account the intended purpose of the high-risk AI system;

Art. 14. 2: Human oversight aimed to prevent or minimise the risks to health, safety or fundamental rights that may emerge when a high-risk AI system is used in accordance with its intended purpose or under conditions of reasonably foreseeable misuse, in particular where such risks persist despite the application of other requirements set out in this Section.

Art. 19. 1: Providers of high-risk AI systems shall keep the logs referred to in Article 12(1), automatically generated by their high-risk AI systems, to the extent such logs are under their control. Without prejudice to applicable Union or national law, the logs shall be kept for a period appropriate to the intended purpose of the high-risk AI system, of at least six months, unless provided otherwise in the applicable Union or national law, in particular in Union law on the protection of personal data.

Art. 25. (c): they modify the intended purpose of an AI system, including a general-purpose AI system, which has not been classified as high-risk and has already been placed on the market or put into service in such a way that the AI system concerned becomes a high-risk AI system in accordance with Article 6.

Art. 26. 4: Without prejudice to paragraphs 1 and 2, to the extent the deployer exercises control over the input data, that deployer shall ensure that input data is relevant and sufficiently representative in view of the intended purpose of the high-risk AI system.

Art. 26. 6: Deployers of high-risk AI systems shall keep the logs automatically generated by that high-risk AI system to the extent such logs are under their control, for a period appropriate to the intended purpose of the high-risk AI system, of at least six months, unless provided otherwise in applicable Union or national law, in particular in Union law on the protection of personal data. Deployers that are financial institutions subject to requirements regarding their internal governance, arrangements or processes under Union financial services law shall maintain the logs as part of the documentation kept pursuant to the relevant Union financial service law.

Art. 27. (a): a description of the deployer's processes in which the high-risk AI system will be used in line with its intended purpose;

Art. 28. 3: Codes of conduct may be drawn up by individual providers or deployers of AI systems or by organisations representing them or by both, including with the involvement of any interested stakeholders and their representative organisations, including civil society organisations and academia. Codes of conduct may cover one or more AI systems taking into account the similarity of the intended purpose of the relevant systems.

6 Interaction

Art. 3. (13): 'reasonably foreseeable misuse' means the use of an AI system in a way that is not in accordance with its intended purpose, but which may result from reasonably foreseeable human behaviour or interaction with other systems, including other AI systems;

Art. 9. 4: The risk management measures referred to in paragraph 2, point (d), shall give due consideration to the effects and possible interaction resulting from the combined application of the requirements set out in this Section, with a view to minimising risks more effectively while achieving an appropriate balance in implementing the measures to fulfil those requirements.

Art. 15. 4: High-risk AI systems shall be as resilient as possible regarding errors, faults or inconsistencies that may occur within the system or the environment in which the system operates, in particular due to their interaction with natural persons or other systems. Technical and organisational measures shall be taken in this regard. The robustness of high-risk AI systems may be achieved through technical redundancy solutions, which may include backup or fail-safe plans. High-risk AI systems that continue to learn after being placed on the market or put into service shall be developed in such a way as to eliminate or reduce as far as possible the risk of possibly biased outputs influencing input for future operations (feedback loops), and as to ensure that any such feedback loops are duly addressed with appropriate mitigation measures.

Art. 16. 2: The information referred to in paragraphs 1 to 4 shall be provided to the natural persons concerned in a clear and distinguishable manner at the latest at the time of the first interaction or exposure. The information shall conform to the applicable accessibility requirements.

Art. 57. 15: National competent authorities shall inform the AI Office and the Board of the establishment of a sandbox, and may ask them for support and guidance. The AI Office shall make publicly available a list of planned and existing sandboxes and keep it up to date in order to encourage more interaction in the AI regulatory sandboxes and cross-border cooperation.

Art. 58. 3: The post-market monitoring system shall actively and systematically collect, document and analyse relevant data which may be provided by deployers or which may be collected through other sources on the performance of high-risk AI systems throughout their lifetime, and which allow the provider to evaluate the continuous compliance of AI systems with the requirements set out in Chapter III, Section 2. Where relevant, post-market monitoring shall include an analysis of the interaction with other AI systems. This obligation shall not cover sensitive operational data of deployers which are law-enforcement authorities.

0 Interaction capability (See also: Usability)

0 Internal context

1 Internal market

Art. 1. 1: The purpose of this Regulation is to improve the functioning of the internal market and promote the uptake of human-centric and trustworthy artificial intelligence (AI), while ensuring a high level of protection of health, safety, fundamental rights enshrined in the Charter, including democracy, the rule of law and environmental protection, against the harmful effects of AI systems in the Union and supporting innovation.

0 Interoperability

0 Interpretability

0 Intervenability

1 IT system

Art. 111. 1: Without prejudice to the application of Article 5 as referred to in Article 113(3), point (a), AI systems which are components of the large-scale IT systems established by the legal acts listed in Annex X that have been placed on the market or put into service before 2 August 2027 shall be brought into compliance with this Regulation by 31 December 2030. The requirements laid down in this Regulation shall be taken into account in the evaluation of each large-scale IT system established by the legal acts listed in Annex X to be undertaken as provided for in those legal acts and where those legal acts are replaced or amended.

7 Knowledge

Art. 3. (56): 'AI literacy' means skills, knowledge and understanding that allow providers, deployers and affected persons, taking into account their respective rights and obligations in the context of this Regulation, to make an informed deployment of AI systems, as well as to gain awareness about the opportunities and risks of AI and possible harm it can cause;

Art. 4: Providers and deployers of AI systems shall take measures to ensure, to their best extent, a sufficient level of AI literacy of their staff and other persons dealing with the operation and use of AI systems on their behalf, taking into account their technical knowledge, experience, education and training and the context of the AI systems are to be used in, and considering the persons or groups of persons on whom the AI systems are to be used.

Art. 7. 2(h): the extent to which there is an imbalance of power, or the persons who are potentially harmed or suffer an adverse impact are in a vulnerable position in relation to the deployer of an AI system, in particular due to status, authority, knowledge, economic or social circumstances, or age;

Art. 9. 5(c): provision of information required pursuant to Article 13 and, where appropriate, training to deployers. With a view to eliminating or reducing risks related to the use of the high-risk AI system, due consideration shall be given to the technical knowledge, experience, education, the training to be expected by the deployer, and the presumable context in which the system is intended to be used.

Art. 31. 11: Notified bodies shall have sufficient internal competences to be able effectively to evaluate the tasks conducted by external parties on their behalf. The notified body shall have permanent availability of sufficient administrative, technical, legal and scientific personnel who possess experience and knowledge relating to the relevant types of AI systems, data and data computing, and relating to the requirements set out in Section 2.

Art. 38. 3: The Commission shall provide for the exchange of knowledge and best practices between notifying authorities.

Art. 70. 3: Member States shall ensure that their national competent authorities are provided with adequate technical, financial and human resources, and with infrastructure to fulfil their tasks effectively under this Regulation. In particular, the national competent authorities shall have a sufficient number of personnel permanently available whose competences and expertise shall include an in-depth understanding of AI technologies, data and data computing, personal data protection, cybersecurity, fundamental rights, health and safety risks and knowledge of existing standards and legal requirements. Member States shall assess and, if necessary, update competence and resource requirements referred to in this paragraph on an annual basis.

0 Knowledge acquisition

4 Labelling

Art. 5. 1(g): the placing on the market, the putting into service for its specific purpose, or the use of biometric categorisation systems that categorise individually natural persons based on their biometric data to deduce or infer their race, political opinions, trade union membership, religious or philosophical beliefs, sex life or sexual orientation; this provision does not cover any labelling or filtering of lawfully acquired biometric datasets, such as images, based on biometric data or categorizing of biometric data in the area of law enforcement;

Art. 10. 2(c): relevant data-preparation processing operations, such as annotation, labelling, cleaning, updating, enrichment and aggregation;

Art. 17. 1(f): systems and procedures for data management, including data acquisition, data collection, data analysis, data labelling, data storage, data filtration, data mining, data aggregation, data retention and any other operation regarding the data that is performed before and for the purpose of the placing on the market or the putting into service of high-risk AI systems;

Art. 50. 7: The AI Office shall encourage and facilitate the drawing up of codes of practice at Union level to facilitate the effective implementation of the obligations regarding the detection and labelling of artificially generated or manipulated content. The Commission may adopt implementing acts to approve those codes of practice in accordance with the procedure laid down in Article 56 (6). If it deems the code is not adequate, the Commission may adopt an implementing act specifying common rules for the implementation of those obligations in accordance with the examination procedure laid down in Article 98(2).

0 Leadership

Terms and AI Act Articles

0 Level of risk

3 Lifecycle

Art. 9, 2: The risk management system shall be understood as a continuous iterative process planned and run throughout the entire lifecycle of a high-risk AI system, requiring regular systematic review and updating. It shall comprise the following steps:
Art. 15, 1: High-risk AI systems shall be designed and developed in such a way that they achieve an appropriate level of accuracy, robustness, and cybersecurity, and that they perform consistently in those respects throughout their lifecycle.
Art. 40, 2: In accordance with Article 10 of Regulation (EU) No 1025/2012, the Commission shall issue, without undue delay, standardisation requests covering all requirements set out in Section 2 of this Chapter and, as applicable, standardisation requests covering obligations set out in Chapter V, Sections 2 and 3, of this Regulation. The standardisation request shall also ask for deliverables on reporting and documentation processes to improve AI systems' resource performance, such as reducing the high-risk AI system's consumption of energy and of other resources during its lifecycle, and on the energy-efficient development of general-purpose AI models. When preparing a standardisation request, the Commission shall consult the Board and relevant stakeholders, including the advisory forum. When issuing a standardisation request to European standardisation organisations, the Commission shall specify that standards have to be clear, consistent, including with the standards developed in the various sectors for products covered by the existing Union harmonisation legislation listed in Annex I, and aiming to ensure that high-risk AI systems or general-purpose AI models placed on the market or put into service in the Union meet the relevant requirements or obligations laid down in this Regulation. The Commission shall request the European standardisation organisations to provide evidence of their best efforts to fulfil the objectives referred to in the first and the second subparagraph of this paragraph in accordance with Article 24 of Regulation (EU) No 1025/2012.

5 Literacy

Art. 3, (56): 'AI literacy' means skills, knowledge and understanding that allow providers, deployers and affected persons, taking into account their respective rights and obligations in the context of this Regulation, to make an informed deployment of AI systems, as well as to gain awareness about the opportunities and risks of AI and possible harm it can cause;
Art. 4: AI literacy
Art. 4: Providers and deployers of AI systems shall take measures to ensure, to their best extent, a sufficient level of AI literacy of their staff and other persons dealing with the operation and use of AI systems on their behalf, taking into account their technical knowledge, experience, education and training and the context the AI systems are to be used in, and considering the persons or groups of persons on whom the AI systems are to be used;
Art. 66, (f): support the Commission in promoting AI literacy, public awareness and understanding of the benefits, risks, safeguards and rights and obligations in relation to the use of AI systems;
Art. 95, 2(c): promoting AI literacy, in particular that of persons dealing with the development, operation and use of AI;

1 Located in a third country

Art. 2, 1(c): providers and deployers of AI systems that have their place of establishment or are located in a third country, where the output produced by the AI system is used in the Union;

1 Located in the Union

Art. 2, 1(g): affected persons that are located in the Union.

0 Location

10 Log

Art. 12, 1: High-risk AI systems shall technically allow for the automatic recording of events (logs) over the lifetime of the system.
Art. 13, 3(f): where relevant, a description of the mechanisms included within the high-risk AI system that allows deployers to properly collect, store and interpret the logs in accordance with Article 12.
Art. 16, (e): when under their control, keep the logs automatically generated by their high-risk AI systems as referred to in Article 19;
Art. 19: Automatically generated logs
Art. 19, 1: Providers of high-risk AI systems shall keep the logs referred to in Article 12(1), automatically generated by their high-risk AI systems, to the extent such logs are under their control. Without prejudice to applicable Union or national law, the logs shall be kept for a period appropriate to the intended purpose of the high-risk AI system, of at least six months, unless provided otherwise in the applicable Union or national law, in particular in Union law on the protection of personal data.
Art. 19, 2: Providers that are financial institutions subject to requirements regarding their internal governance, arrangements or processes under Union financial services law shall maintain the logs automatically generated by their high-risk AI systems as part of the documentation kept under the relevant financial services law.
Art. 21, 2: Upon a reasoned request by a competent authority, providers shall also give the requesting competent authority, as applicable, access to the automatically generated logs of the high-risk AI system referred to in Article 12(1), to the extent such logs are under their control.
Art. 22, 3(c): provide a competent authority, upon a reasoned request, with all the information and documentation, including that referred to in point (b) of this subparagraph, necessary to demonstrate the conformity of a high-risk AI system with the requirements set out in Section 2, including access to the logs, as referred to in Article 12(1), automatically generated by the high-risk AI system, to the extent such logs are under the control of the provider;
Art. 26, 6: Deployers of high-risk AI systems shall keep the logs automatically generated by that high-risk AI system to the extent such logs are under their control, for a period appropriate to the intended purpose of the high-risk AI system, of at least six months, unless provided otherwise in applicable Union or national law, in particular in Union law on the protection of personal data. Deployers that are financial institutions subject to requirements regarding their internal governance, arrangements or processes under Union financial services law shall maintain the logs as part of the documentation kept pursuant to the relevant Union financial service law.
Art. 59, 1(h): the logs of the processing of personal data in the context of the sandbox are kept for the duration of the participation in the sandbox, unless provided otherwise by Union or national law;

2 Logging

Art. 12, 2: In order to ensure a level of traceability of the functioning of a high-risk AI system that is appropriate to the intended purpose of the system, logging capabilities shall enable the recording of events relevant for:
Art. 12, 3: For high-risk AI systems referred to in point 1 (a), of Annex II, the logging capabilities shall provide, at a minimum:

0 Machine intelligence

0 Machine learning

0 Maintainability

0 Maintenance process

Terms and AI Act Articles

34 Management

Art. 3. (49)(b): a serious and irreversible disruption of the management or operation of critical infrastructure;

Art. 8. 1: High-risk AI systems shall comply with the requirements laid down in this Section, taking into account their intended purpose as well as the generally acknowledged state of the art on AI and AI-related technologies. The risk management system referred to in Article 9 shall be taken into account when ensuring compliance with those requirements.

Art. 9: Risk management system

Art. 9. 1: A risk management system shall be established, implemented, documented and maintained in relation to high-risk AI systems.

Art. 9. 2: The risk management system shall be understood as a continuous iterative process planned and run throughout the entire lifecycle of a high-risk AI system, requiring regular systematic review and updating. It shall comprise the following steps:

Art. 9. 2(d): the adoption of appropriate and targeted risk management measures designed to address the risks identified pursuant to point (a);

Art. 9. 4: The risk management measures referred to in paragraph 2, point (d), shall give due consideration to the effects and possible interaction resulting from the combined application of the requirements set out in this Section, with a view to minimising risks more effectively while achieving an appropriate balance in implementing the measures to fulfil those requirements.

Art. 1. 1: The risk management measures referred to in paragraph 2, point (d), shall be such that the relevant residual risk associated with each hazard, as well as the overall residual risk of the high-risk AI systems is judged to be acceptable. In identifying the most appropriate risk management measures, the following shall be ensured:

Art. 9. 6: High-risk AI systems shall be tested for the purpose of identifying the most appropriate and targeted risk management measures. Testing shall ensure that high-risk AI systems perform consistently for their intended purpose and that they are in compliance with the requirements set out in this Section.

Art. 9. 9: When implementing the risk management system as provided for in paragraphs 1 to 7, providers shall give consideration to whether in view of its intended purpose the high-risk AI system is likely to have an adverse impact on persons under the age of 18 and, as appropriate, other vulnerable groups.

Art. 10. 2: For providers of high-risk AI systems that are subject to requirements regarding internal risk management processes under other relevant provisions of Union law, the aspects provided in paragraphs 1 to 9 may be part of, or combined with, the risk management procedures established pursuant to that law.

Art. 10. 2: Training, validation and testing data sets shall be subject to data governance and management practices appropriate for the intended purpose of the high-risk AI system. Those practices shall concern in particular:

Art. 16. (g): have a quality management system in place which complies with Article 17;

Art. 17: Quality management system

Art. 17. 1: Providers of high-risk AI systems shall put a quality management system in place that ensures compliance with this Regulation. That system shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions, and shall include at least the following aspects:

Art. 17. 1(a): a strategy for regulatory compliance, including compliance with conformity assessment procedures and procedures for the management of modifications to the high-risk AI system;

Art. 17. 1(f): systems and procedures for data management, including data acquisition, data collection, data analysis, data labelling, data storage, data filtration, data mining, data aggregation, data retention and any other operation regarding the data that is performed before and for the purpose of the placing on the market or the putting into service of high-risk AI systems;

Art. 17. 1(g): the risk management system referred to in Article 9;

Art. 17. 1(i): resource management, including security-of-supply related measures;

Art. 17. 1(m): an accountability framework setting out the responsibilities of the management and other staff with regard to all the aspects listed in this paragraph.

Art. 17. 3: Providers of high-risk AI systems that are subject to obligations regarding quality management systems or an equivalent function under relevant sectoral Union law may include the aspects listed in paragraph 1 as part of the quality management systems pursuant to that law.

Art. 17. 4: For providers that are financial institutions subject to requirements regarding their internal governance, arrangements or processes under Union financial services law, the obligation to put in place a quality management system, with the exception of paragraph 1, points (g), (h) and (i) of this Article, shall be deemed to be fulfilled by complying with the rules on internal governance arrangements or processes pursuant to the relevant Union financial services law. To that end, any harmonised standards referred to in Article 40 shall be taken into account.

Art. 18. 1(b): the documentation concerning the quality management system referred to in Article 17;

Art. 19: Notified bodies shall satisfy the organisational, quality management, resources and process requirements that are necessary to fulfil their tasks, as well as suitable cybersecurity requirements.

Art. 31. 5: Neither a conformity assessment body, its top-level management nor the personnel responsible for carrying out its conformity assessment tasks shall be directly involved in the design, development, marketing or use of high-risk AI systems, nor shall they represent the parties engaged in those activities. They shall not engage in any activity that might conflict with their independence of judgement or integrity in relation to conformity assessment activities for which they are notified. This shall, in particular, apply to consultancy services.

Art. 45. 1(b): the assessment of the quality management system and the assessment of the technical documentation, with the involvement of a notified body, referred to in Annex VII. In demonstrating the compliance of a high-risk AI system with the requirements set out in Section 2, the provider shall follow the conformity assessment procedure set out in Annex VII where:

Art. 45. 1(a): any Union technical documentation assessment certificates, any supplements to those certificates, and any quality management system approvals issued in accordance with the requirements of Annex VII;

Art. 45. 1(c): any refusal, restriction, suspension or withdrawal of a Union technical documentation assessment certificate or a quality management system approval issued in accordance with the requirements of Annex VII;

Art. 45. 2(a): quality management system approvals which it has refused, suspended or withdrawn, and, upon request, of quality system approvals which it has issued;

Art. 49. 4: For high-risk AI systems referred to in points 1, 6 and 7 of Annex III, in the areas of law enforcement, migration, asylum and border control management, the registration referred to in paragraphs 1, 2 and 3 of this Article shall be in a secure non-public section of the EU database referred to in Article 71 and shall include only the following information, as applicable, referred to in:

Art. 56. 2(d): the measures, procedures and modalities for the assessment and management of the systemic risks at Union level, including the documentation thereof, which shall be proportionate to the risks, take into consideration their severity and probability and take into account the specific challenges of tackling those risks in light of the possible ways in which such risks may emerge and materialise along the AI value chain.

Art. 72. 1(c): the information on the providers or prospective providers of high-risk AI systems referred to in points 1, 6 and 7 of Annex III in the areas of law enforcement, migration, asylum and border control management, and high-risk AI systems referred to in point 2 of Annex III has registered the testing in real world conditions in accordance with Article 71(4) with a Union-wide unique single identification number and with the information specified in Annex IX; the provider or prospective provider of high-risk AI systems referred to in points 1, 6 and 7 of Annex III in the areas of law enforcement, migration, asylum and border control management, has registered the testing in real-world conditions in the secure non-public section of the EU database according to Article 49(4), point (d), with a Union-wide unique single identification number and with the information specified therein; the provider or prospective provider of high-risk AI systems referred to in point 2 of Annex III has registered the testing in real-world conditions in accordance with Article 49(5);

Art. 63. 1: Microenterprises within the meaning of Recommendation 2003/361/EC may comply with certain elements of the quality management system required by Article 17 of this Regulation in a simplified manner, provided that they do not have partner enterprises or linked enterprises within the meaning of that Recommendation. For that purpose, the Commission shall develop guidelines on the elements of the quality management system which may be complied with in a simplified manner considering the needs of microenterprises, without affecting the level of protection or the need for compliance with the requirements in respect of high-risk AI systems.

Art. 74. 8: For high-risk AI systems listed in point 1 of Annex III to this Regulation, in so far as the systems are used for law enforcement purposes, border management and justice and democracy, and for high-risk AI systems listed in points 6, 7 and 8 of Annex III to this Regulation, Member States shall designate as market surveillance authorities for the purposes of this Regulation either the competent data protection supervisory authorities under Regulation (EU) 2016/679 or Directive (EU) 2016/680, or any other authority designated pursuant to the same conditions laid down in Articles 41 to 44 of Directive (EU) 2016/680. Market surveillance activities shall in no way affect the independence of judicial authorities, or otherwise interfere with their activities when acting in their judicial capacity.

17 Management system

Art. 8. 1: High-risk AI systems shall comply with the requirements laid down in this Section, taking into account their intended purpose as well as the generally acknowledged state of the art on AI and AI-related technologies. The risk management system referred to in Article 9 shall be taken into account when ensuring compliance with those requirements.

Art. 9: Risk management system

Art. 9. 1: A risk management system shall be established, implemented, documented and maintained in relation to high-risk AI systems.

Art. 9. 2: The risk management system shall be understood as a continuous iterative process planned and run throughout the entire lifecycle of a high-risk AI system, requiring regular systematic review and updating. It shall comprise the following steps:

Art. 9. 9: When implementing the risk management system as provided for in paragraphs 1 to 7, providers shall give consideration to whether in view of its intended purpose the high-risk AI system is likely to have an adverse impact on persons under the age of 18 and, as appropriate, other vulnerable groups.

Art. 16. (c): have a quality management system in place which complies with Article 17;

Art. 17: Quality management system

Art. 17. 1: Providers of high-risk AI systems shall put a quality management system in place that ensures compliance with this Regulation. That system shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions, and shall include at least the following aspects:

Art. 17. 1(g): the risk management system referred to in Article 9;

Art. 17. 3: Providers of high-risk AI systems that are subject to obligations regarding quality management systems or an equivalent function under relevant sectoral Union law may include the aspects listed in paragraph 1 as part of the quality management systems pursuant to that law.

Art. 17. 4: For providers that are financial institutions subject to requirements regarding their internal governance, arrangements or processes under Union financial services law, the obligation to put in place a quality management system, with the exception of paragraph 1, points (g), (h) and (i) of this Article, shall be deemed to be fulfilled by complying with the rules on internal governance arrangements or processes pursuant to the relevant Union financial services law. To that end, any harmonised standards referred to in Article 40 shall be taken into account.

Art. 18. 1(b): the documentation concerning the quality management system referred to in Article 17;

Art. 43. 1(b): the assessment of the quality management system and the assessment of the technical documentation, with the involvement of a notified body, referred to in Annex VII. In demonstrating the compliance of a high-risk AI system with the requirements set out in Section 2, the provider shall follow the conformity assessment procedure set out in Annex VII where:

Art. 45. 1(a): any Union technical documentation assessment certificates, any supplements to those certificates, and any quality management system approvals issued in accordance with the requirements of Annex VII;

Art. 45. 1(c): any refusal, restriction, suspension or withdrawal of a Union technical documentation assessment certificate or a quality management system approval issued in accordance with the requirements of Annex VII;

Art. 45. 2(a): quality management system approvals which it has refused, suspended or withdrawn, and, upon request, of quality system approvals which it has issued;

Art. 63. 1: Microenterprises within the meaning of Recommendation 2003/361/EC may comply with certain elements of the quality management system required by Article 17 of this Regulation in a simplified manner, provided that they do not have partner enterprises or linked enterprises within the meaning of that Recommendation. For that purpose, the Commission shall develop guidelines on the elements of the quality management system which may be complied with in a simplified manner considering the needs of microenterprises, without affecting the level of protection or the need for compliance with the requirements in respect of high-risk AI systems.

1 Market for medical or safety reasons

Art. 5. 1(i): the placing on the market, the putting into service for this specific purpose, or the use of AI systems to infer emotions of a natural person in the areas of workplace and education institutions, except where the use of the AI system is intended to be put in place or into the market for medical or safety reasons;

0 Master data

14 Measure

Art. 3. (16): 'recall of an AI system' means any measure aiming to achieve the return to the provider or taking out of service or disabling the use of an AI system made available to deployers;

Art. 3. (17): 'withdrawal of an AI system' means any measure aiming to prevent an AI system in the supply chain being made available on the market;

Art. 10. 2(d): the formulation of assumptions, in particular with respect to the information that the data are supposed to measure and represent;

Art. 15. 2: To address the technical aspects of how to measure the appropriate levels of accuracy and robustness set out in paragraph 1 and any other relevant performance metrics, the Commission shall, in cooperation with relevant stakeholders and organisations such as metrology and benchmarking authorities, encourage, as appropriate, the development of benchmarks and measurement methodologies.

Art. 16. 7: The market surveillance authority of the Member State with the principal rights of the concerned operator in accordance with Article 18 of Regulation (EU) 2019/1020. The three-month period referred to in this paragraph shall be reduced to 30 days in the event of non-compliance with the prohibition of the AI practices referred to in Article 5 of this Regulation.

Art. 79. 8: Where, within three months of receipt of the notification referred to in paragraph 5 of this Article, no objection has been raised by either a market surveillance authority of a Member State or by the Commission in respect of a provisional measure taken by a market surveillance authority of another Member State, the measure shall be without prejudice to the principal rights of the concerned operator in accordance with Article 18 of Regulation (EU) 2019/1020. The three-month period referred to in this paragraph shall be reduced to 30 days in the event of non-compliance with the prohibition of the AI practices referred to in Article 5 of this Regulation.

Art. 81. 1: Where, within three months of receipt of the notification referred to in Article 79(5), or within 30 days in the case of non-compliance with the prohibition of the AI practices referred to in Article 5, objections are raised by the market surveillance authority of a Member State to a measure taken by another market surveillance authority, or where the Commission considers the measure to be contrary to Union law, the Commission shall without undue delay enter into consultation with the market surveillance authority of the relevant Member State and the operator or operators, and shall evaluate the national measure. On the basis of the results of that evaluation, the Commission shall, within six months, or within 60 days in the case of non-compliance with the prohibition of the AI practices referred to in Article 5, starting from the notification referred to in Article 79(5), decide whether the national measure is justified and shall notify its decision to the market surveillance authority of the Member State concerned. The Commission shall also inform all other market surveillance authorities of its decision.

Art. 81. 2: Where the Commission considers the measure taken by the relevant Member State to be justified, all Member States shall ensure that they take appropriate restrictive measures in respect of the AI system concerned, such as requiring the withdrawal of the AI system from their market without undue delay, and shall inform the Commission accordingly. Where the Commission considers the national measure to be unjustified, the Member State concerned shall withdraw the measure and shall inform the Commission accordingly.

Art. 81. 3: Where the national measure is considered justified and the non-compliance of the AI system is attributed to shortcomings in the harmonised standards or common specifications referred to in Articles 40 and 41 of this Regulation, the Commission shall apply the procedure provided for in Article 11 of Regulation (EU) No 1025/2012.

Art. 82. 4: The Commission shall without undue delay enter into consultation with the Member States concerned and the relevant operators, and shall evaluate the national measures taken. On the basis of the results of that evaluation, the Commission shall decide whether the measure is justified and, where necessary, propose other appropriate measures.

Art. 90. 2: Upon such qualified alert, the Commission, through the AI Office and after having informed the Board, may exercise the powers laid down in this Section for the purpose of assessing the matter. The AI Office shall inform the Board of any measure according to Articles 91 to 94.

Art. 93. 2: Before a measure is requested, the AI Office may initiate a structured dialogue with the provider of the general-purpose AI model.

Art. 95. 2: The AI Office and the Member States shall facilitate the drawing up of codes of conduct concerning the voluntary application, including by deployers, of specific requirements to all AI systems, on the basis of clear objectives and key performance indicators to measure the achievement of those objectives, including elements such as, but not limited to:

Art. 101. 1(c): failed to comply with a measure requested under Article 93;

2 Measurement (See also: Measuring)

Art. 15. 2: To address the technical aspects of how to measure the appropriate levels of accuracy and robustness set out in paragraph 1 and any other relevant performance metrics, the Commission shall, in cooperation with relevant stakeholders and organisations such as metrology and benchmarking authorities, encourage, as appropriate, the development of benchmarks and measurement methodologies.

Art. 53. 5: For the purpose of facilitating compliance with Annex XI, in particular points 2 (d) and (e) thereof, the Commission is empowered to adopt delegated acts in accordance with Article 97 to detail measurement and calculation methodologies with a view to allowing for comparable and verifiable documentation.

0 Measuring (See also: Measurement)

4 Metric

Art. 9. 8: The testing of high-risk AI systems shall be performed, as appropriate, at any time throughout the development process, and, in any event, prior to their being placed on the market or put into service. Testing shall be carried out against prior defined metrics and probabilistic thresholds that are appropriate to the intended purpose of the high-risk system.

Art. 13. 3(b)(ii): the level of accuracy, including its metrics, robustness and cybersecurity referred to in Article 15 against which the high-risk AI system has been tested and validated and which can be expected, and any known and foreseeable circumstances that may have an impact on that expected level of accuracy, robustness and cybersecurity;

Art. 15. 2: To address the technical aspects of how to measure the appropriate levels of accuracy and robustness set out in paragraph 1 and any other relevant performance metrics, the Commission shall, in cooperation with relevant stakeholders and organisations such as metrology and benchmarking authorities, encourage, as appropriate, the development of benchmarks and measurement methodologies.

Art. 15. 3: The levels of accuracy and the relevant accuracy metrics of high-risk AI systems shall be declared in the accompanying instructions of use.

Terms and AI Act Articles

27 Monitoring

Art. 1, 2(f): rules on market monitoring, market surveillance, governance and enforcement;

Art. 3, (19): notifying authority' means the national authority responsible for setting up and carrying out the necessary procedures for the assessment, designation and notification of conformity assessment bodies and for their monitoring;

Art. 3, (25): 'post-market monitoring system' means all activities carried out by providers of AI systems to collect and review experience gained from the use of AI systems they place on the market or put into service for the purpose of identifying any need to immediately apply any necessary corrective or preventive actions;

Art. 3, (47): 'AI Office' means the Commission's function of contributing to the implementation, monitoring and supervision of AI systems and general-purpose AI models, and AI governance, provided for in Commission Decision of 24 January 2024; references in this Regulation to the AI Office shall be construed as references to the Commission;

Art. 3, (53): 'real-world testing plan' means a document that describes the objectives, methodology, geographical population and temporal scope, monitoring, organisation and conduct of testing in real-world conditions;

Art. 9, 2(c): the evaluation of other risks possibly arising, based on the analysis of data gathered from the post-market monitoring system referred to in Article 72;

Art. 12, 2(b): facilitating the post-market monitoring referred to in Article 72; and

Art. 12, 2(c): monitoring the operation of high-risk AI systems referred to in Article 26(5).

Art. 17, (1h): the setting-up, implementation and maintenance of a post-market monitoring system, in accordance with Article 72;

Art. 26, 5: Deployers shall monitor the operation of the high-risk AI system on the basis of the instructions for use and, where relevant, inform providers in accordance with Article 72. Where deployers have reason to consider that the use of the high-risk AI system in accordance with the instructions may result in that AI system presenting a risk within the meaning of Article 79(1), they shall, without undue delay, inform the provider or distributor and the relevant market surveillance authority, and shall suspend the use of that system. Where deployers have identified a serious incident, they shall also immediately inform first the provider, and then the importer or distributor and the relevant market surveillance authorities of that incident. If the deployer is not able to reach the provider, Article 73 shall apply mutatis mutandis. This obligation shall not cover sensitive operational data of deployers of AI systems which are law enforcement authorities. For deployers that are financial institutions subject to requirements regarding their internal governance, arrangements or processes under Union financial services law, the monitoring obligation set out in the first subparagraph shall be deemed to be fulfilled by complying with the rules on internal governance arrangements, processes and mechanisms pursuant to the relevant financial service law.

Art. 28, 1: Each Member State shall designate or establish at least one notifying authority responsible for setting up and carrying out the necessary procedures for the assessment, designation and notification of conformity assessment bodies and for their monitoring. Those procedures shall be developed in cooperation between the notifying authorities of all Member States.

Art. 28, 2: Member States may decide that the assessment and monitoring referred to in paragraph 1 is to be carried out by a national accreditation body within the meaning of, and in accordance with, Regulation (EC) No 765/2008.

Art. 29, 3: Where the conformity assessment body concerned cannot provide an accreditation certificate, it shall provide the notifying authority with all the documentary evidence necessary for the verification, recognition and regular monitoring of its compliance with the requirements laid down in Article 31.

Art. 34, 3: Notified bodies shall make available and submit upon request all relevant documentation, including the providers' documentation, to the notifying authority referred to in Article 28 to allow that authority to conduct its assessment, designation, notification and monitoring activities, and to facilitate the assessment outlined in this Section.

Art. 58, 1(b): procedures for the application, participation, monitoring, exiting from and termination of the AI regulatory sandbox, including the sandbox plan and the exit report;

Art. 59, 1(c): there are effective monitoring mechanisms to identify any high risks to the rights and freedoms of the data subjects, as referred to in Article 35 of Regulation (EU) 2016/679 and in Article 39 of Regulation (EU) 2018/1725, may arise during the sandbox experimentation, as well as response mechanisms to promptly mitigate those risks and, where necessary, stop the processing;

Art. 66, 10: receive opinions by the Member States on qualified alerts regarding general-purpose AI models, and on national experiences and practices on the monitoring and enforcement of AI systems, in particular systems integrating the general-purpose AI models.

CHAPTER IX. POST-MARKET MONITORING, INFORMATION SHARING AND MARKET SURVEILLANCE

SECTION 1: Post-market monitoring

Art. 72: Post-market monitoring by providers and post-market monitoring plan for high-risk AI systems

Art. 72, 1: Providers shall establish and document a post-market monitoring system in a manner that is proportionate to the nature of the AI technologies and the risks of the high-risk AI system.

Art. 72, 2: The post-market monitoring system shall actively and systematically collect, document and analyse relevant data which may be provided by deployers or which may be collected through other sources on the performance of high-risk AI systems throughout their lifetime, and which allow the provider to evaluate the continuous compliance of AI systems with the requirements set out in Chapter III, Section 2. Where relevant, post-market monitoring shall include an analysis of the interaction with other AI systems. This obligation shall not cover sensitive operational data of deployers which are law-enforcement authorities.

Art. 72, 3: The post-market monitoring system shall be based on a post-market monitoring plan. The post-market monitoring plan shall be part of the technical documentation referred to in Annex IV. The Commission shall adopt an implementing act laying down detailed provisions establishing a template for the post-market monitoring plan and the list of elements to be included in the plan by 2 February 2026. That implementing act shall be adopted in accordance with the examination procedure referred to in Article 98(2).

Art. 72, 4: For high-risk AI systems covered by the Union harmonisation legislation listed in Section A of Annex I, where a post-market monitoring system and plan are already established under that legislation, in order to ensure consistency, avoid duplications and minimise additional burdens, providers shall have a choice of integrating, as appropriate, the necessary elements described in paragraphs 1, 2 and 3 using the template referred in paragraph 3 into systems and plans already existing under that legislation, provided that it achieves an equivalent level of protection. The first subparagraph of this paragraph shall also apply to high-risk AI systems referred to in point 5 of Annex III placed on the market or put into service by financial institutions that are subject to requirements under Union financial services law regarding their internal governance, arrangements or processes.

Art. 75, 1: Where an AI system is based on a general-purpose AI model, and the model and the system are developed by the same provider, the AI Office shall have powers to monitor and supervise compliance of that AI system with obligations under this Regulation. To carry out its monitoring and supervision tasks, the AI Office shall have all the powers of a market surveillance authority provided for in this Section and Regulation (EU) 2019/1020.

SECTION 5: Supervision, investigation, enforcement and monitoring in respect of providers of general-purpose AI models

Art. 89: Monitoring actions

1 Mutual assistance

Art. 75: Mutual assistance, market surveillance and control of general-purpose AI systems

0 Neural network

18 Non-compliance

Art. 20, 2: Where the high-risk AI system presents a risk within the meaning of Article 79(1) and the provider becomes aware of that risk, it shall immediately investigate the causes, in collaboration with the reporting deployer, where applicable, and inform the market surveillance authorities competent for the high-risk AI system concerned and, where applicable, the notified body that issued a certificate for that high-risk AI system in accordance with Article 44, in particular, of the nature of the non-compliance and of any relevant corrective action taken.

Art. 24, 4: A distributor that considers or has reason to consider, on the basis of the information in its possession, a high-risk AI system which it has made available on the market not to be in conformity with the requirements set out in Section 2, shall take the corrective actions necessary to bring that system into conformity with those requirements, to withdraw it or recall it, or shall ensure that the provider, the importer or any relevant operator, as appropriate, takes those corrective actions. Where the high-risk AI system presents a risk within the meaning of Article 79(1), the distributor shall immediately inform the provider or importer of the system and the authorities competent for the high-risk AI system concerned, giving details, in particular, of the non-compliance and of any corrective actions taken.

Art. 74, 11: Market surveillance authorities and the Commission shall be able to propose joint activities, including joint investigations, to be conducted by either market surveillance authorities or market surveillance authorities jointly with the Commission, that have the aim of promoting compliance, identifying non-compliance, raising awareness or providing guidance in relation to this Regulation with respect to specific categories of high-risk AI systems that are found to present a serious risk across two or more Member States in accordance with Article 9 of Regulation (EU) 2019/1020. The AI Office shall provide coordination support for joint investigations.

Art. 79, 3: Where the market surveillance authority considers that the non-compliance is not restricted to its national territory, it shall inform the Commission and the other Member States without undue delay of the results of the evaluation and of the actions which it has required the operator to take.

Art. 79, 6: The notification referred to in paragraph 5 shall include all available details, in particular the information necessary for the identification of the non-compliant AI system, the origin of the AI system and the supply chain, the nature of the non-compliance alleged and the risk involved, the nature and duration of the national measures taken and the arguments put forward by the relevant operator. In particular, the market surveillance authorities shall indicate whether the non-compliance is due to one or more of the following:

Art. 79, 6(a): non-compliance with the prohibition of the AI practices referred to in Article 5;

Art. 79, 6(d): non-compliance with Article 50.

Art. 79, 7: The market surveillance authorities other than the market surveillance authority of the Member State initiating the procedure shall, without undue delay, inform the Commission and the other Member States of any measures adopted and of any additional information at their disposal relating to the non-compliance of the AI system concerned, and, in the event of disagreement with the notified national measure, of their objections.

Art. 79, 8: Where, within three months of receipt of the notification referred to in paragraph 5 of this Article, no objection has been raised by either a market surveillance authority of a Member State or by the Commission in respect of a provisional measure taken by a market surveillance authority of another Member State, that measure shall be deemed justified. This shall be without prejudice to the procedural rights of the concerned operator in accordance with Article 18 of Regulation (EU) 2019/1020. The three-month period referred to in this paragraph shall be reduced to 30 days in the event of non-compliance with the prohibition of the AI practices referred to in Article 5 of this Regulation.

Art. 81, 1: Where, within three months of receipt of the notification referred to in Article 79(5), or within 30 days in the case of non-compliance with the prohibition of the AI practices referred to in Article 5, objections are raised by the market surveillance authority of a Member State to a measure taken by another market surveillance authority, or where the Commission considers the measure to be contrary to Union law, the Commission shall without undue delay enter into consultation with the market surveillance authority of the relevant Member State and the operator or operators, and shall evaluate the national measure. On the basis of the results of that evaluation, the Commission shall, within six months, or within 60 days in the case of non-compliance with the prohibition of the AI practices referred to in Article 5, starting from the notification referred to in Article 79(5), decide whether the national measure is justified and shall notify its decision to the market surveillance authority of the Member State concerned. The Commission shall also inform all other market surveillance authorities of its decision.

Art. 81, 2: Where the national measure is considered justified and the non-compliance of the AI system is attributed to shortcomings in the harmonised standards or common specifications referred to in Articles 40 and 41 of this Regulation, the Commission shall apply the procedure provided for in Article 11 of Regulation (EU) No 1025/2012.

Art. 83: Formal non-compliance

Art. 83, 1: Where the market surveillance authority of a Member State makes one of the following findings, it shall require the relevant provider to put an end to the non-compliance concerned, within a period it may prescribe:

Art. 83, 2: Where the non-compliance referred to in paragraph 1 persists, the market surveillance authority of the Member State concerned shall take appropriate and proportionate measures to restrict or prohibit the high-risk AI system being made available on the market or to ensure that it is recalled or withdrawn from the market without delay.

Art. 99, 3: Non-compliance with the prohibition of the AI practices referred to in Article 5 shall be subject to administrative fines of up to EUR 35 000 000 or, if the offender is an undertaking, up to 7 % of its total worldwide annual turnover for the preceding financial year, whichever is higher.

Art. 99, 4: Non-compliance with any of the following provisions related to operators or notified bodies, other than those laid down in Articles 5, shall be subject to administrative fines of up to EUR 15 000 000 or, if the offender is an undertaking, up to 3 % of its total worldwide annual turnover for the preceding financial year, whichever is higher.

Art. 100, 2: Non-compliance with the prohibition of the AI practices referred to in Article 5 shall be subject to administrative fines of up to EUR 1 500 000.

Art. 100, 3: The non-compliance of the AI system with any requirements or obligations under this Regulation, other than those laid down in Article 5, shall be subject to administrative fines of up to EUR 750 000.

