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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) (Text with EEA relevance)

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►B 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)

(Text with EEA relevance)

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REGULATION (EU) 2024/1689 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

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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)

(Text with EEA relevance)

CHAPTER I

GENERAL PROVISIONS

Article 1

Subject matter'

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.
2.
This Regulation lays down:

(a)
harmonised rules for the placing on the market, the putting into service, and the use of AI systems in the Union;

(b)
prohibitions of certain AI practices;

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

(d)
harmonised transparency rules for certain AI systems;

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

(f)
rules on market monitoring, market surveillance, governance and enforcement;

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(g)
measures to support innovation, with a particular focus on small mid-cap enterprises (SMCs) and small and medium-sized enterprises (SMEs), including start-ups.

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Article 2

Scope

1.
This Regulation applies to:

(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;

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

(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;

(d)
importers and distributors of AI systems;

(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;

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

(g)
affected persons that are located in the Union.

▼M1

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), Article 60a and Articles 102 to 112 shall apply. Articles 57, 58 and 59 shall apply only in so far as the requirements for high-risk AI systems under this Regulation have been integrated in that Union harmonisation legislation.
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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.

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.
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.
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.
▼M1

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. Without prejudice to Articles 4a and 59 of this Regulation, this Regulation shall not affect Regulation (EU) 2016/679 or (EU) 2018/1725, or Directive 2002/58/EC or (EU) 2016/680.

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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.
9.
This Regulation is without prejudice to the rules laid down by other Union legal acts related to consumer protection and product safety.
10.
This Regulation does not apply to obligations of deployers who are natural persons using AI systems in the course of a purely personal non-professional activity.
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.
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.
▼M1

13.
For high-risk AI systems referred to in Article 6(1), the application of specific requirements or obligations laid down in Articles 9 to 15 and 17 to 25 may be limited, where and to the extent that:

(a)
Union harmonisation legislation listed in Section A of Annex I lays down requirements or obligations providing an equivalent or higher level of protection of health, safety or fundamental rights as the requirement or obligation concerned; and

(b)
such limitation does not reduce the overall level of protection provided for by this Regulation.

By 2 August 2027, the Commission shall adopt delegated acts in accordance with Article 97 in order to supplement this Regulation by specifying the high-risk AI systems concerned, the requirements or obligations that may be limited, the conditions under which such limitation applies, and the scope of the limitation.

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Article 3

Definitions

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

(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;

(2)
‘risk’ means the combination of the probability of an occurrence of harm and the severity of that harm;

(3)

‘provider’ means a natural or legal person, public authority, agency or other body that develops an AI system or a general-purpose AI model or that has an AI system or a general-purpose AI model developed and places it on the market or puts the AI system into service under its own name or trademark, whether for payment or free of charge;

(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;

(5)
‘authorised representative’ means a natural or legal person located or established in the Union who has received and accepted a written mandate from a provider of an AI system or a general-purpose AI model to, respectively, perform and carry out on its behalf the obligations and procedures established by this Regulation;

(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;

(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;

(8)
‘operator’ means a provider, product manufacturer, deployer, authorised representative, importer or distributor;

(9)
‘placing on the market’ means the first making available of an AI system or a general-purpose AI model on the Union market;

(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;

(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;

(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;

(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;

▼M1

(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; for the purposes of this definition, a component fulfils a safety function where its intended purpose is to prevent or mitigate risks to health and safety of persons or property;

▼M1

(14a)

‘micro, small and medium-sized enterprise’ or ‘SME’ means a micro, small or medium-sized enterprise as defined in Article 2 of the Annex to Recommendation 2003/361/EC;

(14b)
‘small mid-cap enterprise’ or ‘SMC’ means a small mid-cap enterprise as defined in point (2) of the Annex to Recommendation (EU) 2025/1099;

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(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;

(16)
‘recall of an AI system’ means any measure aiming to achieve the return to the provider or taking out of service or disabling the use of an AI system made available to deployers;

(17)
‘withdrawal of an AI system’ means any measure aiming to prevent an AI system in the supply chain being made available on the market;

(18)
‘performance of an AI system’ means the ability of an AI system to achieve its intended purpose;

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

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

(21)
‘conformity assessment body’ means a body that performs third-party conformity assessment activities, including testing, certification and inspection;

(22)
‘notified body’ means a conformity assessment body notified in accordance with this Regulation and other relevant Union harmonisation legislation;

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

(24)
‘CE marking’ means a marking by which a provider indicates that an AI system is in conformity with the requirements set out in Chapter III, Section 2 and other applicable Union harmonisation legislation providing for its affixing;

