AI ACT and relative Article in AI Act

Annexes and relative Article in AI Act

Art. 1

Subject matter`

Terms *Variant* 1

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.

Terms *Variant* 2

- AI systems
- Artificial intelligence
- Democracy
- Environmental protection
- Fundamental rights
- Harmful effects
- Health
- Human-centric
- Innovation
- Internal market
- Protection
- Purpose
- Safety
- Trustworthy

Art. 1, 2

This Regulation lays down:

Terms *Variant* 3

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;

Terms *Variant* 4

- AI systems
- Service

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Art. 1, 2(b)

prohibitions of certain AI practices;

Terms *Variant* 1

1

Art. 1, 2(c)

specific requirements for high-risk AI systems and obligations for operators of such systems;

Terms *Variant* 6

AI systems

Risk

6

Art. 1, 2(d)

harmonised transparency rules for certain AI systems;

Terms *Variant* 7

AI systems

Transparency

7

Art. 1, 2(e)

harmonised rules for the placing on the market of general-purpose AI models;

Terms *Variant* 8

AI models

Purpose

8

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Art. 1, 2(f)

rules on market monitoring, market surveillance, governance and enforcement;

Terms	Variant	9
Governance		
Monitoring		
Surveillance		

Art. 1, 2(g)

measures to support innovation, with a particular focus on SMEs, including start-ups.

Terms	Variant	10
Innovation		
Support		

Art. 2

Scope

Terms	Variant	282

Art. 2, 1

This Regulation applies to:

1	List of Union harmonisation legislation

Terms	Variant	12

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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;

1	List of Union harmonisation legislation

Terms	Variant	13
AI models		
AI systems		
Located in the Union		
Providers		
Purpose		
Service		

Art. 2, 1(b)

deployers of AI systems that have their place of establishment or are located within the Union;

1	List of Union harmonisation legislation

Terms	Variant	14
AI systems		
Deployers		

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;

Terms	Variant	15
AI systems		
Deployers		
Located in the Union		
Providers		
System		

Art. 2, 1(d)

importers and distributors of AI systems;

Terms	Variant	16
AI systems		
Importers		

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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;

Terms	Variant	
Product manufacturers		17
Service		
System		

Art. 2, 1(f)

authorised representatives of providers, which are not established in the Union;

Terms	Variant	
Providers		18

Art. 2, 1(g)

affected persons that are located in the Union.

Terms	Variant	
Located in the Union		19

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.

AI ACT and relative Article in AI Act	Annexes and relative Article in AI Act
Art. 6, 1	*1 List of Union harmonisation legislation*
Art. 102	
Art. 103	
Art. 104	
Art. 105	
Art. 106	
Art. 107	
Art. 108	
Art. 109	
Art. 112	
Art. 57	

Terms	Variant	
AI systems		20
Products		
Risk		

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

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.

Terms	*Variant*	21
AI systems		
Security (*Cybersecurity*)		
Service		

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.

Terms	*Variant*	22
AI systems		
Fundamental rights		
Protection		

Art. 2, 5

This Regulation shall not affect the application of the provisions on the liability of providers of intermediary services as set out in Chapter II of Regulation (EU) 2022/2065.

Terms	*Variant*	23
Providers		

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.

Terms	*Variant*	24
AI models		
AI systems		
Purpose		
Service		

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.

AI ACT and relative Article in AI Act	*Annexes and relative Article in AI Act*
Art. 10, 5	
Art. 59	

Terms	*Variant*
Confidentiality (*personal data, identifiability*)	
Data	
Data protection (*privacy*)	
Personal data	
Privacy	
Protection	
Protection of personal data	

25

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.

Terms	*Variant*
AI models	
AI systems	
Service	
Testing	

26

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.

Terms	*Variant*
Protection	
Safety	

27

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.

Terms	*Variant*
AI systems	
Deployers	

28

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

Art. 2, 11

This Regulation does not preclude the Union or Member States from maintaining or introducing laws, regulations or administrative provisions which are more 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.

Terms | *Variant* | 29

AI application

AI systems

29

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. 5

Art. 50

Terms | *Variant* | 30

AI systems

Risk

Service

System

30

Art. 3

Definitions

Terms | *Variant* | 31

31

Art. 3

For the purposes of this Regulation, the following definitions apply:

Terms | *Variant* | 32

32

AI ACT and relative Article in AI Act

Annexes and relative Article in AI Act

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;

Terms	Variant	33
Autonomy		
IT system		
System		

Art. 3, (2)

'risk' means the combination of the probability of an occurrence of harm and the severity of that harm;

Terms	Variant	34
Risk		

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;

Terms	Variant	35
IT system		
Purpose		
Service		
System		

Art. 3, (4)

'deployer' 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;

Terms	Variant	36
System		

AI ACT and relative Article in AI Act

Annexes and relative Article in AI Act

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;

Terms *Variant* 37

Located in the Union

Purpose

System

37

Art. 3, (6)

'importer' 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;

Terms *Variant* 38

Located in the Union

System

38

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;

Terms *Variant* 39

System

39

Art. 3, (8)

'operator' means a provider, product manufacturer, deployer, authorised representative, importer or distributor;

Terms *Variant* 40

40

AI ACT and relative Article in AI Act | **Annexes and relative Article in AI Act**

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;

Terms	Variant	41
Purpose		
System		

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;

Terms	Variant	42
Purpose		
System		

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;

Terms	Variant	43
Purpose		
Service		
System		

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;

Terms	Variant	44
Context of use		
Documentation		
Information		
Information system		
Purpose		
System		
Technical documentation		

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

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;

Terms	*Variant*	45
AI systems		
Purpose		
System		

Art. 3, (14)

'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;

Terms	*Variant*	46
Health		
Safety		
System		

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;

Terms	*Variant*	47
Information		
Information system		
Purpose		
System		

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;

Terms	*Variant*	48
Deployers		
Measure		
Service		
System		

***AI ACT* and relative Article in AI Act**

***Annexes* and relative Article in AI Act**

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;

Terms	*Variant*	49
Measure		
System		

Art. 3, (18)

'performance of an AI system' means the ability of an AI system to achieve its intended purpose;

Terms	*Variant*	50
Purpose		
System		

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;

Terms	*Variant*	51
Assessment		
Assessment procedures		
Conformity		
Conformity assessment		
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;

Terms	*Variant*	52
Assessment		
Conformity		
Conformity assessment		
Risk		
System		

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

Art. 3, (21)

'conformity assessment body' means a body that performs third-party conformity assessment activities, including testing, certification and inspection;

Terms	*Variant*	53
Assessment		
Conformity		
Conformity assessment		
Testing		

Art. 3, (22)

'notified body' means a conformity assessment body notified in accordance with this Regulation and other relevant Union harmonisation legislation;

Terms	*Variant*	54
Assessment		
Conformity		
Conformity assessment		

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;

Terms	*Variant*	55
Assessment		
Compliance (*complete*)		
Compliance with the requirements		
Conformity		
Conformity assessment		
Purpose		
Service		
System		

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;

Terms	*Variant*	56
Conformity		
System		

AI ACT and relative Article in AI Act | **Annexes and relative Article in AI Act**

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;

Terms	Variant	57
AI systems		
Experience		
Monitoring		
Post-market (*Quaity in use, Post production*)		
Providers		
Purpose		
Service		
System		

Art. 3, (26)

'market surveillance authority' means the national authority carrying out the activities and taking the measures pursuant to Regulation (EU) 2019/1020;

Terms	Variant	58
Surveillance		

Art. 3, (27)

'harmonised standard' means a harmonised standard as defined in Article 2(1), point (c), of Regulation (EU) No 1025/2012;

Art. 2, 1(c)

Terms	Variant	59

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. 2, 4

Terms	Variant	60

***AI ACT* and relative Article in AI Act**

***Annexes* and relative Article in AI Act**

Art. 3, (29)

'training data' means data used for training an AI system through fitting its learnable parameters;

Terms	*Variant*	61
Data		
System		
Training		

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;

Terms	*Variant*	62
Data		
Evaluation (*Evaluating*)		
System		
Validation		

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;

Terms	*Variant*	63
Data		
Data set (*File*)		
Training		
Validation		

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;

Terms	*Variant*	64
Data		
Evaluation (*Evaluating*)		
Service		
System		
Testing		

AI ACT and relative Article in AI Act

Annexes and relative Article in AI Act

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;

Terms	Variant	65
Data		
Input data		
System		

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;

Terms	Variant	66
Biometric characteristic		
Biometric data		
Data		
Personal 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;

Terms	Variant	67
Biometric data		
Biometric identification		
Data		
Database		
Purpose		

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;

Terms	Variant	68
Authentication		
Biometric data		
Data		
Verification		

AI ACT and relative Article in AI Act | **Annexes and relative Article in AI Act**

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. 10, 1	

Terms	Variant	69
Data		
Personal data		

Art. 3, (38)

'sensitive operational data' means operational data related to activities of prevention, detection, investigation or prosecution of criminal offences, the disclosure of which could jeopardise the integrity of criminal proceedings;

Terms	Variant	70
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;

Terms	Variant	71
Biometric data		
Data		
Purpose		
System		

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;

Terms	Variant	72
Biometric data		
Data		
IT system		
Purpose		
Service		
System		

AI ACT and relative Article in AI Act | **Annexes and relative Article in AI Act**

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;

Terms	Variant	73
Biometric data		
Biometric identification		
Data		
Database		
Purpose		
System		

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;

Terms	Variant	74
Biometric data		
Biometric identification		
Data		
System		

Art. 3, (43)

'post-remote biometric identification system' means a remote biometric identification system other than a real-time remote biometric identification system;

Terms	Variant	75
Biometric identification		
System		

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;

Terms	Variant	76

	AI ACT and relative Article in AI Act	Annexes and relative Article in AI Act	Terms	Variant	
Art. 3, (45)‘ law enforcement authority’ means:					77
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			Security (*Cybersecurity*)		78
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;			Security (*Cybersecurity*)		79
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;			Security (*Cybersecurity*)		80

AI ACT and relative Article in AI Act

Annexes and relative Article in AI Act

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;

Terms	*Variant*	81
AI models		
AI systems		
Governance		
Monitoring		
Purpose		

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;

Terms	*Variant*	82
AI systems		
Data		
Data protection (*privacy*)		
Protection		
Service		
Surveillance		

Art. 3, (49)

'serious incident' means an incident or malfunctioning of an AI system that directly or indirectly leads to any of the following:

Terms	*Variant*	83
Incident		
System		

Art. 3, (49)(a)

the death of a person, or serious harm to a person's health;

Terms	*Variant*	84
Health		

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

Art. 3, (49)(b)

a serious and irreversible disruption of the management or operation of critical infrastructure;

Terms	Variant	
Management		85
Operation		

Art. 3, (49)(c)

the infringement of obligations under Union law intended to protect fundamental rights;

Terms	Variant	
Fundamental rights		86

Art. 3, (49)(d)

serious harm to property or the environment;

Terms	Variant	
		87

Art. 3, (50)

'personal data' means personal data as defined in Article 4, point (1), of Regulation (EU) 2016/679;

Terms	Variant	
Data		88
Personal data		

AI ACT and relative Article in AI Act

Annexes and relative Article in AI Act

Art. 3, (51)

'non-personal data' means data other than personal data as defined in Article 4, point (1), of Regulation (EU) 2016/679;

Terms *Variant* 89

Data

Personal data

89

Art. 3, (52)

'profiling' means profiling as defined in Article 4, point (4), of Regulation (EU) 2016/679;

Terms *Variant* 90

90

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;

Terms *Variant* 91

Monitoring

Testing

91

Art. 3, (54)

'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;

Terms *Variant* 92

92

***AI ACT* and relative Article in AI Act**

***Annexes* and relative Article in AI Act**

Art. 3, (55)

'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 limited time under regulatory supervision;

Terms	*Variant*	93
AI systems		
Providers		
System		

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;

Terms	*Variant*	94
AI literacy		
AI systems		
Deployers		
IT system		
Knowledge		
Literacy		
Providers		

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;

Terms	*Variant*	95
Conformity		
Data		
Data requirements (*Data quality model*)		
IT system		
Purpose		
Service		
System		
Testing		

Art. 3, (58)

'subject', for the purpose of real-world testing, means a natural person who participates in testing in real-world conditions;

Terms	*Variant*	96
Purpose		
Testing		

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

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;

Terms *Variant* 97

Testing

97

Art. 3, (60)

'deep fake' means AI-generated or manipulated image, audio or video content that resembles existing persons, objects, places, entities or events and would falsely appear to a person to be authentic or truthful;

Terms *Variant* 98

98

Art. 3, (61)

'widespread infringement' means any act or omission contrary to Union law protecting the interest of individuals, which:

Terms *Variant* 99

99

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:

Terms *Variant* 100

?

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

Art. 3, (61)(i)

the act or omission originated or took place;

Terms *Variant* 101

Art. 3, (61)(ii)

the provider concerned, or, where applicable, its authorised representative is located or established; or

Terms *Variant* 102

Art. 3, (61)(iii)

the deployer is established, when the infringement is committed by the deployer;

Terms *Variant* 103

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;

Terms *Variant* 104

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

Art. 3, (62)

'critical infrastructure' means critical infrastructure as defined in Article 2, point (4), of Directive (EU) 2022/2557;

Terms *Variant* 105

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;

Terms *Variant* 106

- AI application
- AI models
- AI systems
- Data
- Purpose

Art. 3, (64)

'high-impact capabilities' means capabilities that match or exceed the capabilities recorded in the most advanced general-purpose AI models;

Terms *Variant* 107

- AI models
- Purpose

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;

Terms *Variant* 108

- AI models
- Fundamental rights
- Health
- Health risk
- Purpose
- Risk
- Safety
- Security (*Cybersecurity*)
- Society

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

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;

Terms	Variant	109
AI systems		
Purpose		
System		
		?

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	Variant	110
Operation		
Precision		
		?

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.

Terms	Variant	111
Purpose		
System		
		?

Art. 4

AI literacy

Terms	Variant	112
AI literacy		
Literacy		
Planning		
		?

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

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.

Terms *Variant* 113

- AI literacy
- AI systems
- Context of use
- Deployers
- Education
- Experience
- Knowledge
- Literacy
- Operation
- Providers
- Training
- ?

CHAPTER II

PROHIBITED AI PRACTICES

Terms *Variant* 114

- ?

Art. 5

Prohibited AI practices

Terms *Variant* 115

- ?

Art. 5, 1

The following AI practices shall be prohibited:

Terms *Variant* 116

- ?

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

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;

Terms	*Variant*	117
Service		
System		
		?

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;

Terms	*Variant*	118
Disability		
Service		
System		
		?

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:

Terms	*Variant*	119
AI systems		
Classification (*categorization*)		
Evaluation (*Evaluating*)		
Service		
		?

Art. 5, 1(c)(i)

detrimental or unfavourable treatment of certain natural persons or groups of persons in social contexts that are unrelated to the contexts in which the data was originally generated or collected;

Terms	*Variant*	120
Data		
		?

AI ACT and relative Article in AI Act | **Annexes and relative Article in AI Act**

Art. 5, 1(c)(ii)

detrimental or unfavourable treatment of certain natural persons or groups of persons that is unjustified or disproportionate to their social behaviour or its gravity;

Terms	Variant	121

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;

Terms	Variant	122
AI systems		
Assessment		
Purpose		
Risk		
Service		
Support		
System		

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;

Terms	Variant	123
AI systems		
Purpose		
Service		

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;

Terms	Variant	124
AI systems		
Education		
Market for medical or safety reasons		
Purpose		
Safety		
Service		
System		

***AI ACT* and relative Article in AI Act** | ***Annexes* and relative Article in AI Act**

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;

Terms	*Variant*	125
Biometric data		
Data		
Data labelling		
Datasets (*Data set*)		
Labelling		
Purpose		
Service		
		?

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:

Terms	*Variant*	126
Biometric identification		
		?

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;

Terms	*Variant*	127
		?

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;

Terms	*Variant*	128
Attack		
Safety		
		?

2 *List of criminal offences referred to*

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

Art. 5, 1(h)(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 (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.

2 *List of criminal offences referred to in Article 5(1)(h)(iii)*

Terms	*Variant*	129
Biometric data		
Biometric identification		
Data		
Purpose		

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), shall be deployed for the purposes set out in that point only to confirm the identity of the specifically targeted individual, and it shall take into account the following elements:

Terms	*Variant*	130
Biometric identification		
IT system		

Art. 5, 2(a)

the nature of the situation giving rise to the possible use, in particular the seriousness, probability and scale of the harm that would be caused if the system were not used;

Terms	*Variant*	131
System		

Art. 5, 2(b)

the consequences of the use of the system for the rights and freedoms of all persons concerned, in particular the seriousness, probability and scale of those consequences.

Terms	*Variant*	132
System		

AI ACT and relative Article in AI Act | **Annexes and relative Article in AI Act**

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.

Terms	Variant	133
Assessment		
Biometric data		
Biometric identification		
Database		
Fundamental rights		
Impact assessment		
Personal data		
System		
		?

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 of 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 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 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.

Terms	Variant	134
Biometric data		
Biometric identification		
Data		
IT system		
Personal data		
System		
		?

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.

Terms	Variant	135
Biometric data		
Biometric identification		
Data		
Data protection (*privacy*)		
Information		
Information system		
Protection		
Surveillance		
System		
		?

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 3. 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)(iii) 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.

Terms	Variant	136
Biometric identification		
		?

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

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.

Terms *Variant* 137

- Biometric data
- Biometric identification
- Data
- Data protection (*privacy*)
- Information
- Information system
- Protection
- Purpose
- Surveillance

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.