0 Non-repudiation

Terms and AI Act Articles

33 Notification

- Art. 3. (19):** notifying authority' means the national authority responsible for setting up and carrying out the necessary procedures for the assessment, designation and notification of conformity assessment bodies and for their monitoring;
- Art. 5. 4:** Without prejudice to paragraph 3, each use of a real-time remote biometric identification system in publicly accessible spaces for law enforcement purposes shall be notified to the relevant market surveillance authority and the national data protection authority in accordance with the national rules referred to in paragraph 5. The notification shall, as a minimum, contain the information specified under paragraph 6 and shall not include sensitive operational data.
- Art. 27. 3:** Once the assessment referred to in paragraph 1 of this Article has been performed, the deployer shall notify the market surveillance authority of its results, submitting the filled-out template referred to in paragraph 5 of this Article as part of the notification. In the case referred to in Article 46(1), deployers may be exempt from that obligation to notify.
- Art. 28. 1:** Each Member State shall designate or establish at least one notifying authority responsible for setting up and carrying out the necessary procedures for the assessment, designation and notification of conformity assessment bodies and for their monitoring. Those procedures shall be developed in cooperation between the notifying authorities of all Member States.
- Art. 28. 4:** Notifying authorities shall be organised in such a way that decisions relating to the notification of conformity assessment bodies are taken by competent persons different from those who carried out the assessment of those bodies.
- Art. 29:** Application of a conformity assessment body for notification
- Art. 29. 1:** Conformity assessment bodies shall submit an application for notification to the notifying authority of the Member State in which they are established.
- Art. 29. 2:** The application for notification shall be accompanied by a description of the conformity assessment activities, the conformity assessment module or modules and the types of AI systems for which the conformity assessment body claims to be competent, as well as by an accreditation certificate, where one exists, issued by a national accreditation body attesting that the conformity assessment body fulfils the requirements laid down in Article 31. Any valid document related to existing designations of the applicant notified body under any other Union harmonisation legislation shall be added.
- Art. 30:** Notification procedure
- Art. 30. 2:** Notifying authorities shall notify the Commission and the other Member States, using the electronic notification tool developed and managed by the Commission, of each conformity assessment body referred to in paragraph 1.
- Art. 30. 3:** The notification referred to in paragraph 2 of this Article shall include full details of the conformity assessment activities, the conformity assessment module or modules, the types of AI systems concerned, and the relevant attestation of competence. Where a notification is not based on an accreditation certificate as referred to in Article 29(2), the notifying authority shall provide the Commission and the other Member States with documentary evidence which attests to the competence of the conformity assessment body and to the arrangements in place to ensure that that body will be monitored regularly and will continue to satisfy the requirements laid down in Article 31.
- Art. 30. 4:** The conformity assessment body concerned may perform the activities of a notified body only where no objections are raised by the Commission or the other Member States within two weeks of a notification by a notifying authority where it includes an accreditation certificate referred to in Article 29(2), or within two months of a notification by the notifying authority where it includes documentary evidence referred to in Article 29(3).
- Art. 34. 3:** Notified bodies shall make available and submit upon request all relevant documentation, including the providers' documentation, to the notifying authority referred to in Article 28 to allow that authority to conduct its assessment, designation, notification and monitoring activities, and to facilitate the assessment outlined in this Section.
- Art. 36:** Changes to notifications
- Art. 36. 1:** The notifying authority shall notify the Commission and the other Member States of any relevant changes to the notification of a notified body via the electronic notification tool referred to in Article 30(2).
- Art. 36. 2:** The procedures laid down in Articles 29 and 30 shall apply to extensions of the scope of the notification. For changes to the notification other than extensions of its scope, the procedures laid down in paragraphs (3) to (9) shall apply.
- Art. 37. 2:** The notifying authority shall provide the Commission, on request, with all relevant information relating to the notification or the maintenance of the competence of the notified body concerned.
- Art. 37. 4:** Where the Commission ascertains that a notified body does not meet or no longer meets the requirements for its notification, it shall inform the notifying Member State accordingly and request it to take the necessary corrective measures, including the suspension or withdrawal of the notification if necessary. Where the Member State fails to take the necessary corrective measures, the Commission may, by means of an implementing act, suspend, restrict or withdraw the designation. That implementing act shall be adopted in accordance with the examination procedure referred to in Article 98(2).
- Art. 43. 3:** For high-risk AI systems covered by the Union harmonisation legislation listed in Section A of Annex I, the provider shall follow the relevant conformity assessment procedure as required under those legal acts. The requirements set out in Section 2 of this Chapter shall apply to those high-risk AI systems and shall be part of that assessment. Points 4.3, 4.4, 4.5 and the fifth paragraph of point 4.6 of Annex VII shall also apply. For the purposes of that assessment, notified bodies which have been notified under those legal acts shall be entitled to control the conformity of the high-risk AI systems with the requirements set out in Section 2, provided that the compliance of those notified bodies with requirements laid down in Article 31(4), (5), (10) and (11) has been assessed in the context of the notification procedure under those legal acts. Where a legal act listed in Section A of Annex I enables the product manufacturer to opt out from a third-party conformity assessment, provided that that manufacturer has applied all harmonised standards covering all the relevant requirements, that manufacturer may use that option only if it has also applied harmonised standards or, where applicable, common specifications referred to in Article 41, covering all requirements set out in Section 2 of this Chapter.
- Art. 45. (c):** any circumstances affecting the scope of or conditions for notification;
- Art. 45. (e):** on request, conformity assessment activities performed within the scope of their notification and any other activity performed, including cross-border activities and subcontracting.
- Art. 46. 5:** Where, within 15 calendar days of receipt of the notification referred to in paragraph 3, objections are raised by a Member State against an authorisation issued by a market surveillance authority of another Member State, or where the Commission considers the authorisation to be contrary to Union law, or the conclusion of the Member States regarding the compliance of the system as referred to in paragraph 3 to be unfounded, the Commission shall, without delay, enter into consultations with the relevant Member State. The operators concerned shall be consulted and have the possibility to present their views. Having regard thereto, the Commission shall decide whether the authorisation is justified. The Commission shall address its decision to the Member State concerned and to the relevant operators.
- Art. 52. 1:** Where a general-purpose AI model meets the condition referred to in Article 51(1), point (a), the relevant provider shall notify the Commission without delay and in any event within two weeks after that requirement is met or it becomes known that it will be met. That notification shall include the information necessary to demonstrate that the relevant requirement has been met. If the Commission becomes aware of a general-purpose AI model presenting systemic risks of which it has not been notified, it may decide to designate it as a model with systemic risk.
- Art. 52. 2:** The provider of a general-purpose AI model that meets the condition referred to in Article 51(1), point (a), may present, with its notification, sufficiently substantiated arguments to demonstrate that, exceptionally, although it meets that requirement, the general-purpose AI model does not present, due to its specific characteristics, systemic risks and therefore should not be classified as a general-purpose AI model with systemic risk.
- Art. 60. 4(f):** the testing in real world conditions does not last longer than necessary to achieve its objectives and in any case not longer than six months, which may be extended for an additional period of six months, subject to prior notification by the provider or prospective provider to the market surveillance authority, accompanied by an explanation of the need for such an extension;
- Art. 73. 7:** Upon receiving a notification related to a serious incident referred to in Article 3, point (49)(c), the relevant market surveillance authority shall inform the national public authorities or bodies referred to in Article 77(1). The Commission shall develop dedicated guidance to facilitate compliance with the obligations set out in paragraph 1 of this Article. That guidance shall be issued by 2 August 2025, and shall be assessed regularly.
- Art. 73. 8:** The market surveillance authority shall take appropriate measures, as provided for in Article 19 of Regulation (EU) 2019/1020, within seven days from the date it received the notification referred to in paragraph 1 of this Article, and shall follow the notification procedures as provided in that Regulation.
- Art. 73. 9:** For high-risk AI systems referred to in Annex III that are placed on the market or put into service by providers that are subject to Union legislative instruments laying down reporting obligations equivalent to those set out in this Regulation, the notification of serious incidents shall be limited to those referred to in Article 3, point (49)(c).
- Art. 73. 10:** For high-risk AI systems which are safety components of devices, or are themselves devices, covered by Regulations (EU) 2017/745 and (EU) 2017/746, the notification of serious incidents shall be limited to those referred to in Article 3, point (49)(c) of this Regulation, and shall be made to the national competent authority chosen for that purpose by the Member States where the incident occurred.
- Art. 79. 6:** The notification referred to in paragraph 5 shall include all available details, in particular the information necessary for the identification of the non-compliant AI system, the origin of the AI system and the supply chain, the nature of the non-compliance alleged and the risk involved, the nature and duration of the national measures taken and the arguments put forward by the relevant operator. In particular, the market surveillance authorities shall indicate whether the non-compliance is due to one or more of the following:
- Art. 79. 6:** Where, within three months of receipt of the notification referred to in paragraph 5 of this Article, no objection has been raised by either a market surveillance authority of a Member State or by the Commission in respect of a provisional measure taken by a market surveillance authority of another Member State, that measure shall be deemed justified. This shall be without prejudice to the procedural rights of the concerned operator in accordance with Article 18 of Regulation (EU) 2019/1020. The three-month period referred to in this paragraph shall be reduced to 30 days in the event of non-compliance with the prohibition of the AI practices referred to in Article 5 of this Regulation.
- Art. 81. 1:** Where, within three months of receipt of the notification referred to in Article 79(5), or within 30 days in the case of non-compliance with the prohibition of the AI practices referred to in Article 5, objections are raised by the market surveillance authority of a Member State to a measure taken by another market surveillance authority, or where the Commission considers the measure to be contrary to Union law, the Commission shall without undue delay enter into consultation with the market surveillance authority of the relevant Member State and the operator or operators, and shall evaluate the national measure. On the basis of the results of that evaluation, the Commission shall, within six months, or within 60 days in the case of non-compliance with the prohibition of the AI practices referred to in Article 5, starting from the notification referred to in Article 79(5), decide whether the national measure is justified and shall notify its decision to the market surveillance authority of the Member State concerned. The Commission shall also inform all other market surveillance authorities of its decision.
- Art. 97. 6:** Any delegated act adopted pursuant to Article 6(6) or (7), Article 1(1) or (3), Article 11(3), Article 43(5) or (6), Article 47(5), Article 51(3), Article 52(4) or Article 53(5) or (6) shall enter into force only if no objection has been expressed by either the European Parliament or the Council within a period of three months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by three months at the initiative of the European Parliament or of the Council.

Terms and AI Act Articles

75 Notified body

Art. 3. (22): 'notified body' means a conformity assessment body notified in accordance with this Regulation and other relevant Union harmonisation legislation;

Art. 11. 1: The technical documentation of a high-risk AI system shall be drawn up before that system is placed on the market or put into service and shall be kept up-to-date. The technical documentation shall be drawn up in such a way as to demonstrate that the high-risk AI system complies with the requirements set out in this Section and to provide national competent authorities and notified bodies with the necessary information in a clear and comprehensive form to assess the compliance of the AI system with those requirements. It shall contain, at a minimum, the information set out in Annex VI. For systems covered by Article 6 in a simplified manner, the Commission shall establish a simplified technical documentation form targeted at the needs of small and micro-enterprises. Where an SME, including a start-up, opts to provide the information required in Annex IV in a simplified manner, it shall use the form referred to in this paragraph. Notified bodies shall accept the form for the purposes of the conformity assessment.

Art. 17. (j): the handling of communication with national competent authorities, other relevant authorities, including those providing or supporting the access to data, notified bodies, other operators, customers or other interested parties;

Art. 18. (f): the documentation and information referred to in Articles 11, 17 and 19, including the technical documentation and information referred to in this Regulation, as well as any other documents issued by the notified body, where applicable;

Art. 20. 2: Where the high-risk AI system presents a risk within the meaning of Article 79(1) and the provider becomes aware of that risk, it shall immediately investigate the causes, in collaboration with the reporting deployer, where applicable, and inform the market surveillance authorities concerned for the high-risk AI system concerned as well as the reporting deployer, where applicable, and request that the reporting deployer take the necessary measures to prevent or minimise the risk, in accordance with Article 44, in particular, of the nature of the non-compliance and of any relevant corrective action taken.

Art. 22. (b): keep at the disposal of the competent authorities and national authorities or bodies referred to in Article 74(10), for a period of 10 years after the high-risk AI system has been placed on the market or put into service, the contact details of the provider that appointed the authorised representative, a copy of the EU declaration of conformity referred to in Article 47, the technical documentation and, if applicable, the certificate issued by the notified body;

Art. 22. 4: The authorised representative shall terminate the mandate or has reason to consider the provider to be acting contrary to its obligations pursuant to this Regulation. In such a case, it shall immediately inform the relevant market surveillance authority, as well as, where applicable, the relevant notified body, about the termination of the mandate and the reasons therefor.

Art. 23. 5: Importers shall keep, for a period of 10 years after the high-risk AI system has been placed on the market or put into service, a copy of the certificate issued by the notified body, where applicable, of the instructions for use, and of the EU declaration of conformity referred to in Article 47.

SECTION 4: Notifying authorities and notified bodies
Art. 29. 2: The application for notification shall be accompanied by a description of the conformity assessment activities, the conformity assessment module or modules and the types of AI systems for which the conformity assessment body claims to be competent, as well as by an accreditation certificate, issued by a national accreditation body attesting that the conformity assessment body fulfils the requirements laid down in Article 31. Any valid document related to existing designations of the applicant notified body under any other Union harmonisation legislation shall be added.

Art. 29. 4: For notified bodies which are designated under any other Union harmonisation legislation, all documents and certificates linked to those designations may be used to support their designation procedure under this Regulation, as appropriate. The notified body shall update the documentation referred to in paragraphs 2 and 3 of this Article whenever relevant changes occur, in order to enable the authority responsible for notified bodies to monitor and verify continuous compliance with all the requirements laid down in Article 31.

Art. 30. 4: The conformity assessment body concerned may perform the activities of a notified body only where no objections are raised by the Commission or the other Member States within two weeks of a notification by a notifying authority where it includes an accreditation certificate referred to in Article 29(2), or within two months of a notification by the notifying authority where it includes documentary evidence referred to in Article 29(3).

Art. 31. Requirements relating to notified bodies
Art. 31. 1: A notified body shall be established under the national law of a Member State and shall have legal personality.

Art. 31. 2: Notified bodies shall satisfy the organisational, quality management, resources and process requirements that are necessary to fulfil their tasks, as well as suitable cybersecurity requirements.

Art. 31. 3: The organisational structure, allocation of responsibilities, reporting lines and operation of notified bodies shall ensure confidence in their performance, and in the results of the conformity assessment activities that the notified bodies conduct.

Art. 31. 4: Notified bodies shall be independent of the provider of a high-risk AI system in relation to which they perform conformity assessment activities. Notified bodies shall also be independent of any other operator having an economic interest in high-risk AI systems assessed, as well as of any competitors of the provider. This shall not preclude the use of assessed high-risk AI systems that are necessary for the operations of the conformity assessment body, or the use of such high-risk AI systems for personal purposes.

Art. 31. 5: Notified bodies shall ensure the performance of conformity assessment activities, except when its disclosure is required by law. The staff of notified bodies shall be bound to observe professional secrecy with regard to all information obtained in carrying out their tasks under this Regulation, except in relation to the notifying authorities of the Member State in which their activities are carried out.

Art. 31. 6: Notified bodies shall have procedures for the performance of activities which take due account of the size of a provider, the sector in which it operates, its structure, and the degree of complexity of the AI system concerned.

Art. 31. 8: Notified bodies shall take out appropriate liability insurance for their conformity assessment activities, unless liability is assumed by the Member State in which they are established in accordance with national law and that Member State is itself directly responsible for the conformity assessment.

Art. 31. 10: Notified bodies shall be capable of carrying out all their tasks under this Regulation with the highest degree of professional integrity and the requisite competence in the specific field, whether those tasks are carried out by notified bodies themselves or on their behalf and under their responsibility.

Art. 31. 11: Notified bodies shall have sufficient internal competences to be able effectively to evaluate the tasks conducted by external parties on their behalf. The notified body shall have permanent availability of sufficient administrative, technical, legal and scientific personnel who possess the experience and the necessary competences of AI systems, data, and information, and relating to the requirements set out in Section 2.

Art. 31. 12: Notified bodies shall participate in coordination activities as referred to in Article 38. They shall also take part directly, or be represented in, European standardisation organisations, or ensure that they are aware and up to date in respect of relevant standards.

Art. 32. Presumption of conformity with requirements relating to notified bodies
Art. 32. 1: Subsidiaries of notifying authorities or notified bodies shall ensure that the conformity assessment or has recourse to a subsidiary, it shall ensure that the subcontractor or the subsidiary meets the requirements laid down in Article 31, and shall inform the notifying authority accordingly.

Art. 33. 2: Activities may be subcontracted or carried out by a subsidiary only with the agreement of the provider. Notified bodies shall make a list of their subsidiaries publicly available.

Art. 34. Operational obligations of notified bodies
Art. 34. 1: Notified bodies shall notify the national law of a Member State in which they are established, and shall comply with the requirements set out in Article 43.

Art. 34. 2: Notified bodies shall avoid unnecessary burdens for providers when performing their activities, and take due account of the size of the provider, the sector in which it operates, its structure and the degree of complexity of the high-risk AI system concerned, in particular in view of minimising administrative burdens and compliance costs for micro- and small enterprises within the meaning of Recommendation 2003/361/EC. The notified body shall, nevertheless, respect the degree of rigour and the level of protection required for the compliance of the high-risk AI system with the requirements set out in Article 43.

Art. 34. 3: Notified bodies shall make available and submit upon request all relevant documentation, including the providers' documentation, to the notifying authority referred to in Article 28 to allow that authority to conduct its assessment, designation, notification and monitoring activities, and to facilitate the assessment outlined in this Section.

Art. 35. Identification number and single identification number
Art. 35. 1: The Commission shall assign a single identification number to each notified body, even where a body is notified under more than one Union act.

Art. 36. 1: The notifying authority shall notify the Commission and the other Member States of any relevant changes to the notification of a notified body via the electronic notification tool referred to in Article 30(2).

Art. 36. 2: Where a notified body ceases its activities, or where the provider ceases its activities, or where the provider ceases to provide products or services, the notifying authority shall, at least one year before ceasing its activities, the certificates of the notified body may remain valid for a period of nine months after cessation of the notified body's activities, on condition that another notified body has confirmed in writing that it will assume responsibilities for the high-risk AI systems covered by those certificates. The latter notified body shall complete a full assessment of the high-risk AI systems affected by the end of that nine-month-period before issuing new certificates for those systems. Where the notified body has ceased its activity, the notifying authority shall withdraw the designation.

Art. 36. 4: Where a notified body ceases its activities, or where the provider ceases its activities, or where the provider ceases to provide products or services, the notifying authority shall, at least one year before ceasing its activities, the certificates of the notified body may remain valid for a period of nine months after cessation of the notified body's activities, on condition that another notified body has confirmed in writing that it will assume responsibilities for the high-risk AI systems covered by those certificates. The latter notified body shall complete a full assessment of the high-risk AI systems affected by the end of that nine-month-period before issuing new certificates for those systems. Where the notified body has ceased its activity, the notifying authority shall withdraw the designation.

Art. 36. 5: Where its designation has been suspended, restricted, or withdrawn, the notified body shall, at least one year before ceasing its activities, the certificates of the notified body may remain valid for a period of nine months after cessation of the notified body's activities, on condition that another notified body has confirmed in writing that it will assume responsibilities for the high-risk AI systems covered by those certificates. The latter notified body shall complete a full assessment of the high-risk AI systems affected by the end of that nine-month-period before issuing new certificates for those systems. Where the notified body has ceased its activity, the notifying authority shall withdraw the designation.

Art. 36. 6: In the event of the restriction, suspension or withdrawal of a designation, the notifying authority shall take appropriate steps to ensure that the files of the notified body concerned are kept, and to make them available to notifying authorities in other Member States and to market surveillance authorities at their request.

Art. 36. (f): assess the impact of the certificates issued by the notified body;

Art. 36. (g): assess the impact of the certificates issued by the notified body;

Art. 36. (h): assess the impact of the certificates issued by the notified body;

Art. 36. (i): assess the impact of the certificates issued by the notified body;

Art. 36. (j): assess the impact of the certificates issued by the notified body;

Art. 36. (k): assess the impact of the certificates issued by the notified body;

Art. 36. (l): assess the impact of the certificates issued by the notified body;

Art. 36. (m): assess the impact of the certificates issued by the notified body;

Art. 36. (n): assess the impact of the certificates issued by the notified body;

Art. 36. (o): assess the impact of the certificates issued by the notified body;

Art. 36. (p): assess the impact of the certificates issued by the notified body;

Art. 36. (q): assess the impact of the certificates issued by the notified body;

Art. 36. (r): assess the impact of the certificates issued by the notified body;

Art. 36. (s): assess the impact of the certificates issued by the notified body;

Art. 36. (t): assess the impact of the certificates issued by the notified body;

Art. 36. (u): assess the impact of the certificates issued by the notified body;

Art. 36. (v): assess the impact of the certificates issued by the notified body;

Art. 36. (w): assess the impact of the certificates issued by the notified body;

Art. 36. (x): assess the impact of the certificates issued by the notified body;

Art. 36. (y): assess the impact of the certificates issued by the notified body;

Art. 36. (z): assess the impact of the certificates issued by the notified body;

Art. 36. (aa): assess the impact of the certificates issued by the notified body;

Art. 36. (ab): assess the impact of the certificates issued by the notified body;

Art. 36. (ac): assess the impact of the certificates issued by the notified body;

Art. 36. (ad): assess the impact of the certificates issued by the notified body;

Art. 36. (ae): assess the impact of the certificates issued by the notified body;

Art. 36. (af): assess the impact of the certificates issued by the notified body;

Art. 36. (ag): assess the impact of the certificates issued by the notified body;

Art. 36. (ah): assess the impact of the certificates issued by the notified body;

Art. 36. (ai): assess the impact of the certificates issued by the notified body;

Art. 36. (aj): assess the impact of the certificates issued by the notified body;

Art. 36. (ak): assess the impact of the certificates issued by the notified body;

Art. 36. (al): assess the impact of the certificates issued by the notified body;

Art. 36. (am): assess the impact of the certificates issued by the notified body;

Art. 36. (an): assess the impact of the certificates issued by the notified body;

Art. 36. (ao): assess the impact of the certificates issued by the notified body;

Art. 36. (ap): assess the impact of the certificates issued by the notified body;

Art. 36. (aq): assess the impact of the certificates issued by the notified body;

Art. 36. (ar): assess the impact of the certificates issued by the notified body;

Art. 36. (as): assess the impact of the certificates issued by the notified body;

Art. 36. (at): assess the impact of the certificates issued by the notified body;

Art. 36. (au): assess the impact of the certificates issued by the notified body;

Art. 36. (av): assess the impact of the certificates issued by the notified body;

Art. 36. (aw): assess the impact of the certificates issued by the notified body;

Art. 36. (ax): assess the impact of the certificates issued by the notified body;

Art. 36. (ay): assess the impact of the certificates issued by the notified body;

Art. 36. (az): assess the impact of the certificates issued by the notified body;

Art. 36. (ba): assess the impact of the certificates issued by the notified body;

Art. 36. (bb): assess the impact of the certificates issued by the notified body;

Art. 36. (bc): assess the impact of the certificates issued by the notified body;

Art. 36. (bd): assess the impact of the certificates issued by the notified body;

Art. 36. (be): assess the impact of the certificates issued by the notified body;

Art. 36. (bf): assess the impact of the certificates issued by the notified body;

Art. 36. (bg): assess the impact of the certificates issued by the notified body;

Art. 36. (bh): assess the impact of the certificates issued by the notified body;

Art. 36. (bi): assess the impact of the certificates issued by the notified body;

Art. 36. (bj): assess the impact of the certificates issued by the notified body;

Art. 36. (bk): assess the impact of the certificates issued by the notified body;

Art. 36. (bl): assess the impact of the certificates issued by the notified body;

Art. 36. (bm): assess the impact of the certificates issued by the notified body;

Art. 36. (bn): assess the impact of the certificates issued by the notified body;

Art. 36. (bo): assess the impact of the certificates issued by the notified body;

Art. 36. (bp): assess the impact of the certificates issued by the notified body;

Art. 36. (bq): assess the impact of the certificates issued by the notified body;

Art. 36. (br): assess the impact of the certificates issued by the notified body;

Art. 36. (bs): assess the impact of the certificates issued by the notified body;

Terms and AI Act Articles

34 Notifying authority

Art. 3. (19): notifying authority' means the national authority responsible for setting up and carrying out the necessary procedures for the assessment, designation and notification of conformity assessment bodies and for their monitoring;

Art. 3. (48): 'national competent authority' means a notifying authority or a market surveillance authority, as regards AI systems put into service or used by Union institutions, agencies, offices and bodies, references to national competent authorities or market surveillance authorities in this Regulation shall be construed as references to the European Data Protection Supervisor;

SECTION 4: Notifying authorities and notified bodies

Art. 28: Notifying authorities

Art. 28. 1: Each Member State shall designate or establish at least one notifying authority responsible for setting up and carrying out the necessary procedures for the assessment, designation and notification of conformity assessment bodies and for their monitoring. Those procedures shall be developed in cooperation between the notifying authorities of all Member States.

Art. 28. 2: Notifying authorities shall be established, organised and operated in such a way that no conflict of interest arises with conformity assessment bodies, and that the objectivity and impartiality of their activities are safeguarded.

Art. 28. 3: Notifying authorities shall be organised in such a way that decisions relating to the notification of conformity assessment bodies are taken by competent persons different from those who carried out the assessment of those bodies.

Art. 28. 4: Notifying authorities shall offer or provide neither any activities that conformity assessment bodies perform, nor any consultancy services on a commercial or competitive basis.

Art. 28. 5: Notifying authorities shall safeguard the confidentiality of the information that they obtain, in accordance with Article 78.

Art. 28. 7: Notifying authorities shall have an adequate number of competent personnel at their disposal for the proper performance of their tasks. Competent personnel shall have the necessary expertise, where applicable, for their function, in fields such as information technologies, AI and law, including the supervision of fundamental rights.

Art. 29. 1: Conformity assessment bodies shall submit an application for notification to the notifying authority of the Member State in which they are established.

Art. 29. 2: Where the conformity assessment body concerned cannot provide an accreditation certificate, it shall provide the notifying authority with all the documentary evidence necessary for the verification, recognition and regular monitoring of its compliance with the requirements laid down in Article 31.

Art. 30. 1: Notifying authorities may notify only conformity assessment bodies which have satisfied the requirements laid down in Article 31.

Art. 30. 2: Notifying authorities shall notify the Commission and the other Member States, using the electronic notification tool developed and managed by the Commission, of each conformity assessment body referred to in paragraph 1.

Art. 30. 3: The notification referred to in paragraph 2 of this Article shall include full details of the conformity assessment activities, the conformity assessment module or modules, the types of AI systems concerned, and the relevant attestation of competence. Where a notification is not based on an accreditation certificate as referred to in Article 29(2), the notifying authority shall provide the Commission and the other Member States with documentary evidence which attests to the competence of the conformity assessment body and to the arrangements in place to ensure that that body will be monitored regularly and will continue to satisfy the requirements laid down in Article 31.

Art. 30. 4: The conformity assessment body concerned may perform the activities of a notified body only where no objections are raised by the Commission or the other Member States within two weeks of a notification by a notifying authority where it includes an accreditation certificate referred to in Article 29(2), or within two months of a notification by the notifying authority where it includes documentary evidence referred to in Article 29(3).

Art. 31. 1: Notified bodies shall have documented procedures in place ensuring that their personnel, committees, subsidiaries, subcontractors and any associated body or personnel of external bodies maintain, in accordance with Article 78, the confidentiality of the information which comes into their possession during the performance of conformity assessment activities, except when its disclosure is required by law. The staff of notified bodies shall be bound to observe professional secrecy with regard to all information obtained in carrying out their tasks under this Regulation, except in relation to the notifying authorities of the Member State in which their activities are carried out.

Art. 33. 1: Where a notified body subcontracts specific tasks connected with the conformity assessment or has recourse to a subsidiary, it shall ensure that the subcontractor or the subsidiary meets the requirements laid down in Article 31, and shall inform the notifying authority accordingly.

Art. 33. 4: The relevant documents concerning the assessment of the qualifications of the subcontractor or the subsidiary and the work carried out by them under this Regulation shall be kept at the disposal of the notifying authority for a period of five years from the termination date of the subcontracting.

Art. 34. 2: Notified bodies shall make available and submit upon request all relevant documentation, including the providers' documentation, to the notifying authority referred to in Article 28 to allow that authority to conduct its assessment, designation, notification and monitoring activities, and to facilitate the assessment outlined in this Section.

Art. 36. 1: The notifying authority shall notify the Commission and the other Member States of any relevant changes to the notification of a notified body via the electronic notification tool referred to in Article 30(2).

Art. 36. 3: Where a notified body decides to cease its conformity assessment activities, it shall inform the notifying authority and the providers concerned as soon as possible and, in the case of a planned cessation, at least one year before ceasing its activities. The certificates of the notified body may remain valid for a period of nine months after cessation of the notified body's activities, on condition that another notified body has confirmed in writing that it will assume responsibilities for the high-risk AI systems covered by those certificates. The latter notified body shall complete a full assessment of the high-risk AI systems affected by the end of that nine-month-period before issuing new certificates for those systems. Where the notified body has ceased its activity, the notifying authority shall withdraw the designation.

Art. 36. 4: Where a notifying authority has sufficient reason to consider that a notified body no longer meets the requirements laid down in Article 31, or that it is failing to fulfil its obligations, the notifying authority shall without delay investigate the matter with the utmost diligence. In that context, it shall inform the notified body concerned about the objections raised and give it the possibility to make its views known. If the notifying authority comes to the conclusion that the notified body no longer meets the requirements laid down in Article 31 or that it is failing to fulfil its obligations, it shall restrict, suspend or withdraw the designation as appropriate, depending on the seriousness of the failure to meet those requirements or fulfil those obligations. It shall immediately inform the Commission and the other Member States accordingly.

Art. 36. 6: In the event of the restriction, suspension or withdrawal of a designation, the notifying authority shall take appropriate steps to ensure that the files of the notified body concerned are kept, and to make them available to notifying authorities in other Member States and to market surveillance authorities at their request.

Art. 36. 7: In the event of the restriction, suspension or withdrawal of a designation, the notifying authority shall:

Art. 36. 7(a): the notifying authority has confirmed, within one month of the suspension or restriction, that there is no risk to health, safety or fundamental rights in relation to certificates affected by the suspension or restriction, and the notifying authority has outlined a timeline for actions to remedy the suspension or restriction; or

Art. 36. 7(b): the notifying authority has confirmed that no certificates relevant to the suspension will be issued, amended or re-issued during the course of the suspension or restriction, and states whether the notified body has the capability of continuing to monitor and remain responsible for existing certificates issued for the period of the suspension or restriction; in the event that the notifying authority determines that the notified body does not have the capability to support existing certificates issued, the provider of the system covered by the certificate shall confirm in writing to the national competent authorities of the Member State in which it has its registered place of business, within three months of the suspension or restriction, that another qualified notified body is temporarily assuming the functions of the notified body to monitor and remain responsible for the certificates during the period of suspension or restriction.

Art. 37. 2: The notifying authority shall provide the Commission, on request, with all relevant information relating to the notification or the maintenance of the competence of the notified body concerned.

Art. 38. 2: Each notifying authority shall ensure that the bodies notified by it participate in the work of a group referred to in paragraph 1, directly or through designated representatives.

Art. 38. 3: The Commission shall provide for the exchange of knowledge and best practices between notifying authorities.

Art. 45. 1: Notified bodies shall inform the notifying authority of the following:

Art. 65. 6: The Board shall establish two standing sub-groups to provide a platform for cooperation and exchange among market surveillance authorities and notifying authorities about issues related to market surveillance and notified bodies respectively. The standing sub-group for market surveillance should act as the administrative cooperation group (ADCO) for this Regulation within the meaning of Article 30 of Regulation (EU) 2019/1020. The Board may establish other standing or temporary sub-groups as appropriate for the purpose of examining specific issues. Where appropriate, representatives of the advisory forum referred to in Article 67 may be invited to such sub-groups or to specific meetings of those subgroups as observers.

Art. 70. 1: Each Member State shall establish or designate as national competent authorities at least one notifying authority and at least one market surveillance authority for the purposes of this Regulation. Those national competent authorities shall exercise their powers independently, impartially and without bias so as to safeguard the objectivity of their activities and tasks, and to ensure the application and implementation of this Regulation. The members of those authorities shall refrain from any action incompatible with their duties. Provided that those principles are observed, such activities and tasks may be performed by one or more designated authorities, in accordance with the organisational needs of the Member State.

Art. 70. 2: Member States shall communicate to the Commission the identity of the notifying authorities and the market surveillance authorities and the tasks of those authorities, as well as any subsequent changes thereto. Member States shall make publicly available information on how competent authorities and single points of contact can be contacted, through electronic communication means by 2 August 2025. Member States shall designate a market surveillance authority to act as the single point of contact for this Regulation, and shall notify the Commission of the identity of the single point of contact. The Commission shall make a list of the single points of contact publicly available.

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114 Obligation

Art. 1 (2)(c): specific requirements for high-risk AI systems and obligations for operators of such systems;
Art. 2: Scope
Art. 2. 1: Union law on the protection of personal data, privacy and the confidentiality of communications applies to personal data processed in connection with the rights and obligations laid down in this Regulation.
Art. 2. 1(2): or Directive 2002/96/EC or 2012/19/EU
Art. 2. 10: This Regulation does not apply to obligations of deployers who are natural persons using AI systems in the course of a purely personal non-professional activity.
Art. 3 (5): 'authorised representative' means a natural or legal person located or established in the Union who has received and accepted a written mandate from a provider of an AI system or a general-purpose AI model to, respectively, perform and carry out on its behalf the obligations and procedures established in this Regulation...

Terms and AI Act Articles

as provided for in the relevant Union harmonisation legislation. The market surveillance authority shall inform the relevant notified body accordingly. Article 18 of Regulation (EU) 2019/1020 shall apply to the measures referred to in the second subparagraph of this paragraph.

Art. 80, 2: Where, in the course of that evaluation the market surveillance authority finds that the AI system concerned is high-risk, it shall without undue delay inform the relevant provider to take all necessary actions to bring the AI system into compliance with the requirements and obligations laid down in this Regulation, as well as take appropriate corrective action within a period the market surveillance authority may prescribe.

Art. 80, 4: The provider shall ensure that all necessary action is taken to bring the AI system into compliance with the requirements and obligations laid down in this Regulation. Where the provider of an AI system concerned does not bring the AI system into compliance with those requirements and obligations within the period referred to in paragraph 2 of this Article, the provider shall be subject to fines in accordance with Article 99.

Art. 86, 2: Paragraph 1 shall not apply to the use of AI systems for which exceptions from, or restrictions to, the obligation under that paragraph follow from Union or national law in compliance with Union law.

Art. 88: Enforcement of the obligations of providers of general-purpose AI models

Art. 92: (1a): to assess compliance of the provider with obligations under this Regulation, where the information gathered pursuant to Article 91 is insufficient; or

Art. 93, 1(a): take appropriate measures to comply with the obligations set out in Articles 53 and 54;

Art. 95, 1(a): the application of the requirements and obligations referred to in Articles 8 to 15 and in Article 25;

Art. 96, 1(a): the practical implementation of transparency obligations laid down in Article 50;

Art. 99, 4(a): obligations of providers pursuant to Article 16;

Art. 99, 4(b): obligations of authorised representatives pursuant to Article 22;

Art. 99, 4(c): obligations of importers pursuant to Article 26;

Art. 99, 4(d): obligations of distributors pursuant to Article 24;

Art. 99, 4(e): obligations of deployers pursuant to Article 26;

Art. 99, 4(f): requirements and obligations of notified bodies pursuant to Article 31, Article 33(1), (3) and (4) or Article 34;

Art. 99, 4(g): transparency obligations for providers and deployers pursuant to Article 50.

Art. 100, 3: The non-compliance with the requirements or obligations under this Regulation, other than those laid down in Article 5, shall be subject to administrative fines up to EUR 750 000.

Art. 111, 2: Without prejudice to the application of Article 5 as referred to in Article 113(3), point (a), this Regulation shall apply to operators of high-risk AI systems, other than the systems referred to in paragraph 1 of this Article, that have been placed on the market or put into service before 2 August 2026, only if, as from that date, those systems are subject to significant changes in their designs. In any case, the providers and deployers of high-risk AI systems intended to be used by public authorities shall take the necessary steps to comply with the requirements and obligations of this Regulation by 2 August 2026.

Art. 111, 3: Providers of general-purpose AI models that have been placed on the market before 2 August 2025 shall take the necessary steps in order to comply with the obligations laid down in this Regulation by 2 August 2027.

Art. 113, (c): Article 6(1) and the corresponding obligations in this Regulation shall apply from 2 August 2027.

0 Ontology

16 Operation

Art. 3, (49)(b): a serious and irreversible disruption of the management or operation of critical infrastructure;

Art. 3, (67): 'floating-point operation' means any mathematical operation or assignment involving floating-point numbers, which are a subset of the real numbers typically represented on computers by an integer of fixed precision scaled by an integer exponent of a fixed base;

Art. 4: Providers and deployers of AI systems shall take measures to ensure, to their best extent, a sufficient level of AI literacy of their staff and other persons dealing with the operation and use of AI systems on their behalf, taking into account their technical knowledge, experience, education and training and the context the AI systems are to be used in, and considering the persons or groups of persons on whom the AI systems are to be used.

Art. 12, 2(c): monitoring the operation of high-risk AI systems referred to in Article 26(5).

Art. 13, 1: High-risk AI systems shall be designed and developed in such a way as to ensure that their operation is sufficiently transparent to enable deployers to interpret a system's output and use it appropriately. An appropriate type and degree of transparency shall be ensured with a view to achieving compliance with the relevant obligations of the provider and deployer set out in Section 3.

Art. 14, 4(a): to properly understand the relevant capacities and limitations of the high-risk AI system and be able to duly monitor its operation, including in view of detecting and addressing anomalies, dysfunctions and unexpected performance;

Art. 14, 4(e): to intervene in the operation of the high-risk AI system or interrupt the system through a 'stop' button or a similar procedure that allows the system to come to a halt in a safe state.

Art. 15, 1(1): systems and procedures for data management, including data acquisition, data collection, data analysis, data labelling, data storage, data filtration, data mining, data aggregation, data retention and any other operation regarding the data that is performed before and for the purpose of the placing on the market or the putting into service of high-risk AI systems;

Art. 26, 5: Deployers shall monitor the operation of the high-risk AI system on the basis of the instructions for use and, where relevant, inform providers in accordance with Article 72. Where deployers have reason to consider that the use of the high-risk AI system in accordance with the instructions may result in that AI system presenting a risk within the meaning of Article 75(1), they shall, without undue delay, inform the provider or distributor and the relevant market surveillance authority, and shall suspend the use of that system. Where deployers have identified a serious incident, they shall also immediately inform first the provider, and then the importer or distributor and the relevant market surveillance authorities of that incident. If the deployer is not able to reach the provider, Article 73 shall apply mutatis mutandis. This obligation shall not cover sensitive operational data of deployers of AI systems which are law enforcement authorities. For deployers that are financial institutions subject to requirements regarding their internal governance, arrangements or processes under Union financial services law, the monitoring obligation set out in the first subparagraph shall be fulfilled by complying with the rules on internal governance arrangements, processes and mechanisms pursuant to the relevant financial services law.

Art. 31, 3: The organisational structure, allocation of responsibilities, reporting lines and operation of notified bodies shall ensure confidence in their performance, and in the results of the conformity assessment activities that the notified bodies conduct.

Art. 50, 3: Deployers of an emotion recognition system or a biometric categorisation system shall inform the natural persons exposed thereto of the operation of the system, and shall process the personal data in accordance with Regulations (EU) 2016/679 and (EU) 2018/725 and Directive (EU) 2016/680, as applicable. This obligation shall not apply to AI systems used for biometric categorisation and emotion recognition, which are permitted by law to detect, prevent or investigate criminal offences, subject to appropriate safeguards for the rights and freedoms of third parties, and in accordance with Union law.

Art. 57, 1: Member States shall ensure that their competent authorities establish at least one AI regulatory sandbox at national level, which shall be operational by 2 August 2026. That sandbox may also be established jointly with the competent authorities of other Member States. The Commission may provide technical advice and tools for the establishment and operation of AI regulatory sandboxes. The obligation under the first subparagraph may also be fulfilled by participating in an existing sandbox in so far as that participation provides an equivalent level of national coverage for the participating Member States.

Art. 57, 10: National competent authorities shall ensure that, to the extent the innovative AI systems involve the processing of personal data or otherwise fall under the supervisory remit of other national authorities or competent authorities providing or supporting access to data, the national data protection authorities and those other national or competent authorities are associated with the operation of the AI regulatory sandbox and involved in the supervision of those aspects to the extent of their respective tasks and powers.

Art. 58, 1: In order to avoid fragmentation across the Union, the Commission shall adopt implementing acts specifying the detailed arrangements for the establishment, development, implementation, operation and supervision of the AI regulatory sandboxes. The implementing acts shall include common principles on the following issues:

Art. 95, 2(c): promoting AI literacy, in particular that of persons dealing with the development, operation and use of AI;

Art. 100, 6: Funds collected by imposition of fines in this Article shall contribute to the general budget of the Union. The fines shall not affect the effective operation of the Union institution, body, office or agency fined.

20 Operator

Art. 3, (8): 'operator' means a provider, product manufacturer, deployer, authorised representative, importer or distributor;

Art. 3, (61)(b): has caused, causes or is likely to cause harm to the collective interests of individuals and has common features, including the same unlawful practice or the same interest being infringed, and is occurring concurrently, committed by the same operator, in at least three Member States;

Art. 24, 4: A distributor that considers or has reason to consider, on the basis of the information in its possession, a high-risk AI system which it has made available on the market not to be in conformity with the requirements set out in Section 2, shall take the corrective actions necessary to bring that system into conformity with those requirements, to withdraw it or recall it, or shall ensure that the provider, the importer or any relevant operator, as appropriate, takes those corrective actions. Where the high-risk AI system presents a risk within the meaning of Article 79(1), the distributor shall immediately inform the provider or importer of the system and the authorities competent for the high-risk AI system concerned, giving details, in particular, of the non-compliance alleged and of any corrective actions taken.

Art. 31, 4: Notified bodies shall be independent of the provider of a high-risk AI system in relation to which they perform conformity assessment activities. Notified bodies shall also be independent of any other operator having an economic interest in high-risk AI systems assessed, as well as of any notified body of the provider. This shall not preclude the use of assessed high-risk AI systems that are necessary for the operations of the conformity assessment body, or the use of such high-risk AI systems for personal purposes.

Art. 74, 1(a): any reference to an operator under Regulation (EU) 2019/1020 shall be understood as including all operators identified in Article 2(1) of this Regulation;

Art. 79, 2: Where the market surveillance authority of a Member State has sufficient reason to consider an AI system to present a risk as referred to in paragraph 1 of this Article, it shall carry out an evaluation of the AI system concerned in respect of its compliance with all the requirements and obligations laid down in this Regulation. Particular attention shall be given to AI systems presenting a risk to vulnerable groups. Where risks to fundamental rights are identified, the market surveillance authority shall also inform and fully cooperate with the relevant national public authorities or bodies referred to in Article 77(1). The relevant operators shall cooperate as necessary with the market surveillance authority and with the other national public authorities or bodies referred to in Article 77(1). Where, in the course of that evaluation, the market surveillance authority or, where applicable the market surveillance authority in cooperation with the national public authority referred to in Article 77(1), finds that the AI system does not comply with the requirements and obligations laid down in this Regulation, it shall without undue delay require the relevant operator to take all appropriate corrective actions to bring the AI system into compliance, to withdraw the AI system from the market, or to recall it within a period the market surveillance authority may prescribe, and in any event within the shorter of 15 working days, or as provided for in the relevant Union harmonisation legislation. The market surveillance authority shall inform the relevant notified body accordingly. Article 18 of Regulation (EU) 2019/1020 shall apply to the measures referred to in the second subparagraph of this paragraph.

Art. 79, 3: Where the market surveillance authority considers that the non-compliance is not restricted to its national territory, it shall inform the Commission and the other Member States without undue delay of the results of the evaluation and of the actions which it has required the operator to take.

Art. 79, 4: The operator shall ensure that all appropriate corrective action is taken in respect of all the AI systems concerned that it has made available on the Union market.

Art. 79, 5: Where the operator of an AI system does not take adequate corrective action within the period referred to in paragraph 2, the market surveillance authority shall take all appropriate provisional measures to prohibit or restrict the AI system's being made available on its national market or put into service, to withdraw the product or the standalone AI system from that market or to recall it. That authority shall without undue delay notify the Commission and the other Member States of those measures.

Art. 79, 6: The notification referred to in paragraph 5 shall include all available details, in particular the information necessary for the identification of the non-compliant AI system, the origin of the AI system and the supply chain, the nature of the non-compliance alleged and the risk involved, the nature and duration of the national measures taken and the arguments put forward by the relevant operator. In particular, the market surveillance authorities shall indicate whether the non-compliance is due to one or more of the following:

Art. 79, 6: Where, within three months of receipt of the notification referred to in paragraph 5 of this Article, no objection has been raised by either a market surveillance authority of a Member State or by the Commission in respect of a provisional measure taken by a market surveillance authority of another Member State, that measure shall be deemed justified. This shall be without prejudice to the procedural rights of the concerned operator in accordance with Article 18 of Regulation (EU) 2019/1020. The three-month period referred to in this paragraph shall be reduced to 30 days in the event of non-compliance with the prohibition of the AI practices referred to in Article 5 of this Regulation.

Art. 81, 1: Where, within three months of receipt of the notification referred to in Article 79(5), or within 30 days in the case of non-compliance with the prohibition of the AI practices referred to in Article 5, objections are raised by the market surveillance authority of a Member State to a measure taken by another market surveillance authority, or where the Commission considers the measure to be contrary to Union law, the Commission shall without undue delay enter into consultation with the market surveillance authority of the relevant Member State and the operator or operators, and shall evaluate the national measure. On the basis of the results of that evaluation, the Commission shall, within six months, or within 60 days in the case of non-compliance with the prohibition of the AI practices referred to in Article 5, starting from the notification referred to in Article 79(5), decide whether the national measure is justified and shall notify its decision to the market surveillance authority of the Member State concerned. The Commission shall also inform all other market surveillance authorities of its decision.

