

ARTICLE 1

Art. 1

Subject matter

Subject: 25024, 24027, 5259, 5259, 24029, 23894, 22989, 25010, 27000, 14971, 12182, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 62304, 20547

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.

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; **Trustworthy:** 25019; **Human:** 24027, 42001, 5259, 25059, 24029, 25019, 22989, 25010, 27000, 31010, 14971, 82079, 24030, 31000, 25012, 8000, 24028, 26514, 29119, 9868, 62304, 5392, 23053, 42105, 42109; **Artificial intelligence:** 5259, 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 5469, 24970, 24368, 24030, 8000, 38507, 24028, 6254, 8200, 4213, 25058, 17847, 29119, 22443, 9868, 5339, 42006, 5392, 17903, 23053, 24372, 22989, 23053; **Regulation:** 5259, 22989, 14971, 8000, 29119, 9868, 62304; **Fundamental right:** 9868; **Health:** 42001, 5338, 25019, 25010, 27000, 14971, 5469, 12182, 29119, 9868, 5339, 62304, 22989, 18988; **Safety:** 42001, 5338, 24029, 25019, 22989, 25010, 27000, 14971, 5469, 24368, 8000, 24028, 29119, 9868, 62304, 25059, 22440, 22440, 22440; **Human-centric:** 9868; **Innovation:** 42001, 23894, 8000, 29119, 20547, 20547; **Purpose:** 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 82079, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 20547; **Protection:** 23894, 25010, 27000, 8000, 29119, 9868, 62304, 17903

Art. 1, 2

This Regulation lays down:

Regulation: 5259, 22989, 14971, 8000, 29119, 9868, 62304

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;

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; **Service:** 25024, 8183, 42001, 5259, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 82079, 12182, 8000, 38507, 24028, 26514, 29119, 9868, 5339, 62304, 25059, 5392, 20547, 24668

Art. 1, 2(b)

prohibitions of certain AI practices;

Subject: 25024, 24027, 5259, 5259, 24029, 23894, 22989, 25010, 27000, 14971, 12182, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 62304, 20547

Art. 1, 2(c)

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

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; **Risk:** 8183, 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42005, 24668; **Obligation:** 42001, 24028; **High-risk:** 9868

Art. 1, 2(d)

harmonised transparency rules for certain AI systems;

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; **Transparency:** 42001, 25059, 25019, 22989, 5469, 24028, 29119, 9868, 25223, 12792

Art. 1, 2(e)

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

AI model: 22989, 5469, 4213; **Purpose:** 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 82079, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 20547

Art. 1, 2(f)

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

Governance: 8183, 42001, 5259, 25019, 22989, 27000, 31000, 8000, 38500, 38507, 24028, 22443, 18115; **Monitoring:** 42001, 23894, 25019, 27000, 31010, 14971, 5469, 8000, 24028, 29119, 9868, 62304; **Surveillance:** 9868

Art. 1, 2(g)

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

Support: 25024, 8183, 42001, 5259, 5338, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 82079, 24030, 25012, 8000, 38500, 26514, 29119, 62304, 42006, 17903, 20547, 24668, 25029; **Innovation:** 42001, 23894, 8000, 29119, 20547, 20547; **SME:** 26514

ARTICLE 2

Art. 2

Scope

Obligation: 42001, 24028

Art. 2, 1

This Regulation applies to:

Regulation: 5259, 22989, 14971, 8000, 29119, 9868, 62304

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;

AI model: 22989, 5469, 4213; **AI system:** 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; **Provider:** 5259, 25019, 12182, 38507, 24028, 9868, 42112; **Service:** 25024, 8183, 42001, 5259, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 82079, 12182, 8000, 38507, 24028, 26514, 29119, 9868, 5339, 62304, 25059, 5392, 20547, 24668; **Purpose:** 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 82079, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 20547

Art. 2, 1(b)

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

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115

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;

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; **System:** 25024, 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119; **Provider:** 5259, 25019, 12182, 38507, 24028, 9868, 42112

Art. 2, 1(d)

importers and distributors of AI systems;

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; **Importer:** 14971

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;

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; **System:** 25024, 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119; **Service:** 25024, 8183, 42001, 5259, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 82079, 12182, 8000, 38507, 24028, 26514, 29119, 9868, 5339, 62304, 25059, 5392, 20547, 24668

Art. 2, 1(f)

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

Provider: 5259, 25019, 12182, 38507, 24028, 9868, 42112; **Authorised representative:** 14971

Art. 2, 1(g)

affected persons that are located in the Union.

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 system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; **Risk:** 8183, 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42005, 24668; **Regulation:** 5259, 22989, 14971, 8000, 29119, 9868, 62304; **High-risk:** 9868; **Product:** 25024, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 82079, 12182, 25012, 8000, 24028, 26514, 29119, 62304, 5392, 17903, 20547, 24372

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.

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; **Security:** 25024, 42001, 25059, 24029, 25019, 22989, 25010, 27000, 14971, 24030, 24028, 29119, 9868, 62304, 42006, 20547, 20547; **Regulation:** 5259, 22989, 14971, 8000, 29119, 9868, 62304; **Service:** 25024, 8183, 42001, 5259, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 82079, 12182, 8000, 38507, 24028, 26514, 29119, 9868, 5339, 62304, 25059, 5392, 20547, 24668; **Task:** 42001, 5259, 25059, 24029, 24029, 25019, 22989, 25010, 14971, 24030, 25012, 24028, 26514, 29119, 62304, 4213, 12791, 20547, 23281, 25258; **Event:** 24027, 42001, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 31000, 25012, 24028, 62304

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.

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; **Authority:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Cooperation:** 24029, 26514, 5392; **Regulation:** 5259, 22989, 14971, 8000, 29119, 9868, 62304; **Safeguard:** 42001, 25012; **Fundamental right:** 9868; **Protection:** 23894, 25010, 27000, 8000, 29119, 9868, 62304, 17903

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.

Regulation: 5259, 22989, 14971, 8000, 29119, 9868, 62304; **Provider:** 5259, 25019, 12182, 38507, 24028, 9868, 42112

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.

AI model: 22989, 5469, 4213; **AI system:** 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; **Regulation:** 5259, 22989, 14971, 8000, 29119, 9868, 62304; **Service:** 25024, 8183, 42001, 5259, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 82079, 12182, 8000, 38507, 24028, 26514, 29119, 9868, 5339, 62304, 25059, 5392, 20547, 24668; **Purpose:** 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 82079, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 20547

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.

Confidentiality: 25024, 5259, 42001, 22989, 25010, 27000, 25012; **Confidential:** 42001, 22989, 25010, 27000; **Obligation:** 42001, 24028; **Regulation:** 5259, 22989, 14971, 8000, 29119, 9868, 62304; **Data:** 25024, 5259, 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 12182, 24030, 31000, 25012, 38507, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 25223, 5259, 5392, 17903, 20546, 20547, 20547, 20547, 20547, 23053, 24372, 24668, 25223, 42103; **Personal data:** 22989, 29119; **Protection:** 23894, 25010, 27000, 8000, 29119, 9868, 62304, 17903; **Privacy:** 42001, 25059, 24029, 25019, 22989, 24030, 29119, 9868, 20547

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.

AI model: 22989, 5469, 4213; **AI system:** 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; **Testing:** 25024, 24027, 25059, 24029, 24029, 25019, 22989, 25010, 82079, 12182, 24028, 26514, 25058, 29119, 9868, 62304, 12791, 42119; **Regulation:** 5259, 22989, 14971, 8000, 29119, 9868, 62304; **Service:** 25024, 8183, 42001, 5259, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 82079, 12182, 8000, 38507, 24028, 26514, 29119, 9868, 5339, 62304, 20547, 24668

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.

Regulation: 5259, 22989, 14971, 8000, 29119, 9868, 62304; **Safety:** 42001, 5338, 24029, 25019, 22989, 25010, 27000, 14971, 5469, 24368, 8000, 24028, 29119, 9868, 62304, 25059, 22440, 22440, 22440; **Protection:** 23894, 25010, 27000, 8000, 29119, 9868, 62304, 17903

Art. 2, 10

This Regulation does not apply to obligations of employers who are natural persons using AI systems in the course of a purely personal non-professional activity.

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; **Obligation:** 42001, 24028; **Regulation:** 5259, 22989, 14971, 8000, 29119, 9868, 62304

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.

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; **Regulation:** 5259, 22989, 14971, 8000, 29119, 9868, 62304

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.

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; **Risk:** 8183, 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 20546, 20547, 20547, 20547, 23053, 24372, 20226, 22440, 22440, 22440, 23053, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119; **System:** 25024, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 25059, 5392, 20547, 24668; **System:** 25024, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119; **Autonomy:** 22989, 29119

ARTICLE 3

Art. 3

Definitions

Definition: 25024, 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 82079, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 20546, 20547, 23282, 25029

Art. 3

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

Definition: 25024, 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 82079, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 20546, 20547, 23282, 25029; **Regulation:** 5259, 22989, 14971, 8000, 29119, 9868, 62304

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;

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; **System:** 25024, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119; **Autonomy:** 22989, 29119

Art. 3, (2)

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

Risk: 8183, 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42005, 24668

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 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;

AI model: 22989, 5469, 4213; **AI system:** 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; **Authority:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **System:** 25024, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119; **Provider:** 5259, 25019, 12182, 38507, 24028, 9868, 42112; **Service:** 25024, 8183, 42001, 5259, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 82079, 12182, 8000, 38507, 24028, 26514, 29119, 9868, 5339, 62304, 25059, 5392, 20547, 24668; **Purpose:** 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 82079, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 20547

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;

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; **System:** 25024, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971

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

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;

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; **System:** 25024, 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119; **Purpose:** 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119; **Provider:** 5259, 25019, 12182, 38507, 24028, 9868, 42112; **Operator:** 25059, 25019, 25010, 26514, 9868, 17903; **Authorised representative:** 14971

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;

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; **System:** 25024, 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119; **Purpose:** 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119; **Provider:** 5259, 25019, 12182, 38507, 24028, 9868, 42112

Art. 3, (8)

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

Distributor: 31010, 14971, 82079; **Provider:** 5259, 25019, 12182, 38507, 24028, 9868, 42112; **Operator:** 25059, 25019, 25010, 26514, 9868, 17903; **Authorised representative:** 14971

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;

AI model: 22989, 5469, 4213; **AI system:** 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; **System:** 25024, 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119; **Purpose:** 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119; **Provider:** 5259, 25019, 12182, 38507, 24028, 9868, 42112

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;

AI model: 22989, 5469, 4213; **AI system:** 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; **System:** 25024, 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119; **Purpose:** 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119; **Provider:** 5259, 25019, 12182, 38507, 24028, 9868, 42112

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;

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; **System:** 25024, 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119; **Service:** 25024, 8183, 24027, 42001, 5259, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 82079, 12182, 8000, 38507, 24028, 26514, 29119, 9868, 5339, 62304, 20547, 24668; **Purpose:** 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 82079, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 20547; **Intended purpose:** 5259, 14971

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;

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; **System:** 25024, 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119; **Provider:** 5259, 25019, 12182, 38507, 24028, 9868, 42112; **Technical documentation:** 25019; **Documentation:** 42001, 5259, 25019, 25010, 27000, 14971, 5469, 82079, 26514, 29119, 62304, 20547, 24668; **Information:** 25024, 5259, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 24368, 12182, 24030, 31000, 25012, 8000, 38500, 38507, 24028, 6254, 8200, 24028, 26514, 29119, 22443, 9868, 5339, 62304, 20547, 24668; **Purpose:** 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 82079, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 20547; **Instructions for use:** 25010, 14971, 82079, 26514

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;

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; **Interaction:** 22989, 25010, 31010, 31000, 17847, 29119; **System:** 25024, 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119; **Human:** 24027, 42001, 25059, 24029, 25019, 22989, 25010, 27000, 31010, 14971, 82079, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 20547, 24668; **Purpose:** 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 82079, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 20547; **Intended purpose:** 5259, 14971; **Reasonably foreseeable misuse:** 14971

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;

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; **System:** 25024, 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119; **Health:** 42001, 5338, 25019, 25010, 27000, 14971, 5469, 12182, 29119, 9868, 5339, 62304, 22989, 18988; **Safety:** 42001, 5338, 24029, 25019, 22989, 25010, 27000, 14971, 5469, 24368, 8000, 24028, 29119, 9868, 62304, 20509, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119; **Intended purpose:** 5259, 14971

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;

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119;

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;

Monitoring: 42001, 23894, 25019, 27000, 31010, 14971, 5469, 8000, 24028, 29119, 9868, 62304; **Testing:** 25024, 24027, 25059, 24029, 24029, 25019, 22989, 25010, 82079, 12182, 24028, 26514, 25058, 29119, 9868, 62304, 12791, 42119

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;

Authority: 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Provider:** 5259, 25019, 12182, 38507, 24028, 9868, 42112

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;

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; **System:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **System:** 25024, 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119; **Conformity:** 25024, 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119; **Provider:** 5259, 25019, 12182, 38507, 24028, 9868, 42112

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;

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; **Obligation:** 42001, 24028; **Regulation:** 5259, 22989, 14971, 8000, 29119, 9868, 62304; **Provider:** 5259, 25019, 12182, 38507, 24028, 9868, 42112; **Knowledge:** 25024, 8183, 24027, 42001, 5338, 24029, 25019, 22989, 25010, 27000, 14971, 24030, 31000, 25012, 26514, 29119, 9868, 5339, 62304, 5392, 23053, 24372

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 59 are fulfilled;

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; **System:** 25024, 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119; **Conformity:** 25024, 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 12182, 24030, 31000, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 42006, 24668; **Testing:** 25024, 24027, 25059, 24029, 24029, 25019, 22989, 25010, 82079, 12182, 24028, 26514, 25058, 29119, 9868, 62304, 12791, 42119; **Regulation:** 5259, 22989, 14971, 8000, 29119, 9868, 62304; **Service:** 25024, 8183, 24001, 5259, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 82079, 12182, 8000, 38507, 24028, 26514, 29119, 9868, 5339, 62304, 25223, 5259, 5392, 17903, 20546, 20547, 24668; **Data:** 25024, 5259, 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 12182, 24030, 31000, 25012, 38507, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 25223, 5259, 5392, 17903, 20546, 20547, 20547, 23053, 24372, 24668, 25223, 42103; **Purpose:** 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 82079, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 20547; **Intended purpose:** 5259, 14971

Art. 3, (58)

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

Testing: 25024, 24027, 25059, 24029, 24029, 25019, 22989, 25010, 82079, 12182, 24028, 26514, 25058, 29119, 9868, 62304, 12791, 42119; **Purpose:** 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 82079, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 20547; **Subject:** 25024, 24027, 5259, 25059, 24029, 23894, 22989, 25010, 27000, 14971, 12182, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 62304, 20547

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;

Testing: 25024, 24027, 25059, 24029, 24029, 25019, 22989, 25010, 82079, 12182, 24028, 26514, 25058, 29119, 9868, 62304, 12791, 42119; **Subject:** 25024, 24027, 5259, 25059, 24029, 23894, 22989, 25010, 27000, 14971, 12182, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 62304, 20547

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;

Art. 3, (61)

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

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:

Definition: 25024, 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 82079, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 20546, 20547, 23282, 25029

Art. 3, (61)(i)

the act or omission originated or took place;

Art. 3, (61)(ii)

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

Provider: 5259, 25019, 12182, 38507, 24028, 9868, 42112; **Authorised representative:** 14971

Art. 3, (61)(iii)

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

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;

Operator: 25059, 25019, 25010, 26514, 9868, 17903

Art. 3, (62)

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

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;

AI model: 22989, 5469, 4213; **Data:** 25024, 5259, 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 12182, 24030, 31000, 25012, 38507, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 25223, 5259, 5392, 17903, 20546, 20547, 23053, 24372, 24668, 25223, 42103; **Task:** 42001, 5259, 25059, 24029, 24029, 25019, 22989, 25010, 14971, 24030, 25012, 24028, 26514, 29119, 62304, 4213, 12791, 20547, 23281, 25258; **Purpose:** 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 82079, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 20547

Art. 3, (64)

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

AI model: 22989, 5469, 4213; **Purpose:** 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 82079, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 20547

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;

AI model: 22989, 5469, 4213; **Chain:** 12182, 8000; **Security:** 25024, 42001, 5259, 25059, 24029, 25019, 22989, 25010, 27000, 14971, 24030, 24028, 29119, 9868, 62304, 42006, 20547, 20547; **Risk:** 8183, 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42005, 24668; **Society:** 42001, 25059, 25019, 14971, 24368, 26514, 22443, 5339, 42005; **Fundamental right:** 9868; **Health:** 42001, 5338, 25019, 25010, 27000, 14971, 5469, 12182, 29119, 9868, 5339, 62304, 22989, 18988; **Safety:** 42001, 5338, 24029, 25019, 22989, 25010, 27000, 14971, 5469, 24368, 8000, 24028, 29119, 9868, 62304, 25059, 22440, 22440, 22440; **Purpose:** 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 82079, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 20547

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;

AI model: 22989, 5469, 4213; **AI system:** 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; **System:** 25024, 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119; **Purpose:** 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 82079, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 20547

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;

Precision: 25024, 5259, 25059, 25010, 25012, 8000, 4213, 29119; **Operation:** 25024, 8183, 42001, 5259, 25059, 25019, 22989, 25010, 27000, 5469, 24030, 25012, 8000, 24028, 26514, 29119, 9868, 62304, 20547

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;

AI model: 22989, 5469, 4213; **AI system:** 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; **System:** 25024, 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22

ARTICLE 4

Art. 4

AI literacy
Planning: 25024, 42001, 5338, 25019, 22989, 25010, 27000, 82079, 12182, 26514

Art. 4,1

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.
AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; Operation: 25024, 8183, 42001, 5259, 25059, 25019, 22989, 25010, 27000, 82079, 12182, 26514, 29119, 9868, 62304, 20547; Expertise: 42001, 25019, 22989, 25010, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 12182, 38507, 24028, 9868, 42112; Knowledge: 25024, 8183, 24027, 42001, 5338, 24029, 25019, 22989, 25010, 27000, 14971, 24030, 31000, 25012, 26514, 29119, 9868, 5339, 62304, 5392, 23053, 24372; Education: 25010, 14971, 26514, 5339, 17903; Training: 24027, 5259, 5338, 24029, 22989, 5469, 25012, 8000, 24028, 4213, 26514, 29119, 9868, 5339, 62304, 20547, 24668

ARTICLE 5

CHAPTER II

PROHIBITED AI PRACTICES

Art. 5

Prohibited AI practices

Art. 5, 1

The following AI practices shall be prohibited:

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.
AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; System: 25024, 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119; Service: 25024, 8183, 42001, 5259, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 82079, 12182, 8000, 38507, 24028, 26514, 29119, 9868, 5339, 62304, 25059, 5392, 20547, 24668

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.
AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; System: 25024, 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119; Service: 25024, 8183, 42001, 5259, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 82079, 12182, 8000, 38507, 24028, 26514, 29119, 9868, 5339, 62304, 25059, 5392, 20547, 24668; Disability: 25010, 14971, 26514

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:
AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; Evaluation: 25024, 24027, 42001, 5259, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 82079, 12182, 25012, 8000, 4213, 26514, 25058, 17847, 29119, 9868, 62304, 20547, 24668; Categorization: 31010, 12182, 25012; Classification: 24029, 22989, 12182, 4213, 25058, 29119, 9868, 4213, 12791; Service: 25024, 8183, 42001, 5259, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 82079, 12182, 8000, 38507, 24028, 26514, 29119, 9868, 5339, 62304, 25059, 5392, 20547, 24668

Art. 5, 1(c)(i)

discriminatory 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;
Data: 25024, 5259, 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 12182, 24030, 31000, 25012, 38507, 24028, 4213, 26514, 25058, 17847, 29119, 9868, 5339, 62304, 25223, 5259, 5392, 17903, 20546, 20547, 20547, 20547, 20547, 23053, 24372, 24668, 25523, 42103

Art. 5, 1(c)(ii)

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

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;
AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; Support: 25024, 8183, 42001, 5259, 5338, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 82079, 24030, 25012, 8000, 38500, 26514, 29119, 62304, 42006, 17903, 20547, 24668, 25029; Risk: 8183, 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42005, 24668; System: 25024, 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119; Human: 24027, 42001, 25059, 24029, 25019, 22989, 25010, 27000, 31010, 14971, 82079, 12182, 8000, 38507, 24028, 26514, 29119, 9868, 5339, 62304, 25059, 5392, 20547, 24668; Assessment: 25024, 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 17847, 29119, 9868, 5339, 62304, 20547, 24668; Profiling: 8000

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;
AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; Service: 25024, 8183, 42001, 5259, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 82079, 12182, 8000, 38507, 24028, 26514, 29119, 9868, 5339, 62304, 25059, 5392, 20547, 24668; Purpose: 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 82079, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 17847, 29119, 9868, 5339, 62304, 20547

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;
AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; System: 25024, 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119; Safety: 42001, 5338, 24029, 25019, 22989, 25010, 27000, 14971, 5469, 24368, 8000, 24028, 29119, 9868, 62304, 25059, 22440, 22440, 22440; Education: 25010, 14971, 26514, 5339, 17903; Service: 25024, 8183, 42001, 5259, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 82079, 12182, 8000, 38507, 24028, 26514, 29119, 9868, 5339, 62304, 25059, 5392, 20547, 24668; Purpose: 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 82079, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 17847, 29119, 9868, 5339, 62304, 20547

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;
Labelling: 5259, 22989, 14971, 62304; Service: 25024, 8183, 42001, 5259, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 82079, 12182, 8000, 38507, 24028, 26514, 29119, 9868, 5339, 62304, 25059, 5392, 20547, 24668; Data: 25024, 5259, 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119; Safety: 42001, 5338, 24029, 25019, 22989, 25010, 27000, 14971, 5469, 24368, 8000, 24028, 29119, 9868, 62304, 25059, 22440, 22440, 22440; Education: 25010, 14971, 26514, 5339, 17903; Service: 25024, 8183, 42001, 5259, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 82079, 12182, 8000, 38507, 24028, 26514, 29119, 9868, 5339, 62304, 25059, 5392, 20547, 24668; Purpose: 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 82079, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 17847, 29119, 9868, 5339, 62304, 20547

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:

Biometric identification: 9868; Remote biometric identification system: 9868; Publicly accessible space: 9868

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;

Human: 24027, 42001, 25059, 24029, 25019, 22989, 25010, 27000, 31010, 14971, 82079, 24030, 31000, 25012, 8000, 24028, 26514, 29119, 9868, 62304, 5392, 23053, 42105, 42109

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;

Attack: 25010, 27000, 29119, 9868, 20547; Safety: 42001, 5338, 24029, 25019, 22989, 25010, 27000, 14971, 5469, 24368, 8000, 24028, 26514, 29119, 9868, 62304, 25059, 22440, 22440, 22440

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 (n) 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.

Regulation: 5259, 22989, 14971, 8000, 29119, 9868, 62304; Data: 25024, 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 12182, 24030, 31000, 25012, 38507, 24028, 4213, 26514, 25058, 17847, 29119, 9868, 5339, 62304, 25223, 5259, 5392, 17903, 20546, 20547, 20547, 20547, 20547, 23053, 24372, 24668, 25523, 42103; Biometric data: 9868; Purpose: 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22

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

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:

Biometric identification: 9668; **Remote biometric identification system:** 9668; **Publicly accessible space:** 9668

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;

System: 25024, 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119

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.

System: 25024, 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119

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.

Confidentiality: 25024, 5259, 42001, 22989, 25010, 27000, 25012; **Authority:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9668; **System:** 25024, 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119; **Safeguard:** 42001, 25012; **Fundamental right:** 9668; **Assessment:** 25024, 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119; **Biometric identification:** 9668; **Database:** 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24030, 31000, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 25223, 20546; **Impact assessment:** 42001, 22443, 42005; **Remote biometric identification system:** 9668; **Publicly accessible space:** 9668

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

Confidentiality: 25024, 5259, 42001, 22989, 25010, 27000, 25012; **Authority:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9668; **System:** 25024, 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119; **Data:** 25024, 5259, 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119; **Biometric identification:** 9668; **Subject:** 25024, 24027, 5259, 5259, 24029, 23894, 22989, 25010, 27000, 14971, 12182, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 62304, 20547; **Remote biometric identification system:** 9668; **Publicly accessible space:** 9668

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.

Authority: 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9668; **System:** 25024, 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119; **Notification:** 5259, 14971; **Data:** 25024, 5259, 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119; **Information:** 25024, 5259, 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119; **Biometric identification:** 9668; **Surveillance:** 9668; **Purpose:** 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119; **Protection:** 23894, 25010, 27000, 8000, 29119, 9868, 62304, 20547; **Data protection:** 29119; **Remote biometric identification system:** 9668; **Publicly accessible space:** 9668

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)(ii) thereof, the competent authorities may be authorised to use those systems for the purposes of law enforcement. Member States shall notify those rules to the Commission at the latest 30 days following the adoption thereof. Member States may introduce, in accordance with Union law, more restrictive laws on the use of remote biometric identification systems.

Authority: 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9668; **Biometric identification:** 9668; **Remote biometric identification system:** 9668; **Publicly accessible space:** 9668

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.

Authority: 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9668; **Data:** 25024, 5259, 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119; **Information:** 25024, 5259, 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119; **Biometric identification:** 9668; **Surveillance:** 9668; **Purpose:** 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119; **Protection:** 23894, 25010, 27000, 8000, 29119, 9868, 62304, 20547; **Data protection:** 29119; **Remote biometric identification system:** 9668; **Publicly accessible space:** 9668

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.

Data: 25024, 5259, 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119; **Biometric identification:** 9668; **Remote biometric identification system:** 9668; **Publicly accessible space:** 9668

Art. 5, 8

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

ARTICLE 6

CHAPTER III

HIGH-RISK AI SYSTEMS

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; **Risk:** 8183, 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42005, 24668; **High-risk:** 9668

SECTION 1

Classification of AI systems as high-risk

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; **Risk:** 8183, 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42005, 24668; **High-risk:** 9668; **Categorization:** 31010, 12182, 25012; **Classification:** 24029, 22989, 12182, 4213, 25058, 29119, 9868, 4213, 12791

Art. 6

Classification rules for high-risk AI systems

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; **Risk:** 8183, 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42005, 24668; **High-risk:** 9668; **Categorization:** 31010, 12182, 25012; **Classification:** 24029, 22989, 12182, 4213, 25058, 29119, 9868, 4213, 12791

Art. 6, 1

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.

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115, **Risk:** 8183, 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42005, 24668, **High-risk:** 9868

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:

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115, **Risk:** 8183, 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42005, 24668, **System:** 25024, 8183, 24027, 42001, 5259, 25059, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, **Fundamental right:** 9868, **Health:** 42001, 5338, 25019, 25010, 27000, 14971, 5469, 12182, 29119, 9868, 5339, 62304, 22989, 18988, **Safety:** 42001, 5338, 24029, 25019, 22989, 25010, 27000, 14971, 5469, 24368, 8000, 24028, 29119, 9868, 62304, 25059, 22440, 22440, 22440, **High-risk:** 9868, **Decision-making:** 24027, 42001, 5259, 25059, 27000, 31000, 8000, 29119, 62304, 24668

Art. 6, 3(a)

The AI system is intended to perform a narrow procedural task:

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115, **System:** 25024, 8183, 24027, 42001, 5259, 25059, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, **Task:** 42001, 5259, 25059, 24029, 24029, 25019, 22989, 25010, 14971, 24030, 25012, 24028, 26514, 29119, 62304, 4213, 12791, 20547, 23281, 25258

Art. 6, 3(b)

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

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115, **System:** 25024, 8183, 24027, 42001, 5259, 25059, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, **Human:** 24027, 42001, 25059, 24029, 25019, 22989, 25010, 14971, 24030, 25012, 24028, 26514, 29119, 62304, 8000, 24028, 26514, 29119, 9868, 62304, 5392, 23053, 42105, 42109, **Review:** 42001, 23894, 25019, 25010, 27000, 31010, 14971, 82079, 31000, 6254, 26514, 29119, 9868, 62304, **Decision-making:** 24027, 42001, 5259, 25059, 27000, 31000, 8000, 29119, 62304, 24668, **Assessment:** 25024, 8183, 24027, 42001, 5259, 25059, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 22443, 9868, 5339, 62304, 42006, 42005, 24668, 42119

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

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115, **System:** 25024, 8183, 24027, 42001, 5259, 25059, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, **Human:** 24027, 42001, 25059, 24029, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 62304, 25019, 9868, 62304, 5392, 23053, 42105, 42109, **Review:** 42001, 23894, 25019, 25010, 27000, 31010, 14971, 82079, 31000, 6254, 26514, 29119, 9868, 62304, **Decision-making:** 24027, 42001, 5259, 25059, 27000, 31000, 8000, 29119, 62304, 24668, **Assessment:** 25024, 8183, 24027, 42001, 5259, 25059, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 22443, 9868, 5339, 62304, 42006, 42005, 24668, 42119

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.

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115, **Risk:** 8183, 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42005, 24668, **System:** 25024, 8183, 24027, 42001, 5259, 25059, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, **High-risk:** 9868, **Assessment:** 25024, 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 22443, 9868, 5339, 62304, 42006, 42005, 24668, 42119, **Task:** 42001, 5259, 25059, 24029, 24029, 25019, 22989, 25010, 14971, 24030, 25012, 24028, 26514, 29119, 62304, 4213, 12791, 20547, 23281, 25258, **Profiling:** 8000

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.

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115, **Authority:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868, **Risk:** 8183, 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42005, 24668, **System:** 25024, 8183, 24027, 42001, 5259, 25059, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, **Obligation:** 42001, 24028, **High-risk:** 9868, **Provider:** 5259, 25019, 12182, 38507, 24028, 9868, 42112, **Documentation:** 42001, 5259, 25019, 25010, 27000, 14971, 5469, 82079, 26514, 29119, 62304, 42005, **Service:** 25024, 8183, 42001, 5259, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 82079, 12182, 8000, 38507, 24028, 26514, 29119, 9868, 5339, 62304, 25059, 5392, 20547, 24668, **Assessment:** 25024, 8183, 24027, 42001, 5259, 25059, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 22443, 9868, 5339, 62304, 42006, 42005, 24668, 42119, **Subject:** 25024, 24027, 5259, 25059, 24029, 23894, 22989, 25010, 27000, 14971, 12182, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 62304, 20547

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.

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115, **Risk:** 8183, 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42005, 24668, **Artificial intelligence:** 5259, 8183, 24027, 42001, 5259, 25059, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 8200, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, **High-risk:** 9868

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.

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115, **Risk:** 8183, 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42005, 24668, **Fundamental right:** 9868, **Health:** 42001, 5338, 25019, 25010, 27000, 14971, 5469, 12182, 29119, 9868, 5339, 62304, 22989, 18988, **Safety:** 42001, 5338, 24029, 25019, 22989, 25010, 27000, 14971, 5469, 24368, 8000, 24028, 29119, 9868, 62304, 25059, 22440, 22440, 22440

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.