Terms *Variant* 138

- Biometric data
- Biometric identification
- Data

Art. 5, 8

This Article shall not affect the prohibitions that apply where an AI practice infringes other Union law.

Terms *Variant* 139

CHAPTER III

HIGH-RISK AI SYSTEMS

Terms *Variant* 140

- AI systems
- Risk

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

SECTION 1

Classification of AI systems as high-risk

Terms	Variant	141
AI systems		
Classification (*categorization*)		
Risk		
		?

Art. 6

Classification rules for high-risk AI systems

Terms	Variant	142
AI systems		
Classification (*categorization*)		
Risk		
		?

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:

Terms	Variant	143
Products		
Risk		
Service		
System		
		?

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;

Terms	Variant	144
Safety		
System		
		?

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

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.

Terms *Variant* 145

- Assessment
- Conformity
- Conformity assessment
- Safety
- Service
- System

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.

3 High-risk AI systems referred to in Article 6

Terms *Variant* 146

- AI systems
- 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 shall apply where any of the following conditions is fulfilled:

8 Information to be submitted upon the

Terms *Variant* 147

- Fundamental rights
- Health
- Health risk
- IT system
- Risk
- Safety
- System

Art. 6, 3(a)

the AI system is intended to perform a narrow procedural task;

Terms *Variant* 148

- System

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

Art. 6, 3(b)

the AI system is intended to improve the result of a previously completed human activity;

Terms	Variant	149
System		

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

Terms	Variant	150
Assessment		
Decision-making		
System		

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.

Terms	Variant	151
Assessment		
Risk		
System		

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.

Terms	Variant	152
Assessment		
Documentation		
Risk		
Service		
System		

AI ACT and relative Article in AI Act

Annexes and relative Article in AI Act

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.

Terms	*Variant*	153
AI systems		
Artificial intelligence		
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.

Terms	*Variant*	154
AI systems		
Fundamental rights		
Health		
Health risk		
Risk		
Safety		
		?

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.

Terms	*Variant*	155
Fundamental rights		
Health		
Protection		
Safety		
		?

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.

Terms	*Variant*	156
Consistency		
Fundamental rights		
Health		
Protection		
Safety		
		?

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

Art. 7

Amendments to Annex III

Terms *Variant* 157

?

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:

Terms *Variant* 158

AI systems

Risk

Use-cases (*Segmentation*)

?

Art. 7, 1(a)

the AI systems are intended to be used in any of the areas listed in Annex III;

Terms *Variant* 159

AI systems

?

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.

Terms *Variant* 160

AI systems

Fundamental rights

Health

Health risk

Risk

Safety

?

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

Art. 7, 2

When assessing the condition under paragraph 1, point (b), the Commission shall take into account the following criteria:

Terms *Variant* 161

Art. 7, 2(a)

the intended purpose of the AI system;

Terms *Variant* 162

Purpose

System

Art. 7, 2(b)

the extent to which an AI system has been used or is likely to be used;

Terms *Variant* 163

System

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;

Terms *Variant* 164

Data

Personal data

System

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

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;

Terms	Variant	165
System		

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;

Terms	Variant	166
Fundamental rights		
Health		
Safety		
System		

Art. 7, 2(f)

the potential extent of such harm or such adverse impact, in particular in terms of its intensity and its ability to affect multiple persons or to disproportionately affect a particular group of persons;

Terms	Variant	167

Art. 7, 2(g)

the extent to which persons who are potentially harmed or suffer an adverse impact are dependent on the outcome produced with an AI system, in particular because for practical or legal reasons it is not reasonably possible to opt-out from that outcome;

Terms	Variant	168
IT system		
System		

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

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;

Terms	Variant	169
Knowledge		
System		

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;

Terms	Variant	170
Fundamental rights		
Health		
IT system		
Safety		
System		

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;

Terms	Variant	171
Benefit		
Safety		
Society		
System		

Art. 7, 2(k)

the extent to which existing Union law provides for:

Terms	Variant	172

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act* | *Terms* | *Variant* | 173

Art. 7, 2(k)(i)

effective measures of redress in relation to the risks posed by an AI system, with the exclusion of claims for damages;

System

?

Terms | *Variant* | 174

Art. 7, 2(k)(ii)

effective measures to prevent or substantially minimise those risks.

?

Terms | *Variant* | 175

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:

AI systems

Risk

?

Terms | *Variant* | 176

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;

Fundamental rights

Health

Health risk

Risk

Safety

System

?

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

Art. 7, 3(b)

the deletion does not decrease the overall level of protection of health, safety and fundamental rights under Union law.

Terms	*Variant*	177
Fundamental rights		
Health		
Protection		
Safety		
		?

SECTION 2

Requirements for high-risk AI systems

Terms	*Variant*	178
AI systems		
Risk		
		?

Art. 8

Compliance with the requirements

Terms	*Variant*	179
Compliance (*complete*)		
Compliance with the requirements		
		?

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.

Terms	*Variant*	180
AI systems		
Compliance (*complete*)		
Compliance with the requirements		
Management		
Management system		
Purpose		
Risk		
Risk management		
System		
		?

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

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.

Terms	*Variant*	181
AI systems		
Compliance (*complete*)		
Compliance with the requirements		
Consistency		
Documentation		
Information		
Information system		
Processes		
Providers		
Risk		
System		
Testing		
		?

Art. 9

Risk management system

	4 *Technical documentation*

Terms	*Variant*	182
Management		
Management system		
Risk		
Risk management		
System		
		?

Art. 9, 1

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

Terms	*Variant*	183
AI systems		
Management		
Management system		
Risk		
Risk management		
System		
		?

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:

Terms	*Variant*	184
AI system lifecycle		
IT system		
Lifecycle		
Management		
Management system		
Risk		
Risk management		
Risk management process		
System		
Updating		
		?

AI ACT and relative Article in AI Act | **Annexes and relative Article in AI Act**

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;

Terms	Variant	185
Fundamental rights		
Health		
Health risk		
Purpose		
Risk		
Risk analysis		
Safety		
System		
		?

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;

Terms	Variant	186
Evaluation (*Evaluating*)		
Purpose		
Risk		
Risk estimation		
Risk evaluation		
System		
		?

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;

Terms	Variant	187
Data		
Data analysis		
Evaluation (*Evaluating*)		
Monitoring		
Post-market (*Quaity in use, Post production*)		
System		
		?

Art. 9, 2(d)

the adoption of appropriate and targeted risk management measures designed to address the risks identified pursuant to point (a).

Terms	Variant	188
Management		
Risk		
Risk management		
		?

AI ACT and relative Article in AI Act

Annexes and relative Article in AI Act

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.

Terms	*Variant*	189
Design		
Information		
Information system		
Risk		
System		

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.

Terms	*Variant*	190
Balance		
Management		
Risk		
Risk management		

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:

Terms	*Variant*	191
AI systems		
Management		
Management system		
Residual risk		
Risk		
Risk management		

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;

Terms	*Variant*	192
Design		
Risk		
System		

AI ACT and relative Article in AI Act

Annexes and relative Article in AI Act

Art. 9, 5(b)

where appropriate, implementation of adequate mitigation and control measures addressing risks that cannot be eliminated;

Terms *Variant* 193

?

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.

Terms *Variant* 194

- Context of use
- Deployers
- Education
- Experience
- Information
- Information system
- Knowledge
- Risk
- System
- Training

?

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.

Terms *Variant* 195

- AI systems
- Compliance (*complete*)
- Compliance with the requirements
- Management
- Management system
- Purpose
- Risk
- Risk management
- Testing

?

Art. 9, 7

Testing procedures may include testing in real-world conditions in accordance with Article 60.

Terms *Variant* 196

- Testing

?

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

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.

Terms *Variant* 197

- AI systems
- Metrics
- Purpose
- Risk
- Service
- System
- Testing

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.

Terms *Variant* 198

- Management
- Management system
- Providers
- Purpose
- Risk
- Risk management
- System

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.

Terms *Variant* 199

- AI systems
- Management
- Management system
- Processes
- Providers
- Risk
- Risk management
- Risk management process

Art. 10

Data and data governance

Terms *Variant* 200

- Data
- Data governance
- Governance

AI ACT and relative Article in AI Act | **Annexes and relative Article in AI Act**

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.

	4 Technical documentation

Terms	Variant	201
AI models		
AI systems		
Data		
Data quality		
Data quality model (*Quality criteria*)		
Data set (*File*)		
Quality criteria (*Quality model*)		
Quality model		
Risk		
Testing		
Testing data sets		
Training		
Validation		?

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:

Terms	Variant	202
Data		
Data governance		
Data management		
Data set (*File*)		
Governance		
Management		
Management system		
Purpose		
Risk		
Risk governance		
Risk management		
System		
Testing		?
Testing data sets		

Art. 10, 2(a)

the relevant design choices;

Terms	Variant	203
Design		
		?

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;

Terms	Variant	204
Data		
Data collection processes		
Origin of data (*provenance*)		
Personal data		
Personal data, the original purpose of the data collection		
Processes		
Purpose		
		?

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

Art. 10, 2(c)

relevant data-preparation processing operations, such as annotation, labelling, cleaning, updating, enrichment and aggregation;

Terms	*Variant*	205
Aggregation		
Annotation		
Cleaning		
Data		
Data aggregation		
Data labelling		
Data-preparation processing		
Enrichment		
Labelling		
Preparation		
Updating		
		?

Art. 10, 2(d)

the formulation of assumptions, in particular with respect to the information that the data are supposed to measure and represent;

Terms	*Variant*	206
Data		
Information		
Measure		
		?

Art. 10, 2(e)

an assessment of the availability, quantity and suitability of the data sets that are needed;

Terms	*Variant*	207
Assessment		
Assessment of the availability		
Availability		
Data		
Data set (*File*)		
Suitability		
		?

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;

Terms	*Variant*	208
Data		
Data bias		
Fundamental rights		
Fundamental rights or lead to discrimination prohibited under Union law		
Health		
Safety		
		?

Art. 10, 2(g)

appropriate measures to detect, prevent and mitigate possible biases identified according to point (f);

Terms	*Variant*	209
Appropriate measures to detect, prevent and mitigate possible biases identified		

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.

Terms	*Variant*	210
Compliance (*complete*)		
Data		
Relevant data gaps or shortcomings that prevent compliance with this Regulation		

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.

Terms	*Variant*	211
Applicable, as regards the persons or groups		
Appropriate statistical properties		
Characteristics of the data sets may be met at the level of individual data sets or combination		
Complete		
Data		
Data set (*File*)		
Free of errors (*Accuracy*)		
Level of risk		
Purpose		
Risk		
System		
Testing		
Testing data sets		
Training		

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.

Terms	*Variant*	212
Characteristics or elements that are particular to the specific geographical, contextual,		
Data		
Data set (*File*)		
Functional setting		
Purpose		
Risk		
System		

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

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:

Terms *Variant* 213

- AI systems
- Bias
- Bias detection and correction (*dataset*)
- Bias in AI system
- Data
- Data bias
- Data set (*File*)
- Fundamental rights
- IT system
- Personal data
- Providers
- Purpose
- Risk

Art. 10, 5(a)

the bias detection and correction cannot be effectively fulfilled by processing other data, including synthetic or anonymised data;

Terms *Variant* 214

- Bias
- Bias detection and correction (*dataset*)
- Data
- Data bias
- Synthetic or anonymised data

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;

Terms *Variant* 215

- Data
- Personal data
- Privacy
- Re-use of the personal data (*Quality control*)
- Security (*Cybersecurity*)

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;

Terms *Variant* 216

- Access control
- Appropriate confidentiality
- Confidentiality (*personal data, identifiability*)
- Data
- Data processed are secured, protected, subject to suitable safeguards, including strict
- Documentation
- Documentation of the access, to avoid misuse and ensure that only authorised persons
- Personal data

AI ACT and relative Article in AI Act

Annexes and relative Article in AI Act

Art. 10, 5(d)

the special categories of personal data are not to be transmitted, transferred or otherwise accessed by other parties;

Terms	*Variant*	217
Data		
Personal data		
Personal data are not to be transmitted, transferred or otherwise accessed by other		
		?

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;

Terms	*Variant*	218
Bias		
Data		
Data bias		
Data retention (*Data recoverability*)		
Personal data		
		?

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.

Terms	*Variant*	219
Data		
Data bias		
Personal data		
		?

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.

Terms	*Variant*	220
AI models		
AI systems		
Data		
Data set (*File*)		
Risk		
Testing		
Testing data sets		
Training		
		?

AI ACT and relative Article in AI Act | **Annexes and relative Article in AI Act**

Art. 11

Technical documentation

Terms	Variant	221
Documentation		
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.

Terms	Variant	222
Assessment		
Compliance (*complete*)		
Compliance with the requirements		
Conformity		
Conformity assessment		
Documentation		
Information		
Information system		
IT system		
Risk		
Service		
System		
Technical documentation		?

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.

Terms	Variant	223
Documentation		
Information		
Information system		
Risk		
Service		
System		
Technical documentation		
		?

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.

Terms	Variant	224
Compliance (*complete*)		
Compliance with the requirements		
Documentation		
Information		
Information system		
System		
Technical documentation		
		?

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

Art. 12

Record-keeping

Terms *Variant* 225

?

Art. 12, 1

High-risk AI systems shall technically allow for the automatic recording of events (logs) over the lifetime of the system.

Terms *Variant* 226

AI systems

Logs

Risk

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:

Terms *Variant* 227

Level of risk

Logging

Purpose

Risk

System

Traceability

?

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;

Terms *Variant* 228

Risk

System

?

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

Art. 12, 2(b)

facilitating the post-market monitoring referred to in Article 72; and

Terms	Variant	229
Monitoring		
Post-market (*Quaity in use, Post production*)		

Art. 12, 2(c)

monitoring the operation of high-risk AI systems referred to in Article 26(5).

Terms	Variant	230
AI systems		
Monitoring		
Operation		
Risk		

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:

Terms	Variant	231
AI systems		
Logging		
Risk		

Art. 12, 3(a)

recording of the period of each use of the system (start date and time and end date and time of each use);

Terms	Variant	232
System		

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

Art. 12, 3(b)

the reference database against which input data has been checked by the system;

Terms	Variant	233
Data		
Database		
Input data		
System		

Art. 12, 3(c)

the input data for which the search has led to a match;

Terms	Variant	234
Data		
Input 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).

Terms	Variant	235
Verification		

Art. 13

Transparency and provision of information to deployers

Terms	Variant	236
Deployers		
Information		
Transparency		

***AI ACT* and relative Article in AI Act** | ***Annexes* and relative Article in AI Act**

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.

Terms *Variant* 237

- AI systems
- Compliance (*complete*)
- Deployers
- IT system
- Operation
- Risk
- System
- Transparency

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.

Terms *Variant* 238

- AI systems
- Complete
- Deployers
- Information
- Information system
- Risk

Art. 13, 3

The instructions for use shall contain at least the following information:

4 *Technical documentation*

Terms *Variant* 239

- Information

Art. 13, 3(a)

the identity and the contact details of the provider and, where applicable, of its authorised representative;

Terms *Variant* 240

- Contact

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

Art. 13, 3(b)

the characteristics, capabilities and limitations of performance of the high-risk AI system, including:

Terms	*Variant*	241
Risk		
System		

Art. 13, 3(b)(i)

its intended purpose;

Terms	*Variant*	242
Purpose		

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;

Terms	*Variant*	243
Accuracy (*free of errors*)		
Cybersecurity		
Level of risk		
Metrics		
Risk		
System		

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 9(2);

Terms	*Variant*	244
Fundamental rights		
Health		
Health risk		
Purpose		
Risk		
Safety		
System		

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

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;

Terms	*Variant*	245
Information		
Information system		
Risk		
System		

Art. 13, 3(b)(v)

when appropriate, its performance regarding specific persons or groups of persons on which the system is intended to be used;

Terms	*Variant*	246
System		

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;

Terms	*Variant*	247
Data		
Data set (*File*)		
Information		
Information system		
Input data		
Purpose		
Risk		
System		
Testing		
Testing data sets		
Training		
Validation		

Art. 13, 3(b)(vii)

where applicable, information to enable deployers to interpret the output of the high-risk AI system and use it appropriately;

Terms	*Variant*	248
Deployers		
Information		
Information system		
IT system		
Risk		
System		

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

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;

Terms *Variant* 249

- Assessment
- Conformity
- Conformity assessment
- Risk
- System

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;

4 Technical documentation

Terms *Variant* 250

- AI systems
- Deployers
- Human oversight
- Risk

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;

Terms *Variant* 251

- Risk
- Software
- 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.

4 Technical documentation

Terms *Variant* 252

- Deployers
- Logs
- Risk
- System

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

Art. 14

Human oversight

4 *Technical documentation referred to in*

Terms *Variant* 253

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.

Terms *Variant* 254

AI systems

Risk

?

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.

Terms *Variant* 255

AI application

Fundamental rights

Health

Health risk

Human oversight

Purpose

Risk

Safety

System

?

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:

Terms *Variant* 256

Autonomy

Context of use

Level of risk

Risk

System

?

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

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;

Terms	Variant	257
IT system		
Risk		
Service		
System		

Art. 14, 3(b)

measures identified 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.