Art. 82, 1: Where, having performed an evaluation under Article 79, after consulting the relevant national public authority referred to in Article 77(1), the market surveillance authority of a Member State finds that although a high-risk AI system complies with this Regulation, it nevertheless presents a risk to the health or safety of persons, to fundamental rights, or to other aspects of public interest protection, it shall require the relevant operator to take all appropriate measures to ensure that the AI system concerned, when placed on the market or put into service, no longer presents that risk without undue delay, within a period it may prescribe.

Art. 82, 2: The provider or other relevant operator shall ensure that corrective action is taken in respect of all the AI systems concerned that it has made available on the Union market within the timeline prescribed by the market surveillance authority of the Member State referred to in paragraph 1.

Art. 89, 7(b): whether administrative fines have already been applied by other market surveillance authorities to the same operator for the same infringement;

Art. 89, 7(c): whether administrative fines have already been applied by other authorities to the same operator for infringements of other Union or national law, when such infringements result from the same activity or omission constituting a relevant infringement of this Regulation;

Art. 89, 7(d): the size, the annual turnover and market share of the operator committing the infringement;

Art. 89, 7(e): the degree of responsibility of the operator taking into account the technical and organisational measures implemented by it;

Art. 89, 7(f): the manner in which the infringement became known to the national competent authorities, in particular whether, and if so to what extent, the operator notified the infringement;

Art. 89, 7(g): any action taken by the operator to mitigate the harm suffered by the affected persons.

0 Organization

2 Origin of data (See also: *Data provenance*)

Art. 10, 2(b): data collection processes and the origin of data, and in the case of personal data, the original purpose of the data collection;

Art. 82, 3: The Member States shall immediately inform the Commission and the other Member States of a finding under paragraph 1. That information shall include all available details, in particular the data necessary for the identification of the AI system concerned, the origin and the supply chain of the AI system, the nature of the risk involved and the nature and duration of the national measures taken.

0 Out-of-distribution data (See also: *Outlier*)

0 Outlier (See also: *out-of-distribution data*)

0 Outsourcing

Terms and AI Act Articles**11 Penalty**

Art. 3. (45)(a): any public authority competent for the prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, including the safeguarding against and the prevention of threats to public security; or

Art. 3. (45)(b): any other body or entity entrusted by Member State law to exercise public authority and public powers for the purposes of the prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, including the safeguarding against and the prevention of threats to public security;

Art. 3. (46): 'law enforcement' means activities carried out by law enforcement authorities or on their behalf for the prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, including safeguarding against and preventing threats to public security;

Art. 5. 1(b)(iii): the localisation or identification of a person suspected of having committed a criminal offence, for the purpose of conducting a criminal investigation or prosecution or executing a criminal penalty for offences referred to in Annex II and punishable in the Member State concerned by a custodial sentence or a detention order for a maximum period of at least four years. Point (ii) of the first subparagraph is without prejudice to Article 9 of Regulation (EU) 2016/679 for the processing of biometric data for purposes other than law enforcement, regard shall be had to the nature, gravity and duration of the infringement, taking due account of the principles of proportionality and appropriateness. The Commission shall also to account commitments made in accordance with Article 93(3) or made in relevant codes of practice in accordance with Article 56

CHAPTER XII: PENALTIES

Art. 99: Penalties

Art. 99. 1: In accordance with the terms and conditions laid down in this Regulation, Member States shall lay down the rules on penalties and other enforcement measures, which may also include warnings and non-monetary measures, applicable to infringements of this Regulation by operators, and shall take all measures necessary to ensure that they are properly and effectively implemented, thereby taking into account the guidelines issued by the Commission pursuant to Article 56. The penalties provided for shall be effective, proportionate and dissuasive. They shall take into account the interests of SMEs, including start-ups, and their economic viability.

Art. 99. 2: The Member States shall, without delay and at the latest by the date of entry into application, notify the Commission of the rules on penalties and of other enforcement measures referred to in paragraph 1, and shall notify it, without delay, of any subsequent amendment to them.

Art. 101. 1(a): failed to make available to the Commission access to the general-purpose AI model or general-purpose AI model with systemic risk with a view to conducting an evaluation pursuant to Article 52.

Art. 112. 4(b): the state of penalties, in particular administrative fines as referred to in Article 99(1), applied by Member States for infringements of this Regulation;

0 Performance efficiency**33 Personal data (See also: Confidentiality, Identifiability)**

Art. 2. 7: Union law on the protection of personal data, privacy and the confidentiality of communications applies to personal data processed in connection with the rights and obligations laid down in this Regulation. This Regulation shall not affect Regulation (EU) 2016/679 or (EU) 2016/1725, or Directive 2002/58/EC or (EU) 2016/680, without prejudice to Article 10(5) and Article 59 of this Regulation.

Art. 3. (34): 'biometric data' means personal data resulting from specific technical processing relating to the physical, physiological or behavioural characteristics of a natural person, such as facial images or dactyloscopic data;

Art. 3. (37): 'special categories of personal data' means the categories of personal data referred to in Article 9(1) of Regulation (EU) 2016/679, Article 10 of Directive (EU) 2016/680 and Article 10(1) of Regulation (EU) 2018/1725;

Art. 3. (40): 'personal data as defined in Article 4, point (1), of Regulation (EU) 2016/679' means personal data as defined in Article 4, point (1), of Regulation (EU) 2016/679;

Art. 3. (51): 'non-personal data' means data other than personal data as defined in Article 4, point (1), of Regulation (EU) 2016/679;

Art. 7. 2(c): the nature and amount of the data processed and used by the AI system, in particular whether special categories of personal data are processed;

Art. 10. 1(b): data collection and the processing and the original purpose of the data collection;

Art. 10. 5: to the extent that it is strictly necessary for the purpose of ensuring bias detection and correction in relation to the high-risk AI systems in accordance with paragraph (2), points (f) and (g) of this Article, the providers of such systems may exceptionally process special categories of personal data, subject to appropriate safeguards for the fundamental rights and freedoms of natural persons. In addition to the provisions set out in Regulations (EU) 2016/679 and (EU) 2018/1725 and Directive (EU) 2016/680, all the following conditions must be met in order for such processing to occur:

Art. 10. 5(b): the special categories of personal data are subject to technical limitations on the re-use of the personal data, and state-of-the-art security and privacy-preserving measures, including pseudonymisation;

Art. 10. 5(c): the special categories of personal data are subject to measures to ensure that the personal data processed are secured, protected, subject to suitable safeguards, including strict controls and documentation of the access, to avoid misuse and ensure that only authorised persons have access to those personal data with appropriate confidentiality obligations;

Art. 10. 5(d): the special categories of personal data are not to be transmitted, transferred or otherwise accessed by other parties;

Art. 10. 5(e): the special categories of personal data are deleted once the bias has been corrected or the personal data has reached the end of its retention period, whichever comes first;

Art. 10. 5(f): the records of processing activities pursuant to Regulations (EU) 2016/679 and (EU) 2018/1725 and Directive (EU) 2016/680 include the reasons why the processing of special categories of personal data was strictly necessary to detect and correct biases, and why that objective could not be achieved by processing other data.

Art. 19. 1: Providers of high-risk AI systems shall keep the logs referred to in Article 12(1), automatically generated by their high-risk AI systems, to the extent such logs are under their control. Without prejudice to applicable Union or national law, the logs shall be kept for a period appropriate to the intended purpose of the high-risk AI system, of at least six months, unless provided otherwise in the applicable Union or national law, in particular in Union law on the protection of personal data.

Art. 26. 6: Deployers of high-risk AI systems shall keep the logs automatically generated by that high-risk AI system to the extent such logs are under their control, for a period appropriate to the intended purpose of the high-risk AI system, of at least six months, unless provided otherwise in applicable Union or national law, in particular in Union law on the protection of personal data. Deployers that are financial institutions subject to requirements regarding their internal governance, arrangements or processes under Union financial services law shall maintain the logs as part of the documentation kept pursuant to the relevant Union financial service law.

Art. 26. 10: Without prejudice to Directive (EU) 2016/680, in the framework of an investigation for a person suspected or convicted of having committed a criminal offence, the deployer of a high-risk AI system for post-remote biometric identification shall request an authorisation, ex ante, or without undue delay and no later than 48 hours, by a judicial authority or an administrative authority whose decision is binding and subject to judicial review, for the use of that system, except when it is used for the initial identification of a potential suspect based on objective and verifiable facts directly linked to the offence. Each use shall be limited to what is strictly necessary for the investigation of a specific criminal offence. If the authorisation requested pursuant to the first subparagraph is rejected, the use of the post-remote biometric identification system linked to that requested authorisation shall be stopped with immediate effect and the personal data linked to the use of the high-risk AI system for which the authorisation was requested shall be deleted. In no case shall such high-risk AI system for post-remote biometric identification be used for law enforcement purposes in an untargeted way, without any link to a criminal offence, a criminal proceeding, a genuine and present or foreseeable threat of a criminal offence, or the search for a specific missing person. It shall be ensured that the use of such an adverse legal effect on a person may be taken by the law enforcement authorities based solely on the output of such post-remote biometric identification systems. This paragraph is without prejudice to Article 9 of Regulation (EU) 2016/679 and Article 10 of Directive (EU) 2016/680 for the processing of biometric data. Regardless of the purpose or deployer, each use of such high-risk AI systems shall be documented in the relevant police file and shall be made available to the relevant market surveillance authority and the national data protection authority upon request, excluding the disclosure of sensitive operational data related to law enforcement. This subparagraph shall be without prejudice to the powers conferred by Directive (EU) 2016/680 on supervisory authorities. Deployers shall submit annual reports to the relevant market surveillance and national data protection authorities on their use of post-remote biometric identification systems, excluding the disclosure of sensitive operational data related to law enforcement. The reports may be aggregated to cover more than one deployment. Member States may introduce, in accordance with Union law, more restrictive laws on the use of post-remote biometric identification systems.

Art. 50. 3: Providers of an emotion recognition system or a biometric categorisation system shall inform the natural persons exposed thereto of the operation of the system, and shall process the personal data in accordance with Regulations (EU) 2016/679 and (EU) 2018/1725 and Directive (EU) 2016/680, as applicable. This obligation shall not apply to AI systems used for biometric categorisation and emotion recognition, which are permitted by law to detect, prevent or investigate criminal offences, which are permitted by law to detect, prevent or investigate criminal offences, which are permitted by law to detect, prevent or investigate criminal offences, and which are permitted by law to detect, prevent or investigate criminal offences.

Art. 57. 10: National competent authorities shall ensure that, to the extent the innovative AI systems involve the processing of personal data or otherwise fall under the supervisory remit of other national authorities or competent authorities providing or supporting access to data, the national data protection authorities and those other national or competent authorities are consulted with the operation of the AI regulatory sandbox and involved in the supervision of those aspects to the extent of their respective tasks and powers.

Art. 59: Further processing of personal data for developing certain AI systems in the public interest in the AI regulatory sandbox

Art. 59. 1: In the AI regulatory sandbox, personal data lawfully collected for other purposes may be processed solely for the purpose of developing, training and testing certain AI systems in the sandbox when all of the following conditions are met:

Art. 59. 1(a): the data processed are necessary for complying with one or more of the requirements referred to in Chapter III, Section 2 where those requirements cannot effectively be fulfilled by processing anonymised, synthetic or other non-personal data;

Art. 59. 1(d): any personal data to be processed in the context of the sandbox are in a functionally separate, isolated and protected data processing environment under the control of the prospective provider; and only authorised persons have access to those data;

Art. 59. 1(e): providers can further share the originally collected data only in accordance with Union data protection law, any personal data created in the sandbox cannot be shared outside the sandbox;

Art. 59. 1(f): any processing of personal data in the context of the sandbox neither leads to measures or decisions affecting the data subjects nor does it affect the application of their rights laid down in Union law on the protection of personal data;

Art. 59. 1(g): any personal data processed in the context of the sandbox are protected by means of appropriate technical and organisational measures and deleted once the participation in the sandbox has terminated or the personal data has reached the end of its retention period;

Art. 59. 1(h): the logs of the processing of personal data in the context of the sandbox are kept to the extent of the participation in that sandbox, unless provided otherwise by Union or national law;

Art. 59. 2: For the purposes of the prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, including safeguarding against and preventing threats to public security, under the control and responsibility of law enforcement authorities, the processing of personal data in AI regulatory sandboxes shall be based on a specific Union or national law and subject to the same cumulative conditions as referred to in paragraph 1.

Art. 60. 1: Paragraphs 2 and 3 are necessary for complying with one or more of the requirements referred to in Chapter III, Section 2 where those requirements cannot effectively be fulfilled by processing anonymised, synthetic or other non-personal data.

Art. 60. 4(f): the subjects of the testing in real world conditions have given informed consent in accordance with Article 61, or in the case of law enforcement, where the seeking of informed consent would prevent the AI system from being tested, the testing itself and the outcome of the testing in the real world conditions shall not have any negative effect on the subjects, and their personal data shall be deleted after the test is performed;

Art. 60. 5: Any subjects of the testing in real world conditions, or their legally designated representative, as appropriate, may, without any resulting detriment and without having to provide any justification, withdraw from the testing at any time by revoking their informed consent and may request the immediate and permanent deletion of their personal data. The withdrawal of the informed consent shall not affect the activities already carried out.

Art. 100. 5: The EU data protection authorities shall ensure that the national competent authorities are provided with adequate technical, financial and human resources, and with infrastructure to fulfil their tasks effectively under this Regulation. In particular, the national competent authorities shall have a sufficient number of personnel permanently available whose competences and expertise shall include an in-depth understanding of AI technologies, data and data computing, personal data protection, cybersecurity, fundamental rights, health and safety risks and knowledge of existing standards and legal requirements. Member States shall assess and, if necessary, update competence and resource requirements referred to in this paragraph on an annual basis.

Art. 100. 6: The EU data protection authorities shall ensure that the national competent authorities are provided with adequate technical, financial and human resources, and with infrastructure to fulfil their tasks effectively under this Regulation. That information shall include the names and contact details of natural persons who are responsible for registering the system and have the legal authority to represent the provider or the deployer, as applicable.

Art. 100. 5: The rights of defence of the parties concerned shall be fully respected in the proceedings. They shall be entitled to have access to the European Data Protection Supervisor's file, subject to the legitimate interest of individuals or undertakings in the protection of their personal data or business secrets.

1 Planning**Art. 4: AI literacy****0 Portability****11 Post-market (See also: Quality-in-use, Satisfaction)**

Art. 3. (25): 'post-market monitoring system' means all activities carried out by providers of AI systems to collect and review experience gained from the use of AI systems they place on the market or put into service for the purpose of identifying any need to immediately apply any necessary corrective or preventive actions;

Art. 9. 2(c): the evaluation of other risks possibly arising, based on the analysis of data gathered from the post-market monitoring system referred to in Article 72;

Art. 9. 2(d): the setting-up, implementation and maintenance of a post-market monitoring system, in accordance with Article 72;

Art. 12. 2(b): facilitating the post-market monitoring referred to in Article 72; and

Art. 17. 1(b): the setting-up, implementation and maintenance of a post-market monitoring system, in accordance with Article 72;

CHAPTER III: POST-MARKET MONITORING, INFORMATION SHARING AND MARKET EVALUANCE

SECTION 1: Post-market monitoring

Art. 72: Post-market monitoring by providers and post-market monitoring plan for high-risk AI systems

Art. 72. 1: Providers shall establish and document a post-market monitoring system in a manner that is proportionate to the nature of the AI technologies and the risks of the high-risk AI system.

Art. 72. 2: The post-market monitoring system shall actively and systematically collect, document and analyse relevant data which may be provided by deployers or which may be collected through other sources on the performance of high-risk AI systems throughout their lifetime, and which allow the provider to evaluate the continuous compliance of AI systems with the requirements set out in Chapter III, Section 2. Where relevant, post-market monitoring shall include an analysis of the interaction with other AI systems. This obligation shall not cover sensitive operational data of deployers which are law-enforcement authorities.

Art. 72. 3: The post-market monitoring system shall be based on a post-market monitoring plan. The post-market monitoring plan shall be part of the technical documentation referred to in Annex IV. The Commission shall adopt an implementing act laying down detailed provisions establishing a template for the post-market monitoring plan and the list of elements to be included in the plan by 2 February 2026. That implementing act shall be adopted in accordance with the examination procedure referred to in Article 59(2).

Art. 72. 4: For high-risk AI systems covered by the Union harmonisation legislation listed in Section A of Annex I, where a post-market monitoring system and plan are already established under that legislation, in order to ensure consistency, avoid duplications and minimise additional burdens, providers shall have a choice of integrating, as appropriate, the necessary elements described in paragraphs 1, 2 and 3 using the template referred in paragraph 3 into systems and plans already existing under that legislation, provided that it achieves an equivalent level of protection. The first subparagraph of this paragraph shall also apply to high-risk AI systems referred to in point 5 of Annex III placed on the market or put into service by financial institutions that are subject to requirements under Union financial services law regarding their internal governance, arrangements or processes.

7 Post-market monitoring system

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Art. 12. 2(b): facilitating the post-market monitoring referred to in Article 72; and

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Art. 72. 4: For high-risk AI systems covered by the Union harmonisation legislation listed in Section A of Annex I, where a post-market monitoring system and plan are already established under that legislation, in order to ensure consistency, avoid duplications and minimise additional burdens, providers shall have a choice of integrating, as appropriate, the necessary elements described in paragraphs 1, 2 and 3 using the template referred in paragraph 3 into systems and plans already existing under that legislation, provided that it achieves an equivalent level of protection. The first subparagraph of this paragraph shall also apply to high-risk AI systems referred to in point 5 of Annex III placed on the market or put into service by financial institutions that are subject to requirements under Union financial services law regarding their internal governance, arrangements or processes.

1 Precision**Art. 3. (67):** 'floating-point operation' means any mathematical operation or assignment involving floating-point numbers, which are a subset of the real numbers typically represented on computers by an integer of fixed precision scaled by an integer exponent of a fixed base;

Terms and AI Act Articles

2 Preparation

Art. 10, 2(c): relevant data-preparation processing operations, such as annotation, labelling, cleaning, updating, enrichment and aggregation;

Art. 66, (e)(ii): the evaluation and review of this Regulation pursuant to Article 112, including as regards the serious incident reports referred to in Article 73, and the functioning of the EU database referred to in Article 71, the preparation of the delegated or implementing acts, and as regards possible alignments of this Regulation with the Union harmonisation legislation listed in Annex I;

2 Privacy (See also: Data protection)

Art. 2, 7: Union law on the protection of personal data, privacy and the confidentiality of communications applies to personal data processed in connection with the rights and obligations laid down in this Regulation. This Regulation shall not affect Regulation (EU) 2016/679 or (EU) 2018/1725, or Directive 2002/58/EC or (EU) 2016/680, without prejudice to Article 10(5) and Article 59 of this Regulation.

Art. 10, 5(b): the special categories of personal data are subject to technical limitations on the re-use of the personal data, and state-of-the-art security and privacy-preserving measures, including pseudonymisation;

13 Process

Art. 8, 2: Where a product contains an AI system, to which the requirements of this Regulation as well as requirements of the Union harmonisation legislation listed in Section A of Annex I apply, providers shall be responsible for ensuring that their product is fully compliant with all applicable requirements under applicable Union harmonisation legislation. In ensuring the compliance of high-risk AI systems referred to in paragraph 1 with the requirements set out in this Section, and in order to ensure consistency, avoid duplication and minimise additional burdens, providers shall have a choice of integrating, as appropriate, the necessary testing and reporting processes, information and documentation they provide with regard to their product into documentation and procedures that already exist and are required under the Union harmonisation legislation listed in Section A of Annex I.

Art. 9, 10: For providers of high-risk AI systems that are subject to requirements regarding internal risk management processes under other relevant provisions of Union law, the aspects provided in paragraphs 1 to 9 may be part of, or combined with, the risk management procedures established pursuant to that law.

Art. 10, 2(b): data collection processes and the origin of data, and in the case of personal data, the original purpose of the data collection;

Art. 17, 4: For providers that are financial institutions subject to requirements regarding their internal governance, arrangements or processes under Union financial services law, the obligation to put in place a quality management system, with the exception of paragraph 1, points (g), (h) and (i) of this Article, shall be deemed to be fulfilled by complying with the rules on internal governance arrangements or processes pursuant to the relevant Union financial services law. To that end, any harmonised standards referred to in Article 40 shall be taken into account.

Art. 18, 2: Providers that are financial institutions subject to requirements regarding their internal governance, arrangements or processes under Union financial services law shall maintain the technical documentation as part of the documentation kept under the relevant Union financial services law.

Art. 19, 2: Providers that are financial institutions subject to requirements regarding their internal governance, arrangements or processes under Union financial services law shall maintain the logs automatically generated by their high-risk AI systems as part of the documentation kept under the relevant Union financial services law.

Art. 25, 4: The provider of a high-risk AI system and the third party that supplies an AI system, tools, services, components, or processes that are used or integrated in a high-risk AI system shall, by written agreement, specify the necessary information, capabilities, technical access and other assistance based on the generally acknowledged state of the art, in order to enable the provider of the high-risk AI system to fully comply with the obligations set out in this Regulation. This paragraph shall not apply to third parties making accessible to the public tools, services, components, or processes, other than general-purpose AI models, under a free and open-source licence. The AI Office may develop and recommend voluntary model terms for contracts between providers of high-risk AI systems and third parties that supply tools, services, components or processes that are used for or integrated into high-risk AI systems. When developing those voluntary model terms, the AI Office shall take into account possible contractual requirements applicable in specific sectors or business cases. The voluntary model terms shall be published and be available free of charge in an easily usable electronic format.

Art. 26, 5: Deployers shall monitor the operation of the high-risk AI system on the basis of the instructions for use and, where relevant, inform providers in accordance with Article 72. Where deployers have reason to consider that the use of the high-risk AI system in accordance with the instructions may result in that AI system presenting a risk within the meaning of Article 79(1), they shall, without undue delay, inform the provider or distributor and the relevant market surveillance authority, and shall suspend the use of that system. Where deployers have identified a serious incident, they shall also immediately inform first the provider, and then the importer or distributor and the relevant market surveillance authorities of that incident. If the deployer is not able to reach the provider, Article 73 shall apply mutatis mutandis. This obligation shall not cover sensitive operational data of deployers of AI systems which are law enforcement authorities. For deployers that are financial institutions subject to requirements regarding their internal governance, arrangements or processes under Union financial services law, the monitoring obligation set out in the first subparagraph shall be deemed to be fulfilled by complying with the rules on internal governance arrangements, processes and mechanisms pursuant to the relevant financial service law.

Art. 26, 6: Deployers of high-risk AI systems shall keep the logs automatically generated by that high-risk AI system to the extent such logs are under their control, for a period appropriate to the intended purpose of the high-risk AI system, of at least six months, unless provided otherwise in applicable Union or national law, in particular in Union law on the protection of personal data. Deployers that are financial institutions subject to requirements regarding their internal governance, arrangements or processes under Union financial services law shall maintain the logs as part of the documentation kept pursuant to the relevant Union financial service law.

Art. 27, 1(a): a description of the deployer's processes in which the high-risk AI system will be used in line with its intended purpose;

Art. 28, 5: In accordance with Article 10 of Regulation (EU) No 1025/2012, the Commission shall issue, without undue delay, standardisation requests covering all requirements set out in Section 2 of this Chapter and, as applicable, standardisation requests covering obligations set out in Chapter V, Sections 2 and 3, of this Regulation. The standardisation request shall also ask for deliverables on reporting and documentation processes to improve AI systems' resource performance, such as reducing the high-risk AI system's consumption of energy and of other resources during its lifecycle, and on the energy-efficient development of general-purpose AI models. When preparing a standardisation request, the Commission shall consult the Board and relevant stakeholders, including the advisory forum. When issuing a standardisation request to European standardisation organisations, the Commission shall specify that standards have to be clear, consistent, including with the standards developed in the various sectors for products covered by the existing Union harmonisation legislation listed in Annex I, and aiming to ensure that high-risk AI systems or general-purpose AI models placed on the market or put into service in the Union meet the relevant requirements or obligations laid down in this Regulation. The Commission shall request the European standardisation organisations to provide evidence of their best efforts to fulfil the objectives referred to in the first and the second subparagraph of this paragraph in accordance with Article 24 of Regulation (EU) No 1025/2012.

Art. 58, 2(g): that procedures, processes and administrative requirements for application, selection, participation and exiting the AI regulatory sandbox are simple, easily intelligible, and clearly communicated in order to facilitate the participation of SMEs, including start-ups, with limited legal and administrative capacities and are streamlined across the Union, in order to avoid fragmentation and that participation in an AI regulatory sandbox established by a Member State, or by the European Data Protection Supervisor is mutually and uniformly recognised and carries the same legal effects across the Union.

Art. 74, 4: For high-risk AI systems covered by the Union harmonisation legislation listed in Section A of Annex I, where a post-market monitoring system and plan are already established under that legislation, in order to ensure consistency, avoid duplications and minimise additional burdens, providers shall have a choice of integrating, as appropriate, the necessary elements described in paragraphs 1, 2, and 3 using the template referred in paragraph 3 into systems and plans already existing under that legislation, provided that it achieves an equivalent level of protection. The first subparagraph of this paragraph shall also apply to high-risk AI systems referred to in point 5 of Annex III placed on the market or put into service by financial institutions that are subject to requirements under Union financial services law regarding their internal governance, arrangements or processes.

9 Product

Art. 2, 2: For AI systems classified as high-risk AI systems in accordance with Article 6(1) related to products covered by the Union harmonisation legislation listed in Section B of Annex I, only Article 6(1), Articles 102 to 109 and Article 112 apply. Article 57 applies only in so far as the requirements for high-risk AI systems under this Regulation have been integrated in that Union harmonisation legislation.

Art. 6, 1: Irrespective of whether an AI system is placed on the market or put into service independently of the products referred to in points (a) and (b), that AI system shall be considered to be high-risk where both of the following conditions are fulfilled:

Art. 25, 3: In the case of high-risk AI systems that are safety components of products covered by the Union harmonisation legislation listed in Section A of Annex I, the product manufacturer shall be considered to be the provider of the high-risk AI system, and shall be subject to the obligations under Article 16 under either of the following circumstances:

Art. 40, 2: In accordance with Article 10 of Regulation (EU) No 1025/2012, the Commission shall issue, without undue delay, standardisation requests covering all requirements set out in Section 2 of this Chapter and, as applicable, standardisation requests covering obligations set out in Chapter V, Sections 2 and 3, of this Regulation. The standardisation request shall also ask for deliverables on reporting and documentation processes to improve AI systems' resource performance, such as reducing the high-risk AI system's consumption of energy and of other resources during its lifecycle, and on the energy-efficient development of general-purpose AI models. When preparing a standardisation request, the Commission shall consult the Board and relevant stakeholders, including the advisory forum. When issuing a standardisation request to European standardisation organisations, the Commission shall specify that standards have to be clear, consistent, including with the standards developed in the various sectors for products covered by the existing Union harmonisation legislation listed in Annex I, and aiming to ensure that high-risk AI systems or general-purpose AI models placed on the market or put into service in the Union meet the relevant requirements or obligations laid down in this Regulation. The Commission shall request the European standardisation organisations to provide evidence of their best efforts to fulfil the objectives referred to in the first and the second subparagraph of this paragraph in accordance with Article 24 of Regulation (EU) No 1025/2012.

Art. 46, 7: For high-risk AI systems related to products covered by Union harmonisation legislation listed in Section A of Annex I, only the derogations from the conformity assessment established in that Union harmonisation legislation shall apply.

Art. 57, 17: The Commission shall develop a single and dedicated interface containing all relevant information related to AI regulatory sandboxes to allow stakeholders to interact with AI regulatory sandboxes and to raise enquiries with competent authorities, and to seek non-binding guidance on the conformity of innovative products, services, business models embedding AI technologies, in accordance with Article 62(1), point (c). The Commission shall proactively coordinate with national competent authorities, where relevant.

Art. 60, 1: Testing of high-risk AI systems in real world conditions outside AI regulatory sandboxes may be conducted by providers or prospective providers of high-risk AI systems listed in Annex III, in accordance with this Article and the real-world testing plan referred to in this Article, without prejudice to the prohibitions under Article 5. The Commission shall, by means of implementing acts, specify the detailed elements of the real-world testing plan. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 58(2). This paragraph shall be without prejudice to Union or national law on the testing in real world conditions of high-risk AI systems related to products covered by Union harmonisation legislation listed in Annex I.

Art. 74, 3: For high-risk AI systems related to products covered by the Union harmonisation legislation listed in Section A of Annex I, the market surveillance authority for the purposes of this Regulation shall be the authority responsible for market surveillance activities designated under those legal acts. By derogation from the first subparagraph, and in appropriate circumstances, Member States may designate another relevant authority to act as a market surveillance authority, provided they ensure coordination with the relevant sectoral market surveillance authorities responsible for the enforcement of the Union harmonisation legislation listed in Annex I.

Art. 74, 4: The procedures referred to in Articles 79 to 83 of this Regulation shall not apply to AI systems related to products covered by the Union harmonisation legislation listed in section A of Annex I, where such legal acts already provide for procedures ensuring an equivalent level of protection and having the same objective. In such cases, the relevant sectoral procedures shall apply instead.

1 Product manufacturers

Art. 2, 1(e): product manufacturers placing on the market or putting into service an AI system together with their product and under their own name or trademark;

3 Prohibited AI

CHAPTER II: PROHIBITED AI PRACTICES

Art. 5: Prohibited AI practices

Art. 112, 1: The Commission shall assess the need for amendment of the list set out in Annex III and of the list of prohibited AI practices laid down in Article 5, once a year following the entry into force of this Regulation, and until the end of the period of the delegation of power laid down in Article 97. The Commission shall submit the findings of that assessment to the European Parliament and the Council.

Terms and AI Act Articles

46 Protection

- Art. 1, 1:** The purpose of this Regulation is to improve the functioning of the internal market and promote the uptake of human-centric and trustworthy artificial intelligence (AI), while ensuring a high level of protection of health, safety, fundamental rights enshrined in the Charter, including democracy, the rule of law and environmental protection, against the harmful effects of AI systems in the Union and supporting innovation.
- Art. 2, 4:** This Regulation applies neither to public authorities in a third country nor to international organisations falling within the scope of this Regulation pursuant to paragraph 1, where those authorities or organisations use AI systems in the framework of international cooperation or agreements for law enforcement cooperation with the Union or with one or more Member States, provided that such a third country or international organisation provides adequate safeguards with respect to the protection of fundamental rights and freedoms of individuals.
- Art. 2, 7:** Union law on the protection of personal data, privacy and the confidentiality of communications applies to personal data processed in connection with the rights and obligations laid down in this Regulation. This Regulation shall not affect Regulation (EU) 2016/679 or (EU) 2018/1725, or Directive 2002/58/EC or (EU) 2016/680, without prejudice to Article 10(5) and Article 59 of this Regulation.
- Art. 2, 9:** This Regulation is without prejudice to other Union legal acts related to non-remote identification and product safety.
- Art. 3, (48):** 'national competent authority' means a notifying authority or a market surveillance authority, as regards AI systems put into service or used by Union institutions, agencies, offices and bodies, references to national competent authorities or market surveillance authorities in this Regulation shall be construed as references to the European Data Protection Supervisor.
- Art. 4, 5:** Without prejudice to paragraph 3, each use of a real-time biometric identification system in publicly accessible spaces for law enforcement purposes shall be notified to the relevant market surveillance authority and the national data protection authority in accordance with the national rules referred to in paragraph 5. The notification shall, as a minimum, contain the information specified under paragraph 6 and shall not include sensitive operational data.
- Art. 5, 6:** National market surveillance authorities and the national data protection authorities of Member States that have been notified of the use of 'real-time' remote biometric identification systems in publicly accessible spaces for law enforcement purposes pursuant to paragraph 4 shall submit to the Commission annual reports on such use. For that purpose, the Commission shall provide Member States and national market surveillance and data protection authorities with a template, including information on the number of the decisions taken by competent judicial authorities or an independent administrative authority whose decision is binding upon requests for authorisations in accordance with paragraph 3 and their result.
- Art. 6, 7:** The Commission shall adopt delegated acts in accordance with Article 97 in order to amend paragraph 3, second subparagraph, of this Article by deleting any of the conditions laid down therein, where there is concrete and reliable evidence that this is necessary to maintain the level of protection of health, safety and fundamental rights provided for by this Regulation.
- Art. 6, 8:** Any amendment to the conditions laid down in paragraph 3, second subparagraph, adopted in accordance with paragraphs 6 and 7 of this Article shall not decrease the overall level of protection of health, safety and fundamental rights provided for by this Regulation and shall ensure consistency with the delegated acts adopted pursuant to Article 7(1), and take account of market and technological developments.
- Art. 7, 3(b):** the deletion does not decrease the overall level of protection of health, safety and fundamental rights under Union law.
- Art. 17, 2:** The implementation of the aspects referred to in paragraph 1 shall be proportionate to the size of the provider's organisation. Providers shall, in any event, respect the degree of rigour and the level of protection required to ensure the compliance of their high-risk AI systems with this Regulation.
- Art. 19, 1:** Providers of high-risk AI systems shall keep the logs referred to in Article 12(1), automatically generated by their high-risk AI systems, to the extent such logs are under their control. Without prejudice to applicable Union or national law, the logs shall be kept for a period appropriate to the intended purpose of the high-risk AI system, of at least six months, unless provided otherwise in the applicable Union or national law, in particular in Union law on the protection of personal data.
- Art. 26, 6:** Deployers of high-risk AI systems shall keep the logs automatically generated by that high-risk AI system to the extent such logs are under their control, for a period appropriate to the intended purpose of the high-risk AI system, of at least six months, unless provided otherwise in applicable Union or national law, in particular in Union law on the protection of personal data. Deployers that are financial institutions subject to requirements regarding their internal governance, arrangements or processes under Union financial services law shall maintain the logs as part of the documentation kept pursuant to the relevant Union financial service law.
- Art. 26, 9:** Where applicable, deployers of high-risk AI systems shall use the information provided under Article 13 of this Regulation to comply with their obligation to carry out a data protection impact assessment under Article 35 of Regulation (EU) 2016/679 or Article 27 of Directive (EU) 2016/680.
- Art. 26, 10:** Without prejudice to Directive (EU) 2016/680, in the framework of an investigation for the targeted search of a person suspected or convicted of having committed a criminal offence, the deployer of a high-risk AI system for post-remote biometric identification shall request an authorisation, ex ante, or without undue delay and no later than 48 hours, by a judicial authority or an administrative authority whose decision is binding and subject to judicial review, for the use of that system, except when it is used for the initial identification of a potential suspect based on objective and verifiable facts directly linked to the offence. Each use shall be limited to what is strictly necessary for the investigation of a specific criminal offence. If the authorisation requested pursuant to the first subparagraph is rejected, the use of the post-remote biometric identification system linked to that requested authorisation shall be stopped with immediate effect and the personal data linked to the use of the high-risk AI system for which the authorisation was requested shall be deleted. In no case shall such high-risk AI system for post-remote biometric identification be used for law enforcement purposes in an untargeted way, without any link to a criminal offence, a criminal proceeding, a genuine and present or foreseeable threat of a criminal offence, or the search for a specific missing person. It shall be ensured that no decision that produces an adverse legal effect on a person may be taken by the law enforcement authorities based solely on the output of such post-remote biometric identification systems. This paragraph is without prejudice to Article 9 of Regulation (EU) 2016/679 and Article 10 of Directive (EU) 2016/680 for the processing of biometric data. Regardless of the purpose or deployer, each use of such high-risk AI systems shall be documented in the relevant police file and shall be made available to the relevant market surveillance authority and the national data protection authority upon request, excluding the disclosure of sensitive operational data related to law enforcement. This subparagraph shall be without prejudice to the powers conferred by Directive (EU) 2016/680 on supervisory authorities. Deployers shall submit annual reports to the relevant market surveillance and national data protection authorities on their use of post-remote biometric identification systems, excluding the disclosure of sensitive operational data related to law enforcement. The reports may be aggregated to cover more than one deployment. Member States may introduce, in accordance with Union law, more restrictive laws on the use of post-remote biometric identification systems.
- Art. 27, 4:** If any of the obligations laid down in this Article is already met through a data protection impact assessment conducted pursuant to Article 35 of Regulation (EU) 2016/679 or Article 27 of Directive (EU) 2016/680, the fundamental rights impact assessment referred to in paragraph 1 of this Article shall complement that data protection impact assessment.
- Art. 34, 2:** Notified bodies shall avoid unnecessary burdens for providers when performing their activities, and take due account of the size of the provider, the sector in which it operates, its structure and the degree of complexity of the high-risk AI system concerned, in particular in view of minimising administrative burdens and compliance costs for micro- and small enterprises within the meaning of Recommendation 2003/361/EC. The notified body shall, nevertheless, respect the degree of rigour and the level of protection required for the compliance of the high-risk AI system with the requirements of this Regulation.
- Art. 43, 6:** The Commission is empowered to adopt delegated acts in accordance with Article 97 in order to amend paragraphs 1 and 2 of this Article in order to subject high-risk AI systems referred to in points 2 to 8 of Annex III to the conformity assessment procedure referred to in Annex VII or parts thereof. The Commission shall take into account the effectiveness of the conformity assessment procedure based on internal control referred to in Annex VI in preventing or minimising the risks to health and safety and protection of fundamental rights posed by such systems, as well as the availability of adequate capacities and resources among notified bodies.
- Art. 46, 1:** By way of derogation from Article 43 and upon a duly justified request, any market surveillance authority may authorise the placing on the market or the putting into service of specific high-risk AI systems within the territory of the Member State concerned, for exceptional reasons of public security or the protection of life and health of persons, environmental protection or the protection of key industrial and infrastructural assets. That authorisation shall be for a limited period while the necessary conformity assessment procedures are being carried out, taking into account the exceptional reasons justifying the derogation. The completion of those procedures shall be undertaken without undue delay.
- Art. 46, 2:** In a duly justified situation of urgency for exceptional reasons of public security or in the case of specific, substantial and imminent threat to the life or physical safety of natural persons, law-enforcement authorities or civil protection authorities may put a specific high-risk AI system into service without the authorisation referred to in paragraph 1, provided that such authorisation is requested during or after the use without undue delay. If the authorisation referred to in paragraph 1 is refused, the use of the high-risk AI system shall be stopped with immediate effect and all the results and outputs of such use shall be immediately discarded.
- Art. 55, 1(c):** ensure an adequate level of cybersecurity protection for the general-purpose AI model with systemic risk and the physical infrastructure of the model.
- Art. 57, 3:** The European Data Protection Supervisor may also establish an AI regulatory sandbox for Union institutions, bodies, offices and agencies, and may exercise the roles and the tasks of national competent authorities in accordance with this Chapter.
- Art. 57, 10:** National competent authorities shall ensure that, to the extent the innovative AI systems involve the processing of personal data or otherwise fall under the supervisory remit of other national authorities or competent authorities providing or supporting access to data, the national data protection authorities and those other national or competent authorities are associated with the operation of the AI regulatory sandbox and involved in the supervision of those aspects to the extent of their respective tasks and powers.
- Art. 58, 2(g):** that procedures, processes and administrative requirements for application, selection, participation and exiting the AI regulatory sandbox are simple, easily intelligible, and clearly communicated in order to facilitate the participation of SMEs, including start-ups, with limited legal and administrative capacities and are streamlined across the Union, in order to avoid fragmentation and that participation in an AI regulatory sandbox established by a Member State, or by the European Data Protection Supervisor is mutually and uniformly recognised and carries the same legal effects across the Union;
- Art. 59, 1(a)(ii):** a high level of protection and improvement of the quality of the environment, protection of biodiversity, protection against pollution, green transition measures, climate change mitigation and adaptation measures;
- Art. 59, 1(e):** providers can further share the originally collected data only in accordance with Union data protection law; any personal data created in the sandbox cannot be shared outside the sandbox;
- Art. 59, 1(f):** any processing of personal data in the context of the sandbox neither leads to measures or decisions affecting the data subjects nor does it affect the application of their rights laid down in Union law on the protection of personal data;
- Art. 61, 3:** Paragraph 1 of this Article shall not apply to the processing of personal data for purposes other than those explicitly mentioned in that law, as well as to Union or national law laying down the basis for the processing of personal data which is necessary for the purpose of developing, testing or training of innovative AI systems or any other legal basis, in compliance with Union law on the protection of personal data.
- Art. 63, 1:** Microenterprises within the meaning of Recommendation 2003/361/EC may comply with certain elements of the quality management system required by Article 17 of this Regulation in a simplified manner, provided that they do not have partner enterprises or linked enterprises within the meaning of that Recommendation. For that purpose, the Commission shall develop guidelines on the elements of the quality management system which may be complied with in a simplified manner considering the needs of microenterprises, without affecting the level of protection or the need for compliance with the requirements in respect of high-risk AI systems.
- Art. 65, 2:** The Board shall be composed of one representative per Member State. The European Data Protection Supervisor shall participate as observer. The AI Office shall also attend the Board's meetings, without taking part in the votes. Other national and Union authorities, bodies or agencies may be invited to the meetings by the Board on a case by case basis, where the issues discussed are of relevance for them.
- Art. 66, (h):** cooperate, as appropriate, with other Union institutions, bodies, offices and agencies, as well as relevant Union expert groups and networks, in particular in the fields of product safety, cybersecurity, competition, digital and media services, financial services, consumer protection, data and fundamental rights protection.
- Art. 70, 3:** Member States shall ensure that their national competent authorities are provided with adequate technical, financial and human resources, and with infrastructure to fulfil their tasks effectively under this Regulation. In particular, the national competent authorities shall have a sufficient number of personnel permanently available whose competences and expertise shall include an in-depth understanding of AI technologies, data and data computing, personal data protection, cybersecurity, fundamental rights, health and safety risks and knowledge of existing standards and legal requirements. Member States shall assess and, if necessary, update competence and resource requirements referred to in this paragraph on an annual basis.
- Art. 72, 4:** For high-risk AI systems covered by the Union harmonisation legislation listed in Section A of Annex I, where a post-market monitoring system and plan are already established under that legislation, in order to ensure consistency, avoid duplications and minimise additional burdens, providers shall have a choice of integrating, as appropriate, the necessary elements described in paragraphs 1, 2 and 3 using the templates referred in paragraph 3 into systems and plans already existing under that legislation, provided that it achieves an equivalent level of protection. The first subparagraph of this paragraph shall also apply to high-risk AI systems referred to in point 5 of Annex III placed on the market or put into service by financial institutions that are subject to requirements under Union financial services law regarding their internal governance, arrangements or processes.
- Art. 74, 4:** The procedures referred to in Articles 79 to 83 of this Regulation shall not apply to AI systems related to products covered by the Union harmonisation legislation listed in Section A of Annex I, where such legal acts already provide for procedures ensuring an equivalent level of protection and having the same objective. In such cases, the relevant sectorial procedures shall apply instead.
- Art. 74, 8:** For high-risk AI systems listed in point 1 of Annex III to this Regulation, in so far as the systems are used for law enforcement purposes, border management and justice and democracy, and for high-risk AI systems listed in points 6, 7 and 8 of Annex III to this Regulation, Member States shall designate as market surveillance authorities for the purposes of this Regulation either the competent data protection supervisory authorities under Regulation (EU) 2016/679 or Directive (EU) 2016/680, or any other authority designated pursuant to the same conditions laid down in Articles 41 to 44 of Directive (EU) 2016/680. Market surveillance activities shall in no way affect the independence of judicial authorities, or otherwise interfere with their activities when acting in their judicial capacity.
- Art. 74, 9:** Where Union institutions, bodies, offices or agencies fall within the scope of this Regulation, the European Data Protection Supervisor shall act as their market surveillance authority, except in relation to the Court of Justice of the European Union acting in its judicial capacity.
- Art. 82, 1:** Where, having performed an evaluation under Article 79, after consulting the relevant national public authority referred to in Article 77(1), the market surveillance authority of a Member State finds that although a high-risk AI system complies with this Regulation, it nevertheless presents a risk to the health or safety of persons, to fundamental rights, or to other aspects of public interest protection, it shall require the relevant operator to take all appropriate measures to ensure that the AI system concerned, when placed on the market or put into service, no longer presents that risk without undue delay, within a period it may prescribe.
- Art. 87:** Reporting of infringements and protection of reporting persons.
- Art. 87:** Directive (EU) 2019/1937 shall apply to the reporting of infringements of this Regulation and the protection of persons reporting such infringements.
- Art. 100, 1:** The European Data Protection Supervisor may impose administrative fines on Union institutions, bodies, offices and agencies falling within the scope of this Regulation. When deciding whether to impose an administrative fine and when deciding on the amount of the administrative fine in each individual case, all relevant circumstances of the specific situation shall be taken into account and due regard shall be given to the following:
- Art. 100, 1(a):** the degree of cooperation with the European Data Protection Supervisor in order to remedy the infringement and mitigate the possible adverse effects of the infringement, including compliance with any of the measures previously ordered by the European Data Protection Supervisor against the Union institution, body, office or agency concerned with regard to the same subject matter.
- Art. 100, 1(b):** the manner in which the infringement became known to the European Data Protection Supervisor, in particular whether, and if so to what extent, the Union institution, body, office or agency notified the infringement;
- Art. 100, 4:** Before taking decisions pursuant to this Article, the European Data Protection Supervisor shall give the Union institution, body, office or agency which is the subject of the proceedings conducted by the European Data Protection Supervisor the opportunity of being heard on the matter regarding the possible infringement. The European Data Protection Supervisor shall base his or her decisions only on elements and circumstances on which the parties concerned have been able to comment. Complainants, if any, shall be associated closely with the proceedings.
- Art. 100, 5:** The rights of defence of the parties concerned shall be fully respected in the proceedings. They shall be entitled to have access to the European Data Protection Supervisor's file, subject to the legitimate interest of individuals or undertakings in the protection of their personal data or business secrets.
- Art. 100, 7:** The European Data Protection Supervisor shall, on an annual basis, notify the Commission of the administrative fines it has imposed pursuant to this Article and of any litigation or judicial proceedings it has initiated.