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

Art. 7, 2(a)

the intended purpose of the AI system:

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; System: 25024, 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119; Purpose: 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 82079, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 20547; Intended purpose: 5259, 14971

Art. 7, 2(b)

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

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; System: 25024, 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119; Data: 25024, 5259, 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 12182, 24030, 31000, 25012, 38507, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 25223, 5259, 5392, 17903, 20546, 20547, 20547, 20547, 20547, 23053, 24372, 24668, 25523, 42103; Personal data: 22989, 29119

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:

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; Confidentiality: 25024, 5259, 42001, 22989, 25010, 27000, 25012; System: 25024, 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119; Data: 25024, 5259, 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 12182, 24030, 31000, 25012, 38507, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 25223, 5259, 5392, 17903, 20546, 20547, 20547, 20547, 20547, 23053, 24372, 24668, 25523, 42103; Personal data: 22989, 29119

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:

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; Authority: 25024, 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119; Human: 24027, 42001, 25059, 24029, 25019, 22989, 25010, 27000, 31010, 14971, 82079, 24030, 31000, 25012, 8000, 24028, 26514, 29119, 9868, 62304, 5392, 23053, 42105, 42109

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:

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; Authority: 25024, 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119; Fundamental right: 9868; Health: 42001, 5338, 25019, 25010, 27000, 14971, 5469, 12182, 29119, 9868, 5339, 62304, 22989, 18988; Safety: 42001, 5338, 24029, 25019, 22989, 25010, 27000, 14971, 5469, 24368, 8000, 24028, 29119, 9868, 62304, 25059, 22440, 22440, 22440

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:

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:

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; System: 25024, 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119

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:

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; Authority: 25024, 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119; Knowledge: 25024, 8183, 24027, 42001, 5338, 24029, 25019, 22989, 25010, 27000, 14971, 24030, 31000, 25012, 26514, 29119, 9868, 5339, 62304, 5392, 23053, 24372

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:

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; Authority: 25024, 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119; Fundamental right: 9868; Health: 42001, 5338, 25019, 25010, 27000, 14971, 5469, 12182, 29119, 9868, 5339, 62304, 22989, 18988; Safety: 42001, 5338, 24029, 25019, 22989, 25010, 27000, 14971, 5469, 24368, 8000, 24028, 29119, 9868, 62304, 25059, 22440, 22440, 22440

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:

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; Society: 42001, 25059, 25019, 14971, 24368, 26514, 22443, 5339, 42005; System: 25024, 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119; Safety: 42001, 5338, 24029, 25019, 22989, 25010, 27000, 14971, 5469, 24368, 8000, 24028, 29119, 9868, 62304, 25059, 22440, 22440, 22440; Benefit: 24027, 5259, 5259, 5338, 25019, 25010, 14971, 5469, 25012, 8000, 29119, 21221, 24668

Art. 7, 2(k)

the extent to which existing Union law provides for:

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:

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; System: 25024, 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119

Art. 7, 2(k)(ii)

effective measures to prevent or substantially minimise those risks.

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 system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; Risk: 8183, 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469,

The data presented here is for legal research and not a legal value.

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.

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; **Compliance:** 25024, 5259, 25019, 14971, 5469, 24970, 24030, 8000, 24028, 9868, 62304, 42005, 24668; **Risk management:** 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 24970, 82079, 31000, 24028, 5339, 62304, 42005, 24668; **System:** 25024, 8183, 24027, 42001, 5259, 25059, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42005, 24668; **Information:** 25024, 42001, 5259, 25059, 5338, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 25012, 8000, 38500, 24028, 26514, 29119, 22443, 9868, 5339, 62304, 42006, 42005, 20546, 20547, 24668; **High-risk:** 9868; **Purpose:** 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 20547; **Intended purpose:** 5259, 14971

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 wish 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.

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; **Compliance:** 25024, 5259, 25019, 14971, 5469, 24970, 24030, 8000, 24028, 9868, 62304, 42005, 24668; **Consistency:** 25024, 5259, 24001, 82079, 25012, 8000, 24028, 42006, 20547; **Risk:** 8183, 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42005, 24668; **System:** 25024, 8183, 24027, 42001, 5259, 25059, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 82079, 12182, 24028, 26514, 25058, 29119, 9868, 62304, 12791, 42119; **Regulation:** 25024, 5259, 22989, 14971, 8000, 2919, 9868, 62304, 42005, 24668; **High-risk:** 9868; **Provider:** 5259, 25019, 12182, 38507, 24028, 9868, 4212; **Process:** 8183, 42001, 5259, 25059, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 25012, 8000, 26514, 29119, 22443, 62304, 42006, 42005; **Management:** 25024, 42001, 5259, 25059, 5259, 5259, 5338, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 24030, 31000, 25012, 8000, 38500, 24028, 26514, 29119, 22443, 9868, 5339, 62304, 42006, 42005, 20546, 20547, 24668; **Information:** 25024, 5259, 8183, 24027, 42001, 5259, 25059, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 24368, 12182, 24030, 31000, 25012, 8000, 38500, 24028, 26514, 29119, 22443, 9868, 5339, 62304, 42006, 42005, 20546, 20547, 24668; **Review:** 42001, 23894, 25019, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 25012, 8000, 38500, 24028, 26514, 29119, 22443, 9868, 5339, 62304, 42006, 42005, 20546, 20547, 24668

ARTICLE 9

Art. 9

Risk management system

Risk management: 42001, 5259, 23894, 27000, 31010, 14971, 24970, 82079, 31000, 24028, 5339, 62304, 42005; **Risk:** 8183, 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119; **Management system:** 42001, 5259, 27000, 31000, 14971, 24970, 12182, 31000, 25012, 8000, 26514, 29119, 22443, 62304, 42006, 42005; **Management:** 25024, 42001, 5259, 25059, 5259, 5338, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 25012, 8000, 38500, 24028, 26514, 29119, 22443, 9868, 5339, 62304, 42006, 42005, 20546, 20547, 24668

Art. 9, 1

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

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; **Risk management:** 42001, 5259, 23894, 27000, 31010, 14971, 24970, 82079, 31000, 24028, 5339, 62304, 42005; **Risk:** 8183, 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42005, 24668; **System:** 25024, 8183, 24027, 42001, 5259, 25059, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119; **Management system:** 42001, 5259, 27000, 31000, 14971, 24970, 12182, 31000, 25012, 8000, 26514, 29119, 22443, 62304, 42006, 42005, 20546, 20547, 24668; **Information:** 25024, 5259, 8183, 24027, 42001, 5259, 25059, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 24368, 12182, 24030, 31000, 25012, 8000, 38500, 24028, 26514, 29119, 22443, 9868, 5339, 62304, 42006, 42005, 20546, 20547, 24668; **Review:** 42001, 23894, 25019, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 25012, 8000, 38500, 24028, 26514, 29119, 22443, 9868, 5339, 62304, 42006, 42005, 20546, 20547, 24668

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:

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; **Life cycle:** 24027, 5338, 25019, 25010, 17847, 2243, 62304, 42005, 42102; **Updating:** 22989; **Risk management:** 42001, 5259, 23894, 27000, 31010, 14971, 24970, 82079, 31000, 24028, 5339, 62304, 42005, 24668; **System:** 25024, 8183, 24027, 42001, 5259, 25059, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119; **Management system:** 42001, 5259, 27000, 31000, 14971, 24970, 12182, 31000, 25012, 8000, 26514, 29119, 22443, 62304, 42006, 42005, 20546, 20547, 24668; **Information:** 25024, 5259, 8183, 24027, 42001, 5259, 25059, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 25012, 8000, 38500, 24028, 26514, 29119, 22443, 9868, 5339, 62304, 42006, 42005, 20546, 20547, 24668; **Review:** 42001, 23894, 25019, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 25012, 8000, 38500, 24028, 26514, 29119, 22443, 9868, 5339, 62304, 42006, 42005, 20546, 20547, 24668

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:

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; **Life cycle:** 24027, 5338, 25019, 25010, 17847, 2243, 62304, 42005, 42102; **Updating:** 22989; **Risk management:** 42001, 5259, 23894, 27000, 31010, 14971, 24970, 82079, 31000, 24028, 5339, 62304, 42005, 24668; **System:** 25024, 8183, 24027, 42001, 5259, 25059, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119; **Management system:** 42001, 5259, 27000, 31000, 14971, 24970, 12182, 31000, 25012, 8000, 26514, 29119, 22443, 62304, 42006, 42005, 20546, 20547, 24668; **Information:** 25024, 5259, 8183, 24027, 42001, 5259, 25059, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 25012, 8000, 38500, 24028, 26514, 29119, 22443, 9868, 5339, 62304, 42006, 42005, 20546, 20547, 24668; **Review:** 42001, 23894, 25019, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 25012, 8000, 38500, 24028, 26514, 29119, 22443, 9868, 5339, 62304, 42006, 42005, 20546, 20547, 24668

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:

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; **Evaluation:** 25024, 24027, 42001, 5259, 25059, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 24970, 82079, 12182, 31000, 25012, 8000, 4213, 26514, 17847, 29119, 9868, 62304, 25059, 23282; **Risk:** 8183, 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42005, 24668; **System:** 25024, 8183, 24027, 42001, 5259, 25059, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119; **High-risk:** 9868; **Purpose:** 8183, 24027, 42001, 5259, 25059, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 20547; **Intended purpose:** 5259, 14971; **Reasonably foreseeable misuse:** 14971

Art. 9, 2(c)

The evaluation of the risks possibly arising, based on the analysis of data gathered from the post-market monitoring system referred to in Article 12:

Evaluation: 25024, 24027, 42001, 5259, 25059, 5259, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 82079, 12182, 25012, 8000, 4213, 25058, 17847, 29119, 9868, 62304, 25059, 23282; **Post-market:** 25019, 14971; **Monitoring:** 42001, 23894, 25019, 27000, 31010, 14971, 5469, 8000, 24028, 29119, 9868, 62304, 5339, 25024, 8183, 24027, 42001, 5259, 25059, 5259, 25059, 5338, 2

The data presented here has a **value for research and not a legal value.**

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.

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; **Risk management:** 8183, 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42006, 24668; **System:** 25024, 24027, 42001, 5259, 25059, 5338, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 25012, 8000, 38500, 38507, 24028, 6254, 8200, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119; **Experience:** 42001, 25019, 22989, 25010, 14971, 31000, 26514, 29119, 62304, 23053, 24668; **High-risk:** 9868; **Knowledge:** 25024, 8183, 24027, 42001, 5338, 24029, 25019, 22989, 25010, 27000, 14971, 24030, 31000, 25012, 26514, 29119, 9868, 5339, 62304, 5392, 23053, 24372; **Education:** 25010, 14971, 26514, 5339, 17903; **Training:** 24027, 5259, 5338, 24029, 22989, 5469, 25012, 8000, 24028, 4213, 26514, 29119, 23053, 42112; **Information:** 25024, 5259, 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 24368, 12182, 24030, 31000, 25012, 8000, 38500, 38507, 24028, 6254, 8200, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 42006, 12792, 5392, 17903, 20547, 20547, 20547, 42112

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.

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; **Compliance:** 25024, 5259, 25019, 14971, 5469, 82079, 25012, 8000, 24028, 9868, 62304; **Risk management:** 42001, 5259, 23894, 27000, 31010, 14971, 24970, 82079, 31000, 24028, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119; **Risk management:** 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42006, 24668; **Management:** 25024, 42001, 5259, 25059, 5338, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 25012, 8000, 38500, 24028, 26514, 29119, 22443, 9868, 5339, 62304, 42006, 42005, 20546, 20547, 24668; **Testing:** 25024, 24027, 25059, 24029, 24029, 25019, 22989, 25010, 82079, 12182, 24028, 26514, 25058, 29119, 9868, 62304, 12791, 42119; **High-risk:** 9868; **Purpose:** 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 82079, 12182, 24030, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 20547; **Intended purpose:** 5259, 14971

Art. 9, 7

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

Testing: 25024, 24027, 25059, 24029, 24029, 25019, 22989, 25010, 82079, 12182, 24028, 26514, 25058, 29119, 9868, 62304, 12791, 42119

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.

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; **Risk management:** 42001, 5259, 23894, 27000, 31010, 14971, 24970, 82079, 31000, 24028, 5339, 62304, 42005, 24668; **System:** 8183, 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42006, 24668; **System:** 25024, 8183, 24027, 42001, 5259, 25059, 5338, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 25012, 8000, 38500, 24028, 26514, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 24668; **High-risk:** 9868; **Service:** 25024, 8183, 42001, 5259, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 82079, 12182, 8000, 38507, 24028, 26514, 29119, 9868, 5339, 62304, 20547, 24668; **Metric:** 24027, 5259, 4213, 29119, 23282, 42119; **Purpose:** 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 82079, 12182, 24030, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 20547; **Event:** 24027, 42001, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 31000, 25012, 24028, 62304; **Intended purpose:** 5259, 14971

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.

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; **Risk management:** 42001, 5259, 23894, 27000, 31010, 14971, 24970, 82079, 31000, 24028, 5339, 62304, 42005, 24668; **System:** 8183, 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42006, 24668; **System:** 25024, 8183, 24027, 42001, 5259, 25059, 5338, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 25012, 8000, 38500, 24028, 26514, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119; **Management:** 25024, 42001, 5259, 25059, 5338, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 25012, 8000, 38500, 24028, 26514, 29119, 22443, 9868, 5339, 62304, 42006, 42005, 20546, 20547, 24668; **High-risk:** 9868; **Provider:** 5259, 25019, 12182, 38507, 24028, 9868, 42112; **Purpose:** 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 82079, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 20547; **Intended purpose:** 5259, 14971

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.

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; **Risk management:** 42001, 5259, 23894, 27000, 31010, 14971, 24970, 82079, 31000, 24028, 5339, 62304, 42005, 24668; **System:** 8183, 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42006, 24668; **System:** 25024, 8183, 24027, 42001, 5259, 25059, 5338, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 25012, 8000, 38500, 24028, 26514, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119; **Management system:** 42001, 5259, 27000, 14971, 24970, 12182, 31000, 25012, 8000, 26514, 29119, 22443, 62304, 42006, 42005, 20546, 20547, 24668; **High-risk:** 9868; **Provider:** 5259, 25019, 12182, 38507, 24028, 9868, 42112; **Purpose:** 8183, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 25012, 8000, 38500, 24028, 26514, 29119, 22443, 9868, 5339, 62304, 42006, 42005, 20546, 20547, 24668; **High-risk:** 9868; **Provider:** 5259, 25019, 12182, 38507, 24028, 9868, 42112; **Subject:** 25024, 24027, 5259, 25059, 24029, 23894, 22989, 25010, 27000, 14971, 12182, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 62304, 20547

ARTICLE 10

Art. 10

Data and data governance

Governance: 8183, 42001, 5259, 25019, 22989, 27000, 31000, 8000, 38500, 38507, 24028, 22443, 18115; **Data governance:** 8183, 8000, 18115; **Data:** 25024, 5259, 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 12182, 24030, 31000, 25012, 38507, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 25223, 5259, 5392, 17903, 20546, 20547, 20547, 20547, 20547, 23053, 24372, 24668, 25223, 42103

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.

AI model: 22989, 5469, 4213; **AI system:** 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; **Validation:** 25024, 5259, 25059, 24029, 25019, 22989, 25010, 5469, 8000, 24028, 8200, 4213, 17847, 29119, 22443, 9868, 5339, 62304, 42119; **Governance:** 8183, 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42006, 24668; **System:** 25024, 8183, 24027, 42001, 5259, 25059, 5338, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 25012, 8000, 38500, 24028, 26514, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119; **Data governance:** 8183, 8000, 18115; **Management:** 25024, 42001, 5259, 25059, 5338, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 25012, 8000, 38500, 24028, 26514, 29119, 22443, 9868, 5339, 62304, 42006, 42005, 20546, 20547, 24668; **Testing:** 25024, 24027, 25059, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 12182, 24030, 25012, 38507, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 25223, 5259, 5392, 17903, 20546, 20547, 20547, 20547, 20547, 23053, 24372, 24668, 25223, 42103; **Dataset:** 25024, 5259, 24029, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 12182, 24030, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 62304, 25223, 20546; **Testing data:** 25024

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:

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; **Validation:** 25024, 5259, 25059, 24029, 25019

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

Art. 13, 3(b)

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

AI system: 8183, 24027, 42001, 5259, 5259, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115. **Risk:** 8183, 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42005, 24668. **System:** 25024, 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119. **High-risk:** 9868

Art. 13, 3(b)(i)

its intended purpose:

Purpose: 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 82079, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 20547; **Intended purpose:** 5259, 14971

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;

Accuracy: 25024, 5259, 5259, 24029, 22989, 27000, 25012, 4213, 26514, 29119. **AI system:** 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115. **Robustness:** 25059, 24029, 24029, 24029, 22989, 25010, 82079, 29119. **Risk:** 8183, 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42005, 24668. **System:** 25024, 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119. **Fundamental right:** 9868. **Health:** 42001, 5338, 25019, 25010, 27000, 14971, 5469, 12182, 2919, 9868, 5339, 62304, 22989, 18988. **Safety:** 42001, 5338, 24029, 25019, 22989, 25010, 27000, 14971, 5469, 24368, 8000, 24028, 29119, 9868, 62304, 20599, 22440, 22440, 22440. **High-risk:** 9868. **Purpose:** 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 82079, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 20547; **Intended purpose:** 5259, 14971; **Reasonably foreseeable misuse:** 14971

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);

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115. **Risk:** 8183, 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42005, 24668. **System:** 25024, 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119. **Fundamental right:** 9868. **Health:** 42001, 5338, 25019, 25010, 27000, 14971, 5469, 12182, 2919, 9868, 5339, 62304, 22989, 18988. **Safety:** 42001, 5338, 24029, 25019, 22989, 25010, 27000, 14971, 5469, 24368, 8000, 24028, 29119, 9868, 62304, 20599, 22440, 22440, 22440. **High-risk:** 9868. **Purpose:** 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 82079, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 20547; **Intended purpose:** 5259, 14971; **Reasonably foreseeable misuse:** 14971

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;

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115. **Validation:** 25024, 5259, 25059, 24029, 25019, 22989, 25010, 5469, 8000, 24028, 8200, 4213, 17847, 29119, 62304, 42119. **Risk:** 8183, 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42005, 24668. **System:** 25024, 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119. **High-risk:** 9868. **Information:** 25024, 5259, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 24030, 31000, 25012, 8000, 38500, 38507, 24028, 6254, 8200, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 42006, 12792, 5392, 17903, 20547, 20547, 20547, 42112

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;

System: 25024, 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119

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;

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115. **Validation:** 25024, 5259, 25059, 24029, 25019, 22989, 25010, 5469, 8000, 24028, 8200, 4213, 17847, 29119, 62304, 42119. **Risk:** 8183, 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42005, 24668. **System:** 25024, 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119. **High-risk:** 9868. **Information:** 25024, 5259, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 24030, 31000, 25012, 8000, 38500, 38507, 24028, 6254, 8200, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 20547, 42112. **Training:** 25027, 5259, 5338, 24029, 22989, 5469, 25012, 8000, 24028, 4213, 26514, 29119, 23053, 42112. **Data:** 25024, 5259, 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119. **Input data:** 24029, 24029, 22989, 5469, 4213, 29119. **Dataset:** 25024, 5259, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 25019, 22989, 25010, 27000, 14971, 12182, 24030, 25012, 8000, 24028, 4213, 26514, 29119, 9868, 5339, 62304, 25223, 20546. **Purpose:** 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 82079, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 20547; **Intended purpose:** 5259, 14971; **Testing data:** 25024

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;

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115. **Risk:** 8183, 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42005, 24668. **System:** 25024, 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119. **High-risk:** 9868. **Information:** 25024, 5259, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 24030, 31000, 25012, 8000, 38500, 38507, 24028, 6254, 8200, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 20547, 42112

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;

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115. **Risk:** 8183, 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42005, 24668. **System:** 25024, 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010,

ARTICLE 17

Art. 17

Quality management system

System: 25024, 8183, 24027, 42001, 5259, 5259, 5259, 5259, 5259, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119. Management system: 42001, 5259, 27000, 14971, 24970, 12182, 31000, 25012, 8000, 26514, 29119, 22443, 62304, 42006, 42005; Management: 25024, 42001, 5259, 5259, 5259, 5338, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 25012, 8000, 38500, 24028, 26514, 29119, 22443, 9868, 5339, 62304, 42006, 42005, 20546, 20547, 24668. Quality management: 25024, 42001, 5259, 5259, 5259, 25019, 25010, 14971, 25012, 8000, 62304

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:

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115. Compliance: 25024, 5259, 25019, 14971, 5469, 82079, 25012, 8000, 24028, 9868, 62304. Risk: 8183, 24001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 25012, 8000, 26514, 29119, 22443, 62304, 42006, 42005; Management: 25024, 42001, 5259, 5259, 5259, 5338, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 25012, 8000, 38500, 24028, 26514, 29119, 22443, 9868, 5339, 62304, 42006, 42005, 20546, 20547, 24668. Quality management: 25024, 42001, 5259, 5259, 5259, 5338, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 25012, 8000, 38500, 24028, 26514, 29119, 22443, 9868, 5339, 62304, 42006, 42005, 20546, 20547, 24668. Regulation: 5259, 22989, 14971, 8000, 29119, 9868, 62304. High-risk: 9868; Provider: 5259, 25019, 12182, 38507, 24028, 9868, 62304

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;

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115. Compliance: 25024, 5259, 25019, 14971, 5469, 82079, 25012, 8000, 24028, 9868, 62304. Risk: 8183, 24001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 25012, 8000, 26514, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119. Conformity: 25024, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 25012, 8000, 38500, 24028, 26514, 29119, 22443, 9868, 5339, 62304, 42006, 42005, 20546, 20547, 24668. High-risk: 9868. Assessment: 25024, 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 22443, 9868, 5339, 62304, 42006, 42005, 24668, 42119; Conformity assessment: 25024, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 12182, 24030, 31000, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 42006, 42005, 24668

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;

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115. Design: 25024, 24027, 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 25012, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 20547, 20529; Risk: 8183, 24001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 25012, 8000, 26514, 29119, 22443, 9868, 5339, 62304, 42006, 42005, 20546, 20547, 24668. System: 25024, 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119. High-risk: 9868; Verification: 25059, 24029, 24029, 25019, 22989, 25010, 14971, 5469, 8200, 17847, 29119, 9868, 62304, 42119

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;

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115. Validation: 25024, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 82079, 12182, 31000, 25012, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 20547, 20529; Risk: 8183, 24001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 25012, 8000, 26514, 29119, 22443, 9868, 5339, 62304, 42006, 42005, 24668. System: 25024, 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119. High-risk: 9868; Quality control: 25010; Quality assurance: 25019, 25010, 82079, 25012, 2919

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;

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115. Validation: 25024, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 82079, 12182, 31000, 25012, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 20547, 20529; Risk: 8183, 24001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 25012, 8000, 26514, 29119, 22443, 9868, 5339, 62304, 42006, 42005, 24668. System: 25024, 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119. High-risk: 9868

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;

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115. Risk: 8183, 24001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 25012, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 20547, 20529; Risk: 8183, 24001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 25012, 8000, 26514, 29119, 22443, 9868, 5339, 62304, 42006, 42005, 24668. System: 25024, 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119. High-risk: 9868; Specification: 24029, 25019, 22989, 25010, 14971, 5469, 25012, 29119, 62304, 20547

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;

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115. Operation: 25024, 8183, 24001, 5259, 25059, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 25012, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 20547, 20529; Acquisition: 8183, 24001, 5259, 5338, 25010, 25012, 9868, 5392; Labelling: 5259, 22989, 14971, 62304; Risk: 8183, 24001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 25012, 8000, 38500, 24028, 26514, 29119, 22443, 9868, 5339, 62304, 42006, 42005, 20546, 20547, 24668. Data labelling: 5259; High-risk: 9868; Service: 25024, 8183, 24001, 5259, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 82079, 12182, 31000, 38507, 24028, 26514, 29119, 9868, 5339, 62304, 25059, 5392, 20547, 24668; Data: 25024, 5259, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119. High-risk: 9868; Data acquisition: 5259; Data analysis: 42001, 25019, 22989, 20546; Data storage: 5469, 24372; Data mining: 25024, 22989; Purpose: 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 82079, 12182, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 20547

Art. 17, 1(g)

The risk management system referred to in Article 9;

Risk management: 25019, 14971, 20001, 5259, 23894, 27000, 31010, 14971, 24970, 82079, 31000, 24028, 5339, 62304, 42005; Risk: 8183, 24001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 25012, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119. Management system: 42001, 5259, 27000, 14971, 24970, 12182, 31000, 25012, 8000, 26514, 29119, 22443, 62304, 42006, 42005; Management: 25024, 42001, 5259, 5259, 5259, 5338, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 25012, 8000, 38500, 24028, 26514, 29119, 22443, 9868, 5339, 62304, 42006, 42005, 20

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.

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; **Risk:** 8183, 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42005, 24668; **Management system:** 42001, 5259, 27000, 14971, 24970, 12182, 31000, 25012, 8000, 26514, 29119, 22443, 62304, 42006, 42005, 20546, 20547, 24668; **Obligation:** 42001, 24028; **High-risk:** 9868; **Provider:** 5259, 25019, 12182, 38507, 24028, 9868, 42112; **Quality management:** 25024, 42001, 5259, 5259, 5259, 25019, 25010, 14971, 25012, 8000, 62304; **Subject:** 25024, 24027, 5259, 5259, 24029, 23894, 22989, 25010, 27000, 14971, 12182, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 62304, 20547

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.

Governance: 8183, 42001, 5259, 25019, 22989, 27000, 31000, 8000, 38500, 38507, 24028, 22443, 18115; **System:** 25024, 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119; **Management system:** 42001, 5259, 27000, 14971, 24970, 12182, 31000, 25012, 8000, 26514, 29119, 22443, 62304, 42006, 42005, 20546, 20547, 24668; **Obligation:** 42001, 24028; **Provider:** 5259, 25019, 12182, 38507, 24028, 9868, 42112; **Process:** 8183, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 82079, 24368, 24030, 31000, 25012, 8000, 8200, 4213, 26514, 25058, 17847, 29119, 9868, 5339, 62304, 42005, 5392, 20546, 20547, 24668, 23281, 23282, 25029, 25258, 42119; **Quality management:** 25024, 42001, 5259, 5259, 5259, 25019, 25010, 14971, 25012, 8000, 62304; **Subject:** 25024, 24027, 5259, 5259, 24029, 23894, 22989, 25010, 27000, 14971, 12182, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 62304, 20547

ARTICLE 18**Art. 18**

Documentation keeping

Documentation: 42001, 5259, 25019, 25010, 27000, 14971, 5469, 82079, 26514, 29119, 62304, 42005

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:

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; **Authority:** 25024, 42001, 5259, 27000, 14971, 38507, 24028, 9868; **Risk:** 8183, 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42005, 24668; **System:** 25024, 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119; **High-risk:** 9868; **Provider:** 5259, 25019, 12182, 38507, 24028, 9868, 42112; **Service:** 25024, 8183, 42001, 5259, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 82079, 24368, 24030, 31000, 25012, 8000, 8200, 4213, 26514, 25058, 17847, 29119, 9868, 5339, 62304, 42005, 5392, 20546, 20547, 24668

Art. 18, 1(a)

the technical documentation referred to in Article 11;

Technical documentation: 25019; **Documentation:** 42001, 5259, 25019, 25010, 27000, 14971, 5469, 82079, 26514, 29119, 62304, 42005

Art. 18, 1(b)

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

System: 25024, 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119; **Management system:** 42001, 5259, 27000, 14971, 24970, 12182, 31000, 25012, 8000, 26514, 29119, 22443, 62304, 42006, 42005; **Management:** 25024, 42001, 5259, 5259, 5259, 5338, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 25012, 8000, 38500, 24028, 26514, 29119, 22443, 9868, 5339, 62304, 42006, 42005, 20546, 20547, 24668; **Documentation:** 42001, 5259, 25019, 25010, 27000, 14971, 5469, 82079, 26514, 29119, 62304, 42005; **Quality management:** 25024, 42001, 5259, 5259, 5259, 25019, 25010, 14971, 25012, 8000, 62304

Art. 18, 1(c)

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

Documentation: 42001, 5259, 25019, 25010, 27000, 14971, 5469, 82079, 26514, 29119, 62304, 42005

Art. 18, 1(d)

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

Art. 18, 1(e)

the EU declaration of conformity referred to in Article 47;

Declaration: 25024, 24027, 5259, 24029, 23894, 22989, 27000, 14971, 12182, 31000, 8000, 24028, 4213, 26514, 29119, 9868; **Conformity:** 25024, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 12182, 24030, 31000, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 42006, 24668

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.

Authority: 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Provider:** 5259, 25019, 12182, 38507, 24028, 9868, 42112; **Documentation:** 42001, 5259, 25019, 25010, 27000, 14971, 5469, 82079, 26514, 29119, 62304, 42005; **Authorised representative:** 14971

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.

Governance: 8183, 42001, 5259, 25019, 22989, 27000, 31000, 8000, 38500, 38507, 24028, 22443, 18115; **Provider:** 5259, 25019, 12182, 38507, 24028, 9868, 42112; **Process:** 8183, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 82079, 24368, 24030, 31000, 25012, 8000, 8200, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 42005, 5392, 20546, 20547, 24668, 23281, 23282, 25029, 25258, 42119; **Technical documentation:** 25019; **Documentation:** 42001, 5259, 25019, 25010, 27000, 14971, 5469, 82079, 26514, 29119, 62304, 42005; **Subject:** 25024, 24027, 5259, 5259, 24029, 23894, 22989, 25010, 27000, 14971, 12182, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 62304, 20547

ARTICLE 19**Art. 19**

Automatically generated logs

Log: 24027, 42001, 22989, 27000, 5469, 24970, 25012, 8000, 29119, 62304

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.

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; **Confidentiality:** 25024, 5259, 42001, 22989, 25010, 27000, 25012; **Risk:** 8183, 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42005, 24668; **System:** 25024, 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119; **High-risk:** 9868; **Provider:** 5259, 25019, 12182, 38507, 24028, 9868, 42112; **Data:** 25024, 5259, 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 82079, 24368, 24030, 31000, 25012, 8000, 8200, 4213, 26514, 25058, 17847, 29119, 9868, 5339, 62304, 42005, 5392, 20546, 20547, 24668, 23281, 23282, 25029, 25258, 42119; **Personal data:** 22989, 29119; **Log:** 24027, 42001, 22989, 27000, 5469, 24970, 25012, 8000, 29119, 62304; **Purpose:** 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 82079, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 20547; **Protection:** 23894, 25010, 27000, 8000, 29119, 9868, 62304, 17903; **Intended purpose:** 5259, 14971

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.

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; **Governance:** 42001, 5259, 25019, 22989, 27000, 31000, 8000, 38500, 38507, 24028, 22443, 18115; **Risk:** 8183, 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42005, 24668; **High-risk:** 9868; **Provider:** 5259, 25019, 12182, 38507, 24028, 9868, 42112; **Process:** 8183, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 82079, 24368, 24030, 31000, 25012, 8000, 8200, 4213, 26514, 25058, 17847, 29119, 9868, 5339, 62304, 42005, 5392, 20546, 20547, 24668, 23281, 23282, 25029, 25258, 42119; **Documentation:** 42001, 5259, 25019, 25010, 27000, 14971, 5469, 82079, 26514, 29119, 62304, 42005; **Log:** 24027, 42001, 22989, 27000, 5469, 24970, 25012, 8000, 29119, 62304; **Subject:** 25024, 24027, 5259, 5259, 24029, 23894, 22989, 25010, 27000, 14971, 12182, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 20547

ARTICLE 20**Art. 20**

Corrective actions and duty of information

Corrective action: 42001, 27000, 14971; **Information:** 25024, 5259, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 24368, 12182, 24030, 31000, 25012, 8000, 38500, 38507, 24028, 6254, 8200, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 42006, 12792, 5392, 17903, 20547, 20547, 20547, 42112

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.

AI system: 8183, 2402

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.

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115, **Compliance:** 25024, 5259, 25019, 14971, 5469, 82079, 25012, 8000, 24028, 9868, 62304, **Authority:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868, **Corrective action:** 42001, 27000, 14971, **Risk:** 8183, 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42005, 24668, **System:** 25024, 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20547, 20547, 20547, 23053, 24372, 20226, 22440, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, **High-risk:** 9868, **Provider:** 5259, 25019, 12182, 38507, 24028, 9868, 42112, **Surveillance:** 9868

ARTICLE 21

Art. 21

Cooperation with competent authorities

Authority: 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868, **Cooperation:** 24029, 26514, 5392

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.

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115, **Authority:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868, **Risk:** 8183, 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42005, 24668, **System:** 25024, 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, **Conformity:** 25024, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20547, 20547, 20547, 23053, 24372, 20226, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, **Documentation:** 25024, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 82079, 26514, 29119, 62304, 42005, **Information:** 25024, 5259, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42006, 24668, **High-risk:** 9868, **Provider:** 5259, 25019, 12182, 38507, 24028, 9868, 42112

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.

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115, **Authority:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868, **Access:** 25024, 25019, 22989, 25010, 27000, 14971, 82079, 26514, 29119, 9868, 5339, 62304, 17903, **Risk:** 8183, 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42005, 24668, **System:** 25024, 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, **Conformity:** 25024, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 82079, 26514, 29119, 62304, 42005, **Information:** 25024, 5259, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42006, 24668, **High-risk:** 9868, **Provider:** 5259, 25019, 12182, 38507, 24028, 9868, 42112

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.