Terms	Variant	258
IT system		
Risk		
Service		
System		

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:

Terms	Variant	259
Human oversight		
Purpose		
Risk		
System		

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;

Terms	Variant	260
Operation		
Risk		
System		

AI ACT and relative Article in AI Act | **Annexes and relative Article in AI Act**

Art. 14, 4(b)

to remain aware of the possible tendency of automatically relying 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;

Terms	Variant	261
AI systems		
Bias		
Bias in AI system		
Information		
Information system		
Risk		
System		

Art. 14, 4(c)

to correctly interpret the high-risk AI system's output, taking into account, for example, the interpretation tools and methods available;

Terms	Variant	262
Risk		
System		

Art. 14, 4(d)

to decide, in any particular situation, not to use the high-risk AI system or to otherwise disregard, override or reverse the output of the high-risk AI system;

Terms	Variant	263
Risk		
System		

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.

Terms	Variant	264
Operation		
Risk		
System		

AI ACT and relative Article in AI Act | **Annexes and relative Article in AI Act**

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.

Terms	Variant	265
AI application		
AI systems		
Competence		
Risk		
System		
Training		
Verification		
		?

Art. 15

Accuracy, robustness and cybersecurity

Terms	Variant	266
Accuracy (*free of errors*)		
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.

Terms	Variant	267
Accuracy (*free of errors*)		
AI system lifecycle		
AI systems		
Cybersecurity		
Level of risk		
Lifecycle		
Risk		
		?

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.

Terms	Variant	268
Accuracy (*free of errors*)		
Measure		
Measurement (*measuring*)		
Measurement and method		
Metrics		
		?

AI ACT and relative Article in AI Act

Annexes and relative Article in AI Act

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	Variant	269
Accuracy (*free of errors*)		
AI systems		
Metrics		
Risk		
		?

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.

Terms	Variant	270
AI systems		
Eliminate or reduce biased output		
Interaction with natural person or other systems		
Risk		
Service		
System		
		?

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.

Terms	Variant	271
AI systems		
Appropriate confidentiality		
Confidentiality (*personal data, identifiability*)		
Cybersecurity		
Data		
Data set (*File*)		
Risk		
System		
Training		
		?

SECTION 3

Obligations of providers and deployers of high-risk AI systems and other parties

Terms	Variant	272
AI systems		
Deployers		
Providers		
Risk		
		?

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

Art. 16

Obligations of providers of high-risk AI systems. Providers of high-risk AI systems shall:

Terms	Variant	273
AI systems		
Providers		
Risk		
		?

Art. 16, (a)

ensure that their high-risk AI systems are compliant with the requirements set out in Section 2;

Terms	Variant	274
AI systems		
Risk		
		?

Art. 16, (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;

Terms	Variant	275
Documentation		
Risk		
System		
		?

Art. 16, (c)

have a quality management system in place which complies with Article 17;

Terms	Variant	276
Management		
Management system		
Quality management		
System		
		?

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

Art. 16, (d)

keep the documentation referred to in Article 18;

Terms *Variant* 277

Documentation

?

Art. 16, (e)

when under their control, keep the logs automatically generated by their high-risk AI systems as referred to in Article 19;

Terms *Variant* 278

AI systems

Logs

Risk

?

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;

Terms *Variant* 279

Assessment

Conformity

Conformity assessment

Risk

Service

System

?

Art. 16, (g)

draw up an EU declaration of conformity in accordance with Article 47;

Terms *Variant* 280

Conformity

?

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

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;

Terms *Variant* 281

Conformity

Documentation

Risk

System

?

Art. 16, (i)

comply with the registration obligations referred to in Article 49(1);

Terms *Variant* 282

?

Art. 16, (j)

take the necessary corrective actions and provide information as required in Article 20;

Terms *Variant* 283

Information

?

Art. 16, (k)

upon a reasoned request of a national competent authority, demonstrate the conformity of the high-risk AI system with the requirements set out in Section 2;

Terms *Variant* 284

Conformity

Risk

System

?

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

Art. 16, (l)

ensure that the high-risk AI system complies with accessibility requirements in accordance with Directives (EU) 2016/2102 and (EU) 2019/882.

Terms *Variant* 285

- Accessibility (*access*)
- Risk
- System

Art. 17

Quality management system

6 Conformity assessment

7 Conformity based on an assessment of the

Terms *Variant* 286

- Management
- Management system
- Quality management
- System

Art. 17

6 Conformity assessment

7 Conformity based on an assessment of the

Terms *Variant* 287

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:

Terms *Variant* 288

- AI systems
- Compliance (*complete*)
- Management
- Management system
- Providers
- Quality management
- Risk
- Risk management
- System

AI ACT and relative Article in AI Act | **Annexes and relative Article in AI Act**

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;

Terms	Variant	289
Assessment		
Assessment procedures		
Compliance (*complete*)		
Conformity		
Conformity assessment		
Management		
Management system		
Risk		
Risk management		
System		
		?

Art. 17, 1(b)

techniques, procedures and systematic actions to be used for the design, design control and design verification of the high-risk AI system;

Terms	Variant	290
Design		
Risk		
System		
Verification		
		?

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;

Terms	Variant	291
Quality assurance (*Quality model*)		
Quality control		
Risk		
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;

Terms	Variant	292
Risk		
System		
Validation		
		?

AI ACT and relative Article in AI Act | **Annexes and relative Article in AI Act**

Art. 17, 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;

Terms	Variant	293
Risk		
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;

Terms	Variant	294
Acquisition		
Aggregation		
AI systems		
Data		
Data acquisition		
Data aggregation		
Data analysis		
Data filtration		
Data labelling		
Data management		
Data mining		
Data retention (*Data recoverability*)		
Data storage (*Data recoverability, Data retention*)		
Labelling		

Art. 17, 1(g)

the risk management system referred to in Article 9;

Terms	Variant	295
Management		
Management system		
Risk		
Risk management		
System		

Art. 17, 1(h)

the setting-up, implementation and maintenance of a post-market monitoring system, in accordance with Article 72;

Terms	Variant	296
Monitoring		
Post-market (*Quaity in use, Post production*)		
System		

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

Art. 17, 1(i)

procedures related to the reporting of a serious incident in accordance with Article 73;

Terms	Variant	297
Incident		

Art. 17, 1(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;

Terms	Variant	298
Data		

Art. 17, 1(k)

systems and procedures for record-keeping of all relevant documentation and information;

Terms	Variant	299
Documentation		
Information		
Information system		

Art. 17, 1(l)

resource management, including security-of-supply related measures;

Terms	Variant	300
Management		
Security (*Cybersecurity*)		

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

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.

Terms *Variant* 301

- Accountability
- Management

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.

Terms *Variant* 302

- AI systems
- Compliance (*complete*)
- Level of risk
- Protection
- Providers
- Risk

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.

Terms *Variant* 303

- AI systems
- Management
- Management system
- Providers
- Quality management
- Risk
- Risk management

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.

Terms *Variant* 304

- Governance
- Management
- Management system
- Processes
- Providers
- Quality management
- Quality management process
- System

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

Art. 18

Documentation keeping

Terms *Variant* 305

Documentation

?

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:

Terms *Variant* 306

Risk

Service

System

?

Art. 18, 1(a)

the technical documentation referred to in Article 11;

Terms *Variant* 307

Documentation

Technical documentation

?

Art. 18, 1(b)

the documentation concerning the quality management system referred to in Article 17;

Terms *Variant* 308

Documentation

Management

Management system

Quality management

System

?

AI ACT and relative Article in AI Act

Annexes and relative Article in AI Act

Art. 18, 1(c)

the documentation concerning the changes approved by notified bodies, where applicable;

Terms *Variant* 309

Documentation

Art. 18, 1(d)

the decisions and other documents issued by the notified bodies, where applicable;

Terms *Variant* 310

Art. 18, 1(e)

the EU declaration of conformity referred to in Article 47.

Terms *Variant* 311

Conformity

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.

Terms *Variant* 312

Documentation

AI ACT and relative Article in AI Act | **Annexes and relative Article in AI Act**

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.

Terms *Variant* 313

- Documentation
- Governance
- Processes
- Providers
- Technical documentation

Art. 19

Automatically generated logs

Terms *Variant* 314

- 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.

Terms *Variant* 315

- AI systems
- Data
- Data protection (*privacy*)
- Logs
- Personal data
- Protection
- Protection of personal data
- Providers
- Purpose
- Risk
- System

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.

Terms *Variant* 316

- AI systems
- Documentation
- Governance
- Logs
- Processes
- Providers
- Risk
- Risk governance

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

Art. 20

Corrective actions and duty of information

Terms *Variant* 317

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.

Terms *Variant* 318

AI systems

Conformity

Deployers

Importers

IT system

Providers

Risk

Service

System

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.

Terms *Variant* 319

Compliance (*complete*)

IT system

Risk

Surveillance

System

Art. 21

Cooperation with competent authorities

Terms *Variant* 320

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

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.

Terms	*Variant*	321
AI systems		
Conformity		
Documentation		
Information		
Information system		
Providers		
Risk		
System		

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.

Terms	*Variant*	322
Access control		
Logs		
Providers		
Risk		
System		

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.

Terms	*Variant*	323
Confidentiality (*personal data, identifiability*)		
Information		

Art. 22

Authorised representatives of providers of high-risk AI systems

Terms	*Variant*	324
AI systems		
Providers		
Risk		

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

Art. 22, 1

Prior to making their high-risk AI systems available on the Union market, providers established in third countries shall, by written mandate, appoint an authorised representative which is established in the Union.

Terms *Variant* 325

AI systems

Providers

Risk

?

Art. 22, 2

The provider shall enable its authorised representative to perform the tasks specified in the mandate received from the provider.

Terms *Variant* 326

?

Art. 22, 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:

Terms *Variant* 327

Surveillance

?

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;

Terms *Variant* 328

Assessment

Conformity

Conformity assessment

Documentation

Technical documentation

?

AI ACT and relative Article in AI Act

Annexes and relative Article in AI Act

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;

Terms	*Variant*	329
Conformity		
Contact		
Documentation		
Risk		
Service		
System		
Technical documentation		
		?

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;

Terms	*Variant*	330
Access control		
Conformity		
Documentation		
Information		
Information system		
Logs		
Risk		
System		
		?

Art. 22, 3(d)

cooperate with competent authorities, upon a reasoned request, in any action the latter take in relation to the high-risk AI system, in particular to reduce and mitigate the risks posed by the high-risk AI system;

Terms	*Variant*	331
Risk		
System		
		?

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.

Terms	*Variant*	332
Compliance (*complete*)		
Information		
		?

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

Art. 22, 4

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 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.

Terms *Variant* 333

Surveillance

Art. 23

Obligations of importers

Terms *Variant* 334

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:

Terms *Variant* 335

Conformity

Importers

Risk

System

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;

Terms *Variant* 336

Assessment

Conformity

Conformity assessment

Risk

System

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

Art. 23, 1(b)

the provider has drawn up the technical documentation in accordance with Article 11 and Annex IV;

Terms	Variant	337
Documentation		
Technical documentation		

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;

Terms	Variant	338
Conformity		
System		

Art. 23, 1(d)

the provider has appointed an authorised representative in accordance with Article 22(1).

Terms	Variant	339

Art. 23, 2

Where an importer has sufficient reason to consider that a high-risk AI system 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.

Terms	Variant	340
Conformity		
Documentation		
IT system		
Risk		
Surveillance		
System		

AI ACT and relative Article in AI Act | **Annexes and relative Article in AI Act**

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.

Terms	Variant	341
Documentation		
Importers		
Risk		
System		
		?

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.

Terms	Variant	342
Compliance (*complete*)		
Compliance with the requirements		
Importers		
Risk		
System		
		?

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.

Terms	Variant	343
Conformity		
Importers		
Risk		
Service		
System		
		?

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.

Terms	Variant	344
Conformity		
Documentation		
Importers		
Information		
Information system		
Purpose		
Risk		
System		
Technical documentation		
		?

AI ACT and relative Article in AI Act

Annexes and relative Article in AI Act

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.

Terms *Variant* 345

- Importers
- IT system
- Risk
- System

Art. 24

Obligations of distributors

Terms *Variant* 346

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).

Terms *Variant* 347

- Conformity
- IT system
- Risk
- System

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 those requirements. Furthermore, where the high-risk AI system presents a risk within the meaning of Article 79(1), the distributor shall inform the provider or the importer of the system, as applicable, to that effect.

Terms *Variant* 348

- Conformity
- Information
- Information system
- IT system
- Risk
- System

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

Art. 24, 3

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.

Terms *Variant* 349

- Compliance (*complete*)
- Compliance with the requirements
- Risk
- System

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.

Terms *Variant* 350

- Compliance (*complete*)
- Compliance with the requirements
- Conformity
- Information
- Information system
- IT system
- Risk
- System

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 Section 2.

Terms *Variant* 351

- Conformity
- Documentation
- Information
- Information system
- Risk
- System

Art. 24, 6

Distributors shall cooperate with the relevant competent authorities in any action those authorities take in relation to a high-risk AI system made available on the market by the distributors, in particular to reduce or mitigate the risk posed by it.

Terms *Variant* 352

- IT system
- Risk
- System

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act* | *Terms* | *Variant* | 353

Art. 25

Responsibilities along the AI value chain

Terms | *Variant* | 354

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:

Terms	Variant
Risk	
System	

Terms | *Variant* | 355

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;

Terms	Variant
Risk	
Service	
System	

Terms | *Variant* | 356

Art. 25, 1(b)

they make a substantial modification to a high-risk AI system that has already been placed on the market or has already been put into service in such a way that it remains a high-risk AI system pursuant to Article 6;

Terms	Variant
IT system	
Risk	
Service	
System	

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

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.

Terms *Variant* 357

- Purpose
- Risk
- Service
- 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 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.

Terms *Variant* 358

- AI systems
- Assessment
- Compliance (*complete*)
- Conformity
- Conformity assessment
- Documentation
- Information
- Information system
- IT system
- Providers
- Risk
- Service
- System
- Technical documentation

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:

Terms *Variant* 359

- AI systems
- Products
- Risk
- Safety
- System

Art. 25, 3(a)

the high-risk AI system is placed on the market together with the product under the name or trademark of the product manufacturer;

Terms *Variant* 360

- Risk
- System

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

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.

Terms *Variant* 361

- Risk
- Service
- System

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.

Terms *Variant* 362

- AI models
- AI systems
- Business requirements
- Information
- Information system
- Processes
- Providers
- Purpose
- Risk
- System

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 Union and national law.

Terms *Variant* 363

- Information

Art. 26

Obligations of deployers of high-risk AI systems

Terms *Variant* 364

- AI systems
- Deployers
- Risk

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

Art. 26, 1

Deployers of high-risk AI systems shall take appropriate technical and organisational measures to ensure they use such systems in accordance with the instructions for use accompanying the systems, pursuant to paragraphs 3 and 6.

Terms *Variant* 365

- AI systems
- Deployers
- Risk

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.

Terms *Variant* 366

- Competence
- Deployers
- Human oversight
- Support
- Training

Art. 26, 3

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.

Terms *Variant* 367

- Human oversight
- Purpose

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.

Terms *Variant* 368

- Data
- Input data
- Purpose
- Risk
- System

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

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.

Terms *Variant* 369

- AI systems
- Data
- Data governance
- Data requirements (*Data quality model*)
- Data set (*File*)
- Deployers
- Governance
- Incident
- Internal market
- Monitoring
- Operation
- Processes
- Providers
- Risk

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.

Terms *Variant* 370

- AI systems
- Data
- Data governance
- Data protection (*privacy*)
- Data requirements (*Data quality model*)
- Deployers
- Documentation
- Governance
- Logs
- Personal data
- Processes
- Protection
- Protection of personal data
- Purpose

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.

Terms *Variant* 371

- Deployers
- Information
- Information system
- Risk
- Service
- 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 shall inform the provider or the distributor.

8 *Information to be submitted upon the*

Terms *Variant* 372

- AI systems
- Database
- Deployers
- Risk
- System

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.

Terms	*Variant*	373
AI systems		
Assessment		
Data		
Data protection (*privacy*)		
Deployers		
Impact assessment		
Information		
Information system		
Protection		
Risk		
		?

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.

Terms	*Variant*	374
AI systems		
Biometric data		
Biometric identification		
Data		
Data protection (*privacy*)		
Deployers		
IT system		
Personal data		
Protection		
Protection of personal data		
Purpose		
Risk		
Surveillance		?
System		

Art. 26, 11

Without prejudice to Article 50 of this Regulation, deployers of high-risk AI systems referred to in Annex III that make decisions or assist in making decisions related to natural persons shall inform the natural persons that they are subject to the use of the high-risk AI system. For high-risk AI systems used for law enforcement purposes Article 13 of Directive (EU) 2016/680 shall apply.

Terms	*Variant*	375
AI systems		
Deployers		
Risk		
System		
		?

Art. 26, 12

Deployers shall cooperate with the relevant competent authorities in any action those authorities take in relation to the high-risk AI system in order to implement this Regulation.

Terms	*Variant*	376
Deployers		
Risk		
System		
		?

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

Art. 27

Fundamental rights impact assessment for high-risk AI systems

8 *Information to be submitted upon the*

Terms	*Variant*	377
AI systems		
Assessment		
Fundamental rights		
Impact assessment		
Risk		

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:

Terms	*Variant*	378
AI systems		
Assessment		
Deployers		
Fundamental rights		
Impact assessment		
Purpose		
Risk		
System		

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;

Terms	*Variant*	379
Processes		
Purpose		
Risk		
System		

Art. 27, 1(b)

a description of the period of time within which, and the frequency with which, each high-risk AI system is intended to be used;

Terms	*Variant*	380
Risk		
System		

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

Art. 27, 1(c)

the categories of natural persons and groups likely to be affected by its use in the specific context;

Terms *Variant* 381

Context of use

Art. 27, 1(d)

the specific risks of harm likely to have an impact on the categories of natural persons or groups of persons identified pursuant to point (c) of this paragraph, taking into account the information given by the provider pursuant to Article 13;

Terms *Variant* 382

Information

Art. 27, 1(e)

a description of the implementation of human oversight measures, according to the instructions for use;

Terms *Variant* 383

Human oversight

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.