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

(26)

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

(27)
‘harmonised standard’ means a harmonised standard as defined in Article 2(1), point (c), of Regulation (EU) No 1025/2012;

(28)
‘common specification’ means a set of technical specifications as defined in Article 2, point (4) of Regulation (EU) No 1025/2012, providing means to comply with certain requirements established under this Regulation;

(29)
‘training data’ means data used for training an AI system through fitting its learnable parameters;

(30)
‘validation data’ means data used for providing an evaluation of the trained AI system and for tuning its non-learnable parameters and its learning process in order, inter alia, to prevent underfitting or overfitting;

(31)
‘validation data set’ means a separate data set or part of the training data set, either as a fixed or variable split;

(32)
‘testing data’ means data used for providing an independent evaluation of the AI system in order to confirm the expected performance of that system before its placing on the market or putting into service;

(33)
‘input data’ means data provided to or directly acquired by an AI system on the basis of which the system produces an output;

(34)
‘biometric data’ means personal data resulting from specific technical processing relating to the physical, physiological or behavioural characteristics of a natural person, such as facial images or dactyloscopic data;

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

(36)
‘biometric verification’ means the automated, one-to-one verification, including authentication, of the identity of natural persons by comparing their biometric data to previously provided biometric data;

(37)
‘special categories of personal data’ means the categories of personal data referred to in Article 9(1) of Regulation (EU) 2016/679, Article 10 of Directive (EU) 2016/680 and Article 10(1) of Regulation (EU) 2018/1725;

(38)
‘sensitive operational data’ means operational data related to activities of prevention, detection, investigation or prosecution of criminal offences, the disclosure of which could jeopardise the integrity of criminal proceedings;

(39)
‘emotion recognition system’ means an AI system for the purpose of identifying or inferring emotions or intentions of natural persons on the basis of their biometric data;

(40)
‘biometric categorisation system’ means an AI system for the purpose of assigning natural persons to specific categories on the basis of their biometric data, unless it is ancillary to another commercial service and strictly necessary for objective technical reasons;

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

(42)
‘real-time remote biometric identification system’ means a remote biometric identification system, whereby the capturing of biometric data, the comparison and the identification all occur without a significant delay, comprising not only instant identification, but also limited short delays in order to avoid circumvention;

(43)
‘post-remote biometric identification system’ means a remote biometric identification system other than a real-time remote biometric identification system;

(44)
‘publicly accessible space’ means any publicly or privately owned physical place accessible to an undetermined number of natural persons, regardless of whether certain conditions for access may apply, and regardless of the potential capacity restrictions;

(45)
‘law enforcement authority’ means:

(a)
any public authority competent for the prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, including the safeguarding against and the prevention of threats to public security; or

(b)
any other body or entity entrusted by Member State law to exercise public authority and public powers for the purposes of the prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, including the safeguarding against and the prevention of threats to public security;

(46)
‘law enforcement’ means activities carried out by law enforcement authorities or on their behalf for the prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, including safeguarding against and preventing threats to public security;

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

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

(49)
‘serious incident’ means an incident or malfunctioning of an AI system that directly or indirectly leads to any of the following:

(a)
the death of a person, or serious harm to a person’s health;

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

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

(d)
serious harm to property or the environment;

(50)
‘personal data’ means personal data as defined in Article 4, point (1), of Regulation (EU) 2016/679;

(51)
‘non-personal data’ means data other than personal data as defined in Article 4, point (1), of Regulation (EU) 2016/679;

(52)
‘profiling’ means profiling as defined in Article 4, point (4), of Regulation (EU) 2016/679;

(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;

(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;

(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;

(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;

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

(58)
‘subject’, for the purpose of real-world testing, means a natural person who participates in testing in real-world conditions;

(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;

(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;

(61)

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

(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:

(i)
the act or omission originated or took place;

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

(iii)
the deployer is established, when the infringement is committed by the deployer;

(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;

(62)
‘critical infrastructure’ means critical infrastructure as defined in Article 2, point (4), of Directive (EU) 2022/2557;

(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;

(64)
‘high-impact capabilities’ means capabilities that match or exceed the capabilities recorded in the most advanced general-purpose AI models;

(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;

(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;

(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;

(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.