5 Protection of personal data

- Art. 2, 7:** Union law on the protection of personal data, privacy and the confidentiality of communications applies to personal data processed in connection with the rights and obligations laid down in this Regulation. This Regulation shall not affect Regulation (EU) 2016/679 or (EU) 2018/1725, or Directive 2002/58/EC or (EU) 2016/680, without prejudice to Article 10(5) and Article 59 of this Regulation.
- Art. 19, 1:** Providers of high-risk AI systems shall keep the logs referred to in Article 12(1), automatically generated by their high-risk AI systems, to the extent such logs are under their control. Without prejudice to applicable Union or national law, the logs shall be kept for a period appropriate to the intended purpose of the high-risk AI system, of at least six months, unless provided otherwise in the applicable Union or national law, in particular in Union law on the protection of personal data.
- Art. 26, 6:** Deployers of high-risk AI systems shall keep the logs automatically generated by that high-risk AI system to the extent such logs are under their control, for a period appropriate to the intended purpose of the high-risk AI system, of at least six months, unless provided otherwise in applicable Union or national law, in particular in Union law on the protection of personal data. Deployers that are financial institutions subject to requirements regarding their internal governance, arrangements or processes under Union financial services law shall maintain the logs as part of the documentation kept pursuant to the relevant Union financial service law.
- Art. 59, 1(f):** any processing of personal data in the context of the sandbox neither leads to measures or decisions affecting the data subjects nor does it affect the application of their rights laid down in Union law on the protection of personal data;
- Art. 61, 3:** Paragraph 1 of this Article shall not apply to the processing of personal data for purposes other than those explicitly mentioned in that law, as well as to Union or national law laying down the basis for the processing of personal data which is necessary for the purpose of developing, testing or training of innovative AI systems or any other legal basis, in compliance with Union law on the protection of personal data.

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Art. 99, 4(g): transparency obligations for providers and deployers pursuant to Article 50.

Art. 101: Fines for providers of general-purpose AI models

Art. 101, 1: The Commission may impose on providers of general-purpose AI models fines not exceeding 3 % of their annual total worldwide turnover in the preceding financial year or EUR 15 000 000, whichever is higher., when the Commission finds that the provider intentionally or negligently:

Art. 101, 2: Before adopting the decision pursuant to paragraph 1, the Commission shall communicate its preliminary findings to the provider of the general-purpose AI model and give it an opportunity to be heard.

Art. 111, 2: Without prejudice to the application of Article 5 as referred to in Article 113(3), point (a), this Regulation shall apply to operators of high-risk AI systems, other than the systems referred to in paragraph 1 of this Article, that have been placed on the market or put into service before 2 August 2026, only if, as from that date, those systems are subject to significant changes in their designs. In any case, the providers and deployers of high-risk AI systems intended to be used by public authorities shall take the necessary steps to comply with the requirements and obligations of this Regulation by 2 August 2030.

Art. 111, 3: Providers of general-purpose AI models that have been placed on the market before 2 August 2025 shall take the necessary steps in order to comply with the obligations laid down in this Regulation by 2 August 2027.

1 Pseudonymisation

Art. 10, 5(b): the special categories of personal data are subject to technical limitations on the re-use of the personal data, and state-of-the-art security and privacy-preserving measures, including pseudonymisation;

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161 Purpose

Art. 1. The purpose of this Regulation is to improve the functioning of the internal market and promote the uptake of human-centric and trustworthy artificial intelligence (AI), while ensuring a high level of protection of health, safety, fundamental rights enshrined in the Charter, including democracy, the rule of law and environmental protection, against the harmful effects of AI systems in the Union and supporting innovation.
Art. 1. 2(a): 'harmonised rules for the placing on the market of general-purpose AI models' means...

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for the purpose of developing, testing or training of innovative AI systems or any other legal basis, in compliance with Union law on the protection of personal data.

Art. 65 (e) data collected and processed for the purposes of this Regulation in real world conditions shall be transferred to third countries only provided that appropriate and applicable safeguards under Union law are implemented;

Art. 61, 7: For the purpose of testing in real world conditions under Article 60, freely-given informed consent shall be obtained from the subjects of testing prior to their participation in such testing and after their having been duly informed with concise, clear, relevant, and understandable information regarding

Art. 63, 1: Microenterprises within the meaning of Recommendation 2003/361/EC may comply with certain elements of the quality management system required by Article 17 of this Regulation in a simplified manner, provided that they do not have partner enterprises or linked enterprises within the meaning of that Recommendation. For that purpose, the Commission shall develop guidelines on the elements of the quality management system which may be complied with in a simplified manner considering the needs of microenterprises, without affecting the level of protection or the need for compliance with the requirements in respect of high-risk AI systems.

Art. 65, (g) are empowered to facilitate consistency and coordination between national competent authorities in their Member State as regards the implementation of this Regulation, including through the collection of relevant data and information for the purpose of fulfilling their tasks on the Board.

Art. 65, 6: The Board shall establish two standing sub-groups to provide a platform for cooperation and exchange among market surveillance authorities and notifying authorities about issues related to market surveillance and notified bodies respectively. The standing sub-group for market surveillance should act as the administrative coordination group (ADCO) for this Regulation within the meaning of Article 30 of Regulation (EU) 2019/1020. The Board may establish other standing or temporary sub-groups as appropriate for the purpose of examining specific issues. Where appropriate, representatives of the advisory forum referred to in Article 67 may be invited to such sub-groups or to specific meetings of those subgroups as observers.

Art. 66, (c): provide advice on the implementation of this Regulation, in particular as regards the enforcement of rules on general-purpose AI models;

Art. 66, (n): provide opinions to the Commission on the qualified alerts regarding general-purpose AI models;

Art. 66, (o): receive opinions by the Member States on qualified alerts regarding general-purpose AI models, and on national experiences and practices on the monitoring and enforcement of AI systems, in particular systems integrating the general-purpose AI models.

Art. 67, 3: The advisory forum may establish standing or temporary sub-groups as appropriate for the purpose of examining specific questions related to the objectives of this Regulation.

Art. 68, 2(b): independence from any provider of AI systems or general-purpose AI models;

Art. 68, 3(a): supporting the implementation and enforcement of this Regulation as regards general-purpose AI models and systems, in particular by:

Art. 68, 3(a)(i) alerting the AI Office of possible systemic risks at Union level of general-purpose AI models, in accordance with Article 90;

Art. 68, 3(a)(ii) contributing to the development of tools and methodologies for evaluating capabilities of general-purpose AI models and systems, including through benchmarks;

Art. 68, 3(a)(iii) providing advice on the classification of general-purpose AI models with systemic risk;

Art. 68, 3(a)(iv) providing advice on the classification of various general-purpose AI models and systems;

Art. 73, 10: For high-risk AI systems which are safety components of devices, or are themselves devices, covered by Regulations (EU) 2017/745 and (EU) 2017/746, the notification of serious incidents shall be limited to those referred to in Article 3, point (49)(c) of this Regulation, and shall be made to the national competent authority chosen for that purpose by the Member States where the incident occurred.

Art. 74, 3: Without prejudice to the powers of market surveillance authorities under Article 14 of Regulation (EU) 2019/1020, for the purpose of ensuring the effective enforcement of this Regulation, market surveillance authorities may exercise the powers referred to in Article 14(4), points (d) and (j), of that Regulation remotely, as appropriate.

Art. 75: Mutual assistance, market surveillance and control of general-purpose AI systems

Art. 75, 1: Where an AI system is based on a general-purpose AI model, and the model and the system are developed by the same provider, the AI Office shall have powers to monitor and supervise compliance of that AI system with obligations under this Regulation. To carry out its monitoring and supervision tasks, the AI Office shall have all the powers of a market surveillance authority provided for in this Section and Regulation (EU) 2019/1020.

Art. 75, 2: Where the relevant market surveillance authorities have sufficient reason to consider general-purpose AI systems that can be used directly by deployers for at least one purpose that is classified as high-risk pursuant to this Regulation to be non-compliant with the requirements laid down in this Regulation, they shall cooperate with the AI Office to carry out compliance evaluations, and shall inform the Board and other market surveillance authorities accordingly.

Art. 75, 3: Where a market surveillance authority is unable to conclude its investigation of the high-risk AI system because of its inability to access certain information related to the general-purpose AI model despite having made all appropriate efforts to obtain that information, it may submit a reasoned request to the AI Office, by which access to that information shall be enforced. In that case, the AI Office shall supply to the applicant authority without delay, and in any event within 30 days, any information that the AI Office considers to be relevant in order to establish if a high-risk AI system is non-compliant. Market surveillance authorities shall safeguard the confidentiality of the information that they obtain in accordance with Article 78 of this Regulation. The procedure provided for in Chapter VI of Regulation (EU) 2019/1020 shall apply mutatis mutandis.

Art. 78, 2: The authorities involved in the application of this Regulation pursuant to paragraph 1 shall request only data that is strictly necessary for the assessment of the risk posed by AI systems and for the exercise of their powers in accordance with this Regulation and with Regulation (EU) 2019/1020. They shall not put in place any restrictive cybersecurity measures to protect the security and confidentiality of the information and data obtained, and shall delete the data collected as soon as it is no longer needed for the purpose for which it was obtained, in accordance with applicable Union or national law.

Art. 85: Without prejudice to other administrative or judicial remedies, any natural or legal person having grounds to consider that there has been an infringement of the provisions of this Regulation may submit complaints to the relevant market surveillance authority. In accordance with Regulation (EU) 2019/1020, such complaints shall be taken into account for the purpose of conducting market surveillance activities, and shall be handled in line with the dedicated procedures established therefor by the market surveillance authorities.

SECTION 5: Supervision, investigation, enforcement and monitoring in respect of providers of general-purpose AI models

Art. 88: Enforcement of the obligations of providers of general-purpose AI models

Art. 89, 1: For the purpose of carrying out the tasks assigned to it under this Section, the AI Office may take the necessary actions to monitor the effective implementation and compliance with this Regulation by providers of general-purpose AI models, including their adherence to approved codes of practice.

Art. 89, 2(a): the point of contact of the provider of the general-purpose AI model concerned;

Art. 89, 2(b): a description of the relevant facts, the provisions of this Regulation concerned, and the reason why the downstream provider considers that the provider of the general-purpose AI model concerned infringed this Regulation;

Art. 90, 1(a): a general-purpose AI model poses concrete identifiable risk at Union level; or

Art. 90, 1(b): a general-purpose AI model meets the conditions referred to in Article 51.

Art. 90, 2: Upon receipt of a qualified alert, the Commission, through the AI Office and after having informed the Board, may exercise the powers laid down in this Section for the purpose of assessing the matter. The AI Office shall inform the Board of any measure according to Articles 91 to 94.

Art. 90, 3(a): the point of contact of the provider of the general-purpose AI model with systemic risk concerned;

Art. 91, 1: The Commission may request the provider of the general-purpose AI model concerned to provide the documentation drawn up by the provider in accordance with Articles 53 and 55, or any additional information that is necessary for the purpose of assessing compliance of the provider with this Regulation.

Art. 91, 2: Before sending the request for information, the AI Office may initiate a structured dialogue with the provider of the general-purpose AI model.

Art. 91, 3: Upon a duly substantiated request from the scientific panel, the Commission may issue a request for information to a provider of a general-purpose AI model, where the access to information is necessary and proportionate for the fulfilment of the tasks of the scientific panel under Article 69(2).

Art. 91, 4: The request for information shall state the legal basis and the purpose of the request, specify what information is required, set a period within which the information is to be provided, and indicate the fines provided for in Article 101 for supplying incorrect, incomplete or misleading information.

Art. 91, 5: The provider of the general-purpose AI model concerned, or its representative shall supply the information requested. In the case of legal persons, companies or firms, or where the provider has no legal personality, the persons authorised to represent them by law or by their statutes, shall supply the information requested on behalf of the provider of the general-purpose AI model concerned. Lawyers duly authorised to act may supply information on behalf of their clients. The clients shall nevertheless remain fully responsible if the information supplied is incomplete, incorrect or misleading.

Art. 92, 1: The AI Office, after consulting the Board, may conduct evaluations of the general-purpose AI model concerned:

Art. 92, 1(b): to investigate systemic risks at Union level of general-purpose AI models with systemic risk, in particular following a qualified alert from the scientific panel in accordance with Article 90(1), point (a).

Art. 92, 3: For the purposes of paragraph 1, the Commission may request access to the general-purpose AI model concerned through APIs or further appropriate technical means and tools, including source code.

Art. 92, 4: The request for access shall state the legal basis, the purpose and reasons of the request and set the period within which the access is to be provided, and the fines provided for in Article 101 for failure to provide access.

Art. 92, 5: The providers of the general-purpose AI model concerned or its representative shall supply the information requested. In the case of legal persons, companies or firms, or where the provider has no legal personality, the persons authorised to represent them by law or by their statutes, shall provide the access requested on behalf of the provider of the general-purpose AI model concerned.

Art. 92, 7: Prior to requesting access to the general-purpose AI model concerned, the AI Office may initiate a structured dialogue with the provider of the general-purpose AI model to gather more information on the internal testing of the model, internal safeguards for preventing systemic risks, and other internal procedures and measures the provider has taken to mitigate such risks.

Art. 93, 2: Before a measure is requested, the AI Office may initiate a structured dialogue with the provider of the general-purpose AI model.

Art. 93, 3: If, during the structured dialogue referred to in paragraph 2, the provider of the general-purpose AI model with systemic risk offers commitments to implement mitigation measures to address a systemic risk at Union level, the Commission may, by decision, make those commitments binding and declare that there are no further grounds for action.

Art. 94: Procedural rights of economic operators of the general-purpose AI model

Art. 94, Article 18 of Regulation (EU) 2019/1020 shall apply mutatis mutandis to the providers of the general-purpose AI model, without prejudice to more specific procedural rights provided for in this Regulation.

Art. 95, 3: Codes of conduct may be drawn up by individual providers or deployers of AI systems or by organisations representing them or by both, including with the involvement of any interested stakeholders and their representative organisations, including civil society organisations and academia. Codes of conduct shall be taken into account for the purpose of the relevant systems.

Art. 99, 1(a): the nature, gravity and duration of the infringement and of its consequences, taking into account the purpose of the AI system, as well as, where appropriate, the number of affected persons and the level of damage suffered by them;

Art. 100, 1(a): the nature, gravity and duration of the infringement and of its consequences, taking into account the purpose of the AI system concerned, as well as, where appropriate, the number of affected persons and the level of damage suffered by them;

Art. 101: Fines for providers of AI models

Art. 101, 1: The Commission may impose on providers of general-purpose AI models fines not exceeding 3 % of their annual total worldwide turnover in the preceding financial year or EUR 15 000 000, whichever is higher, when the Commission finds that the provider intentionally or negligently:

Art. 101, 1(d): failed to make available to the Commission access to the general-purpose AI model or general-purpose AI model with systemic risk with a view to conducting an evaluation pursuant to Article 92. In fixing the amount of the fine or periodic penalty payment, regard shall be had to the nature, gravity and duration of the infringement, taking due account of the principles of proportionality and appropriateness. The Commission shall also take account of commitments made in accordance with Article 93(3) or made in relevant codes of practice in accordance with Article 56.

Art. 101, 2: Before adopting the decision pursuant to paragraph 1, the Commission shall communicate its preliminary findings to the provider of the general-purpose AI model and give it an opportunity to be heard.

Art. 111: AI systems already placed on the market or put into service and general-purpose AI models already placed on the market

Art. 111, 3: Providers of general-purpose AI models that have been placed on the market before 2 August 2025 shall take the necessary steps in order to comply with the obligations laid down in this Regulation by 2 August 2027.

Art. 112, 6: By 2 August 2028, such complaints shall be taken into account for the purpose of conducting market surveillance activities, and shall be handled in line with the dedicated procedures established therefor by the market surveillance authorities.

Art. 63, 1: Microenterprises within the meaning of Recommendation 2003/361/EC may comply with certain elements of the quality management system required by Article 17 of this Regulation in a simplified manner, provided that they do not have partner enterprises or linked enterprises within the meaning of that Recommendation. For that purpose, the Commission shall develop guidelines on the elements of the quality management system which may be complied with in a simplified manner considering the needs of microenterprises, without affecting the level of protection or the need for compliance with the requirements in respect of high-risk AI systems.

1 Quality assurance (See also: Data quality model, Data quality requirements, Data requirements, Quality criteria, Quality model)

Art. 17, 1(c): techniques, procedures and systematic actions to be used for the development, quality control and quality assurance of the high-risk AI system;

0 Quality characteristics

1 Quality control (See also: Re-use of the personal data)

Art. 17, 1(c): techniques, procedures and systematic actions to be used for the development, quality control and quality assurance of the high-risk AI system;

1 Quality criteria (See also: Data quality requirements, Data quality model, Data requirements, Quality model, Quality criteria, Quality assurance)

Art. 10, 1: High-risk AI systems which make use of techniques involving the training of AI models with data shall be developed on the basis of training, validation and testing data sets that meet the quality criteria referred to in paragraphs 2 to 5 whenever such data sets are used.

12 Quality management

Art. 16, (c): have a quality management system in place which complies with Article 17;

Art. 17: Quality management system

Art. 17, 1: Providers of high-risk AI systems shall put a quality management system in place that ensures compliance with this Regulation. That system shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions, and shall include at least the following aspects:

Art. 17, 3: Providers of high-risk AI systems that are subject to obligations regarding quality management systems or an equivalent function under relevant sectoral Union law may include the aspects listed in paragraph 1 as part of the quality management systems pursuant to that law.

Art. 18, 1(a): any Union technical document assessment certificates, any supplements to those certificates, and any quality management system approvals issued in accordance with the requirements of Annex VII;

Art. 18, 1(b): the documentation concerning the quality management system referred to in Article 17;

Art. 31, 2: Notified bodies shall satisfy the organisational, quality management, resources and process requirements that are necessary to fulfil their tasks, as well as suitable cybersecurity requirements.

Art. 43, 1(b): the assessment of the quality management system and the assessment of the technical documentation, with the involvement of a notified body, referred to in Annex VII. In demonstrating the compliance of a high-risk AI system with the requirements set out in Section 2, the provider shall follow the conformity assessment procedure set out in Annex VII where:

Art. 45, 1(a): any Union technical document assessment certificates, any supplements to those certificates, and any quality management system approvals issued in accordance with the requirements of Annex VII;

Art. 45, 1(b): any refusal, restriction, suspension or withdrawal of a Union technical document assessment certificate or a quality management system approval issued in accordance with the requirements of Annex VII;

Art. 45, 2(a): quality management system approvals which it has refused, suspended or withdrawn, and, upon request, of quality system approvals which it has issued.

Art. 63, 1: Microenterprises within the meaning of Recommendation 2003/361/EC may comply with certain elements of the quality management system required by Article 17 of this Regulation in a simplified manner, provided that they do not have partner enterprises or linked enterprises within the meaning of that Recommendation. For that purpose, the Commission shall develop guidelines on the elements of the quality management system which may be complied with in a simplified manner considering the needs of microenterprises, without affecting the level of protection or the need for compliance with the requirements in respect of high-risk AI systems.

0 Quality management process

0 Quality model (See also: Data quality model, Data quality requirements, Data requirements, Quality criteria, Quality assurance)

0 Quality-in-use (See also: Satisfaction, Post-market)

0 Quantification

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0 Randomness

1 Re-use of the personal data (See also: [Quality control](#))

Art. 10, 5(b): the special categories of personal data are subject to technical limitations on the re-use of the personal data, and state-of-the-art security and privacy-preserving measures, including pseudonymisation;

2 Record-keeping

Art. 12: Record-keeping

Art. 17, 1(k): systems and procedures for record-keeping of all relevant documentation and information;

0 Recoverability

10 Registration

Art. 2: Scope

Art. 5, 2: In addition, the use of 'real-time' remote biometric identification systems in publicly accessible spaces for the purposes of law enforcement for any of the objectives referred to in paragraph 1, first subparagraph, point (h), of this Article shall comply with necessary and proportionate safeguards and conditions in relation to the use in accordance with the national law authorising the use thereof, in particular as regards the temporal, geographic and personal limitations. The use of the 'real-time' remote biometric identification system in publicly accessible spaces shall be authorised only if the law enforcement authority has completed a fundamental rights impact assessment as provided for in Article 27 and has registered the system in the EU database according to Article 49. However, in duly justified cases of urgency, the use of such systems may be commenced without the registration in the EU database, provided that such registration is completed without undue delay.

Art. 6, 4: A provider who considers that an AI system referred to in Annex III is not high-risk shall document its assessment before that system is placed on the market or put into service. Such provider shall be subject to the registration obligation set out in Article 49(2). Upon request of national competent authorities, the provider shall provide the documentation of the assessment.

Art. 16, (i): comply with the registration obligations referred to in Article 49(1);

Art. 22, 3(e): where applicable, comply with the registration obligations referred to in Article 49(1), or, if the registration is carried out by the provider itself, ensure that the information referred to in point 3 of Section A of Annex VIII is correct. The mandate shall empower the authorised representative to be addressed, in addition to or instead of the provider, by the competent authorities, on all issues related to ensuring compliance with this Regulation.

Art. 26, 8: Deployers of high-risk AI systems that are public authorities, or Union institutions, bodies, offices or agencies shall comply with the registration obligations referred to in Article 49. When such deployers find that the high-risk AI system that they envisage using has not been registered in the EU database referred to in Article 71, they shall not use that system and shall inform the provider or the distributor.

SECTION 5: Standards, conformity assessment, certificates, registration

Art. 49: Registration

Art. 49, 4: For high-risk AI systems referred to in points 1, 6 and 7 of Annex III, in the areas of law enforcement, migration, asylum and border control management, the registration referred to in paragraphs 1, 2 and 3 of this Article shall be in a secure non-public section of the EU database referred to in Article 71 and shall include only the following information, as applicable, referred to in:

Art. 83, 1(e): the registration in the EU database referred to in Article 71 has not been carried out;

0 Regression

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before 2 August 2026, only if, as from that date, those systems are subject to significant changes in their designs. In any case, the providers and deployers of high-risk AI systems intended to be used by public authorities shall take the necessary steps to comply with the requirements and obligations of this Regulation by 2 August 2030.

Art. 111, 3: Providers of general-purpose AI models that have been placed on the market before 2 August 2025 shall take the necessary steps in order to comply with the obligations laid down in this Regulation by 2 August 2027.

Art. 112, 1: The Commission shall assess the need for amendment of the list set out in Annex III and of the list of prohibited AI practices laid down in Article 5, once a year following the entry into force of this Regulation, and until the end of the period of the delegation of power laid down in Article 97. The Commission shall submit the findings of that assessment to the European Parliament and the Council.

Art. 112, 3: By 2 August 2029 and every four years thereafter, the Commission shall submit a report on the evaluation and review of this Regulation to the European Parliament and to the Council. The report shall include an assessment with regard to the structure of enforcement and the possible need for a Union agency to resolve any identified shortcomings. On the basis of the findings, that report shall, where appropriate, be accompanied by a proposal for amendment of this Regulation. The reports shall be made public.

Art. 112, 4(a): the status of the financial, technical and human resources of the national competent authorities in order to effectively perform the tasks assigned to them under this Regulation;

Art. 112, 4(b): the state of penalties, in particular administrative fines as referred to in Article 99(1), applied by Member States for infringements of this Regulation;

Art. 112, 4(c): adopted harmonised standards and common specifications developed to support this Regulation;

Art. 112, 4(d): the number of undertakings that enter the market after the entry into application of this Regulation, and how many of them are SMEs.

Art. 112, 5: By 2 August 2028, the Commission shall evaluate the functioning of the AI Office, whether the AI Office has been given sufficient powers and competences to fulfil its tasks, and whether it would be relevant and needed for the proper implementation and enforcement of this Regulation to upgrade the AI Office and its enforcement competences and to increase its resources. The Commission shall submit a report on its evaluation to the European Parliament and to the Council.

Art. 112, 10: The Commission shall, if necessary, submit appropriate proposals to amend this Regulation, in particular taking into account developments in technology, the effect of AI systems on health and safety, and on fundamental rights, and in light of the state of progress in the information society.

Art. 112, 12: Any amendment to this Regulation pursuant to paragraph 10, or relevant delegated or implementing acts, which concerns sectoral Union harmonisation legislation listed in Section B of Annex I shall take into account the regulatory specificities of each sector, and the existing governance, conformity assessment and enforcement mechanisms and authorities established therein.

Art. 112, 13: By 2 August 2021, the Commission shall carry out an assessment of the enforcement of this Regulation and shall report on it to the European Parliament, the Council and the European Economic and Social Committee, taking into account the first years of application of this Regulation. On the basis of that report shall, where appropriate, be accompanied by a proposal for amendment of this Regulation with regard to the structure of enforcement and the need for a Union agency to resolve any identified shortcomings.

Art. 113: This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union. It shall apply from 2 August 2026. However:

Art. 113, (c): Article 6(1) and the corresponding obligations in this Regulation shall apply from 2 August 2027.

1 Relevance

Art. 65, 2: The Board shall be composed of one representative per Member State. The European Data Protection Supervisor shall participate as observer. The AI Office shall also attend the Board's meetings, without taking part in the votes. Other national and Union authorities, bodies or experts may be invited to the meetings by the Board on a case by case basis, where the issues discussed are of relevance for them.

4 Relevant data

Art. 10, 2(c): relevant data-preparation processing operations, such as annotation, labelling, cleaning, updating, enrichment and aggregation;

Art. 10, 2(h): the identification of relevant data gaps or shortcomings that prevent compliance with this Regulation, and how those gaps and shortcomings can be addressed.

Art. 65, 4(c): are empowered to facilitate consistency and coordination between national competent authorities in their Member State as regards the implementation of this Regulation, including through the collection of relevant data and information for the purpose of fulfilling their tasks on the Board.

Art. 112, 2: The post-market monitoring system shall actively and systematically collect, document and analyse relevant data which may be provided by deployers or which may be collected through other sources on the performance of high-risk AI systems throughout their lifetime, and which allow the provider to evaluate the continuous compliance of AI systems with the requirements set out in Chapter III, Section 2. Where relevant, post-market monitoring shall include an analysis of the interaction with other AI systems. This obligation shall not cover sensitive operational data of deployers which are law-enforcement authorities.

0 Reliability

2 Representation

Art. 40, 3: The participants in the standardisation process shall seek to promote investment and innovation in AI, including through increasing legal certainty, as well as the competitiveness and growth of the Union market, to contribute to strengthening global cooperation on standardisation and taking into account existing international standards in the field of AI that are consistent with Union values, fundamental rights and interests, and to enhance multi-stakeholder governance ensuring a balanced representation of interests and the effective participation of all relevant stakeholders in accordance with Articles 5, 6, and 7 of Regulation (EU) No 1025/2012.

Art. 68, 2(c): an ability to carry out activities diligently, accurately and objectively. The Commission, in consultation with the Board, shall determine the number of experts on the panel in accordance with the required needs and shall ensure fair gender and geographical representation.

0 Representativeness

1 Residual risk

Art. 9, 5: The risk management measures referred to in paragraph 2, point (d), shall be such that the relevant residual risk associated with each hazard, as well as the overall residual risk of the high-risk AI systems is judged to be acceptable. In identifying the most appropriate risk management measures, the following shall be ensured:

10 Resource

Art. 13, 3(e): the computational and hardware resources needed, the expected lifetime of the high-risk AI system and any necessary maintenance and care measures, including their frequency, to ensure the proper functioning of that AI system, including as regards software updates;

Art. 13, 3(f): the obligations set out in paragraphs 1 and 2, are without prejudice to other deployer obligations under Union or national law and to the deployer's freedom to organise its own resources and activities for the purpose of implementing the human oversight measures indicated by the provider.

Art. 31, 2: Notified bodies shall satisfy the organisational, quality management, resources and process requirements that are necessary to fulfil their tasks, as well as suitable cybersecurity requirements.

Art. 40, 2: In accordance with Article 10 of Regulation (EU) No 1025/2012, the Commission shall issue, without undue delay, standardisation requests covering all requirements set out in Section 2 of this Chapter and, as applicable, standardisation requests covering obligations set out in Chapter V, Sections 2 and 3, of this Regulation. The standardisation request shall also ask for deliverables on reporting and documentation processes to improve AI systems' resource performance, such as reducing the high-risk AI system's consumption of energy and of other resources during its lifecycle, and on the energy-efficient development of general-purpose AI models. When preparing a standardisation request, the Commission shall consult the Board and relevant stakeholders, including the advisory forum. When issuing a standardisation request to European standardisation organisations, the Commission shall specify that standards have to be clear, consistent, including with the standards developed in the various sectors for products covered by the existing Union harmonisation legislation listed in Annex I, and aiming to ensure that high-risk AI systems or general-purpose AI models placed on the market or put into service in the Union meet the relevant requirements or obligations laid down in this Regulation. The Commission shall request the European standardisation organisations to provide evidence of their best efforts to fulfil the objectives referred to in the first and the second subparagraph of this paragraph in accordance with Article 24 of Regulation (EU) No 1025/2012.

Art. 43, 6: The Commission is empowered to adopt delegated acts in accordance with Article 97 in order to amend paragraphs 1 and 2 of this Article in order to subject high-risk AI systems referred to in points 2 to 8 of Annex III to the conformity assessment procedure referred to in Annex VII or parts thereof. The Commission shall adopt such delegated acts taking into account the effectiveness of the conformity assessment procedure based on internal control referred to in Annex VI in preventing or minimising the risks to health and safety and protection of fundamental rights posed by such systems, as well as the availability of adequate capacities and resources among notified bodies.

Art. 57, 4: Member States shall ensure that the competent authorities referred to in paragraphs 1 and 2 allocate sufficient resources to comply with this Article effectively and in a timely manner. Where appropriate, national competent authorities shall cooperate with other relevant authorities, and may allow for the involvement of other actors within the AI ecosystem. This Article shall not affect other regulatory sandboxes established under Union or national law. Member States shall ensure an appropriate level of cooperation between the authorities supervising those other sandboxes and the national competent authorities.

Art. 70, 3: Member States shall ensure that their national competent authorities are provided with adequate technical, financial and human resources, and with infrastructure to fulfil their tasks effectively under this Regulation. In particular, the national competent authorities shall have a sufficient number of personnel permanently available whose competences and expertise shall include an in-depth understanding of AI technologies, data and data computing, personal data protection, cybersecurity, fundamental rights, health and safety risks and knowledge of existing standards and legal requirements. Member States shall assess and, if necessary, update competence and resource requirements referred to in this paragraph on an annual basis.

Art. 70, 6: By 2 August 2025, and once every two years thereafter, Member States shall report to the Commission on the status of the financial and human resources of the national competent authorities, with an assessment of their adequacy. The Commission shall transmit that information to the Board for discussion and possible recommendations.

Art. 112, 4(a): the status of the financial, technical and human resources of the national competent authorities in order to effectively perform the tasks assigned to them under this Regulation;

Art. 112, 5: By 2 August 2026, the Commission shall evaluate the functioning of the AI Office, whether the AI Office has been given sufficient powers and competences to fulfil its tasks, and whether it would be relevant and needed for the proper implementation and enforcement of this Regulation to upgrade the AI Office and its enforcement competences and to increase its resources. The Commission shall submit a report on its evaluation to the European Parliament and to the Council.

16 Responsibility

Art. 17, 1(m): an accountability framework setting out the responsibilities of the management and other staff with regard to all the aspects listed in this paragraph.

Art. 23, 4: Importers shall ensure that, while a high-risk AI system is under their responsibility, storage or transport conditions, where applicable, do not jeopardise its compliance with the requirements set out in Section 2.

Art. 23, 5: Distributors shall ensure that, while a high-risk AI system is under their responsibility, storage or transport conditions, where applicable, do not jeopardise the compliance of the system with the requirements set out in Section 2.

Art. 25: Responsibilities along the AI value chain

Art. 31, 3: The organisational structure, allocation of responsibilities, reporting lines and operation of notified bodies shall ensure confidence in their performance, and in the results of the conformity assessment activities that the notified bodies conduct.

Art. 31, 10: Notified bodies shall be capable of carrying out all their tasks under this Regulation with the highest degree of professional integrity and the requisite competence in the specific field, whether those tasks are carried out by notified bodies themselves or on their behalf and under their responsibility.

Art. 33, 2: Notified bodies shall take full responsibility for the tasks performed by any subcontractors or subsidiaries.

Art. 36, 3: Where a notified body decides to cease its conformity assessment activities, it shall inform the notifying authority and the providers concerned as soon as possible and, in the case of a planned cessation, at least one year before ceasing its activities. The certificates of the notified body may remain valid for a period of nine months after cessation of the notified body's activities, on condition that another notified body has confirmed in writing that it will assume responsibilities for the high-risk AI systems covered by those certificates. The latter notified body shall complete a full assessment of the high-risk AI systems affected by the end of that nine-month-period before issuing new certificates for those systems. Where the notified body has ceased its activity, the notifying authority shall withdraw the designation.

Art. 36, 3(b): another notified body has confirmed in writing that it will assume immediate responsibility for those AI systems and completes its assessment within 12 months of the withdrawal of the designation. In the circumstances referred to in the first subparagraph, the national competent authority of the Member State in which the provider of the system covered by the certificate has its place of business may extend the provisional validity of the certificates for additional periods of three months, which shall not exceed 12 months in total. The national competent authority or the notified body assuming the functions of the notified body affected by the change of designation shall immediately inform the Commission, the other Member States and the other notified bodies thereof.

Art. 37, 1: The Commission shall, where necessary, investigate all cases where there are reasons to doubt the competence of a notified body or the continued fulfilment by a notified body of the requirements laid down in Article 31 and of its applicable responsibilities.

Art. 47, 4: By drawing up the EU declaration of conformity, the provider shall assume responsibility for compliance with the requirements set out in Section 2. The provider shall keep the EU declaration of conformity up-to-date as appropriate.

Art. 50, 4: Deployers of an AI system that generates or manipulates image, audio or video content constituting a deep fake, shall disclose that the content has been artificially generated or manipulated. This obligation shall not apply where the use is authorised by law to detect, prevent, investigate or prosecute criminal offences where the content forms part of an evidently artistic, creative, satirical, fictional or analogous work or programme, the transparency obligations set out in this paragraph are limited to disclosure of the existence of such generated or manipulated content in an appropriate manner that does not hamper the display or enjoyment of the work. Deployers of an AI system that generates or manipulates text which is published with the purpose of informing the public on matters of public interest shall disclose that the text has been artificially generated or manipulated. This obligation shall not apply where the use is authorised by law to detect, prevent, investigate or prosecute criminal offences or where the AI-generated content has undergone a process of human review or editorial control and where a natural or legal person holds editorial responsibility for the publication of the content.

Art. 59, 2: For the purposes of the prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, including safeguarding against and preventing threats to public security, under the control and responsibility of law enforcement authorities, the processing of personal data in AI regulatory sandboxes shall be based on a specific Union or national law and subject to the same cumulative conditions as referred to in paragraph 1.

Art. 60, 4(f): where a provider or prospective provider organises the testing in real world conditions in cooperation with one or more deployers or prospective deployers, the latter have been informed of all aspects of the testing that are relevant to their decision to participate, and given the relevant instructions for use of the AI system referred to in Article 13; the provider or prospective provider and the deployer or prospective deployer shall conclude an agreement specifying their roles and responsibilities with a view to ensuring compliance with the provisions for testing in real world conditions under this Regulation and under other applicable Union and national law;

Art. 93, 7(g): the degree of responsibility of the provider and organisational measures implemented by it;

Art. 100, 1(b): the degree of responsibility of the Union institution, body, office or agency, taking into account technical and organisational measures implemented by them;

0 Responsibility of governing body

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14 ?

Art. 3. (25): 'post-market monitoring system' means all activities carried out by providers of AI systems to collect and review experience gained from the use of AI systems they place on the market or put into service for the purpose of identifying any need to immediately apply any necessary corrective or preventive actions.

Art. 6. 3(c): The AI system is intended to detect decision-making patterns or deviations from prior decision-making patterns and is not meant to replace or influence the previously completed human assessment, without proper human review, or

Art. 9. 2: The risk management system shall be understood as a continuous iterative process planned and run throughout the entire lifecycle of a high-risk AI system, requiring regular systematic review and updating. It shall comprise the following steps:

Art. 26. 10: Without prejudice to Directive (EU) 2016/680, in the framework of an investigation for the targeted search of a person suspected or convicted of having committed a criminal offence, the deployer of a high-risk AI system for post-remote biometric identification shall request an authorisation, ex ante, or without undue delay and no later than 48 hours, by a judicial authority or an administrative authority whose decision is binding and subject to judicial review, for the use of that system, except when it is used for the initial identification of a potential suspect based on objective and verifiable facts directly linked to the offence. Each use shall be limited to what is strictly necessary for the investigation of a specific criminal offence. If the authorisation requested pursuant to the first subparagraph is rejected, the use of the post-remote biometric identification system linked to that requested authorisation shall be stopped with immediate effect and the personal data linked to the use of the high-risk AI system for which the authorisation was requested shall be deleted. In no case shall such high-risk AI system for post-remote biometric identification be used for law enforcement purposes in an untargeted way, without any link to a criminal offence, a criminal proceeding, a genuine and present or genuine and foreseeable threat of a criminal offence, or the search for a specific missing person. It shall be ensured that no decision that produces an adverse legal effect on a person may be taken by the law enforcement authorities based solely on the output of such post-remote biometric identification systems. This paragraph is without prejudice to Article 9 of Regulation (EU) 2016/679 and Article 10 of Directive (EU) 2016/680 for the processing of biometric data. Regardless of the purpose or deployer, each use of such high-risk AI systems shall be documented in the relevant police file and shall be made available to the relevant market surveillance authority and the national data protection authority upon request, excluding the disclosure of sensitive operational data related to law enforcement. This subparagraph shall be without prejudice to the powers conferred by Directive (EU) 2016/680 on supervisory authorities. Deployers shall submit annual reports to the relevant market surveillance and national data protection authorities on their use of post-remote biometric identification systems, excluding the disclosure of sensitive operational data related to law enforcement. The reports may be aggregated to cover more than one deployment. Member States may introduce, in accordance with Union law, more restrictive laws on the use of post-remote biometric identification systems.

Art. 50. 4: Deployers of an AI system that generates or manipulates image, audio or video content constituting a deep fake, shall disclose that the content has been artificially generated or manipulated. This obligation shall not apply where the use is authorised by law to detect, prevent, investigate or prosecute criminal offences. Where the content forms part of an evidently artistic, creative, satirical, fictional or analogous work or programme, the transparency obligations set out in this paragraph are limited to disclosure of the existence of such generated or manipulated content in an appropriate manner that does not hamper the display or enjoyment of the work. Deployers of an AI system that generates or manipulates text which is published with the purpose of informing the public on matters of public interest shall disclose that the text has been artificially generated or manipulated. This obligation shall not apply where the use is authorised by law to detect, prevent, investigate or prosecute criminal offences or where the AI-generated content has undergone a process of human review or editorial control and where a natural or legal person holds editorial responsibility for the publication of the content.

Art. 56. 8: The AI Office shall, as appropriate, also encourage and facilitate the review and adaptation of the codes of practice, in particular in light of emerging standards. The AI Office shall assist in the assessment of available standards.

Art. 60. 9: The testing of high-risk AI systems in real world conditions under this Article shall be without prejudice to any ethical review that is required by Union or national law.

Art. 65. (e)(ii): the evaluation and review of this Regulation pursuant to Article 112, including as regards the serious incident reports referred to in Article 73, and the functioning of the EU database referred to in Article 71, the preparation of the delegated or implementing acts, and as regards possible alignments of this Regulation with the Union harmonisation legislation listed in Annex I.

Art. 101. 5: The Court of Justice of the European Union shall have unlimited jurisdiction to review decisions of the Commission fixing a fine under this Article. It may cancel, reduce or increase the fine imposed.

Art. 112: Evaluation and review

Art. 112. 3: By 2 August 2029 and every four years thereafter, the Commission shall submit a report on the evaluation and review of this Regulation to the European Parliament and to the Council. The report shall include an assessment with regard to the structure of enforcement and the possible need for a Union agency to resolve any identified shortcomings. On the basis of the findings, that report shall, where appropriate, be accompanied by a proposal for amendment of this Regulation. The reports shall be made public.

Art. 112. 6: By 2 August 2028 and every four years thereafter, the Commission shall submit a report on the review of the progress on the development of standardisation deliverables on the energy-efficient development of general-purpose AI models, and assess the need for further measures or actions, including binding measures or actions. The report shall be submitted to the European Parliament and to the Council, and it shall be made public.

Art. 112. 9: In carrying out the evaluations and reviews referred to in paragraphs 1 to 7, the Commission shall take into account the positions and findings of the Board, of the European Parliament, of the Council, and of other relevant bodies or sources.

Art. 112. 11: To guide the evaluations and reviews referred to in paragraphs 1 to 7 of this Article, the AI Office shall undertake to develop an objective and participative methodology for the evaluation of risk levels based on the criteria outlined in the relevant Articles and the inclusion of new systems in:

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affect any subsequent evaluation of the causes of the incident, prior to informing the competent authorities of such action.

Art. 73, 9: For high-risk AI systems placed on the market or put into service by providers that are subject to Union legislative instruments laying down reporting obligations equivalent to those set out in this Regulation, the notification of serious incidents shall be limited to those referred to in Article 3, point (49)(c).

Art. 73, 10: For high-risk AI systems which are safety components of devices, or are themselves devices, covered by Regulations (EU) 2017/745 and (EU) 2017/746, the notification of serious incidents shall be limited to those referred to in Article 3, point (49)(c) of this Regulation, and shall be made to the national competent authority chosen for that purpose by the Member States where the incident occurred.

Art. 74, 3: For high-risk AI systems related to products covered by the Union harmonisation legislation listed in Section A of Annex I, the market surveillance authority for the purposes of this Regulation shall be the authority responsible for market surveillance activities designated under those legal acts. By derogation from the first subparagraph, and in appropriate circumstances, Member States may designate another relevant authority to act as a market surveillance authority, provided they ensure coordination with the relevant sectoral market surveillance authorities responsible for the enforcement of the Union harmonisation legislation listed in Annex I.