Terms *Variant* 384

Governance

AI ACT and relative Article in AI Act | **Annexes and relative Article in AI Act**

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.

Terms	Variant	385
Fundamental rights		
Impact assessment		
Information		
Information system		
Risk		
System		

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.

Terms	Variant	386
Assessment		
Deployers		
Surveillance		

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.

Terms	Variant	387
Assessment		
Data		
Data protection (*privacy*)		
Fundamental rights		
Impact assessment		
Protection		

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.

Terms	Variant	388
Deployers		

AI ACT and relative Article in AI Act

Annexes and relative Article in AI Act

SECTION 4

Notifying authorities and notified bodies

Terms *Variant* 389

Art. 28

Notifying authorities

Terms *Variant* 390

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.

Terms *Variant* 391

- Assessment
- Assessment procedures
- Conformity
- Conformity assessment
- Monitoring

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.

Terms *Variant* 392

- Assessment
- Monitoring

AI ACT and relative Article in AI Act

Annexes and relative Article in AI Act

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.

Terms	*Variant*	393
Assessment		
Conformity		
Conformity assessment		
		?

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.

Terms	*Variant*	394
Assessment		
Conformity		
Conformity assessment		
		?

Art. 28, 5

Notifying authorities shall offer or provide neither any activities that conformity assessment bodies perform, nor any consultancy services on a commercial or competitive basis.

Terms	*Variant*	395
Assessment		
Conformity		
Conformity assessment		
		?

Art. 28, 6

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

Terms	*Variant*	396
Confidentiality (*personal data, identifiability*)		
Information		
		?

AI ACT and relative Article in AI Act

Annexes and relative Article in AI Act

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.

Terms	*Variant*	397
Fundamental rights		
Information		

Art. 29

Application of a conformity assessment body for notification

Terms	*Variant*	398
Assessment		
Conformity		
Conformity assessment		

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.

Terms	*Variant*	399
Assessment		
Conformity		
Conformity assessment		

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.

Terms	*Variant*	400
AI application		
AI systems		
Assessment		
Conformity		
Conformity assessment		

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

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.

Terms *Variant* 401

- Assessment
- Compliance (*complete*)
- Compliance with the requirements
- Conformity
- Conformity assessment
- Monitoring
- Verification

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.

Terms *Variant* 402

- Compliance (*complete*)
- Compliance with the requirements
- Documentation
- Support

Art. 30

Notification procedure

Terms *Variant* 403

Art. 30, 1

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

Terms *Variant* 404

- Assessment
- Conformity
- Conformity assessment

AI ACT and relative Article in AI Act

Annexes and relative Article in AI Act

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.

Terms	Variant	405
Assessment		
Conformity		
Conformity assessment		
		?

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.

Terms	Variant	406
AI systems		
Assessment		
Competence		
Conformity		
Conformity assessment		
		?

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).

Terms	Variant	407
Assessment		
Conformity		
Conformity assessment		
		?

Art. 30, 5

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.

Terms	Variant	408
Assessment		
Conformity		
Conformity assessment		
		?

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

Art. 31

Requirements relating to notified bodies

Terms *Variant* 409

Art. 31, 1

A notified body shall be established under the national law of a Member State and shall have legal personality.

Terms *Variant* 410

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.

Terms *Variant* 411

- Cybersecurity
- Management
- Quality management
- Quality management process

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.

Terms *Variant* 412

- Assessment
- Conformity
- Conformity assessment
- Operation

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

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.

Terms	*Variant*	413
AI systems		
Assessment		
Conformity		
Conformity assessment		
Economic risk		
Risk		
System		
		?

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.

Terms	*Variant*	414
AI systems		
Assessment		
Conformity		
Conformity assessment		
Design		
Level of risk		
Management		
Management system		
Risk		
Risk management		
		?

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.

Terms	*Variant*	415
Assessment		
Assessment procedures		
		?

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.

Terms	*Variant*	416
Assessment		
Assessment procedures		
Confidentiality (*personal data, identifiability*)		
Conformity		
Conformity assessment		
Documented information		
Information		
		?

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

Art. 31, 8

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.

Terms	*Variant*	417
IT system		
System		

Art. 31, 9

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.

Terms	*Variant*	418
Assessment		
Conformity		
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.

Terms	*Variant*	419
Competence		

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.

Terms	*Variant*	420
AI systems		
Availability		
Data		
Data requirements (*Data quality model*)		
Data set (*File*)		
Experience		
Knowledge		

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act* | *Terms* | *Variant* | 421

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.

Terms | *Variant* | 422

Art. 32

Presumption of conformity with requirements relating to notified bodies

Terms	Variant
Conformity	

Terms | *Variant* | 423

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.

Terms	Variant
Assessment	
Conformity	
Conformity assessment	

Terms | *Variant* | 424

Art. 33

Subsidiaries of notified bodies and subcontracting

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

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.

Terms *Variant* 425

Assessment

Conformity

Conformity assessment

Art. 33, 2

Notified bodies shall take full responsibility for the tasks performed by any subcontractors or subsidiaries.

Terms *Variant* 426

Art. 33, 3

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.

Terms *Variant* 427

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.

Terms *Variant* 428

Assessment

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

Art. 34

Operational obligations of notified bodies

Terms *Variant* 429

?

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.

Terms *Variant* 430

- AI systems
- Assessment
- Assessment procedures
- Conformity
- Conformity assessment
- Risk

?

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.

Terms *Variant* 431

- Compliance (*complete*)
- Compliance with the requirements
- IT system
- Level of risk
- Protection
- Providers
- Risk
- System

?

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.

Terms *Variant* 432

- Assessment
- Documentation
- Monitoring
- Providers

?

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

Art. 35

Identification numbers and lists of notified bodies

8 *Information to be submitted upon the*

Terms *Variant* 433

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.

Terms *Variant* 434

Art. 35, 2

The Commission shall make publicly available the list of the bodies notified under this Regulation, including their identification numbers and the activities for which they have been notified. The Commission shall ensure that the list is kept up to date.

Terms *Variant* 435

Art. 36

Changes to notifications

Terms *Variant* 436

AI ACT and relative Article in AI Act

Annexes and relative Article in AI 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).

Terms *Variant* 437

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.

Terms *Variant* 438

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.

Terms *Variant* 439

AI systems
Assessment
Complete
Conformity
Conformity assessment
IT system
Providers
Risk

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.

Terms *Variant* 440

AI ACT and relative Article in AI Act

Annexes and relative Article in AI Act

Art. 36, 5

Where its designation has been suspended, restricted, or fully or partially withdrawn, the notified body shall inform the providers concerned within 10 days.

Terms *Variant* 441

Providers

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.

Terms *Variant* 442

Surveillance

Art. 36, 7

In the event of the restriction, suspension or withdrawal of a designation, the notifying authority shall:

Terms *Variant* 443

Art. 36, 7(a)

assess the impact on the certificates issued by the notified body;

Terms *Variant* 444

AI ACT and relative Article in AI Act

Annexes and relative Article in AI Act

Art. 36, 7(b)

submit a report on its findings to the Commission and the other Member States within three months of having notified the changes to the designation;

Terms | Variant | 445

Art. 36, 7(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;

Terms | Variant | 446

- AI systems
- Conformity
- Risk

Art. 36, 7(d)

inform the Commission and the Member States about certificates the suspension or withdrawal of which it has required;

Terms | Variant | 447

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.

Terms | Variant | 448

- Fundamental rights
- Health
- Health risk
- Information
- Risk
- Safety

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:

Terms *Variant* 449

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

Terms *Variant* 450

Terms
Fundamental rights
Health
Health risk
Risk
Safety

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.

Terms *Variant* 451

Terms
IT system
Support
System

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:

Terms *Variant* 452

AI ACT and relative Article in AI Act

Annexes and relative Article in AI Act

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

Terms *Variant* 453

- AI systems
- Fundamental rights
- Health
- Health risk
- Risk
- Safety
- System

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 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.

Terms *Variant* 454

- AI systems
- Assessment
- IT system
- System

Art. 37

Challenge to the competence of notified bodies

Terms *Variant* 455

- Competence

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.

Terms *Variant* 456

- Competence

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

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.

Terms	Variant	
Competence		457
Information		

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.

Terms	Variant	
Information		458

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).

Terms	Variant	
		459

Art. 38

Coordination of notified bodies

Terms	Variant	
		460

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

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.

Terms *Variant* 461

- AI systems
- Assessment
- Assessment procedures
- Conformity
- Conformity assessment
- Risk

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.

Terms *Variant* 462

Art. 38, 3

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

Terms *Variant* 463

- Knowledge

Art. 39

Conformity assessment bodies of third countries

Terms *Variant* 464

- Assessment
- Conformity
- Conformity assessment

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

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.

Terms *Variant* 465

- Assessment
- Compliance (*complete*)
- Compliance with the requirements
- Conformity
- Conformity assessment

SECTION 5

Standards, conformity assessment, certificates, registration

Terms *Variant* 466

- Assessment
- Conformity
- Conformity assessment

Art. 40

Harmonised standards and standardisation deliverables

Terms *Variant* 467

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 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.

Terms *Variant* 468

- AI models
- AI systems
- Conformity
- Purpose
- Risk

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

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.

Terms	*Variant*	469
AI models		
AI system lifecycle		
AI systems		
Documentation		
Lifecycle		
Processes		
Products		
Purpose		
Risk		
Service		
System		
		?

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.

Terms	*Variant*	470
Fundamental rights		
Governance		
Innovation		
Stakeholder		
		?

Art. 41

Common specifications

Terms	*Variant*	471
		?

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:

Terms	*Variant*	472
		?

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

Art. 41, 1(a)

the Commission has requested, pursuant to Article 10(1) of 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:

Terms *Variant* 473

?

Art. 41, 1(a)(i)

the request has not been accepted by any of the European standardisation organisations; or

Terms *Variant* 474

?

Art. 41, 1(a)(ii)

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

Terms *Variant* 475

?

Art. 41, 1(a)(iii)

the relevant harmonised standards insufficiently address fundamental rights concerns; or

Terms *Variant* 476

Fundamental rights

?

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

Art. 41, 1(a)(iv)

the harmonised standards do not comply with the request; and

Terms *Variant* 477

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).

Terms *Variant* 478

Art. 41, 2

Before preparing a draft implementing act, the Commission shall inform the committee referred to in Article 22 of Regulation (EU) No 1025/2012 that it considers the conditions laid down in paragraph 1 of this Article to be fulfilled.

Terms *Variant* 479

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.

Terms *Variant* 480

Terms	Variant
AI models	
AI systems	
Conformity	
Purpose	
Risk	

AI ACT and relative Article in AI Act

Annexes and relative Article in AI Act

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.

Terms	Variant	481

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.

Terms	Variant	482
AI models		
AI systems		
Level of risk		
Providers		
Purpose		
Risk		

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.

Terms	Variant	483
Information		

Art. 42

Presumption of conformity with certain requirements

Terms	Variant	484
Conformity		

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

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).

Terms	*Variant*	485
AI systems		
Data		
Data requirements (*Data quality model*)		
Data set (*File*)		
Functional setting		
Risk		
		?

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.

Terms	*Variant*	486
AI systems		
Conformity		
Cybersecurity		
Risk		
		?

Art. 43

Conformity assessment

Terms	*Variant*	487
Assessment		
Conformity		
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:

Terms	*Variant*	488
AI systems		
Assessment		
Assessment procedures		
Compliance (*complete*)		
Compliance with the requirements		
Conformity		
Conformity assessment		
Risk		
System		
		?

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

Art. 43, 1(a)

the internal control referred to in Annex VI; or

Terms *Variant* 489

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:

Terms *Variant* 490

- Assessment
- Compliance (*complete*)
- Compliance with the requirements
- Conformity
- Conformity assessment
- Documentation
- Management
- Management system
- Quality management
- Risk
- Risk management
- System
- Technical documentation

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;

Terms *Variant* 491

Art. 43, 1(b)

the provider has not applied, or has applied only part of, the harmonised standard;

Terms *Variant* 492

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

Art. 43, 1(c)

the common specifications referred to in point (a) exist, but the provider has not applied them;

Terms *Variant* 493

Art. 43, 1(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.

Terms *Variant* 494

- Assessment
- Conformity
- Conformity assessment
- Risk
- Service
- Surveillance
- System

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.

Terms *Variant* 495

- AI systems
- Assessment
- Conformity
- Conformity assessment
- Providers
- Risk

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.

Terms *Variant* 496

- AI systems
- Assessment
- Compliance (*complete*)
- Compliance with the requirements
- Conformity
- Conformity assessment
- Context of use
- IT system
- Risk

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

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.

7 *Conformity based on an assessment of the quality management*

Terms	*Variant*	497
AI systems		
Assessment		
Conformity		
Conformity assessment		
Documentation		
Information		
Information system		
Risk		
Service		
System		
Technical documentation		
		?

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.

Terms	*Variant*	498
Updating		
		?

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.

Terms	*Variant*	499
AI systems		
Assessment		
Assessment of the availability		
Availability		
Conformity		
Conformity assessment		
Effectiveness		
Fundamental rights		
Health		
Health risk		
Protection		
Risk		
Safety		?

Art. 44

Certificates

Terms	*Variant*	500
		?

AI ACT and relative Article in AI Act

Annexes and relative Article in AI Act

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.

Terms *Variant* 501

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.

Terms *Variant* 502

AI systems
Assessment
Assessment procedures
Conformity
Conformity assessment
IT system

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.

Terms *Variant* 503

Compliance (*complete*)
Compliance with the requirements
Conformity
IT system
System

Art. 45

Information obligations of notified bodies

Terms *Variant* 504

Information

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

Art. 45, 1

Notified bodies shall inform the notifying authority of the following:

Terms *Variant* 505

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;

Terms *Variant* 506

- Assessment
- Documentation
- Management
- Management system
- Quality management
- System
- Technical documentation

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;

Terms *Variant* 507

- Assessment
- Documentation
- Management
- Management system
- Quality management
- System
- Technical documentation

Art. 45, 1(c)

any circumstances affecting the scope of or conditions for notification;

Terms *Variant* 508

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

Art. 45, 1(d)

any request for information which they have received from market surveillance authorities regarding conformity assessment activities;

Terms	Variant	509
Assessment		
Conformity		
Conformity assessment		
Information		
Surveillance		

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.

Terms	Variant	510
Assessment		
Conformity		
Conformity assessment		

Art. 45, 2

Each notified body shall inform the other notified bodies of:

Terms	Variant	511

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;

Terms	Variant	512
IT system		
Management		
Management system		
Quality management		
System		

AI ACT and relative Article in AI Act | **Annexes and relative Article in AI Act**

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.

Terms	Variant	513
Assessment		
Documentation		
Technical documentation		
		?

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.

Terms	Variant	514
AI systems		
Assessment		
Conformity		
Conformity assessment		
Information		
Information system		
		?

Art. 45, 4

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

Terms	Variant	515
Confidentiality (*personal data, identifiability*)		
Information		
		?

Art. 46

Derogation from conformity assessment procedure

Terms	Variant	516
Assessment		
Conformity		
Conformity assessment		
		?

AI ACT and relative Article in AI Act

Annexes and relative Article in AI Act

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.

Terms	Variant	517
AI systems		
Assessment		
Assessment procedures		
Conformity		
Conformity assessment		
Environmental protection		
Environmental risk		
Health		
Health risk		
Protection		
Risk		
Security (*Cybersecurity*)		
Service		?
Surveillance		

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.

Terms	Variant	518
Protection		
Risk		
Safety		
Security (*Cybersecurity*)		
Service		
System		
		?

Art. 46, 3

The authorisation referred to in paragraph 1 shall be issued only if the market surveillance authority concludes that the high-risk AI system complies with the requirements of Section 2. The market surveillance authority shall inform the Commission and the other Member States of any authorisation issued pursuant to paragraphs 1 and 2. This obligation shall not cover sensitive operational data in relation to the activities of law-enforcement authorities.

Terms	Variant	519
Data		
Data requirements (*Data quality model*)		
Risk		
Surveillance		
System		
		?

Art. 46, 4

Where, within 15 calendar days of receipt of the information referred to in paragraph 3, no objection has been raised by either a Member State or the Commission in respect of an authorisation issued by a market surveillance authority of a Member State in accordance with paragraph 1, that authorisation shall be deemed justified.

Terms	Variant	520
Information		
Surveillance		
		?

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

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.

Terms *Variant* 521

- Compliance (*complete*)
- Surveillance
- System

Art. 46, 6

Where the Commission considers the authorisation unjustified, it shall be withdrawn by the market surveillance authority of the Member State concerned.

Terms *Variant* 522

- Surveillance

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.

Terms *Variant* 523

- AI systems
- Assessment
- Conformity
- Conformity assessment
- Products
- Risk

Art. 47

EU declaration of conformity

- ***4*** *Technical documentation*
- ***5*** *EU declaration of conformity*
- ***8*** *Information to be submitted upon the*

Terms *Variant* 524

- Conformity

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

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.

Terms	*Variant*	525
Conformity		
IT system		
Risk		
Service		
System		
		?

Art. 47, 2

The EU declaration of conformity shall state that the high-risk AI system concerned meets the requirements set out in Section 2. 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.

Terms	*Variant*	526
Conformity		
Information		
Information system		
Risk		
System		
		?

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 Union harmonisation legislation to which the declaration relates.

Terms	*Variant*	527
AI systems		
Conformity		
Information		
Information system		
Risk		
System		
		?