▼M1

Article 4

AI literacy

1.
Providers and deployers of AI systems shall take measures to support the development 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. This obligation does not require providers or deployers to guarantee any specific level of AI literacy of any individual.
2.
The Commission and the Member States shall support and facilitate the efforts of providers and deployers of AI systems, in particular SMEs, in fulfilling their obligation under paragraph 1 of this Article. For that purpose, the Commission shall publish practical examples of how to comply with that obligation on the single information platform referred to in Article 62(3), point (b).
3.
The Board shall adopt recommendations, taking into account European competence frameworks, to support the Commission and Member States in the promotion of AI literacy required under paragraph 1, including by setting out common objectives.
▼M1

Article 4a

Processing of special categories of personal data for bias detection and correction

1.
To the extent strictly necessary to ensure bias detection and correction in relation to high-risk AI systems in accordance with Article 10(2), points (f) and (g), of this Regulation, providers of such systems may exceptionally process special categories of personal data, subject to appropriate safeguards for the fundamental rights and freedoms of natural persons. In addition to the provisions set out in Regulations (EU) 2016/679 and (EU) 2018/1725 and Directive (EU) 2016/680, as applicable, all the following conditions shall be met in order for such processing to occur:

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

(b)
the special categories of personal data are subject to technical limitations on the re-use of personal data, and state-of-the-art security and privacy-preserving measures, including pseudonymisation;

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

(d)
the special categories of personal data are not transmitted, transferred or otherwise accessed by other parties;

(e)
the special categories of personal data are deleted once the bias has been corrected or the personal data has reached the end of its retention period, whichever comes first; and

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

2.
Providers and deployers of other AI systems and models and deployers of high-risk AI systems may exceptionally process special categories of personal data to the extent that:

(a)
such processing is strictly necessary to ensure bias detection and correction in view of possible biases that are likely to affect the health and safety of persons, have a negative impact on fundamental rights or lead to discrimination prohibited pursuant to Union law, especially where data outputs influence inputs for future operations; and

(b)
all of the conditions and safeguards set out in paragraph 1 are applied.

This paragraph does not create any obligation to conduct such bias detection and correction.

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CHAPTER II

PROHIBITED AI PRACTICES

Article 5

Prohibited AI practices

1.
The following AI practices shall be prohibited:

(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;

(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;

▼M1

(ba)
the placing on the market, the putting into service or the use of an AI system that generates or manipulates realistic images, videos, audio or similar material of an identifiable natural person's intimate parts, or of an identifiable natural person engaged in sexually explicit activities, without that person's freely-given, specific, informed, unambiguous and explicit consent for that generation or manipulation;

(bb)
the placing on the market, the putting into service or the use of an AI system that generates or manipulates material or performance within the meaning of Article 2, points (c) and (e), of Directive 2011/93/EU, except where a 'without right' defence applies under national law;

▼B

(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:

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

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

(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;

(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;

(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;

(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;

(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:

(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;

(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;

(iii)
the localisation or identification of a person suspected of having committed a criminal offence, for the purpose of conducting a criminal investigation or prosecution or executing a criminal penalty for offences referred to in Annex II and punishable in the Member State concerned by a custodial sentence or a detention order for a maximum period of at least four years.

Point (h) of the first subparagraph is without prejudice to Article 9 of Regulation (EU) 2016/679 for the processing of biometric data for purposes other than law enforcement.

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1a.
For the purposes of paragraph 1, first subparagraph, points (ba) and (bb):

(a)
the placing on the market or putting into service of an AI system that generates or manipulates the material or performance referred to in paragraph 1, first subparagraph, point (ba) or (bb) is only prohibited where:

(i)
that generation or manipulation is the intended purpose of the AI system; or

(ii)
the system's design, training, architecture, capabilities or user-facing functionalities make that generation or manipulation a reasonably foreseeable and reproducible outcome, without requiring significant technical modification, and the system does not have reasonable and adequate technical safety measures and other safeguards to reliably prevent that generation or manipulation, taking into account reasonably foreseeable misuse, and to correct observed or reported misuse;

(b)
the use of an AI system that generates or manipulates the material or performance referred to in paragraph 1, first subparagraph, points (ba) and (bb) is only prohibited where the deployer uses the system for the purpose of generating or manipulating such material or performance.

1b.
For the purposes of paragraph 1, first subparagraph, point (ba), an AI system that manipulates material in a way that does not increase the exposure of any depicted intimate parts or alter the nature of any depicted sexually explicit activities shall not constitute manipulation.

▼B

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:

(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;

(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.

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.

3.