Confidentiality: 25024, 5259, 42001, 22989, 25010, 27000, 25012, **Authority:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868, **Confidential:** 42001, 22989, 25010, 27000, **Obligation:** 42001, 24028, **Information:** 25024, 5259, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 24030, 31000, 25012, 8000, 38500, 38507, 24028, 6254, 8200, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 42006, 12792, 5392, 17903, 20547, 20547, 20547, 42112

ARTICLE 22

Art. 22

Authorised representatives of providers of high-risk AI systems

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115, **Risk:** 8183, 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42005, 24668, **High-risk:** 9868, **Provider:** 5259, 25019, 12182, 38507, 24028, 9868, 42112; **Authorised representative:** 14971

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.

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115, **Risk:** 8183, 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42005, 24668, **High-risk:** 9868, **Provider:** 5259, 25019, 12182, 38507, 24028, 9868, 42112; **Authorised representative:** 14971

Art. 22, 2

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

Provider: 5259, 25019, 12182, 38507, 24028, 9868, 42112, **Task:** 42001, 5259, 25059, 24029, 24029, 23894, 25019, 22989, 25010, 14971, 24030, 25012, 24028, 26514, 29119, 62304, 4213, 12791, 20547, 23281, 25258, **Authorised representative:** 14971

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:

Authority: 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868, **Regulation:** 5259, 22989, 14971, 8000, 29119, 9868, 62304, **Provider:** 5259, 25019, 12182, 38507, 24028, 9868, 42112, **Task:** 42001, 5259, 25059, 24029, 25019, 22989, 25010, 14971, 24030, 25012, 24028, 26514, 29119, 62304, 4213, 12791, 20547, 23281, 25258, **Surveillance:** 9868, **Authorised representative:** 14971

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.

Declaration: 25024, 24027, 5259, 24029, 23894, 22989, 27000, 14971, 12182, 31000, 8000, 24028, 4213, 26514, 29119, 9868, **Conformity:** 25024, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 12182, 24030, 31000, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, **Technical documentation:** 25019, **Documentation:** 42001, 5259, 25019, 25010, 27000, 14971, 5469, 82079, 26514, 29119, 62304, 42005, **Assessment:** 25024, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 42006, 42005, 24668, 42119, **Conformity assessment:** 25024, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 12182, 24030, 31000, 8000, 24028, 4213, 26514, 25058, 17847, 29119, 9868, 5339, 62304, 42006, 24668

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.

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115, **Authority:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868, **Risk:** 8183, 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42005, 24668, **System:** 25024, 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, **Declaration:** 25024, 24027, 5259, 24029, 23894, 22989, 27000, 14971, 12182, 31000, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 42005, 24668, **High-risk:** 9868, **Provider:** 5259, 25019, 12182, 38507, 24028, 9868, 42112, **Technical documentation:** 25019, **Documentation:** 42001, 5259, 25019, 25010, 27000, 14971, 5469, 82079, 26514, 29119, 62304, 42005, **Service:** 25024, 8183, 24001, 5259, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 82079, 12182, 31000, 38507, 24028, 26514, 29119, 9868, 5339, 62304, 25059, 5392, 20547, 20547, 20547, 23053, 24372, 20226, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, **Conformity assessment:** 25024, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 82079, 12182, 24030, 31000, 25012, 8000, 38500, 38507, 24028, 6254, 8200, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 42006, 24668, **High-risk:** 9868, **Provider:** 5259, 25019, 12182, 38507, 24028, 9868, 42112, **Surveillance:** 9868, **Contact:** 31010, 14971, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42005, 24668

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

ARTICLE 23

Art. 23

Obligations of importers

Obligation: 42001, 24028; Importer: 14971

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:

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; Risk: 8183, 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42005, 24668; System: 25024, 8183, 24027, 42001, 5259, 25059, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 12182, 24030, 31000, 8000, 24028, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119; Conformity: 25024, 8183, 24027, 42001, 5259, 25059, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 12182, 24030, 31000, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 42006, 24668; High-risk: 9868; Provider: 5259, 25019, 12182, 38507, 24028, 9868, 42112; Assessment: 25024, 8183, 24027, 42001, 5259, 25059, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 22443, 9868, 5339, 62304, 42006, 42005, 24668, 42119; Conformity assessment: 25024, 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 12182, 24030, 31000, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 42006, 24668; Regulation: 25024, 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 12182, 24030, 31000, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 42006, 24668

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;

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; Risk: 8183, 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42005, 24668; System: 25024, 8183, 24027, 42001, 5259, 25059, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 12182, 24030, 31000, 8000, 24028, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119; Conformity: 25024, 8183, 24027, 42001, 5259, 25059, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 12182, 24030, 31000, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 42006, 24668; High-risk: 9868; Provider: 5259, 25019, 12182, 38507, 24028, 9868, 42112; Assessment: 25024, 8183, 24027, 42001, 5259, 25059, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 22443, 9868, 5339, 62304, 42006, 42005, 24668, 42119; Conformity assessment: 25024, 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 12182, 24030, 31000, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 42006, 24668

Art. 23, 1(b)

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

Provider: 5259, 25019, 12182, 38507, 24028, 9868, 42112; Technical documentation: 25019; Documentation: 42001, 5259, 25019, 25010, 27000, 14971, 5469, 82079, 26514, 29119, 62304, 42005

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;

System: 25024, 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; Risk: 8183, 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42005, 24668; System: 25024, 8183, 24027, 42001, 5259, 25059, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 12182, 24030, 31000, 8000, 24028, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119; Conformity: 25024, 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 12182, 24030, 31000, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 42006, 24668; Instructions for use: 25010, 14971, 82079, 26514

Art. 23, 1(d)

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

Provider: 5259, 25019, 12182, 38507, 24028, 9868, 42112; Authorised representative: 14971

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.

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; Authority: 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; Risk: 8183, 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42005, 24668; System: 25024, 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119; Conformity: 25024, 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 12182, 24030, 31000, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 42006, 24668; Regulation: 25024, 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 12182, 24030, 31000, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 42006, 24668; High-risk: 9868; Provider: 5259, 25019, 12182, 38507, 24028, 9868, 42112; Documentation: 42001, 5259, 25019, 25010, 27000, 14971, 5469, 82079, 26514, 29119, 62304, 42005; Surveillance: 9868; Authorised representative: 14971

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.

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; Risk: 8183, 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42005, 24668; System: 25024, 8183, 24027, 42001, 5259, 25059, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 12182, 24030, 31000, 8000, 24028, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119; High-risk: 9868; Importer: 14971; Documentation: 42001, 5259, 25019, 25010, 27000, 14971, 5469, 82079, 26514, 29119, 62304, 42005

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.

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; Compliance: 25024, 5259, 25019, 14971, 5469, 82079, 26514, 8000, 24028, 9868, 62304; Risk: 8183, 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42005, 24668; System: 25024, 8183, 24027, 42001, 5259, 25059, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119; Conformity: 25024, 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 12182, 24030, 31000, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 42006, 24668; High-risk: 9868; Importer: 14971; Responsibility: 25024, 42001, 25059, 25019, 22989, 27000, 14971, 8000, 24028, 26514, 9868, 5339, 62304

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.

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; Risk: 8183, 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42005, 24668; System: 25024, 8183, 24027, 42001, 5259, 25059, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 12182, 24030, 31000, 8000, 24028, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119; Declaration: 25024, 24027, 5259, 24029, 23894, 22989, 27000, 14971, 12182, 31000, 8000, 24028, 4213, 26514, 29119, 9868; Conformity: 25024, 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 12182, 24030, 31000, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 42006, 24668; High-risk: 9868; Importer: 14971; Service: 25024, 8183, 24027, 42001, 5259, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 82079, 12182, 8000, 38507, 24028, 26514, 29119, 9868, 5339, 62304, 42006, 24668; Instructions for use: 25010, 14971, 82079, 26514

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.

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; Authority: 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; Risk:

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 7(1), the distributor shall inform the provider or the importer of the system, as applicable, to that effect.

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115. **Distributor:** 31010, 14971, 82079. **Risk:** 8183, 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42005, 24668. **System:** 25024, 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119. **Conformity:** 25024, 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119. **High-risk:** 9868. **Provider:** 5259, 25019, 12182, 38507, 24028, 9868, 42112. **Information:** 25024, 5259, 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 24368, 12182, 24030, 31000, 25012, 8000, 38507, 24028, 6254, 8200, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 42006, 12792, 5392, 17903, 20547, 20547, 20547, 42112.

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.

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115. **Compliance:** 25024, 5259, 25019, 14971, 5469, 82079, 25012, 8000, 24028, 9868, 62304. **Distributor:** 31010, 14971, 82079. **Authority:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868. **Corrective action:** 42001, 27000, 14971. **Risk:** 8183, 42001, 5259, 25059, 5338, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42005, 24668. **System:** 25024, 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119. **High-risk:** 9868. **Responsibility:** 25024, 42001, 25059, 25019, 22989, 27000, 14971, 8000, 24028, 26514, 9868, 5339, 62304.

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 7(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.

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115. **Compliance:** 25024, 5259, 25019, 14971, 5469, 82079, 25012, 8000, 24028, 9868, 62304. **Distributor:** 31010, 14971, 82079. **Authority:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868. **Corrective action:** 42001, 27000, 14971. **Risk:** 8183, 42001, 5259, 25059, 5338, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42005, 24668. **System:** 25024, 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119. **Conformity:** 25024, 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119. **High-risk:** 9868. **Provider:** 5259, 25019, 12182, 38507, 24028, 9868, 42112. **Information:** 25024, 5259, 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 24368, 12182, 24030, 31000, 25012, 8000, 38507, 24028, 6254, 8200, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 42006, 12792, 5392, 17903, 20547, 20547, 20547, 42112. **Operator:** 25059, 25019, 25010, 26514, 9868, 17903.

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.

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115. **Compliance:** 25024, 5259, 25019, 14971, 38507, 24028, 9868. **Risk:** 8183, 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42005, 24668. **System:** 25024, 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119. **Conformity:** 25024, 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119. **High-risk:** 9868. **Documentation:** 42001, 5259, 25019, 25010, 27000, 14971, 5469, 82079, 26514, 29119, 62304, 42006. **Information:** 25024, 5259, 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 38507, 24028, 6254, 8200, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 42006, 12792, 5392, 17903, 20547, 20547, 20547, 42112.

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.

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115. **Authority:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868. **Risk:** 8183, 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42005, 24668. **System:** 25024, 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119. **High-risk:** 9868. **Documentation:** 42001, 5259, 25019, 25010, 27000, 14971, 5469, 82079, 26514, 29119, 62304, 42006. **Information:** 25024, 5259, 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 38507, 24028, 6254, 8200, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 42006, 12792, 5392, 17903, 20547, 20547, 20547, 42112.

ARTICLE 25

Art. 25

Responsibilities along the AI value chain

Chain: 12182, 8000. **Responsibility:** 25024, 42001, 25059, 25019, 22989, 27000, 14971, 8000, 24028, 26514, 9868, 5339, 62304.

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:

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115. **Distributor:** 31010, 14971, 82079. **Risk:** 8183, 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42005, 24668. **System:** 25024, 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119. **Obligation:** 42001, 24028. **Regulation:** 5259, 22989, 14971, 8000, 29119, 9868, 62304. **High-risk:** 9868. **Provider:** 5259, 25019, 12182, 38507, 24028, 9868, 42112. **Subject:** 25024, 24027, 5259, 25019, 24029, 23894, 22989, 25010, 27000, 14971, 82079, 12182, 31000, 25012, 8000, 38507, 24028, 6254, 8200, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 20547, 42112.

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.

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115. **Risk:** 8183, 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42005, 24668. **System:** 25024, 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17

The data presented here has a value for research and not a legal value.

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.

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115. **Risk:** 8183, 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42005, 24668. **System:** 25024, 8183, 24027, 42001, 5259, 25059, 5338, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 20547, 23053, 24372, 20226, 22440, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119. **High-risk:** 9868. **Service:** 25024, 8183, 24027, 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42005, 24668. **25024, 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 25012, 8000, 38500, 38507, 24028, 6254, 8200, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 42006, 12792, 5392, 17903, 20547, 20547, 20547, 42112. Purpose:** 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 25012, 8000, 38500, 38507, 24028, 6254, 8200, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 42005, 24668. **Obligation:** 42001, 24028. **High-risk:** 9868

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.

AI model: 22989, 5469, 42103, **AI system:** 8183, 24027, 42001, 5259, 25059, 5338, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115. **Access:** 25024, 25019, 22989, 25010, 27000, 14971, 82079, 26514, 29119, 9868, 5339, 62304, 17903. **Actor:** 42001, 5259, 25059, 22989, 27000, 31000, 8000, 24028, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42005, 24668. **System:** 25024, 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 20547, 23053, 24372, 20226, 22440, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119. **Obligation:** 42001, 24028. **Regulation:** 5259, 22989, 14971, 8000, 29119, 9868, 62304. **High-risk:** 9868. **Provider:** 5259, 25019, 12182, 38507, 24028, 9868, 42112. **Process:** 8183, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 24368, 24030, 31000, 25012, 8000, 8200, 4213, 26514, 25058, 17847, 29119, 9868, 5339, 62304, 42006, 12792, 5392, 17903, 20547, 20547, 20547, 42112. **Information:** 25024, 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 25012, 8000, 38500, 38507, 24028, 6254, 8200, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 42006, 12792, 5392, 17903, 20547, 20547, 20547, 42112. **Purpose:** 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 25012, 8000, 38500, 38507, 24028, 6254, 8200, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 42005, 24668. **24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 20547**

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.

Confidential: 42001, 22989, 25010, 27000. **Information:** 25024, 5259, 8183, 24027, 42001, 5259, 25059, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 24368, 12182, 24030, 31000, 25012, 8000, 38500, 38507, 24028, 6254, 8200, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 42006, 12792, 5392, 17903, 20547, 20547, 20547, 42112

ARTICLE 26

Art. 26, 1

Obligations of deployers of high-risk AI systems

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115. **Risk:** 8183, 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42005, 24668. **Obligation:** 42001, 24028. **High-risk:** 9868

Art. 26, 2

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.

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115. **Risk:** 8183, 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42005, 24668. **High-risk:** 9868. **Instructions for use:** 25010, 14971, 82079, 26514

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.

Authority: 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868. **Support:** 25024, 8183, 24027, 42001, 5259, 5338, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 82079, 24030, 25012, 8000, 38500, 26514, 29119, 62304, 42006, 17903, 20547, 24668, 25029. **Competence:** 42001, 27000, 42006. **Human oversight:** 24027, 42001, 25059, 24029, 25019, 22989, 25010, 27000, 31010, 14971, 82079, 24030, 25012, 8000, 24028, 26514, 29119, 9868, 62304, 5392, 23053, 42105, 42109. **Training:** 24027, 5259, 5338, 24029, 22989, 5469, 25012, 8000, 24028, 4213, 26514, 29119, 23053, 42112. **Human oversight:** 42105

Art. 26, 3

The obligations set out in paragraphs 1 and 2 are without prejudice to the 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.

Human: 24027, 42001, 25059, 24029, 25019, 22989, 25010, 27000, 31010, 14971, 82079, 24030, 31000, 25012, 8000, 24028, 26514, 29119, 9868, 62304, 5392, 23053, 42105, 42109. **Obligation:** 42001, 24028. **Provider:** 5259, 25019, 12182, 38507, 24028, 9868, 42112. **Resource:** 5259, 42001, 5259, 25019, 22989, 25010, 27000, 82079, 12182, 25012, 26514, 29119, 5339, 62304, 20547, 23282. **Purpose:** 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 20547. **Human oversight:** 42105

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.

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115. **Risk:** 8183, 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42005, 24668. **System:** 25024, 8183, 24027, 42001, 5259, 25059, 5338, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 20547, 23053, 24372, 20226, 22440, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119. **High-risk:** 9868. **Data:** 25024, 5259, 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42005, 24668. **25024, 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 42006, 12792, 5392, 17903, 20546, 20547, 20547, 20547, 23053, 24372, 20226, 22440, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119. **Input data:** 24029, 24029, 22989, 5469, 4213, 29119. **Purpose:** 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 42005, 24668. **Intended purpose:** 5259, 14971**

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 provider is unable 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 providers 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, processes and mechanisms pursuant to the relevant financial service law.

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115. **Distributor:** 31010, 14971, 82079. **Authority:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868. **Operation:** 25024, 8183, 24027, 42001, 5259, 25059, 25059, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42005, 24668. **25024, 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 25012, 8000, 24028, 26514, 29119, 9868, 5339, 62304, 42006, 12792, 5392, 17903, 20546, 20547, 20547, 23053, 24372, 20226, 22440, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119. **Monitoring:** 42001, 23894, 25019, 27000, 31010, 14971, 5469, 8000, 24028, 29119, 9868, 62304. **Risk:** 8183, 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42005, 24668. **System:** 25024, 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 20547, 23053, 24372, 20226, 22440, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119. **Obligation:** 42001, 24028. **High-risk:** 9868. **Provider:** 5259, 25019, 12182, 38507, 24028, 9868, 42112. **Process:** 8183, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000,**

Art. 28

Notifying authorities

Authority: 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868**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.

Authority: 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Cooperation:** 24029, 26514, 5392; **Monitoring:** 42001, 23894, 25019, 27000, 31010, 14971, 5469, 8000, 24028, 29119, 9868, 62304; **Conformity:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Assessment:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Notification:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Information:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Confidentiality:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Task:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Conformity assessment body:** 42006

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.

Monitoring: 42001, 23894, 25019, 27000, 31010, 14971, 5469, 8000, 24028, 29119, 9868, 62304; **Regulation:** 5259, 22989, 14971, 8000, 29119, 9868, 62304; **Assessment:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Notification:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Information:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Confidentiality:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Task:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Conformity assessment body:** 42006

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.

Authority: 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Conformity:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Assessment:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Notification:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Information:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Confidentiality:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Task:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Conformity assessment body:** 42006

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.

Authority: 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Conformity:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Assessment:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Notification:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Information:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Confidentiality:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Task:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Conformity assessment body:** 42006

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.

Authority: 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Conformity:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Assessment:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Notification:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Information:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Confidentiality:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Task:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Conformity assessment body:** 42006

Art. 28, 6

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

Confidentiality: 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Confidential:** 42001, 22989, 25010, 27000; **Safeguard:** 42001, 25012; **Information:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Confidentiality:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Task:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Conformity assessment body:** 42006

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.

Authority: 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Fundamental right:** 9868; **Information:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Confidentiality:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Task:** 42001, 25019, 25059, 24029, 24029, 25019, 22989, 25010, 14971, 24030, 25012, 24028, 26514, 29119, 62304, 4213, 12791, 20547, 23281, 25258

ARTICLE 29**Art. 29**

Application of a conformity assessment body for notification

Conformity: 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Cooperation:** 24029, 26514, 5392; **Monitoring:** 42001, 23894, 25019, 27000, 31010, 14971, 5469, 8000, 24028, 29119, 9868, 62304; **Conformity:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Assessment:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Notification:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Information:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Confidentiality:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Task:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Conformity assessment body:** 42006

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.

Authority: 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Conformity:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Assessment:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Notification:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Information:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Confidentiality:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Task:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Conformity assessment body:** 42006

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.

AI system: 8183, 24027, 42001, 25019, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23063, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; **Conformity:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Assessment:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Notification:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Information:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Confidentiality:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Task:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Conformity assessment body:** 42006

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.

Compliance: 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Authority:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Monitoring:** 42001, 23894, 25019, 27000, 31010, 14971, 5469, 8000, 24028, 29119, 9868, 62304; **Conformity:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Assessment:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Notification:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Information:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Confidentiality:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Task:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Conformity assessment body:** 42006

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.

Compliance: 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Authority:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Support:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Information:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Confidentiality:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Task:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Conformity assessment body:** 42006

ARTICLE 30**Art. 30**

Notification procedure

Notification: 5259, 14971**Art. 30, 1**

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

Authority: 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Conformity:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Assessment:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Notification:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Information:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Confidentiality:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Task:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Conformity assessment body:** 42006

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.

Authority: 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Conformity:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Assessment:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Notification:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Information:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Confidentiality:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Task:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Conformity assessment body:** 42006

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.

AI system: 8183, 24027, 42001, 25019, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23063, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; **Authority:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Cooperation:** 24029, 26514, 5392; **Monitoring:** 42001, 23894, 25019, 27000, 31010, 14971, 5469, 8000, 24028, 29119, 9868, 62304; **Conformity:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Assessment:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Notification:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Information:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Confidentiality:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Task:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Conformity assessment body:** 42006

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).

Authority: 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Conformity:** 25024, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 12182, 24030, 31000, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 42006, 42005, 24668; **Notification:** 5259, 14971; **Assessment:** 25024, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 22443, 9868, 5339, 62304, 42006, 42005, 24668, 42119; **Conformity assessment:** 25024, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 12182, 24030, 31000, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 42006, 24668; **Conformity assessment body:** 42006

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.

Conformity: 25024, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 12182, 24030, 31000, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 42006, 24668; **Assessment:** 25024, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 22443, 9868, 5339, 62304, 42006, 42005, 24668, 42119; **Conformity assessment:** 25024, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 12182, 24030, 31000, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 42006, 24668; **Conformity assessment body:** 42006

ARTICLE 31**Art. 31**

Requirements relating to notified bodies

Art. 31, 1

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

Art. 31, 2

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

Management: 25024, 42001, 5259, 5259, 25059, 5338, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 25012, 8000, 38500, 24028, 26514, 29119, 22443, 9868, 5339, 62304, 42006, 42005, 20546, 20547, 24668; **Cybersecurity:** 22989, 9868; **Quality management:** 25024, 42001, 5259, 5259, 25019, 25010, 14971, 25012, 8000, 62304; **Task:** 42001, 5259, 25059, 24029, 24029, 25019, 22989, 25010, 14971, 24030, 25012, 24028, 26514, 29119, 62304, 4213, 12791, 20547, 23281, 25258; **Resource:** 5259, 42001, 5259, 25019, 22989, 25010, 27000, 82079, 12182, 25012, 26514, 29119, 5339, 62304, 20547, 23282

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.

Operation: 25024, 8183, 24027, 42001, 5259, 25059, 25019, 22989, 25010, 27000, 5469, 24030, 25012, 8000, 24028, 26514, 29119, 9868, 62304, 20547; **Conformity:** 25024, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 12182, 24030, 31000, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 42006, 42005, 20546, 20547, 24668; **System:** 25024, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 12182, 24030, 31000, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 42006, 42005, 20546, 20547, 24668; **High-risk:** 9868; **Provider:** 5259, 25019, 12182, 38507, 24028, 9868, 42112; **Assessment:** 25024, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 22443, 9868, 5339, 62304, 42006, 42005, 24668, 42119; **Conformity assessment:** 25024, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 12182, 24030, 31000, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 42006, 24668

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.

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; **Risk:** 8183, 24001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42005, 24668; **System:** 25024, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 12182, 24030, 31000, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 42006, 42005, 20546, 20547, 24668; **High-risk:** 9868; **Operator:** 5259, 25019, 12182, 38507, 24028, 9868, 42112; **Assessment:** 25024, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 22443, 9868, 5339, 62304, 42006, 42005, 24668, 42119; **Conformity assessment:** 25024, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 12182, 24030, 31000, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 42006, 24668; **Operator:** 25059, 25019, 25010, 26514, 9868, 17903; **Conformity assessment body:** 42006

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.

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; **Design:** 25024, 24029, 24029, 23894, 25019, 22989, 25010, 14971, 5469, 24970, 82079, 12182, 24030, 25012, 8000, 4213, 26514, 29119, 9868, 62304, 20547, 20529; **Risk:** 8183, 24001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 12182, 24030, 31000, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 42006, 42005, 20546, 20547, 24668; **Conformity:** 25024, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 12182, 24030, 31000, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 42006, 24668; **Management:** 25024, 42001, 5259, 5259, 25059, 5338, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 25012, 8000, 38500, 24028, 26514, 29119, 22443, 9868, 5339, 62304, 42006, 42005, 20546, 20547, 24668; **High-risk:** 9868; **Assessment:** 25024, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 22443, 9868, 5339, 62304, 42006, 42005, 24668, 42119; **Conformity assessment:** 25024, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 12182, 24030, 31000, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 42006, 24668; **Operator:** 25059, 25019, 25010, 26514, 9868, 17903; **Conformity assessment body:** 42006

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.

Safeguard: 42001, 25012; **Assessment:** 25024, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 22443, 9868, 5339, 62304, 42006, 42005, 24668, 42119

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.

Confidentiality: 25024, 5259, 42001, 22989, 25010, 27000, 25012; **Authority:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Confidential:** 42001, 22989, 25010, 27000; **Conformity:** 25024, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 12182, 24030, 31000, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 42006, 42005, 20546, 20547, 24668; **Information:** 25024, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 22443, 9868, 5339, 62304, 42006, 42005, 20546, 20547, 24668; **Risk:** 8183, 24001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 12182, 24030, 31000, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 42006, 42005, 20546, 20547, 24668; **Assessment:** 25024, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 22443, 9868, 5339, 62304, 42006, 42005, 20546, 20547, 24668; **High-risk:** 9868; **Task:** 42001, 5259, 25059, 24029, 24029, 25019, 22989, 25010, 27000, 14971, 5469, 12182, 24030, 31000, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 42006, 24668

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.

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; **System:** 25024, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 42006, 42005, 20546, 20547, 24668; **Availability:** 42001, 25019, 22989, 25010, 27000, 5469, 25012, 20547; **Knowledge:** 25024, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 12182, 24030, 31000, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 42006, 42005, 20546, 20547, 24668; **Data:** 25024, 5259, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 22443, 9868, 5339, 62304, 42006, 42005, 24668, 42119; **Conformity assessment:** 25024, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 12182, 24030, 31000, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 42006, 24668

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.

Conformity: 25024, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 22443, 9868, 5339, 62304, 42006, 24668; **Assessment:** 25024, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 22443, 9868, 5339, 62304, 42006, 42005, 20546, 20547, 24668; **Conformity assessment:** 25024, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 12182, 24030, 31000, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 42006, 24668

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.

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

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.

Conformity: 25024, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 12182, 24030, 31000, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 42006, 24668; **Assessment:** 25024, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 22443, 9868, 5339, 62304, 42006, 42005, 24668, 42119; **Conformity assessment:** 25024, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 12182, 24030, 31000, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 42006, 24668; **Conformity assessment body:** 42006

ARTICLE 33

Art. 33

Subsidiaries of notified bodies and subcontracting

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.

Authority: 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Conformity:** 25024, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 12182, 24030, 31000, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 42006, 24668; **Assessment:** 25024, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 22443, 9868, 5339, 62304, 42006, 42005, 24668, 42119; **Task:** 42001, 5259, 25059, 24029, 24029, 25019, 22989, 25010, 14971, 24030, 25012, 24028, 26514, 29119, 62304, 4213, 12791, 20547, 23281, 25258; **Conformity assessment:** 25024, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 12182, 24030, 31000, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 42006, 24668

Art. 33, 2

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

Responsibility: 25024, 42001, 25059, 25019, 22989, 27000, 14971, 8000, 24028, 26514, 9868, 5339, 62304; **Task:** 42001, 5259, 25059, 24029, 24029, 25019, 22989, 25010, 14971, 24030, 25012, 24028, 26514, 29119, 62304, 4213, 12791, 20547, 23281, 25258

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.

Provider: 5259, 25019, 12182, 38507, 24028, 9868, 42112

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.

Authority: 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Regulation:** 5259, 22989, 14971, 8000, 29119, 9868, 62304; **Assessment:** 25024, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 22443, 9868, 5339, 62304, 42006, 42005, 24668, 42119

ARTICLE 34

Art. 34

Operational obligations of notified bodies

Obligation: 42001, 24028

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.

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; **Risk:** 8183, 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42005, 24668; **Conformity:** 25024, 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 12182, 24030, 31000, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 42006, 24668; **High-risk:** 9868; **Assessment:** 25024, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 22443, 9868, 5339, 62304, 42006, 42005, 24668, 42119; **Conformity assessment:** 25024, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 12182, 24030, 31000, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 42006, 24668

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.

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; **Compliance:** 25024, 5259, 25019, 14971, 5469, 82079, 25012, 8000, 24028, 9868, 62304; **Risk:** 8183, 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42005, 24668; **System:** 25024, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 42006, 42005, 24668, 42119; **High-risk:** 9868; **Assessment:** 25024, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 22443, 9868, 5339, 62304, 42006, 42005, 24668, 42119; **Protection:** 23894, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119; **Regulation:** 5259, 22989, 14971, 8000, 29119, 9868, 62304; **High-risk:** 9868; **Provider:** 5259, 25019, 12182, 38507, 24028, 9868, 42112; **Conformity assessment:** 23894, 25010, 27000, 8000, 29119, 9868, 62304, 17903

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.

Authority: 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Monitoring:** 42001, 23894, 25019, 27000, 31010, 14971, 5469, 8000, 24028, 29119, 9868, 62304; **Notification:** 5259, 14971; **Provider:** 5259, 25019, 12182, 38507, 24028, 9868, 42112; **Documentation:** 42001, 5259, 25019, 25010, 27000, 14971, 5469, 82079, 26514, 29119, 62304, 42005; **Assessment:** 25024, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 22443, 9868, 5339, 62304, 42006, 42005, 24668, 42119

ARTICLE 35

Art. 35

Identification numbers and lists of notified bodies

Art. 35, 1

The Commission shall assign a single identification number to each notified body, even where a body is notified under more than one Union act.

Art. 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.

Regulation: 5259, 22989, 14971, 8000, 29119, 9868, 62304

ARTICLE 36

Art. 36

Changes to notifications

Notification: 5259, 14971

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).

Authority: 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Notification:** 5259, 14971

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.

Notification: 5259, 14971

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.

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; **Complete:** 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 14971, 5469, 24030, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 25059; **Completeness:** 25024, 5259, 25059, 22989, 25010, 27000, 82079, 25012, 29119, 62304, 25059; **Authority:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Risk:** 8183, 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42005, 24668; **Conformity:** 25024, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 12182, 24030, 31000, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 42006, 24668; **High-risk:** 9868; **Provider:** 5259, 25019, 12182, 38507, 24028, 9868, 42112; **Responsibility:** 25024, 42001, 25059, 25019, 22989, 27000, 14971, 8000, 24028, 26514, 9868, 5339, 62304; **Assessment:** 25024, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 22443, 9868, 5339, 62304, 42006, 42005, 24668, 42119; **Conformity assessment:** 25024, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 12182, 24030, 31000, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 42006, 24668

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.

Authority: 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Obligation:** 42001, 24028

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

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.

Provider: 5259, 25019, 12182, 38507, 24028, 9868, 42112

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.

Authority: 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868, **Surveillance:** 9868, **Event:** 24027, 42001, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 31000, 25012, 24028, 62304

Art. 36, 7

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

Authority: 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868, **Event:** 24027, 42001, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 31000, 25012, 24028, 62304

Art. 36, 7(a)

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

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;

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;

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115, **Authority:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868, **Risk:** 8183, 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42005, 24668, **Conformity:** 25024, 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 12182, 24030, 31000, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 42006, 24668, **High-risk:** 9868

Art. 36, 7(d)

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

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.

Authority: 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868, **Risk:** 8183, 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42005, 24668, **Fundamental right:** 9868, **Health:** 42001, 5338, 25019, 25010, 27000, 14971, 5469, 12182, 29119, 9868, 5339, 62304, 22989, 18988, **Safety:** 42001, 5338, 24029, 25019, 22989, 25010, 27000, 14971, 5469, 24368, 8000, 24028, 29119, 9868, 62304, 25059, 22440, 22440, 22440, **Provider:** 5259, 25019, 12182, 38507, 24028, 9868, 42112, **Information:** 25024, 5259, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 24368, 12182, 24030, 31000, 25012, 8000, 38500, 38507, 24028, 6254, 8200, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 42006, 12792, 5392, 17903, 20547, 20547, 20547, 42112

Art. 36, 8

With the exception of certificates unduly issued, and where a designation has been suspended or restricted, the certificates shall remain valid in one of the following circumstances:

Art. 36, 8(a)

the notifying authority has confirmed, within one month of the suspension or restriction, that there is no risk to health, safety or fundamental rights in relation to certificates affected by the suspension or restriction, and the notifying authority has outlined a timeline for actions to remedy the suspension or restriction; or

Authority: 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868, **Risk:** 8183, 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42005, 24668, **Fundamental right:** 9868, **Health:** 42001, 5338, 25019, 25010, 27000, 14971, 5469, 12182, 29119, 9868, 5339, 62304, 22989, 18988, **Safety:** 42001, 5338, 24029, 25019, 22989, 25010, 27000, 14971, 5469, 24368, 8000, 24028, 29119, 9868, 62304, 25059, 22440, 22440, 22440

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.