Art. 74, 6: For high-risk AI systems placed on the market, put into service, or used by financial institutions regulated by Union financial services law, the market surveillance authority for the purposes of this Regulation shall be the relevant national authority responsible for the financial supervision of those institutions under that legislation in so far as the placing on the market, putting into service, or the use of the AI system is in direct connection with the provision of those financial services.

Art. 74, 9: For high-risk AI systems listed in point 1 of Annex II to this Regulation, in so far as the systems are used for law enforcement purposes, border management and justice and democracy, and for high-risk AI systems listed in points 6, 7 and 8 of Annex III to this Regulation, Member States shall designate as market surveillance authorities for the purposes of this Regulation either the competent data protection supervisory authorities under Regulation (EU) 2016/679 or Directive (EU) 2016/680, or any other authority designated pursuant to the same conditions laid down in Articles 41 to 44 of Directive (EU) 2016/680. Market surveillance activities shall in no way affect the independence of judicial authorities, or otherwise interfere with their activities when acting in their judicial capacity.

Art. 74, 10: Member States shall facilitate coordination between market surveillance authorities designated under this Regulation and other relevant national authorities or bodies which supervise the application of Union harmonisation legislation listed in Annex I, or in other Union law, that might be relevant for the high-risk AI systems referred to in Annex II.

Art. 74, 11: Market surveillance authorities and the Commission shall be able to propose joint activities, including joint investigations, to be conducted by either market surveillance authorities or market surveillance authorities jointly with the Commission, that have the aim of promoting compliance, identifying non-compliance, raising awareness or providing guidance in relation to this Regulation with respect to specific categories of high-risk AI systems that are found to present a serious risk across two or more Member States in accordance with Article 9 of Regulation (EU) 2019/1020. The AI Office shall provide coordination support for joint investigations.

Art. 74, 12: Without prejudice to the powers provided for under Regulation (EU) 2019/1020, and where relevant and limited to what is necessary to fulfil their tasks, the market surveillance authorities shall be granted full access by providers to the documentation as well as the training, validation and testing data sets used for the development of high-risk AI systems, including, where appropriate and subject to security safeguards, through application programming interfaces (API) or other relevant technical means and tools enabling remote access.

Art. 74, 13: Market surveillance authorities shall be granted access to the source code of the high-risk AI system upon a reasoned request and only when both of the following conditions are fulfilled:

Art. 74, 13(a): access to source code is necessary to assess the conformity of a high-risk AI system with the requirements set out in Chapter III, Section 2; and

Art. 75, 2: Where the relevant market surveillance authorities have sufficient reason to consider general-purpose AI systems that can be used directly by deployers for at least one purpose that is classified as high-risk pursuant to this Regulation to be non-compliant with the requirements laid down in this Regulation, they shall cooperate with the AI Office to carry out compliance evaluations, and shall inform the Board and other market surveillance authorities accordingly.

Art. 75, 3: Where a market surveillance authority is unable to conclude its investigation of the high-risk AI system because of its inability to access certain information related to the general-purpose AI model despite having made all appropriate efforts to obtain that information, it may submit a reasoned request to the AI Office, by which access to that information shall be enforced. In that case, the AI Office shall supply to the applicant authority without delay, and in any event within 30 days, any information that the AI Office considers to be relevant in order to establish whether a high-risk AI system is non-compliant. Market surveillance authorities shall safeguard the confidentiality of the information that they obtain in accordance with Article 78 of this Regulation. The procedure provided for in Chapter VI of Regulation (EU) 2019/1020 shall apply mutatis mutandis.

Art. 77, 1: National public authorities or bodies which supervise or enforce the respect of obligations under Union law protecting fundamental rights, including the right to non-discrimination, in relation to the use of high-risk AI systems referred to in Annex III shall have the power to request and access any documentation created or maintained under this Regulation in accessible language and format when access to that documentation is necessary for effectively fulfilling their mandates within the limits of their jurisdiction. The relevant public authority or body shall inform the market surveillance authorities of the Member States concerned of any such request.

Art. 77, 3: Where the documentation referred to in paragraph 1 is insufficient to ascertain whether an infringement of obligations under Union law protecting fundamental rights has occurred, the public authority or body referred to in paragraph 1 may make a reasoned request to the market surveillance authority, to organise testing of the high-risk AI system through technical means. The market surveillance authority shall organise the testing with the close involvement of the requesting public authority or body within a reasonable time following the request.

Art. 75, 3: Where a market surveillance authority is unable to conclude its investigation of the high-risk AI system because of its inability to access certain information related to the general-purpose AI model despite having made all appropriate efforts to obtain that information, it may submit a reasoned request to the AI Office, by which access to that information shall be enforced. In that case, the AI Office shall supply to the applicant authority without delay, and in any event within 30 days, any information that the AI Office considers to be relevant in order to establish whether a high-risk AI system is non-compliant. Market surveillance authorities shall safeguard the confidentiality of the information that they obtain in accordance with Article 78 of this Regulation. The procedure provided for in Chapter VI of Regulation (EU) 2019/1020 shall apply mutatis mutandis.

Art. 79: Procedure at national level for dealing with AI systems presenting a risk.

Art. 79, 1: AI systems presenting a risk shall be understood as 'a product presenting a risk' as defined in Article 3, point 19 of Regulation (EU) 2019/1020, in so far as they present risks to the health or safety, or to fundamental rights, of persons.

Art. 79, 2: Where the market surveillance authority of a Member State has sufficient reason to consider an AI system to present a risk as referred to in paragraph 1 of this Article, it shall carry out an evaluation of the AI system concerned in respect of its compliance with all the requirements and obligations laid down in this Regulation. Particular attention shall be given to AI systems presenting a risk to vulnerable groups. Where risks to fundamental rights are identified, the market surveillance authority shall also inform and fully cooperate with the relevant national public authorities or bodies referred to in Article 77(1). Where, in the course of that evaluation, the market surveillance authority or, where applicable the market surveillance authority in cooperation with the national public authority referred to in Article 77(1), finds that the AI system does not comply with the requirements and obligations laid down in this Regulation, it shall without undue delay require the relevant operator to take all appropriate corrective actions to bring the AI system into compliance, to withdraw the AI system from the market, or to recall it within a period the market surveillance authority may prescribe, and in any event within the shorter of 15 working days, or as provided for in the relevant Union harmonisation legislation. The market surveillance authority shall inform the relevant notified body accordingly. Article 18 of Regulation (EU) 2019/1020 shall apply to the measures referred to in the second subparagraph of this paragraph.

Art. 79, 6: The notification referred to in paragraph 5 shall include all available details, in particular the information necessary for the identification of the non-compliant AI system, the origin of the AI system and the supply chain, the nature of the non-compliance alleged and the risk involved, the nature and duration of the national measures taken and the arguments put forward by the relevant operator. In particular, the market surveillance authorities shall indicate whether the non-compliance is due to one or more of the following:

Art. 79, 6(a): a failure of a high-risk AI system to meet requirements set out in Chapter III, Section 2;

Art. 80: Procedure for dealing with AI systems classified by the provider as non-high-risk in application of Annex III

Art. 80, 1: Where a market surveillance authority has sufficient reason to consider that an AI system classified by the provider as non-high-risk pursuant to Article 6(3) is indeed high-risk, the market surveillance authority shall carry out an evaluation of the AI system concerned in respect of its classification as a high-risk AI system based on the conditions set out in Article 6(3) and the Commission guidelines.

Art. 80, 2: Where, in the course of that evaluation, the market surveillance authority finds that the AI system concerned is high-risk, it shall without undue delay require the relevant provider to take all necessary actions to bring the AI system into compliance with the requirements and obligations laid down in this Regulation, as well as take appropriate corrective action within a period the market surveillance authority may prescribe.

Art. 80, 7: Where, in the course of the evaluation pursuant to paragraph 1 of this Article, the market surveillance authority establishes that the AI system was misclassified by the provider as non-high-risk in order to circumvent the application of requirements in Chapter III, Section 2, the provider shall be subject to fines in accordance with Article 99.

Art. 82: Compliant AI systems which present a risk

Art. 82, 1: Where, having performed an evaluation under Article 79, after consulting the relevant national public authority referred to in Article 77(1), the market surveillance authority of a Member State finds that although a high-risk AI system complies with this Regulation, it nevertheless presents a risk to the health or safety of persons, to fundamental rights, or to other aspects of public interest protection, it shall require the relevant operator to take all appropriate measures to ensure that the AI system concerned, when placed on the market or put into service, no longer presents that risk without undue delay within a period which may prescribe.

Art. 82, 3: The Member States shall immediately inform the Commission and the other Member States of a finding under paragraph 1. That information shall include all available details, in particular the data necessary for the identification of the AI system concerned, the origin and the supply chain of the AI system, the nature of the risk involved and the nature and duration of the national measures taken.

Art. 85, 2: Where the non-compliance referred to in paragraph 1 persists, the market surveillance authority of the Member State concerned shall take appropriate and proportionate measures to restrict or prohibit the high-risk AI system being made available on the market or to ensure that it is recalled or withdrawn from the market without delay.

Art. 86, 1: Any affected person subject to a decision which is taken by the deployer on the basis of the output from a high-risk AI system listed in Annex III, with the exception of systems listed under point 2 thereof, and which produces legal effects or similarly significantly affects that person in a way that they consider to have an adverse impact on their health, safety or fundamental rights shall have the right to obtain from the deployer clear and meaningful explanations of the role of the AI system in the decision-making procedure and the main elements of the decision taken.

Art. 90, 1(a): a general-purpose AI model poses concrete identifiable risk at Union level; or

Art. 90, 1(b): the part of codes of the provider of the general-purpose AI model with systemic risk concerned;

Art. 92, 1(b): to investigate systemic risks at Union level of general-purpose AI models with systemic risk, in particular following a qualified alert from the scientific panel in accordance with Article 90(1), point (a).

Art. 93, 1(b): implement mitigation measures, where the evaluation carried out in accordance with Article 92 has given rise to serious and substantiated concern of a systemic risk at Union level;

Art. 93, 3: if, during the structured dialogue referred to in paragraph 2, the provider of the general-purpose AI model with systemic risk offers commitments to implement mitigation measures to address a systemic risk at Union level, the Commission may, by decision, make those commitments binding and declare that there are no further grounds for action.

Art. 95, 1: The AI Office and the Member States shall encourage and facilitate the drawing up of codes of conduct, including related governance mechanisms, intended to foster the voluntary application to AI systems, other than high-risk AI systems, of some or all of the requirements set out in Chapter III, Section 2 taking into account the available technical solutions and industry best practices allowed for the application of such requirements.

Art. 101, 1(d): failed to make available to the Commission access to the general-purpose AI model or general-purpose AI model with systemic risk with a view to conducting an evaluation pursuant to Article 92. In fixing the amount of the fine or periodic penalty payment, regard shall be had to the nature, gravity and duration of the infringement, taking due account of the principles of proportionality and appropriateness. The Commission shall also take into account commitments made in accordance with Article 93(3) or made in relevant codes of practice in accordance with Article 95.

Art. 111, 2: Without prejudice to the application of Article 5 as referred to in Article 113(3), point (a), this Regulation shall apply to operators of high-risk AI systems, other than the systems referred to in paragraph 1 of this Article, that have been placed on the market or put into service before 2 August 2026, only if, as from that date, those systems are subject to significant changes in their designs. In any case, the providers and deployers of high-risk AI systems intended to be used by public authorities shall take the necessary steps to comply with the requirements and obligations of this Regulation by 2 August 2030.

Art. 112, 7: By 2 August 2028 and every three years thereafter, the Commission shall evaluate the impact and effectiveness of voluntary codes of conduct to foster the application of the requirements set out in Chapter III, Section 2 for AI systems other than high-risk AI systems and possibly other additional requirements for AI systems other than high-risk AI systems, including as regards environmental sustainability.

Art. 9, 11: To guide the evaluations and reviews referred to in paragraphs 10 and 11 of this Article, the AI Office shall undertake to develop an objective and participative methodology for the evaluation of risk levels based on the criteria outlined in the relevant Articles and the inclusion of new systems in:

0 Risk acceptance

0 Risk analysis

0 Risk assessment techniques

0 Risk communication and consultation

0 Risk estimation

0 Risk evaluation

0 Risk factors

11 Risk management

Art. 8, 1: High-risk AI systems shall comply with the requirements laid down in this Section, taking into account their intended purpose as well as the generally acknowledged state of the art on AI and AI-related technologies. The risk management system referred to in Article 9 shall be taken into account when ensuring compliance with those requirements.

Art. 9: Risk management system

Art. 9, 1: A risk management system shall be established, implemented, documented and maintained in relation to high-risk AI systems.

Art. 9, 2: The risk management system shall be understood as a continuous iterative process planned and run throughout the entire lifecycle of a high-risk AI system, requiring regular systematic review and updating. It shall comprise the following steps:

Art. 9, 2(a): the adoption of appropriate and targeted risk management measures designed to address the risks identified pursuant to point (a).

Art. 9, 3: If, during the structured dialogue referred to in paragraph 2, the provider of the general-purpose AI model with systemic risk offers commitments to implement mitigation measures to address a systemic risk at Union level, the Commission may, by decision, make those commitments binding and declare that there are no further grounds for action.

Art. 9, 5: The risk management measures referred to in paragraph 2, point (d), shall be such that the relevant residual risk associated with each hazard, as well as the overall residual risk of the high-risk AI systems is judged to be acceptable. In identifying the most appropriate risk management measures, the following shall be ensured:

Art. 9, 6: High-risk AI systems shall be tested for the purpose of identifying the most appropriate and targeted risk management measures. Testing shall ensure that high-risk AI systems perform consistently for their intended purpose and that they are in compliance with the requirements set out in this Section.

Art. 9, 9: When implementing the risk management system as provided for in paragraphs 1 to 7, providers shall give consideration to whether in view of its intended purpose the high-risk AI system is likely to have an adverse impact on persons under the age of 18 and, as appropriate, other vulnerable groups.

Art. 9, 10: For providers of high-risk AI systems that are subject to requirements regarding internal risk management processes under other relevant provisions of Union law, the aspects provided in paragraphs 1 to 9 may be part of, or combined with, the risk management procedures established pursuant to that law.

Art. 17, 1(g): the risk management system referred to in Article 9;

0 Risk management process

0 Risk treatment

Terms and AI Act Articles

0 Robot

6 Robustness

Art. 13, 3(b)(ii): the level of accuracy, including its metrics, robustness and cybersecurity referred to in Article 15 against which the high-risk AI system has been tested and validated and which can be expected, and any known and foreseeable circumstances that may have an impact on that expected level of accuracy, robustness and cybersecurity;

Art. 15: Accuracy, robustness and cybersecurity

Art. 15, 1: High-risk AI systems shall be designed and developed in such a way that they achieve an appropriate level of accuracy, robustness, and cybersecurity, and that they perform consistently in those respects throughout their lifecycle.

Art. 15, 2: To address the technical aspects of how to measure the appropriate levels of accuracy and robustness set out in paragraph 1 and any other relevant performance metrics, the Commission shall, in cooperation with relevant stakeholders and organisations such as metrology and benchmarking authorities, encourage, as appropriate, the development of benchmarks and measurement methodologies.

Art. 15, 4: High-risk AI systems shall be as resilient as possible regarding errors, faults or inconsistencies that may occur within the system or the environment in which the system operates, in particular due to their interaction with natural persons or other systems. Technical and organisational measures shall be taken in this regard. The robustness of high-risk AI systems may be achieved through technical redundancy solutions, which may include backup or fail-safe plans. High-risk AI systems that continue to learn after being placed on the market or put into service shall be developed in such a way as to eliminate or reduce as far as possible the risk of possibly biased outputs influencing input for future operations (feedback loops), and as to ensure that any such feedback loops are duly addressed with appropriate mitigation measures.

Art. 58, 2(f): that AI regulatory sandboxes facilitate the development of tools and infrastructure for testing, benchmarking, assessing and explaining dimensions of AI systems relevant for regulatory learning, such as accuracy, robustness and cybersecurity, as well as measures to mitigate risks to fundamental rights and society at large.

27 Safeguard

Art. 2, 4: This Regulation applies neither to public authorities in a third country nor to international organisations falling within the scope of this Regulation pursuant to paragraph 1, where those authorities or organisations use AI systems in the framework of international cooperation or agreements for law enforcement and judicial cooperation with the Union or with one or more Member States, provided that such a third country or international organisation provides adequate safeguards with respect to the protection of fundamental rights and freedoms of individuals;

Art. 3, (45)(a): any public authority competent for the prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, including the safeguarding against and the prevention of threats to public security; or

Art. 3, (45)(b): any other body or entity entrusted by Member State law to exercise public authority and public powers for the purposes of the prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, including the safeguarding against and the prevention of threats to public security;

Art. 3, (46): 'law enforcement' means activities carried out by law enforcement authorities or on their behalf for the prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, including safeguarding against and preventing threats to public security;

Art. 5, 2: In addition, the use of 'real-time' remote biometric identification systems in publicly accessible spaces for the purposes of law enforcement for any of the objectives referred to in paragraph 1, first subparagraph, point (h), of this Article shall comply with necessary and proportionate safeguards and conditions in relation to the use in accordance with the national law authorising the use thereof, in particular as regards the temporal, geographic and personal limitations. The use of the 'real-time' remote biometric identification system in publicly accessible spaces shall be authorised only if the law enforcement authority has completed a fundamental rights impact assessment as provided for in Article 27 and has registered the system in the EU database according to Article 49. However, in duly justified cases of urgency, the use of such systems may be commenced without the registration in the EU database, provided that such registration is completed without undue delay.

Art. 10, 5: To the extent that it is strictly necessary for the purpose of ensuring bias detection and correction in relation to the high-risk AI systems in accordance with paragraph (2), points (f) and (g) of this Article, the providers of such systems may exceptionally process special categories of personal data, subject to appropriate safeguards for the fundamental rights and freedoms of natural persons. In addition to the provisions set out in Regulations (EU) 2016/679 and (EU) 2018/1725 and Directive (EU) 2016/680, all the following conditions must be met in order for such processing to occur:

Art. 10, 5(c): the special categories of personal data are subject to measures to ensure that the personal data processed are secured, protected, subject to suitable safeguards, including strict controls and documentation of the access, to avoid misuse and ensure that only authorised persons have access to those personal data with appropriate confidentiality obligations;

Art. 28, 3: Notifying authorities shall be established, organised and operated in such a way that no conflict of interest arises with conformity assessment bodies, and that the objectivity and impartiality of their activities are safeguarded.

Art. 28, 6: Notifying authorities shall safeguard the confidentiality of the information that they obtain, in accordance with Article 78.

Art. 31, 6: Notified bodies shall be organised and operated so as to safeguard the independence, objectivity and impartiality of their activities. Notified bodies shall document and implement a structure and procedures to safeguard impartiality and to promote and apply the principles of impartiality throughout their organisation, personnel and assessment activities.

Art. 45, 4: Notified bodies shall safeguard the confidentiality of the information that they obtain, in accordance with Article 78.

Art. 50, 1: Providers shall ensure that AI systems intended to interact directly with natural persons are designed and developed in such a way that the natural persons concerned are informed that they are interacting with an AI system, unless this is obvious from the point of view of a natural person who is reasonably well-informed, observant and circumspect, taking into account the circumstances and the context of use. This obligation shall not apply to AI systems authorised by law to detect, prevent, investigate or prosecute criminal offences, subject to appropriate safeguards for the rights and freedoms of third parties, unless those systems are available for the public to report a criminal offence.

Art. 50, 3: Deployers of an emotion recognition system or a biometric categorisation system shall inform the natural persons exposed thereto of the operation of the system, and shall process the personal data in accordance with Regulations (EU) 2016/679 and (EU) 2018/1725 and Directive (EU) 2016/680, as applicable. This obligation shall not apply to AI systems used for biometric categorisation and emotion recognition, which are permitted by law to detect, prevent or investigate criminal offences, subject to appropriate safeguards for the rights and freedoms of third parties, and in accordance with Union law.

Art. 58, 4: Where national competent authorities consider authorising testing in real world conditions supervised within the framework of an AI regulatory sandbox to be established under this Article, they shall specifically agree the terms and conditions of such testing and, in particular, the appropriate safeguards with the participants, with a view to protecting fundamental rights, health and safety. Where appropriate, they shall cooperate with other national competent authorities with a view to ensuring consistent practices across the Union.

Art. 59, 1(a): AI systems shall be developed for safeguarding substantial public interest by a public authority or another natural or legal person and in one or more of the following areas:

Art. 59, 2: For the purposes of the prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, including safeguarding against and preventing threats to public security, under the control and responsibility of law enforcement authorities, the processing of personal data in AI regulatory sandboxes shall be based on a specific Union or national law and subject to the same cumulative conditions as referred to in paragraph 1.

Art. 60, 3(a): data collected and processed for the purpose of the testing in real world conditions shall be transferred to third countries only provided that appropriate and applicable safeguards under Union law are implemented;

Art. 65, 7: The Board shall be organised and operated so as to safeguard the objectivity and impartiality of its activities.

Art. 66, (f): support the Commission in promoting AI literacy, public awareness and understanding of the benefits, risks, safeguards and rights and obligations in relation to the use of AI systems;

Art. 68, 3(d): supporting the AI Office in carrying out its duties in the context of the Union safeguard procedure pursuant to Article 81.

Art. 70, 1: Each Member State shall establish or designate as national competent authorities at least one notifying authority and at least one market surveillance authority for the purposes of this Regulation. Those national competent authorities shall exercise their powers independently, impartially and without bias so as to safeguard the objectivity of their activities and tasks, and to ensure the application and implementation of this Regulation. The members of those authorities shall refrain from any action incompatible with their duties. Provided that those principles are observed, such activities and tasks may be performed by one or more designated authorities, in accordance with the organisational needs of the Member State.

Art. 74, 12: Without prejudice to the powers provided for under Regulation (EU) 2019/1020, and where relevant and limited to what is necessary to fulfil their tasks, the market surveillance authorities shall be granted full access by providers to the documentation as well as the training, validation and testing data sets used for the development of high-risk AI systems, including, where appropriate and subject to security safeguards, through application programming interfaces (API) or other relevant technical means and tools enabling remote access.

Art. 75, 3: Where a market surveillance authority is unable to conclude its investigation of the high-risk AI system because of its inability to access certain information related to the general-purpose AI model despite having made all appropriate efforts to obtain that information, it may submit a reasoned request to the AI Office, by which access to that information shall be enforced. In that case, the AI Office shall supply to the applicant authority without delay, and in any event within 30 days, any information that the AI Office considers to be relevant in order to establish whether a high-risk AI system is non-compliant. Market surveillance authorities shall safeguard the confidentiality of the information that they obtain in accordance with Article 78 of this Regulation. The procedure provided for in Chapter VI of Regulation (EU) 2019/1020 shall apply mutatis mutandis.

Art. 81: Union safeguard procedure

Art. 92, 7: Prior to requesting access to the general-purpose AI model concerned, the AI Office may initiate a structured dialogue with the provider of the general-purpose AI model to gather more information on the internal testing of the model, internal safeguards for preventing systemic risks, and other internal procedures and measures the provider has taken to mitigate such risks.

Art. 99, 10: The exercise of powers under this Article shall be subject to appropriate procedural safeguards in accordance with Union and national law, including effective judicial remedies and due process.

Art. 101, 6: The Commission shall adopt implementing acts containing detailed arrangements and procedural safeguards for proceedings in view of the possible adoption of decisions pursuant to paragraph 1 of this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 98(2).

Terms and AI Act Articles

52 Safety (See also: Examination of biases, health and safety of persons, Health)

- Art. 1, 1:** The purpose of this Regulation is to improve the functioning of the internal market and promote the uptake of human-centric and trustworthy artificial intelligence (AI), while ensuring a high level of protection of health, safety, fundamental rights enshrined in the Charter, including democracy, the rule of law and environmental protection, against the harmful effects of AI systems in the Union and supporting innovation.
- Art. 2, 9:** This Regulation is without prejudice to the rules laid down by other Union legal acts related to consumer protection and product safety.
- Art. 3, 1(4):** "safety component" means a component of a product or of an AI system which fulfils a safety function for that product or AI system, or the failure or malfunctioning of which endangers the health and safety of persons or property;
- Art. 3, 6(5):** "systemic risk" means a risk that is specific to the high-impact capabilities of general-purpose AI models, having a significant impact on the Union market due to their reach, or due to actual or reasonably foreseeable negative effects on public health, safety, public security, fundamental rights, or the society as a whole, that can be propagated at scale across the value chain.
- Art. 6, 1(b):** the placing on the market, the putting into service for this specific purpose, or the use of AI systems to infer emotions of a natural person in the areas of workplace and education institutions, except where the use of the AI system is intended to be put in place or into the market for medical or safety reasons;
- Art. 5, 1(h)(ii):** the prevention of a specific, substantial and imminent threat to the life or physical safety of natural persons or a genuine and present or genuine and foreseeable threat of a terrorist attack;
- Art. 6, 1(a):** the AI system is intended to be used as a safety component of a product or of the AI system itself as a product, covered by the Union harmonisation legislation listed in Annex I;
- Art. 6, 1(b):** the product whose safety component pursuant to point (a) is the AI system, or the AI system itself as a product, is required to undergo a third-party conformity assessment, with a view to the placing on the market or the putting into service of that product pursuant to the Union harmonisation legislation listed in Annex I.
- Art. 6, 3:** By derogation from paragraph 1, an AI system referred to in Annex III shall not be considered to be high-risk where it does not pose a significant risk of harm to the health, safety or fundamental rights of natural persons, including by not materially influencing the outcome of decision making. The first subparagraph shall apply where any of the following conditions is fulfilled:
- Art. 6, 6:** The Commission is empowered to adopt delegated acts in accordance with Article 97 in order to amend paragraph 3, second subparagraph, of this Article by adding new conditions to those laid down therein, or by modifying them, where there is concrete and reliable evidence of the existence of AI systems that all under the scope of Annex III, but do not pose a significant risk of harm to the health, safety or fundamental rights of natural persons.
- Art. 6, 7:** The Commission shall adopt delegated acts in accordance with Article 97 in order to amend paragraph 3, second subparagraph, of this Article by deleting any of the conditions laid down therein, where there is concrete and reliable evidence that this is necessary to maintain the level of protection of health, safety and fundamental rights provided for by this Regulation.
- Art. 6, 8:** Any amendment to the conditions laid down in paragraph 3, second subparagraph, adopted in accordance with paragraphs 6 and 7 of this Article shall not decrease the overall level of protection of health, safety and fundamental rights provided for by this Regulation and shall ensure consistency with the delegated acts adopted pursuant to Article 7(1), and take account of market and technological developments.
- Art. 7, 1(b):** the AI systems pose a risk of harm to health and safety, or an adverse impact on fundamental rights, and that risk is equivalent to, or greater than, the risk of harm or of adverse impact posed by the high-risk AI systems already referred to in Annex III.
- Art. 8, 2(a):** the extent to which the use of an AI system has already caused harm to health and safety, has had an adverse impact on fundamental rights or has given rise to significant concerns in relation to the likelihood of such harm or adverse impact, as demonstrated, for example, by reports of documented allegations submitted to national competent authorities or by other reports, as appropriate;
- Art. 7, 2(i):** the extent to which the outcome produced involving an AI system is easily corrigible or reversible, taking into account the technical solutions available to correct or reverse it, whereby outcomes having an adverse impact on health, safety or fundamental rights, shall not be considered to be easily corrigible or reversible;
- Art. 7, 2(j):** the magnitude and likelihood of benefit of the deployment of the AI system for individuals, groups, or society at large, including possible improvements in product safety;
- Art. 7, 3(a):** the high-risk AI system concerned no longer poses any significant risks to fundamental rights, health or safety, taking into account the criteria listed in paragraph 2;
- Art. 9, 2(a):** the deletion does not affect the overall level of protection of health, safety and fundamental rights under Union law;
- Art. 9, 2(a):** the identification and analysis of the known and the reasonably foreseeable risks that the high-risk AI system can pose to health, safety or fundamental rights when the high-risk AI system is used in accordance with its intended purpose;
- Art. 10, 3(b):** examination in view of possible biases that are likely to affect the health and safety of persons, have a negative impact on fundamental rights or lead to discrimination prohibited under Union law, especially where data outputs influence inputs for future operations;
- Art. 10, 3, c:** any known or reasonably foreseeable risks to health and safety or fundamental rights, which may lead to risks to the health and safety or fundamental rights referred to in Article 9(2).
- Art. 14, 2:** Human oversight shall aim to prevent or minimise the risks to health, safety or fundamental rights that may emerge when a high-risk AI system is used in accordance with its intended purpose or under conditions of reasonably foreseeable misuse, in particular where such risks persist despite the application of other requirements set out in this Section.
- Art. 25, 3:** In the case of high-risk AI systems that are safety components of products covered by the Union harmonisation legislation listed in Section A of Annex I, the product manufacturer shall be considered to be the provider of the high-risk AI system, and shall be subject to the obligations under Article 16 under either of the following circumstances:
- Art. 36, 7(e):** provide the national competent authority of the Member State in which the provider has its registered place of business with all relevant information about the certificates of which it has required the suspension or withdrawal; that authority shall take the appropriate measures, where necessary, to avoid a potential risk to health, safety or fundamental rights.
- Art. 36, 8(a):** the notifying authority has confirmed, within one month of the suspension or restriction, that there is no risk to health, safety or fundamental rights in relation to certificates affected by the suspension or restriction, and the notifying authority has outlined a timeline for actions to remedy the suspension or restriction;
- Art. 36, 9(a):** the national competent authority of the Member State in which the provider of the high-risk AI system covered by the certificate has its registered place of business has confirmed that there is no risk to health, safety or fundamental rights associated with the high-risk AI systems concerned;
- Art. 43, 6:** The Commission is empowered to adopt delegated acts in accordance with Article 97 in order to amend paragraphs 1 and 2 of this Article in order to subject high-risk AI systems referred to in points 2 to 8 of Annex III to the conformity assessment procedure referred to in Annex IV or parts thereof. The Commission shall adopt such delegated acts taking into account the effectiveness of the conformity assessment procedure based on internal control referred to in Annex IV in preventing or minimising the risks to health and safety and protection of fundamental rights and the safety of the system.
- Art. 46, 2:** In a duly justified situation of urgency for exceptional reasons of public security or in the case of specific, substantial and imminent threat to the life or physical safety of natural persons, law-enforcement authorities or civil protection authorities may put a specific high-risk AI system into service without the authorisation referred to in paragraph 1, provided that such authorisation is requested during or after the use without undue delay. If the authorisation referred to in paragraph 1 is refused, the use of the high-risk AI system shall be stopped with immediate effect and all the results or outputs of such use shall be immediately discarded.
- Art. 57, 6:** Competent authorities shall provide, as appropriate, guidance, supervision and support within the AI regulatory sandbox with a view to identifying risks, in particular to fundamental rights, health and safety, testing, mitigation measures, and their effectiveness in relation to the obligations and requirements of this Regulation and, where relevant, other Union and national law supervised within the sandbox.
- Art. 57, 11:** The AI regulatory sandbox shall not affect the supervisory or corrective powers of the competent authorities supervising the sandboxes, including at regional or local level. Any significant risks to health and safety and fundamental rights identified during the development and testing of such AI systems shall result in an adequate mitigation. National competent authorities shall have the power to temporarily or permanently suspend the testing process, or the participation in the sandbox if no effective mitigation is possible, and shall inform the AI Office of such decision. National competent authorities shall exercise their supervisory powers within the limits of the relevant law, using their discretionary powers when implementing legal provisions in respect of a specific AI regulatory sandbox project, with the objective of supporting innovation in AI in the Union.
- Art. 58, 4:** Where national competent authorities consider authorising testing in real world conditions supervised within the framework of an AI regulatory sandbox to be established under this Article, they shall specifically agree the terms and conditions of such testing and, in particular, the appropriate safeguards with the participants, with a view to protecting fundamental rights, health and safety. Where appropriate, they shall cooperate with other national competent authorities with a view to ensuring consistent practices across the Union.
- Art. 58, 1(a)(ii):** public health, including disease detection, diagnosis prevention, control and treatment and improvement of health care systems;
- Art. 59, 1(a)(iv):** safety and resilience of transport systems and mobility, critical infrastructure and networks;
- Art. 66, (h):** cooperate, as appropriate, with other Union institutions, bodies, offices and agencies, as well as relevant Union expert groups and networks, in particular in the fields of product safety, cybersecurity, competition, digital and media services, financial services, consumer protection, data and functions, and digital and functional mobility;
- Art. 70, 3:** Member States shall ensure that their national competent authorities are provided with adequate technical, financial and human resources, and with infrastructure to fulfil their tasks effectively under this Regulation. In particular, the national competent authorities shall have a sufficient number of personnel permanently available whose competences and expertise shall include an in-depth understanding of AI technologies, data and data computing, personal data protection, cybersecurity, fundamental rights, health and safety risks and knowledge of existing standards and legal provisions in force in their Member States.
- Art. 73, 10:** For high-risk AI systems which are safety components of devices, or are themselves devices, covered by Regulations (EU) 2017/745 and (EU) 2017/746, the notification of serious incidents shall be limited to those referred to in Article 3, point (49)(c) of this Regulation, and shall be made to the national competent authority chosen for that purpose by the Member States where the incident occurred.
- Art. 73, 1:** AI systems presenting a public health or safety risk as defined in Article 3, point 13 of this Regulation shall be considered to be high-risk AI systems for the purposes of this Regulation.
- Art. 82, 1:** Where, having performed an evaluation under Article 79, after consulting the relevant national public authority referred to in Article 77(1), the market surveillance authority of a Member State finds that although a high-risk AI system complies with this Regulation, it nevertheless presents a risk to the health or safety of persons, to fundamental rights, or to other aspects of public interest protection, it shall require the relevant operator to take all appropriate measures to ensure that the AI system concerned, when placed on the market or put into service, no longer presents that risk without undue delay, or until it is no longer present.
- Art. 86, 1:** Any affected person subject to a decision which is taken by the deployer on the basis of the output from a high-risk AI system listed in Annex III, with the exception of systems listed under point 2 thereof, and which produces legal effects or similarly significantly affects that person in a way that they consider to have an adverse impact on their health, safety or fundamental rights shall have the right to obtain from the deployer clear and meaningful explanations of the role of the AI system in the decision-making procedure and the main elements of the decision taken.
- Art. 103:** In Article 17(5) of Regulation (EU) No 167/2013, the following subparagraph is added: "When adopting delegated acts pursuant to the first subparagraph concerning artificial intelligence systems which are safety components within the meaning of Regulation (EU) 2024/1689 of the European Parliament and of the Council (4), the requirements set out in Chapter III, Section 2, of that Regulation shall be taken into account."
- Art. 104:** In Article 22(5) of Regulation (EU) No 168/2013, the following subparagraph is added: "When adopting delegated acts pursuant to the first subparagraph concerning Artificial Intelligence systems which are safety components within the meaning of Regulation (EU) 2024/1689 of the European Parliament and of the Council (4), the requirements set out in Chapter III, Section 2, of that Regulation shall be taken into account."
- Art. 105:** In Article 9 of Directive 2014/90/EU, the following paragraph is added: "5. For Artificial Intelligence systems which are safety components within the meaning of Regulation (EU) 2024/1689 of the European Parliament and of the Council (4), when carrying out its activities pursuant to paragraph 1 and when adopting technical specifications and testing standards in accordance with paragraphs 2 and 3, the Commission shall take into account the requirements set out in Chapter III, Section 2, of that Regulation."
- Art. 106:** In Article 5 of Directive (EU) 2016/797, the following paragraph is added: "12. When adopting delegated acts pursuant to paragraph 1 and implementing acts pursuant to paragraph 11 concerning Artificial Intelligence systems which are safety components within the meaning of Regulation (EU) 2024/1689 of the European Parliament and of the Council (4), the requirements set out in Chapter III, Section 2, of that Regulation shall be taken into account."
- Art. 107:** In Article 5 of Regulation (EU) 2018/858 the following paragraph is added: "4. When adopting delegated acts pursuant to paragraph 3 concerning Artificial Intelligence systems which are safety components within the meaning of Regulation (EU) 2024/1689 of the European Parliament and of the Council (4), the requirements set out in Chapter III, Section 2, of that Regulation shall be taken into account."
- Art. 108(1):** In Article 17, the following paragraph is added: "3. Without prejudice to paragraph 2, when adopting implementing acts pursuant to paragraph 1 concerning Artificial Intelligence systems which are safety components within the meaning of Regulation (EU) 2024/1689, the requirements set out in Chapter III, Section 2, of that Regulation shall be taken into account."
- Art. 108(2):** In Article 19, the following paragraph is added: "4. When adopting delegated acts pursuant to paragraphs 1 and 2 concerning Artificial Intelligence systems which are safety components within the meaning of Regulation (EU) 2024/1689, the requirements set out in Chapter III, Section 2, of that Regulation shall be taken into account."
- Art. 108(3):** In Article 43, the following paragraph is added: "4. When adopting implementing acts pursuant to paragraph 1 concerning Artificial Intelligence systems which are safety components within the meaning of Regulation (EU) 2024/1689, the requirements set out in Chapter III, Section 2, of that Regulation shall be taken into account."
- Art. 108(4):** In Article 47, the following paragraph is added: "3. When adopting delegated acts pursuant to paragraphs 1 and 2 concerning Artificial Intelligence systems which are safety components within the meaning of Regulation (EU) 2024/1689, the requirements set out in Chapter III, Section 2, of that Regulation shall be taken into account."
- Art. 108(5):** In Article 57, the following subparagraph is added: "When adopting those implementing acts concerning Artificial Intelligence systems which are safety components within the meaning of Regulation (EU) 2024/1689, the requirements set out in Chapter III, Section 2, of that Regulation shall be taken into account."
- Art. 108(6):** In Article 58, the following paragraph is added: "3. When adopting delegated acts pursuant to paragraphs 1 and 2 concerning Artificial Intelligence systems which are safety components within the meaning of Regulation (EU) 2024/1689, the requirements set out in Chapter III, Section 2, of that Regulation shall be taken into account."
- Art. 109:** In Article 11 of Regulation (EU) 2019/1214, the following paragraph is added: "3. When adopting the implementing acts pursuant to paragraph 2, concerning artificial intelligence systems which are safety components within the meaning of Regulation (EU) 2024/1689 of the European Parliament and of the Council (4), the requirements set out in Chapter III, Section 2, of that Regulation shall be taken into account."
- Art. 112, 10:** The Commission shall, if necessary, submit appropriate proposals to amend this Regulation, in particular taking into account developments in technology, the effect of AI systems on health and safety, and on fundamental rights, and in light of the state of progress in the information society.

17 Safety component

- Art. 3, 1(4):** "safety component" means a component of a product or of an AI system which fulfils a safety function for that product or AI system, or the failure or malfunctioning of which endangers the health and safety of persons or property;
- Art. 6, 1(a):** the AI system is intended to be used as a safety component of a product, or the AI system itself as a product, covered by the Union harmonisation legislation listed in Annex I;
- Art. 6, 1(b):** the product whose safety component pursuant to point (a) is the AI system, or the AI system itself as a product, is required to undergo a third-party conformity assessment, with a view to the placing on the market or the putting into service of that product pursuant to the Union harmonisation legislation listed in Annex I.
- Art. 6, 3:** In the case of high-risk AI systems that are safety components of products covered by the Union harmonisation legislation listed in Section A of Annex I, the product manufacturer shall be considered to be the provider of the high-risk AI system, and shall be subject to the obligations under Article 16 under either of the following circumstances:
- Art. 73, 10:** For high-risk AI systems which are safety components of devices, or are themselves devices, covered by Regulations (EU) 2017/745 and (EU) 2017/746, the notification of serious incidents shall be limited to those referred to in Article 3, point (49)(c) of this Regulation, and shall be made to the national competent authority chosen for that purpose by the Member States where the incident occurred.
- Art. 73, 1:** AI systems presenting a public health or safety risk as defined in Article 3, point 13 of this Regulation shall be considered to be high-risk AI systems for the purposes of this Regulation.
- Art. 82, 1:** Where, having performed an evaluation under Article 79, after consulting the relevant national public authority referred to in Article 77(1), the market surveillance authority of a Member State finds that although a high-risk AI system complies with this Regulation, it nevertheless presents a risk to the health or safety of persons, to fundamental rights, or to other aspects of public interest protection, it shall require the relevant operator to take all appropriate measures to ensure that the AI system concerned, when placed on the market or put into service, no longer presents that risk without undue delay, or until it is no longer present.
- Art. 86, 1:** Any affected person subject to a decision which is taken by the deployer on the basis of the output from a high-risk AI system listed in Annex III, with the exception of systems listed under point 2 thereof, and which produces legal effects or similarly significantly affects that person in a way that they consider to have an adverse impact on their health, safety or fundamental rights shall have the right to obtain from the deployer clear and meaningful explanations of the role of the AI system in the decision-making procedure and the main elements of the decision taken.
- Art. 103:** In Article 17(5) of Regulation (EU) No 167/2013, the following subparagraph is added: "When adopting delegated acts pursuant to the first subparagraph concerning artificial intelligence systems which are safety components within the meaning of Regulation (EU) 2024/1689 of the European Parliament and of the Council (4), the requirements set out in Chapter III, Section 2, of that Regulation shall be taken into account."
- Art. 104:** In Article 22(5) of Regulation (EU) No 168/2013, the following subparagraph is added: "When adopting delegated acts pursuant to the first subparagraph concerning Artificial Intelligence systems which are safety components within the meaning of Regulation (EU) 2024/1689 of the European Parliament and of the Council (4), the requirements set out in Chapter III, Section 2, of that Regulation shall be taken into account."
- Art. 105:** In Article 9 of Directive 2014/90/EU, the following paragraph is added: "5. For Artificial Intelligence systems which are safety components within the meaning of Regulation (EU) 2024/1689 of the European Parliament and of the Council (4), when carrying out its activities pursuant to paragraph 1 and when adopting technical specifications and testing standards in accordance with paragraphs 2 and 3, the Commission shall take into account the requirements set out in Chapter III, Section 2, of that Regulation."
- Art. 106:** In Article 5 of Directive (EU) 2016/797, the following paragraph is added: "12. When adopting delegated acts pursuant to paragraph 1 and implementing acts pursuant to paragraph 11 concerning Artificial Intelligence systems which are safety components within the meaning of Regulation (EU) 2024/1689 of the European Parliament and of the Council (4), the requirements set out in Chapter III, Section 2, of that Regulation shall be taken into account."
- Art. 107:** In Article 5 of Regulation (EU) 2018/858 the following paragraph is added: "4. When adopting delegated acts pursuant to paragraph 3 concerning Artificial Intelligence systems which are safety components within the meaning of Regulation (EU) 2024/1689 of the European Parliament and of the Council (4), the requirements set out in Chapter III, Section 2, of that Regulation shall be taken into account."
- Art. 108(1):** In Article 17, the following paragraph is added: "3. Without prejudice to paragraph 2, when adopting implementing acts pursuant to paragraph 1 concerning Artificial Intelligence systems which are safety components within the meaning of Regulation (EU) 2024/1689, the requirements set out in Chapter III, Section 2, of that Regulation shall be taken into account."
- Art. 108(2):** In Article 19, the following paragraph is added: "4. When adopting delegated acts pursuant to paragraphs 1 and 2 concerning Artificial Intelligence systems which are safety components within the meaning of Regulation (EU) 2024/1689, the requirements set out in Chapter III, Section 2, of that Regulation shall be taken into account."
- Art. 108(3):** In Article 43, the following paragraph is added: "4. When adopting implementing acts pursuant to paragraph 1 concerning Artificial Intelligence systems which are safety components within the meaning of Regulation (EU) 2024/1689, the requirements set out in Chapter III, Section 2, of that Regulation shall be taken into account."
- Art. 108(4):** In Article 47, the following paragraph is added: "3. When adopting delegated acts pursuant to paragraphs 1 and 2 concerning Artificial Intelligence systems which are safety components within the meaning of Regulation (EU) 2024/1689, the requirements set out in Chapter III, Section 2, of that Regulation shall be taken into account."
- Art. 108(5):** In Article 57, the following subparagraph is added: "When adopting those implementing acts concerning Artificial Intelligence systems which are safety components within the meaning of Regulation (EU) 2024/1689, the requirements set out in Chapter III, Section 2, of that Regulation shall be taken into account."
- Art. 108(6):** In Article 58, the following paragraph is added: "3. When adopting delegated acts pursuant to paragraphs 1 and 2 concerning Artificial Intelligence systems which are safety components within the meaning of Regulation (EU) 2024/1689, the requirements set out in Chapter III, Section 2, of that Regulation shall be taken into account."
- Art. 109:** In Article 11 of Regulation (EU) 2019/1214, the following paragraph is added: "3. When adopting the implementing acts pursuant to paragraph 2, concerning artificial intelligence systems which are safety components within the meaning of Regulation (EU) 2024/1689 of the European Parliament and of the Council (4), the requirements set out in Chapter III, Section 2, of that Regulation shall be taken into account."