For the purposes of paragraph 1, first subparagraph, point (h) and paragraph 2, each use for the purposes of law enforcement of a ‘real-time’ remote biometric identification system in publicly accessible spaces shall be subject to a prior authorisation granted by a judicial authority or an independent administrative authority whose decision is binding of the Member State in which the use is to take place, issued upon a reasoned request and in accordance with the detailed rules of national law referred to in paragraph 5. However, in a duly justified situation of urgency, the use of such system may be commenced without an authorisation provided that such authorisation is requested without undue delay, at the latest within 24 hours. If such authorisation is rejected, the use shall be stopped with immediate effect and all the data, as well as the results and outputs of that use shall be immediately discarded and deleted.

The competent judicial authority or an independent administrative authority whose decision is binding shall grant the authorisation only where it is satisfied, on the basis of objective evidence or clear indications presented to it, that the use of the ‘real-time’ remote biometric identification system concerned is necessary for, and proportionate to, achieving one of the objectives specified in paragraph 1, first subparagraph, point (h), as identified in the request and, in particular, remains limited to what is strictly necessary concerning the period of time as well as the geographic and personal scope. In deciding on the request, that authority shall take into account the elements referred to in paragraph 2. No decision that produces an adverse legal effect on a person may be taken based solely on the output of the ‘real-time’ remote biometric identification system.

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.

5.

A Member State may decide to provide for the possibility to fully or partially authorise the use of ‘real-time’ remote biometric identification systems in publicly accessible spaces for the purposes of law enforcement within the limits and under the conditions listed in paragraph 1, first subparagraph, point (h), and paragraphs 2 and 3. Member States concerned shall lay down in their national law the necessary detailed rules for the request, issuance and exercise of, as well as supervision and reporting relating to, the authorisations referred to in paragraph 3. Those rules shall also specify in respect of which of the objectives listed in paragraph 1, first subparagraph, point (h), including which of the criminal offences referred to in point (h)(iii) thereof, the competent authorities may be authorised to use those systems for the purposes of law enforcement. Member States shall notify those rules to the Commission at the latest 30 days following the adoption thereof. Member States may introduce, in accordance with Union law, more restrictive laws on the use of remote biometric identification systems.

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.

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.

8.

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

CHAPTER III

HIGH-RISK AI SYSTEMS

SECTION 1

Classification of AI systems as high-risk

Article 6

Classification rules for high-risk AI systems

1.
Irrespective of whether an AI system is placed on the market or put into service independently of the products referred to in points (a) and (b), that AI system shall be considered to be high-risk where both of the following conditions are fulfilled:

(a)
the AI system is intended to be used as a safety component of a product, or the AI system is itself a product, covered by the Union harmonisation legislation listed in Annex I;

(b)
the product whose safety component pursuant to point (a) is the AI system, or the AI system itself as a product, is required to undergo a third-party conformity assessment, with a view to the placing on the market or the putting into service of that product pursuant to the Union harmonisation legislation listed in Annex I.

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1a.
For the purposes of this Regulation, including paragraph 1 of this Article, AI systems that are solely used for non-safety related aspects of user assistance, performance optimisation, service efficiency, automation or convenience or quality control shall not qualify as safety components.
1b.
Notwithstanding paragraph 1a, AI systems the failure or malfunctioning of which would endanger health and safety shall qualify as safety components.
1c.
A product that is required to undergo a third-party conformity assessment solely due to risks other than risks to health and safety, in particular risks relating to the distribution of radio spectrum or electromagnetic interference that do not affect health and safety, shall not be considered as fulfilling the condition in paragraph 1, point (b).
▼B

2.
In addition to the high-risk AI systems referred to in paragraph 1, AI systems referred to in Annex III shall be considered to be high-risk.
3.
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:

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

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

(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

(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.

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

Amendments to Annex III

1.
The Commission is empowered to adopt delegated acts in accordance with Article 97 to amend Annex III by adding or modifying use-cases of high-risk AI systems where both of the following conditions are fulfilled:

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

(b)
the AI systems pose a risk of harm to health and safety, or an adverse impact on fundamental rights, and that risk is equivalent to, or greater than, the risk of harm or of adverse impact posed by the high-risk AI systems already referred to in Annex III.

2.
When assessing the condition under paragraph 1, point (b), the Commission shall take into account the following criteria:

(a)
the intended purpose of the AI system;

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

(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;

(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;

(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;

(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;

(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;

(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;

(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;

(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;

(k)
the extent to which existing Union law provides for:

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

(ii)
effective measures to prevent or substantially minimise those risks.