Authority: 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868, **Support:** 25024, 8183, 42001, 5259, 5338, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 82079, 24030, 25012, 8000, 38500, 26514, 29119, 62304, 42006, 17903, 20547, 24668, 25029, **System:** 25024, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, **Provider:** 5259, 25019, 12182, 38507, 24028, 9868, 42112, **Event:** 24027, 42001, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 31000, 25012, 24028, 62304

Art. 36, 9

With the exception of certificates unduly issued, and where a designation has been withdrawn, the certificates shall remain valid for a period of nine months under the following circumstances:

Art. 36, 9(a)

the national competent authority of the Member State in which the provider of the high-risk AI system covered by the certificate has its registered place of business has confirmed that there is no risk to health, safety or fundamental rights associated with the high-risk AI systems concerned; and

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115, **Authority:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868, **Risk:** 8183, 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42005, 24668, **System:** 25024, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, **Fundamental right:** 9868, **Health:** 42001, 5338, 25019, 25010, 27000, 14971, 5469, 12182, 29119, 9868, 5339, 62304, 22989, 18988, **Safety:** 42001, 5338, 24029, 25019, 22989, 25010, 27000, 14971, 5469, 24368, 8000, 24028, 29119, 9868, 62304, 25059, 22440, 22440, 22440, **High-risk:** 9868, **Provider:** 5259, 25019, 12182, 38507, 24028, 9868, 42112

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.

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115, **Authority:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868, **System:** 25024, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, **Provider:** 5259, 25019, 12182, 38507, 24028, 9868, 42112, **Responsibility:** 25024, 42001, 25059, 25019, 22989, 27000, 14971, 8000, 24028, 26514, 9868, 5339, 62304, **Assessment:** 25024, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 42006, 42005, 24668, 42119

ARTICLE 37

Art. 37

Challenge to the competence of notified bodies

Competence: 42001, 27000, 42006

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.

Competence: 42001, 27000, 42006, **Responsibility:** 25024, 42001, 25059, 25019, 22989, 27000, 14971, 8000, 24028, 26514, 9868, 5339, 62304

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.

Authority: 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868, **Competence:** 42001, 27000, 42006, **Notification:** 5259, 14971, **Information:** 25024, 5259, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 24368, 12182, 24030, 31000, 25012, 8000, 38500, 38507, 24028, 6254, 8200, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 42006, 12792, 5392, 17903, 20547, 20547, 20547, 42112

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.

Confidential: 42001, 22989, 25010, 27000, **Information:** 25024, 5259, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 24368, 12182, 24030, 31000, 25012, 8000, 38500, 38507, 24028, 6254, 8200, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 42006, 12792, 5392, 17903, 20547, 20547, 20547, 42112

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).

Notification: 5259, 14971

ARTICLE 38

Art. 38

Coordination of notified bodies

Coordination: 12182

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.

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; **Cooperation:** 24029, 26514, 5392; **Coordination:** 12182; **Risk:** 8183, 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42005, 24668; **Conformity:** 25024, 8183, 24027, 42001, 5259, 25259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 12182, 24030, 31000, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 42006, 24668; **Regulation:** 5259, 22989, 14971, 8000, 29119, 9868, 62304; **High-risk:** 9868; **Assessment:** 25024, 8183, 24027, 42001, 5259, 25259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 12182, 24030, 31000, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 42006, 24668, 42119; **Conformity assessment:** 25024, 8183, 24027, 42001, 5259, 25259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 12182, 24030, 31000, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 42006, 24668

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.

Authority: 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868

Art. 38, 3

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

Authority: 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Best practice:** 18115; **Knowledge:** 25024, 8183, 24027, 42001, 5338, 24029, 25019, 22989, 25010, 27000, 14971, 24030, 31000, 25012, 26514, 29119, 9868, 5339, 62304, 5392, 23053, 24372

ARTICLE 39**Art. 39**

Conformity assessment bodies of third countries

Conformity: 25024, 8183, 24027, 42001, 5259, 25259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 12182, 24030, 31000, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 42006, 24668; **Assessment:** 25024, 8183, 24027, 42001, 5259, 25259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 22443, 9868, 5339, 62304, 42006, 42005, 24668, 42119; **Conformity assessment:** 25024, 8183, 24027, 42001, 5259, 25259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 12182, 24030, 31000, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 42006, 24668; **Conformity assessment body:** 42006

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.

Compliance: 25024, 5259, 25019, 14971, 5469, 82079, 25012, 8000, 24028, 9868, 62304; **Conformity:** 25024, 8183, 24027, 42001, 5259, 25259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 12182, 24030, 31000, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 42006, 24668; **Regulation:** 5259, 22989, 14971, 8000, 29119, 9868, 62304; **Assessment:** 25024, 8183, 24027, 42001, 5259, 25259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 22443, 9868, 5339, 62304, 42006, 42005, 24668, 42119; **Conformity assessment:** 25024, 8183, 24027, 42001, 5259, 25259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 12182, 24030, 31000, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 42006, 24668; **Conformity assessment body:** 42006

ARTICLE 40**SECTION 5**

Standards, conformity assessment, certificates, registration

Conformity: 25024, 8183, 24027, 42001, 5259, 25259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 12182, 24030, 31000, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 42006, 24668; **Assessment:** 25024, 8183, 24027, 42001, 5259, 25259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 22443, 9868, 5339, 62304, 42006, 42005, 24668, 42119; **Conformity assessment:** 25024, 8183, 24027, 42001, 5259, 25259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 12182, 24030, 31000, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 42006, 24668

Art. 40

Harmonised standards and standardisation deliverables

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 Chapter V, Sections 2 and 3, of this Regulation, to the extent that those standards cover those requirements or obligations.

AI model: 22989, 5469, 4213; **AI system:** 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; **Life-cycle:** 24027, 5338, 25019, 25010, 17847, 22443, 5339, 62304, 42005, 42102; **Sector:** 42001, 5259, 22989, 27000, 31000, 9868, 24668; **Risk:** 8183, 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 24368, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42005, 24668; **Conformity:** 25024, 8183, 24027, 42001, 5259, 25259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 12182, 24030, 31000, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 42006, 24668; **Obligation:** 42001, 24028; **Regulation:** 5259, 22989, 14971, 8000, 29119, 9868, 62304; **High-risk:** 9868; **Purpose:** 8183, 24027, 42001, 5259, 25259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 82079, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 20547

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 the best efforts to address the objectives referred to in the first and second subparagraphs of this paragraph in accordance with Article 9 of Regulation (EU) No 1025/2012.

AI model: 22989, 5469, 4213; **AI system:** 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; **Life-cycle:** 24027, 5338, 25019, 25010, 17847, 22443, 5339, 62304, 42005, 42102; **Sector:** 42001, 5259, 22989, 27000, 31000, 9868, 24668; **Risk:** 8183, 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 24368, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42005, 24668; **Conformity:** 25024, 8183, 24027, 42001, 5259, 25259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 12182, 24030, 31000, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 42006, 24668; **Obligation:** 42001, 24028; **Regulation:** 5259, 22989, 14971, 8000, 29119, 9868, 62304; **High-risk:** 9868; **Process:** 8183, 42001, 5259, 25259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 82079, 24368, 24030, 31000, 25012, 8000, 8200, 4213, 26514, 25058, 17847, 29119, 9868, 5339, 62304, 42005, 5392, 20546, 20547, 20547, 24668, 23281, 2382, 25029, 25258, 42119; **Product:** 25024, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 82079, 12182, 25012, 8000, 24028, 26514, 29119, 62304, 5392, 17903, 20547, 24372; **Documentation:** 42001, 5259, 25019, 25010, 27000, 14971, 5469, 82079, 26514, 29119, 62304, 42005; **Service:** 25024, 8183, 42001, 5259, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 82079, 12182, 8000, 38507, 24028, 26514, 29119, 9868, 5339, 62304, 25059, 5392, 20547, 24668; **Resource:** 5259, 42001, 5259, 25019, 22989, 25010, 27000, 82079, 12182, 25012, 26514, 29119, 5339, 62304, 20547, 2382; **Purpose:** 8183, 24027, 42001, 5259, 25259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 82079, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 20547

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.

Cooperation: 24029, 26514, 5392; **Governance:** 8183, 42001, 5259, 25019, 22989, 27000, 31000, 8000, 38500, 38507, 24028, 22443, 18115; **Stakeholder:** 24027, 25059, 5338, 25019, 22989, 25010, 27000, 31010, 14971, 12182, 24030, 31000, 8000, 24028, 6254, 4213, 29119, 5339, 21221, 12791, 12792, 17903, 20547, 20547, 24668, 42102; **Regulation:** 5259, 22989, 14971, 8000, 29119, 9868, 62304; **Representation:** 25024, 24027, 25019, 22989, 5469, 25012, 8000, 29119, 62304, 5392; **Fundamental right:** 9868; **Innovation:** 42001, 23894, 8000, 29119, 20547, 20547

ARTICLE 41**Art. 41**

Common specifications

Specification: 24029, 25019, 22989, 25010, 14971, 5469, 25012, 29119, 62304, 20547

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:

Obligation: 42001, 24028; **Specification:** 24029, 25019, 22989, 25010, 14971, 5469, 25012, 29119, 62304, 20547

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:

Obligation: 42001, 24028; **Regulation:** 5259, 22989, 14971, 8000, 29119, 9868, 62304

Art. 41, 1(a)(i)

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

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

Regulation: 5259, 22989, 14971, 8000, 29119, 9868, 62304

Art. 41, 1(a)(iii)

the relevant harmonised standards insufficiently address fundamental rights concerns; or

Fundamental right: 9868

Art. 41, 1(a)(iv)

the harmonised standards do not comply with the request; and

Art. 41, 1(b)

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

Obligation: 42001, 24028; **Regulation:** 5259, 22989, 14971, 8000, 29119, 9868, 62304; **Specification:** 24029, 25019, 22989, 25010, 14971, 5469, 25012, 29119, 62304, 20547

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

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.

Regulation: 5259, 22989, 14971, 8000, 29119, 9868, 62304

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.

AI model: 22989, 5469, 4213; AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; Risk: 8183, 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42005, 24668; Conformity: 25024, 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 82079, 12182, 24030, 31000, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 42006, 24668; Obligation: 42001, 24028; High-risk: 9868; Specification: 24029, 25019, 22989, 25010, 14971, 5469, 25012, 29119, 62304, 20547; Purpose: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 82079, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 20547

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 repeat 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.

Obligation: 42001, 24028; Regulation: 5259, 22989, 14971, 8000, 29119, 9868, 62304

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.

AI model: 22989, 5469, 4213; AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; Risk: 8183, 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42005, 24668; Obligation: 42001, 24028; High-risk: 9868; Provider: 5259, 25019, 12182, 38507, 24028, 9868, 42112; Specification: 24029, 25019, 22989, 25010, 14971, 5469, 25012, 29119, 62304, 20547; Purpose: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 82079, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 20547

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.

Obligation: 42001, 24028; Specification: 24029, 25019, 22989, 25010, 14971, 5469, 25012, 29119, 62304, 20547; Information: 25024, 5259, 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 24368, 12182, 24030, 31000, 25012, 8000, 38500, 38507, 24028, 6254, 8200, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 42006, 12792, 5392, 17903, 20547, 20547, 20547, 42112

ARTICLE 42

Art. 42

Presumption of conformity with certain requirements

Conformity: 25024, 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 12182, 24030, 31000, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 42006, 24668

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).

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; Risk: 8183, 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42005, 24668; High-risk: 9868; Data: 25024, 5259, 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 12182, 24030, 31000, 25012, 38507, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 25223, 5259, 5392, 17903, 20546, 20547, 20547, 20547, 20547, 23053, 24372, 24668, 25523, 42103; Dataset: 25024, 5259, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 82079, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 20547

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.

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; Risk: 8183, 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42005, 24668; Conformity: 25024, 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 12182, 24030, 31000, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 42006, 24668; Regulation: 5259, 22989, 14971, 8000, 29119, 9868, 62304; Cybersecurity: 22989, 9868; High-risk: 9868

ARTICLE 43

Art. 43

Conformity assessment

Conformity: 25024, 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 12182, 24030, 31000, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 42006, 24668; Assessment: 25024, 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 22443, 9868, 5339, 62304, 42006, 42005, 24668, 42119; Conformity assessment: 25024, 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 12182, 24030, 31000, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 42006, 24668

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:

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; Compliance: 25024, 5259, 25019, 14971, 5469, 82079, 25012, 8000, 24028, 9868, 62304; Risk: 8183, 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42005, 24668; System: 25024, 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119; Conformity: 25024, 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42005, 24668; Assessment: 25024, 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 12182, 24030, 31000, 8000, 24028, 4213, 26514, 25058, 29119, 22443, 9868, 5339, 62304, 42006, 24668, 42119; Conformity assessment: 25024, 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 12182, 24030, 31000, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 42006, 24668

Art. 43, 1(a)

the internal control referred to in Annex VI, or

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:

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; Compliance: 25024, 5259, 25019, 14971, 5469, 82079, 25012, 8000, 24028, 9868, 62304; Risk: 8183, 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42005, 24668; System: 25024, 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119; Conformity: 25024, 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42005, 24668; Management system: 42001, 5259, 27000, 14971, 24970, 12182, 31000, 25012, 8000, 26514, 29119, 22443, 62304, 42006, 42005; Management: 25024, 42001, 5259, 25059, 5338, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 12182, 24030, 31000, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 42006, 24668, 42112; Technical documentation: 25019; Documentation: 42001, 5259, 25019, 25010, 27000, 14971, 5469, 82079, 26514, 29119, 62304, 42005; Assessment: 25024, 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 22443, 9868, 5339, 62304, 42006, 42005, 24668, 42119; Quality management: 25024, 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 12182, 24030, 31000, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 42006, 24668, 42119; Conformity assessment: 25024, 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 12182, 24030, 31000, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 42006, 24668

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;

Specification: 24029, 25019, 22989, 25010, 14971, 5469, 25012, 29119, 62304, 20547

Art. 43, 1(b)

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

Provider: 5259, 25019, 12182, 38507, 24028, 9868, 42112

Art. 43, 1(c)

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

Provider: 5259, 25019, 12182, 38507, 24028, 9868, 42112; Specification: 24029, 25019, 22989, 25010, 14971, 5469, 25012, 29119, 62304, 20547

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.

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; Authority: 25024, 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27

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.

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115. **Risk:** 8183, 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42006, 24668. **Conformity:** 25024, 8183, 24027, 42001, 5259, 2529, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 12182, 24030, 31000, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 42006, 24668. **High-risk:** 9868. **Provider:** 5259, 25019, 12182, 38507, 24028, 9868, 42112. **Assessment:** 25024, 8183, 24027, 42001, 5259, 2529, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 22443, 9868, 5339, 62304, 42006, 42005, 24668, 42119. **Conformity assessment:** 25024, 8183, 24027, 42001, 5259, 2529, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 12182, 24030, 31000, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 42006, 24668

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.

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115. **Compliance:** 25024, 5259, 25019, 14971, 5469, 82079, 25012, 8000, 24028, 9868, 62304. **Risk:** 8183, 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42006, 24668. **Conformity:** 25024, 8183, 24027, 42001, 5259, 2529, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 42006, 24668. **Notification:** 5259, 14971. **High-risk:** 9868. **Provider:** 5259, 25019, 12182, 38507, 24028, 9868, 42112. **Specification:** 24029, 25019, 22989, 25010, 14971, 5469, 25012, 29119, 62304, 20547. **Assessment:** 25024, 8183, 24027, 42001, 5259, 2529, 25059, 5338, 24029, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 22443, 9868, 5339, 62304, 42006, 42005, 24668, 42119. **Conformity assessment:** 25024, 8183, 24027, 42001, 5259, 2529, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 12182, 24030, 31000, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 42006, 24668

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.

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115. **Compliance:** 25024, 5259, 25019, 14971, 5469, 82079, 25012, 8000, 24028, 9868, 62304. **Risk:** 8183, 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42006, 24668. **Conformity:** 25024, 8183, 24027, 42001, 5259, 2529, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 42006, 24668. **Notification:** 5259, 14971. **High-risk:** 9868. **Provider:** 5259, 25019, 12182, 38507, 24028, 9868, 42112. **Specification:** 24029, 25019, 22989, 25010, 14971, 5469, 25012, 29119, 62304, 20547. **Assessment:** 25024, 8183, 24027, 42001, 5259, 2529, 25059, 5338, 24029, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 22443, 9868, 5339, 62304, 42006, 42005, 24668, 42119. **Conformity assessment:** 25024, 8183, 24027, 42001, 5259, 2529, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 12182, 24030, 31000, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 42006, 24668. **Event:** 24027, 42001, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 31000, 25012, 24028, 62304. **Subject:** 25024, 24027, 5259, 2529, 24029, 23894, 22989, 25010, 27000, 14971, 12182, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 62304, 20547

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.

Updating: 23898

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.

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115. **Effectiveness:** 5259, 42001, 25019, 25010, 27000, 31010, 14971, 12182, 8000, 26514, 29119, 62304, 17903, 20546. **Risk:** 8183, 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42006, 24668. **Conformity:** 25024, 8183, 24027, 42001, 5259, 2529, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 42006, 24668. **Fundamental rights:** 9868. **Health:** 42001, 5338, 25019, 25010, 27000, 14971, 5469, 12182, 29119, 9868, 5339, 62304, 22989, 18088. **Safety:** 42001, 5338, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42006, 24668. **High-risk:** 9868. **Assessment:** 25024, 8183, 24027, 42001, 5259, 2529, 25059, 5338, 24029, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 22443, 9868, 5339, 62304, 42006, 42005, 24668, 42119. **Conformity assessment:** 25024, 8183, 24027, 42001, 5259, 2529, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 42006, 42005, 24668, 42119. **Provider:** 5259, 25019, 12182, 38507, 24028, 9868, 42112. **Assessment:** 25024, 8183, 24027, 42001, 5259, 2529, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 42006, 24668. **Event:** 24027, 42001, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 31000, 25012, 24028, 62304. **Subject:** 25024, 24027, 5259, 2529, 24029, 23894, 22989, 25010, 27000, 14971, 12182, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 62304, 20547

ARTICLE 44**Art. 44**

Certificates

Art. 44, 1

Certificates issued by notified bodies in accordance with Annex VII shall be drawn-up in a language which can be easily understood by the relevant authorities in the Member State in which the notified body is established.

Authority: 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868

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.

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115. **Compliance:** 25024, 5259, 25019, 14971, 5469, 82079, 25012, 8000, 24028, 9868, 62304. **Risk:** 8183, 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42006, 24668. **Conformity:** 25024, 8183, 24027, 42001, 5259, 2529, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 42006, 24668. **Provider:** 5259, 25019, 12182, 38507, 24028, 9868, 42112. **Assessment:** 25024, 8183, 24027, 42001, 5259, 2529, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 22443, 9868, 5339, 62304, 42006, 42005, 24668, 42119. **Conformity assessment:** 25024, 8183, 24027, 42001, 5259, 2529, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 12182, 24030, 31000, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 42006, 24668

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.

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115. **Compliance:** 25024, 5259, 25019, 14971, 5469, 82079, 25012, 8000, 24028, 9868, 62304. **Corrective action:** 42001, 27000, 14971. **System:** 25024, 8183, 24027, 42001, 5259, 2529, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42006, 24668. **High-risk:** 9868. **Assessment:** 25024, 8183, 24027, 42001, 5259, 2529, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 22443, 9868, 5339, 62304, 42006, 42005, 24668, 42119. **Conformity assessment:** 25024, 8183, 24027, 42001, 5259, 2529, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 12182, 24030, 31000, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 42006, 24668

ARTICLE 45**Art. 45**

Information obligations of notified bodies

Obligation: 42001, 24028, **Information:** 25024, 5259, 8183, 24027, 42001, 5259, 2529, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 24368, 12182, 24030, 31000, 25012, 8000, 38500, 38507, 24028, 6254, 8200, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 42006, 12792, 5392, 17903, 20547, 20547, 20547, 42112

Art. 45, 1

Notified bodies shall inform the notifying authority of the following:

Authority: 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868

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;

System: 25024, 8183, 24027, 42001, 5259, 2529, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 240

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

Art. 51

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

AI model: 22989, 5469, 4213; **Risk:** 8183, 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42005, 24668; **Category:** 31010, 12182, 25012; **Classification:** 24029, 22989, 12182, 4213, 25058, 29119, 9868, 4213, 12791; **Purpose:** 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 82079, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 20547

Art. 51**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:

AI model: 22989, 5469, 4213; **Risk:** 8183, 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42005, 24668; **Purpose:** 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 82079, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 20547

Art. 51, 1(a)

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

Art. 51, 1(b)

based on a decision of the Commission, ex officio or following a qualified alert from the scientific panel, it has capabilities or an impact equivalent to those set out in point (a) having regard to the criteria set out in Annex XIII.

Art. 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.

AI model: 22989, 5469, 4213; **Training:** 24027, 5259, 5338, 24029, 22989, 5469, 25012, 8000, 24028, 4213, 26514, 29119, 23053, 42112; **Purpose:** 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 82079, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 20547

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.

Efficiency: 25024, 5259, 5338, 25019, 25010, 12182, 25012, 8000, 24028, 4213, 26514, 29119, 17903, 20546, 42112

ARTICLE 52**Art. 52**

Procedure

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.

AI model: 22989, 5469, 4213; **Risk:** 8183, 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42005, 24668; **Notification:** 5259, 14971; **Provider:** 5259, 25019, 12182, 38507, 24028, 9868, 42112; **Information:** 25024, 5259, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 24368, 12182, 24030, 31000, 25012, 8000, 38500, 38507, 24028, 6254, 8200, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 42006, 12792, 5392, 17903, 20547, 20547, 20547, 42112; **Purpose:** 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 82079, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 20547; **Event:** 24027, 42001, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 31000, 25012, 24028, 62304

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.

AI model: 22989, 5469, 4213; **Risk:** 8183, 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42005, 24668; **Notification:** 5259, 14971; **Provider:** 5259, 25019, 12182, 38507, 24028, 9868, 42112; **Purpose:** 8183, 24027, 42001, 5259, 5259, 5259, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 82079, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 20547

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.

AI model: 22989, 5469, 4213; **Risk:** 8183, 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42005, 24668; **Provider:** 5259, 25019, 12182, 38507, 24028, 9868, 42112; **Purpose:** 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 82079, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 20547

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.

AI model: 22989, 5469, 4213; **Updating:** 22989; **Purpose:** 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 82079, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 20547

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.

AI model: 22989, 5469, 4213; **Risk:** 8183, 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42005, 24668; **Provider:** 5259, 25019, 12182, 38507, 24028, 9868, 42112; **Purpose:** 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 82079, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 20547

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.

AI model: 22989, 5469, 4213; **Confidential:** 42001, 22989, 25010, 27000; **Risk:** 8183, 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42005, 24668; **Information:** 25024, 5259, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 24368, 12182, 24030, 31000, 25012, 8000, 38500, 38507, 24028, 6254, 8200, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 42006, 12792, 5392, 17903, 20547, 20547, 20547, 42112; **Purpose:** 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 82079, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 20547

ARTICLE 53**SECTION 2**

Obligations for providers of general-purpose AI models

AI model: 22989, 5469, 4213; **Obligation:** 42001, 24028; **Provider:** 5259, 25019, 12182, 38507, 24028, 9868, 42112; **Purpose:** 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 82079, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 20547

Art. 53

Obligations for providers of general-purpose AI models

AI model: 22989, 5469, 4213; **Obligation:** 42001, 24028; **Provider:** 5259, 25019, 12182, 38507, 24028, 9868, 42112; **Purpose:** 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 82079, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 20547

Art. 53, 1

Providers of general-purpose AI models shall:

AI model: 22989, 5469, 4213; **Provider:** 5259, 25019, 12182, 38507, 24028, 9868, 42112; **Purpose:** 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 82079, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 20547

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;

Authority: 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Evaluation:** 25024, 24027, 42001, 5259, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 82079, 12182, 25012, 8000, 4213, 26514, 25058, 17847, 29119, 9868, 62304, 25059, 23282; **Testing:** 25024, 24027, 25059, 24029, 24029, 25019, 22989, 25010, 82079, 12182, 24028, 26514, 25058, 29119, 9868, 62304, 12791, 42119; **Training:** 24027, 5259, 5338, 24029, 22989, 5469, 25012, 8000, 24028, 4213, 26514, 29119, 23053, 42112; **Technical documentation:** 25019; **Documentation:** 42001, 5259, 25019, 25010, 27000, 14971, 5469, 82079, 26514, 29119, 62304, 42005; **Information:** 25024, 5259, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 24368, 12182, 24030, 31000, 25012, 8000, 38500, 38507, 24028, 6254, 8200, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 42006, 12792, 5392, 17903, 20547, 20547, 20547, 42112; **Purpose:** 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 82079, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 20547

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:

AI model: 22989, 5469, 4213; **AI system:** 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; **Confidential:** 42001, 22989, 25010, 27000; **Provider:** 5259, 25019, 12182, 38507, 24028, 9868, 42112; **Documentation:** 42001, 5259, 25019, 25010, 27000, 14971, 5469, 82079, 26514, 29119, 62304, 42005; **Information:** 25024, 5259, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 42006, 12792, 5392, 17903, 20547, 20547, 20547, 42112; **Purpose:** 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 82079, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 20547

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

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

AI model: 22989, 5469, 4213; **AI system:** 8183, 24027, 42001, 5259, 5259, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; **Obligation:** 42001, 24028; **Regulation:** 5259, 22989, 14971, 8000, 29119, 9868, 62304; **Provider:** 5259, 25019, 12182, 38507, 24028, 9868, 42112; **Purpose:** 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 82079, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 20547

Art. 53, 1(ii)

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

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;

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.

AI model: 22989, 5469, 4213; **Training:** 24027, 5259, 5338, 24029, 22989, 5469, 25012, 8000, 24028, 4213, 26514, 29119, 23053, 42112; **Purpose:** 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 82079, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 20547

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.

AI model: 22989, 5469, 4213; **Access:** 25024, 25019, 22989, 25010, 27000, 14971, 82079, 26514, 29119, 9868, 5339, 62304, 17903; **Obligation:** 42001, 24028; **Architecture:** 24029, 12182, 25012, 26514, 29119, 62304, 5392, 20546, 20547, 20547, 20547, 20547; **Provider:** 5259, 25019, 12182, 38507, 24028, 9868, 42112; **Information:** 25024, 5259, 8183, 24027, 42001, 5259, 5259, 5259, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 24368, 12182, 24030, 31000, 25012, 8000, 38500, 38507, 24028, 6254, 8200, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 42006, 12792, 5392, 17903, 20547, 20547, 20547, 42112; **Purpose:** 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 82079, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 20547

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.

AI model: 22989, 5469, 4213; **Authority:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Regulation:** 5259, 22989, 14971, 8000, 29119, 9868, 62304; **Provider:** 5259, 25019, 12182, 38507, 24028, 9868, 42112; **Purpose:** 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 82079, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 20547

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.

AI model: 22989, 5469, 4213; **Compliance:** 25024, 25019, 14971, 5469, 82079, 25012, 8000, 24028, 9868, 62304; **Conformity:** 25024, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 12182, 24030, 31000, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 42006, 24668; **Obligation:** 42001, 24028; **Provider:** 5259, 25019, 12182, 38507, 24028, 9868, 42112; **Assessment:** 25024, 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 42006, 24668, 42119; **Purpose:** 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 82079, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 20547

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.

Compliance: 25024, 5259, 25019, 14971, 5469, 82079, 25012, 8000, 24028, 9868, 62304; **Measurement:** 25024, 24027, 42001, 5259, 25059, 25019, 22989, 25010, 27000, 14971, 25012, 8000, 4213, 25058, 25059, 4213, 24668; **Documentation:** 42001, 5259, 25019, 25010, 27000, 14971, 5469, 82079, 26514, 29119, 62304, 42005; **Purpose:** 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 82079, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 20547

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.

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.

Confidentiality: 25024, 5259, 25019, 42001, 22989, 25010, 27000, 25012; **Confidential:** 42001, 22989, 25010, 27000; **Obligation:** 42001, 24028; **Documentation:** 42001, 5259, 25019, 25010, 27000, 14971, 5469, 82079, 26514, 29119, 62304, 42005; **Information:** 25024, 5259, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 24368, 12182, 24030, 31000, 25012, 8000, 38500, 38507, 24028, 6254, 8200, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 42006, 12792, 5392, 17903, 20547, 20547, 20547, 42112

ARTICLE 54

Art. 54

Authorised representatives of providers of general-purpose AI models

AI model: 22989, 5469, 4213; **Provider:** 5259, 25019, 12182, 38507, 24028, 9868, 42112; **Purpose:** 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 82079, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 20547; **Authorised representative:** 14971

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.

AI model: 22989, 5469, 4213; **Provider:** 5259, 25019, 12182, 38507, 24028, 9868, 42112; **Purpose:** 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 82079, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 20547; **Authorised representative:** 14971

Art. 54, 2

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

Provider: 5259, 25019, 12182, 38507, 24028, 9868, 42112; **Task:** 42001, 5259, 25059, 24029, 24029, 25019, 22989, 25010, 14971, 24030, 25012, 24028, 26514, 29119, 62304, 4213, 12791, 20547, 23281, 25258; **Authorised representative:** 14971

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:

Regulation: 5259, 22989, 14971, 8000, 29119, 9868, 62304; **Provider:** 5259, 25019, 12182, 38507, 24028, 9868, 42112; **Task:** 42001, 5259, 25059, 24029, 24029, 25019, 22989, 25010, 14971, 24030, 25012, 24028, 26514, 29119, 62304, 4213, 12791, 20547, 23281, 25258; **Authorised representative:** 14971

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;

Obligation: 42001, 24028; **Provider:** 5259, 25019, 12182, 38507, 24028, 9868, 42112; **Technical documentation:** 25019; **Documentation:** 42001, 5259, 25019, 25010, 27000, 14971, 5469, 82079, 26514, 29119, 62304, 42005

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;

AI model: 22989, 5469, 4213; **Authority:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Provider:** 5259, 25019, 12182, 38507, 24028, 9868, 42112; **Technical documentation:** 25019; **Documentation:** 42001, 5259, 25019, 25010, 27000, 14971, 5469, 82079, 26514, 29119, 62304, 42005; **Contact:** 31010, 14971, 82079; **Purpose:** 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 82079, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 20547; **Authorised representative:** 14971

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;

Compliance: 25024, 5259, 25019, 14971, 5469, 82079, 25012, 8000, 24028, 9868, 62304; **Obligation:** 42001, 24028; **Documentation:** 42001, 5259, 25019, 25010, 27000, 14971, 5469, 82079, 26514, 29119, 62304, 42005; **Information:** 25024, 5259, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 24368, 12182, 24030, 31000, 25012, 8000, 38500, 38507, 24028, 6254, 8200, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 42006, 12792, 5392, 17903, 20547, 20547, 20547, 42112

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.

AI model: 22989, 5469, 4213; **AI system:** 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; **Authority:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Service:** 25024, 8183, 24001, 5259, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 82079, 12182, 8000, 38507, 24028, 26514, 29119, 9868, 5339, 62304, 25059, 5392, 20547, 24668; **Purpose:** 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 82079, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 20547

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.

Compliance: 25024, 5259, 25019, 14971, 5469, 82079, 25012, 8000, 24028, 9868, 62304; **Authority:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Regulation:** 5259, 22989, 14971, 8000, 29119, 9868, 62304; **Provider:** 5259, 25019, 12182, 38507, 24028, 9868, 42112; **Authorised representative:** 14971

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.