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.

Terms	*Variant*	528
Compliance (*complete*)		
Compliance with the requirements		
Conformity		
		?

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

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.

Terms	Variant	529
Conformity		
Updating		

Art. 48

CE marking

Terms	Variant	530

Art. 48, 1

The CE marking shall be subject to the general principles set out in Article 30 of Regulation (EC) No 765/2008.

Terms	Variant	531

Art. 48, 2

For high-risk AI systems provided digitally, a digital CE marking shall be used, only 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.

Terms	Variant	532
AI systems		
IT system		
Risk		
System		

AI ACT and relative Article in AI Act

Annexes and relative Article in AI Act

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.

Terms *Variant* 533

- AI systems
- Documentation
- IT system
- Risk
- System

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.

Terms *Variant* 534

- Assessment
- Assessment procedures
- Conformity
- Conformity assessment
- Risk
- System

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.

Terms *Variant* 535

- AI systems
- Risk
- System

Art. 49

Registration

8 *Information to be submitted upon the registration of high*

Terms *Variant* 536

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

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.

8 *Information to be submitted upon the*

Terms *Variant* 537

- AI systems
- Database
- Risk
- Service
- System

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.

8 *Information to be submitted upon the*

Terms *Variant* 538

- Database
- IT system
- Risk
- Service
- System

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.

8 *Information to be submitted upon the*

Terms *Variant* 539

- AI systems
- Database
- Deployers
- Risk
- Service
- System

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:

Terms *Variant* 540

- AI systems
- Database
- Information
- Information system
- Management
- Management system
- Risk
- Risk management

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act* | *Terms* | *Variant* | 541

Art. 49, 4(a)

Section A, points 1 to 10, of Annex VIII, with the exception of points 6, 8 and 9;

Terms | *Variant* | 542

Art. 49, 4(b)

Section B, points 1 to 5, and points 8 and 9 of Annex VIII;

Terms | *Variant* | 543

Art. 49, 4(c)

Section C, points 1 to 3, of Annex VIII;

Terms | *Variant* | 544

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.

Database

AI ACT and relative Article in AI Act

Annexes and relative Article in AI Act

Art. 49, 5

High-risk AI systems referred to in point 2 of Annex III shall be registered at national level.

Terms *Variant* 545

AI systems

Level of risk

Risk

?

Terms *Variant* 546

?

CHAPTER IV

TRANSPARENCY OBLIGATIONS FOR PROVIDERS AND DEPLOYERS OF CERTAIN AI SYSTEMS

Terms *Variant* 547

AI systems

Deployers

Providers

Transparency

?

Art. 50

Transparency obligations for providers and deployers of certain AI systems

Terms *Variant* 548

AI systems

Deployers

Providers

Transparency

?

AI ACT and relative Article in AI Act | **Annexes and relative Article in AI Act**

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.

Terms	Variant	549
AI systems		
Context of use		
Providers		
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	Variant	550
AI systems		
Data		
Data format		
Input data		
Providers		
Purpose		
System		

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.

Terms	Variant	551
AI systems		
Biometric data		
Data		
Deployers		
Operation		
Personal data		
System		

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 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.

Terms	Variant	552
Deployers		
Purpose		
System		
Transparency		

AI ACT and relative Article in AI Act

Annexes and relative Article in AI Act

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.

Terms	Variant	553
Accessibility (access)		
Information		

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.

Terms	Variant	554
AI systems		
Deployers		
Transparency		

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).

Terms	Variant	555
Labelling		

CHAPTER V

GENERAL-PURPOSE AI MODELS

Terms	Variant	556
AI models		
Purpose		

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

SECTION 1

Classification rules

Terms *Variant* 557

Classification (*categorization*)

?

Art. 51

Classification of general-purpose AI models as general-purpose AI models with systemic risk

13 *Criteria for the designation of*

Terms *Variant* 558

AI models

Classification (*categorization*)

Purpose

Risk

?

Art. 51

13 *Criteria for the designation of*

Terms *Variant* 559

?

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:

13 *Criteria for the designation of*

Terms *Variant* 560

IT system

Purpose

Risk

?

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

Art. 51, 1(a)

it has high impact capabilities evaluated on the basis of appropriate technical tools and methodologies, including indicators and benchmarks;

Terms *Variant* 561

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.

Terms *Variant* 562

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.

Terms *Variant* 563

Purpose

Training

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.

Terms *Variant* 564

Efficiency

Art. 52

Procedure

Terms *Variant* 565

?

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.

Terms *Variant* 566

- Information
- Information system
- IT system
- Purpose
- 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.

Terms *Variant* 567

- IT system
- Purpose
- 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.

Terms *Variant* 568

- IT system
- Purpose
- Risk

?

AI ACT and relative Article in AI Act

Annexes and relative Article in AI Act

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.

Terms *Variant* 569

Purpose

Updating

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.

Terms *Variant* 570

Providers

Purpose

Risk

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.

Terms *Variant* 571

AI models

Information

Information system

Purpose

Risk

SECTION 2

Obligations for providers of general-purpose AI models

Terms *Variant* 572

AI models

Providers

Purpose

AI ACT and relative Article in AI Act

Annexes and relative Article in AI Act

Art. 53

Obligations for providers of general-purpose AI models

Terms *Variant* 573

AI models

Providers

Purpose

?

Art. 53, 1

Providers of general-purpose AI models shall:

11 *Technical documentation*

12 *Transparency information referred*

Terms *Variant* 574

AI models

Providers

Purpose

?

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;

Terms *Variant* 575

Documentation

Evaluation (*Evaluating*)

Information

Purpose

Technical documentation

Testing

Training

?

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:

Terms *Variant* 576

AI systems

Documentation

Information

Information system

Providers

Purpose

?

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

Art. 53, 1(i)

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

Terms	Variant	577
AI systems		
Providers		
Purpose		

Art. 53, 1(ii)

contain, at a minimum, the elements set out in Annex XII;

Terms	Variant	578

Art. 53, 1(c)

put in place a policy to comply with Union law on copyright and related rights, and in particular to identify and comply with, including through state-of-the-art technologies, a reservation of rights expressed pursuant to Article 4(3) of Directive (EU) 2019/790;

Terms	Variant	579

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.

Terms	Variant	580
Purpose		
Training		

AI ACT and relative Article in AI Act

Annexes and relative Article in AI Act

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.

Terms	*Variant*	581
AI models		
Architecture		
Information		
Information system		
Providers		
Purpose		
		?

Art. 53, 3

Providers of general-purpose AI models shall cooperate as necessary with the Commission and the national competent authorities in the exercise of their competences and powers pursuant to this Regulation.

Terms	*Variant*	582
AI models		
Providers		
Purpose		
		?

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.

Terms	*Variant*	583
AI models		
Assessment		
Compliance (*complete*)		
Conformity		
Conformity assessment		
Providers		
Purpose		
		?

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.

Terms	*Variant*	584
Compliance (*complete*)		
Documentation		
Measurement (*measuring*)		
Measurement and method		
Purpose		
		?

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

Art. 53, 6

The Commission is empowered to adopt delegated acts in accordance with Article 97(2) to amend Annexes XI and XII in light of evolving technological developments.

Terms *Variant* 585

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.

Terms *Variant* 586

- Confidentiality (*personal data, identifiability*)
- Documentation
- Information

Art. 54

Authorised representatives of providers of general-purpose AI models

Terms *Variant* 587

- AI models
- Providers
- Purpose

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.

Terms *Variant* 588

- Providers
- Purpose

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

Art. 54, 2

The provider shall enable its authorised representative to perform the tasks specified in the mandate received from the provider.

Terms *Variant* 589

?

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:

Terms *Variant* 590

?

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;

Terms *Variant* 591

Documentation

Technical documentation

?

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;

Terms *Variant* 592

Contact

Documentation

Purpose

Technical documentation

?

AI ACT and relative Article in AI Act

Annexes and relative Article in AI Act

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;

Terms	*Variant*	593
Compliance (*complete*)		
Documentation		
Information		
		?

Art. 54, 3(d)

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.

Terms	*Variant*	594
AI systems		
Purpose		
Service		
		?

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.

Terms	*Variant*	595
Compliance (*complete*)		
		?

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.

Terms	*Variant*	596
		?

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

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.

Terms *Variant* 597

- AI models
- Architecture
- Information
- Information system
- Providers
- Purpose

SECTION 3

Obligations of providers of general-purpose AI models with systemic risk

Terms *Variant* 598

- AI models
- Providers
- Purpose
- Risk

Art. 55

Obligations of providers of general-purpose AI models with systemic risk

Terms *Variant* 599

- AI models
- Providers
- Purpose
- 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:

Terms *Variant* 600

- AI models
- Providers
- Purpose
- Risk

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

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;

Terms *Variant* 601

- Evaluation (*Evaluating*)
- Testing

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;

Terms *Variant* 602

- AI models
- Level of risk
- Purpose
- Risk

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;

Terms *Variant* 603

- Information

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.

Terms *Variant* 604

- Cybersecurity
- Level of risk
- Protection
- Purpose
- Risk

AI ACT and relative Article in AI Act | **Annexes and relative Article in AI Act**

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.

Terms	Variant	605
AI models		
Assessment		
Compliance (*complete*)		
Conformity		
Conformity assessment		
Providers		
Purpose		
Risk		
		?

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.

Terms	Variant	606
Confidentiality (*personal data, identifiability*)		
Documentation		
Information		
		?

SECTION 4

Codes of practice

Terms	Variant	607
		?

Art. 56

Codes of practice

Terms	Variant	608
		?

AI ACT and relative Article in AI Act

Annexes and relative Article in AI Act

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.

Terms *Variant* 609

AI application

?

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:

Terms *Variant* 610

?

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;

Terms *Variant* 611

Information

?

Art. 56, 2(b)

the adequate level of detail for the summary about the content used for training;

Terms *Variant* 612

Training

?

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

Art. 56, 2(c)

the identification of the type and nature of the systemic risks at Union level, including their sources, where appropriate;

Terms *Variant* 613

Level of risk

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.

Terms *Variant* 614

Assessment

Assessment procedures

Documentation

Level of risk

Management

Management system

Probability measure

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.

Terms *Variant* 615

AI models

Providers

Purpose

Society

Support

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.

Terms *Variant* 616

AI ACT and relative Article in AI Act

Annexes and relative Article in AI Act

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 reporting commitments shall reflect differences in size and capacity between various participants.

Terms	Variant	617

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).

Terms	Variant	618
AI application		
Assessment		

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.

Terms	Variant	619
AI models		
Providers		
Purpose		

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.

Terms	Variant	620
Assessment		

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).

Terms *Variant* 621

Assessment

Providers

?

CHAPTER VI

MEASURES IN SUPPORT OF INNOVATION

Terms *Variant* 622

Innovation

Support

?

Art. 57

AI regulatory sandboxes

Terms *Variant* 623

?

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.

Terms *Variant* 624

Operation

Support

?

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

Art. 57, 2

Additional AI regulatory sandboxes at regional or local level, or established jointly with the competent authorities of other Member States may also be established.

Terms *Variant* 625

?

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.

Terms *Variant* 626

Data

Data protection (*privacy*)

Protection

?

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.

Terms *Variant* 627

AI Ecosystem

?

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.

Terms *Variant* 628

AI systems

Innovation

Providers

Service

Testing

Training

Validation

?

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

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.

Terms *Variant* 629

- Effectiveness
- Fundamental rights
- Health
- Health risk
- Safety
- Support
- Testing

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.

Terms *Variant* 630

- Assessment
- Assessment procedures
- Compliance (*complete*)
- Compliance with the requirements
- Conformity
- Conformity assessment
- Documentation
- Providers
- Surveillance
- System

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.

Terms *Variant* 631

- Appropriate confidentiality
- Confidentiality (*personal data, identifiability*)
- Information

Art. 57, 9

The establishment of AI regulatory sandboxes shall aim to contribute to the following objectives:

Terms *Variant* 632

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

Art. 57, 9(a)

improving legal certainty to achieve regulatory compliance with this Regulation or, where relevant, other applicable Union and national law;

Terms	Variant	633
Compliance (*complete*)		

Art. 57, 9(b)

supporting the sharing of best practices through cooperation with the authorities involved in the AI regulatory sandbox;

Terms	Variant	634

Art. 57, 9(c)

fostering innovation and competitiveness and facilitating the development of an AI ecosystem;

Terms	Variant	635
AI Ecosystem		
Innovation		

Art. 57, 9(d)

contributing to evidence-based regulatory learning;

Terms	Variant	636

AI ACT and relative Article in AI Act

Annexes and relative Article in AI Act

Art. 57, 9(e)

facilitating and accelerating access to the Union market for AI systems, in particular when provided by SMEs, including start-ups.

Terms	*Variant*	637
AI systems		
		?

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.

Terms	*Variant*	638
AI systems		
Data		
Data protection (*privacy*)		
Operation		
Personal data		
Protection		
Protection of personal data		
		?

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.

Terms	*Variant*	639
AI systems		
Fundamental rights		
Health		
Health risk		
Innovation		
Level of risk		
Safety		
Testing		
		?

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.

Terms	*Variant*	640
Compliance (*complete*)		
Providers		
System		
		?

AI ACT and relative Article in AI Act

Annexes and relative Article in AI Act

Art. 57, 13

The AI regulatory sandboxes shall be designed and implemented in such a way that, where relevant, they facilitate cross-border cooperation between national competent authorities.

Terms *Variant* 641

Art. 57, 14

National competent authorities shall coordinate their activities and cooperate within the framework of the Board.

Terms *Variant* 642

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.

Terms *Variant* 643

Support

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.

Terms *Variant* 644

AI application

Information

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

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.

Terms	*Variant*	645
AI models		
Conformity		
Information		
Products		

Art. 58

Detailed arrangements for, and functioning of, AI regulatory sandboxes

Terms	*Variant*	646

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:

Terms	*Variant*	647
Operation		

Art. 58, 1(a)

eligibility and selection criteria for participation in the AI regulatory sandbox;

Terms	*Variant*	648

AI ACT and relative Article in AI Act

Annexes and relative Article in AI Act

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;

Terms	Variant	649
AI application		
Monitoring		

Art. 58, 1(c)

the terms and conditions applicable to the participants. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 98(2).

Terms	Variant	650

Art. 58, 2

The implementing acts referred to in paragraph 1 shall ensure:

Terms	Variant	651

Art. 58, 2(a)

that AI regulatory sandboxes are open to any applying provider or prospective provider of an AI system who fulfils eligibility and selection criteria, which shall be transparent and fair, and that national competent authorities inform applicants of their decision within three months of the application;

Terms	Variant	652
AI application		
System		

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

Art. 58, 2(b)

that AI regulatory sandboxes allow 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;

Terms *Variant* 653

- AI application
- Deployers
- Providers

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;

Terms *Variant* 654

- Flexibility
- Support

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;

Terms *Variant* 655

Art. 58, 2(e)

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 95;

Terms *Variant* 656

- AI application
- Assessment
- Conformity
- Conformity assessment
- Providers

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

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;

Terms	*Variant*	657
AI Ecosystem		
Innovation		
Testing		
		?

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;

Terms	*Variant*	658
AI application		
Data		
Data protection (*privacy*)		
Data requirements (*Data quality model*)		
Processes		
Protection		
		?

Art. 58, 2(h)

that participation in the AI regulatory sandbox is limited to a period that is appropriate to the complexity and scale of the project and that may be extended by the national competent authority;

Terms	*Variant*	659
		?

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.

Terms	*Variant*	660
Accuracy (*free of errors*)		
AI systems		
Cybersecurity		
Fundamental rights		
Society		
Testing		
		?

AI ACT and relative Article in AI Act | **Annexes and relative Article in AI Act**

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.

Terms	Variant	661
Innovation		
Providers		
Testing		
		?

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.

Terms	Variant	662
Fundamental rights		
Health		
Safety		
Testing		
		?

Art. 59

Further processing of personal data for developing certain AI systems in the public interest in the AI regulatory sandbox

Terms	Variant	663
AI systems		
Data		
Personal data		
		?

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:

Terms	Variant	664
AI systems		
Data		
Personal data		
Purpose		
Testing		
Training		
		?

AI ACT and relative Article in AI Act

Annexes and relative Article in AI Act

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:

Terms	Variant	665
AI systems		

Art. 59, 1(a)(i)

public safety and public health, including disease detection, diagnosis prevention, control and treatment and improvement of health care systems;

Terms	Variant	666
Health		
Improvement		
Safety		

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	Variant	667
Improvement		
Protection		

Art. 59, 1(a)(iii)

energy sustainability;

Terms	Variant	668

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

Art. 59, 1(a)(iv)

safety and resilience of transport systems and mobility, critical infrastructure and networks;

Terms	Variant	
Safety		669

Art. 59, 1(a)(v)

efficiency and quality of public administration and public services;

Terms	Variant	
Efficiency		670

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;

Terms	Variant	
Data		671
Data requirements (*Data quality model*)		
Personal data		
Synthetic or anonymised data		

Art. 59, 1(c)

there are effective monitoring mechanisms to identify if 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;

Terms	Variant	
Data		672
Monitoring		

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

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;

Terms *Variant* 673

- Access control
- Data
- Personal 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;

Terms *Variant* 674

- Data
- Data protection (*privacy*)
- Personal data
- Protection
- Providers
- ?

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;

Terms *Variant* 675

- Data
- Data protection (*privacy*)
- Personal data
- Protection
- 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;

Terms *Variant* 676

- Data
- Data retention (*Data recoverability*)
- Personal data
- ?