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:

(a)
the high-risk AI system concerned no longer poses any significant risks to fundamental rights, health or safety, taking into account the criteria listed in paragraph 2;

(b)

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

SECTION 2

Requirements for high-risk AI systems

Article 8

Compliance with the requirements

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

Risk management system

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

(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;

(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;

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

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

3.
The risks referred to in this Article shall concern only those which may be reasonably mitigated or eliminated through the development or design of the high-risk AI system, or the provision of adequate technical

information.
4.
The risk management measures referred to in paragraph 2, point (d), shall give due consideration to the effects and possible interaction resulting from the combined application of the requirements set out in this Section, with a view to minimising risks more effectively while achieving an appropriate balance in implementing the measures to fulfil those requirements.
5.
The risk management measures referred to in paragraph 2, point (d), shall be such that the relevant residual risk associated with each hazard, as well as the overall residual risk of the high-risk AI systems is judged to be acceptable.
In identifying the most appropriate risk management measures, the following shall be ensured:

(a)
elimination or reduction of risks identified and evaluated pursuant to paragraph 2 in as far as technically feasible through adequate design and development of the high-risk AI system;

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

(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.

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.
7.
Testing procedures may include testing in real-world conditions in accordance with Article 60.
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.
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.
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.
Article 10

Data and data governance

▼M1

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, 3 and 4 of this Article and in Article 4a(1) whenever such data sets are used.

▼B

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:

(a)
the relevant design choices;

(b)
data collection processes and the origin of data, and in the case of personal data, the original purpose of the data collection;

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

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

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

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

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

(h)
the identification of relevant data gaps or shortcomings that prevent compliance with this Regulation, and how those gaps and shortcomings can be addressed.

3.
Training, validation and testing data sets shall be relevant, sufficiently representative, and to the best extent possible, free of errors and complete in view of the intended purpose. They shall have the appropriate statistical properties, including, where applicable, as regards the persons or groups of persons in relation to whom the high-risk AI system is intended to be used. Those characteristics of the data sets may be met at the level of individual data sets or at the level of a combination thereof.
4.
Data sets shall take into account, to the extent required by the intended purpose, the characteristics or elements that are particular to the specific geographical, contextual, behavioural or functional setting within which the high-risk AI system is intended to be used.
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▼M1

6.
For the development of high-risk AI systems not using techniques involving the training of AI models, paragraphs 2, 3 and 4 of this Article and Article 4a(1) shall apply only to the testing data sets.
▼B

Article 11

Technical documentation

1.
The technical documentation of a high-risk AI system shall be drawn up before that system is placed on the market or put into service and shall be kept up-to date.
▼M1

That technical documentation shall be drawn up in such a way as to demonstrate that the high-risk AI system complies with the requirements set out in this Section and to provide national competent authorities and notified bodies with the necessary information in a clear and comprehensive form to assess the compliance of the AI system with those requirements. It shall contain, at a minimum, the elements set out in Annex IV. SMEs, including start-ups, and SMCs, may provide the elements of the technical documentation specified in Annex IV in a simplified manner. To that end, the Commission shall establish a simplified technical documentation form targeted at the needs of SMEs, including start-ups, and SMCs. Where an SME, including a start-up, or an SMC, opts to provide the information required in Annex IV in a simplified manner, it shall use the form referred to in this paragraph. Notified bodies shall accept the form for the purposes of the conformity assessment.

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2.
Where a high-risk AI system related to a product covered by the Union harmonisation legislation listed in Section A of Annex I is placed on the market or put into service, a single set of technical documentation shall be drawn up containing all the information set out in paragraph 1, as well as the information required under those legal acts.
3.
The Commission is empowered to adopt delegated acts in accordance with Article 97 in order to amend Annex IV, where necessary, to ensure that, in light of technical progress, the technical documentation provides all the information necessary to assess the compliance of the system with the requirements set out in this Section.
Article 12

Record-keeping

1.
High-risk AI systems shall technically allow for the automatic recording of events (logs) over the lifetime of the system.
2.
In order to ensure a level of traceability of the functioning of a high-risk AI system that is appropriate to the intended purpose of the system, logging capabilities shall enable the recording of events relevant for:

(a)
identifying situations that may result in the high-risk AI system presenting a risk within the meaning of Article 79(1) or in a substantial modification;

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

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

3.
For high-risk AI systems referred to in point 1 (a), of Annex III, the logging capabilities shall provide, at a minimum:

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

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

(c)

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

(d)
the identification of the natural persons involved in the verification of the results, as referred to in Article 14(5).