Obligation: 42001, 24028; **Regulation:** 5259, 22989, 14971, 8000, 29119, 9868, 62304; **Provider:** 5259, 25019, 12182, 38507, 24028, 9868, 42112; **Authorised representative:** 14971

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

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.

AI model: 22989, 5469, 4213; **Access:** 25024, 25019, 22989, 25010, 27000, 14971, 82079, 26514, 29119, 9868, 5339, 62304, 17903; **Obligation:** 42001, 24028; **Architecture:** 24029, 12182, 25012, 26514, 29119, 62304, 5392, 20546, 20547, 20547, 20547, 20547; **Provider:** 5259, 25019, 12182, 38507, 24028, 9868, 42112; **Information:** 25024, 5259, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 24368, 12182, 24030, 31000, 25012, 8000, 38500, 38507, 24028, 6254, 8200, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 42006, 12792, 5392, 17903, 20547, 20547, 20547, 42112; **Purpose:** 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 82079, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 20547

CHAPTER VII

GOVERNANCE

Governance: 8183, 42001, 5259, 25019, 22989, 27000, 31000, 8000, 38500, 38507, 24028, 22443, 18115

ARTICLE 55

SECTION 3

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

AI model: 22989, 5469, 4213; **Risk:** 8183, 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42005, 24668; **Obligation:** 42001, 24028; **Provider:** 5259, 25019, 12182, 38507, 24028, 9868, 42112; **Purpose:** 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 82079, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 20547

Art. 55

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

AI model: 22989, 5469, 4213; **Risk:** 8183, 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42005, 24668; **Obligation:** 42001, 24028; **Provider:** 5259, 25019, 12182, 38507, 24028, 9868, 42112; **Purpose:** 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 82079, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 20547

Art. 55, 1

In addition to the obligations listed in Articles 53 and 54, providers of general-purpose AI models with systemic risk shall:

AI model: 22989, 5469, 4213; **Risk:** 8183, 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42005, 24668; **Obligation:** 42001, 24028; **Provider:** 5259, 25019, 12182, 38507, 24028, 9868, 42112; **Purpose:** 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 82079, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 20547

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;

Evaluation: 25024, 24027, 42001, 5259, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 82079, 12182, 25012, 8000, 4213, 25058, 17847, 29119, 9868, 62304, 25059, 23282; **Testing:** 25024, 24027, 25059, 24029, 24029, 25019, 22989, 25010, 82079, 12182, 24028, 26514, 25058, 29119, 9868, 62304, 12791, 42119

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;

AI model: 22989, 5469, 4213; **Risk:** 8183, 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42005, 24668; **Purpose:** 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 82079, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 20547

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;

Authority: 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Information:** 25024, 5259, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 24368, 12182, 24030, 31000, 25012, 8000, 38500, 38507, 24028, 6254, 8200, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 42006, 12792, 5392, 17903, 20547, 20547, 20547, 42112

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.

AI model: 22989, 5469, 4213; **Risk:** 8183, 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42005, 24668; **Cybersecurity:** 22989, 9868; **Purpose:** 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 82079, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 20547; **Protection:** 23894, 25010, 27000, 8000, 29119, 9868, 62304, 17903

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.

AI model: 22989, 5469, 4213; **Compliance:** 25024, 5259, 25019, 14971, 5469, 82079, 25012, 8000, 24028, 9868, 62304; **Risk:** 8183, 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42005, 24668; **Conformity:** 25024, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 12182, 24030, 31000, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 42006, 24668; **Obligation:** 42001, 24028; **Provider:** 5259, 25019, 12182, 38507, 24028, 9868, 42112; **Assessment:** 25024, 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 22443, 9868, 5339, 62304, 42006, 42005, 24668, 42119; **Purpose:** 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 82079, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 20547

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.

Confidentiality: 25024, 5259, 42001, 22989, 25010, 27000, 5012; **Confidential:** 42001, 22989, 25010, 27000; **Obligation:** 42001, 24028; **Documentation:** 42001, 5259, 25019, 25010, 27000, 14971, 5469, 82079, 26514, 29119, 62304, 42005; **Information:** 25024, 5259, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 24368, 12182, 24030, 31000, 25012, 8000, 38500, 38507, 24028, 6254, 8200, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 42006, 12792, 5392, 17903, 20547, 20547, 20547, 42112

ARTICLE 56

SECTION 4

Codes of practice

Art. 56

Codes of practice

Art. 56, 1

The AI Office shall encourage and facilitate the drawing up of codes of practice at Union level in order to contribute to the proper application of this Regulation, taking into account international approaches.

Regulation: 5259, 22989, 14971, 8000, 29119, 9868, 62304

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:

Obligation: 42001, 24028

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;

Accuracy: 25024, 5259, 5259, 24029, 24029, 22989, 27000, 25012, 4213, 26514, 29119; **Information:** 25024, 5259, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 24368, 12182, 24030, 31000, 25012, 8000, 38500, 38507, 24028, 6254, 8200, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 42006, 12792, 5392, 17903, 20547, 20547, 20547, 42112

Art. 56, 2(b)

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

Training: 24027, 5259, 5338, 24029, 22989, 5469, 25012, 8000, 24028, 4213, 26514, 29119, 23053, 42112

Art. 56, 2(c)

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

Art. 56, 2(d)

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

Chain: 12182, 8000; **Management:** 25024, 42001, 5259, 5259, 5259, 5338, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 25012, 8000, 38500, 24028, 26514, 29119, 22443, 9868, 5339, 62304, 42006, 42005, 20546, 20547, 24668; **Documentation:** 42001, 5259, 25019, 25010, 27000, 14971, 5469, 82079, 26514, 29119, 62304, 42005; **Assessment:** 25024, 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 22443, 9868, 5339, 62304, 42006, 42005, 24668, 42119

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.

AI model: 22989, 5469, 4213; **Authority:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Support:** 25024, 8183, 42001, 5259, 5338, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 82079, 24030, 25012, 8000, 38500, 26514, 29119, 62304, 42006, 17903, 20547, 24668, 25029; **Society:** 42001, 25059, 25019, 14971, 24368, 26514, 22443, 5339, 42005; **Provider:** 5259, 25019, 12182, 38507, 24028, 9868, 42112; **Purpose:** 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 82079, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 20547

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

Art. 56, 4

The AI Office and the Board shall aim to ensure that the codes of practice clearly set out their specific objectives and contain commitments or measures, including key performance indicators as appropriate, to ensure the achievement of those objectives, and that they take due account of the needs and interests of all interested parties, including affected persons, at Union level.

Art. 56, 5

The AI Office shall aim to ensure that participants to the codes of practice report regularly to the AI Office on the implementation of the commitments and the measures taken and their outcomes, including as measured against the key performance indicators as appropriate. Key performance indicators and reporting commitments shall reflect differences in size and capacity between various participants.

Art. 56, 6

The AI Office and the Board shall regularly monitor and evaluate the achievement of the objectives of the codes of practice by the participants and their contribution to the proper application of this Regulation. The AI Office and the Board shall assess whether the codes of practice cover the obligations provided for in Articles 53 and 55, and shall regularly monitor and evaluate the achievement of their objectives. They shall publish their assessment of the adequacy of the codes of practice. The Commission may, by way of an implementing act, approve a code of practice and give it a general validity within the Union. That implementing act shall be adopted in accordance with the examination procedure referred to in Article 98(2).

Obligation: 42001, 24028; **Regulation:** 5259, 22989, 14971, 8000, 29119, 9868, 62304; **Assessment:** 25024, 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 42006, 42005, 24668, 42119

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.

AI model: 22989, 5469, 4213; **Obligation:** 42001, 24028; **Provider:** 5259, 25019, 12182, 38507, 24028, 9868, 42112; **Purpose:** 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 82079, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 20547

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.

Review: 42001, 23894, 25019, 25010, 27000, 31010, 14971, 82079, 31000, 6254, 26514, 29119, 9868, 62304; **Assessment:** 25024, 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 22443, 9868, 5339, 62304, 42006, 42005, 24668, 42119

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).

Obligation: 42001, 24028; **Provider:** 5259, 25019, 12182, 38507, 24028, 9868, 42112; **Assessment:** 25024, 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 22443, 9868, 5339, 62304, 42006, 42005, 24668, 42119

ARTICLE 57

CHAPTER VI

MEASURES IN SUPPORT OF INNOVATION

Support: 25024, 8183, 42001, 5259, 5338, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 82079, 24030, 25012, 8000, 38500, 26514, 29119, 62304, 42006, 17903, 20547, 24668, 25029; **Innovation:** 42001, 23894, 8000, 29119, 20547, 20547

Art. 57

AI regulatory sandboxes

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.

Authority: 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Support:** 25024, 8183, 42001, 5259, 5338, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 82079, 24030, 25012, 8000, 38500, 26514, 29119, 62304, 42006, 17903, 20547, 24668, 25029; **Operation:** 25024, 8183, 42001, 5259, 25059, 25019, 22989, 25010, 27000, 5469, 24030, 25012, 8000, 24028, 26514, 29119, 9868, 62304, 20547; **Obligation:** 42001, 24028

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.

Authority: 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868

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.

Authority: 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Data:** 25024, 5259, 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 12182, 24030, 31000, 25012, 38507, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 25223, 5259, 5392, 17903, 20546, 20547, 20547, 20547, 20547, 23053, 24372, 24668, 25523, 42103; **Task:** 42001, 5259, 25059, 24029, 24029, 25019, 22989, 25010, 14971, 24030, 25012, 24028, 26514, 29119, 62304, 4213, 12791, 20547, 23281, 25258; **Protection:** 23894, 25010, 27000, 8000, 29119, 9868, 62304, 17903; **Data protection:** 29119

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.

Authority: 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Cooperation:** 24029, 26514, 5392; **AI Ecosystem:** 23053; **Resource:** 5259, 42001, 5259, 25019, 22989, 25010, 27000, 82079, 12182, 25012, 26514, 29119, 5339, 62304, 20547, 23282

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.

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; **Compliance:** 25024, 5259, 25019, 14971, 5469, 82079, 25012, 8000, 24028, 9868, 62304; **Authority:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **System:** 25024, 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 42006, 24668; **Obligation:** 42001, 24028, 25258, 42102, 42103, 42105, 42106, 42111, 42119; **Conformity:** 25024, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 12182, 24030, 31000, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 42006, 24668; **Regulation:** 5259, 22989, 14971, 8000, 29119, 9868, 62304; **Provider:** 5259, 25019, 12182, 38507, 24028, 9868, 42112; **Documentation:** 42001, 5259, 25019, 25010, 27000, 14971, 5469, 82079, 26514, 29119, 62304, 42005; **Assessment:** 25024, 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 22443, 9868, 5339, 62304, 42006, 42005, 24668, 42119; **Surveillance:** 9868; **Conformity assessment:** 25024, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 12182, 24030, 31000, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 42006, 24668

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.

Effectiveness: 5259, 42001, 25019, 25010, 27000, 31010, 14971, 12182, 8000, 26514, 29119, 62304, 17903, 20546; **Authority:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Support:** 25024, 8183, 42001, 5259, 5338, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 82079, 24030, 25012, 8000, 38500, 26514, 29119, 62304, 42006, 17903, 20547, 24668, 25029; **Obligation:** 42001, 24028; **Testing:** 25024, 24027, 25059, 24029, 24029, 25019, 22989, 25010, 82079, 12182, 24028, 26514, 25058, 29119, 9868, 62304, 12791, 42119; **Regulation:** 5259, 22989, 14971, 8000, 29119, 9868, 62304; **Fundamental right:** 9868; **Health:** 42001, 5338, 25019, 25010, 27000, 14971, 5469, 12182, 29119, 9868, 5339, 62304, 22989, 18988; **Safety:** 42001, 5338, 24029, 25019, 22989, 25010, 27000, 14971, 5469, 24368, 8000, 24028, 29119, 9868, 62304, 25059, 22440, 22440, 22440

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.

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; **Compliance:** 25024, 5259, 25019, 14971, 5469, 82079, 25012, 8000, 24028, 9868, 62304; **Authority:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **System:** 25024, 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 42006, 24668; **Obligation:** 42001, 24028, 25258, 42102, 42103, 42105, 42106, 42111, 42119; **Conformity:** 25024, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 12182, 24030, 31000, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 42006, 24668; **Regulation:** 5259, 22989, 14971, 8000, 29119, 9868, 62304; **Provider:** 5259, 25019, 12182, 38507, 24028, 9868, 42112; **Documentation:** 42001, 5259, 25019, 25010, 27000, 14971, 5469, 82079, 26514, 29119, 62304, 42005; **Assessment:** 25024, 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 22443, 9868, 5339, 62304, 42006, 42005, 24668, 42119; **Surveillance:** 9868; **Conformity assessment:** 25024, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 12182, 24030, 31000, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 42006, 24668

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.

Confidentiality: 25024, 5259, 42001, 22989, 25010, 27000, 25012; **Authority:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Access:** 25024, 25019, 22989, 25010, 27000, 14971, 82079, 26514, 29119, 9868, 5339, 62304, 17903; **Confidential:** 42001, 22989, 25010, 27000; **Regulation:** 5259, 22989, 14971, 8000, 29119, 9868, 62304; **Provider:** 5259, 25019, 12182, 38507, 24028, 9868, 42112; **Information:** 25024, 5259, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 24368, 12182, 24030, 31000, 25012, 8000, 38500, 38507, 24028, 6254, 8200, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 42006, 12792, 5392, 17903, 20547, 20547, 20547, 42112; **Task:** 42001, 5259, 25059, 24029, 24029, 25019, 22989, 25010, 14971, 24030, 25012, 24028, 26514, 29119, 62304, 4213, 12791, 20547, 23281, 25258; **Subject:** 25024, 24027, 5259, 5259, 24029, 23894, 22989, 25010, 27000, 14971, 12182, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 62304, 20547

Art. 57, 9

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

Art. 57, 9(a)

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

Compliance: 25024, 5259, 25019, 14971, 5469, 82079, 25012, 8000, 24028, 9868, 62304; **Regulation:** 5259, 22989, 14971, 8000, 29119, 9868, 62304

Art. 57, 9(b)

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

Authority: 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Cooperation:** 24029, 26514, 5392; **Best practice:** 18115

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

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;

Testing: 25024, 24027, 25059, 24029, 24029, 25019, 22989, 25010, 82079, 12182, 24028, 26514, 25058, 29119, 9868, 62304, 12791, 42119; **Provider:** 5259, 25019, 12182, 38507, 24028, 9868, 42112

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;

Testing: 25024, 24027, 25059, 24029, 24029, 25019, 22989, 25010, 82079, 12182, 24028, 26514, 25058, 29119, 9868, 62304, 12791, 42119; **Safeguard:** 42001, 25012; **Data:** 25024, 2529, 8183, 24027, 42001, 5259, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 12182, 24030, 31000, 25012, 38507, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 25223, 5259, 5392, 17903, 20546, 20547, 20547, 20547, 20547, 23053, 24372, 24668, 25523, 42103; **Purpose:** 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 82079, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 20547

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;

Authority: 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Notification:** 5259, 14971; **Testing:** 25024, 24027, 25059, 24029, 24029, 25019, 22989, 25010, 82079, 12182, 24028, 26514, 25058, 29119, 9868, 62304, 12791, 42119; **Provider:** 5259, 25019, 12182, 38507, 24028, 9868, 42112; **Surveillance:** 9868; **Subject:** 25024, 24027, 5259, 5259, 24029, 23894, 22989, 25010, 27000, 14971, 12182, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 62304, 20547

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;

Testing: 25024, 24027, 25059, 24029, 24029, 25019, 22989, 25010, 82079, 12182, 24028, 26514, 25058, 29119, 9868, 62304, 12791, 42119; **Disability:** 25010, 14971, 26514; **Subject:** 25024, 24027, 5259, 5259, 24029, 23894, 22989, 25010, 27000, 14971, 12182, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 62304, 20547

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;

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; **Compliance:** 25024, 5259, 25019, 14971, 5469, 82079, 25012, 8000, 24028, 9868, 62304; **Cooperation:** 24029, 26514, 5392; **System:** 25024, 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119; **Testing:** 25024, 24027, 25059, 24029, 25019, 22989, 25010, 82079, 12182, 24028, 26514, 25058, 29119, 9868, 62304, 12791, 42119; **Data:** 25024, 2529, 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 12182, 24030, 31000, 25012, 38507, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 25223, 5259, 5392, 17903, 20546, 20547, 20547, 20547, 20547, 23053, 24372, 24668, 25523, 42103; **Personal data:** 22989, 29119; **Subject:** 25024, 24027, 5259, 5259, 24029, 23894, 22989, 25010, 27000, 14971, 12182, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 62304, 20547

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;

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; **Confidentiality:** 25024, 2529, 42001, 22989, 25010, 27000, 25012; **System:** 25024, 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119; **Testing:** 25024, 24027, 25059, 24029, 25019, 22989, 25010, 82079, 12182, 24028, 26514, 25058, 29119, 9868, 62304, 12791, 42119; **Data:** 25024, 2529, 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 12182, 24030, 31000, 25012, 38507, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 25223, 5259, 5392, 17903, 20546, 20547, 20547, 20547, 20547, 23053, 24372, 24668, 25523, 42103; **Personal data:** 22989, 29119; **Subject:** 25024, 24027, 5259, 5259, 24029, 23894, 22989, 25010, 27000, 14971, 12182, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 62304, 20547

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;

Authority: 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Testing:** 25024, 24027, 25059, 24029, 24029, 25019, 22989, 25010, 82079, 12182, 24028, 26514, 25058, 29119, 9868, 62304, 12791, 42119; **Provider:** 5259, 25019, 12182, 38507, 24028, 9868, 42112; **Training:** 24027, 5259, 5338, 24029, 22989, 5469, 25012, 8000, 24028, 4213, 26514, 29119, 23053, 42112; **Task:** 42001, 5259, 25059, 24029, 24029, 25019, 22989, 25010, 14971, 24030, 25012, 24028, 26514, 29119, 62304, 4213, 12791, 20547, 23281, 25258

Art. 60, 4(k)

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

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; **System:** 25024, 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119

Art. 60, 5

any subjects of the testing in real world conditions, or their legally established 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.

Confidentiality: 25024, 5259, 42001, 22989, 25010, 27000, 25012; **Testing:** 25024, 24027, 25059, 24029, 24029, 25019, 22989, 25010, 82079, 12182, 24028, 26514, 25058, 29119, 9868, 62304, 12791, 42119; **Data:** 25024, 2529, 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 12182, 24030, 31000, 25012, 38507, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 25223, 5259, 5392, 17903, 20546, 20547, 20547, 20547, 20547, 23053, 24372, 24668, 25523, 42103; **Personal data:** 22989, 29119; **Subject:** 25024, 24027, 5259, 5259, 24029, 23894, 22989, 25010, 27000, 14971, 12182, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 62304, 20547

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.

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; **Authority:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Risk:** 8183, 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42005, 24668; **Testing:** 25024, 24027, 25059, 24029, 25019, 22989, 25010, 82079, 12182, 24028, 26514, 25058, 29119, 9868, 62304, 12791, 42119; **High-risk:** 9868; **Provider:** 5259, 25019, 12182, 38507, 24028, 9868, 42112; **Information:** 25024, 5259, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 20547, 20547, 20547, 20547, 23053, 24372, 24668, 25523, 42103; **Personal data:** 22989, 29119; **Subject:** 25024, 24027, 5259, 5259, 24029, 23894, 22989, 25010, 27000, 14971, 12182, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 20547, 20547, 20547, 20547, 23053, 24372, 24668, 25523, 42103; **Surveillance:** 9868

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.

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; **Authority:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **System:** 25024, 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119; **Testing:** 25024, 24027, 25059, 24029, 24029, 25019, 22989, 25010, 82079, 12182, 24028, 26514, 25058, 29119, 9868, 62304, 12791, 42119; **Provider:** 5259, 25019, 12182, 38507, 24028, 9868, 42112; **Incident:** 22989, 27000, 62304; **Surveillance:** 9868

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.

Authority: 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Testing:** 25024, 24027, 25059, 24029, 24029, 25019, 22989, 25010, 82079, 12182, 24028, 26514, 25058, 29119, 9868, 62304, 12791, 42119; **Provider:** 5259, 25019, 12182, 38507, 24028, 9868, 42112; **Surveillance:** 9868

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.

Testing: 25024, 24027, 25059, 24029, 24029, 25019, 22989, 25010, 82079, 12182, 24028, 26514, 25058, 29119, 9868, 62304, 12791, 42119; **Provider:** 5259, 25019, 12182, 38507, 24028, 9868, 42112

ARTICLE 61

Art. 61

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

Testing: 25024, 24027, 25059, 24029, 24029, 25019, 22989, 25010, 82079, 12182, 24028, 26514, 25058, 29119,

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

Art. 61, 1(d)

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

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; **System:** 25024, 8183, 24027, 42001, 5259, 5259, 5259, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119

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.

Testing: 25024, 24027, 25059, 24029, 24029, 25019, 22989, 25010, 82079, 12182, 24028, 26514, 25058, 29119, 9868, 62304, 12791, 42119; **Provider:** 5259, 25019, 12182, 38507, 24028, 9868, 42112; **Information:** 25024, 5259, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 42006, 12792, 5392, 17903, 20547, 20547, 20547, 42112; **Contact:** 31010, 14971, 82079

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.

Testing: 25024, 24027, 25059, 24029, 24029, 25019, 22989, 25010, 82079, 12182, 24028, 26514, 25058, 29119, 9868, 62304, 12791, 42119; **Subject:** 25024, 24027, 5259, 5259, 24029, 23894, 22989, 25010, 27000, 14971, 12182, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 62304, 20547

ARTICLE 62

Art. 62

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

Provider: 5259, 25019, 12182, 38507, 24028, 9868, 42112; **SME:** 26514

Art. 62

Art. 62, 1

Member States shall undertake the following actions:

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;

Access: 25024, 25019, 22989, 25010, 27000, 14971, 82079, 26514, 29119, 9868, 5339, 62304, 17903; **SME:** 26514

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;

Authority: 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Regulation:** 5259, 22989, 14971, 8000, 29119, 9868, 62304; **Training:** 24027, 5259, 5338, 24029, 22989, 5469, 25012, 8000, 24028, 4213, 26514, 29119, 23053, 42112; **SME:** 26514

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;

Authority: 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Regulation:** 5259, 22989, 14971, 8000, 29119, 9868, 62304; **SME:** 26514

Art. 62, 1(d)

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

SME: 26514

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.

Conformity: 25024, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 12182, 24030, 31000, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 42006, 24668; **Provider:** 5259, 25019, 12182, 38507, 24028, 9868, 42112; **SME:** 26514; **Assessment:** 25024, 8183, 24027, 42001, 5259, 5259, 5259, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 22443, 9868, 5339, 62304, 42006, 42005, 24668, 42119; **Conformity assessment:** 25024, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 12182, 24030, 31000, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 42006, 24668

Art. 62, 3

The AI Office shall undertake the following actions:

Art. 62, 3(a)

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

Regulation: 5259, 22989, 14971, 8000, 29119, 9868, 62304

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;

Regulation: 5259, 22989, 14971, 8000, 29119, 9868, 62304; **Information:** 25024, 5259, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 24368, 12182, 24030, 31000, 25012, 8000, 38500, 38507, 24028, 6254, 8200, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 42006, 12792, 5392, 17903, 20547, 20547, 20547, 42112

Art. 62, 3(c)

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

Obligation: 42001, 24028; **Regulation:** 5259, 22989, 14971, 8000, 29119, 9868, 62304

Art. 62, 3(d)

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

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; **Best practice:** 18115

ARTICLE 63

Art. 63

Derogations for specific operators

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.

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; **Compliance:** 25024, 5259, 25019, 14971, 5469, 82079, 25012, 8000, 24028, 9868, 62304; **Risk:** 8183, 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42005, 24668; **System:** 25024, 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119; **Management system:** 42001, 5259, 27000, 14971, 24970, 12182, 31000, 25012, 8000, 26514, 29119, 22443, 62304, 42006, 42005; **Management:** 25024, 42001, 5259, 5259, 5259, 5338, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 25012, 8000, 38500, 24028, 26514, 29119, 22443, 9868, 5339, 62304, 42006, 42005, 20546, 20547, 24668; **Regulation:** 5259, 22989, 14971, 8000, 29119, 9868, 62304; **High-risk:** 9868; **Quality management:** 25024, 42001, 5259, 5259, 5259, 25019, 25010, 14971, 25012, 8000, 62304; **Purpose:** 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 82079, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 20547; **Protection:** 23894, 25010, 27000, 8000, 29119, 9868, 62304, 17903

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.

Obligation: 42001, 24028; **Regulation:** 5259, 22989, 14971, 8000, 29119, 9868, 62304

ARTICLE 64

SECTION 1

Governance at Union level

Governance: 8183, 42001, 5259, 25019, 22989, 27000, 31000, 8000, 38500, 38507, 24028, 22443, 18115

Art. 64

AI Office

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

Art. 64, 1

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

Art. 64, 2

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

Regulation: 5259, 22989, 14971, 8000, 29119, 9868, 62304; **Task:** 42001, 5259, 25059, 24029, 24029, 25019, 22989, 25010, 14971, 24030, 25012, 24028, 26514, 29119, 62304, 4213, 12791, 20547, 23281, 25258

ARTICLE 65**Art. 65**

Establishment and structure of the European Artificial Intelligence Board

Artificial intelligence: 5259, 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 24029, 23894, 25019, 22989, 25010, 5469, 24970, 24368, 24030, 8000, 38507, 24028, 6254, 8200, 4213, 25058, 17847, 29119, 22443, 9868, 5339, 42006, 5392, 17903, 23053, 24372, 22989, 23053

Art. 65**Art. 65, 1**

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

Artificial intelligence: 5259, 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 24029, 23894, 25019, 22989, 25010, 5469, 24970, 24368, 24030, 8000, 38507, 24028, 6254, 8200, 4213, 25058, 17847, 29119, 22443, 9868, 5339, 42006, 5392, 17903, 23053, 24372, 22989, 23053

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.

Authority: 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Relevance:** 25024, 5259, 25059, 24029, 25019, 22989, 4213, 29119, 12792; **Data:** 25024, 5259, 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 12182, 24030, 31000, 25012, 38507, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 25223, 5259, 5392, 17903, 20546, 20547, 20547, 20547, 20547, 23053, 24372, 24668, 25523, 42103; **Protection:** 23894, 25010, 27000, 8000, 29119, 9868, 62304, 17903; **Data protection:** 29119

Art. 65, 3

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

Art. 65, 4

Member States shall ensure that their representatives on the Board:

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.

Task: 42001, 5259, 25059, 24029, 24029, 25019, 22989, 25010, 14971, 24030, 25012, 24028, 26514, 29119, 62304, 4213, 12791, 20547, 23281, 25258

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;

Contact: 31010, 14971, 82079

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.

Consistency: 25024, 5259, 42001, 82079, 25012, 8000, 24028, 42006, 20547; **Authority:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Coordination:** 12182; **Regulation:** 5259, 22989, 14971, 8000, 29119, 9868, 62304; **Data:** 25024, 5259, 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 12182, 24030, 31000, 25012, 38507, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 25223, 5259, 5392, 17903, 20546, 20547, 20547, 20547, 20547, 23053, 24372, 24668, 25523, 42103; **Information:** 25024, 5259, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 38500, 38507, 24028, 6254, 8200, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 42006, 12792, 5392, 17903, 20547, 20547, 42112; **Task:** 42001, 5259, 25059, 24029, 24029, 25019, 22989, 25010, 14971, 24030, 25012, 24028, 26514, 29119, 62304, 4213, 12791, 20547, 23281, 25258; **Purpose:** 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 82079, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 20547

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.

Specification: 24029, 25019, 22989, 25010, 14971, 5469, 25012, 29119, 62304, 20547; **Task:** 42001, 5259, 25059, 24029, 24029, 25019, 22989, 25010, 14971, 24030, 25012, 24028, 26514, 29119, 62304, 4213, 12791, 20547, 23281, 25258

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.

Authority: 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Cooperation:** 24029, 26514, 5392; **Regulation:** 5259, 22989, 14971, 8000, 29119, 9868, 62304; **Surveillance:** 9868; **Purpose:** 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 82079, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 20547

Art. 65, 7

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

Safeguard: 42001, 25012

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.

Regulation: 5259, 22989, 14971, 8000, 29119, 9868, 62304; **Task:** 42001, 5259, 25059, 24029, 24029, 25019, 22989, 25010, 14971, 24030, 25012, 24028, 26514, 29119, 62304, 4213, 12791, 20547, 23281, 25258

ARTICLE 66**Art. 66**

Tasks of the Board

Task: 42001, 5259, 25059, 24029, 24029, 25019, 22989, 25010, 14971, 24030, 25012, 24028, 26514, 29119, 62304, 4213, 12791, 20547, 23281, 25258

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:

Regulation: 5259, 22989, 14971, 8000, 29119, 9868, 62304

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);

Authority: 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Cooperation:** 24029, 26514, 5392; **Coordination:** 12182; **Support:** 25024, 8183, 42001, 5259, 5338, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 82079, 24030, 25012, 8000, 38500, 26514, 29119, 62304, 42006, 17903, 20547, 24668, 25029; **Regulation:** 5259, 22989, 14971, 8000, 29119, 9868, 62304; **Surveillance:** 9868; **Subject:** 25024, 24027, 5259, 5259, 24029, 23894, 22989, 25010, 27000, 14971, 12182, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 62304, 20547

Art. 66, (b)

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

Best practice: 18115

Art. 66, (c)

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

AI model: 22989, 5469, 4213; **Regulation:** 5259, 22989, 14971, 8000, 29119, 9868, 62304; **Purpose:** 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 82079, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 20547

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;

Conformity: 25024, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 12182, 24030, 31000, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 42006, 24668; **Testing:** 25024, 24027, 25059, 24029, 24029, 25019, 22989, 25010, 82079, 12182, 24028, 26514, 25058, 29119, 9868, 62304, 12791, 42119; **Assessment:** 25024, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 22443, 9868, 5339, 62304, 42006, 42005, 24668, 42119; **Conformity assessment:** 25024, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 12182, 24030, 31000, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 42006, 24668

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:

Regulation: 5259, 22989, 14971, 8000, 29119, 9868, 62304

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

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;

Regulation: 5259, 22989, 14971, 8000, 29119, 9868, 62304

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;

Evaluation: 25024, 24027, 42001, 5259, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 82079, 12182, 25012, 8000, 4213, 25058, 17847, 29119, 9868, 62304, 25059, 23282; **Preparation:** 8183, 5259, 82079, 26514, 62304; **Regulation:** 5259, 22989, 14971, 8000, 29119, 9868, 62304; **Review,** : 42001, 23894, 25019, 25010, 27000, 31010, 14971, 82079, 31000, 6254, 26514, 29119, 9868, 62304; **Incident:** 22989, 27000, 62304; **Database:** 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24030, 31000, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 25223, 20546

Art. 66, (e)(iii)

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

Specification: 24029, 25019, 22989, 25010, 14971, 5469, 25012, 29119, 62304, 20547

Art. 66, (e)(iv)

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

Specification: 24029, 25019, 22989, 25010, 14971, 5469, 25012, 29119, 62304, 20547

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;

Art. 66, (e)(vi)

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

Chain: 12182, 8000; **Accountability:** 42001, 25059, 25019, 22989, 25010, 27000, 29119, 9868, 5339

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;

Amendment: 8183, 42001, 5259, 25059, 5338, 24029, 23894, 31010, 5469, 82079, 25012, 8000, 24028, 4213, 26514, 25058, 9868, 5339, 62304, 22989, 23053

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;

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; **Support:** 25024, 8183, 42001, 5259, 5338, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 82079, 24030, 25012, 8000, 38500, 26514, 29119, 62304, 42006, 17903, 20547, 24668, 25029; **Obligation:** 42001, 24028; **Safeguard:** 42001, 25012

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;

Authority: 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Regulation:** 5259, 22989, 14971, 8000, 29119, 9868, 62304

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;

Fundamental right: 9868; **Safety:** 42001, 5338, 24029, 25019, 22989, 25010, 27000, 14971, 5469, 24368, 8000, 24028, 29119, 9868, 62304, 25059, 22440, 22440, 22440; **Cybersecurity:** 22989, 9868; **Data:** 25024, 5259, 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 12182, 24030, 31000, 25012, 38507, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 25223, 5259, 5392, 17903, 20546, 20547, 20547, 20547, 20547, 23053, 24372, 24668, 25253, 42103; **Protection:** 23894, 25010, 27000, 8000, 29119, 9868, 62304, 17903

Art. 66, (i)

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

Authority: 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Cooperation:** 24029, 26514, 5392

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;

Authority: 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Regulation:** 5259, 22989, 14971, 8000, 29119, 9868, 62304; **Training:** 24027, 5259, 5338, 24029, 22989, 5469, 25012, 8000, 24028, 4213, 26514, 29119, 23053, 42112; **Assessment:** 25024, 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 22443, 9868, 5339, 62304, 42006, 42005, 24668, 42119

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;

Authority: 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Cooperation:** 24029, 26514, 5392; **Information:** 25024, 5259, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 24368, 12182, 24030, 31000, 25012, 8000, 38500, 38507, 24028, 6254, 8200, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 42006, 12792, 5392, 17903, 20547, 20547, 20547, 42112

Art. 66, (l)

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

Art. 66, (m)

advise the Commission in relation to international matters on AI;

Art. 66, (n)

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

AI model: 22989, 5469, 4213; **Purpose:** 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 82079, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 20547

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.