AI ACT and relative Article in AI Act

Annexes and relative Article in AI Act

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;

Terms *Variant* 677

- Data
- Logs
- Personal data
- ?

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;

Terms *Variant* 678

- Complete
- Documentation
- System
- Technical documentation
- Testing
- Training
- Validation
- ?

Art. 59, 1(j)

a short summary of the AI project developed in the sandbox, its objectives and expected results is published on the website of the competent authorities; this obligation shall not cover sensitive operational data in relation to the activities of law enforcement, border control, immigration or asylum authorities.

Terms *Variant* 679

- Data
- ?

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.

Terms *Variant* 680

- Data
- Personal data
- Security (*Cybersecurity*)
- ?

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.

Terms	Variant	681
AI systems		
Compliance (*complete*)		
Data		
Data protection (*privacy*)		
Personal data		
Protection		
Protection of personal data		
Purpose		
Testing		
Training		
		?

Art. 60

Testing of high-risk AI systems in real world conditions outside AI regulatory sandboxes

9	Information to be submitted upon the

Terms	Variant	682
AI systems		
Risk		
Testing		
		?

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 98(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.

Terms	Variant	683
AI systems		
Products		
Providers		
Risk		
Testing		
		?

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.

Terms	Variant	684
AI systems		
Deployers		
Providers		
Risk		
Service		
System		
Testing		
		?

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

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.

Terms	*Variant*	685
AI systems		
Ethical review		
Ethical risk		
Risk		
Testing		
		?

Art. 60, 4

Providers or prospective providers may conduct the testing in real world conditions only where all of the following conditions are met:

Terms	*Variant*	686
Providers		
Testing		
		?

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;

Terms	*Variant*	687
Surveillance		
Testing		
		?

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;

Terms	*Variant*	688
Surveillance		
Testing		
		?

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

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);

Terms	*Variant*	689
AI systems		
Database		
Information		
Information system		
Management		
Management system		
Providers		
Risk		
Risk management		
Testing		
		?

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;

Terms	*Variant*	690
Testing		
		?

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;

Terms	*Variant*	691
Data		
Purpose		
Testing		
		?

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;

Terms	*Variant*	692
Surveillance		
Testing		
		?

AI ACT and relative Article in AI Act

Annexes and relative Article in AI Act

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;

Terms	Variant	693
Disability		
Testing		

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;

Terms	Variant	694
Compliance (*complete*)		
Deployers		
System		
Testing		

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;

Terms	Variant	695
Data		
Personal data		
System		
Test data		
Testing		

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;

Terms	Variant	696
Deployers		
Testing		
Training		

AI ACT and relative Article in AI Act | **Annexes and relative Article in AI Act**

Art. 60, 4(k)

the predictions, recommendations or decisions of the AI system can be effectively reversed and disregarded.

Terms	Variant	697
System		

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.

Terms	Variant	698
Data		
Personal data		
Testing		

Art. 60, 6

In accordance with Article 75, Member States shall confer on their market surveillance authorities the powers of 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.

Terms	Variant	699
AI systems		
Information		
Information system		
Providers		
Risk		
Surveillance		
Testing		

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.

Terms	Variant	700
Incident		
IT system		
Surveillance		
System		
Testing		

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

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.

Terms	Variant	701
Providers		
Surveillance		
Testing		
		?

Art. 60, 9

The provider or prospective provider shall be liable under applicable Union and national liability law for any damage caused in the course of their testing in real world conditions.

Terms	Variant	702
Testing		
		?

Art. 61

Informed consent to participate in testing in real world conditions outside AI regulatory sandboxes

Terms	Variant	703
Testing		
		?

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:

Terms	Variant	704
Information		
Purpose		
Testing		
		?

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

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;

Terms	Variant	
Testing		705

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 or subjects' participation;

Terms	Variant	
Testing		706

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;

Terms	Variant	
Testing		707

Art. 61, 1(d)

the arrangements for requesting the reversal or the disregarding of the predictions, recommendations or decisions of the AI system;

Terms	Variant	
System		708

AI ACT and relative Article in AI Act

Annexes and relative Article in AI Act

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.

Terms *Variant* 709

Contact

Information

Testing

?

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.

Terms *Variant* 710

Testing

?

Art. 62

Measures for providers and deployers, in particular SMEs, including start-ups

Terms *Variant* 711

Deployers

Providers

?

Art. 62

Terms *Variant* 712

?

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

Art. 62, 1

Member States shall undertake the following actions:

Terms *Variant* 713

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;

Terms *Variant* 714

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;

Terms *Variant* 715

Deployers

Training

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;

Terms *Variant* 716

Deployers

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

Art. 62, 1(d)

facilitate the participation of SMEs and other relevant stakeholders in the standardisation development process.

Terms *Variant* 717

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.

Terms *Variant* 718

Assessment

Conformity

Conformity assessment

Providers

Art. 62, 3

The AI Office shall undertake the following actions:

Terms *Variant* 719

Art. 62, 3(a)

provide standardised templates for areas covered by this Regulation, as specified by the Board in its request;

Terms *Variant* 720

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

Art. 62, 3(b)

develop and maintain a single information platform providing easy to use information in relation to this Regulation for all operators across the Union;

Terms *Variant* 721

Information

Art. 62, 3(c)

organise appropriate communication campaigns to raise awareness about the obligations arising from this Regulation;

Terms *Variant* 722

Art. 62, 3(d)

evaluate and promote the convergence of best practices in public procurement procedures in relation to AI systems.

Terms *Variant* 723

AI systems

Art. 63

Derogations for specific operators

Terms *Variant* 724

AI ACT and relative Article in AI Act

Annexes and relative Article in AI Act

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.

Terms	Variant	725
AI systems		
Compliance (*complete*)		
Compliance with the requirements		
Level of risk		
Management		
Management system		
Protection		
Purpose		
Quality management		
Risk		
Risk management		
System		
		?

Art. 63, 2

Paragraph 1 of this Article shall not be interpreted as exempting those operators from fulfilling any other requirements or obligations laid down in this Regulation, including those established in Articles 9, 10, 11, 12, 13, 14, 15, 72 and 73.

Terms	Variant	726
		?

CHAPTER VII

GOVERNANCE

Terms	Variant	727
Governance		
		?

SECTION 1

Governance at Union level

Terms	Variant	728
Governance		
		?

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

Art. 64

AI Office

Terms *Variant* 729

Art. 64, 1

The Commission shall develop Union expertise and capabilities in the field of AI through the AI Office.

Terms *Variant* 730

Art. 64, 2

Member States shall facilitate the tasks entrusted to the AI Office, as reflected in this Regulation.

Terms *Variant* 731

Art. 65

Establishment and structure of the European Artificial Intelligence Board

Terms *Variant* 732

Artificial intelligence

AI ACT and relative Article in AI Act

Annexes and relative Article in AI Act

Art. 65

Terms *Variant* 733

Art. 65, 1

A European Artificial Intelligence Board (the 'Board') is hereby established.

Terms *Variant* 734

Artificial intelligence

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.

Terms *Variant* 735

Data

Data protection (*privacy*)

Protection

Relevance

Art. 65, 3

Each representative shall be designated by their Member State for a period of three years, renewable once.

Terms *Variant* 736

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

Art. 65, 4

Member States shall ensure that their representatives on the Board:

Terms *Variant* 737

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;

Terms *Variant* 738

Art. 65, 4(b)

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;

Terms *Variant* 739

Contact

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.

Terms *Variant* 740

Consistency

Data

Information

Purpose

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.

Terms *Variant* 741

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.

Terms *Variant* 742

Purpose

Surveillance

Art. 65, 7

The Board shall be organised and operated so as to safeguard the objectivity and impartiality of its activities.

Terms *Variant* 743

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.

Terms *Variant* 744

Art. 66

Tasks of the Board

Terms Variant 745

Art. 66

The Board shall advise and assist the Commission and the Member States in order to facilitate the consistent and effective application of this Regulation. To that end, the Board may in particular:

Terms Variant 746

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);

Terms Variant 747

Support

Surveillance

Art. 66, (b)

collect and share technical and regulatory expertise and best practices among Member States;

Terms Variant 748

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

Art. 66, (c)

provide advice on the implementation of this Regulation, in particular as regards the enforcement of rules on general-purpose AI models;

Terms	Variant	749
AI models		
Purpose		

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;

Terms	Variant	750
Assessment		
Assessment procedures		
Conformity		
Conformity assessment		
Testing		

Art. 66, (e)

at the request of the Commission or on its own initiative, issue recommendations and written opinions on any relevant matters related to the implementation of this Regulation and to its consistent and effective application, including:

Terms	Variant	751

Art. 66, (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;

Terms	Variant	752

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

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;

Terms	*Variant*	753
Database		
Evaluation (*Evaluating*)		
Incident		
Preparation		
		?

Art. 66, (e)(iii)

on technical specifications or existing standards regarding the requirements set out in Chapter III, Section 2;

Terms	*Variant*	754
		?

Art. 66, (e)(iv)

on the use of harmonised standards or common specifications referred to in Articles 40 and 41;

Terms	*Variant*	755
		?

Art. 66, (e)(v)

trends, such as European global competitiveness in AI, the uptake of AI in the Union, and the development of digital skills;

Terms	*Variant*	756
		?

AI ACT and relative Article in AI Act

Annexes and relative Article in AI Act

Art. 66, (e)(vi)

trends on the evolving typology of AI value chains, in particular on the resulting implications in terms of accountability;

Terms	Variant	
Accountability		757

Art. 66, (e)(vii)

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;

Terms	Variant	
		758

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;

Terms	Variant	
AI literacy		759
AI systems		
Literacy		
Support		

Art. 66, (g)

facilitate the development of common criteria and a shared understanding among market operators and competent authorities of the relevant concepts provided for in this Regulation, including by contributing to the development of benchmarks;

Terms	Variant	
		760

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

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;

Terms *Variant* 761

- Cybersecurity
- Data
- Data protection (*privacy*)
- Fundamental rights
- Protection
- Safety

Art. 66, (i)

contribute to effective cooperation with the competent authorities of third countries and with international organisations;

Terms *Variant* 762

Art. 66, (j)

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;

Terms *Variant* 763

- Assessment
- Training

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;

Terms *Variant* 764

- Information

AI ACT and relative Article in AI Act

Annexes and relative Article in AI Act

Art. 66, (l)

contribute to, and provide relevant advice on, the development of guidance documents;

Terms | Variant | 765

Art. 66, (m)

advise the Commission in relation to international matters on AI;

Terms | Variant | 766

Art. 66, (n)

provide opinions to the Commission on the qualified alerts regarding general-purpose AI models;

Terms | Variant | 767

AI models

Purpose

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.

Terms | Variant | 768

AI models

AI systems

Monitoring

Purpose

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act* | *Terms* | *Variant* | 769

Art. 67

Advisory forum

Terms | *Variant* | 770

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.

Terms | *Variant* | 771

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.

Society

Terms | *Variant* | 772

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.

AI ACT and relative Article in AI Act

Annexes and relative Article in AI Act

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.

Terms *Variant* 773

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.

Terms *Variant* 774

Fundamental rights

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.

Terms *Variant* 775

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.

Terms *Variant* 776

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

Art. 67, 8

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

Terms *Variant* 777

?

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.

Terms *Variant* 778

Purpose

?

Art. 67, 10

The advisory forum shall prepare an annual report on its activities. That report shall be made publicly available.

Terms *Variant* 779

?

Art. 68

Scientific panel of independent experts

Terms *Variant* 780

?

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

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).

Terms *Variant* 781

Support

Art. 68, 2

The scientific panel shall consist of experts selected 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:

Terms *Variant* 782

Art. 68, 2(a)

having particular expertise and competence and scientific or technical expertise in the field of AI;

Terms *Variant* 783

Competence

Art. 68, 2(b)

independence from any provider of AI systems or general-purpose AI models;

Terms *Variant* 784

AI models

AI systems

Purpose

AI ACT and relative Article in AI Act

Annexes and relative Article in AI Act

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.

Terms *Variant* 785

Art. 68, 3

The scientific panel shall advise and support the AI Office, in particular with regard to the following tasks:

Terms *Variant* 786

Support

Art. 68, 3(a)

supporting the implementation and enforcement of this Regulation as regards general-purpose AI models and systems, in particular by:

Terms *Variant* 787

AI models

AI systems

Purpose

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;

Terms *Variant* 788

AI models

Level of risk

Purpose

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

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;

Terms	*Variant*	789
AI models		
AI systems		
Purpose		

Art. 68, 3(a)(iii)

providing advice on the classification of general-purpose AI models with systemic risk;

Terms	*Variant*	790
AI models		
Classification (*categorization*)		
Purpose		
Risk		

Art. 68, 3(a)(iv)

providing advice on the classification of various general-purpose AI models and systems;

Terms	*Variant*	791
AI models		
AI systems		
Classification (*categorization*)		
Purpose		

Art. 68, 3(a)(v)

contributing to the development of tools and templates;

Terms	*Variant*	792

Art. 68, 3(b)

supporting the work of market surveillance authorities, at their request;

Terms	Variant	793
Surveillance		

Art. 68, 3(c)

supporting cross-border market surveillance activities as referred to in Article 74(11), without prejudice to the powers of market surveillance authorities;

Terms	Variant	794
Surveillance		

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.

Terms	Variant	795

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.

Terms	Variant	796
AI systems		
Confidentiality (*personal data, identifiability*)		
Data		
Information		
Information system		

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act* | *Terms* | *Variant*

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.

797

Art. 69

Access to the pool of experts by the Member States

798

Art. 69, 1

Member States may call upon experts of the scientific panel to support their enforcement activities under this Regulation.

799

Support

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.

800

Effectiveness

Support

AI ACT and relative Article in AI Act

Annexes and relative Article in AI Act

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.

Terms	Variant	801
Support		
Testing		
		?

SECTION 2

National competent authorities

Terms	Variant	802
		?

Art. 70

Designation of national competent authorities and single points of contact

Terms	Variant	803
Contact		
		?

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.

Terms	Variant	804
Bias		
Surveillance		
		?

AI ACT and relative Article in AI Act

Annexes and relative Article in AI Act

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.

Terms	*Variant*	805
Contact		
Information		
Surveillance		
		?

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.

Terms	*Variant*	806
Competence		
Cybersecurity		
Data		
Data protection (*privacy*)		
Data requirements (*Data quality model*)		
Data resources		
Fundamental rights		
Health		
Health risk		
Knowledge		
Personal data		
Protection		
Protection of personal data		?
Safety		

Art. 70, 4

National competent authorities shall take appropriate measures to ensure an adequate level of cybersecurity.

Terms	*Variant*	807
Cybersecurity		
		?

Art. 70, 5

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

Terms	*Variant*	808
Confidentiality (*personal data, identifiability*)		
		?

AI ACT and relative Article in AI Act

Annexes and relative Article in AI Act

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.

Terms	*Variant*	809
Assessment		
Information		

Art. 70, 7

The Commission shall facilitate the exchange of experience between national competent authorities.

Terms	*Variant*	810
Experience		

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. 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.

Terms	*Variant*	811
System		

Art. 70, 9

Where Union institutions, bodies, offices or agencies fall within the scope of this Regulation, the European Data Protection Supervisor shall act as the competent authority for their supervision.

Terms	*Variant*	812
Data		
Data protection (*privacy*)		
Protection		

AI ACT and relative Article in AI Act

Annexes and relative Article in AI Act

CHAPTER VIII

EU DATABASE FOR HIGH-RISK AI SYSTEMS

Terms	Variant	813
AI systems		
Database		
Risk		
		?

Art. 71

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

Terms	Variant	814
AI systems		
Database		
Risk		
		?

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.

Terms	Variant	815
AI systems		
Database		
Functional setting		
Information		
Information system		
Risk		
Updating		
		?

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.

Terms	Variant	816
Data		
Database		
		?

AI ACT and relative Article in AI Act

Annexes and relative Article in AI Act

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).

Terms *Variant* 817

- Data
- Database

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 the public.

Terms *Variant* 818

- Database
- Information
- Surveillance
- User

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.

Terms *Variant* 819

- Contact
- Data
- Database
- Information
- Information system
- Personal data
- System

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.

Terms *Variant* 820

- Accessibility (*access*)
- Controller
- Database
- Deployers
- Providers
- Support

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

CHAPTER IX

POST-MARKET MONITORING, INFORMATION SHARING AND MARKET SURVEILLANCE

Terms *Variant* 821

- Information
- Monitoring
- Post-market (*Quaity in use, Post production*)
- Surveillance

SECTION 1

Post-market monitoring

Terms *Variant* 822

- Monitoring
- Post-market (*Quaity in use, Post production*)

Art. 72

Post-market monitoring by providers and post-market monitoring plan for high-risk AI systems

- *4 Technical documentation*
- *6 Conformity assessment*

Terms *Variant* 823

- AI systems
- Monitoring
- Post-market (*Quaity in use, Post production*)
- Providers
- Risk

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.

Terms *Variant* 824

- Monitoring
- Post-market (*Quaity in use, Post production*)
- Providers
- Risk
- System

AI ACT and relative Article in AI Act

Annexes and relative Article in AI Act

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.

Terms *Variant* 825

- AI systems
- Compliance (*complete*)
- Compliance with the requirements
- Data
- Data analysis
- Data requirements (*Data quality model*)
- Data set (*File*)
- Deployers
- Monitoring
- Post-market (*Quaity in use, Post production*)
- Risk
- Risk analysis
- System

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).

3 *High-risk AI systems referred to in Article 6*

Terms *Variant* 826

- Documentation
- Monitoring
- Post-market (*Quaity in use, Post production*)
- System
- Technical documentation

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.