Article 13

Transparency and provision of information to deployers

1.
High-risk AI systems shall be designed and developed in such a way as to ensure that their operation is sufficiently transparent to enable deployers to interpret a system's output and use it appropriately. An appropriate type and degree of transparency shall be ensured with a view to achieving compliance with the relevant obligations of the provider and deployer set out in Section 3.
2.
High-risk AI systems shall be accompanied by instructions for use in an appropriate digital format or otherwise that include concise, complete, correct and clear information that is relevant, accessible and comprehensible to deployers.
3.
The instructions for use shall contain at least the following information:

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

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

(i)
its intended purpose;

(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;

(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);

(iv)
where applicable, the technical capabilities and characteristics of the high-risk AI system to provide information that is relevant to explain its output;

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

(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;

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

(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;

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

(e)
the computational and hardware resources needed, the expected lifetime of the high-risk AI system and any necessary maintenance and care measures, including their frequency, to ensure the proper functioning of that AI system, including as regards software updates;

(f)
where relevant, a description of the mechanisms included within the high-risk AI system that allows deployers to properly collect, store and interpret the logs in accordance with Article 12.

Article 14

Human oversight

1.
High-risk AI systems shall be designed and developed in such a way, including with appropriate human-machine interface tools, that they can be effectively overseen by natural persons during the period in which they are in use.
2.
Human oversight shall aim to prevent or minimise the risks to health, safety or fundamental rights that may emerge when a high-risk AI system is used in accordance with its intended purpose or under conditions of reasonably foreseeable misuse, in particular where such risks persist despite the application of other requirements set out in this Section.
3.
The oversight measures shall be commensurate with the risks, level of autonomy and context of use of the high-risk AI system, and shall be ensured through either one or both of the following types of measures:

(a)
measures identified and built, when technically feasible, into the high-risk AI system by the provider before it is placed on the market or put into service;

(b)
measures identified by the provider before placing the high-risk AI system on the market or putting it into service and that are appropriate to be implemented by the deployer.

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

(a)
to properly understand the relevant capacities and limitations of the high-risk AI system and be able to duly monitor its operation, including in view of detecting and addressing anomalies, dysfunctions and unexpected performance;

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

(c)

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

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

(e)
to intervene in the operation of the high-risk AI system or interrupt the system through a 'stop' button or a similar procedure that allows the system to come to a halt in a safe state.

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

Article 15

Accuracy, robustness and cybersecurity

1.
High-risk AI systems shall be designed and developed in such a way that they achieve an appropriate level of accuracy, robustness, and cybersecurity, and that they perform consistently in those respects throughout their lifecycle.
2.
To address the technical aspects of how to measure the appropriate levels of accuracy and robustness set out in paragraph 1 and any other relevant performance metrics, the Commission shall, in cooperation with relevant stakeholders and organisations such as metrology and benchmarking authorities, encourage, as appropriate, the development of benchmarks and measurement methodologies.
3.
The levels of accuracy and the relevant accuracy metrics of high-risk AI systems shall be declared in the accompanying instructions of use.
4.
High-risk AI systems shall be as resilient as possible regarding errors, faults or inconsistencies that may occur within the system or the environment in which the system operates, in particular due to their interaction with natural persons or other systems. Technical and organisational measures shall be taken in this regard.
The robustness of high-risk AI systems may be achieved through technical redundancy solutions, which may include backup or fail-safe plans.

High-risk AI systems that continue to learn after being placed on the market or put into service shall be developed in such a way as to eliminate or reduce as far as possible the risk of possibly biased outputs influencing input for future operations (feedback loops), and as to ensure that any such feedback loops are duly addressed with appropriate mitigation measures.

5.
High-risk AI systems shall be resilient against attempts by unauthorised third parties to alter their use, outputs or performance by exploiting system vulnerabilities.
The technical solutions aiming to ensure the cybersecurity of high-risk AI systems shall be appropriate to the relevant circumstances and the risks.

The technical solutions to address AI specific vulnerabilities shall include, where appropriate, measures to prevent, detect, respond to, resolve and control for attacks trying to manipulate the training data set (data

poisoning), or pre-trained components used in training (model poisoning), inputs designed to cause the AI model to make a mistake (adversarial examples or model evasion), confidentiality attacks or model flaws.