AI model: 22989, 5469, 4213; **AI system:** 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; **Monitoring:** 42001, 23894, 25019, 27000, 31010, 14971, 5469, 8000, 24028, 29119, 9868, 62304; **Purpose:** 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 82079, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 20547

ARTICLE 67**Art. 67**

Advisory forum

Art. 67, 1

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

Regulation: 5259, 22989, 14971, 8000, 29119, 9868, 62304; **Task:** 42001, 5259, 25059, 24029, 24029, 25019, 22989, 25010, 14971, 24030, 25012, 24028, 26514, 29119, 62304, 4213, 12791, 20547, 23281, 25258

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: 42001, 25059, 25019, 14971, 24368, 26514, 22443, 5339, 42005; **SME:** 26514

Art. 67, 3

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

Art. 67, 4

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

Art. 67, 5

The Fundamental Rights Agency, 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.

Fundamental right: 9868; **Standardization:** 25024, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 20547

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.

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

Art. 67, 7

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

Art. 67, 8

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

Art. 67, 9

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

Regulation: 5259, 22989, 14971, 8000, 29119, 9868, 62304; **Purpose:** 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 82079, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 20547

Art. 67, 10

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

ARTICLE 68**Art. 68**

Scientific panel of independent experts

Art. 68, 1

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

Support: 25024, 8183, 42001, 5259, 5338, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 82079, 24030, 25012, 8000, 38500, 26514, 29119, 62304, 42006, 17903, 20547, 24668, 25029; **Regulation:** 5259, 22989, 14971, 8000, 29119, 9868, 62304

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:

Task: 42001, 5259, 25059, 24029, 24029, 25019, 22989, 25010, 14971, 24030, 25012, 24028, 26514, 29119, 62304, 4213, 12791, 20547, 23281, 25258

Art. 68, 2(a)

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

Competence: 42001, 27000, 42006

Art. 68, 2(b)

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

AI model: 22989, 5469, 4213; **AI system:** 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 23281, 25029, 25258, 42103, 42105, 42106, 42111, 42119, 18115; **Provider:** 5259, 25019, 12182, 38507, 24028, 9868, 42112; **Purpose:** 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 82079, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 20547

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.

Representation: 25024, 24027, 25019, 22989, 5469, 25012, 8000, 29119, 62304, 5392

Art. 68, 3

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

Support: 25024, 8183, 42001, 5259, 5338, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 82079, 24030, 25012, 8000, 38500, 26514, 29119, 62304, 42006, 17903, 20547, 24668, 25029; **Task:** 42001, 5259, 25059, 24029, 24029, 25019, 22989, 25010, 14971, 24030, 25012, 24028, 26514, 29119, 62304, 4213, 12791, 20547, 23281, 25258

Art. 68, 3(a)

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

AI model: 22989, 5469, 4213; **Regulation:** 5259, 22989, 14971, 8000, 29119, 9868, 62304; **Purpose:** 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 82079, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 20547

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;

AI model: 22989, 5469, 4213; **Purpose:** 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 82079, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 20547

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;

AI model: 22989, 5469, 4213; **Evaluating:** 25024, 42001, 5259, 25059, 25019, 27000, 14971, 25012, 4213, 62304, 25059, 20547; **Purpose:** 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 82079, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 20547

Art. 68, 3(a)(iii)

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

AI model: 22989, 5469, 4213; **Risk:** 8183, 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42005, 24668; **Categorization:** 31010, 12182, 25012; **Classification:** 24029, 22989, 12182, 4213, 25058, 29119, 9868, 4213, 12791; **Purpose:** 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 82079, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 20547

Art. 68, 3(a)(iv)

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

AI model: 22989, 5469, 4213; **Categorization:** 31010, 12182, 25012; **Classification:** 24029, 22989, 12182, 4213, 25058, 29119, 9868, 4213, 12791; **Purpose:** 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 82079, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 20547

Art. 68, 3(a)(v)

contributing to the development of tools and templates;

Art. 68, 3(b)

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

Authority: 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Surveillance:** 9868

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;

Authority: 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Surveillance:** 9868

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.

Safeguard: 42001, 25012

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.

Confidentiality: 25024, 5259, 42001, 22989, 25010, 27000, 25012; **Confidential:** 42001, 22989, 25010, 27000; **Declaration:** 25024, 24027, 5259, 24029, 23894, 22989, 27000, 14971, 12182, 31000, 8000, 24028, 4213, 26514, 29119, 9868; **Data:** 25024, 5259, 8183, 24027, 42001, 5259, 5259, 25059, 5259, 25059, 5338, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 12182, 24030, 31000, 25012, 38507, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 25223, 5259, 5392, 17903, 20546, 20547, 20547, 20547, 20547, 23053, 24372, 24668, 25523, 42103; **Information:** 25024, 5259, 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 24368, 12182, 24030, 31000, 25012, 8000, 38500, 38507, 24028, 6254, 8200, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 42006, 12792, 5392, 17903, 20547, 20547, 20547, 42112; **Task:** 42001, 5259, 25059, 24029, 24029, 25019, 22989, 25010, 14971, 24030, 25012, 24028, 26514, 29119, 62304, 4213, 12791, 20547, 23281, 25258

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.

Task: 42001, 5259, 25059, 24029, 24029, 25019, 22989, 25010, 14971, 24030, 25012, 24028, 26514, 29119, 62304, 4213, 12791, 20547, 23281, 25258

ARTICLE 69

Art. 69

Access to the pool of experts by the Member States

Access: 25024, 25019, 22989, 25010, 27000, 14971, 82079, 26514, 29119, 9868, 5339, 62304, 17903

Art. 69, 1

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

Support: 25024, 8183, 42001, 5259, 5338, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 82079, 24030, 25012, 8000, 38500, 26514, 29119, 62304, 42006, 17903, 20547, 24668, 25029; **Regulation:** 5259, 22989, 14971, 8000, 29119, 9868, 62304

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.

Effectiveness: 5259, 42001, 25019, 25010, 27000, 31010, 14971, 12182, 8000, 26514, 29119, 62304, 17903, 20546; **Access:** 25024, 25019, 22989, 25010, 27000, 14971, 82079, 26514, 29119, 9868, 5339, 62304, 17903; **Support:** 25024, 8183, 42001, 5259, 5338, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 82079, 24030, 25012, 8000, 38500, 26514, 29119, 62304, 42006, 17903, 20547, 24668, 25029; **Regulation:** 5259, 22989, 14971, 8000, 29119, 9868, 62304

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.

Access: 25024, 25019, 22989, 25010, 27000, 14971, 82079, 26514, 29119, 9868, 5339, 62304, 17903; **Support:** 25024, 8183, 42001, 5259, 5338, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 82079, 24030, 25012, 8000, 38500, 26514, 29119, 62304, 42006, 17903, 20547, 24668, 25029; **Testing:** 25024, 24027, 25059, 24029, 24029, 25019, 22989, 25010, 82079, 12182, 24028, 26514, 25058, 29119, 9868, 62304, 12791, 42119

ARTICLE 70

SECTION 2

National competent authorities

Authority: 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868

Art. 70

Designation of national competent authorities and single points of contact

Authority: 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Contact:** 31010, 14971, 82079

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 plans of the Member State.

Bias: 8183, 24027, 22989, 5469, 24028, 29119, 9868, 12791; **Authority:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Regulation:** 5259, 22989, 14971, 8000, 29119, 9868, 62304; **Safeguard:** 42001, 25012; **Task:** 42001, 5259, 25059, 24029, 24029, 25019, 22989, 25010, 14971, 24030, 25012, 24028, 26514, 29119, 62304, 4213, 12791, 20547, 23281, 25258; **Surveillance:** 9868

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.

Authority: 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Regulation:** 5259, 22989, 14971, 8000, 29119, 9868, 62304; **Information:** 25024, 5259, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 24368, 12182, 24030, 31000, 25012, 8000, 38500, 38507, 24028, 6254, 8200, 4213, 26514, 29119, 62304, 42006, 17903, 20547, 20547, 20547, 42112; **Contact:** 31010, 14971, 82079; **Task:** 42001, 5259, 25059, 24029, 24029, 25019, 22989, 25010, 14971, 24030, 25012, 24028, 26514, 29119, 62304, 4213, 12791, 20547, 23281, 25258; **Surveillance:** 9868

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.

Confidentiality: 25024, 5259, 42001, 22989, 25010, 27000, 25012; **Authority:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Competence:** 42001, 27000, 42006; **Human:** 24027, 42001, 25059, 24029, 25019, 22989, 25010, 27000, 31010, 14971, 82079, 24030, 31000, 25012, 8000, 24028, 26514, 29119, 9868, 62304, 5392, 23053, 42105, 42109; **Regulation:** 5259, 22989, 14971, 8000, 29119, 9868, 62304; **Fundamental right:** 9868; **Health:** 42001, 5338, 25019, 25010, 27000, 14971, 5469, 12182, 29119, 9868, 5338, 62304, 22989, 18988; **Safety:** 42001, 5338, 24029, 25019, 22989, 25010, 27000, 14971, 5469, 24368, 8000, 24028, 29119, 9868, 62304, 25059, 22440, 22440, 22440; **Cybersecurity:** 22989, 9868; **Knowledge:** 25024, 8183, 24027, 42001, 5338, 24029, 25019, 22989, 25010, 27000, 14971, 24030, 31000, 25012, 26514, 29119, 9868, 5339, 62304, 5392, 23053, 24372; **Data:** 25024, 5259, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 12182, 24030, 31000, 25012, 38507, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 25223, 5259, 5392, 17903, 20546, 20547, 20547, 20547, 20547, 23053, 24372, 24668, 25523, 42103; **Personal data:** 22989, 29119; **Task:** 42001, 5259, 25059, 24029, 24029, 25019, 22989, 25010, 27000, 14971, 24030, 25012, 24028, 26514, 29119, 62304, 4213, 12791, 20547, 23281, 25258; **Resource:** 5259, 42001, 5259, 25019, 22989, 25010, 27000, 82079, 12182, 25012, 26514, 29119, 5339, 62304, 20547, 23282; **Protection:** 23894, 25010, 27000, 8000, 29119, 9868, 62304, 17903; **Data protection:** 29119

Art. 70, 4

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

Authority: 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Cybersecurity:** 22989, 9868

Art. 70, 5

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

Confidentiality: 25024, 5259, 42001, 22989, 25010, 27000, 25012; **Authority:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Confidential:** 42001, 22989, 25010, 27000; **Obligation:** 42001, 24028; **Task:** 42001, 5259, 25059, 24029, 24029, 25019, 22989, 25010, 14971, 24030, 25012, 24028, 26514, 29119, 62304, 4213, 12791, 20547, 23281, 25258

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.

Authority: 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Human:** 24027, 42001, 25059, 24029, 25019, 22989, 25010, 27000, 31010, 14971, 82079, 24030, 31000, 25012, 8000, 24028, 26514, 29119, 9868, 62304, 5392, 23053, 42105, 42109; **Information:** 25024, 5259, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 26514, 29119, 62304, 42006, 17903, 20547, 20547, 42112; **Assessment:** 25024, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 12182, 24030, 31000, 25012, 8000, 24028, 26514, 29119, 62304, 42006, 42005, 24668, 42119; **Resource:** 5259, 42001, 5259, 25019, 22989, 25010, 27000, 82079, 12182, 25012, 26514, 29119, 5339, 62304, 20547, 23282

Art. 70, 7

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

Authority: 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Experience:** 42001, 25019, 22989, 25010, 14971, 31000, 26514, 29119, 62304, 23053, 24668

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.

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; **Authority:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **System:** 25024, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 42005, 24668; **High-risk:** 9868; **Database:** 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24030, 31000, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 25223, 20546

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.

Authority: 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Regulation:** 5259, 22989, 14971, 8000, 29119, 9868, 62304; **Data:** 25024, 5259, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 17903; **Data protection:** 29119

ARTICLE 71

CHAPTER VIII

EU DATABASE FOR HIGH-RISK AI SYSTEMS

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; **Risk:** 8183, 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42005, 24668; **High-risk:** 9868; **Database:** 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24030, 31000, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 25223, 20546

Art. 71

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

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; **Risk:** 8183, 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42005, 24668; **High-risk:** 9868; **Database:** 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24030, 31000, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 25223, 20546

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.

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; **Updating:** 22989; **Risk:** 8183, 24027, 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42005, 24668; **High-risk:** 9868; **Specification:** 24029, 25019, 22989, 25010, 14971, 5469, 25012, 29119, 62304, 20547, 20547, 20547, 20547, 20547, 23053, 24372, 24668, 25223, 42103; **Database:** 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24030, 31000, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 25223, 20546

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.

Provider: 5259, 25019, 12182, 38507, 24028, 9868, 42112; **Data:** 25024, 5259, 8183, 24027, 42001, 5259, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 12182, 24030, 31000, 25012, 38507, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 25223, 5259, 5392, 17903, 20546, 20547, 20547, 20547, 20547, 23053, 24372, 24668, 25223, 42103; **Database:** 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24030, 31000, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 25223, 20546; **Authorised representative:** 14971

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).

Authority: 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Data:** 25024, 5259, 8183, 24027, 42001, 5259, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 12182, 24030, 31000, 25012, 38507, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 25223, 5259, 5392, 17903, 20546, 20547, 20547, 20547, 20547, 23053, 24372, 24668, 25223, 42103; **Database:** 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24030, 31000, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 25223, 20546

Art. 71, 4

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

Authority: 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **User:** 25024, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 82079, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 5392, 20547, 20547, 20547, 24372; **Provider:** 5259, 25019, 12182, 38507, 24028, 9868, 42112; **Information:** 25024, 5259, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 24368, 12182, 24030, 31000, 25012, 8000, 38500, 38507, 24028, 6254, 8200, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 42006, 12792, 5392, 17903, 20547, 20547, 20547, 20547, 23053, 24372, 24668, 25223, 42103; **Information:** 25024, 5259, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 24368, 12182, 24030, 31000, 25012, 8000, 38500, 38507, 24028, 6254, 8200, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 42006, 12792, 5392, 17903, 20547, 20547, 20547, 20547, 23053, 24372, 24668, 25223, 42103; **Database:** 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24030, 31000, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 25223, 20546; **Surveillance:** 9868

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.

Confidentiality: 25024, 5259, 42001, 22989, 25010, 27000, 25012; **Authority:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **System:** 25024, 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 5392, 20547, 20547, 20547, 24372; **Provider:** 5259, 25019, 12182, 38507, 24028, 9868, 42112; **Data:** 25024, 5259, 8183, 24027, 42001, 5259, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 24368, 12182, 24030, 31000, 25012, 8000, 38500, 38507, 24028, 6254, 8200, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 42006, 12792, 5392, 17903, 20547, 20547, 20547, 20547, 23053, 24372, 24668, 25223, 42103; **Information:** 25024, 5259, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 24368, 12182, 24030, 31000, 25012, 8000, 38500, 38507, 24028, 6254, 8200, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 42006, 12792, 5392, 17903, 20547, 20547, 20547, 20547, 23053, 24372, 24668, 25223, 42103; **Personal data:** 22989, 29119, 14971, 82079, 24368, 12182, 24030, 31000, 25012, 8000, 38500, 38507, 24028, 6254, 8200, 4213, 26514, 25058, 29119, 9868, 5339, 25223, 20546

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.

Accessibility: 25024, 5259, 25059, 25019, 25010, 27000, 14971, 82079, 25012, 26514, 29119; **Support:** 25024, 8183, 42001, 5259, 5338, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 82079, 24030, 25012, 8000, 38500, 26514, 29119, 62304, 42006, 17903, 20547, 24668, 25029; **Provider:** 5259, 25019, 12182, 38507, 24028, 9868, 42112; **Controller:** 5469, 6200; **Database:** 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24030, 31000, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 25223, 20546

ARTICLE 72

CHAPTER IX

POST-MARKET MONITORING, INFORMATION SHARING AND MARKET SURVEILLANCE

Post-market: 25019, 14971; **Monitoring:** 42001, 23894, 25019, 27000, 31010, 14971, 5469, 8000, 24028, 29119, 9868, 62304; **Information:** 25024, 5259, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 24368, 12182, 24030, 31000, 25012, 8000, 38500, 38507, 24028, 6254, 8200, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 42006, 12792, 5392, 17903, 20547, 20547, 20547, 42112; **Surveillance:** 9868

SECTION 1

Post-market monitoring

Post-market: 25019, 14971; **Monitoring:** 42001, 23894, 25019, 27000, 31010, 14971, 5469, 8000, 24028, 29119, 9868, 62304

Art. 72

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

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; **Post-market:** 25019, 14971; **Monitoring:** 42001, 23894, 25019, 27000, 31010, 14971, 5469, 8000, 24028, 29119, 9868, 62304; **Risk:** 8183, 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42005, 24668; **High-risk:** 9868; **Provider:** 5259, 25019, 12182, 38507, 24028, 9868, 42112

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.

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; **Post-market:** 25019, 14971; **Monitoring:** 42001, 23894, 25019, 27000, 31010, 14971, 5469, 8000, 24028, 29119, 9868, 62304; **Risk:** 8183, 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42005, 24668; **System:** 25024, 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 20547, 20547, 20547, 23053, 24372, 20226, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119; **High-risk:** 9868; **Provider:** 5259, 25019, 12182, 38507, 24028, 9868, 42112

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.

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; **Compliance:** 25024, 5259, 25019, 14971, 5469, 82079, 25012, 8000, 24028, 9868, 62304; **Authority:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Interaction:** 22989, 25010, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42005, 24668; **System:** 25024, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42005, 24668; **Data:** 25024, 5259, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 20547, 20547, 20547, 20547, 23053, 24372, 24668, 25223, 42103; **Dataset:** 25024, 5259, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 12182, 24030, 25012, 8000, 24028, 4213, 26514, 29119, 9868, 62304, 25223, 20546

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).

Post-market: 25019, 14971; **Monitoring:** 42001, 23894, 25019, 27000, 31010, 14971, 5469, 8000, 24028, 29119, 9868, 62304; **System:** 25024, 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 20547, 20547, 20547, 23053, 24372, 20226, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119; **Technical documentation:** 25019; **Documentation:** 25001, 5259, 25019, 25010, 27000, 14971, 5469, 82079, 26514, 29119, 62304, 42005

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.

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; **Consistency:** 25024, 5259, 42001,

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.

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115. **Regulation:** 5259, 22989, 14971, 8000, 29119, 9868, 62304. **Product:** 25024, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 82079, 12182, 25012, 8000, 24028, 26514, 29119, 62304, 5392, 17903, 20547, 24372. **Protection:** 23894, 25010, 27000, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 17903.

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.

Authority: 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868. **Regulation:** 5259, 22989, 14971, 8000, 29119, 9868, 62304. **Surveillance:** 9868. **Purpose:** 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 82079, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 20547.

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.

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115. **Authority:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868. **Risk:** 8183, 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42005, 24668. **System:** 25024, 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119. **Regulation:** 5259, 22989, 14971, 8000, 29119, 9868, 62304. **High-risk:** 9868. **Service:** 25024, 8183, 42001, 5259, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 82079, 12182, 8000, 38507, 24028, 26514, 29119, 9868, 5339, 62304, 25059, 5392, 20547, 24668. **Surveillance:** 9868.

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.

Authority: 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868. **Coordination:** 12182. **Regulation:** 5259, 22989, 14971, 8000, 29119, 9868, 62304. **Information:** 25024, 5259, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 24368, 12182, 24030, 31000, 25012, 8000, 38507, 24028, 6254, 8200, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 42006, 12792, 5392, 17903, 20547, 20547, 20547, 42112. **Task:** 42001, 5259, 25059, 24029, 24029, 25019, 22989, 25010, 14971, 24030, 25012, 24028, 26514, 29119, 62304, 4213, 12791, 20547, 23281, 25258. **Surveillance:** 9868.

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.

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115. **Authority:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868. **Risk:** 8183, 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 26514, 29119, 22443, 9868, 5339, 62304, 42006, 42005, 20546, 20547, 24668. **Regulation:** 5259, 22989, 14971, 8000, 29119, 9868, 62304. **High-risk:** 9868. **Data:** 25024, 5259, 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 12182, 24030, 31000, 25012, 38507, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 25223, 5259, 5392, 17903, 20546, 20547, 20547, 20547, 23053, 24372, 24668, 25223, 42103. **Surveillance:** 9868. **Protection:** 23894, 25010, 27000, 8000, 29119, 9868, 62304, 17903. **Data protection:** 29119.

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.

Authority: 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868. **Regulation:** 5259, 22989, 14971, 8000, 29119, 9868, 62304. **Data:** 25024, 5259, 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 12182, 24030, 31000, 25012, 38507, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 25223, 5259, 5392, 17903, 20546, 20547, 20547, 20547, 23053, 24372, 24668, 25223, 42103. **Surveillance:** 9868. **Protection:** 23894, 25010, 27000, 8000, 29119, 9868, 62304, 17903. **Data protection:** 29119.

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.

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115. **Authority:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868. **Coordination:** 12182. **Risk:** 8183, 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42005, 24668. **Regulation:** 5259, 22989, 14971, 8000, 29119, 9868, 62304. **High-risk:** 9868. **Surveillance:** 9868.

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.

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115. **Compliance:** 25024, 5259, 25019, 14971, 5469, 82079, 25012, 8000, 24028, 9868, 62304. **Authority:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868. **Coordination:** 12182. **Support:** 25024, 8183, 42001, 5259, 5338, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 82079, 12182, 8000, 38500, 26514, 29119, 62304, 42006, 17903, 20547, 24668, 25029. **Risk:** 8183, 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42005, 24668. **Regulation:** 5259, 22989, 14971, 8000, 29119, 9868, 62304. **High-risk:** 9868. **Surveillance:** 9868.

Art. 74, 12

Without prejudice to the powers provided 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.

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115. **Authority:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868. **Access:** 25024, 25019, 22989, 25010, 27000, 14971, 82079, 26514, 29119, 9868, 5339, 62304, 17903. **Security:** 25024, 42001, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42006, 20546, 20547. **Validation:** 25024, 5259, 25059, 24029, 25019, 22989, 25010, 5469, 8000, 24028, 8200, 4213, 17847, 29119, 62304, 20226, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119. **Risk:** 8183, 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42006, 42005, 20546, 20547, 24668. **Testing:** 25024, 24027, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 82079, 12182, 24028, 26514, 25058, 29119, 9868, 62304, 17903, 42112. **Regulation:** 5259, 22989, 14971, 8000, 29119, 9868, 62304. **Safeguard:** 42001, 25012. **High-risk:** 9868. **Provider:** 5259, 25019, 12182, 38507, 24028, 9868, 42112. **Training:** 24027, 5259, 5338, 24029, 22989, 5469, 25012, 8000, 24028, 4213, 26514, 29119, 23053, 42112. **Documentation:** 42001, 5259, 25019, 25010, 27000, 14971, 5469, 82079, 26514, 29119, 62304, 42005. **Data:** 25024, 5259, 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 12182, 24030, 31000, 25012, 8000, 38500, 26514, 29119, 62304, 4213, 12791, 20547, 23281, 25258. **Datasets:** 25024, 5259, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 25019, 22989, 25010, 27000, 14971, 12182, 24030, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 62304, 20547. **Testing data:** 25024, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 12182, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 62304, 20547. **Testing data:** 25024, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119. **High-risk:** 9868. **Surveillance:** 9868.

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:

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115. **Authority:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868. **Access:** 25024, 25019, 22989, 25010, 27000, 14971, 82079, 26514, 29119, 9868, 5339, 62304, 17903. **Risk:** 8183, 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42006, 42005, 20546, 20547, 24668. **System:** 25024, 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 82079, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119. **Conformity:** 25024, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 12182, 24030, 31000, 25012, 8000, 38500, 26514, 29119, 62304, 5392, 17903, 20547, 20547, 20547,

The data presented here has a value for research and not a legal value.

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.

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; Compliance: 25024, 5259, 25019, 14971, 5469, 82079, 25012, 8000, 24028, 9868, 62304; Authority: 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; Risk: 8183, 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42005, 24668; Regulation: 5259, 22989, 14971, 8000, 29119, 9868, 62304; High-risk: 9868; Surveillance: 9868; Purpose: 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 82079, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 20547

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.

AI model: 22989, 5469, 4213; AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; Confidentiality: 25024, 5259, 42001, 22989, 25010, 27000, 25012; Authority: 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; Access: 25024, 25019, 22989, 25010, 27000, 14971, 82079, 26514, 29119, 9868, 5339, 62304, 17903; Confidential: 42001, 22989, 25010, 27000; Risk: 8183, 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42005, 24668; System: 25024, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119; Regulation: 5259, 22989, 14971, 8000, 29119, 9868, 62304; Safeguard: 42001, 25012; High-risk: 9868; Information: 25024, 5259, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 24368, 12182, 24030, 31000, 25012, 8000, 38500, 38507, 24028, 6254, 8200, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 42006, 12792, 5392, 17903, 20547, 20547, 20547, 42112; Surveillance: 9868; Purpose: 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 82079, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 20547; Event: 24027, 42001, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 31000, 25012, 24028, 62304

ARTICLE 76

Art. 76

Supervision of testing in real world conditions by market surveillance authorities

Authority: 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; Testing: 25024, 24027, 25059, 24029, 24029, 25019, 22989, 25010, 82079, 12182, 24028, 26514, 25058, 29119, 9868, 62304, 12791, 42119; Surveillance: 9868

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.

Authority: 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; Testing: 25024, 24027, 25059, 24029, 24029, 25019, 22989, 25010, 82079, 12182, 24028, 26514, 25058, 29119, 9868, 62304, 12791, 42119; Regulation: 5259, 22989, 14971, 8000, 29119, 9868, 62304; Surveillance: 9868

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).

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; Authority: 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; Access: 25024, 25019, 22989, 25010, 27000, 14971, 82079, 26514, 29119, 9868, 5339, 62304, 17903; Confidential: 42001, 22989, 25010, 27000; Risk: 8183, 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42005, 24668; System: 25024, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119; Regulation: 5259, 22989, 14971, 8000, 29119, 9868, 62304; Safeguard: 42001, 25012; High-risk: 9868; Information: 25024, 5259, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 24368, 12182, 24030, 31000, 25012, 8000, 38500, 38507, 24028, 6254, 8200, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 42006, 12792, 5392, 17903, 20547, 20547, 20547, 42112; Surveillance: 9868; Purpose: 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 82079, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 20547; Event: 24027, 42001, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 31000, 25012, 24028, 62304

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:

Authority: 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; Provider: 5259, 25019, 12182, 38507, 24028, 9868, 42112; Incident: 22989, 27000, 62304; Surveillance: 9868

Art. 76, 3(a)

to suspend or terminate the testing in real world conditions;

Testing: 25024, 24027, 25059, 24029, 24029, 25019, 22989, 25010, 82079, 12182, 24028, 26514, 25058, 29119, 9868, 62304, 12791, 42119

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.

Testing: 25024, 24027, 25059, 24029, 24029, 25019, 22989, 25010, 82079, 12182, 24028, 26514, 25058, 29119, 9868, 62304, 12791, 42119; Provider: 5259, 25019, 12182, 38507, 24028, 9868, 42112

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 63(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.

Authority: 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; Provider: 5259, 25019, 12182, 38507, 24028, 9868, 42112; Surveillance: 9868

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.

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; Authority: 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; System: 25024, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119; Testing: 25024, 24027, 25059, 24029, 24029, 25019, 22989, 25010, 82079, 12182, 24028, 26514, 25058, 29119, 9868, 62304, 12791, 42119; Surveillance: 9868

ARTICLE 77

Art. 77

Powers of authorities protecting fundamental rights

Authority: 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; Fundamental right: 9868

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.

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; Authority: 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; Access: 25024, 25019, 22989, 25010, 27000, 14971, 82079, 26514, 29119, 9868, 5339, 62304, 17903; Risk: 8183, 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119; Obligation: 42001, 24028; Testing: 25024, 24027, 25059, 24029, 24029, 25019, 22989, 25010, 82079, 12182, 24028, 26514, 25058, 29119, 9868, 62304, 12791, 42119; Surveillance: 9868

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.

Authority: 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868

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.

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; Authority: 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; Risk: 8183, 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119; Obligation: 42001, 24028; Testing: 25024, 24027, 25059, 24029, 24029, 25019, 22989, 25010, 82079, 12182, 24028, 26514, 25058, 29119, 9868, 62304, 12791, 42119; Fundamental right: 9868; High-risk: 9868; Documentation: 42001, 5259, 25019, 25010, 27000, 14971, 5469, 82079, 26514, 29119, 62304, 42005; Surveillance: 9868

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.