1 Safety components of devices

- Art. 73, 10:** For high-risk AI systems which are safety components of devices, or are themselves devices, covered by Regulations (EU) 2017/745 and (EU) 2017/746, the notification of serious incidents shall be limited to those referred to in Article 3, point (49)(c) of this Regulation, and shall be made to the national competent authority chosen for that purpose by the Member States where the incident occurred.

4 Sandbox plan

- Art. 3, 5(4):** "sandbox plan" means a document agreed between the participating provider and the competent authority describing the objectives, conditions, timeframe, methodology and requirements for the activities carried out within the sandbox;
- Art. 3, 5(5):** "AI regulatory sandbox" means a controlled framework set up by a competent authority which offers providers or prospective providers of AI systems the possibility to develop, train, validate and test, where appropriate in real-world conditions, an innovative AI system, pursuant to a sandbox plan for a regulatory supervision;
- Art. 57, 8:** AI regulatory sandboxes established under paragraph 1 shall provide for a controlled environment that fosters innovation and facilitates the development, training, testing and validation of innovative AI systems for a limited time before their being placed on the market or put into service pursuant to a specific sandbox plan agreed between the providers or prospective providers and the competent authority. Such sandboxes may include testing in real world conditions supervised therein.
- Art. 58, 1(b):** procedures for the application, participation, monitoring, exiting from and termination of the AI regulatory sandbox, including the sandbox plan and the exit report;

0 Satisfaction (See also: Quality-in-use, Post-market)

Terms and AI Act Articles

4 Sector (See also: [Domain](#))

Art. 25. 4. The provider of a high-risk AI system and the third party that supplies an AI system, tools, services, components, or processes that are used or integrated in a high-risk AI system shall, by written agreement, specify the necessary information, capabilities, technical access and other assistance based on the generally acknowledged state of the art, in order to enable the provider of the high-risk AI system to fully comply with the obligations set out in this Regulation. This paragraph shall not apply to third parties making accessible to the public tools, services, processes, or components, other than general-purpose AI models, under a free and open-source licence. The AI Office may develop and recommend voluntary model terms for contracts between providers of high-risk AI systems and third parties that supply tools, services, components or processes that are used for or integrated into high-risk AI systems. When developing those voluntary model terms, the AI Office shall take into account possible contractual requirements applicable in specific sectors or business cases. The voluntary model terms shall be published and be available free of charge in an easily usable electronic format.

Art. 40. 2. In accordance with Article 10 of Regulation (EU) No 1025/2012, the Commission shall issue, without undue delay, standardisation requests covering all requirements set out in Section 2 of this Chapter and, as applicable, standardisation requests covering obligations set out in Chapter V, Section 2 and 3 of this Regulation. The standardisation requests shall also ask for deliverables on reporting and documentation processes to improve AI systems' resource performance, such as reducing the high-risk AI system's consumption of energy and of other resources during its lifecycle, and on the energy-efficient development of general-purpose AI models. When preparing a standardisation request, the Commission shall consult the Board and relevant stakeholders, including the advisory forum. When issuing a standardisation request to European standardisation organisations, the Commission shall specify that standards have to be clear, consistent, including with the standards developed in the various sectors for products covered by the existing Union harmonisation legislation listed in Annex I, and aiming to ensure that high-risk AI systems or general-purpose AI models placed on the market or put into service in the Union meet the relevant requirements or obligations laid down in this Regulation. The Commission shall request the European standardisation organisations to provide evidence of their best efforts to fulfil the objectives referred to in the first and the second subparagraph of this paragraph in accordance with Article 24 of Regulation (EU) No 1025/2012.

Art. 58. 2(f). That AI regulatory sandboxes facilitate the involvement of other relevant actors within the AI ecosystem, such as notified bodies and standardisation organisations, SMEs, including start-ups, enterprises, innovators, testing and experimentation facilities, research and experimentation labs and European Digital Innovation Hubs, centres of excellence, individual researchers, in order to allow and facilitate cooperation with the public and private sectors;

Art. 96. 1(f). the application of the definition of an AI system as set out in Article 3, point (1). When issuing such guidelines, the Commission shall pay particular attention to the needs of SMEs including start-ups, of local public authorities and of the sectors most likely to be affected by this Regulation. The guidelines referred to in the first subparagraph of this paragraph shall take due account of the generally acknowledged state of the art on AI, as well as of relevant harmonised standards and common specifications that are referred to in Articles 40 and 41, or of those harmonised standards or technical specifications that are set out pursuant to Union harmonisation law.

15 Security (See also: [Cybersecurity](#))

Art. 2. 3. This Regulation does not apply to areas outside the scope of Union law, and shall not, in any event, affect the competences of the Member States concerning national security, regardless of the type of entity entrusted by the Member States with carrying out tasks in relation to those competences. This Regulation does not apply to AI systems where and in so far as they are placed on the market, put into service, or used with or without modification exclusively for military, defence or national security purposes, regardless of the type of entity carrying out those activities. This Regulation does not apply to AI systems which are not placed on the market or put into service in the Union, where the output is used in the Union exclusively for military, defence or national security purposes, regardless of the type of entity carrying out those activities.

Art. 3. (45)(b) any public authority competent for the prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, including the safeguarding against and the prevention of threats to public security; or

Art. 3. (45)(b) any other body or entity entrusted by Member State law to exercise public authority and public powers for the purposes of the prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, including the safeguarding against and the prevention of threats to public security;

Art. 3. (46) 'law enforcement' means activities carried out by law enforcement authorities or on their behalf for the prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, including safeguarding against and preventing threats to public security;

Art. 3. (65) 'systemic risk' means a risk that is specific to the high-impact capabilities of general-purpose AI models, having a significant impact on the Union market due to their reach, or due to actual or reasonably foreseeable negative effects on public health, safety, public security, fundamental rights, or the society as a whole, that can be propagated at scale across the value chain;

Art. 10. 5(b) the personal data are subject to technical limitations on the re-use of the personal data, and state-of-the-art security and privacy-preserving measures, including pseudonymisation;

Art. 17. 1(i) resource management, including security-of-supply related measures;

Art. 46. 1. By way of derogation from Article 43 and upon a duly justified request, any market surveillance authority may authorise the placing on the market or the putting into service of specific high-risk AI systems within the territory of the Member State concerned, for exceptional reasons of public security or the protection of life and health of persons, environmental protection or the protection of key industrial and infrastructural assets. That authorisation shall be for a limited period while the necessary conformity assessment procedures are being carried out, taking into account the exceptional reasons justifying the derogation. The completion of those procedures shall be undertaken without undue delay.

Art. 59. 2. In a duly justified situation of urgency for exceptional reasons of public security or in the case of specific, substantial and imminent threat to the life or physical safety of natural persons, law-enforcement authorities or civil protection authorities may put a specific high-risk AI system into service without the authorisation referred to in paragraph 1, provided that such authorisation is requested during or after the use without undue delay. If the authorisation referred to in paragraph 1 is refused, the use of the high-risk AI system shall be stopped with immediate effect and all the results and outputs of such use shall be immediately discarded.

Art. 74. 12. Without prejudice to the powers provided for under Regulation (EU) 2019/1020, and where relevant and limited to what is necessary to fulfil their tasks, the market surveillance authorities shall be granted full access by providers to the documentation as well as the training, validation and testing data sets used in the development of high-risk AI systems, including, where appropriate and subject to security safeguards, through application programming interfaces (API) or other relevant technical means and tools enabling remote access.

Art. 78. 1(c) public and national security interests;

Art. 78. 2. The authorities involved in the application of this Regulation pursuant to paragraph 1 shall request only data that is strictly necessary for the assessment of the risk posed by AI systems and for the exercise of their powers in accordance with this Regulation and with Regulation (EU) 2019/1020. They shall put in place adequate and effective cybersecurity measures to protect the security and confidentiality of the information and data obtained, and shall delete the data collected as soon as it is no longer needed for the purpose for which it was obtained, in accordance with applicable Union or national law.

Art. 78. 3. Without prejudice to paragraphs 1 and 2, information exchanged on a confidential basis between the national competent authorities or between national competent authorities and the Commission shall not be disclosed without prior consultation of the originating national competent authority and the deployer when high-risk AI systems referred to in point 1, 6 or 7 of Annex III are used by law enforcement, border control, immigration or asylum authorities and when such disclosure would jeopardise public and national security interests. This exchange of information shall not cover sensitive operational data in relation to the activities of law enforcement, border control, immigration or asylum authorities. When the law enforcement, immigration or asylum authorities are providers of high-risk AI systems referred to in point 1, 6 or 7 of Annex III, the technical documentation referred to in Annex IV shall remain within the premises of those authorities. Those authorities shall ensure that the market surveillance authorities referred to in Article 74(8) and (9), as applicable, can, upon request, immediately access the documentation or obtain a copy thereof. Only staff of the market surveillance authority holding the appropriate level of security clearance shall be allowed to access that documentation or any copy thereof.

Art. 102. In Article 4(3) of Regulation (EC) No 300/2008, the following subparagraph is added: 'When adopting detailed measures related to technical specifications and procedures for approval and use of security equipment concerning Artificial Intelligence systems within the meaning of Regulation (EU) 2024/1689 of the European Parliament and of the Council ("1), the requirements set out in Chapter II, Section 2, of that Regulation shall be taken into account.'

0 Security and privacy

0 Segmentation (See also: [Use-cases](#))

18 Serious incident

Art. 3. (49) 'serious incident' means an incident or malfunctioning of an AI system that directly or indirectly leads to any of the following:

Art. 17. 1(i) procedures related to the reporting of a serious incident in accordance with Article 73;

Art. 26. 5. Deployers shall monitor the operation of the high-risk AI system on the basis of the instructions for use and, where relevant, inform providers in accordance with Article 72. Where deployers have reason to consider that the use of the high-risk AI system in accordance with the instructions may result in that AI system presenting a risk within the meaning of Article 73(1), they shall, without undue delay, inform the provider or distributor and the relevant market surveillance authority, and shall suspend the use of that system. Where deployers have identified a serious incident, they shall also immediately inform first the provider, and then the importer or distributor and the relevant market surveillance authorities of that incident. If the deployer is not able to reach the provider, Article 73 shall apply mutatis mutandis. This obligation shall not cover sensitive operational data of deployers of AI systems which are law enforcement authorities. For deployers that are financial institutions subject to requirements regarding their internal governance, arrangements or processes under Union financial services law, the monitoring obligation set out in the first subparagraph shall be deemed to be fulfilled by complying with the rules on internal governance arrangements, processes and mechanisms pursuant to the relevant financial services law.

Art. 55. 1(c) keep track of, document, and report, without undue delay, to the AI Office and, as appropriate, to national competent authorities, relevant information about serious incidents and possible corrective measures to address them;

Art. 60. 7. Any serious incident identified in the course of the testing in real world conditions shall be reported to the national market surveillance authority in accordance with Article 73. The provider or prospective provider shall adopt immediate mitigation measures or, failing that, shall suspend the testing in real world conditions until such mitigation takes place, or otherwise terminate it. The provider or prospective provider shall establish a procedure for the prompt recall of the AI system upon such termination of the testing in real world conditions.

Art. 66. 6(e)(ii) the evaluation and review of this Regulation pursuant to Article 112, including as regards the serious incident reports referred to in Article 73, and the functioning of the EU database referred to in Article 71, the preparation of the delegated or implementing acts, and as regards possible alignments of this Regulation with the Union harmonisation legislation listed in Annex I;

SECTION 2. Sharing of information on serious incidents

Art. 73. Reporting of serious incidents

Art. 73. 1. Providers of high-risk AI systems placed on the Union market shall report any serious incident to the market surveillance authorities of the Member States where that incident occurred, where applicable, the deployer becomes aware of that incident.

Art. 73. 3. Notwithstanding paragraph 2 of this Article, in the event of a widespread infringement or a serious incident as defined in Article 3, point (49)(b), the report referred to in paragraph 1 of this Article shall be provided immediately, and not later than two days after the provider or, where applicable, the deployer becomes aware of that incident.

Art. 73. 4. Notwithstanding paragraph 2, in the event of the death of a person, the report shall be provided immediately after the provider or the deployer has established, or as soon as it suspects, a causal relationship between the high-risk AI system and the serious incident, but not later than 10 days after the date on which the provider or, where applicable, the deployer becomes aware of the serious incident.

Art. 73. 6. Following the reporting of a serious incident pursuant to paragraph 1, the provider shall, without delay, perform the necessary investigations in relation to the serious incident and the AI system concerned. This shall include a risk assessment of the incident, and corrective action. The provider shall cooperate with the competent authorities, and where relevant with the notified body concerned, during the investigations referred to in the first subparagraph, and shall not perform any investigation which involves altering the AI system concerned in a way which may affect any subsequent evaluation of the causes of the incident, prior to informing the competent authorities of such action.

Art. 73. 9. Upon receiving a notification related to a serious incident referred to in Article 3, point (49)(c), the relevant market surveillance authority shall inform the national public authorities or bodies referred to in Article 77(1). The Commission shall develop dedicated guidance to facilitate compliance with the obligations set out in paragraph 1 of this Article. That guidance shall be issued by 2 August 2025, and shall be assessed regularly.

Art. 73. 9. For high-risk AI systems referred to in Annex III that are placed on the market or put into service by providers that are subject to Union legislative instruments laying down reporting obligations equivalent to those set out in this Regulation, the notification of serious incidents shall be limited to those referred to in Article 3, point (49)(c).

Art. 73. 10. For high-risk AI systems which are safety components of devices, or are themselves devices, covered by Regulations (EU) 2017/745 and (EU) 2017/746, the notification of serious incidents shall be limited to those referred to in Article 3, point (49)(c) of this Regulation, and shall be made to the national competent authority chosen for that purpose by the Member States where the incident occurred.

Art. 73. 11. National competent authorities shall immediately notify the Commission of any serious incident, whether or not they have taken action on it, in accordance with Article 20 of Regulation (EU) 2019/1020.

Art. 76. 3. Where a market surveillance authority has been informed by the prospective provider, the provider or any third party of a serious incident or has other grounds for considering that the conditions set out in Articles 60 and 61 are not met, it may take either of the following decisions on its territory, as appropriate:

The data presented here have a value for research and not a legal value.

Terms and AI Act Articles

66 Service

- Art. 1. 2(a):** harmonised rules for the placing on the market, the putting into service, and the use of AI systems in the Union;
- Art. 2. 1(a):** providers placing on the market or putting into service AI systems or placing on the market general-purpose AI models in the Union, irrespective of whether those providers are established or located within the Union or in a third country;
- Art. 2. 1(b):** product manufacturers placing on the market or putting into service an AI system together with their product and under their own name or trademark;
- Art. 2. 3:** this Regulation does not apply to AI systems or AI models that are not in the competence of the Member State concerning national security, regardless of the type of entity entrusted by the Member States with carrying out tasks in relation to those competences. This Regulation does not apply to AI systems where and in so far they are placed on the market, put into service, or used with or without modification exclusively for military, defence or national security purposes, regardless of the type of entity carrying out those activities. This Regulation does not apply to AI systems which are not placed on the market or put into service in the Union, where the output is used in the Union exclusively for military, defence or national security purposes, regardless of the type of entity carrying out those activities.
- Art. 2. 4:** This Regulation does not apply to AI systems or AI models, including their output, specially developed and put into service for the purpose of scientific research and development.
- Art. 2. 8:** This Regulation does not apply to any research, testing or development activity regarding AI systems or AI models prior to their being placed on the market or put into service. Such activities shall be conducted in accordance with applicable Union law. Testing in real world conditions shall not be covered by that exclusion.
- Art. 2. 12:** This Regulation does not apply to AI systems released under free and open-source licences, unless they are placed on the market or put into service as high-risk AI systems or as an AI system that falls under Article 5 or 50.
- Art. 3. (3):** 'provider' means a natural or legal person, public authority, agency or other body that develops an AI system or a general-purpose AI model or that has an AI system or a general-purpose AI model developed and places it on the market or puts the AI system into service under its own name or trademark, whether for payment or free of charge;
- Art. 3. (11):** 'putting into service' means the supply of an AI system for first use directly to the deployer or for own use in the Union for its intended purpose;
- Art. 3. (16):** 'recall of an AI system' means any measure aiming to achieve the return to the provider or taking out of service or disabling the use of an AI system made available to deployers;
- Art. 3. (23):** 'substantial modification' means a change to an AI system after its placing on the market or putting into service which is not foreseen or planned in the initial conformity assessment carried out by the provider and as a result of which the compliance of the AI system with the requirements set out in Chapter III, Section 5 is affected or results in a modification to the intended purpose for which the AI system has been assessed;
- Art. 3. (25):** 'post-market monitoring system' means all activities carried out by providers of AI systems to collect and review experience gained from the use of AI systems they place on the market or put into service for the purpose of identifying any need to immediately apply any necessary corrective or preventive actions;
- Art. 3. (32):** 'testing data' means data used for providing an independent evaluation of the AI system in order to confirm the expected performance of that system before its placing on the market or putting into service;
- Art. 3. (40):** 'biometric categorisation system' means an AI system for the purpose of assigning natural persons to specific categories on the basis of their biometric data, unless it is ancillary to another commercial service and strictly necessary for objective technical reasons;
- Art. 3. (48):** 'national competent authority' means a notifying authority or a market surveillance authority, as regards AI systems put into service or used by Union institutions, agencies, offices and bodies, references to national competent authorities or market surveillance authorities in this Regulation shall be construed as references to the project covered by the Union harmonisation legislation listed in Section A of Annex I placed on the market or put into service;
- Art. 3. (57):** 'testing in real-world conditions' means the temporary testing of an AI system for its intended purpose in real-world conditions outside a laboratory or otherwise simulated environment, with a view to gathering reliable and robust data and to assessing and verifying the conformity of the AI system with the requirements of this Regulation and it does not qualify as placing the AI system on the market or putting it into service within the meaning of this Regulation, provided that all the conditions laid down in Article 57 or 60 are fulfilled;
- Art. 5. 1(a):** the placing on the market, the putting into service or the use of an AI system that deploys subliminal techniques beyond a person's consciousness or purposefully manipulative or deceptive techniques, with the objective, or the effect of materially distorting the behaviour of a person or a group of persons by appreciably impairing their ability to make an informed decision, thereby causing them to take a decision that they would not have otherwise taken in a manner that causes or is reasonably likely to cause that person, another person or group of persons significant harm;
- Art. 5. 1(b):** the placing on the market, the putting into service or the use of an AI system that exploits any of the vulnerabilities of a natural person or a specific group of persons due to their age, disability or a specific social or economic situation, with the objective, or the effect of materially distorting the behaviour of that person or a person belonging to that group in a manner that causes or is reasonably likely to cause that person or another person significant harm;
- Art. 5. 1(c):** the placing on the market, the putting into service or the use of AI systems for the evaluation or classification of natural persons or groups of persons over a certain period of time based on their social behaviour or known, inferred or predicted personal or personality characteristics, with the objective, or the effect of materially distorting the behaviour of a person or a group of persons by appreciably impairing their ability to make an informed decision, thereby causing them to take a decision that they would not have otherwise taken in a manner that causes or is reasonably likely to cause that person, another person or group of persons significant harm;
- Art. 5. 1(d):** the placing on the market, the putting into service for this specific purpose, or the use of an AI system for making risk assessments of natural persons in order to assess or predict the risk of a natural person committing a criminal offence, based solely on the profiling of a natural person or on assessing their personality traits and characteristics; this prohibition shall not apply to AI systems used to support the human assessment of the involvement of a person in a criminal activity, which is already based on objective and verifiable facts directly linked to a criminal activity;
- Art. 5. 1(e):** the placing on the market, the putting into service for this specific purpose, or the use of AI systems that create or expand facial recognition databases through the untargeted scraping of facial images from the internet or CCTV footage;
- Art. 5. 1(f):** the placing on the market, the putting into service for this specific purpose, or the use of AI systems to infer emotions of a natural person in the areas of workplace and education institutions, except where the use of the AI system is intended to be put in place or into the market for medical or safety reasons;
- Art. 5. 1(g):** the placing on the market, the putting into service for this specific purpose, or the use of biometric categorisation systems that categorise individually natural persons based on their biometric data to deduce or infer their race, political opinions, trade union membership, religious or philosophical beliefs or orientation; this prohibition does not cover the marking or labelling or filtering of already acquired biometric datasets, such as images, based on biometric data or categorisation of biometric data in the area of law enforcement;
- Art. 6. 1:** Irrespective of whether an AI system is placed on the market or put into service independently of the products referred to in points (a) and (b), that AI system shall be considered to be high-risk where both of the following conditions are fulfilled:
 - Art. 6. 1(a):** the product whose safety compliance pursuant to point (a) is the AI system, or the AI system itself as a product, is required to undergo a third-party conformity assessment, with a view to the placing on the market or the putting into service of that product pursuant to the Union harmonisation legislation listed in Section A of Annex I placed on the market or put into service;
 - Art. 6. 4:** A provider who considers that an AI system referred to in Annex III is not high-risk shall document its assessment before that system is placed on the market or put into service. Such provider shall be subject to the registration obligation set out in Article 49(2). Upon request of national competent authorities, the provider shall provide the documentation of the assessment.
- Art. 5. 10(a):** The testing of high-risk AI systems shall be carried out at any time throughout the development process, and, in any event, prior to their being placed on the market or put into service. Testing shall be carried out against prior defined metrics and probabilistic thresholds that are appropriate to the intended purpose of the high-risk AI system.
- Art. 11. 1:** The technical documentation of a high-risk AI system shall be drawn up before that system is placed on the market or put into service and shall be kept up-to-date. The technical documentation shall be drawn up in such a way as to demonstrate that the high-risk AI system conforms with the requirements of this Regulation. The technical documentation shall be drawn up in a clear and comprehensive form to assess the compliance of the AI system with those requirements. It shall contain, at a minimum, the elements set out in Annex IV. SMEs, including start-ups, may provide the elements of the technical documentation specified in Annex IV in a simplified manner. To that end, the Commission shall establish a simplified technical documentation form targeted at the needs of small and microenterprises. Where an SME, including a start-up, opts to provide the information required in Annex IV in a simplified manner, it shall use the form referred to in this paragraph. Notified bodies shall accept the form for the purposes of the conformity assessment.
- Art. 12. 2:** Where the technical documentation of a high-risk AI system is placed on the market or put into service, a single set of technical documentation shall be drawn up containing all the information set out in paragraph 1, as well as the information required under those legal acts.
- Art. 14. 3(a):** measures identified and built, when technically feasible, into the high-risk AI system by the provider before it is placed on the market or put into service;
- Art. 15. 1(b):** measures to be taken by the provider before placing the high-risk AI system on the market or putting it into service and that are appropriate to be implemented by the deployer.
- Art. 15. 4:** High-risk AI systems shall be as resilient as possible regarding errors, faults or inconsistencies that may occur within the system or the environment in which the system operates, in particular due to their interaction with natural persons or other systems. Technical and organisational measures shall be taken in this regard. The robustness of high-risk AI systems may be achieved through technical redundancy solutions, which may include backup or fail-safe plans. High-risk AI systems that continue to learn after being placed on the market or put into service shall be designed in such a way as to eliminate or reduce as far as possible the risk of possibly biased outputs influencing input for future operations (feedback loops), and as to ensure that any such feedback loops are duly addressed with appropriate mitigation measures.
- Art. 16. 1(f):** ensure that the high-risk AI system undergoes the relevant conformity assessment procedure as referred to in Article 43, prior to its being placed on the market or put into service;
- Art. 17. 1(i):** systems and procedures for data management, including data acquisition, data collection, data analysis, data labelling, data storage, data filtration, data mining, data aggregation, data retention and any other operation regarding the data that is performed before and for the purpose of the placing on the market or putting into service of the high-risk AI system;
- Art. 18. 1:** The provider shall, for a period ending 10 years after the high-risk AI system has been placed on the market or put into service, keep at the disposal of the national competent authorities:
 - Art. 20. 1:** Providers of high-risk AI systems which consider or have reason to consider that a high-risk AI system that they have placed on the market or put into service is not in conformity with this Regulation shall immediately take the necessary corrective actions to bring that system into conformity, to withdraw it or recall it, as appropriate. They shall inform the distributors of the high-risk AI system concerned and, where applicable, the deployers, the authorised representative and importers accordingly.
 - Art. 22. 2(b):** keep at the disposal of the competent authorities and national authorities or bodies referred to in Article 74(10), for a period of 10 years after the high-risk AI system has been placed on the market or put into service, the contact details of the provider that appointed the authorised representative, a copy of the EU declaration of conformity referred to in Article 47, the technical documentation and, if applicable, the certificate issued by the notified body.
- Art. 23. 5:** Importers shall keep, for a period of 10 years after the high-risk AI system has been placed on the market or put into service, a copy of the certificate issued by the notified body, where applicable, of the instructions for use, and of the EU declaration of conformity referred to in Article 47.
- Art. 25. 1(a):** they put their name or trademark on a high-risk AI system already placed on the market or put into service, without prejudice to contractual arrangements stipulating that the obligations are otherwise allocated;
- Art. 25. 1(b):** they make a substantial modification to a high-risk AI system that has already been placed on the market or put into service and that remains a high-risk AI system pursuant to Article 6;
- Art. 25. 1(c):** they modify the intended purpose of an AI system, including a general-purpose AI system, which has not been classified as high-risk and has already been placed on the market or put into service in such a way that the AI system concerned becomes a high-risk AI system in accordance with Article 6.
- Art. 25. 2:** Where the circumstances referred to in paragraph 1 occur, the provider that initially placed the AI system on the market or put it into service shall no longer be considered to be a provider of that specific AI system for the purposes of this Regulation. That initial provider shall closely cooperate with new providers and shall make available the necessary information and provide the reasonably expected technical access and other assistance that are required for the fulfilment of the obligations set out in this Regulation, in particular regarding the compliance with the conformity assessment of high-risk AI systems. This paragraph shall not apply in cases where the initial provider has clearly specified that its AI system is not to be changed into a high-risk AI system and therefore does not fall under the obligation to hand over the documentation.
- Art. 25. 3(b):** the high-risk AI system is put into service under the name or trademark of the product manufacturer after the product has been placed on the market.
- Art. 26. 5:** Deployers shall monitor the operation of the high-risk AI system on the basis of the instructions for use and, where relevant, inform providers in accordance with Article 72. Where deployers have reason to consider that the use of the high-risk AI system in accordance with the instructions may result in that AI system presenting a risk within the meaning of Article 73(1), they shall, without undue delay, inform the provider or distributor and the relevant market surveillance authority, and shall suspend the use of that system. Where deployers have identified a serious incident, they shall also immediately inform first the provider, and then the importer or distributor and the relevant market surveillance authorities of that incident. If the deployer is not able to reach the provider, Article 73 shall apply mutatis mutandis. This obligation shall not cover sensitive operational data of deployers of AI systems which are law enforcement authorities. For deployers that are financial institutions subject to requirements regarding their internal governance, arrangements or processes under Union financial services law, the monitoring obligation set out in the first subparagraph shall be deemed to be fulfilled by complying with the rules on internal governance arrangements, processes and mechanisms pursuant to the relevant financial service law.
- Art. 26. 6:** Deployers of high-risk AI systems shall keep the logs automatically generated by that high-risk AI system to the extent such logs are under their control, for a period appropriate to the intended purpose of the high-risk AI system, of at least six months, unless provided otherwise in applicable Union or national law, in particular in Union law on the protection of personal data. Deployers that are financial institutions subject to requirements regarding their internal governance, arrangements or processes under Union financial services law shall maintain the logs as part of the documentation of the purposes to the relevant Union financial service law.
- Art. 26. 7:** Before putting into service or using a high-risk AI system at the workplace, deployers who are employers shall inform workers' representatives and the affected workers that they will be subject to the use of the high-risk AI system. This information shall be provided, where applicable, in accordance with the rules and procedures laid down in Union and national law and practice on information of workers and their representatives.
- Art. 43. 10(a):** one or more of the harmonised standards referred to in point (a) has been published with a restriction, and only on the part of the standard that was restricted. For the purposes of the conformity assessment procedure referred to in Annex VII, the provider may choose any of the notified bodies. However, where the high-risk AI system is intended to be put into service by law enforcement, immigration or asylum authorities or by Union institutions, bodies, offices or agencies, the market surveillance authority referred to in Article 74(8) or (9), as applicable, shall act as a notified body.
- Art. 43. 2:** High-risk AI systems that have already been subject to a conformity assessment procedure shall undergo a new conformity assessment procedure in the event of a substantial modification, regardless of whether the modified system is intended to be further distributed or continues to be used by the current deployer. For high-risk AI systems that continue to learn after being placed on the market or put into service, changes to the high-risk AI system and its performance that have been pre-determined by the provider at the moment of the initial conformity assessment and are part of the information contained in the technical documentation referred to in point 2(b) of Annex IV shall not constitute a substantial modification.
- Art. 46. 1:** By way of justified situation of urgency for exceptional reasons of public security or in the case of specific, substantial and imminent threat to the life or physical safety of natural persons, law-enforcement authorities or civil protection authorities may put a specific high-risk AI system into service without the authorisation referred to in paragraph 1, provided that such authorisation is requested during or after the use without undue delay. If the authorisation referred to in paragraph 1 is refused, the use of the high-risk AI system shall be stopped with immediate effect and all the results and outputs of such use shall be immediately discarded.
- Art. 47. 1:** The provider shall draw up a written machine readable, physical or electronically signed EU declaration of conformity for each high-risk AI system, and keep it at the disposal of the national competent authorities for 10 years after the high-risk AI system has been placed on the market or put into service. The EU declaration of conformity shall identify the high-risk AI system for which it has been drawn up. A copy of the EU declaration of conformity shall be submitted to the relevant national competent authorities upon request.
- Art. 49. 1:** Before placing on the market or putting into service a high-risk AI system listed in Annex III, with the exception of high-risk AI systems referred to in point 2 of Annex III, the provider or, where applicable, the authorised representative shall register themselves and their system in the EU database referred to in Article 71.
- Art. 49. 2:** Before placing on the market or putting into service an AI system for which the provider has concluded that it is not high-risk according to Article 6(3), that provider or, where applicable, the authorised representative shall register themselves and that system in the EU database referred to in Article 71.
- Art. 49. 3:** Before putting into service or using a high-risk AI system listed in Annex III, with the exception of high-risk AI systems listed in point 2 of Annex III, deployers that are public authorities, Union institutions, bodies, offices or agencies or persons acting on their behalf shall register themselves, select the system and register its use in the EU database referred to in Article 71.
- Art. 54. 3(d):** cooperate with the AI Office and competent authorities, upon a reasoned request, in any action that takes relation to the general-purpose AI model, including when the model is integrated into AI systems placed on the market or put into service in the Union.
- Art. 62. 1:** Where, having performed an evaluation under Article 79, after consulting the relevant national public authority referred to in Article 77(1), the market surveillance authority of a Member State finds that although a high-risk AI system complies with this Regulation, it nevertheless presents a risk to the health or safety of persons, to fundamental rights, or to other aspects of public interest protection, it shall require the relevant deployer to take all appropriate measures to ensure that the AI system concerned, when placed on the market or put into service, no longer presents that risk without undue delay, within a period it may prescribe.
- Art. 111:** AI systems already placed on the market or put into service and general-purpose AI models already placed on the market
- Art. 111. 1:** Without prejudice to the application of Article 5 as referred to in Article 113(3), point (a), AI systems which are components of the large-scale IT systems established by the legal acts listed in Annex X that have been placed on the market or put into service before 2 August 2027 shall be brought into compliance with this Regulation by 31 December 2030. The requirements laid down in this Regulation shall be taken into account in the evaluation of each large-scale IT system established by the legal acts listed in Annex X to be undertaken as provided for in those legal acts and where those legal acts are replaced or amended.
- Art. 111. 2:** Without prejudice to the application of Article 5 as referred to in Article 113(3), point (a), this Regulation shall apply to operators of high-risk AI systems, other than the systems referred to in paragraph 1 of this Article, that have been placed on the market or put into service before 2 August 2026, only if, as from that date, those systems are subject to significant changes in their designs. In any case, the providers and deployers of high-risk AI systems intended to be used by public authorities shall take the necessary steps to comply with the requirements and obligations of this Regulation by 2 August 2030.

1 Similarity

Art. 95. 3: Codes of conduct may be drawn up by individual providers or deployers of AI systems or by organisations representing them or by both, including with the involvement of any interested stakeholders and their representative organisations, including civil society organisations and academia. Codes of conduct may cover one or more AI systems taking into account the similarity of the relevant systems.

0 Simulatability

Terms and AI Act Articles

20 SME

Art. 1, 2(g): measures to support innovation, with a particular focus on SMEs, including start-ups.
Art. 11, 1: The technical documentation of a high-risk AI system shall be drawn up before that system is placed on the market or put into service and shall be kept up-to-date. The technical documentation shall be drawn up in such a way as to demonstrate that the high-risk AI system complies with the requirements set out in this Section and to provide national competent authorities and notified bodies with the necessary information in a clear and comprehensive form to assess the compliance of the AI system with those requirements. It shall contain, at a minimum, the elements set out in Annex IV. SMEs, including start-ups, may provide the elements of the technical documentation specified in Annex IV in a simplified manner. To that end, the Commission shall establish a simplified technical documentation form targeted at the needs of small and microenterprises. Where an SME, including a start-up, opts to provide the information required in Annex IV in a simplified manner, it shall use the form referred to in this paragraph. Notified bodies shall accept the form for the purposes of the conformity assessment.
Art. 57, 9(e): facilitating and accelerating access to the Union market for AI systems, in particular when provided by SMEs, including start-ups.
Art. 58, 2(d): that access to the AI regulatory sandboxes is free of charge for SMEs, including start-ups, without prejudice to exceptional costs that national competent authorities may recover in a fair and proportionate manner;
Art. 58, 2(f): that AI regulatory sandboxes facilitate the involvement of other relevant actors within the AI ecosystem, such as notified bodies and standardisation organisations, SMEs, including start-ups, enterprises, innovators, testing and experimentation facilities, research and experimentation labs and European Digital Innovation Hubs, centres of excellence, individual researchers, in order to allow and facilitate cooperation with the public and private sectors;
Art. 58, 2(g): that procedures and administrative requirements for application, selection, participation and exiting the AI regulatory sandbox are simple, easily intelligible, and clearly communicated in order to facilitate the participation of SMEs, including start-ups, with limited legal and administrative capacities and are streamlined across the Union, in order to avoid fragmentation and that participation in an AI regulatory sandbox established by a Member State, or by the European Data Protection Supervisor is mutually and uniformly recognised and carries the same legal effects across the Union.
Art. 58, 3: Prospective providers in the AI regulatory sandboxes, in particular SMEs and start-ups, shall be directed, where relevant, to pre-deployment services such as guidance on the implementation of this Regulation, to other value-adding services such as help with standardisation documents and certification, testing and experimentation facilities, European Digital Innovation Hubs and centres of excellence.
Art. 62: Measures for providers and deployers, in particular SMEs, including start-ups.
Art. 62, 1(a): provide SMEs, including start-ups, having a registered office or a branch in the Union, with priority access to the AI regulatory sandboxes, to the extent that they fulfil the eligibility conditions and selection criteria; the priority access shall not preclude other SMEs, including start-ups, other than those referred to in this paragraph from access to the AI regulatory sandbox, provided that they also fulfil the eligibility conditions and selection criteria;
Art. 62, 1(b): organise specific awareness raising and training activities on the application of this Regulation tailored to the needs of SMEs including start-ups, deployers and, as appropriate, local public authorities;
Art. 62, 1(c): utilise existing dedicated channels and where appropriate, establish new ones for communication with SMEs including start-ups, deployers, other innovators and, as appropriate, local public authorities to provide advice and respond to queries about the implementation of this Regulation, including as regards participation in AI regulatory sandboxes;
Art. 62, 1(d): facilitate the participation of SMEs and other relevant stakeholders in the standardisation development process.
Art. 62, 2: The specific interests and needs of SME providers, including start-ups, shall be taken into account when setting the fees for conformity assessment under Article 43, reducing those fees proportionately to their size, market size and other relevant indicators.
Art. 67, 2: The membership of the advisory forum shall represent a balanced selection of stakeholders, including industry, start-ups, SMEs, civil society and academia. The membership of the advisory forum shall be balanced with regard to commercial and non-commercial interests and, within the category of commercial interests, with regard to SMEs and other undertakings.
Art. 67, 3: National competent authorities may provide guidance and advice on the implementation of this Regulation, in particular to SMEs including start-ups, taking into account the guidance and advice of the Board and the Commission, as appropriate. Whenever national competent authorities intend to provide guidance and advice with regard to an AI system in areas covered by other Union law, the national competent authorities under that Union law shall be consulted, as appropriate.
Art. 95, 4: The AI Office and the Member States shall take into account the specific interests and needs of SMEs, including start-ups, when encouraging and facilitating the drawing up of codes of conduct.
Art. 95, 1(c): the application of the definition of an AI system as set out in Article 3, point (1). When issuing such guidelines, the Commission shall pay particular attention to the needs of SMEs including start-ups, of local public authorities and of the sectors most likely to be affected by this Regulation. The guidelines referred to in the first subparagraph of this paragraph shall take due account of the generally acknowledged state of the art on AI, as well as of relevant harmonised standards and common specifications that are referred to in Articles 40 and 41, or of those harmonised standards or technical specifications that are set out pursuant to Union harmonisation law.
Art. 96, 1: In accordance with the terms and conditions laid down in this Regulation, Member States shall lay down the rules on penalties and other enforcement measures, which may also include warnings and non-monetary measures, applicable to infringements of this Regulation by operators, and shall take all measures necessary to ensure that they are properly and effectively implemented, thereby taking into account the guidelines issued by the Commission pursuant to Article 96. The penalties provided for shall be effective, proportionate and dissuasive. They shall be set into account the interests of SMEs, including start-ups, and their economic viability.
Art. 99, 6: In the case of SMEs, including start-ups, each referred to in this Article shall be up to the percentages or amount referred to in paragraphs 3, 4 and 5, whichever thereof is lower.
Art. 112, 4(d): the number of undertakings that enter the market after the entry into application of this Regulation, and how many of them are SMEs.

0 Social responsibility

0 Societal concerns

0 Societal Impact

7 Society

Art. 3, (65): 'systemic risk' means a risk that is specific to the high-impact capabilities of general-purpose AI models, having a significant impact on the Union market due to their reach, or due to actual or reasonably foreseeable negative effects on public health, safety, public security, fundamental rights, or the society as a whole, that can be propagated at scale across the value chain;
Art. 7, 2(d): the impact on the benefit of the deployment of the AI system for individuals, groups, or society at large, including possible improvements in product safety;
Art. 56, 3: The AI Office may invite all providers of general-purpose AI models, as well as relevant national competent authorities, to participate in the drawing-up of codes of practice. Civil society organisations, industry, academia and other relevant stakeholders, such as downstream providers and independent experts, may support the process.
Art. 58, 2(f): that AI regulatory sandboxes facilitate the development of tools and infrastructure for testing, benchmarking, assessing and explaining dimensions of AI systems relevant for regulatory learning, such as accuracy, robustness and cybersecurity, as well as measures to mitigate risks to fundamental rights and society at large.
Art. 67, 2: The membership of the advisory forum shall represent a balanced selection of stakeholders, including industry, start-ups, SMEs, civil society and academia. The membership of the advisory forum shall be balanced with regard to commercial and non-commercial interests and, within the category of commercial interests, with regard to SMEs and other undertakings.
Art. 95, 3: Codes of conduct may be drawn up by individual providers or deployers of AI systems or by organisations representing them or by both, including with the involvement of any interested stakeholders and their representative organisations, including civil society organisations and academia. Codes of conduct may cover one or more AI systems taking into account the similarity of the intended purpose of the relevant systems.
Art. 112, 10: The Commission shall, if necessary, submit appropriate proposals to amend this Regulation, in particular taking into account developments in technology, the effect of AI systems on health and safety, and on fundamental rights, and in light of the state of progress in the information society.