SECTION 3

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

Article 16

Obligations of providers of high-risk AI systems

Providers of high-risk AI systems shall:

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

(b)
indicate on the high-risk AI system or, where that is not possible, on its packaging or its accompanying documentation, as applicable, their name, registered trade name or registered trade mark, the address at which they can be contacted;

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

(d)
keep the documentation referred to in Article 18;

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

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

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

(h)
affix the CE marking to the high-risk AI system or, where that is not possible, on its packaging or its accompanying documentation, to indicate conformity with this Regulation, in accordance with Article 48;

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

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

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

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

Article 17

Quality management system

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:

(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;

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

(c)
techniques, procedures and systematic actions to be used for the development, quality control and quality assurance of the high-risk AI system;

(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;

(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;

(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;

(g)
the risk management system referred to in Article 9;

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

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

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

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

(l)
resource management, including security-of-supply related measures;

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

▼M1

2.

The implementation of the aspects referred to in paragraph 1 shall be proportionate to the size of the provider's organisation, in particular, if the provider is an SME, including a start-up, or an SMC. Providers shall, in any event, respect the degree of rigour and the level of protection required to ensure the compliance of their high-risk AI systems with this Regulation.
▼B

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.
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.
Article 18

Documentation keeping

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:

(a)
the technical documentation referred to in Article 11;

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

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

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

(e)
the EU declaration of conformity referred to in Article 47.

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.
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.
Article 19

Automatically generated logs

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.

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.

Article 20

Corrective actions and duty of information

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.

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.

Article 21

Cooperation with competent authorities

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.

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.

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.

Article 22

Authorised representatives of providers of high-risk AI systems

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.

2.

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

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:

(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;

(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;

(c)
provide a competent authority, upon a reasoned request, with all the information and documentation, including that referred to in point (b) of this subparagraph, necessary to demonstrate the conformity of a high-risk AI system with the requirements set out in Section 2, including access to the logs, as referred to in Article 12(1), automatically generated by the high-risk AI system, to the extent such logs are under the control of the provider;

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

(e)
where applicable, comply with the registration obligations referred to in Article 49(1), or, if the registration is carried out by the provider itself, ensure that the information referred to in point 3 of Section A of Annex VIII is correct.

The mandate shall empower the authorised representative to be addressed, in addition to or instead of the provider, by the competent authorities, on all issues related to ensuring compliance with this Regulation.

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

Article 23

Obligations of importers

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:

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

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

(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;

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

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.

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.

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.

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.

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.

7.

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

Article 24

Obligations of distributors

1.

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

2.

Where a distributor considers or has reason to consider, on the basis of the information in its possession, that a high-risk AI system is not in conformity with the requirements set out in Section 2, it shall not make the high-risk AI system available on the market until the system has been brought into conformity with those requirements. Furthermore, where the high-risk AI system presents a risk within the meaning of Article 79(1), the distributor shall inform the provider or the importer of the system, as applicable, to that effect.

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.

4.

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

authorities competent for the high-risk AI system concerned, giving details, in particular, of the non-compliance and of any corrective actions taken.

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.

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.

Article 25

Responsibilities along the AI value chain

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:

(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;

(b)

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

(c)

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

▼M1

2.

Where the circumstances referred to in paragraph 1 occur, the provider that initially placed the AI system on the market or put it into service shall no longer be considered to be a provider of that specific AI system for the purposes of this Regulation.

That initial provider shall closely cooperate with new providers and shall make available the necessary information and provide the reasonably expected technical access and other assistance that are required for the fulfilment of the obligations set out in this Regulation, in particular with regard to compliance with the conformity assessment of high-risk AI systems.

In particular, the obligation laid down in the second subparagraph shall include, where relevant for the purposes specified therein, the following:

(a)

making available of technical documentation sufficient to assess compliance with the requirements laid down in Article 16;

(b)

informing the new providers about known limitations and failure modes; and

(c)

providing the new providers with targeted technical access, including for testing and validation.

This paragraph shall not apply in cases where the initial provider has clearly specified that its AI system is not to be changed into a high-risk AI system and therefore does not fall under the obligation to cooperate with the new

providers and hand over the documentation.

▼B

3.
In the case of high-risk AI systems that are safety components of products covered by the Union harmonisation legislation listed in Section A of Annex I, the product manufacturer shall be considered to be the provider of the high-risk AI system, and shall be subject to the obligations under Article 16 under either of the following circumstances:

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

(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.

▼M1

4.
The provider of a high-risk AI system and the third party that supplies an AI system, AI model, 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.

▼B

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.

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.

Article 26

Obligations of deployers of high-risk AI systems

1.
Deployers of high-risk AI systems shall take appropriate technical and organisational measures to ensure they use such systems in accordance with the instructions for use accompanying the systems, pursuant to paragraphs 3 and 6.

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

3.
The obligations set out in paragraphs 1 and 2, are without prejudice to other deployer obligations under Union or national law and to the deployer’s freedom to organise its own resources and activities for the purpose of implementing the human oversight measures indicated by the provider.