Confidentiality: 25024, 5259, 42001, 22989, 25010, 27000, 25012; Authority: 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; Confidential: 42001, 22989, 25010, 27000; Obligation: 42001, 24028; Documentation: 42001, 5259, 25019, 25010, 27000, 14971, 5469, 82079, 26514, 29119, 62304, 42005; Information: 25024, 5259, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 24368, 12182, 24030, 31000, 25012, 8000, 38500, 38507, 24028, 6254, 8200, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 42006, 12792, 5392, 17903, 20547, 20547, 20547, 42112

ARTICLE 78

Art. 78

Confidentiality

Confidentiality: 25024, 5259, 42

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

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); Confidential: 42001, 22989, 25010, 27000, Information: 25024, 5259, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 24368, 12182, 24030, 31000, 25012, 8000, 38500, 38507, 24028, 6254, 8200, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 20547, 12792, 5392, 17903, 20547, 20547, 20547, 42112

Art. 78, 1(b) the effective implementation of this Regulation, in particular for the purposes of inspections, investigations or audits; Regulation: 5259, 22989, 14971, 8000, 29119, 9868, 62304

Art. 78, 1(c) public and national security interests; Security: 25024, 42001, 25059, 24029, 25019, 22989, 25010, 27000, 14971, 24030, 24028, 29119, 9868, 62304, 42006, 20547, 20547

Art. 78, 1(d) the conduct of criminal or administrative proceedings;

Art. 78, 1(e) information classified pursuant to Union or national law; Information: 25024, 5259, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 24368, 12182, 24030, 31000, 25012, 8000, 38500, 38507, 24028, 6254, 8200, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 20547, 12792, 5392, 17903, 20547, 20547, 42112

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. AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; Confidentiality: 25024, 5259, 42001, 22989, 25010, 27000, 25012; Authority: 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; Security: 25024, 42001, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42005, 24668; Regulation: 5259, 22989, 14971, 8000, 29119, 9868, 62304; Cybersecurity: 22989, 9868; Data: 25024, 5259, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 12182, 24030, 31000, 25012, 38507, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 25223, 5259, 5392, 17903, 20546, 20547, 20547, 20547, 23053, 24372, 24668, 25253, 42103; Information: 25024, 5259, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 24368, 12182, 24030, 31000, 25012, 8000, 38500, 38507, 24028, 6254, 8200, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 42006, 42005, 24668, 42119; Purpose: 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 82079, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 20547

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 jeopardize 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. AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; Confidentiality: 25024, 5259, 42001, 22989, 25010, 27000, 25012; Authority: 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; Security: 25024, 42001, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42005, 24668; Regulation: 5259, 22989, 14971, 8000, 29119, 9868, 62304; Cybersecurity: 22989, 9868; Data: 25024, 5259, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 12182, 24030, 31000, 25012, 38507, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 25223, 5259, 5392, 17903, 20546, 20547, 20547, 20547, 23053, 24372, 24668, 25253, 42103; Information: 25024, 5259, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 24368, 12182, 24030, 31000, 25012, 8000, 38500, 38507, 24028, 6254, 8200, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 42006, 42005, 24668, 42119; Purpose: 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 82079, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 20547

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. Authority: 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; Cooperation: 24029, 26514, 5392; Obligation: 42001, 24028; Information: 25024, 5259, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 24368, 12182, 24030, 31000, 25012, 8000, 38500, 38507, 24028, 6254, 8200, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 42006, 12792, 5392, 17903, 20547, 20547, 20547, 42112

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. Confidentiality: 25024, 5259, 42001, 22989, 25010, 27000, 25012; Authority: 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; Confidential: 42001, 22989, 25010, 27000; Information: 25024, 5259, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 24368, 12182, 24030, 31000, 25012, 8000, 38500, 38507, 24028, 6254, 8200, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 42006, 12792, 5392, 17903, 20547, 20547, 20547, 42112

ARTICLE 79

Art. 79 Procedure at national level for dealing with AI systems presenting a risk AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; Risk: 8183, 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42005, 24668

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. AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; Risk: 8183, 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42005, 24668; Regulation: 5259, 22989, 14971, 8000, 29119, 9868, 62304; Fundamental right: 9868; Health: 42001, 5338, 25019, 25010, 27000, 14971, 5469, 12182, 29119, 9868, 5339, 62304, 22989, 18988; Safety: 42001, 5338, 24029, 25019, 22989, 25010, 27000, 14971, 5469, 24368, 8000, 24028, 29119, 9868, 62304, 25059, 22440, 22440, 22440

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 to take other appropriate measures. AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; Compliance: 25024, 5259, 25019, 14971, 5469, 82079, 25012, 8000, 24028, 9868, 62304; Authority: 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; Cooperation: 24029, 26514, 5392; Evaluation: 25024, 24027, 42001, 5259, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42005, 24668; System: 25024, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 8200, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 20547, 23053, 24372, 20226, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119; Obligation: 42001, 24028; Regulation: 5259, 22989, 14971, 8000, 29119, 9868, 62304; Fundamental right: 9868; Surveillance: 9868; Event: 24027, 42001, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 31000, 25012, 24028, 62304; Operator: 25059, 25019, 25010, 26514, 9868, 17903

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. Compliance: 25024, 5259, 25019, 14971, 5469, 82079, 25012, 8000, 24028, 9868, 62304; Authority: 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; Evaluation: 25024, 24027, 42001, 5259, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 82079, 12182, 25012, 8000, 4213, 25058, 17847, 29119, 9868, 62304, 25059, 23282; Surveillance: 9868; Operator: 25059, 25019, 25010, 26514, 9868, 17903

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. AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; Corrective action: 42001, 27000, 14971; Operator: 25059, 25019, 25010, 26514, 9868, 17903

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. AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; Authority: 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; Corrective action: 42001, 27000, 14971; System: 25024, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 8200, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 20547, 23053, 24372, 20226, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119; Notification: 5259, 14971; Information: 25024, 5259, 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 24368, 12182, 24030, 31000, 25012, 8000, 38500, 38507, 24028, 6254, 8200, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 42006, 12792, 5392, 17903, 20547, 20547, 20547, 42112; Surveillance: 9868; Operator: 25059, 25019, 25010, 26514, 9868, 17903

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: AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; Compliance: 25024, 5259, 25019, 14971, 5469, 82079, 25012, 8000, 24028, 9868, 62304; Authority: 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; Chain: 12182, 8000; Risk: 8183, 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42005, 24668; System: 25024, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 8200, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 20547, 23053, 24372, 20226, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102,

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

Art. 79, 6(a)

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

Compliance: 25024, 5259, 25019, 14971, 5469, 82079, 25012, 8000, 24028, 9868, 62304

Art. 79, 6(b)

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

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; **Risk:** 8183, 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31000, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42005, 24668; **System:** 25024, 8183, 24027, 42001, 5259, 25059, 5338, 24029, 23894, 25019, 22989, 25010, 27000, 31000, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119; **High-risk:** 9868

Art. 79, 6(c)

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

Conformity: 25024, 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 82079, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 42006, 24668; **Specification:** 24029, 25019, 22989, 25010, 14971, 5469, 25012, 29119, 62304, 20547

Art. 79, 6(d)

non-compliance with Article 50.

Compliance: 25024, 5259, 25019, 14971, 5469, 82079, 25012, 8000, 24028, 9868, 62304

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.

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; **Compliance:** 25024, 5259, 25019, 14971, 5469, 82079, 25012, 8000, 24028, 9868, 62304; **Authority:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **System:** 25024, 8183, 24027, 42001, 5259, 25059, 5338, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119; **Information:** 25024, 5259, 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31000, 14971, 5469, 24970, 82079, 24368, 12182, 24030, 31000, 25012, 8000, 38500, 38507, 24028, 6254, 8200, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 42006, 12792, 5392, 17903, 20547, 20547, 20547, 42112; **Measure:** 25024, 5259, 24027, 42001, 5259, 25059, 25019, 22989, 25010, 27000, 14971, 5469, 31000, 25012, 8000, 4213, 25058, 29119, 9868, 4213, 25223, 24668; **Surveillance:** 9868; **Event:** 24027, 42001, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 31000, 25012, 24028, 62304

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.

Compliance: 25024, 5259, 25019, 14971, 5469, 82079, 25012, 8000, 24028, 9868, 62304; **Authority:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Notification:** 5259, 14971; **Regulation:** 5259, 22989, 14971, 8000, 29119, 9868, 62304; **Measure:** 25024, 5259, 24027, 42001, 5259, 25059, 25019, 22989, 25010, 27000, 14971, 5469, 31000, 25012, 8000, 4213, 25058, 29119, 9868, 4213, 25223, 24668; **Surveillance:** 9868; **Event:** 24027, 42001, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 31000, 25012, 24028, 62304; **Operator:** 25059, 25019, 25010, 26514, 9868, 17903

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.

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; **Authority:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **System:** 25024, 8183, 24027, 42001, 5259, 25059, 5338, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119; **Surveillance:** 9868

ARTICLE 80

Art. 80

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

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; **Risk:** 8183, 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31000, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42005, 24668; **High-risk:** 9868; **Provider:** 5259, 25019, 12182, 38507, 24028, 9868, 42112

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.

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; **Authority:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Evaluation:** 25024, 24027, 42001, 5259, 25059, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119; **High-risk:** 9868; **Provider:** 5259, 25019, 12182, 38507, 24028, 9868, 42112; **Categorization:** 31010, 12182, 25012; **Classification:** 24029, 22989, 12182, 4213, 25058, 29119, 9868, 4213, 12791; **Surveillance:** 9868

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.

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; **Compliance:** 25024, 5259, 25019, 14971, 5469, 82079, 25012, 8000, 24028, 9868, 62304; **Authority:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Evaluation:** 25024, 24027, 42001, 5259, 25059, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119; **Obligation:** 42001, 24028; **Regulation:** 5259, 22989, 14971, 8000, 29119, 9868, 62304; **High-risk:** 9868; **Provider:** 5259, 25019, 12182, 38507, 24028, 9868, 42112; **Surveillance:** 9868

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.

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; **Authority:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Evaluation:** 25024, 24027, 42001, 5259, 25059, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119; **Provider:** 5259, 25019, 12182, 38507, 24028, 9868, 42112; **Surveillance:** 9868

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.

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; **Compliance:** 25024, 5259, 25019, 14971, 5469, 82079, 25012, 8000, 24028, 9868, 62304; **Authority:** 25024, 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119; **Fine:** 31010; **Obligation:** 42001, 24028; **Regulation:** 5259, 22989, 14971, 8000, 29119, 9868, 62304; **Subject:** 25024, 24027, 5259, 25059, 24029, 23894, 22989, 25010, 27000, 14971, 12182, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 62304, 20547

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.

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; **Corrective action:** 42001, 27000, 14971; **Provider:** 5259, 25019, 12182, 38507, 24028, 9868, 42112

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.

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; **Corrective action:**

ARTICLE 81

Art. 81

Union safeguard procedure

Safeguard: 42001, 25012

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.

Compliance: 25024, 5259, 25019, 14971, 5469, 82079, 25012, 8000, 24028, 9868, 62304; **Authority:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Evaluation:** 25024, 24027, 42001, 5259, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 82079, 12182, 25012, 8000, 4213, 25058, 29119, 9868, 4213, 25223, 24668; **Surveillance:** 9868; **Operator:** 25059, 25019, 25010, 26514, 9868, 17903

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.

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; **System:** 25024, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119; **Measure:** 25024, 5259, 24027, 42001, 5259, 25059, 25019, 22989, 25010, 27000, 14971, 5469, 31000, 25012, 8000, 4213, 25058, 29119, 9868, 4213, 25223, 24668

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.

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; **Compliance:** 25024, 5259, 25019, 14971, 5469, 82079, 25012, 8000, 24028, 9868, 62304; **System:** 25024, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119; **Regulation:** 5259, 22989, 14971, 8000, 29119, 9868, 62304; **Specification:** 24029, 25019, 22989, 25010, 14971, 5469, 25012, 29119, 62304, 20547; **Measure:** 25024, 5259, 24027, 42001, 5259, 25059, 25019, 22989, 25010, 27000, 14971, 5469, 31000, 25012, 8000, 4213, 25058, 29119, 9868, 4213, 25223, 24668

ARTICLE 82

Art. 82

Compliant AI systems which present a risk

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; **Risk:** 8183, 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42005, 24668

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.

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; **Authority:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Evaluation:** 25024, 24027, 42001, 5259, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 82079, 12182, 25012, 8000, 4213, 25058, 17847, 29119, 9868, 62304, 25059, 23282; **Risk:** 8183, 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42005, 24668; **System:** 25024, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119; **Regulation:** 5259, 22989, 14971, 8000, 29119, 9868, 62304; **Fundamental right:** 9868; **Health:** 42001, 5338, 25019, 25010, 27000, 14971, 5469, 12182, 29119, 9868, 5339, 62304, 22989, 18988; **Safety:** 42001, 5338, 24029, 25019, 22989, 25010, 27000, 14971, 5469, 24368, 8000, 24028, 29119, 9868, 62304, 25059, 22440, 22440, 22440; **High-risk:** 9868; **Service:** 25024, 8183, 42001, 5259, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 82079, 12182, 8000, 38507, 24028, 26514, 29119, 9868, 5339, 62304, 25059, 5392, 20547, 24668; **Surveillance:** 9868; **Protection:** 23894, 25010, 27000, 8000, 29119, 9868, 62304, 17903; **Operator:** 25059, 25019, 25010, 26514, 9868, 17903

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.

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; **Authority:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Corrective action:** 42001, 27000, 14971; **Provider:** 5259, 25019, 12182, 38507, 24028, 9868, 42112; **Surveillance:** 9868; **Operator:** 25059, 25019, 25010, 26514, 9868, 17903

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.

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; **Chain:** 12182, 8000; **Origin of data:** 5259; **Risk:** 8183, 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42005, 24668; **System:** 25024, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119; **Data:** 25024, 5259, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 12182, 24030, 31000, 25012, 38507, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 25223, 5259, 5392, 17903, 20546, 20547, 20547, 20547, 23053, 24372, 24668, 25223, 42103; **Information:** 25024, 5259, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 24030, 31000, 25012, 8000, 38500, 38507, 24028, 6254, 8200, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 42006, 12792, 5392, 17903, 20547, 20547, 20547, 42112

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.

Evaluation: 25024, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; **Authority:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Measure:** 25024, 5259, 24027, 42001, 5259, 25059, 25019, 22989, 25010, 27000, 14971, 5469, 31000, 25012, 8000, 4213, 25058, 29119, 9868, 4213, 25223, 24668

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.

ARTICLE 83

Art. 83

Formal non-compliance

Compliance: 25024, 5259, 25019, 14971, 5469, 82079, 25012, 8000, 24028, 9868, 62304

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:

Compliance: 25024, 5259, 25019, 14971, 5469, 82079, 25012, 8000, 24028, 9868, 62304; **Authority:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Provider:** 5259, 25019, 12182, 38507, 24028, 9868, 42112; **Surveillance:** 9868

Art. 83, 1(a)

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

Art. 83, 1(b)

the CE marking has not been affixed;

Art. 83, 1(c)

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

Declaration: 25024, 24027, 5259, 24029, 23894, 22989, 27000, 14971, 12182, 31000, 8000, 24028, 4213, 26514, 29119, 9868; **Conformity:** 25024, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 12182, 24030, 31000, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 42006, 24668

Art. 83, 1(d)

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

Declaration: 25024, 24027, 5259, 24029, 23894, 22989, 27000, 14971, 12182, 31000, 8000, 24028, 4213, 26514, 29119, 9868; **Conformity:** 25024, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 12182, 24030, 31000, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 42006, 24668

Art. 83, 1(e)

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

Database: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24030, 31000, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 25223, 20546

Art. 83, 1(f)

where applicable, no authorised representative has been appointed;

Authorised representative: 14971

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

Art. 83, 1(g)

Technical documentation is not available.

Technical documentation: 25019; **Documentation:** 42001, 5259, 25019, 25010, 27000, 14971, 5469, 82079, 26514, 29119, 62304, 42005

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.

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; **Compliance:** 25024, 5259, 25019, 14971, 5469, 82079, 25012, 8000, 24028, 9868, 62304; **Authority:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Risk:** 8183, 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42005, 24668; **System:** 25024, 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119; **High-risk:** 9868; **Surveillance:** 9868

ARTICLE 84

Art. 84

Union AI testing support structures

Support: 25024, 8183, 42001, 5259, 5338, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 82079, 24030, 25012, 8000, 38500, 26514, 29119, 62304, 42006, 17903, 20547, 24668, 25029; **Testing:** 25024, 24027, 25059, 24029, 24029, 25019, 22989, 25010, 82079, 12182, 24028, 26514, 25058, 29119, 9868, 62304, 12791, 42119

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.

Support: 25024, 8183, 42001, 5259, 5338, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 82079, 24030, 25012, 8000, 38500, 26514, 29119, 62304, 42006, 17903, 20547, 24668, 25029; **Testing:** 25024, 24027, 25059, 24029, 24029, 25019, 22989, 25010, 82079, 12182, 24028, 26514, 25058, 29119, 9868, 62304, 12791, 42119; **Regulation:** 5259, 22989, 14971, 8000, 29119, 9868, 62304; **Task:** 42001, 5259, 25059, 24029, 24029, 25019, 22989, 25010, 14971, 24030, 25012, 24028, 26514, 29119, 62304, 4213, 12791, 20547, 23281, 25258

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.

Authority: 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Support:** 25024, 8183, 42001, 5259, 5338, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 82079, 24030, 25012, 8000, 38500, 26514, 29119, 62304, 42006, 17903, 20547, 24668, 25029; **Testing:** 25024, 24027, 25059, 24029, 24029, 25019, 22989, 25010, 82079, 12182, 24028, 26514, 25058, 29119, 9868, 22989, 25010, 82079, 12182, 24028, 26514, 25058, 29119, 9868, 62304, 12791, 42119; **Task:** 42001, 5259, 25059, 24029, 24029, 25019, 22989, 25010, 14971, 24030, 25012, 24028, 26514, 29119, 62304, 4213, 12791, 20547, 23281, 25258; **Surveillance:** 9868

ARTICLE 85

SECTION 4

Remedies

Art. 85

Right to lodge a complaint with a market surveillance authority

Authority: 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Surveillance:** 9868

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.

Authority: 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Regulation:** 5259, 22989, 14971, 8000, 29119, 9868, 62304; **Surveillance:** 9868; **Purpose:** 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 82079, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 20547

ARTICLE 86

Art. 86

Right to explanation of individual decision-making

Decision-making: 24027, 42001, 5259, 25059, 27000, 31000, 8000, 29119, 62304, 24668

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.

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; **Risk:** 8183, 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42005, 24668; **System:** 25024, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119; **Fundamental right:** 9868; **Health:** 42001, 5338, 25019, 25010, 27000, 14971, 5469, 12182, 29119, 9868, 5339, 62304, 22989, 18988; **Safety:** 42001, 5338, 24029, 25019, 22989, 25010, 27000, 14971, 5469, 24368, 8000, 24028, 29119, 9868, 62304, 25059, 22440, 22440, 22440; **High-risk:** 9868; **Decision-making:** 24027, 42001, 5259, 25059, 27000, 31000, 8000, 29119, 62304, 24668; **Subject:** 25024, 24027, 5259, 5259, 24029, 23894, 22989, 25010, 27000, 14971, 12182, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 62304, 20547

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.

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; **Compliance:** 25024, 5259, 25019, 14971, 5469, 82079, 25012, 8000, 24028, 9868, 62304; **Obligation:** 42001, 24028

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.

ARTICLE 87

Art. 87

Reporting of infringements and protection of reporting persons

Protection: 23894, 25010, 27000, 8000, 29119, 9868, 62304, 17903

Art. 87

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

Regulation: 5259, 22989, 14971, 8000, 29119, 9868, 62304; **Protection:** 23894, 25010, 27000, 8000, 29119, 9868, 62304, 17903

ARTICLE 88

SECTION 5

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

AI model: 22989, 5469, 4213; **Monitoring:** 42001, 23894, 25019, 27000, 31010, 14971, 5469, 8000, 24028, 29119, 9868, 62304; **Provider:** 5259, 25019, 12182, 38507, 24028, 9868, 42112; **Purpose:** 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 82079, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 20547

Art. 88

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

AI model: 22989, 5469, 4213; **Obligation:** 42001, 24028; **Provider:** 5259, 25019, 12182, 38507, 24028, 9868, 42112; **Purpose:** 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 82079, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 20547

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.

Task: 42001, 5259, 25059, 24029, 24029, 25019, 22989, 25010, 14971, 24030, 25012, 24028, 26514, 29119, 62304, 4213, 12791, 20547, 23281, 25258

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.

Authority: 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Regulation:** 5259, 22989, 14971, 8000, 29119, 9868, 62304; **Task:** 42001, 5259, 25059, 24029, 24029, 25019, 22989, 25010, 14971, 24030, 25012, 24028, 26514, 29119, 62304, 4213, 12791, 20547, 23281, 25258; **Surveillance:** 9868

ARTICLE 89

Art. 89

Monitoring actions

Monitoring: 42001, 23894, 25019, 27000, 31010, 14971, 5469, 8000, 24028, 29119, 9868, 62304

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.

AI model: 22989, 5469, 4213; **Compliance:** 25024, 5259, 25019, 14971, 5469, 82079, 25012, 8000, 24028, 9868, 62304; **Regulation:** 5259, 22989, 14971, 8000, 29119, 9868, 62304; **Provider:** 5259, 25019, 12182, 38507, 24028, 9868, 42112; **Task:** 42001, 5259, 25059, 24029, 24029, 25019, 22989, 25010, 14971, 24030, 25012, 24028, 26514, 29119, 62304, 4213, 12791, 20547, 23281, 25258; **Purpose:** 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 82079, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 20547

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:

Regulation: 5259, 22989, 14971, 8000, 29119, 9868, 62304; **Provider:** 5259, 25019, 12182, 38507, 24028, 9868, 42112

Art. 89, 2(a)

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

AI model: 22989, 5469, 4213; **Provider:** 5259, 25019, 12182, 38507, 24028, 9868, 42112; **Contact:** 31010, 14971, 82079; **Purpose:** 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 82079, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 20547

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;

AI model: 22989, 5469, 4213; **Regulation:** 5259, 22989, 14971, 8000, 29119, 9868, 62304; **Provider:** 5259, 25019, 12182, 38507, 24028, 9868, 42112; **Purpose:** 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 82079, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 20547

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.

Provider: 5259, 25019, 12182, 38507, 24028, 9868, 42112; **Information:** 25024, 5259, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 24368, 12182, 24030, 31000, 25012, 8000, 38500, 38507, 24028, 6254, 8200, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 42006, 12792, 5392, 17903, 20547, 20547, 20547, 42112

ARTICLE 90

Art. 90

Alerts of systemic risks by the scientific panel

Art. 90, 1

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

Art. 90, 1(a)

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

AI model: 22989, 5469, 4213; **Risk:** 8183, 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42005, 24668; **Purpose:** 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 82079, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 20547

Art. 90, 1(b)

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

AI model: 22989, 5469, 4213; **Purpose:** 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 82079, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 20547

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.

Measure: 25024, 5259, 24027, 42001, 5259, 25059, 25019, 22989, 25010, 27000, 14971, 5469, 31000, 25012, 8000, 4213, 25058, 29119, 9868, 4213, 25223, 24668; **Purpose:** 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 82079, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 20547

Art. 90, 3

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

Art. 90, 3(a)

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

AI model: 22989, 5469, 4213; **Risk:** 8183, 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42005, 24668; **Provider:** 5259, 25019, 12182, 38507, 24028, 9868, 42112; **Contact:** 31010, 14971, 82079; **Purpose:** 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 82079, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 20547

Art. 90, 3(b)

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

Art. 90, 3(c)

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

Information: 25024, 5259, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 24368, 12182, 24030, 31000, 25012, 8000, 38500, 38507, 24028, 6254, 8200, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 42006, 12792, 5392, 17903, 20547, 20547, 20547, 42112

ARTICLE 91

Art. 91

Power to request documentation and information

Documentation: 42001, 5259, 25019, 25010, 27000, 14971, 5469, 82079, 26514, 29119, 62304, 42005; **Information:** 25024, 5259, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 24368, 12182, 24030, 31000, 25012, 8000, 38500, 38507, 24028, 6254, 8200, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 42006, 12792, 5392, 17903, 20547, 20547, 20547, 42112

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.

AI model: 22989, 5469, 4213; **Compliance:** 25024, 5259, 25019, 14971, 5469, 82079, 25012, 8000, 24028, 9868, 62304; **Regulation:** 5259, 22989, 14971, 8000, 29119, 9868, 62304; **Provider:** 5259, 25019, 12182, 38507, 24028, 9868, 42112; **Documentation:** 42001, 5259, 25019, 25010, 27000, 14971, 5469, 82079, 26514, 29119, 62304, 42005; **Information:** 25024, 5259, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 24368, 12182, 24030, 31000, 25012, 8000, 38500, 38507, 24028, 6254, 8200, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 42006, 12792, 5392, 17903, 20547, 20547, 20547, 42112; **Task:** 42001, 5259, 25059, 24029, 24029, 25019, 22989, 25010, 14971, 24030, 25012, 24028, 26514, 29119, 62304, 4213, 12791, 20547, 23281, 25258; **Purpose:** 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 82079, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 20547

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.

AI model: 22989, 5469, 4213; **Provider:** 5259, 25019, 12182, 38507, 24028, 9868, 42112; **Information:** 25024, 5259, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 24368, 12182, 24030, 31000, 25012, 8000, 38500, 38507, 24028, 6254, 8200, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 42006, 12792, 5392, 17903, 20547, 20547, 20547, 42112; **Purpose:** 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 82079, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 20547

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).

AI model: 22989, 5469, 4213; **Access:** 25024, 25019, 22989, 25010, 27000, 14971, 82079, 26514, 29119, 9868, 5339, 62304, 17903; **Provider:** 5259, 25019, 12182, 38507, 24028, 9868, 42112; **Information:** 25024, 5259, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 24368, 12182, 24030, 31000, 25012, 8000, 38500, 38507, 24028, 6254, 8200, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 42006, 12792, 5392, 17903, 20547, 20547, 20547, 42112; **Task:** 42001, 5259, 25059, 24029, 24029, 25019, 22989, 25010, 14971, 24030, 25012, 24028, 26514, 29119, 62304, 4213, 12791, 20547, 23281, 25258; **Purpose:** 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 82079, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 20547

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.

Fine: 31010; **Information:** 25024, 5259, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 24368, 12182, 24030, 31000, 25012, 8000, 38500, 38507, 24028, 6254, 8200, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 42006, 12792, 5392, 17903, 20547, 20547, 20547, 42112; **Purpose:** 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 82079, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 20547

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

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.

AI model: 22989, 5469, 4213; **Provider:** 5259, 25019, 12182, 38507, 24028, 9868, 42112; **Information:** 25024, 5259, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 24368, 12182, 24030, 31000, 25012, 8000, 38500, 38507, 24028, 6254, 8200, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 42006, 12792, 5392, 17903, 20547, 20547, 20547, 42112; **Purpose:** 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 82079, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 20547

ARTICLE 92

Art. 92

Power to conduct evaluations

Art. 92, 1

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

AI model: 22989, 5469, 4213; **Purpose:** 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 82079, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 20547

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

Compliance: 25024, 5259, 25019, 14971, 5469, 82079, 25012, 8000, 24028, 9868, 62304; **Obligation:** 42001, 24028; **Regulation:** 5259, 22989, 14971, 8000, 29119, 9868, 62304; **Provider:** 5259, 25019, 12182, 38507, 24028, 9868, 42112; **Information:** 25024, 5259, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 24368, 12182, 24030, 31000, 25012, 8000, 38500, 38507, 24028, 6254, 8200, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 42006, 12792, 5392, 17903, 20547, 20547, 20547, 42112

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).

AI model: 22989, 5469, 4213; **Risk:** 8183, 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 6339, 62304, 42005, 24668; **Purpose:** 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 82079, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 20547

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).

Task: 42001, 5259, 25059, 24029, 24029, 25019, 22989, 25010, 14971, 24030, 25012, 24028, 26514, 29119, 62304, 4213, 12791, 20547, 23281, 25258

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.

AI model: 22989, 5469, 4213; **Access:** 25024, 25019, 22989, 25010, 27000, 14971, 82079, 26514, 29119, 9868, 5339, 62304, 17903; **Purpose:** 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 82079, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 20547

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.

Access: 25024, 25019, 22989, 25010, 27000, 14971, 82079, 26514, 29119, 9868, 5339, 62304, 17903; **Fine:** 31010; **Purpose:** 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 82079, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 20547

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.

AI model: 22989, 5469, 4213; **Access:** 25024, 25019, 22989, 25010, 27000, 14971, 82079, 26514, 29119, 9868, 5339, 62304, 17903; **Provider:** 5259, 25019, 12182, 38507, 24028, 9868, 42112; **Information:** 25024, 5259, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 24368, 12182, 24030, 31000, 25012, 8000, 38500, 38507, 24028, 6254, 8200, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 42006, 12792, 5392, 17903, 20547, 20547, 20547, 42112; **Purpose:** 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 82079, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 20547

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).

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.

AI model: 22989, 5469, 4213; **Access:** 25024, 25019, 22989, 25010, 27000, 14971, 82079, 26514, 29119, 9868, 5339, 62304, 17903; **Testing:** 25024, 24027, 25059, 24029, 24029, 25019, 22989, 25010, 82079, 12182, 24028, 26514, 25058, 29119, 9868, 62304, 12791, 42118; **Safeguard:** 42001, 25012; **Provider:** 5259, 25019, 12182, 38507, 24028, 9868, 42112; **Information:** 25024, 5259, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 24368, 12182, 24030, 31000, 25012, 8000, 38500, 38507, 24028, 6254, 8200, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 42006, 12792, 5392, 17903, 20547, 20547, 20547, 42112; **Purpose:** 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 82079, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 20547

ARTICLE 93

Art. 93

Power to request measures

Art. 93, 1

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

Provider: 5259, 25019, 12182, 38507, 24028, 9868, 42112

Art. 93, 1(a)

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

Obligation: 42001, 24028

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;

Evaluation: 25024, 24027, 42001, 5259, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 82079, 12182, 25012, 8000, 4213, 25058, 17847, 29119, 9868, 62304, 25059, 23282; **Risk:** 8183, 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42005, 24668

Art. 93, 1(c)

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

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.

AI model: 22989, 5469, 4213; **Provider:** 5259, 25019, 12182, 38507, 24028, 9868, 42112; **Measure:** 25024, 5259, 24027, 42001, 5259, 25059, 25019, 22989, 25010, 27000, 14971, 5469, 31000, 25012, 8000, 4213, 25058, 29119, 9868, 4213, 25223, 24668; **Purpose:** 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 82079, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 20547

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.

AI model: 22989, 5469, 4213; **Risk:** 8183, 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42005, 24668; **Provider:** 5259, 25019, 12182, 38507, 24028, 9868, 42112; **Purpose:** 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 82079, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 20547

ARTICLE 94

Art. 94

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

AI model: 22989, 5469, 4213; **Purpose:** 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 82079, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 20547

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.

AI model: 22989, 5469, 4213; **Regulation:** 5259, 22989, 14971, 8000, 29119, 9868, 62304; **Provider:** 5259, 25019, 12182, 38507, 24028, 9868, 42112; **Purpose:** 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 82079, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 20547

ARTICLE 95

CHAPTER X

CODES OF CONDUCT AND GUIDELINES

Art. 95

Codes of conduct for voluntary application of specific requirements

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.

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; **Best practice:** 18115; **Governance:** 8183, 42001, 5259, 25019, 22989, 27000, 31000, 8000, 38500, 38507, 24028, 22443, 18115; **Risk:** 8183, 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42005, 24668; **High-risk:** 9868

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:

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; **Measure:** 25024, 5259, 24027, 42001, 5259, 25059, 25019, 22989, 25010, 27000, 14971, 5469, 31000, 25012, 8000, 4213, 25058, 29119, 9868, 4213, 25223, 24668

Art. 95, 2(a)

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

Trustworthy: 25019; **Ethic,** : 18115

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;

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; **Design:** 25024, 24027, 42001, 25059, 24029, 24029, 23894, 25019, 22989, 25010, 14971, 5469, 24970, 82079, 12182, 24030, 25012, 8000, 4213, 26514, 29119, 9868, 62304, 20547, 25029; **Training:** 24027, 5259, 5338, 24029, 22989, 5469, 25012, 8000, 24028, 4213, 26514, 29119, 23053, 42112; **Sustainability:** 20226

Art. 95, 2(c)

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

Operation: 25024, 8183, 42001, 5259, 25059, 25019, 22989, 25010, 27000, 5469, 24030, 25012, 8000, 24028, 26514, 29119, 9868, 62304, 20547

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;

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; **Design:** 25024, 24027, 42001, 25059, 24029, 24029, 23894, 25019, 22989, 25010, 14971, 5469, 24970, 82079, 12182, 24030, 25012, 8000, 4213, 26514, 29119, 9868, 62304, 20547, 25029

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.

Accessibility: 25024, 5259, 25059, 25019, 25010, 27000, 14971, 82079, 25012, 26514, 29119; **AI system:** 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; **Disability:** 25010, 14971, 26514

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.

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; **Similarity:** 5259; **Society:** 42001, 25059, 25019, 14971, 24368, 26514, 22443, 5339, 42005; **Provider:** 5259, 25019, 12182, 38507, 24028, 9868, 42112; **Purpose:** 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 82079, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 20547; **Intended purpose:** 5259, 14971

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.

SME: 26514

ARTICLE 96

Art. 96

Guidelines from the Commission on the implementation of this Regulation

Regulation: 5259, 22989, 14971, 8000, 29119, 9868, 62304

Art. 96, 1

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

Regulation: 5259, 22989, 14971, 8000, 29119, 9868, 62304

Art. 96, 1(a)

the application of the requirements and obligations referred to in Articles 8 to 15 and in Article 25;

Obligation: 42001, 24028

Art. 96, 1(b)

the prohibited practices referred to in Article 5;

Art. 96, 1(c)

the practical implementation of the provisions related to substantial modification;

Art. 96, 1(d)

the practical implementation of transparency obligations laid down in Article 50;

Obligation: 42001, 24028; **Transparency:** 42001, 25059, 25019, 22989, 5469, 24028, 29119, 9868, 25223, 12792

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;

Consistency: 25024, 5259, 42001, 82079, 25012, 8000, 24028, 42006, 20547; **Regulation:** 5259, 22989, 14971, 8000, 29119, 9868, 62304; **Information:** 25024, 5259, 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 24368, 12182, 24030, 31000, 25012, 8000, 38500, 38507, 24028, 6254, 8200, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 42006, 12792, 5392, 17903, 20547, 20547, 20547, 42112

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.