1 Software

Art. 13, 3(e): the computational and hardware resources needed, the expected lifetime of the high-risk AI system and any necessary maintenance and care measures, including their frequency, to ensure the proper functioning of that AI system, including as regards software updates;

0 Software quality

0 Software testing

23 Specification

Art. 3, (28): 'common specification' means a set of technical specifications as defined in Article 2, point (4) of Regulation (EU) No 1025/2012, providing means to comply with certain requirements established under this Regulation;
Art. 13, 3(b)(vi): when appropriate, specifications for the input data, or any other relevant information in terms of the training, validation and testing data sets used, taking into account the intended purpose of the high-risk AI system;
Art. 13, 1(e): technical specifications, including standards, to be applied and, where the relevant harmonised standards are not applied in full or do not cover all of the relevant requirements set out in Section 2, the means to be used to ensure that the high-risk AI system complies with those requirements;
Art. 41: Common specifications
Art. 41, 1: The Commission may adopt, implementing acts establishing common specifications for the requirements set out in Section 2 of this Chapter or, as applicable, for the obligations set out in Sections 2 and 3 of Chapter V where the following conditions have been fulfilled:
Art. 41, 1(b): no reference to harmonised standards covering the requirements referred to in Section 2 of this Chapter or, as applicable, the obligations referred to in Sections 2 and 3 of Chapter V has been published in the Official Journal of the European Union in accordance with Regulation (EU) No 1025/2012, and no such reference is expected to be published within a reasonable period. When drafting the common specifications, the Commission shall consult the advisory forum referred to in Article 67. The implementing acts referred to in the first subparagraph of this paragraph shall be adopted in accordance with the examination procedure referred to in Article 89(2).
Art. 41, 3: High-risk AI systems or general-purpose AI models which are in conformity with the common specifications referred to in paragraph 1, or parts of those specifications, shall be presumed to be in conformity with the requirements set out in Section 2 of this Chapter or, as applicable, to comply with the obligations referred to in Sections 2 and 3 of Chapter V, to the extent those common specifications cover those requirements or those obligations.
Art. 41, 5: Where providers of high-risk AI systems or general-purpose AI models do not comply with the common specifications referred to in paragraph 1, they shall duly justify that they have adopted technical solutions that meet the requirements referred to in Section 2 of this Chapter or, as applicable, comply with the obligations set out in Sections 2 and 3 of Chapter V to a level at least equivalent thereto.
Art. 41, 6: Where a Member State considers that a common specification does not entirely meet the requirements set out in Section 2, or as applicable, comply with obligations set out in Sections 2 and 3 of Chapter V, it shall inform the Commission thereof with a detailed explanation. The Commission shall assess that information and, if appropriate, amend the implementing act establishing the common specification concerned.
Art. 43, 1: For high-risk AI systems listed in point 1 of Annex III, where, in demonstrating the compliance of a high-risk AI system with the requirements set out in Section 2, the provider has applied harmonised standards referred to in Article 40, or, where applicable, common specifications referred to in Article 41, the provider shall opt for one of the following conformity assessment procedures based on:
Art. 43, 1(a): harmonised standards referred to in Article 40 do not exist, and common specifications referred to in Article 41 are not available;
Art. 43, 1(c): the common specifications referred to in point (a) exist, but the provider has not applied them.
Art. 43, 3: For high-risk AI systems covered by the Union harmonisation legislation listed in Section A of Annex I, the provider shall follow the relevant conformity assessment procedure as required under those legal acts. The requirements set out in Section 2 of this Chapter shall apply to those high-risk AI systems and shall be part of that assessment. Points 4.3., 4.4., 4.5. and the fifth paragraph of point 4.6 of Annex VII shall also apply. For the purposes of that assessment, notified bodies which have been notified under those legal acts shall be entitled to control the conformity of the high-risk AI systems with the requirements set out in Section 2, provided that the compliance of those notified bodies with requirements laid down in Article 31(4), (5), (10) and (11) has been assessed in the context of the notification procedure under those legal acts. Where a legal act listed in Section A of Annex I enables the product manufacturer to opt out from a third-party conformity assessment, provided that that manufacturer has applied all harmonised standards covering all the relevant requirements, that manufacturer may use that option only if it has also applied harmonised standards or, where applicable, common specifications referred to in Article 41, covering all requirements set out in Section 2 of this Chapter.
Art. 65, 5: The designated representatives of the Member States shall adopt the Board's rules of procedure by a two-thirds majority. The rules of procedure shall, in particular, lay down procedures for the selection process, the duration of the mandate of, and specifications of the tasks of, the Chair, detailed arrangements for voting, and the organisation of the Board's activities and those of its sub-groups.
Art. 66, (e)(iii): on technical specifications or existing standards regarding the requirements set out in Chapter III, Section 2;
Art. 66, (e)(iv): on the use of harmonised standards or common specifications referred to in Articles 40 and 41;
Art. 71, 1: The Commission shall, in collaboration with the Member States, set up and maintain an EU database containing information referred to in paragraphs 2 and 3 of this Article concerning high-risk AI systems referred to in Article 6(2) which are registered in accordance with Articles 49 and 60 and AI systems that are not considered as high-risk pursuant to Article 6(3) and which are registered in accordance with Article 6(4) and Article 49. When setting the functional specifications of such database, the Commission shall consult the relevant experts, and when updating the functional specifications of such database, the Commission shall consult the Board.
Art. 79, 6(e): the short-normed standards or common specifications referred to in Articles 40 and 41 conferring a presumption of conformity;
Art. 81, 3: Where the national measure is considered justified and the non-compliance of the AI system is attributed to shortcomings in the harmonised standards or common specifications referred to in Articles 40 and 41 of this Regulation, the Commission shall apply the procedure provided for in Article 11 of Regulation (EU) No 1025/2012.
Art. 102, 1(f): the application of the definition of an AI system as set out in Article 3, point (1). When issuing such guidelines, the Commission shall pay particular attention to the needs of SMEs including start-ups, of local public authorities and of the sectors most likely to be affected by this Regulation. The guidelines referred to in the first subparagraph of this paragraph shall take due account of the generally acknowledged state of the art on AI, as well as of relevant harmonised standards and common specifications that are referred to in Articles 40 and 41, or of those harmonised standards or technical specifications that are set out pursuant to Union harmonisation law.
Art. 102, 1: In Article 4(c) of Regulation (EC) No 300/2008, the following subparagraph is added: '5. For Artificial Intelligence systems which are safety components within the meaning of Regulation (EU) 2024/1689 of the European Parliament and of the Council (*), the requirements set out in Chapter III, Section 2, of that Regulation shall be taken into account.'
Art. 105: In Article 8 of Directive 2014/50/EU, the following paragraph is added: '5. For Artificial Intelligence systems which are safety components within the meaning of Regulation (EU) 2024/1689 of the European Parliament and of the Council (*), when carrying out its activities pursuant to paragraph 1 and when applying specifications and testing standards in accordance with paragraphs 2 and 3, the Commission shall take into account the requirements set out in Chapter III, Section 2, of that Regulation.'
Art. 112, 4(c): adopted harmonised standards and common specifications developed to support this Regulation;

1 Stakeholder

Art. 40, 3: The participants in the standardisation process shall seek to promote investment and innovation in AI, including through increasing legal certainty, as well as the competitiveness and growth of the Union market, to contribute to strengthening global cooperation on standardisation and taking into account existing international standards in the field of AI that are consistent with Union values, fundamental rights and interests, and to enhance multi-stakeholder governance ensuring a balanced representation of interests and the effective participation of all relevant stakeholders in accordance with Articles 5, 6, and 7 of Regulation (EU) No 1025/2012.

1 Standardization

Art. 67, 5: The Fundamental Rights Agency, ENISA, the European Committee for Standardization (CEN), the European Committee for Electrotechnical Standardization (CENELEC), and the European Telecommunications Standards Institute (ETSI) shall be permanent members of the advisory forum.

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24 Support

- Art. 1, 2(g):** measures to support innovation, with a particular focus on SMEs, including start-ups.
- Art. 5, 1(b):** the placing on the market, the putting into service for this specific purpose, or the use of an AI system for making risk assessments of natural persons in order to assess or predict the risk of a natural person committing a criminal offence, based solely on the profiling of a natural person or on assessing their personality traits and characteristics; this prohibition shall not apply to AI systems used to support the human assessment of the involvement of a person in a criminal activity, which is already based on objective and verifiable facts directly linked to a criminal activity;
- Art. 26, 2:** Deployers shall assign human oversight to natural persons who have the necessary competence, training and authority, as well as the necessary support.
- Art. 29, 4:** For notified bodies which are designated under any other Union harmonisation legislation, all documents and certificates linked to those designations may be used to support their designation procedure under this Regulation, as appropriate. The notified body shall update the documentation referred to in paragraphs 2 and 3 of this Article whenever relevant changes occur, in order to enable the authority responsible for notified bodies to monitor and verify continuous compliance with all the requirements laid down in Article 31.
- Art. 36, 8(b):** the notifying authority has confirmed that no certificates relevant to the suspension will be issued, amended or re-issued during the course of the suspension or restriction, and states whether the notified body has the capability of continuing to monitor and remain responsible for existing certificates issued for the period of the suspension or restriction; in the event that the notifying authority determines that the notified body does not have the capability to support existing certificates issued, the provider of the system covered by the certificate shall confirm in writing to the national competent authorities of the Member State in which it has its registered place of business, within three months of the suspension or restriction, that another qualified notified body is temporarily assuming the functions of the notified body to monitor and remain responsible for the certificates during the period of suspension or restriction.
- Art. 56, 3:** The AI Office may invite all providers of general-purpose AI models, as well as relevant national competent authorities, to participate in the drawing-up of codes of practice. Civil society organisations, industry, academia and other relevant stakeholders, such as downstream providers and independent experts, may support the process.
- CHAPTER VI: MEASURES IN SUPPORT OF INNOVATION**
- Art. 57, 1:** Member States shall ensure that their competent authorities establish at least one AI regulatory sandbox at national level, which shall be operational by 2 August 2026. That sandbox may also be established jointly with the competent authorities of other Member States. The Commission may provide technical support, advice and tools for the establishment and operation of AI regulatory sandboxes. The obligation under the first subparagraph may also be fulfilled by participating in an existing sandbox in so far as that participation provides an equivalent level of national coverage for the participating Member States.
- Art. 57, 6:** Competent authorities shall provide, as appropriate, guidance, supervision and support within the AI regulatory sandbox with a view to identifying risks, in particular to fundamental rights, health and safety, testing, mitigation measures, and their effectiveness in relation to the obligations and requirements of this Regulation and, where relevant, other Union and national law supervised within the sandbox.
- Art. 57, 15:** National competent authorities shall inform the AI Office and the Board of the establishment of a sandbox, and may ask them for support and guidance. The AI Office shall make publicly available a list of planned and existing sandboxes and keep it up to date in order to encourage more interaction in the AI regulatory sandboxes and cross-border cooperation.
- Art. 58, 2(c):** that the detailed arrangements for, and conditions concerning AI regulatory sandboxes support, to the best extent possible, flexibility for national competent authorities to establish and operate their AI regulatory sandboxes;
- Art. 66, (a):** contribute to the coordination among national competent authorities responsible for the application of this Regulation and, in cooperation with and subject to the agreement of the market surveillance authorities concerned, support joint activities of market surveillance authorities referred to in Article 74(11);
- Art. 66, (b):** support the Commission in promoting AI literacy, public awareness and understanding of the benefits, risks, safeguards and rights and obligations in relation to the use of AI systems;
- Art. 68, 1:** The Commission shall, by means of an implementing act, make provisions on the establishment of a scientific panel of independent experts (the 'scientific panel') intended to support the enforcement activities under this Regulation. That implementing act shall be adopted in accordance with the examination procedure referred to in Article 98(2).
- Art. 68, 2:** The scientific panel shall advise and support the AI Office, in particular with regard to the following tasks:
- Art. 69, 1:** Member States may call upon experts of the scientific panel to support their enforcement activities under this Regulation.
- Art. 69, 2:** The Member States may be required to pay fees for the advice and support provided by the experts. The structure and the level of fees as well as the scale and structure of recoverable costs shall be set out in the implementing act referred to in Article 68(1), taking into account the objectives of the adequate implementation of this Regulation, cost-effectiveness and the necessity of ensuring effective access to experts for all Member States.
- Art. 69, 3:** The Commission shall facilitate timely access to the experts by the Member States, as needed, and ensure that the combination of support activities carried out by Union AI testing support pursuant to Article 84 and experts pursuant to this Article is efficiently organised and provides the best possible added value.
- Art. 71, 6:** The Commission shall be the controller of the EU database. It shall make available to providers, prospective providers and deployers adequate technical and administrative support. The EU database shall comply with the applicable accessibility requirements.
- Art. 74, 11:** Market surveillance authorities and the Commission shall be able to propose joint activities, including joint investigations, to be conducted by either market surveillance authorities or market surveillance authorities jointly with the Commission, that have the aim of promoting compliance, identifying non-compliance, raising awareness or providing guidance in relation to this Regulation with respect to specific categories of high-risk AI systems that are found to present a serious risk across two or more Member States in accordance with Article 9 of Regulation (EU) 2019/1020. The AI Office shall provide coordination support for joint investigations.
- Art. 84:** Union AI testing support structures
- Art. 84, 1:** The Commission shall designate one or more Union AI testing support structures to perform the tasks listed under Article 21(6) of Regulation (EU) 2019/1020 in the area of AI.
- Art. 84, 2:** Without prejudice to the tasks referred to in paragraph 1, Union AI testing support structures shall also provide independent technical or scientific advice at the request of the Board, the Commission, or of market surveillance authorities.
- Art. 112, 4(c):** adopted harmonised standards and common specifications developed to support this Regulation;

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Regulation (EU) 2019/1020, such complaints shall be taken into account for the purpose of conducting market surveillance activities, and shall be handled in line with the dedicated procedures established therefor by the market surveillance authorities.
Art. 88, 2. Without prejudice to Article 73(3), market surveillance authorities may request the Commission to exercise the powers laid down in this Section, where that is necessary and proportionate to assist with the fulfilment of their tasks under the Regulation.
Art. 99, 7(b): whether administrative fines have already been applied by other market surveillance authorities to the same operator for the same infringement;

3 Sustainability (See also: [Sustainable](#))

Art. 59, 1(a)(iii): energy sustainability;
Art. 95, 2(b): assessing and minimising the impact of AI systems on environmental sustainability, including as regards energy-efficient programming and techniques for the efficient design, training and use of AI;
Art. 112, 7. By 2 August 2028 and every three years thereafter, the Commission shall evaluate the impact and effectiveness of voluntary codes of conduct to foster the application of the requirements set out in Chapter III, Section 2 for AI systems other than high-risk AI systems and possibly other additional requirements for AI systems other than high-risk AI systems, including as regards environmental sustainability.

0 Sustainable (See also: [Sustainability](#))

3 Synthetic (See also: [Anonymised data](#))

Art. 10, 5(a): the bias detection and correction cannot be effectively fulfilled by processing other data, including synthetic or anonymised data;
Art. 50, 2. Providers of AI systems, including general-purpose AI systems, generating synthetic audio, image, video or text content, shall ensure that the outputs of the AI system are marked in a machine-readable format and detectable as artificially generated or manipulated. Providers shall ensure their technical solutions are effective, interoperable, robust and reliable as far as this is technically feasible, taking into account the specificities and limitations of various types of content, the costs of implementation and the generally acknowledged state of the art, as may be reflected in relevant technical standards. This obligation shall not apply to the extent the AI systems perform an assistive function for standard editing or do not substantially alter the input data provided by the deployer or the semantics thereof, or where authorised by law to detect, prevent, investigate or prosecute criminal offences.
Art. 59, 1(b): the data processed are necessary for complying with one or more of the requirements referred to in Chapter III, Section 2 where those requirements cannot effectively be fulfilled by processing anonymised, synthetic or other non-personal data;

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within the meaning of that Recommendation. For that purpose, the Commission shall develop guidelines on the elements of the quality management system which may be complied with in a simplified manner considering the needs of microenterprises, without affecting the level of protection or the need for compliance with the requirements in respect of high-risk AI systems.
Art. 70. 8. National competent authorities may provide guidance and advice on the implementation of this Regulation, in particular to SMEs including start-ups, taking into account the guidance and advice of the Board and the Commission, as appropriate.
Art. 71. 5. The EU database shall contain personal data only in so far as necessary for collecting and processing information in accordance with this Regulation. That information shall include the names and contact details of natural persons who are responsible for registering the system and have the legal authority to represent the provider or the deployer, as applicable.
Art. 72. 1. Providers shall establish and document a post-market monitoring system in a manner that is proportionate to the nature of the AI technologies and the risks of the high-risk AI system.
Art. 73. 2. The post-market monitoring system shall be designed to collect relevant data which may be provided by deployers or which may be collected through other sources on the performance of high-risk AI systems throughout their lifetime, and which allow the provider to evaluate the continuous compliance of AI systems with the requirements set out in Chapter III, Section 2. Where relevant, post-market monitoring shall include an analysis of the interaction with other AI systems. This obligation shall not cover sensitive operational data of deployers which are law-enforcement authorities.
Art. 74. 4. The post-market monitoring system shall be part of the technical documentation referred to in Annex IV. The Commission shall adopt an implementing act laying down detailed provisions establishing a template for the post-market monitoring plan and the list of elements to be included in the plan by 2 February 2026. That implementing act shall be adopted in accordance with the examination procedure referred to in Article 98(2).
Art. 74. 4. For high-risk AI systems covered by the Union harmonisation legislation listed in Section A of Annex I, where a post-market monitoring system and plan are already established under that legislation, in order to ensure consistency, avoid duplications and minimise additional burdens, providers shall have a choice of integrating, as appropriate, elements described in paragraphs 1, 2 and 3 using the template referred to in paragraph 5 into systems and plans already existing under that legislation, provided that it achieves an equivalent level of protection. The first subparagraph of this paragraph shall also apply to high-risk AI systems referred to in point 5 of Annex III placed on the market or put into service by financial institutions that are subject to requirements under Union financial services law regarding their internal governance, arrangements or procedures.
Art. 73. 2. The report referred to in paragraph 1 shall be made immediately after the provider has established a causal link between the AI system and the serious incident or the reasonable likelihood of such a link, and, in any event, not later than 15 days after the provider or, where applicable, the deployer, becomes aware of the serious incident. The period for the reporting referred to in the first subparagraph shall take account of the severity of the serious incident.
Art. 73. 4. Notwithstanding paragraph 2, in the event of the death of a person, the report shall be provided immediately after the provider or the deployer has established, or as soon as it suspects, a causal relationship between the high-risk AI system and the serious incident, but not later than 10 days after the date on which the provider or, where applicable, the deployer becomes aware of the serious incident.
Art. 73. 6. Following the reporting of a serious incident pursuant to paragraph 1, the provider shall, without delay, perform the necessary investigations in relation to the serious incident and the AI system concerned. This shall include a risk assessment of the incident, and corrective action. The provider shall cooperate with the competent authorities and where relevant with the notified body concerned, during the investigations referred to in the first subparagraph, and shall not perform any investigation which involves altering the AI system concerned in a way which may affect any subsequent evaluation of the causes of the incident, prior to informing the competent authorities of such action.
Art. 74. 6. For high-risk AI systems placed on the market, put into service, or used by financial institutions regulated by Union financial services law, the market surveillance authority for the purposes of this Regulation shall be the relevant national authority responsible for the financial supervision of those institutions under that legislation, in so far as the placing on the market, putting into service, or the use of the AI system is in direct connection with the provision of those financial services.
Art. 74. 13. Market surveillance authorities shall be granted access to the source code of the high-risk AI system upon a reasoned request and only when both of the following conditions are fulfilled:
Art. 74. 13(a): access to source code is necessary to assess the conformity of a high-risk AI system with the requirements set out in Chapter III, Section 2; and
Art. 74. 13(b): the high-risk AI system is based on a general-purpose AI model, and the model and the system are developed by the same provider, the AI Office shall have powers to monitor and supervise compliance of that AI system with obligations under this Regulation. To carry out its monitoring and supervision tasks, the AI Office shall have all the powers of a market surveillance authority provided for in this Section and Regulation (EU) 2019/1020.
Art. 75. 3. Where a market surveillance authority is unable to conclude its investigation of the high-risk AI system because of its inability to access certain information related to the general-purpose AI model despite having made all appropriate efforts to obtain that information, it may suspend the assessment of the AI system until such time as that information can be accessed. Where a market surveillance authority is unable to access that information, it may suspend the assessment of whether a high-risk AI system is non-compliant. Market surveillance authorities shall safeguard the confidentiality of the information that they obtain in accordance with Article 78 of this Regulation. The procedure provided for in Chapter VI of Regulation (EU) 2019/1020 shall apply mutatis mutandis.
Art. 75. 5. Where applicable, where a market surveillance authority has taken a decision referred to in paragraph 3, it shall communicate the grounds therefor to the market surveillance authorities of other Member States in which the AI system has been tested in accordance with the testing plan.
Art. 77. 3. Where the documentation referred to in paragraph 1 is insufficient to ascertain whether an infringement of obligations under Union law protecting fundamental rights has occurred, the public authority or body referred to in paragraph 1 may make a reasoned request to the market surveillance authority to organise testing of the high-risk AI system through technical means. The market surveillance authority shall organise the testing with the close involvement of the requesting public authority or body within a reasonable time following the request.
Art. 79. 2. Where the market surveillance authority of a Member State has sufficient reason to consider an AI system to present a risk as referred to in paragraph 1 of this Article, it shall carry out an evaluation of the AI system concerned in respect of its compliance with all the requirements and obligations laid down in this Regulation. Particular attention shall be given to AI systems presenting a risk to vulnerable groups. Where risks to fundamental rights are identified, the market surveillance authority shall also inform and fully cooperate with the relevant national public authorities or bodies referred to in Article 77(1). Where, in the course of that evaluation, the market surveillance authority or, where applicable the market surveillance authority in cooperation with the national public authority referred to in Article 77(1), finds that the AI system does not comply with the requirements and obligations laid down in this Regulation, it shall without undue delay require the relevant operator to take all appropriate corrective actions to bring the AI system into compliance, to withdraw the AI system from the market, or to recall it within a period the market surveillance authority may prescribe, and in any event within the shorter of 15 working days, or as provided for in the relevant Union harmonisation legislation. The market surveillance authority shall inform the relevant notified body accordingly. Article 18 of Regulation (EU) 2019/1020 shall apply to the measures referred to in the second subparagraph of this paragraph.
Art. 79. 5. Where the operator of an AI system does not take adequate corrective action within the period referred to in paragraph 2, the market surveillance authority shall take all appropriate provisional measures to prohibit or restrict the AI system's being made available on its national market or put into service, to withdraw the product or the standalone AI system from that market or to recall it. That authority shall without undue delay notify the Commission and the other Member States of those measures.
Art. 79. 6. The notification referred to in paragraph 5 shall include all available details, in particular the information necessary for the identification of the non-compliant AI system, the origin of the AI system and the supply chain, the nature of the non-compliance alleged and the risk involved, the nature and duration of the national measures taken and the arguments put forward by the relevant operator. In particular, the market surveillance authorities shall indicate whether the non-compliance is due to one or more of the following:
Art. 79. 6(a): a failure of a high-risk AI system to meet requirements set out in Chapter III, Section 2;
Art. 79. 6(b): the market surveillance authority of a Member State initiating the procedure shall, without undue delay, inform the Commission and the other Member States of any measures adopted and of any additional information at their disposal relating to the non-compliance of the AI system concerned, and, in the event of disagreement with the notified national measure, of their objections.
Art. 79. 8. The market surveillance authorities shall ensure that appropriate restrictive measures are taken in respect of the product or the AI system concerned, such as withdrawal of the product or the AI system from their market, without undue delay.
Art. 80. 1. Where a market surveillance authority has sufficient reason to consider that an AI system classified by the provider as non-high-risk pursuant to Article 6(3) is indeed high-risk, the market surveillance authority shall carry out an evaluation of the AI system concerned in respect of its classification as a high-risk AI system based on the conditions set out in Article 6(3) and the Commission guidelines.
Art. 80. 2. Where, in the course of that evaluation, the market surveillance authority finds that the AI system concerned is high-risk, it shall without undue delay require the relevant provider to take all necessary actions to bring the AI system into compliance with the requirements and obligations laid down in this Regulation.
Art. 80. 3. Where the market surveillance authority considers that the use of the AI system concerned is not restricted to its national territory, it shall inform the Commission and the other Member States without undue delay of the results of the evaluation and of the actions which it has required the provider to take.
Art. 80. 4. The provider shall ensure that all necessary action is taken to bring the AI system into compliance with the requirements and obligations laid down in this Regulation. Where the provider of an AI system concerned does not bring the AI system into compliance with those requirements and obligations within the period referred to in paragraph 2 of this Article, the provider shall be subject to fines in accordance with Article 99.
Art. 80. 6. Where the Commission considers that the measure taken by the relevant Member State to be justified, all Member States shall ensure that they take appropriate restrictive measures in respect of the AI system concerned, such as requiring the withdrawal of the AI system from their market without undue delay, and shall inform the Commission accordingly. Where the Commission considers the national measure to be unjustified, the Member State concerned shall withdraw the measure and shall inform the Commission accordingly.
Art. 81. 3. Where the national measure is considered justified and the non-compliance of the AI system is attributed to shortcomings in the harmonised standards or common specifications referred to in Articles 40 and 41 of this Regulation, the Commission shall apply the procedure provided for in Article 11 of this Regulation.
Art. 82. 1. Where, having performed an evaluation under Article 79, after consulting the relevant national public authority referred to in Article 77(1), the market surveillance authority of a Member State finds that although a high-risk AI system complies with this Regulation, it nevertheless presents a risk to the health or safety of persons, to fundamental rights, or to other aspects of public interest protection, it shall require the relevant operator to take all appropriate measures to ensure that the AI system concerned, when placed on the market or put into service, no longer presents that risk without undue delay, with a generic risk may present.
Art. 82. 3. The Member States shall immediately inform the Commission and the other Member States of a finding under paragraph 1. That information shall include all available details, in particular the data necessary for the identification of the AI system concerned, the origin and the supply chain of the AI system, the nature of the risk involved and the nature and duration of the national measures taken.
Art. 83. 2. Where the non-compliance referred to in paragraph 1 persists, the market surveillance authority of the Member State concerned shall take appropriate and proportionate measures to restrict or prohibit the high-risk AI system being made available on the market or to ensure that it is recalled or withdrawn from the market without delay.
Art. 86. 1. Any affected person subject to a decision which is taken by the deployer on the basis of the output from a high-risk AI system listed in Annex III, with the exception of systems listed under point 2 thereof, and which produces legal effects or similarly significantly affects that person in a way that they consider to have an adverse impact on their health, safety or fundamental rights shall have the right to obtain from the deployer clear and meaningful explanations of the role of the AI system in the decision-making procedure and the main elements of the decision taken.
Art. 96. 1(b): the application of the definition of an AI system as set out in Article 3, point (1). When issuing such guidelines, the Commission shall pay particular attention to the needs of SMEs including start-ups, of local public authorities and of the sectors most likely to be affected by this Regulation. The guidelines referred to in this paragraph shall be issued on the basis of the generally acknowledged state of the art on AI, as well as of relevant harmonised standards and common specifications that are referred to in Articles 40 and 41, or of those harmonised standards or technical specifications that are set out pursuant to Union harmonisation law.
Art. 99. 1(a): the nature, gravity and duration of the infringement and of its consequences, taking into account the purpose of the AI system, as well as, where appropriate, the number of affected persons and the level of damage suffered by them.
Art. 99. 1(b): depending on the legal system of the Member States, the rules on administrative fines may be applied in such a manner that the fines are imposed by competent national courts or by other bodies, as applicable in those Member States. The application of such rules in those Member States shall have an equivalent effect.
Art. 100. 1(a): the nature, gravity and duration of the infringement and of its consequences, taking into account the purpose of the AI system concerned, as well as, where appropriate, the number of affected persons and the level of damage suffered by them;
Art. 100. 3: the non-compliance of the AI system with any requirements or obligations under this Regulation, other than those laid down in Article 5, shall be subject to administrative fines of up to EUR 750 000.
Art. 111. 1: Without prejudice to the application of Article 5 as referred to in Article 113(3), point (a), AI systems which are components of the large-scale IT systems established by the legal acts listed in Annex X that have been placed on the market or put into service before 2 August 2027 shall be brought into compliance with this Regulation by 31 December 2030. The requirements laid down in this Regulation shall be taken into account in the evaluation of each large-scale IT system established by the legal acts listed in Annex X to be undertaken as provided for in those legal acts and without prejudice to their application.
Art. 112. 2(c): amendments enhancing the effectiveness of the supervision and governance system.

30 Systemic risk

Art. 3. (65): 'systemic risk' means a risk that is specific to the high-impact capabilities of general-purpose AI models, having a significant impact on the Union market due to their reach, or due to actual or reasonably foreseeable negative effects on public health, safety, public security, fundamental rights, or the society as a whole, that can be propagated at scale across the value chain.
Art. 51: Classification of general-purpose AI models as general-purpose AI models with systemic risk
Art. 51. 1: A general-purpose AI model shall be classified as a general-purpose AI model with systemic risk if it meets any of the following conditions:
Art. 52. 1: Where a general-purpose AI model meets the condition referred to in Article 51(1), point (a), the relevant provider shall notify the Commission without delay and in any event within two weeks after that requirement is met or it becomes known that it will be met. That notification shall include the information necessary to demonstrate that the relevant requirement has been met. If the Commission becomes aware of a general-purpose AI model presenting systemic risks of which it has not been notified, it may decide to designate it as a model with systemic risk.
Art. 52. 2: The provider of a general-purpose AI model that meets the condition referred to in Article 51(1), point (a), may present, with its notification, sufficiently substantiated arguments to demonstrate that, exceptionally, although it meets that requirement, the general-purpose AI model does not present, due to its specific characteristics, systemic risks and therefore should not be classified as a general-purpose AI model with systemic risk.
Art. 52. 3: Where the Commission concludes that the arguments submitted pursuant to paragraph 2 are not sufficiently substantiated and the relevant provider was not able to demonstrate that the general-purpose AI model does not present, due to its specific characteristics, systemic risks, it shall reject those arguments, and the general-purpose AI model shall be considered to be a general-purpose AI model with systemic risk.
Art. 52. 4: The Commission may designate a general-purpose AI model as presenting systemic risks, ex officio or following a qualified alert from the scientific panel pursuant to Article 90(1), point (a), on the basis of criteria set out in Annex XIII. The Commission is empowered to adopt delegated acts in accordance with Article 97 in order to amend Annex XIII by specifying and updating the criteria set out in that Annex.
Art. 52. 5: Upon a reasoned request of a provider whose model has been designated as a general-purpose AI model with systemic risk pursuant to paragraph 4, the Commission shall take the request into account and may decide to reassess whether the general-purpose AI model can still be considered to present systemic risks on the basis of the criteria set out in Annex XIII. Such a request shall contain objective, detailed and new reasons that have arisen since the designation decision. Providers may request reassessment at the earliest six months after the designation decision. Where the Commission, following its reassessment, decides to maintain the designation as a general-purpose AI model with systemic risk, providers may request reassessment at the earliest six months after that decision.
Art. 52. 6: The Commission shall ensure that a list of general-purpose AI models with systemic risk is published and shall keep that list up to date, without prejudice to the need to observe and protect intellectual property rights and confidential business information or trade secrets in accordance with Union and national law.
Art. 53. 2: In addition to the obligations listed in Articles 53 and 54, providers of general-purpose AI models with systemic risk shall:
Art. 55. 1(a): perform model evaluation in accordance with standardised protocols and tools reflecting the state of the art, including conducting and documenting adversarial testing of the model with a view to identifying and mitigating systemic risks;
Art. 55. 1(b): assess and mitigate possible systemic risks at Union level, including their sources, that may stem from the development, the placing on the market, or the use of general-purpose AI models with systemic risk;
Art. 55. 1(c): ensure an adequate level of cybersecurity protection for the general-purpose AI model with systemic risk and the physical infrastructure of the model;
Art. 55. 2: Providers of general-purpose AI models with systemic risk may rely on codes of practice within the meaning of Article 56 to demonstrate compliance with the obligations set out in paragraph 1 of this Article, until a harmonised standard is published. Compliance with European harmonised standards grants providers the presumption of conformity to the extent that those standards cover those obligations. Providers of general-purpose AI models with systemic risks who do not adhere to an approved code of practice or do not comply with a European harmonised standard shall demonstrate alternative adequate means of compliance for assessment by the Commission.
Art. 56. 2(c): the identification of the type and nature of the systemic risks at Union level, including their sources, where appropriate;
Art. 56. 2(d): the measures, procedures and modalities for the assessment and management of the systemic risks at Union level, including the documentation thereof, which shall be proportionate to the risks, take into consideration their severity and probability and take into account the specific challenges of tackling those risks in light of the possible ways in which such risks may emerge and materialise along the AI value chain.
Art. 56. 7: The AI Office may invite all providers of general-purpose AI models to adhere to the codes of practice. For providers of general-purpose AI models not presenting systemic risks this adherence may be limited to the obligations provided for in Article 53, unless they declare explicitly their intention to join the full code.
Art. 68. 3(a)(i): alerting the AI Office of possible systemic risks at Union level of general-purpose AI models, in accordance with Article 90;
Art. 68. 3(a)(ii): providing advice on the classification of general-purpose AI models with systemic risk;
Art. 90: Acts of systemic risks by the scientific panel;
Art. 90. 3(a): the point of contact of the provider of the general-purpose AI model with systemic risk concerned;
Art. 92. 1(b): to investigate systemic risks at Union level of general-purpose AI models with systemic risk, in particular following a qualified alert from the scientific panel in accordance with Article 90(1), point (a).
Art. 92. 7: Prior to requesting access to the general-purpose AI model concerned, the AI Office may initiate a structured dialogue with the provider of the general-purpose AI model to gather more information on the internal testing of the model, internal safeguards for preventing systemic risks, and other internal procedures and measures the provider has taken to mitigate such risks.
Art. 93. 1(b): implement mitigation measures, where the evaluation carried out in accordance with Article 92 has given rise to serious and substantiated concern of a systemic risk at Union level;
Art. 93. 3: If, during the structured dialogue referred to in paragraph 2, the provider of the general-purpose AI model with systemic risk offers commitments to implement mitigation measures to address a systemic risk at Union level, the Commission may, by decision, make those commitments binding and declare that there are no further grounds for action.
Art. 101. 1(d): failed to make available to the Commission access to the general-purpose AI model or general-purpose AI model with systemic risk with a view to conducting an evaluation pursuant to Article 92. In fixing the amount of the fine or periodic penalty payment, regard shall be had to the nature, gravity and duration of the infringement, taking due account of the principles of proportionality and appropriateness. The Commission shall also take into account commitments made in accordance with Article 93(3) or made in relevant codes of practice in accordance with Article 56.

Terms and AI Act Articles

49 Task

- Art. 2. 3 This Regulation does not apply to areas outside the scope of Union law, and shall not, in any event, affect the competences of the Member States concerning national security, regardless of the type of entity entrusted by the Member States with carrying out tasks in relation to those competences. This Regulation does not apply to AI systems which are not placed on the market or put into service, or used with or without modification exclusively for military, defence or national security purposes, regardless of the type of entity carrying out those activities. This Regulation does not apply to AI systems which are not placed on the market or put into service in the Union, where the output is used in the Union exclusively for military, defence or national security purposes, regardless of the type of entity carrying out those activities.
Art. 3. (63) 'general-purpose AI model, including where such an AI model is trained with a large amount of data using self-supervision at scale, that displays significant generality and is capable of competently performing a wide range of distinct tasks regardless of the way the model is placed on the market and that can be integrated into a variety of downstream systems or applications, except AI models that are used for research, development or prototyping activities before they are placed on the market;
Art. 6. 3(a) The AI system is intended to perform a narrow procedural task;
Art. 6. 3(d) The AI system is intended to perform a preparatory task to an assessment relevant for the purposes of the use cases listed in Annex III. Notwithstanding the first subparagraph, an AI system referred to in Annex III shall always be considered to be high-risk where the AI system performs profiling of natural persons.
Art. 22. 2 The provider shall enable its authorised representative to perform the tasks specified in the mandate received from the provider.
Art. 23. 3 The authorised representative shall perform the tasks specified in the mandate received from the provider. It shall provide a copy of the mandate to the market surveillance authorities upon request, in one of the official languages of the institutions of the Union, as indicated by the competent authority. For the purposes of this Regulation, the mandate shall empower the authorised representative to carry out the following tasks:
Art. 28. 7 Notifying authorities shall have an adequate number of competent personnel at their disposal for the proper performance of their tasks. Competent personnel shall have the necessary expertise, where applicable, for their function, in fields such as information technologies, AI and law, including the supervision of fundamental rights.
Art. 31. 2 Notified bodies shall satisfy the organisational, quality management, resources and process requirements that are necessary to fulfil their tasks, as well as suitable cybersecurity requirements.
Art. 31. 5 Neither a conformity assessment body, its top-level management nor the personnel responsible for carrying out its conformity assessment tasks shall be directly involved in the design, development, marketing or use of high-risk AI systems, nor shall they represent the parties involved in those activities. They shall not engage in any activity that might conflict with their independence of judgement or integrity in relation to conformity assessment activities for which they are notified. This shall, in particular, apply to consultancy services.
Art. 31. 7 Notified bodies shall have documented procedures in place ensuring that their personnel, committees, subsidiaries, subcontractors and any associated body or personnel of external bodies maintain, in accordance with Article 78, the confidentiality of the information which comes into their possession during the performance of conformity assessment activities, except when its disclosure is required by law. The staff of notified bodies shall be bound to observe professional secrecy with regard to all information obtained in carrying out their tasks under this Regulation, except in relation to the notifying authorities of the Member State in which their activities are carried out.
Art. 31. 10 Notified bodies shall be capable of carrying out all their tasks under this Regulation with the highest degree of professional integrity and the requisite competence in the specific field, whether those tasks are carried out by notified bodies themselves or on their behalf and under their responsibility.
Art. 31. 11 Notified bodies shall have sufficient internal competences to be able effectively to evaluate the tasks conducted by external parties on their behalf. The notified body shall have permanent availability of sufficient administrative, technical, legal and scientific personnel who possess experience and knowledge relating to the relevant types of AI systems, data and data computing, and relating to the requirements set out in Section 2.
Art. 33. 1 Where a notified body subcontracts specific tasks connected with the conformity assessment or has recourse to a subsidiary, it shall ensure that the subcontractor or the subsidiary meets the requirements laid down in Article 31, and shall inform the notifying authority accordingly.
Art. 33. 2 Notified bodies shall take full responsibility for the tasks performed by any subcontractors or subsidiaries.
Art. 34. 2 The provider shall enable its authorised representative to perform the tasks specified in the mandate received from the provider.
Art. 34. 3 The authorised representative shall perform the tasks specified in the mandate received from the provider. It shall provide a copy of the mandate to the AI Office upon request, in one of the official languages of the institutions of the Union. For the purposes of this Regulation, the mandate shall empower the authorised representative to carry out the following tasks:
Art. 57. 8 The European Data Protection Supervisor may also establish an AI regulatory sandbox for Union institutions, bodies, offices and agencies, and may exercise the roles and the tasks of national competent authorities in accordance with this Chapter.
Art. 57. 9 The European Data Protection Supervisor shall, in cooperation with the provider or prospective provider and the Commission and the Board, establish and manage the AI regulatory sandbox and shall take them into account, as appropriate, when exercising their tasks under this Regulation. If both the provider or prospective provider and the national competent authority explicitly agree, the exit report may be made publicly available through the single information platform referred to in this Article.
Art. 57. 10 National competent authorities shall ensure that, to the extent the innovative AI systems involve the processing of personal data or otherwise fall under the supervisory remit of other national authorities or competent authorities providing or supporting access to data, the national data protection authorities and those other national or competent authorities are associated with the operation of the AI regulatory sandbox and involved in the supervision of those aspects to the extent of their respective tasks and powers.
Art. 57. 16 National competent authorities shall submit annual reports to the AI Office and to the Board, from one year after the establishment of the AI regulatory sandbox and every year thereafter until its termination, and a final report. Those reports shall provide information on the progress and results of the implementation of those sandboxes, including best practices, incidents, lessons learnt and recommendations on their setup and, where relevant, on the application and possible revision of this Regulation, including its delegated and implementing acts, and on the identification of other relevant law operated by the competent authorities within the sandbox. The national competent authorities shall make those annual reports or abstracts thereof available to the public, online. The Commission shall, where appropriate, take the annual reports into account when exercising its tasks under this Regulation.
Art. 60. 4(j) the testing in real world conditions is effectively overseen by the provider or prospective provider, as well as by deployers or prospective deployers through persons who are suitably qualified in the relevant field and have the necessary capacity, training and authority to perform their tasks;
Art. 64. 2 Member States shall facilitate the tasks entrusted to the AI Office, as reflected in this Regulation.
Art. 65. 4(a), have the relevant competences and powers in their Member State so as to contribute actively to the achievement of the Board's tasks referred to in Article 66;
Art. 65. 4(c), are empowered to facilitate consistency and coordination between national competent authorities in their Member State as regards the implementation of this Regulation, including through the collection of relevant data and information for the purpose of fulfilling their tasks on the Board;
Art. 65. 5 The designated representatives of the Member States shall adopt the Board's rules of procedure by a two-thirds majority. The rules of procedure shall, in particular, lay down procedures for the selection process, the duration of the mandate of, and specifications of the tasks of, the Chair, detailed arrangements for voting, and the organisation of the Board's activities and those of its sub-groups.
Art. 65. 8 The Board shall be chaired by one of the representatives of the Member States. The AI Office shall provide the secretariat for the Board, convene the meetings upon request of the Chair, and prepare the agenda in accordance with the tasks of the Board pursuant to this Regulation and its rules of procedure.
Art. 66. Tasks of the Board
Art. 67. 1 An advisory forum shall be established to provide technical expertise and advise the Board and the Commission, and to contribute to their tasks under this Regulation.
Art. 67. 2 The scientific panel shall consist of experts provided by the Commission on the basis of up-to-date scientific or technical expertise in the field of AI necessary for the tasks set out in paragraph 3, and shall be able to demonstrate meeting all of the following conditions:
Art. 68. 3 The scientific panel shall advise and support the AI Office, in particular with regard to the following tasks:
Art. 68. 4 The experts on the scientific panel shall perform their tasks with impartiality and objectivity, and shall ensure the confidentiality of information and data obtained in carrying out their tasks and activities. They shall neither seek nor take instructions from anyone when exercising their tasks under paragraph 3. Each expert shall submit a declaration of interests, which shall be made publicly available. The authority shall establish systems and procedures to actively manage and prevent any conflicts of interest.
Art. 68. 5 The implementing act referred to in paragraph 1 shall include provisions on the conditions, procedures and detailed arrangements for the scientific panel and its members to issue alerts, and to request the assistance of the AI Office for the performance of the tasks of the scientific panel.
Art. 68. 6 Each Member State shall establish or designate as national competent authorities at least one notifying authority and at least one market surveillance authority for the purposes of this Regulation. Those national competent authorities shall exercise their powers independently, impartially and without bias so as to safeguard the objectivity of their activities and tasks, and to ensure the application and implementation of this Regulation. The members of those authorities shall refrain from any action incompatible with their duties. Provided that those principles are observed, such activities and tasks may be performed by one or more designated authorities, in accordance with the organisational needs of the Member State.
Art. 70. 2 Member States shall ensure that their national competent authorities are provided with adequate technical, financial and human resources, and with infrastructure to fulfil their tasks effectively under this Regulation. In particular, the national competent authorities shall have a sufficient number of personnel permanently available whose competences and expertise shall include an in-depth understanding of AI technologies, data and data computing, personal data protection, cybersecurity, fundamental rights, health and safety risks and knowledge of existing standards and legal requirements. Member States shall assess and, if necessary, update competence and resource requirements referred to in this paragraph on an annual basis.
Art. 70. 5 When performing their tasks, the national competent authorities shall act in accordance with the confidentiality obligations set out in Article 78.
Art. 74. 7 By way of derogation from paragraph 6, in appropriate circumstances, and provided that coordination is ensured, another relevant authority may be identified by the Member State as market surveillance authority for the purposes of this Regulation. National market surveillance authorities supervising regulated credit institutions regulated under Directive 2013/36/EU, which are participating in the Single Supervisory Mechanism established by Regulation (EU) No 1024/2013, should report, without delay, to the European Central Bank any information identified in the course of their market surveillance activities that may be of potential interest for the prudential supervisory tasks of the European Central Bank specified in that Regulation.
Art. 74. 12 Without prejudice to the powers provided for under Regulation (EU) 2019/1020, and where relevant and limited to what is necessary to fulfil their tasks, the market surveillance authorities shall be granted full access by providers to the documentation as well as the training, validation and testing data sets used for the development of high-risk AI systems, including, where appropriate and subject to security safeguards, through application programming interfaces (API) or other relevant technical means and tools enabling remote access.
Art. 78. 1 The Commission, market surveillance authorities and notified bodies and any other natural or legal person involved in the application of this Regulation shall, in accordance with Union or national law, respect the confidentiality of information and data obtained in carrying out their tasks and activities in such a manner as to protect, in particular:
Art. 84. 1 The Commission shall designate one or more Union AI testing support structures to perform the tasks listed under Article 21(6) of Regulation (EU) 2019/1020 in the area of AI.
Art. 84. 2 Without prejudice to what is referred to in paragraph 1, Union AI testing support structures shall also provide independent technical or scientific advice at the request of the Board, the Commission, or of market surveillance authorities.
Art. 88. 1 The Commission shall have exclusive powers to supervise and enforce Chapter V, taking into account the procedural guarantees under Article 94. The Commission shall entrust the implementation of these tasks to the AI Office, without prejudice to the powers of organisation of the Commission and the division of competences between Member States and the Union based on the Treaty.
Art. 88. 2 Without prejudice to the powers of organisation of the Commission, the Commission shall exercise the powers laid down in this Section, where that is necessary and proportionate to assist with the fulfilment of their tasks under this Regulation.
Art. 89. 1 For the purpose of carrying out the tasks assigned to it under this Section, the AI Office may take the necessary actions to monitor the effective implementation and compliance with this Regulation by providers of general-purpose AI models, including their adherence to approved codes of practice.
Art. 89. 2 Upon a duly substantiated request from the scientific panel, the Commission may issue a request for information to a provider of a general-purpose AI model, where the access to information is necessary and proportionate for the fulfilment of the tasks of the scientific panel under Article 68(2).
Art. 92. 2 The Commission may decide to appoint independent experts to carry out evaluations on its behalf, including from the scientific panel established pursuant to Article 68. Independent experts appointed for this task shall meet the criteria outlined in Article 68(2).
Art. 112. 1(a) The AI Office shall have the necessary resources of the national competent authorities in order to effectively perform the tasks assigned to them under this Regulation.
Art. 112. 5 By 2 August 2028, the Commission shall evaluate the functioning of the AI Office, whether the AI Office has been given sufficient powers and competences to fulfil its tasks, and whether it would be relevant and needed for the proper implementation and enforcement of this Regulation to upgrade the AI Office and its enforcement competences and to increase its resources. The Commission shall submit a report on its evaluation to the European Parliament and to the Council.