Terms *Variant* 827

- AI systems
- Consistency
- Governance
- Internal market
- IT system
- Level of risk
- Monitoring
- Post-market (*Quaity in use, Post production*)
- Processes
- Protection
- Providers
- Risk
- Risk governance
- Service

SECTION 2

Sharing of information on serious incidents

Terms *Variant* 828

- Information

AI ACT and relative Article in AI Act

Annexes and relative Article in AI Act

Art. 73

Reporting of serious incidents

Terms | Variant | 829

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.

Terms | Variant | 830

- AI systems
- Incident
- Providers
- Risk
- Surveillance

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.

Terms | Variant | 831

- Incident
- System

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.

Terms | Variant | 832

- Incident

AI ACT and relative Article in AI Act

Annexes and relative Article in AI Act

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.

Terms	*Variant*	833
Incident		
IT system		
Risk		
System		

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	*Variant*	834
Complete		

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.

Terms	*Variant*	835
Assessment		
Evaluation (*Evaluating*)		
Incident		
Risk		
Risk evaluation		
System		

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.

Terms	*Variant*	836
Compliance (*complete*)		
Incident		
Surveillance		

AI ACT and relative Article in AI Act

Annexes and relative Article in AI Act

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.

Terms	Variant	837
Surveillance		

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).

Terms	Variant	838
AI systems		
Providers		
Risk		
Service		

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.

Terms	Variant	839
AI systems		
Incident		
Purpose		
Risk		
Safety		
Safety components of devices		

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.

Terms	Variant	840
Incident		

AI ACT and relative Article in AI Act

Annexes and relative Article in AI Act

SECTION 3

Enforcement

Terms *Variant* 841

Art. 74

Market surveillance and control of AI systems in the Union market

Terms *Variant* 842

AI systems

Surveillance

Art. 74, 1

Regulation (EU) 2019/1020 shall apply to AI systems covered by this Regulation. For the purposes of the effective enforcement of this Regulation:

Terms *Variant* 843

AI systems

Art. 74, 1(a)

any reference to an economic operator under Regulation (EU) 2019/1020 shall be understood as including all operators identified in Article 2(1) of this Regulation;

Terms *Variant* 844

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

Art. 74, 1(b)

any reference to a product under Regulation (EU) 2019/1020 shall be understood as including all AI systems falling within the scope of this Regulation.

Terms *Variant* 845

AI systems

?

Art. 74, 2

As part of their reporting obligations under Article 34(4) of Regulation (EU) 2019/1020, the market surveillance authorities shall report annually to the Commission and relevant national competition authorities any information identified in the course of market surveillance activities that may be of potential interest for the application of Union law on competition rules. They shall also annually report to the Commission about the use of prohibited practices that occurred during that year and about the measures taken.

Terms *Variant* 846

Information

Surveillance

?

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.

Terms *Variant* 847

AI systems

Products

Risk

Surveillance

?

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.

Terms *Variant* 848

AI systems

Products

Protection

?

Art. 74, 5

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.

Terms	Variant	849
Purpose		
Surveillance		

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.

Terms	Variant	850
AI systems		
Risk		
Service		
Surveillance		
System		

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.

Terms	Variant	851
Information		
Surveillance		

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.

Terms	Variant	852
AI systems		
Data		
Data management		
Data protection (*privacy*)		
Democracy		
Management		
Management system		
Protection		
Risk		
Risk management		
Surveillance		

AI ACT and relative Article in AI Act

Annexes and relative Article in AI Act

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.

Terms	*Variant*	853
Data		
Data protection (*privacy*)		
Protection		
Surveillance		

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.

Terms	*Variant*	854
AI application		
AI systems		
Risk		
Surveillance		

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.

Terms	*Variant*	855
AI systems		
Compliance (*complete*)		
Risk		
Support		
Surveillance		

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.

Terms	*Variant*	856
AI application		
AI systems		
Data		
Data set (*File*)		
Documentation		
Providers		
Risk		
Security (*Cybersecurity*)		
Surveillance		
Technical documentation		
Testing		
Testing data sets		
Training		
Validation		

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

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:

Terms	Variant	857
Risk		
Surveillance		
System		
		?

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

Terms	Variant	858
Conformity		
Risk		
System		
		?

Art. 74, 13(b)

testing or auditing procedures and verifications based on the data and documentation provided by the provider have been exhausted or proved insufficient.

Terms	Variant	859
Data		
Documentation		
Testing		
		?

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.

Terms	Variant	860
Confidentiality (*personal data, identifiability*)		
Documentation		
Information		
Surveillance		
		?

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

Art. 75

Mutual assistance, market surveillance and control of general-purpose AI systems

Terms	Variant	861
AI systems		
Purpose		
Surveillance		
		?

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.

Terms	Variant	862
Compliance (*complete*)		
Monitoring		
Purpose		
Surveillance		
System		
		?

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.

Terms	Variant	863
AI systems		
Compliance (*complete*)		
Compliance with the requirements		
Deployers		
Purpose		
Risk		
Risk evaluation		
Surveillance		
		?

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.

Terms	Variant	864
Appropriate confidentiality		
Confidentiality (*personal data, identifiability*)		
Information		
Information system		
IT system		
Purpose		
Risk		
Surveillance		
System		
		?

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

Art. 76

Supervision of testing in real world conditions by market surveillance authorities

Terms	Variant	865
Surveillance		
Testing		

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.

Terms	Variant	866
Surveillance		
Testing		

Art. 76, 2

Where testing in real world conditions is conducted for AI systems that are supervised within 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).

Terms	Variant	867
AI systems		
Compliance (*complete*)		
Surveillance		
Testing		

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:

Terms	Variant	868
Incident		
Surveillance		

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

Art. 76, 3(a)

to suspend or terminate the testing in real world conditions;

Terms *Variant* 869

Testing

?

Art. 76, 3(b)

to require the provider or prospective provider and the deployer or prospective deployer to modify any aspect of the testing in real world conditions.

Terms *Variant* 870

Testing

?

Art. 76, 4

Where a market surveillance authority has taken a decision referred to in paragraph 3 of this Article, or has issued an objection within the meaning of Article 60(4), point (b), the decision or the objection shall indicate the grounds therefor and how the provider or prospective provider can challenge the decision or objection.

Terms *Variant* 871

Surveillance

?

Art. 76, 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.

Terms *Variant* 872

IT system

Surveillance

System

Testing

?

AI ACT and relative Article in AI Act | **Annexes and relative Article in AI Act**

Art. 77

Powers of authorities protecting fundamental rights

Terms	Variant	873
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.

Terms	Variant	874
AI systems		
Documentation		
Fundamental rights		
Risk		
Surveillance		

Art. 77, 2

By 2 November 2024, each Member State shall identify the public authorities or bodies referred to in paragraph 1 and make a list of them publicly available. Member States shall notify the list to the Commission and to the other Member States, and shall keep the list up to date.

Terms	Variant	875

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.

Terms	Variant	876
Documentation		
Fundamental rights		
Risk		
Surveillance		
System		
Technical documentation		
Testing		

AI ACT and relative Article in AI Act

Annexes and relative Article in AI Act

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.

Terms	Variant	877
Confidentiality (*personal data, identifiability*)		
Documentation		
Information		

Art. 78

Confidentiality

Terms	Variant	878
Confidentiality (*personal data, identifiability*)		

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:

Terms	Variant	879
Confidentiality (*personal data, identifiability*)		
Data		
Information		
Surveillance		

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);

Terms	Variant	880
Information		

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

Art. 78, 1(b)

the effective implementation of this Regulation, in particular for the purposes of inspections, investigations or audits;

Terms *Variant* 881

?

Art. 78, 1(c)

public and national security interests;

Terms *Variant* 882

Security (*Cybersecurity*)

?

Art. 78, 1(d)

the conduct of criminal or administrative proceedings;

Terms *Variant* 883

?

Art. 78, 1(e)

information classified pursuant to Union or national law.

Terms *Variant* 884

Information

?

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

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	*Variant*	885
AI application		
AI systems		
Assessment		
Confidentiality (*personal data, identifiability*)		
Cybersecurity		
Data		
Information		
Information security		
Information system		
IT system		
Purpose		
Risk		
Security (*Cybersecurity*)		?

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.

Terms	*Variant*	886
Access control		
AI systems		
Data		
Documentation		
Information		
Information security		
Information system		
Level of risk		
Providers		
Risk		
Security (*Cybersecurity*)		
Surveillance		
Technical documentation		?

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.

Terms	*Variant*	887
Information		
		?

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.

Terms	*Variant*	888
Confidentiality (*personal data, identifiability*)		
Information		
		?

AI ACT and relative Article in AI Act | **Annexes and relative Article in AI Act**

Art. 79

Procedure at national level for dealing with AI systems presenting a risk

Terms	Variant	889
AI systems		
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.

Terms	Variant	890
AI systems		
Fundamental rights		
Health		
Health risk		
Risk		
Safety		

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.

Terms	Variant	891
AI systems		
Compliance (*complete*)		
Compliance with the requirements		
Evaluation (*Evaluating*)		
Fundamental rights		
IT system		
Risk		
Risk evaluation		
Surveillance		
System		

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.

Terms	Variant	892
Compliance (*complete*)		
Evaluation (*Evaluating*)		
Surveillance		

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

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.

Terms	Variant	
AI systems		893
IT system		
		?

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.

Terms	Variant	
IT system		894
Service		
Surveillance		
System		
		?

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:

Terms	Variant	
Compliance (*complete*)		895
Information		
Information system		
Risk		
Surveillance		
System		
		?

Art. 79, 6(a)

non-compliance with the prohibition of the AI practices referred to in Article 5;

Terms	Variant	
Compliance (*complete*)		896
		?

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

Art. 79, 6(b)

a failure of a high-risk AI system to meet requirements set out in Chapter III, Section 2;

Terms *Variant* 897

Risk

System

?

Art. 79, 6(c)

shortcomings in the harmonised standards or common specifications referred to in Articles 40 and 41 conferring a presumption of conformity;

Terms *Variant* 898

Conformity

?

Art. 79, 6(d)

non-compliance with Article 50.

Terms *Variant* 899

Compliance (*complete*)

?

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.

Terms *Variant* 900

Compliance (*complete*)

Information

Information system

Measure

Surveillance

System

?

AI ACT and relative Article in AI Act

Annexes and relative Article in AI Act

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.

Terms	*Variant*	901
Compliance (*complete*)		
Measure		
Surveillance		
		?

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 product or the AI system from their market, without undue delay.

Terms	*Variant*	902
Surveillance		
System		
		?

Art. 80

Procedure for dealing with AI systems classified by the provider as non-high-risk in application of Annex III

Terms	*Variant*	903
AI application		
AI systems		
Risk		
		?

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.

Terms	*Variant*	904
Classification (*categorization*)		
Evaluation (*Evaluating*)		
Risk		
Risk evaluation		
Surveillance		
System		
		?

AI ACT and relative Article in AI Act

Annexes and relative Article in AI Act

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.

Terms *Variant* 905

- Compliance (*complete*)
- Compliance with the requirements
- Evaluation (*Evaluating*)
- IT system
- Risk
- Risk evaluation
- Surveillance
- System

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.

Terms *Variant* 906

- Evaluation (*Evaluating*)
- IT system
- Surveillance
- System

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.

Terms *Variant* 907

- Compliance (*complete*)
- Compliance with the requirements
- System

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.

Terms *Variant* 908

- AI systems
- IT system

***AI ACT* and relative Article in AI Act**

***Annexes* and relative Article in AI Act**

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.

Terms	*Variant*	909
System		

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.

Terms	*Variant*	910
AI application		
Evaluation (*Evaluating*)		
Risk		
Risk evaluation		
Surveillance		
System		

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.

Terms	*Variant*	911
Database		
Information		
Surveillance		

Art. 81

Union safeguard procedure

Terms	*Variant*	912

AI ACT and relative Article in AI Act

Annexes and relative Article in AI Act

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.

Terms	*Variant*	913
Compliance (*complete*)		
Evaluation (*Evaluating*)		
Measure		
Surveillance		
		?

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.

Terms	*Variant*	914
Measure		
System		
		?

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.

Terms	*Variant*	915
Compliance (*complete*)		
Measure		
System		
		?

Art. 82

Compliant AI systems which present a risk

Terms	*Variant*	916
AI systems		
Risk		
		?

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

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.

Terms *Variant* 917

- Evaluation (*Evaluating*)
- Fundamental rights
- Health
- Health risk
- IT system
- Protection
- Risk
- Risk evaluation
- Safety
- Service
- Surveillance
- System
- ?

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.

Terms *Variant* 918

- AI systems
- IT system
- Surveillance
- ?

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.

Terms *Variant* 919

- Data
- Information
- Information system
- Origin of data (*provenance*)
- Risk
- System
- ?

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.

Terms *Variant* 920

- Evaluation (*Evaluating*)
- Measure
- ?

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act* | *Terms* | *Variant*

Art. 82, 5

The Commission shall immediately communicate its decision to the Member States concerned and to the relevant operators. It shall also inform the other Member States.

921

Art. 83

Formal non-compliance

922

Compliance (*complete*)

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:

923

Compliance (*complete*)

Surveillance

Art. 83, 1(a)

the CE marking has been affixed in violation of Article 48;

924

AI ACT and relative Article in AI Act

Annexes and relative Article in AI Act

Art. 83, 1(b)

the CE marking has not been affixed;

Terms *Variant* 925

Art. 83, 1(c)

the EU declaration of conformity referred to in Article 47 has not been drawn up;

Terms *Variant* 926

Conformity

Art. 83, 1(d)

the EU declaration of conformity referred to in Article 47 has not been drawn up correctly;

Terms *Variant* 927

Conformity

Art. 83, 1(e)

the registration in the EU database referred to in Article 71 has not been carried out;

Terms *Variant* 928

Database

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

Art. 83, 1(f)

where applicable, no authorised representative has been appointed;

Terms *Variant* 929

?

Art. 83, 1(g)

technical documentation is not available.

Terms *Variant* 930

Documentation

Technical documentation

?

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.

Terms *Variant* 931

Compliance (*complete*)

IT system

Risk

Surveillance

System

?

Art. 84

Union AI testing support structures

Terms *Variant* 932

Support

Testing

?

AI ACT and relative Article in AI Act

Annexes and relative Article in AI Act

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.

Terms	*Variant*	933
Support		
Testing		

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.

Terms	*Variant*	934
Support		
Surveillance		
Testing		

SECTION 4

Remedies

Terms	*Variant*	935

Art. 85

Right to lodge a complaint with a market surveillance authority

Terms	*Variant*	936
Surveillance		

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

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.

Terms	*Variant*	937
Purpose		
Surveillance		
		?

Art. 86

Right to explanation of individual decision-making

Terms	*Variant*	938
Decision-making		
		?

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.

Terms	*Variant*	939
AI systems		
Decision-making		
Fundamental rights		
Health		
Health risk		
Risk		
Safety		
System		
		?

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.

Terms	*Variant*	940
AI systems		
Compliance (*complete*)		
		?

AI ACT and relative Article in AI Act

Annexes and relative Article in AI Act

Art. 86, 3

This Article shall apply only to the extent that the right referred to in paragraph 1 is not otherwise provided for under Union law.

Terms *Variant* 941

Art. 87

Reporting of infringements and protection of reporting persons

Terms *Variant* 942

Protection

Art. 87

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

Terms *Variant* 943

Protection

SECTION 5

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

Terms *Variant* 944

AI models

Monitoring

Providers

Purpose

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

Art. 88

Enforcement of the obligations of providers of general-purpose AI models

Terms *Variant* 945

AI models

Providers

Purpose

?

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.

Terms *Variant* 946

?

Art. 88, 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.

Terms *Variant* 947

Surveillance

?

Art. 89

Monitoring actions

Terms *Variant* 948

Monitoring

?

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

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.

Terms *Variant* 949

- AI models
- Compliance (*complete*)
- Providers
- Purpose

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:

Terms *Variant* 950

- Providers

Art. 89, 2(a)

the point of contact of the provider of the general-purpose AI model concerned;

Terms *Variant* 951

- Contact
- Purpose

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;

Terms *Variant* 952

- Purpose

Art. 89, 2(c)

any other information that the downstream provider that sent the request considers relevant, including, where appropriate, information gathered on its own initiative.

Terms	Variant	953
Information		

Art. 90

Alerts of systemic risks by the scientific panel

Terms	Variant	954

Art. 90, 1

The scientific panel may provide a qualified alert to the AI Office where it has reason to suspect that:

Terms	Variant	955

Art. 90, 1(a)

a general-purpose AI model poses concrete identifiable risk at Union level; or

Terms	Variant	956
Purpose		
Risk		

AI ACT and relative Article in AI Act

Annexes and relative Article in AI Act

Art. 90, 1(b)

a general-purpose AI model meets the conditions referred to in Article 51.

Terms | Variant | 957

Purpose

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.

Terms | Variant | 958

Measure

Purpose

Art. 90, 3

A qualified alert shall be duly reasoned and indicate at least:

Terms | Variant | 959

Art. 90, 3(a)

the point of contact of the provider of the general-purpose AI model with systemic risk concerned;

Terms | Variant | 960

Contact

Purpose

Risk

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

Art. 90, 3(b)

a description of the relevant facts and the reasons for the alert by the scientific panel;

Terms *Variant* 961

?

Art. 90, 3(c)

any other information that the scientific panel considers to be relevant, including, where appropriate, information gathered on its own initiative.

Terms *Variant* 962

Information

?

Art. 91

Power to request documentation and information

Terms *Variant* 963

Documentation

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 *Variant* 964

Compliance (*complete*)

Documentation

Information

Purpose

?