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; **Authority:** 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Sector:** 42001, 5259, 22989, 27000, 31000, 9868, 24668; **System:** 25024, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119; **Regulation:** 5259, 22989, 14971, 8000, 29119, 9868, 62304; **SME:** 26514; **Specification:** 24029, 25019, 22989, 25010, 14971, 5469, 25012, 29119, 62304, 20547

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.

ARTICLE 97

CHAPTER XI

DELEGATION OF POWER AND COMMITTEE PROCEDURE

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

Art. 97

Exercise of the delegation

Art. 97, 1

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

Subject: 25024, 24027, 5259, 5259, 24029, 23894, 22989, 25010, 27000, 14971, 12182, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 62304, 20547

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.

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.

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.

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.

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.

Notification: 5259, 14971

ARTICLE 98**Art. 98**

Committee procedure

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.

Regulation: 5259, 22989, 14971, 8000, 29119, 9868, 62304

Art. 98, 2

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

Regulation: 5259, 22989, 14971, 8000, 29119, 9868, 62304

ARTICLE 99**CHAPTER XII**

PENALTIES

Art. 99

Penalties

Art. 99, 1

In accordance with the terms and conditions laid down in this Regulation, Member States shall lay down the rules on penalties and other enforcement measures, which may also include warnings and non-monetary measures, applicable to infringements of this Regulation by operators, and shall take all measures necessary to ensure that they are properly and effectively implemented, thereby taking into account the guidelines issued by the Commission pursuant to Article 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.

Regulation: 5259, 22989, 14971, 8000, 29119, 9868, 62304; **SME:** 26514

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.

Amendment: 8183, 42001, 5259, 25059, 5338, 24029, 23894, 31010, 5469, 82079, 25012, 8000, 24028, 4213, 26514, 25058, 9868, 5339, 62304, 22989, 23053

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.

Compliance: 25024, 5259, 25019, 14971, 5469, 82079, 25012, 8000, 24028, 9868, 62304; **Fine:** 31010; **Subject:** 25024, 24027, 5259, 5259, 24029, 23894, 22989, 25010, 27000, 14971, 12182, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 62304, 20547

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:

Compliance: 25024, 5259, 25019, 14971, 5469, 82079, 25012, 8000, 24028, 9868, 62304; **Fine:** 31010; **Subject:** 25024, 24027, 5259, 5259, 24029, 23894, 22989, 25010, 27000, 14971, 12182, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 62304, 20547

Art. 99, 4(a)

obligations of providers pursuant to Article 16;

Obligation: 42001, 24028; **Provider:** 5259, 25019, 12182, 38507, 24028, 9868, 42112

Art. 99, 4(b)

obligations of authorised representatives pursuant to Article 22;

Obligation: 42001, 24028; **Authorised representative:** 14971

Art. 99, 4(c)

obligations of importers pursuant to Article 23;

Obligation: 42001, 24028; **Importer:** 14971

Art. 99, 4(d)

obligations of distributors pursuant to Article 24;

Obligation: 42001, 24028

Art. 99, 4(e)

obligations of employers pursuant to Article 26;

Obligation: 42001, 24028

Art. 99, 4(f)

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

Obligation: 42001, 24028

Art. 99, 4(g)

transparency obligations for providers and employers pursuant to Article 50.

Obligation: 42001, 24028; **Provider:** 5259, 25019, 12182, 38507, 24028, 9868, 42112; **Transparency:** 42001, 25059, 25019, 22989, 5469, 24028, 29119, 9868, 25223, 12792

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.

Authority: 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Fine:** 31010; **Information:** 25024, 5259, 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 24368, 12182, 24030, 31000, 25012, 8000, 38500, 38507, 24028, 6254, 8200, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 42006, 12792, 5392, 17903, 20547, 20547, 20547, 42112; **Subject:** 25024, 24027, 5259, 5259, 24029, 23894, 22989, 25010, 27000, 14971, 12182, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 62304, 20547

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

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.

Fine: 31010, **SME:** 26514

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:

Fine: 31010

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;

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; **System:** 25024, 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119; **Purpose:** 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 82079, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 20547

Art. 99, 7(b)

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

Authority: 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Fine:** 31010; **Surveillance:** 9868; **Operator:** 25059, 25019, 25010, 26514, 9868, 17903

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;

Authority: 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Fine:** 31010; **Regulation:** 5259, 22989, 14971, 8000, 29119, 9868, 62304; **Operator:** 25059, 25019, 25010, 26514, 9868, 17903

Art. 99, 7(d)

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

Operator: 25059, 25019, 25010, 26514, 9868, 17903

Art. 99, 7(e)

any other aggravating or mitigating factor applicable to the circumstances of the case, such as financial benefits gained, or losses avoided, directly or indirectly, from the infringement;

Art. 99, 7(f)

the degree of cooperation with the national competent authorities, in order to remedy the infringement and mitigate the possible adverse effects of the infringement;

Authority: 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Cooperation:** 24029, 26514, 5392

Art. 99, 7(g)

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

Responsibility: 25024, 42001, 25059, 25019, 22989, 27000, 14971, 8000, 24028, 26514, 9868, 5339, 62304; **Operator:** 25059, 25019, 25010, 26514, 9868, 17903

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;

Authority: 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Operator:** 25059, 25019, 25010, 26514, 9868, 17903

Art. 99, 7(i)

the intentional or negligent character of the infringement;

Art. 99, 7(j)

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

Operator: 25059, 25019, 25010, 26514, 9868, 17903

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.

Authority: 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868; **Fine:** 31010

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.

System: 25024, 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119; **Fine:** 31010

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.

Safeguard: 42001, 25012; **Subject:** 25024, 24027, 5259, 5259, 24029, 23894, 22989, 25010, 27000, 14971, 12182, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 62304, 20547

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.

Fine: 31010

ARTICLE 100

Art. 100

Administrative fines on Union institutions, bodies, offices and agencies

Fine: 31010

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:

Fine: 31010; **Regulation:** 5259, 22989, 14971, 8000, 29119, 9868, 62304; **Data:** 25024, 5259, 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 12182, 24030, 31000, 25012, 38507, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 25223, 5259, 5392, 17903, 20546, 20547, 20547, 20547, 20547, 23053, 24372, 24668, 25523, 42103; **Protection:** 23894, 25010, 27000, 8000, 29119, 9868, 62304, 17903; **Data protection:** 29119

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;

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119; **System:** 25024, 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119; **Purpose:** 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 82079, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 20547

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;

Responsibility: 25024, 42001, 25059, 25019, 22989, 27000, 14971, 8000, 24028, 26514, 9868, 5339, 62304

Art. 100, 1(c)

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

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;

Compliance: 25024, 5259, 25019, 14971, 5469, 82079, 25012, 8000, 24028, 9868, 62304; **Cooperation:** 24029, 26514, 5392; **Data:** 25024, 5259, 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 12182, 24030, 31000, 25012, 38507, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 20547, 20547, 20547, 20547, 20547, 23053, 24372, 24668, 25523, 42103; **Protection:** 23894, 25010, 27000, 8000, 29119, 9868, 62304, 17903; **Data protection:** 29119; **Subject:** 25024, 24027, 5259, 5259, 24029, 23894, 22989, 25010, 27000, 14971, 12182, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 62304, 20547

Art. 100, 1(e)

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

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

Art. 102.a

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.'

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; **Security:** 25024, 42001, 25059, 24029, 25019, 22989, 25010, 27000, 14971, 24030, 24028, 29119, 9868, 62304, 42006, 20547, 20547; **Artificial intelligence:** 5259, 8183, 24027, 42001, 5259, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 5469, 24970, 24368, 24030, 8000, 38507, 24028, 6254, 8200, 4213, 25058, 17847, 29119, 22443, 9868, 5339, 42006, 5392, 17903, 23053, 24372, 22989, 23053; **Regulation:** 5259, 22989, 14971, 8000, 29119, 9868, 62304; **Specification:** 24029, 25019, 22989, 25010, 14971, 5469, 25012, 29119, 62304, 20547

ARTICLE 103

Art. 103

Amendment to Regulation (EU) No 167/2013

Amendment: 8183, 42001, 5259, 25059, 5338, 24029, 23894, 31010, 5469, 82079, 25012, 8000, 24028, 4213, 26514, 25058, 9868, 5339, 62304, 22989, 23053; **Regulation:** 5259, 22989, 14971, 8000, 29119, 9868, 62304

Art. 103.a

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.'

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; **Artificial intelligence:** 5259, 8183, 24027, 42001, 5259, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 5469, 24970, 24368, 24030, 8000, 38507, 24028, 6254, 8200, 4213, 25058, 17847, 29119, 22443, 9868, 5339, 42006, 5392, 17903, 23053, 24372, 22989, 23053; **Regulation:** 5259, 22989, 14971, 8000, 29119, 9868, 62304; **Safety:** 42001, 5338, 24029, 25019, 22989, 25010, 27000, 14971, 5469, 24368, 8000, 24028, 29119, 9868, 62304, 25059, 22440, 22440, 22440

ARTICLE 104

Art. 104

Amendment to Regulation (EU) No 168/2013

Amendment: 8183, 42001, 5259, 25059, 5338, 24029, 23894, 31010, 5469, 82079, 25012, 8000, 24028, 4213, 26514, 25058, 9868, 5339, 62304, 22989, 23053; **Regulation:** 5259, 22989, 14971, 8000, 29119, 9868, 62304

Art. 104.a

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.'

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; **Artificial intelligence:** 5259, 8183, 24027, 42001, 5259, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 5469, 24970, 24368, 24030, 8000, 38507, 24028, 6254, 8200, 4213, 25058, 17847, 29119, 22443, 9868, 5339, 42006, 5392, 17903, 23053, 24372, 22989, 23053; **Regulation:** 5259, 22989, 14971, 8000, 29119, 9868, 62304; **Safety:** 42001, 5338, 24029, 25019, 22989, 25010, 27000, 14971, 5469, 24368, 8000, 24028, 29119, 9868, 62304, 25059, 22440, 22440, 22440

ARTICLE 105

Art. 105

Amendment to Directive 2014/90/EU

Amendment: 8183, 42001, 5259, 25059, 5338, 24029, 23894, 31010, 5469, 82079, 25012, 8000, 24028, 4213, 26514, 25058, 9868, 5339, 62304, 22989, 23053

Art. 105.a

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.'

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; **Artificial intelligence:** 5259, 8183, 24027, 42001, 5259, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 5469, 24970, 24368, 24030, 8000, 38507, 24028, 6254, 8200, 4213, 25058, 17847, 29119, 22443, 9868, 5339, 42006, 5392, 17903, 23053, 24372, 22989, 23053; **Testing:** 25024, 24027, 25059, 24029, 24029, 25019, 22989, 25010, 82079, 12182, 24028, 26514, 25058, 29119, 9868, 62304, 12791, 42119; **Regulation:** 5259, 22989, 14971, 8000, 29119, 9868, 62304; **Safety:** 42001, 5338, 24029, 25019, 22989, 25010, 27000, 14971, 5469, 24368, 8000, 24028, 29119, 9868, 62304, 25059, 22440, 22440, 22440

ARTICLE 106

Art. 106

Amendment to Directive (EU) 2016/797

Amendment: 8183, 42001, 5259, 25059, 5338, 24029, 23894, 31010, 5469, 82079, 25012, 8000, 24028, 4213, 26514, 25058, 9868, 5339, 62304, 22989, 23053

Art. 106.a

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.'

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; **Artificial intelligence:** 5259, 8183, 24027, 42001, 5259, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 5469, 24970, 24368, 24030, 8000, 38507, 24028, 6254, 8200, 4213, 25058, 17847, 29119, 22443, 9868, 5339, 42006, 5392, 17903, 23053, 24372, 22989, 23053; **Regulation:** 5259, 22989, 14971, 8000, 29119, 9868, 62304; **Safety:** 42001, 5338, 24029, 25019, 22989, 25010, 27000, 14971, 5469, 24368, 8000, 24028, 29119, 9868, 62304, 25059, 22440, 22440, 22440

ARTICLE 107

Art. 107

Amendment to Regulation (EU) 2018/858

Amendment: 8183, 42001, 5259, 25059, 5338, 24029, 23894, 31010, 5469, 82079, 25012, 8000, 24028, 4213, 26514, 25058, 9868, 5339, 62304, 22989, 23053; **Regulation:** 5259, 22989, 14971, 8000, 29119, 9868, 62304

Art. 107.a

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.'

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; **Artificial intelligence:** 5259, 8183, 24027, 42001, 5259, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 5469, 24970, 24368, 24030, 8000, 38507, 24028, 6254, 8200, 4213, 25058, 17847, 29119, 22443, 9868, 5339, 42006, 5392, 17903, 23053, 24372, 22989, 23053; **Regulation:** 5259, 22989, 14971, 8000, 29119, 9868, 62304; **Safety:** 42001, 5338, 24029, 25019, 22989, 25010, 27000, 14971, 5469, 24368, 8000, 24028, 29119, 9868, 62304, 25059, 22440, 22440, 22440

ARTICLE 108

Art. 108

Amendments to Regulation (EU) 2018/1139

Amendment: 8183, 42001, 5259, 25059, 5338, 24029, 23894, 31010, 5469, 82079, 25012, 8000, 24028, 4213, 26514, 25058, 9868, 5339, 62304, 22989, 23053; **Regulation:** 5259, 22989, 14971, 8000, 29119, 9868, 62304

Art. 108.a

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

Regulation: 5259, 22989, 14971, 8000, 29119, 9868, 62304

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.'

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; **Artificial intelligence:** 5259, 8183, 24027, 42001, 5259, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 5469, 24970, 24368, 24030, 8000, 38507, 24028, 6254, 8200, 4213, 25058, 17847, 29119, 22443, 9868, 5339, 42006, 5392, 17903, 23053, 24372, 22989, 23053; **Regulation:** 5259, 22989, 14971, 8000, 29119, 9868, 62304; **Safety:** 42001, 5338, 24029, 25019, 22989, 25010, 27000, 14971, 5469, 24368, 8000, 24028, 29119, 9868, 62304, 25059, 22440, 22440, 22440

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>);

Artificial intelligence: 5259, 8183, 24027, 42001, 5259, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 5469, 24970, 24368, 24030, 8000, 38507, 24028, 6254, 8200, 4213, 25058, 17847, 29119, 22443, 9868, 5339, 42006, 5392, 17903, 23053, 24372, 22989, 23053; **Regulation:** 5259, 22989, 14971, 8000, 29119, 9868, 62304

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

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.'

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; **Artificial Intelligence:** 5259, 8183, 24027, 42001, 5259, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 24029, 23894, 25019, 22989, 25010, 5469, 24970, 24368, 24030, 8000, 38507, 24028, 6254, 8200, 4213, 25058, 17847, 29119, 22443, 9868, 5339, 42006, 5392, 17903, 23053, 24372, 22989, 23053; **Regulation:** 5259, 22989, 14971, 8000, 29119, 9868, 62304; **Safety:** 42001, 5338, 24029, 25019, 22989, 25010, 27000, 14971, 5469, 24368, 8000, 24028, 29119, 9868, 62304, 25059, 22440, 22440, 22440

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.'

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; **Artificial Intelligence:** 5259, 8183, 24027, 42001, 5259, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 24029, 23894, 25019, 22989, 25010, 5469, 24970, 24368, 24030, 8000, 38507, 24028, 6254, 8200, 4213, 25058, 17847, 29119, 22443, 9868, 5339, 42006, 5392, 17903, 23053, 24372, 22989, 23053; **Regulation:** 5259, 22989, 14971, 8000, 29119, 9868, 62304; **Safety:** 42001, 5338, 24029, 25019, 22989, 25010, 27000, 14971, 5469, 24368, 8000, 24028, 29119, 9868, 62304, 25059, 22440, 22440, 22440

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.'

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; **Artificial Intelligence:** 5259, 8183, 24027, 42001, 5259, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 24029, 23894, 25019, 22989, 25010, 5469, 24970, 24368, 24030, 8000, 38507, 24028, 6254, 8200, 4213, 25058, 17847, 29119, 22443, 9868, 5339, 42006, 5392, 17903, 23053, 24372, 22989, 23053; **Regulation:** 5259, 22989, 14971, 8000, 29119, 9868, 62304; **Safety:** 42001, 5338, 24029, 25019, 22989, 25010, 27000, 14971, 5469, 24368, 8000, 24028, 29119, 9868, 62304, 25059, 22440, 22440, 22440

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.'

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; **Artificial Intelligence:** 5259, 8183, 24027, 42001, 5259, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 24029, 23894, 25019, 22989, 25010, 5469, 24970, 24368, 24030, 8000, 38507, 24028, 6254, 8200, 4213, 25058, 17847, 29119, 22443, 9868, 5339, 42006, 5392, 17903, 23053, 24372, 22989, 23053; **Regulation:** 5259, 22989, 14971, 8000, 29119, 9868, 62304; **Safety:** 42001, 5338, 24029, 25019, 22989, 25010, 27000, 14971, 5469, 24368, 8000, 24028, 29119, 9868, 62304, 25059, 22440, 22440, 22440

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.'

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; **Artificial Intelligence:** 5259, 8183, 24027, 42001, 5259, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 24029, 23894, 25019, 22989, 25010, 5469, 24970, 24368, 24030, 8000, 38507, 24028, 6254, 8200, 4213, 25058, 17847, 29119, 22443, 9868, 5339, 42006, 5392, 17903, 23053, 24372, 22989, 23053; **Regulation:** 5259, 22989, 14971, 8000, 29119, 9868, 62304; **Safety:** 42001, 5338, 24029, 25019, 22989, 25010, 27000, 14971, 5469, 24368, 8000, 24028, 29119, 9868, 62304, 25059, 22440, 22440, 22440

ARTICLE 109

Art. 109

Amendment to Regulation (EU) 2019/2144

Amendment: 8183, 42001, 5259, 25059, 5338, 24029, 23894, 31010, 5469, 82079, 25012, 8000, 24028, 4213, 26514, 25058, 9868, 5339, 62304, 22989, 23053; **Regulation:** 5259, 22989, 14971, 8000, 29119, 9868, 62304

Art. 109.a

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.'

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; **Artificial Intelligence:** 5259, 8183, 24027, 42001, 5259, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 24029, 23894, 25019, 22989, 25010, 5469, 24970, 24368, 24030, 8000, 38507, 24028, 6254, 8200, 4213, 25058, 17847, 29119, 22443, 9868, 5339, 42006, 5392, 17903, 23053, 24372, 22989, 23053; **Regulation:** 5259, 22989, 14971, 8000, 29119, 9868, 62304; **Safety:** 42001, 5338, 24029, 25019, 22989, 25010, 27000, 14971, 5469, 24368, 8000, 24028, 29119, 9868, 62304, 25059, 22440, 22440, 22440

ARTICLE 110

Art. 110

Amendment to Directive (EU) 2020/1828

Amendment: 8183, 42001, 5259, 25059, 5338, 24029, 23894, 31010, 5469, 82079, 25012, 8000, 24028, 4213, 26514, 25058, 9868, 5339, 62304, 22989, 23053

Art. 110.a

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/2024/1689/9>).

Artificial Intelligence: 5259, 8183, 24027, 42001, 5259, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 24029, 23894, 25019, 22989, 25010, 5469, 24970, 24368, 24030, 8000, 38507, 24028, 6254, 8200, 4213, 25058, 17847, 29119, 22443, 9868, 5339, 42006, 5392, 17903, 23053, 24372, 22989, 23053; **Regulation:** 5259, 22989, 14971, 8000, 29119, 9868, 62304

ARTICLE 111

Art. 111

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

AI model: 22989, 5469, 4213; **AI system:** 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; **Service:** 25024, 8183, 42001, 5259, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 82079, 12182, 8000, 38507, 24028, 26514, 29119, 9868, 5339, 62304, 25059, 5392, 20547, 24668; **Purpose:** 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 82079, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 20547

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.

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; **Compliance:** 25024, 5259, 25019, 14971, 5469, 82079, 25012, 8000, 24028, 9868, 62304; **Evaluation:** 25024, 24027, 42001, 5259, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 82079, 12182, 25012, 8000, 4213, 25058, 17847, 29119, 9868, 62304, 25059, 23282; **System:** 25024, 8183, 24027, 42001, 5259, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119; **Regulation:** 5259, 22989, 14971, 8000, 29119, 9868, 62304; **Service:** 25024, 8183, 42001, 5259, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 82079, 12182, 8000, 38507, 24028, 26514, 29119, 9868, 5339, 62304, 25059, 5392, 20547, 24668; **Subject:** 25024, 24027, 5259, 24029, 23894, 22989, 25010, 27000, 14971, 12182, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 62304, 20547

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.

AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115; **Authority:** 25024, 42001, 5259, 25019, 27000, 14971, 38507, 24028, 9868; **Risk:** 8183, 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42005, 24668; **Obligation:** 42001, 24028; **Regulation:** 5259, 22989, 14971, 8000, 29119, 9868, 62304; **High-risk:** 9868; **Provider:** 5259, 25019, 12182, 38507, 24028, 9868, 42112; **Service:** 25024, 8183, 42001, 5259, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 82079, 12182, 8000, 38507, 24028, 26514, 29119, 9868, 5339, 62304, 25059, 5392, 20547, 24668; **Subject:** 25024, 24027, 5259, 24029, 23894, 22989, 25010, 27000, 14971, 12182, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 62304, 20547

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.

AI model: 22989, 5469, 4213; **Obligation:** 42001, 24028; **Regulation:** 5259, 22989, 14971, 8000, 29119, 9868, 62304; **Provider:** 5259, 25019, 12182, 38507, 24028, 9868, 42112; **Purpose:** 8183, 24027, 42001, 5259, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 82079, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 20547

ARTICLE 112

Art

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

Art. 112, 2(a) the need for amendments extending existing area headings or adding new area headings in Annex III. Amendment: 8183, 42001, 5259, 25059, 5338, 24029, 23894, 31010, 5469, 82079, 25012, 8000, 24028, 4213, 26514, 25058, 9868, 5339, 62304, 22989, 23053

Art. 112, 2(b) amendments to the list of AI systems requiring additional transparency measures in Article 50. AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115. Amendment: 8183, 42001, 5259, 25059, 5338, 24029, 23894, 31010, 5469, 82079, 25012, 8000, 24028, 4213, 26514, 25058, 9868, 5339, 62304, 22989, 23053. Transparency: 42001, 25059, 25019, 22989, 5469, 24028, 29119, 9868, 25223, 12792

Art. 112, 2(c) amendments enhancing the effectiveness of the supervision and governance system. Amendment: 8183, 42001, 5259, 25059, 5338, 24029, 23894, 31010, 5469, 82079, 25012, 8000, 24028, 4213, 26514, 25058, 9868, 5339, 62304, 22989, 23053. Effectiveness: 5259, 42001, 25019, 25010, 27000, 31010, 14971, 12182, 8000, 26514, 29119, 62304, 17903, 20546. Governance: 8183, 42001, 5259, 25019, 22989, 27000, 31000, 8000, 38500, 38507, 24028, 22443, 18115. System: 25024, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 24970, 24368, 12182, 24030, 31000, 25012, 8000, 24028, 6254, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 20546, 20547, 23053, 24372, 20226, 22440, 22440, 22440, 23053, 23281, 23282, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119

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. Amendment: 8183, 42001, 5259, 25059, 5338, 24029, 23894, 31010, 5469, 82079, 25012, 8000, 24028, 4213, 26514, 25058, 9868, 5339, 62304, 22989, 23053. Evaluation: 25024, 24027, 42001, 5259, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 12182, 25012, 8000, 4213, 25058, 17847, 29119, 9868, 62304, 25059, 23282. Regulation: 5259, 22989, 14971, 8000, 29119, 9868, 62304. Review: 42001, 23894, 25019, 25010, 27000, 31010, 14971, 82079, 31000, 6254, 26514, 29119, 9868, 62304. Assessment: 25024, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 22443, 9868, 5339, 62304, 42006, 42005, 24668, 42119

Art. 112, 4 The reports referred to in paragraph 2 shall pay specific attention to the following:

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. Authority: 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868. Human: 24027, 42001, 25059, 24029, 25019, 22989, 25010, 27000, 31010, 14971, 82079, 24030, 31000, 25012, 8000, 24028, 26514, 29119, 9868, 62304, 5392, 23053, 42105, 42109. Regulation: 5259, 22989, 14971, 8000, 29119, 9868, 62304. Task: 42001, 5259, 25059, 24029, 24029, 25019, 22989, 25010, 14971, 24030, 25012, 24028, 26514, 29119, 62304, 4213, 12791, 20547, 23281, 25258. Resource: 5259, 42001, 5259, 25019, 22989, 25010, 27000, 82079, 12182, 25012, 26514, 29119, 5339, 62304, 20547, 23282

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. Fine: 31010, Regulation: 5259, 22989, 14971, 8000, 29119, 9868, 62304

Art. 112, 4(c) adopted harmonised standards and common specifications developed to support this Regulation. Support: 25024, 8183, 42001, 5259, 5338, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 82079, 24030, 25012, 8000, 38500, 26514, 29119, 62304, 42006, 17903, 20547, 24668, 25029. Regulation: 5259, 22989, 14971, 8000, 29119, 9868, 62304. Specification: 24029, 25019, 22989, 25010, 14971, 5469, 25012, 29119, 62304, 20547

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. Regulation: 5259, 22989, 14971, 8000, 29119, 9868, 62304. SME: 26514

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. Evaluation: 25024, 24027, 42001, 5259, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 82079, 12182, 25012, 8000, 4213, 25058, 17847, 29119, 9868, 62304, 25059, 23282. Regulation: 5259, 22989, 14971, 8000, 29119, 9868, 62304. Task: 42001, 5259, 25059, 24029, 24029, 25019, 22989, 25010, 14971, 24030, 25012, 24028, 26514, 29119, 62304, 4213, 12791, 20547, 23281, 25258. Resource: 5259, 42001, 5259, 25019, 22989, 25010, 27000, 82079, 12182, 25012, 26514, 29119, 5339, 62304, 20547, 23282

Art. 112, 6 By 2 August 2028 and every four years thereafter, the Commission shall submit a report on the review of the progress on the development of standardisation deliverables on the energy-efficient development of general-purpose AI models, and assess the need for further measures or actions, including binding measures or actions. The report shall be submitted to the European Parliament and to the Council, and it shall be made public. AI model: 22989, 5469, 4213. Review: 42001, 23894, 25019, 25010, 27000, 31010, 14971, 82079, 31000, 6254, 26514, 29119, 9868, 62304. Purpose: 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 82079, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 20547

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. AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115. Effectiveness: 5259, 42001, 25019, 25010, 27000, 31010, 14971, 12182, 8000, 26514, 29119, 62304, 17903, 20546. Risk: 8183, 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42005, 24668. High-risk: 9868. Sustainability: 20226

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. Authority: 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868. Information: 25024, 5259, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 24368, 12182, 24030, 31000, 25012, 8000, 38500, 38507, 24028, 6254, 8200, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 42006, 12792, 5392, 17903, 20547, 20547, 20547, 42112

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. Review: 42001, 23894, 25019, 25010, 27000, 31010, 14971, 82079, 31000, 6254, 26514, 29119, 9868, 62304

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. AI system: 8183, 24027, 42001, 5259, 25059, 5338, 24029, 24029, 23894, 22989, 5469, 24970, 24030, 8000, 24028, 6254, 8200, 25058, 17847, 29119, 22443, 9868, 5339, 21221, 25059, 25223, 12791, 42006, 42005, 12792, 5392, 17903, 23053, 24372, 20226, 22440, 22440, 22440, 23281, 25029, 25258, 42102, 42103, 42105, 42106, 42111, 42119, 18115. Society: 42001, 25059, 25019, 14971, 24368, 26514, 22443, 5339, 42005. Regulation: 5259, 22989, 14971, 8000, 29119, 9868, 62304. Fundamental right: 9868. Health: 42001, 5338, 25019, 25010, 27000, 14971, 5469, 12182, 29119, 9868, 5339, 62304, 22989, 18988. Safety: 42001, 5338, 24029, 25019, 22989, 25010, 27000, 14971, 5469, 24368, 8000, 24028, 29119, 9868, 62304, 25059, 22440, 22440, 22440. Information: 25024, 5259, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 24030, 31000, 25012, 8000, 38500, 38507, 24028, 6254, 8200, 4213, 26514, 25058, 17847, 29119, 22443, 9868, 5339, 62304, 42006, 12792, 5392, 17903, 20547, 20547, 20547, 42112

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: Evaluation: 25024, 24027, 42001, 5259, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 82079, 12182, 25012, 8000, 4213, 25058, 17847, 29119, 9868, 62304, 25059, 23282. Risk: 8183, 42001, 5259, 25059, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 24970, 82079, 12182, 31000, 24028, 29119, 9868, 5339, 62304, 42005, 24668. Review: 42001, 23894, 25019, 25010, 27000, 31010, 14971, 82079, 31000, 6254, 26514, 29119, 9868, 62304

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.

Art. 112, 11(b) the list of prohibited practices set out in Article 5, and

Art. 112, 11(c) the list of AI systems requiring additional transparency measures pursuant to Article 50. AI system: 8183, 42001, 5259, 25059, 5338, 24029, 23894, 31010, 5469, 82079, 25012, 8000, 24028, 4213, 26514, 25058, 9868, 5339, 62304, 22989, 23053. Authority: 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868. Governance: 8183, 42001, 5259, 25019, 22989, 27000, 31000, 8000, 38500, 38507, 24028, 22443, 18115. Conformity: 25024, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 12182, 24030, 31000, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 42006, 24668. Regulation: 5259, 22989, 14971, 8000, 29119, 9868, 62304. Assessment: 25024, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 22443, 9868, 5339, 62304, 42006, 42005, 24668, 42119. Conformity assessment: 25024, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 12182, 24030, 31000, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 42006, 42005, 24668, 42119

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. Amendment: 8183, 42001, 5259, 25059, 5338, 24029, 23894, 31010, 5469, 82079, 25012, 8000, 24028, 4213, 26514, 25058, 9868, 5339, 62304, 22989, 23053. Authority: 25024, 42001, 25019, 27000, 14971, 38507, 24028, 9868. Governance: 8183, 42001, 5259, 25019, 22989, 27000, 31000, 8000, 38500, 38507, 24028, 22443, 18115. Conformity: 25024, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 12182, 24030, 31000, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 42006, 24668. Regulation: 5259, 22989, 14971, 8000, 29119, 9868, 62304. Assessment: 25024, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 22443, 9868, 5339, 62304, 42006, 42005, 24668, 42119. Conformity assessment: 25024, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 14971, 5469, 12182, 24030, 31000, 8000, 24028, 4213, 26514, 25058, 29119, 9868, 5339, 62304, 42006, 42005, 24668, 42119

Art. 112, 13 By 2 August 2031, the Commission shall carry out an assessment of the enforcement of this Regulation and shall report 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. Amendment: 8183, 42001, 5259, 25059, 5338, 24029, 23894, 31010, 5469, 82079, 25012, 8000, 24028, 4213, 26514, 25058, 9868, 5339, 62304, 22989, 23053. Regulation: 5259, 22989, 14971, 8000, 29119, 9868, 62304. Assessment: 25024, 8183, 24027, 42001, 5259, 5259, 25059, 5338, 24029, 24029, 23894, 25019, 22989, 25010, 27000, 31010, 14971, 5469, 12182, 24030, 31000, 25012, 8000, 24028, 4213, 26514, 25058, 29119, 22443, 9868, 5339, 62304, 42006, 42005, 24668, 42119

ARTICLE 113

Art. 113

Entry into force and application

Art. 113.a

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:

Regulation: 5259, 22989, 14971, 8000, 29119, 9868, 62304

Art. 113, (a)

Chapters I and II shall apply from 2 February 2025;

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;

Art. 113, (c)

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

Obligation: 42001, 24028; **Regulation:** 5259, 22989, 14971, 8000, 29119, 9868, 62304