0 Taxonomy

23 Technical documentation

- Art. 3. (12) 'intended purpose' means the use for which an AI system is intended by the provider, including the specific context and conditions of use, as specified in the information supplied by the provider in the instructions for use, promotional or sales materials and statements, as well as in the technical documentation;
Art. 11. Technical documentation
Art. 11. 1 The technical documentation of a high-risk AI system shall be drawn up before that system is placed on the market or put into service and shall be kept up-to-date. The technical documentation shall be drawn up in such a way as to demonstrate that the high-risk AI system complies with the requirements set out in this Section and to provide national competent authorities and notified bodies with the necessary information in a clear and comprehensive form to assess the compliance of the AI system with those requirements. It shall contain, at a minimum, the elements set out in Annex IV. SMEs, including start-ups, may provide the elements of the technical documentation specified in Annex IV in a simplified manner. To that end, the Commission shall establish a simplified technical documentation form targeted at the needs of small and microenterprises. Where an SME, including a start-up, opts to provide the information referred in Annex IV in a simplified manner, it shall use the form referred to in this paragraph. Notified bodies shall accept the form for the purposes of the conformity assessment.
Art. 11. 2 Where a high-risk AI system related to a product covered by the Union harmonisation legislation listed in Section A of Annex I is placed on the market or put into service, a single set of technical documentation shall be drawn up containing all the information set out in paragraph 1, as well as the information required under those legal acts.
Art. 11. 3 The Commission is empowered to adopt delegated acts in accordance with Article 97 in order to amend Annex IV, where necessary, to ensure that, in light of technical progress, the technical documentation provides all the information necessary to assess the compliance of the system with the requirements set out in this Section.
Art. 15. 1(a), the technical documentation referred to in Article 11;
Art. 15. 4 Providers that are financial institutions subject to requirements regarding their internal governance, arrangements or processes under Union financial services law shall maintain the technical documentation as part of the documentation kept under the relevant Union financial services law.
Art. 22. 3(a), verify that the EU declaration of conformity referred to in Article 47 and the technical documentation referred to in Article 11 have been drawn up and that an appropriate conformity assessment procedure has been carried out by the provider;
Art. 22. 3(b), keep at the disposal of the competent authorities and national authorities or bodies referred to in Article 74(10), for a period of 10 years after the high-risk AI system has been placed on the market or put into service, the contact details of the provider that appointed the authorised representative, a copy of the EU declaration of conformity referred to in Article 47, the technical documentation and, if applicable, the certificate issued by the notified body;
Art. 23. 1(b), the provider has drawn up the technical documentation in accordance with Article 11 and Annex IV;
Art. 23. 6 Importers shall provide the relevant competent authorities, upon a reasoned request, with all the necessary information and documentation, including that referred to in paragraph 5, to demonstrate the conformity of a high-risk AI system with the requirements set out in Section 2 in a language which can be easily understood by them. For this purpose, they shall also ensure that the technical documentation can be made available to those authorities.
Art. 43. 1(b), the assessment of the quality management system and the assessment of the technical documentation, with the involvement of a notified body, referred to in Annex VII. In demonstrating the compliance of a high-risk AI system with the requirements set out in Section 2, the provider shall follow the conformity assessment procedure set out in Annex VII where:
Art. 43. 4 High-risk AI systems that have already been subject to a conformity assessment procedure shall undergo a new conformity assessment procedure in the event of a substantial modification, regardless of whether the modified system is intended to be further distributed or continues to be used by the current deployer. For high-risk AI systems that continue to learn after being placed on the market or put into service, changes to the high-risk AI system and its performance that have been pre-determined by the provider at the moment of the initial conformity assessment and are part of the information contained in the technical documentation referred to in point 2(f) of Annex IV, shall not constitute a substantial modification.
Art. 45. 1(a), any Union technical documentation assessment certificates, any supplements to those certificates, and any quality management system approvals issued in accordance with the requirements of Annex VII;
Art. 45. 1(b), any refusal, restriction, suspension or withdrawal of a Union technical documentation assessment certificate or a quality management system approval issued in accordance with the requirements of Annex VII;
Art. 45. 2(b), Union technical documentation assessment certificates or any supplements thereto which it has refused, withdrawn, suspended or otherwise restricted, and, upon request, of the certificates and/or supplements thereto which it has issued.
Art. 53. 1(a), draw up and keep up-to-date the technical documentation of the model, including its training and testing process and the results of its evaluation, which shall contain, at a minimum, the information set out in Annex XI for the purpose of providing it, upon request, to the AI Office and the national competent authorities;
Art. 54. 3(a), verify that the technical documentation specified in Annex XI has been drawn up and all obligations referred to in Article 53 and, where applicable, Article 55 have been fulfilled by the provider;
Art. 54. 3(b), keep a copy of the technical documentation specified in Annex XI at the disposal of the AI Office and national competent authorities, for a period of 10 years after the general-purpose AI model has been placed on the market, and the contact details of the provider that appointed the authorised representative;
Art. 59. 1(i), a complete and detailed description of the process and rationale behind the training, testing and validation of the AI system is kept together with the testing results as part of the technical documentation referred to in Annex IV;
Art. 72. 3 The post-market monitoring system shall be based on a post-market monitoring plan. The post-market monitoring plan shall be part of the technical documentation referred to in Annex IV. The Commission shall adopt an implementing act laying down detailed provisions establishing a template for the post-market monitoring plan and the list of elements to be included in the plan by 2 February 2029. That implementing act shall be adopted in accordance with the examination procedure referred to in Article 98(2).
Art. 78. 3 Without prejudice to paragraphs 1 and 2, information exchanged on a confidential basis between the national competent authorities or between national competent authorities and the Commission shall not be disclosed without prior consultation of the originating national competent authority and the deployer when high-risk AI systems referred to in point 1, 6 or 7 of Annex III are used by law enforcement, border control, immigration or asylum authorities and when such disclosure would jeopardise public and national security interests. This exchange of information shall not cover sensitive operational data in relation to the activities of law enforcement, border control, immigration or asylum authorities. When the law enforcement, immigration or asylum authorities are providers of high-risk AI systems referred to in point 1, 6 or 7 of Annex III, the technical documentation referred to in Annex IV shall remain within the premises of those authorities. Those authorities shall ensure that the market surveillance authorities referred to in Article 74(8) and (9), as applicable, can, upon request, immediately access the documentation or obtain a copy thereof. Only staff of the market surveillance authority holding the appropriate level of security clearance shall be allowed to access that documentation or any copy thereof.
Art. 83. 1(g), technical documentation is not available.

0 Terms related to data

0 Test data

Terms and AI Act Articles

7.1 Testing

- Art. 2, 8:** This Regulation does not apply to any research, testing or development activity regarding AI systems or AI models prior to their being placed on the market or put into service. Such activities shall be conducted in accordance with applicable Union law. Testing in real world conditions shall not be covered by that exclusion.
- Art. 3, (21):** 'conformity assessment body' means a body that performs third-party conformity assessment activities, including testing, certification and inspection;
- Art. 3, (32):** 'testing data' means data used for providing an independent evaluation of the AI system in order to confirm the expected performance of that system before its placing on the market or putting into service;
- Art. 3, (53):** 'real-world testing plan' means a document that describes the objectives, methodology, geographical, population and temporal scope, monitoring, organisation and conduct of testing in real-world conditions;
- Art. 3, (57):** 'testing in real-world conditions' means the temporary testing of an AI system for its intended purpose in real-world conditions outside a laboratory or otherwise simulated environment, with a view to gathering reliable and robust data and to assessing and verifying the conformity of the AI system with the requirements of this Regulation and it does not qualify as placing the AI system on the market or putting it into service within the meaning of this Regulation, provided that all the conditions laid down in Article 57 or 60 are fulfilled;
- Art. 3, (58):** 'subject', for the purpose of real-world testing, means a natural person who participates in testing in real-world conditions;
- Art. 3, (59):** 'informed consent' means a subject's freely given, specific, unambiguous and voluntary expression of his or her willingness to participate in a particular testing in real-world conditions, after having been informed of all aspects of the testing that are relevant to the subject's decision to participate;
- Art. 8, 2:** Where a product contains an AI system, to which the requirements of this Regulation as well as requirements of the Union harmonisation legislation listed in Section A of Annex I apply, providers shall be responsible for ensuring that their product is fully compliant with all applicable requirements under applicable Union harmonisation legislation. In ensuring the compliance of high-risk AI systems referred to in paragraph 1 with the requirements set out in this Section, and in order to ensure consistency, avoid duplication and minimise additional burdens, providers shall have a choice of integrating, as appropriate, the necessary testing and reporting processes, information and documentation they provide with regard to their product into documentation and procedures that already exist and are required under the Union harmonisation legislation listed in Section A of Annex I.
- Art. 9, 6:** High-risk AI systems shall be tested for the purpose of identifying the most appropriate and targeted risk management measures. Testing shall ensure that high-risk AI systems perform consistently for their intended purpose and that they are in compliance with the requirements set out in this Section.
- Art. 9, 7:** Testing procedures may include testing in real-world conditions in accordance with Article 60.
- Art. 9, 8:** The testing of high-risk AI systems shall be performed, as appropriate, at any time throughout the development process, and, in any event, prior to their being placed on the market or put into service. Testing shall be carried out against prior defined metrics and probabilistic thresholds that are appropriate to the intended purpose of the high-risk system.
- Art. 10, 1:** High-risk AI systems which make use of techniques involving the training of AI models with data shall be developed on the basis of training, validation and testing data sets that meet the quality criteria referred to in paragraphs 2 to 5 whenever such data sets are used.
- Art. 10, 2:** Training, validation and testing data sets shall be subject to data governance and management practices appropriate for the intended purpose of the high-risk AI system. Those practices shall concern in particular:
- Art. 10, 3:** Training, validation and testing data sets shall be relevant, sufficiently representative, and to the best extent possible, free of errors and complete in view of the intended purpose. They shall have the appropriate statistical properties, including, where applicable, as regards the persons or groups of persons in relation to whom the high-risk AI system is intended to be used. Those characteristics of the data sets may be met at the level of individual data sets or at the level of a combination thereof.
- Art. 10, 4:** For the development of high-risk AI systems not using techniques involving the training of AI models, paragraphs 2 to 5 apply only to the testing data sets.
- Art. 13, 3(b)(vi):** when appropriate, specifications for the input data, or any other relevant information in terms of the training, validation and testing data sets used, taking into account the intended purpose of the high-risk AI system;
- Art. 53, (a):** draw up and keep up-to-date the technical documentation of the model, including its training and testing process and the results of its evaluation, which shall contain, at a minimum, the information set out in Annex XI for the purpose of providing it, upon request, to the AI Office and the national competent authorities;
- Art. 55, (1a):** perform model evaluation in accordance with standardised protocols and tools reflecting the state of the art, including conducting and documenting adversarial testing of the model with a view to identifying and mitigating systemic risks;
- Art. 57, 3:** AI regulatory sandboxes established under paragraph 1 shall provide for a controlled environment that fosters innovation and facilitates the development, training, testing and validation of innovative AI systems for a limited time before their being placed on the market or put into service pursuant to a specific sandbox plan agreed between the providers or prospective providers and the competent authority. Such sandboxes may include testing in real-world conditions supervised therein.
- Art. 57, 4:** Competent authorities shall provide, as appropriate, guidance, supervision and support within the AI regulatory sandbox with a view to identifying risks, in particular to fundamental rights, health and safety, testing, mitigation measures, and their effectiveness in relation to the obligations and requirements of this Regulation and, where relevant, other Union and national law supervised within the sandbox.
- Art. 57, 7:** The AI regulatory sandboxes shall not affect the supervisory or corrective powers of the competent authorities specified in Article 60. Providers or prospective providers of high-risk AI systems referred to in paragraph 1 may temporarily or permanently suspend the testing process, or the participation in the sandbox if no effective mitigation is possible, and shall inform the AI Office of such decision. National competent authorities shall exercise their supervisory powers within the limits of the relevant law, using their discretionary powers when implementing legal provisions in respect of a specific AI regulatory sandbox project, with the objective of supporting innovation in AI in the Member State.
- Art. 58, 2(f):** that AI regulatory sandboxes facilitate the involvement of other relevant actors within the AI ecosystem, such as notified bodies and standardisation organisations, SMEs, including start-ups, enterprises, innovators, testing and experimentation facilities, research and experimentation labs and European Digital Innovation Hubs, centres of excellence, individual researchers, in order to allow and facilitate cooperation with the public and private sectors;
- Art. 58, 2(g):** that AI regulatory sandboxes facilitate the development of tools and infrastructure for testing, benchmarking, assessing and explaining dimensions of AI systems relevant for regulatory learning, such as accuracy, robustness and cybersecurity, as well as measures to mitigate risks to fundamental rights in society at large.
- Art. 58, 3:** Prospective providers in the AI regulatory sandboxes, in particular SMEs and start-ups, shall be directed, where relevant, to pre-deployment services such as guidance on the implementation of this Regulation, to other value-adding services such as help with standardisation efforts and certification.
- Art. 58, 4:** Where national competent authorities consider authorising testing in real world conditions supervised within the framework of an AI regulatory sandbox to be established under this Article, they shall specifically agree the terms and conditions of such testing and, in particular, the appropriate safeguards with the participants, with a view to protecting fundamental rights, health and safety. Where appropriate, they shall cooperate with other national competent authorities with a view to ensuring consistent practices across the Union.
- Art. 59, 1:** In the areas of law enforcement, migration, asylum and border control management, high-risk AI systems referred to in point 2 of Annex III in the areas of law enforcement, migration, asylum and border control management, shall be tested in real-world conditions in accordance with Article 60.
- Art. 59, 1(a):** a complete and detailed description of the process and rationale behind the training, testing and validation of the AI system is kept together with the testing results as part of the technical documentation referred to in Annex IV;
- Art. 59, 3:** Paragraph 1 is without prejudice to Union or national law which excludes processing of personal data for other purposes than for those explicitly mentioned in that law, as well as to Union or national law laying down the basis for the processing of personal data which is necessary for the purpose of developing, testing or training tools used in compliance with Union law on the protection of personal data.
- Art. 60:** Testing of high-risk AI systems in real world conditions outside AI regulatory sandboxes
- Art. 60, 1:** Testing of high-risk AI systems in real world conditions outside AI regulatory sandboxes may be conducted by providers or prospective providers of high-risk AI systems listed in Annex III. In accordance with this Article and the real-world testing plan referred to in Article 60, testing shall be without prejudice to Union or national law on the testing in real world conditions of high-risk AI systems referred to products covered by Union harmonisation legislation listed in Annex I.
- Art. 60, 2:** Providers or prospective providers may conduct testing of high-risk AI systems referred to in Annex III in real world conditions at any time before the placing on the market or the putting into service of the AI system on their own or in partnership with one or more deployers or prospective deployers.
- Art. 60, 3:** The testing of high-risk AI systems in real world conditions under this Article shall be without prejudice to any ethical review that is required by Union or national law.
- Art. 60, 4:** Providers or prospective providers may conduct the testing in real world conditions only where all of the following conditions are met:
- Art. 60, 4(a):** the provider or prospective provider has drawn up a real-world testing plan and submitted it to the market surveillance authority in the Member State where the testing in real world conditions is to be conducted;
- Art. 60, 4(b):** the market surveillance authority in the Member State where the testing in real world conditions is to be conducted has approved the testing in real world conditions and the real-world testing plan; where the market surveillance authority has not provided an answer within 30 days, the testing in real world conditions and the real-world testing plan shall be understood to have been approved; where national law does not provide for a tacit approval, the testing in real world conditions shall remain subject to an authorisation;
- Art. 60, 4(c):** the provider or prospective provider has registered the testing in real world conditions in the secure non-public section of the EU database according to Article 49(4), point (d), with a Union-wide unique single identification number and with the information specified in Annex IV;
- Art. 60, 4(d):** the provider or prospective provider conducting the testing in real world conditions is established in the Union or has appointed a legal representative who is established in the Union;
- Art. 60, 4(e):** data collected and processed for the purpose of the testing in real world conditions shall be transferred to third countries only provided that appropriate and applicable safeguards under Union law are implemented;
- Art. 60, 4(f):** the testing in real world conditions does not last longer than necessary to achieve its objectives and in any case not longer than six months, which may be extended for an additional period of six months, subject to prior notification by the provider or prospective provider to the market surveillance authority, accompanied by an explanation of the need for such an extension;
- Art. 60, 4(g):** the subjects of the testing in real world conditions who are persons belonging to vulnerable groups due to their age or disability, are appropriately protected;
- Art. 60, 4(h):** where a provider or prospective provider organises the testing in real world conditions in cooperation with one or more deployers or prospective deployers, the latter have been informed of all aspects of the testing that are relevant to their decision to participate, and given the relevant instructions for use of the AI system referred to in Article 13; the provider or prospective provider and the deployer or prospective deployer shall conclude an agreement specifying their roles and responsibilities with a view to ensuring compliance with the provisions for testing in real world conditions under this Regulation and under other applicable Union and national law;
- Art. 60, 4(i):** the subjects of the testing in real world conditions have given informed consent in accordance with Article 61, or in the case of law enforcement, where the seeking of informed consent would prevent the AI system from being tested, the testing itself and the outcome of the testing in the real world conditions shall not have any negative effect on the subjects, and their personal data shall be deleted after the test is performed;
- Art. 60, 4(j):** the testing in real world conditions is effectively overseen by the provider or prospective provider, as well as by deployers or prospective deployers through persons who are suitably qualified in the relevant field and have the necessary capacity, training and authority to perform their tasks.
- Art. 60, 5:** Any subjects of the testing in real world conditions, or their legally designated representative, as appropriate, may, without any resulting detriment and without having to provide any justification, withdraw from the testing at any time by revoking their informed consent and may request the immediate and permanent deletion of their personal data. The withdrawal of the informed consent shall not affect the activities already carried out.
- Art. 60, 6:** In accordance with Article 75, Member States shall confer on their market surveillance authorities the powers requiring providers and prospective providers to provide information, of carrying out unannounced remote or on-site inspections, and of performing checks on the conduct of the testing in real world conditions and the related high-risk AI systems. Market surveillance authorities shall use those powers to ensure the safe development of testing in real world conditions.
- Art. 60, 7:** Any suspension identified in the course of the testing in real world conditions shall be reported to the national market surveillance authority in accordance with Article 73. The provider or prospective provider shall adopt immediate mitigation measures or, failing that, shall suspend the testing in real world conditions until such mitigation takes place, or otherwise terminate it. The provider or prospective provider shall establish a procedure for the prompt recall of the AI system upon such termination of the testing in real world conditions.
- Art. 60, 8:** Providers or prospective providers shall notify the national market surveillance authority in the Member State where the testing in real world conditions is to be conducted of the suspension or termination of the testing in real world conditions and of the final outcomes.
- Art. 60, 9:** The provider or prospective provider shall be liable under applicable Union and national law for any damage caused in the course of their testing in real world conditions.
- Art. 61:** Informed consent to participate in testing in real world conditions outside AI regulatory sandboxes
- Art. 61, 1:** For the purpose of testing in real world conditions under Article 60, freely-given informed consent shall be obtained from the subjects of testing prior to their participation in such testing and after their having been duly informed with concise, clear, relevant, and understandable information regarding:
- Art. 61, 1(a):** the nature and objectives of the testing in real world conditions and the possible inconvenience that may be linked to their participation;
- Art. 61, 1(b):** the conditions under which the testing in real world conditions is to be conducted, including the expected duration of the subject's or subjects' participation;
- Art. 61, 1(c):** their rights, and the guarantees regarding their participation, in particular their right to refuse to participate in, and the right to withdraw from, testing in real world conditions at any time without any resulting detriment and without having to provide any justification;
- Art. 61, 1(e):** the Union-wide unique single identification number of the testing in real world conditions in accordance with Article 60(4) point (c), and the contact details of the provider or its legal representative from whom further information can be obtained.
- Art. 61, 2:** The informed consent shall be dated and documented and a copy shall be given to the subjects of testing or their legal representative.
- Art. 61, 3:** The contribution to the harmonisation of administrative practices in the Member States, including in relation to the derogation from the conformity assessment procedures referred to in Article 46, the functioning of AI regulatory sandboxes, and testing in real world conditions referred to in Articles 57, 59 and 60;
- Art. 69, 3:** The Commission shall facilitate timely access to the experts by the Member States, as needed, and ensure that the combination of support activities carried out by Union AI testing support pursuant to Article 84 and experts pursuant to this Article is efficiently organised and performs the best possible results.
- Art. 74, 12:** Without prejudice to the powers provided for under Regulation (EU) 2019/1020, and where relevant and limited to what is necessary to fulfil their tasks, the market surveillance authorities shall be granted full access by providers to the documentation as well as the training, validation and testing data sets used for the development of high-risk AI systems, including, where appropriate and subject to security safeguards, through application programming interfaces (API) or other relevant technical means and tools enabling remote access.
- Art. 74, 13(b):** testing or auditing procedures and verification and documentation provided by the provider have been exhausted or proved insufficient.
- Art. 76:** Supervision of testing in real world conditions by market surveillance authorities
- Art. 76, 1:** Market surveillance authorities shall have competences and powers to ensure that testing in real world conditions is in accordance with this Regulation.
- Art. 76, 2:** Where testing in real world conditions is conducted in an AI regulatory sandbox under Article 58, the market surveillance authorities shall verify the compliance with Article 60 as part of their supervisory role for the AI regulatory sandbox. Those authorities may, as appropriate, allow the testing in real world conditions to be conducted by the provider or prospective provider, in derogation from the conditions set out in Article 60(4), points (f) and (g).
- Art. 76, 3(a):** to suspend or terminate the testing in real world conditions;
- Art. 76, 3(b):** to request the provider or prospective provider and the deployer or prospective provider to modify any aspect of the testing in real world conditions.
- Art. 76, 3:** Where applicable, where a market surveillance authority has taken a decision referred to in paragraph 3, it shall communicate the grounds thereof to the market surveillance authorities of other Member States in which the AI system has been tested in accordance with the testing plan.
- Art. 77, 3:** Where the documentation referred to in paragraph 1 is insufficient to ascertain whether an infringement of obligations under Union law protecting fundamental rights has occurred, the public authority or body referred to in paragraph 1 may make a reasoned request to the market surveillance authority, to organise testing of the high-risk AI system through technical means. The market surveillance authority shall organise the testing with the close involvement of the requesting public authority or body within a reasonable time following the request.
- Art. 84:** Union AI testing support structures
- Art. 84, 1:** The Commission or one or more Union AI testing support structures to perform the tasks listed under Article 21(6) of Regulation (EU) 2019/1020 in the area of AI.
- Art. 84, 2:** Without prejudice to the tasks referred to in paragraph 1, Union AI testing support structures shall also provide independent technical or scientific advice at the request of the Board, the Commission, or of market surveillance authorities.
- Art. 92, 7:** Prior to requesting access to the general-purpose AI model concerned, the AI Office may initiate a structured dialogue with the provider of the general-purpose AI model to gather more information on the internal testing of the model, internal safeguards for preventing systemic risks, and other internal procedures and measures the provider has taken to mitigate such risks.
- Art. 105:** In Article 8 of Directive 2014/90/EU, the following paragraph is added: ⁵ For Artificial Intelligence systems which are safety components within the meaning of Regulation (EU) 2024/1689 of the European Parliament and of the Council ⁽⁴⁾, when carrying out its activities pursuant to paragraph 1 and when adopting technical specifications and testing standards in accordance with paragraphs 2 and 3, the Commission shall take into account the requirements set out in Chapter III, Section 2, of that Regulation.

7.2 Testing data

- Art. 3, (32):** 'testing data' means data used for providing an independent evaluation of the AI system in order to confirm the expected performance of that system before its placing on the market or putting into service;
- Art. 10, 1:** High-risk AI systems which make use of techniques involving the training of AI models with data shall be developed on the basis of training, validation and testing data sets that meet the quality criteria referred to in paragraphs 2 to 5 whenever such data sets are used.
- Art. 10, 2:** Training, validation and testing data sets shall be subject to data governance and management practices appropriate for the intended purpose of the high-risk AI system. Those practices shall concern in particular:
- Art. 10, 3:** Training, validation and testing data sets shall be relevant, sufficiently representative, and to the best extent possible, free of errors and complete in view of the intended purpose. They shall have the appropriate statistical properties, including, where applicable, as regards the persons or groups of persons in relation to whom the high-risk AI system is intended to be used. Those characteristics of the data sets may be met at the level of individual data sets or at the level of a combination thereof.
- Art. 10, 4:** For the development of high-risk AI systems not using techniques involving the training of AI models, paragraphs 2 to 5 apply only to the testing data sets.
- Art. 13, 3(b)(vi):** when appropriate, specifications for the input data, or any other relevant information in terms of the training, validation and testing data sets used, taking into account the intended purpose of the high-risk AI system;
- Art. 14, 12:** Without prejudice to the powers provided for under Regulation (EU) 2019/1020, and where relevant and limited to what is necessary to fulfil their tasks, the market surveillance authorities shall be granted full access by providers to the documentation as well as the training, validation and testing data sets used for the development of high-risk AI systems, including, where appropriate and subject to security safeguards, through application programming interfaces (API) or other relevant technical means and tools enabling remote access.

6 Testing in real-world conditions

- Art. 3, (53):** 'real-world testing plan' means a document that describes the objectives, methodology, geographical, population and temporal scope, monitoring, organisation and conduct of testing in real-world conditions;
- Art. 3, (57):** 'testing in real-world conditions' means the temporary testing of an AI system for its intended purpose in real-world conditions outside a laboratory or otherwise simulated environment, with a view to gathering reliable and robust data and to assessing and verifying the conformity of the AI system with the requirements of this Regulation and it does not qualify as placing the AI system on the market or putting it into service within the meaning of this Regulation, provided that all the conditions laid down in Article 57 or 60 are fulfilled;
- Art. 3, (58):** 'subject', for the purpose of real-world testing, means a natural person who participates in testing in real-world conditions;
- Art. 3, (59):** 'informed consent' means a subject's freely given, specific, unambiguous and voluntary expression of his or her willingness to participate in a particular testing in real-world conditions, after having been informed of all aspects of the testing that are relevant to the subject's decision to participate.
- Art. 9, 7:** Testing procedures may include testing in real-world conditions in accordance with Article 60.
- Art. 60, 4(c):** the provider or prospective provider has registered the testing in real world conditions in the secure non-public section of the EU database according to Article 49(4), point (d), with a Union-wide unique single identification number and with the information specified therein; the provider or prospective provider of high-risk AI systems referred to in points 1, 6 and 7 of Annex III in the areas of law enforcement, migration, asylum and border control management, has registered the testing in real-world conditions in the secure non-public section of the EU database according to Article 49(4), point (d), with a Union-wide unique single identification number and with the information specified therein; the provider or prospective provider of high-risk AI systems referred to in point 2 of Annex III has registered the testing in real-world conditions in accordance with Article 49(5);

0 Time series

0 Timeliness

1 Traceability

- Art. 12, 2:** In order to ensure a level of traceability of the functioning of a high-risk AI system that is appropriate to the intended purpose of the system, logging capabilities shall enable the recording of events relevant for:

Terms and AI Act Articles

25 Training

Art. 3 (29): 'training data' means data used for training an AI system through fitting its learnable parameters;

Art. 3 (31): 'validation data set' means a separate data set or part of the training data set, either as a fixed or variable split;

Art. 4: Providers and deployers of AI systems shall take measures to ensure, to their best extent, a sufficient level of AI literacy of their staff and other persons dealing with the operation and use of AI systems on their behalf, taking into account their technical knowledge, experience, education and training and the context the AI systems are to be used in, and considering the persons or groups of persons on whom the AI systems are to be used.

Art. 9, 5(c): provision of information required pursuant to Article 13 and, where appropriate, training to deployers. With a view to eliminating or reducing risks related to the use of the high-risk AI system, due consideration shall be given to the technical knowledge, experience, education, the training to be expected by the deployer, and the presumable context in which the system is intended to be used.

Art. 10, 1: High-risk AI systems which make use of techniques involving the training of AI models with data shall be developed on the basis of training, validation and testing data sets that meet the quality criteria referred to in paragraphs 2 to 5 whenever such data sets are used.

Art. 10, 2: Training, validation and testing data sets shall be subject to data governance and management practices appropriate for the intended purpose of the high-risk AI system. Those practices shall concern in particular:

Art. 10, 3: Training, validation and testing data sets shall be relevant, sufficiently representative, and to the best extent possible, free of errors and complete in view of the intended purpose. They shall have the appropriate statistical properties, including, where applicable, as regards the persons or groups of persons in relation to whom the high-risk AI system is intended to be used. Those characteristics of the data sets may be met at the level of individual data sets or at the level of a combination thereof.

Art. 10, 6: For the development of high-risk AI systems not using techniques involving the training of AI models, paragraphs 2 to 5 apply only to the testing data sets.

Art. 13, 3(b)(vi): when appropriate, specifications for the input data, or any other relevant information in terms of the training, validation and testing data sets used, taking into account the intended purpose of the high-risk AI system;

Art. 14, 3: For high-risk AI systems referred to in point (1a) of Annex III, the measures referred to in paragraph 3 of this Article shall be such as to ensure that, in addition, no action or decision is taken by the deployer on the basis of the identification resulting from the system unless that identification has been separately verified and confirmed by at least two natural persons with the necessary competence, training and authority. The requirement for a separate verification by at least two natural persons shall not apply to high-risk AI systems used for the purposes of law enforcement, migration, border control or asylum, where Union or national law considers the application of this requirement to be disproportionate.

Art. 15, 3: High-risk AI systems shall be resilient against attempts by unauthorised third parties to alter their use, outputs or performance by exploiting system vulnerabilities. The technical solutions aiming to ensure the cybersecurity of high-risk AI systems shall be appropriate to the relevant circumstances and the risks. The technical solutions to address AI specific vulnerabilities shall include, where appropriate, measures to prevent, detect, respond to, resolve and control for attacks trying to manipulate the training data set (data poisoning), or pre-trained components used in training (model poisoning), inputs designed to cause the AI model to make a mistake (adversarial examples or model evasion), confidentiality attacks or model flaws.

Art. 25, 2: Deployers shall assign human oversight to natural persons who have the necessary competence, training and authority, as well as the necessary support.

Art. 51, 2: A general-purpose AI model shall be presumed to have high impact capabilities pursuant to paragraph 1, point (a), when the cumulative amount of computation used for its training measured in floating point operations is greater than 1025.

Art. 53, 1(a): draw up and keep up-to-date the technical documentation of the model, including its training and testing process and the results of its evaluation, which shall contain, at a minimum, the information set out in Annex XI for the purpose of providing it, upon request, to the AI Office and the national competent authorities;

Art. 53, 1(d): draw up and make publicly available a sufficiently detailed summary about the content used for training of the general-purpose AI model, according to a template provided by the AI Office.

Art. 56, 2(b): the adequate level of detail for the summary about the content used for training;

Art. 57, 3: AI regulatory sandboxes established under paragraph 1 shall provide for a controlled environment that fosters innovation and facilitates the development, training, testing and validation of innovative AI systems for a limited time before their being placed on the market or put into service pursuant to a specific sandbox plan agreed between the providers or prospective providers and the competent authority. Such sandboxes may include testing in real world conditions supervised therein.

Art. 59, 1: In the AI regulatory sandbox, personal data lawfully collected for other purposes may be processed solely for the purpose of developing, training and testing certain AI systems in the sandbox when all of the following conditions are met:

Art. 59, 1(a): a complete and detailed description of the process and rationale behind the training, testing and validation of the AI system is kept together with the testing results as part of the technical documentation referred to in Annex IV;

Art. 59, 3: Paragraph 1 is without prejudice to Union or national law which excludes processing of personal data for other purposes than those explicitly mentioned in that law, as well as to Union or national law laying down the basis for the processing of personal data which is necessary for the purpose of developing, testing or training of innovative AI systems or any other legal basis, in compliance with Union law on the protection of personal data.

Art. 60, 4(i): the testing in real world conditions is effectively overseen by the provider or prospective provider, as well as by deployers or prospective deployers through persons who are suitably qualified in the relevant field and have the necessary capacity, training and authority to perform their tasks;

Art. 62, 1(b): organise specific awareness raising and training activities on the application of this Regulation tailored to the needs of SMEs including start-ups, deployers and, as appropriate, local public authorities;

Art. 66, 1(i): assist national competent authorities and the Commission in developing the organisational and technical expertise required for the implementation of this Regulation, including by contributing to the assessment of training needs for staff of Member States involved in implementing this Regulation;

Art. 74, 12: Without prejudice to the powers provided for under Regulation (EU) 2019/1020, and where relevant and limited to what is necessary to fulfil their tasks, the market surveillance authorities shall be granted full access to the documentation as well as the training, validation and testing data sets used for the development of high-risk AI systems, including, where appropriate and subject to security safeguards, through application programming interfaces (API) or other relevant technical means and tools enabling remote access.

Art. 95, 2(b): assessing and minimising the impact of AI systems on environmental sustainability, including as regards energy-efficient programming and techniques for the efficient design, training and use of AI;

3 Training data

Art. 3 (29): 'training data' means data used for training an AI system through fitting its learnable parameters;

Art. 3 (31): 'validation data set' means a separate data set or part of the training data set, either as a fixed or variable split;

Art. 4: Providers and deployers of AI systems shall take measures to ensure, to their best extent, a sufficient level of AI literacy of their staff and other persons dealing with the operation and use of AI systems on their behalf, taking into account their technical knowledge, experience, education and training and the context the AI systems are to be used in, and considering the persons or groups of persons on whom the AI systems are to be used.

Art. 9, 5(c): provision of information required pursuant to Article 13 and, where appropriate, training to deployers. With a view to eliminating or reducing risks related to the use of the high-risk AI system, due consideration shall be given to the technical knowledge, experience, education, the training to be expected by the deployer, and the presumable context in which the system is intended to be used.

Art. 10, 1: High-risk AI systems which make use of techniques involving the training of AI models with data shall be developed on the basis of training, validation and testing data sets that meet the quality criteria referred to in paragraphs 2 to 5 whenever such data sets are used.

Art. 10, 2: Training, validation and testing data sets shall be subject to data governance and management practices appropriate for the intended purpose of the high-risk AI system. Those practices shall concern in particular:

Art. 10, 3: Training, validation and testing data sets shall be relevant, sufficiently representative, and to the best extent possible, free of errors and complete in view of the intended purpose. They shall have the appropriate statistical properties, including, where applicable, as regards the persons or groups of persons in relation to whom the high-risk AI system is intended to be used. Those characteristics of the data sets may be met at the level of individual data sets or at the level of a combination thereof.

Art. 10, 6: For the development of high-risk AI systems not using techniques involving the training of AI models, paragraphs 2 to 5 apply only to the testing data sets.

Art. 13, 3(b)(vi): when appropriate, specifications for the input data, or any other relevant information in terms of the training, validation and testing data sets used, taking into account the intended purpose of the high-risk AI system;

Art. 14, 3: For high-risk AI systems referred to in point (1a) of Annex III, the measures referred to in paragraph 3 of this Article shall be such as to ensure that, in addition, no action or decision is taken by the deployer on the basis of the identification resulting from the system unless that identification has been separately verified and confirmed by at least two natural persons with the necessary competence, training and authority. The requirement for a separate verification by at least two natural persons shall not apply to high-risk AI systems used for the purposes of law enforcement, migration, border control or asylum, where Union or national law considers the application of this requirement to be disproportionate.

Art. 15, 3: High-risk AI systems shall be resilient against attempts by unauthorised third parties to alter their use, outputs or performance by exploiting system vulnerabilities. The technical solutions aiming to ensure the cybersecurity of high-risk AI systems shall be appropriate to the relevant circumstances and the risks. The technical solutions to address AI specific vulnerabilities shall include, where appropriate, measures to prevent, detect, respond to, resolve and control for attacks trying to manipulate the training data set (data poisoning), or pre-trained components used in training (model poisoning), inputs designed to cause the AI model to make a mistake (adversarial examples or model evasion), confidentiality attacks or model flaws.

11 Transparency

Art. 1, 2(d): harmonised transparency rules for certain AI systems;

Art. 13: Transparency and provision of information to deployers

Art. 15, 3: High-risk AI systems shall be designed and developed in such a way as to ensure that their operation is sufficiently transparent to enable deployers to interpret a system's output and use it appropriately. An appropriate type and degree of transparency shall be ensured with a view to achieving compliance with the relevant obligations of the provider and deployer set out in Section 3.

CHAPTER IV: TRANSPARENCY OBLIGATIONS FOR PROVIDERS AND DEPLOYERS OF CERTAIN AI SYSTEMS

Art. 50: Transparency obligations for providers and deployers of certain AI systems

Art. 50, 4: Deployers of an AI system that generates or manipulates image, audio or video content constituting a deep fake, shall disclose that the content has been artificially generated or manipulated. This obligation shall not apply where the use is authorised by law to detect, prevent, investigate or prosecute criminal offences. Where the content forms part of an evidentiary artistic, creative, satirical, fictional or analogous work or programme, the transparency obligations set out in this paragraph are limited to disclosure of the existence of such generated or manipulated content in an appropriate manner that does not hamper the display or enjoyment of the work. Deployers of an AI system that generates or manipulates text which is published with the purpose of informing the public on matters of public interest shall disclose that the text has been artificially generated or manipulated. This obligation shall not apply where the use is authorised by law to detect, prevent, investigate or prosecute criminal offences or where the AI-generated content has undergone a process of human review or editorial control and where a natural or legal person holds editorial responsibility for the publication of the content.

Art. 50, 6: Paragraphs 1 to 4 shall not affect the requirements and obligations set out in Chapter III, and shall be without prejudice to other transparency obligations laid down in Union or national law for deployers of AI systems.

Art. 96, 1(d): the practical implementation of transparency obligations laid down in Article 50;

Art. 96, 1(g): transparency obligations for providers and deployers pursuant to Article 50;

Art. 112, 2(b): amendments to the list of AI systems requiring additional transparency measures in Article 50;

Art. 112, 11(c): the list of AI systems requiring additional transparency measures pursuant to Article 50.

0 Trustworthiness

2 Trustworthy

Art. 1, 1: The purpose of this Regulation is to improve the functioning of the internal market and promote the uptake of human-centric and trustworthy artificial intelligence (AI), while ensuring a high level of protection of health, safety, fundamental rights enshrined in the Charter, including democracy, the rule of law and environmental protection, against the harmful effects of AI systems in the Union and supporting innovation.

Art. 95, 2(a): applicable elements provided for in Union ethical guidelines for trustworthy AI;

0 Uncertainty

0 Understandability

6 Updating

Art. 9, 2: The risk management system shall be understood as a continuous iterative process planned and run throughout the entire lifecycle of a high-risk AI system, requiring regular systematic review and updating. It shall comprise the following steps:

Art. 10, 2(c): relevant data-preparation processing operations, such as annotation, labelling, cleaning, updating, enrichment and aggregation;

Art. 43, 5: The Commission is empowered to adopt delegated acts in accordance with Article 97 in order to amend Annexes VI and VII by updating them in light of technical progress.

Art. 43, 6: The Commission is empowered to adopt delegated acts in accordance with Article 97 in order to amend Annex V by updating the content of the EU declaration of conformity set out in that Annex, in order to introduce elements that become necessary in light of technical progress.

Art. 52, 4: The Commission may designate a general-purpose AI model as presenting systemic risks, ex officio or following a qualified alert from the scientific panel pursuant to Article 90(1), point (a), on the basis of criteria set out in Annex XIII. The Commission is empowered to adopt delegated acts in accordance with Article 97 in order to amend Annex V by updating the content of the EU declaration of conformity set out in that Annex, in order to introduce elements that become necessary in light of technical progress.

Art. 71, 1: The Commission shall, in collaboration with the Member States, set up and maintain an EU database containing information referred to in paragraphs 2 and 3 of this Article concerning high-risk AI systems referred to in Article 6(2) which are registered in accordance with Articles 49 and 60 and AI systems that are not considered as high-risk pursuant to Article 6(3) and which are registered in accordance with Article 6(4) and Article 49. When setting the functional specifications of such database, the Commission shall consult the relevant experts, and when updating the functional specifications of such database, the Commission shall consult the Board.

0 Usability (See also: Interaction capability)

1 Use case (See also: Segmentation)

Art. 7, 1: The Commission is empowered to adopt delegated acts in accordance with Article 97 to amend Annex III by adding or modifying use-cases of high-risk AI systems where both of the following conditions are fulfilled:

1 User

Art. 71, 4: With the exception of the section referred to in Article 49(4) and Article 60(4), point (c), the information contained in the EU database registered in accordance with Article 49 shall be accessible and publicly available in a user-friendly manner. The information should be easily navigable and machine-readable. The information registered in accordance with Article 60 shall be accessible only to market surveillance authorities and the Commission, unless the prospective provider or provider has given consent for also making the information accessible to the public.

10 Validation

Art. 3 (30): 'validation data' means data used for providing an evaluation of the trained AI system and for tuning its non-learnable parameters and its learning process in order, inter alia, to prevent underfitting or overfitting;

Art. 3 (31): 'validation data set' means a separate data set or part of the training data set, either as a fixed or variable split;

Art. 10, 1: High-risk AI systems which make use of techniques involving the training of AI models with data shall be developed on the basis of training, validation and testing data sets that meet the quality criteria referred to in paragraphs 2 to 5 whenever such data sets are used.

Art. 10, 2: Training, validation and testing data sets shall be subject to data governance and management practices appropriate for the intended purpose of the high-risk AI system. Those practices shall concern in particular:

Art. 10, 3: Training, validation and testing data sets shall be relevant, sufficiently representative, and to the best extent possible, free of errors and complete in view of the intended purpose. They shall have the appropriate statistical properties, including, where applicable, as regards the persons or groups of persons in relation to whom the high-risk AI system is intended to be used. Those characteristics of the data sets may be met at the level of individual data sets or at the level of a combination thereof.

Art. 13, 3(b)(vi): when appropriate, specifications for the input data, or any other relevant information in terms of the training, validation and testing data sets used, taking into account the intended purpose of the high-risk AI system;

Art. 17, 1(d): examination, test and validation procedures to be carried out before, during and after the development of the high-risk AI system, and the frequency with which they have to be carried out;

Art. 15, 3: High-risk AI systems shall be resilient against attempts by unauthorised third parties to alter their use, outputs or performance by exploiting system vulnerabilities. The technical solutions aiming to ensure the cybersecurity of innovative AI systems for a limited time before their being placed on the market or put into service pursuant to a specific sandbox plan agreed between the providers or prospective providers and the competent authority. Such sandboxes may include testing in real world conditions supervised therein.

Art. 59, 1(a): a complete and detailed description of the process and rationale behind the training, testing and validation of the AI system is kept together with the testing results as part of the technical documentation referred to in Annex IV;

Art. 74, 12: Without prejudice to the powers provided for under Regulation (EU) 2019/1020, and where relevant and limited to what is necessary to fulfil their tasks, the market surveillance authorities shall be granted full access to the documentation as well as the training, validation and testing data sets used for the development of high-risk AI systems, including, where appropriate and subject to security safeguards, through application programming interfaces (API) or other relevant technical means and tools enabling remote access.

Terms and AI Act Articles

2 Validation data

Art. 3. (30): 'validation data' means data used for providing an evaluation of the trained AI system and for tuning its non-learnable parameters and its learning process in order, inter alia, to prevent underfitting or overfitting;
Art. 3. (31): 'validation data set' means a separate data set or part of the training data set, either as a fixed or variable split;

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Art. 3. (30): 'validation data' means data used for providing an evaluation of the trained AI system and for tuning its non-learnable parameters and its learning process in order, inter alia, to prevent underfitting or overfitting;
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1 Validation data set

Art. 3. (31): 'validation data set' means a separate data set or part of the training data set, either as a fixed or variable split;

5 Verification

Art. 3. (36): 'biometric verification' means the automated, one-to-one verification, including authentication, of the identity of natural persons by comparing their biometric data to previously provided biometric data;
Art. 12. 3(d): the identification of the natural persons involved in the verification of the results, as referred to in Article 14(5).
Art. 14. 5: For high-risk AI systems referred to in point 1(a) of Annex III, the measures referred to in paragraph 3 of this Article shall be such as to ensure that, in addition, no action or decision is taken by the deployer on the basis of the identification resulting from the system unless that identification has been separately verified and confirmed by at least two natural persons with the necessary competence, training and authority. The requirement for a separate verification by at least two natural persons shall not apply to high-risk AI systems used for the purposes of law enforcement, migration, border control or asylum, where Union or national law considers the application of this requirement to be disproportionate.
Art. 17. (b): techniques, procedures and systematic actions to be used for the design, design control and design verification of the high-risk AI system;
Art. 29. 3: Where the conformity assessment body concerned cannot provide an accreditation certificate, it shall provide the notifying authority with all the documentary evidence necessary for the verification, recognition and regular monitoring of its compliance with the requirements laid down in Article 31.

0 Visualization

0 Vulnerability