AI ACT and relative Article in AI Act

Annexes and relative Article in AI Act

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.

Terms *Variant* 965

Information

Purpose

?

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).

Terms *Variant* 966

Information

Purpose

?

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.

Terms *Variant* 967

Information

Purpose

?

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.

Terms *Variant* 968

Information

Purpose

?

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

Art. 92

Power to conduct evaluations

Terms *Variant* 969

Art. 92, 1

The AI Office, after consulting the Board, may conduct evaluations of the general-purpose AI model concerned:

Terms *Variant* 970

Purpose

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

Terms *Variant* 971

Compliance (*complete*)

Information

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).

Terms *Variant* 972

AI models

Level of risk

Purpose

Risk

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

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).

Terms *Variant* 973

?

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.

Terms *Variant* 974

Purpose

?

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.

Terms *Variant* 975

Purpose

?

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.

Terms *Variant* 976

Information

Providers

Purpose

?

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

Art. 92, 6

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).

Terms *Variant* 977

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.

Terms *Variant* 978

Information

Information system

Purpose

Testing

Art. 93

Power to request measures

Terms *Variant* 979

Art. 93, 1

Where necessary and appropriate, the Commission may request providers to:

Terms *Variant* 980

Providers

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

Art. 93, 1(a)

take appropriate measures to comply with the obligations set out in Articles 53 and 54;

Terms *Variant* 981

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;

Terms *Variant* 982

- Evaluation (*Evaluating*)
- Level of risk
- Risk
- Risk evaluation

Art. 93, 1(c)

restrict the making available on the market, withdraw or recall the model.

Terms *Variant* 983

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.

Terms *Variant* 984

- Measure
- Purpose

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.

Terms *Variant* 985

Level of risk

Purpose

Risk

?

Art. 94

Procedural rights of economic operators of the general-purpose AI model

Terms *Variant* 986

Purpose

?

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.

Terms *Variant* 987

Providers

Purpose

?

CHAPTER X

CODES OF CONDUCT AND GUIDELINES

Terms *Variant* 988

?

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

Art. 95

Codes of conduct for voluntary application of specific requirements

Terms *Variant* 989

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.

Terms *Variant* 990

- AI application
- AI systems
- Governance
- Risk
- Risk governance

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:

Terms *Variant* 991

- AI application
- AI systems
- Deployers
- Measure

Art. 95, 2(a)

applicable elements provided for in Union ethical guidelines for trustworthy AI;

Terms *Variant* 992

- Trustworthy

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

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;

Terms	Variant	993
AI systems		
Design		
Training		
		?

Art. 95, 2(c)

promoting AI literacy, in particular that of persons dealing with the development, operation and use of AI;

Terms	Variant	994
AI literacy		
Literacy		
Operation		
		?

Art. 95, 2(d)

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;

Terms	Variant	995
AI systems		
Design		
		?

Art. 95, 2(e)

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.

Terms	Variant	996
Accessibility (*access*)		
AI systems		
Disability		
		?

AI ACT and relative Article in AI Act

Annexes and relative Article in AI Act

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.

Terms *Variant* 997

AI systems

Deployers

Providers

Purpose

Similarity

Society

?

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.

Terms *Variant* 998

?

Art. 96

Guidelines from the Commission on the implementation of this Regulation

Terms *Variant* 999

?

Art. 96, 1

The Commission shall develop guidelines on the practical implementation of this Regulation, and in particular on:

Terms *Variant* 1000

?

	AI ACT and relative Article in AI Act	*Annexes and relative Article in AI Act*	*Terms*	*Variant*	1001
Art. 96, 1(a) the application of the requirements and obligations referred to in Articles 8 to 15 and in Article 25;					

			Terms	*Variant*	1002
Art. 96, 1(b) the prohibited practices referred to in Article 5;					

			Terms	*Variant*	1003
Art. 96, 1(c) the practical implementation of the provisions related to substantial modification;					

			Terms	*Variant*	1004
Art. 96, 1(d) the practical implementation of transparency obligations laid down in Article 50;			Transparency		

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

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;

Terms *Variant* 1005

Consistency

Information

?

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.

Terms *Variant* 1006

AI application

System

?

Art. 96, 2

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.

Terms *Variant* 1007

?

CHAPTER XI

DELEGATION OF POWER AND COMMITTEE PROCEDURE

Terms *Variant* 1008

?

AI ACT and relative Article in AI Act

Annexes and relative Article in AI Act

Art. 97

Exercise of the delegation

Terms *Variant* 1009

Art. 97, 1

The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

Terms *Variant* 1010

Art. 97, 2

The power to adopt delegated acts referred to in Article 6(6) and (7), Article 7(1) and (3), Article 11(3), Article 43(5) and (6), Article 47(5), Article 51(3), Article 52(4) and Article 53(5) and (6) shall be conferred on the Commission for a period of five years from 1 August 2024. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.

Terms *Variant* 1011

Art. 97, 3

The delegation of power referred to in Article 6(6) and (7), Article 7(1) and (3), Article 11(3), Article 43(5) and (6), Article 47(5), Article 51(3), Article 52(4) and Article 53(5) and (6) may be revoked at any time by the European Parliament or by the Council. A decision of revocation shall put an end to the delegation of power specified in that decision. It shall take effect the day following that of its publication in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

Terms *Variant* 1012

AI ACT and relative Article in AI Act

Annexes and relative Article in AI Act

Art. 97, 4

Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making.

Terms *Variant* 1013

Art. 97, 5

As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

Terms *Variant* 1014

Art. 97, 6

Any delegated act adopted pursuant to Article 6(6) or (7), Article 7(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 *Variant* 1015

Art. 98

Committee procedure

Terms *Variant* 1016

AI ACT and relative Article in AI Act

Annexes and relative Article in AI Act

Art. 98, 1

The Commission shall be assisted by a committee. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.

Terms *Variant* 1017

Art. 98, 2

Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

Terms *Variant* 1018

CHAPTER XII

PENALTIES

Terms *Variant* 1019

Art. 99

Penalties

Terms *Variant* 1020

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act* | *Terms* | *Variant*

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.

1021

?

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.

1022

?

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.

1023

Compliance (*complete*)

?

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:

1024

Compliance (*complete*)

?

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

Art. 99, 4(a)

obligations of providers pursuant to Article 16;

Terms *Variant* 1025

Providers

?

Art. 99, 4(b)

obligations of authorised representatives pursuant to Article 22;

Terms *Variant* 1026

?

Art. 99, 4(c)

obligations of importers pursuant to Article 23;

Terms *Variant* 1027

Importers

?

Art. 99, 4(d)

obligations of distributors pursuant to Article 24;

Terms *Variant* 1028

?

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act* | *Terms* | *Variant* | 1029

Art. 99, 4(e)

obligations of deployers pursuant to Article 26;

Deployers

?

Terms | *Variant* | 1030

Art. 99, 4(f)

requirements and obligations of notified bodies pursuant to Article 31, Article 33(1), (3) and (4) or Article 34;

?

Terms | *Variant* | 1031

Art. 99, 4(g)

transparency obligations for providers and deployers pursuant to Article 50.

Deployers

Providers

Transparency

?

Terms | *Variant* | 1032

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.

Information

?

AI ACT and relative Article in AI Act

Annexes and relative Article in AI Act

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.

Terms *Variant* 1033

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:

Terms *Variant* 1034

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;

Terms *Variant* 1035

Purpose

System

Art. 99, 7(b)

whether administrative fines have already been applied by other market surveillance authorities to the same operator for the same infringement;

Terms *Variant* 1036

Surveillance

AI ACT and relative Article in AI Act

Annexes and relative Article in AI Act

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;

Terms Variant 1037

Art. 99, 7(d)

the size, the annual turnover and market share of the operator committing the infringement;

Terms Variant 1038

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;

Terms Variant 1039

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;

Terms Variant 1040

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

Art. 99, 7(g)

the degree of responsibility of the operator taking into account the technical and organisational measures implemented by it;

Terms *Variant* 1041

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;

Terms *Variant* 1042

Art. 99, 7(i)

the intentional or negligent character of the infringement;

Terms *Variant* 1043

Art. 99, 7(j)

any action taken by the operator to mitigate the harm suffered by the affected persons.

Terms *Variant* 1044

AI ACT and relative Article in AI Act

Annexes and relative Article in AI Act

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.

Terms *Variant* 1045

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.

Terms *Variant* 1046

System

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.

Terms *Variant* 1047

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.

Terms *Variant* 1048

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act* | *Terms* | *Variant*

Art. 100

Administrative fines on Union institutions, bodies, offices and agencies

1049

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:

1050

Terms	Variant
Data	
Data protection (*privacy*)	
Protection	

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;

1051

Terms	Variant
Purpose	
System	

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;

1052

AI ACT and relative Article in AI Act | **Annexes and relative Article in AI Act**

Art. 100, 1(c)

any action taken by the Union institution, body, office or agency to mitigate the damage suffered by affected persons;

Terms	Variant	1053

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;

Terms	Variant	1054
Compliance (*complete*)		
Data		
Data protection (*privacy*)		
Protection		

Art. 100, 1(e)

any similar previous infringements by the Union institution, body, office or agency;

Terms	Variant	1055

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;

Terms	Variant	1056
Data		
Data protection (*privacy*)		
Protection		

AI ACT and relative Article in AI Act | **Annexes and relative Article in AI Act** | *Terms* | *Variant* | 1057

Art. 100, 1(g)

the annual budget of the Union institution, body, office or agency.

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.

Terms | *Variant* | 1058

Compliance (*complete*)

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.

Terms | *Variant* | 1059

Compliance (*complete*)

Compliance with the requirements

System

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.

Terms | *Variant* | 1060

Data

Data protection (*privacy*)

Protection

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

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	*Variant*	1061
Data		
Data protection (*privacy*)		
Personal data		
Protection		
Protection of personal data		
		?

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.

Terms	*Variant*	1062
Operation		
		?

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.

Terms	*Variant*	1063
Data		
Data protection (*privacy*)		
Protection		
		?

Art. 101

Fines for providers of general-purpose AI models

Terms	*Variant*	1064
AI models		
Providers		
Purpose		
		?

AI ACT and relative Article in AI Act

Annexes and relative Article in AI Act

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:

Terms *Variant* 1065

AI models

Providers

Purpose

Art. 101, 1(a)

infringed the relevant provisions of this Regulation;

Terms *Variant* 1066

Art. 101, 1(b)

failed to comply with a request for a document or for information pursuant to Article 91, or supplied incorrect, incomplete or misleading information;

Terms *Variant* 1067

Information

Art. 101, 1(c)

failed to comply with a measure requested under Article 93;

Terms *Variant* 1068

Measure

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

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 into account commitments made in accordance with Article 93(3) or made in relevant codes of practice in accordance with Article 56.

Terms *Variant* 1069

Evaluation (*Evaluating*)

Purpose

Risk

Risk evaluation

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.

Terms *Variant* 1070

Purpose

Art. 101, 3

Fines imposed in accordance with this Article shall be effective, proportionate and dissuasive.

Terms *Variant* 1071

Art. 101, 4

Information on fines imposed under this Article shall also be communicated to the Board as appropriate.

Terms *Variant* 1072

Information

AI ACT and relative Article in AI Act

Annexes and relative Article in AI Act

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.

Terms *Variant* 1073

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 *Variant* 1074

CHAPTER XIII

FINAL PROVISIONS

Terms *Variant* 1075

Art. 102

Amendment to Regulation (EC) No 300/2008

Terms *Variant* 1076

AI ACT and relative Article in AI Act

Annexes and relative Article in AI Act

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.

Terms	*Variant*	1077
Artificial intelligence		
Security (*Cybersecurity*)		
		?

Art. 103

Amendment to Regulation (EU) No 167/2013

Terms	*Variant*	1078
		?

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.

Terms	*Variant*	1079
Artificial intelligence		
Safety		
		?

Art. 104

Amendment to Regulation (EU) No 168/2013

Terms	*Variant*	1080
		?

AI ACT and relative Article in AI Act

Annexes and relative Article in AI Act

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.

Terms	Variant	1081
Artificial intelligence		
Safety		

Art. 105

Amendment to Directive 2014/90/EU

Terms	Variant	1082

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.

Terms	Variant	1083
Artificial intelligence		
Safety		
Testing		

Art. 106

Amendment to Directive (EU) 2016/797

Terms	Variant	1084

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.

Terms	*Variant*	1085
Artificial intelligence		
Safety		
		?

Art. 107

Amendment to Regulation (EU) 2018/858

Terms	*Variant*	1086
		?

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 (*6), the requirements set out in Chapter III, Section 2, of that Regulation shall be taken into account.

Terms	*Variant*	1087
Artificial intelligence		
Safety		
		?

Art. 108

Amendments to Regulation (EU) 2018/1139

Terms	*Variant*	1088
		?

Art. 108

Regulation (EU) 2018/1139 is amended as follows:

Terms | Variant | 1089

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.

Terms | Variant | 1090

Artificial intelligence

Safety

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).';"

Terms | Variant | 1091

Artificial intelligence

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.'

Terms | Variant | 1092

Artificial intelligence

Safety

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

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.'

Terms *Variant* 1093

Artificial intelligence

Safety

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.'

Terms *Variant* 1094

Artificial intelligence

Safety

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.'

Terms *Variant* 1095

Artificial intelligence

Safety

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.'.

Terms *Variant* 1096

Artificial intelligence

Safety

Art. 109

Amendment to Regulation (EU) 2019/2144

Terms *Variant* 1097

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 (*8), the requirements set out in Chapter III, Section 2, of that Regulation shall be taken into account.

Terms *Variant* 1098

Artificial intelligence

Safety

Art. 110

Amendment to Directive (EU) 2020/1828

Terms *Variant* 1099

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).'.

Terms *Variant* 1100

Artificial intelligence

AI ACT and relative Article in AI Act

Annexes and relative Article in AI Act

Art. 111

AI systems already placed on the market or put into service and general-purpose AI models already placed on the marked

Terms *Variant* 1101

- AI models
- AI systems
- Purpose
- Service
- ?

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.

Terms *Variant* 1102

- AI application
- AI systems
- Compliance (*complete*)
- Compliance with the requirements
- Evaluation (*Evaluating*)
- IT system
- Service
- System
- ?

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.

Terms *Variant* 1103

- AI application
- AI systems
- Deployers
- Providers
- Risk
- Service
- ?

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.

Terms *Variant* 1104

- AI models
- Providers
- Purpose
- ?

AI ACT and relative Article in AI Act	Annexes and relative Article in AI Act	Terms	Variant	
Art. 112 Evaluation and review		Evaluation (*Evaluating*)		1105
Art. 112				1106
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.		Assessment		1107
Art. 112, 2 By 2 August 2028 and every four years thereafter, the Commission shall evaluate and report to the European Parliament and to the Council on the following:				1108

AI ACT and relative Article in AI Act

Annexes and relative Article in AI Act

Art. 112, 2(a)

the need for amendments extending existing area headings or adding new area headings in Annex III;

Terms	Variant	1109

Art. 112, 2(b)

amendments to the list of AI systems requiring additional transparency measures in Article 50;

Terms	Variant	1110
AI systems		
Transparency		

Art. 112, 2(c)

amendments enhancing the effectiveness of the supervision and governance system.

Terms	Variant	1111
Effectiveness		
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.

Terms	Variant	1112
Assessment		
Evaluation (*Evaluating*)		

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

Art. 112, 4

The reports referred to in paragraph 2 shall pay specific attention to the following:

Terms *Variant* 1113

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;

Terms *Variant* 1114

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;

Terms *Variant* 1115

Art. 112, 4(c)

adopted harmonised standards and common specifications developed to support this Regulation;

Terms *Variant* 1116

Support

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.

Terms *Variant* 1117

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.

Terms *Variant* 1118

Evaluation (*Evaluating*)

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 asses 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 *Variant* 1119

AI models

Purpose

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.

Terms *Variant* 1120

AI application

AI systems

Effectiveness

Environmental risk

Risk

AI ACT and relative Article in AI Act | *Annexes and relative Article in AI Act*

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.

Terms	*Variant*	1121
Information		

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.

Terms	*Variant*	1122

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	*Variant*	1123
AI systems		
Fundamental rights		
Health		
Information		
Information system		
Safety		
Society		

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:

Terms	*Variant*	1124
AI systems		
Evaluation (*Evaluating*)		
Risk		
Risk evaluation		

AI ACT and relative Article in AI Act

Annexes and relative Article in AI Act

Art. 112, 11(a)

the list set out in Annex III, including the extension of existing area headings or the addition of new area headings in that Annex;

Terms	Variant	1125

Art. 112, 11(b)

the list of prohibited practices set out in Article 5; and

Terms	Variant	1126

Art. 112, 11(c)

the list of AI systems requiring additional transparency measures pursuant to Article 50.

Terms	Variant	1127
AI systems		
Transparency		

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.

Terms	Variant	1128
Assessment		
Conformity		
Conformity assessment		
Governance		

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.

Terms *Variant* 1129

Assessment

?

Art. 113

Entry into force and application

Terms *Variant* 1130

?

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:

Terms *Variant* 1131

?

Art. 113, (a)

Chapters I and II shall apply from 2 February 2025;

Terms *Variant* 1132

?

AI ACT and relative Article in AI Act

Annexes and relative Article in AI Act

Art. 113, (b)

Chapter III Section 4, Chapter V, Chapter VII and Chapter XII and Article 78 shall apply from 2 August 2025, with the exception of Article 101;

Terms *Variant* 1133

Art. 113, (c)

Article 6(1) and the corresponding obligations in this Regulation shall apply from 2 August 2027.

Terms *Variant* 1134