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.

5.

Deployers shall monitor the operation of the high-risk AI system on the basis of the instructions for use and, where relevant, inform providers in accordance with Article 72. Where deployers have reason to consider that the use of the high-risk AI system in accordance with the instructions may result in that AI system presenting a risk within the meaning of Article 79(1), they shall, without undue delay, inform the provider or distributor and the relevant market surveillance authority, and shall suspend the use of that system. Where deployers have identified a serious incident, they shall also immediately inform first the provider, and then the importer or distributor and the relevant market surveillance authorities of that incident. If the deployer is not able to reach the provider, Article 73 shall apply mutatis mutandis. This obligation shall not cover sensitive operational data of deployers of AI systems which are law enforcement authorities.

For deployers that are financial institutions subject to requirements regarding their internal governance, arrangements or processes under Union financial services law, the monitoring obligation set out in the first subparagraph shall be deemed to be fulfilled by complying with the rules on internal governance arrangements, processes and mechanisms pursuant to the relevant financial service law.

6.

Deployers of high-risk AI systems shall keep the logs automatically generated by that high-risk AI system to the extent such logs are under their control, for a period appropriate to the intended purpose of the high-risk AI system, of at least six months, unless provided otherwise in applicable Union or national law, in particular in Union law on the protection of personal data.

Deployers that are financial institutions subject to requirements regarding their internal governance, arrangements or processes under Union financial services law shall maintain the logs as part of the documentation kept pursuant to the relevant Union financial service law.

7.

Before putting into service or using a high-risk AI system at the workplace, deployers who are employers shall inform workers' representatives and the affected workers that they will be subject to the use of the high-risk AI system. This information shall be provided, where applicable, in accordance with the rules and procedures laid down in Union and national law and practice on information of workers and their representatives.

8.

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

9.

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

10.

Without prejudice to Directive (EU) 2016/680, in the framework of an investigation for the targeted search of a person suspected or convicted of having committed a criminal offence, the deployer of a high-risk AI system for post-remote biometric identification shall request an authorisation, ex ante, or without undue delay and no later than 48 hours, by a judicial authority or an administrative authority whose decision is binding and subject to judicial review, for the use of that system, except when it is used for the initial identification of a potential suspect based on objective and verifiable facts directly linked to the offence. Each use shall be limited to what is strictly necessary for the investigation of a specific criminal offence.

If the authorisation requested pursuant to the first subparagraph is rejected, the use of the post-remote biometric identification system linked to that requested authorisation shall be stopped with immediate effect and the personal data linked to the use of the high-risk AI system for which the authorisation was requested shall be deleted.

In no case shall such high-risk AI system for post-remote biometric identification be used for law enforcement purposes in an untargeted way, without any link to a criminal offence, a criminal proceeding, a genuine and present or genuine and foreseeable threat of a criminal offence, or the search for a specific missing person. It shall be ensured that no decision that produces an adverse legal effect on a person may be taken by the law enforcement authorities based solely on the output of such post-remote biometric identification systems.

This paragraph is without prejudice to Article 9 of Regulation (EU) 2016/679 and Article 10 of Directive (EU) 2016/680 for the processing of biometric data.

Regardless of the purpose or deployer, each use of such high-risk AI systems shall be documented in the relevant police file and shall be made available to the relevant market surveillance authority and the national data protection authority upon request, excluding the disclosure of sensitive operational data related to law enforcement. This subparagraph shall be without prejudice to the powers conferred by Directive (EU) 2016/680 on supervisory authorities.

Deployers shall submit annual reports to the relevant market surveillance and national data protection authorities on their use of post-remote biometric identification systems, excluding the disclosure of sensitive operational data related to law enforcement. The reports may be aggregated to cover more than one deployment.

Member States may introduce, in accordance with Union law, more restrictive laws on the use of post-remote biometric identification systems.

11.
Without prejudice to Article 50 of this Regulation, deployers of high-risk AI systems referred to in Annex III that make decisions or assist in making decisions related to natural persons shall inform the natural persons that they are subject to the use of the high-risk AI system. For high-risk AI systems used for law enforcement purposes Article 13 of Directive (EU) 2016/680 shall apply.
12.
Deployers shall cooperate with the relevant competent authorities in any action those authorities take in relation to the high-risk AI system in order to implement this Regulation.
Article 27

Fundamental rights impact assessment for high-risk AI systems

1.
Prior to deploying a high-risk AI system referred to in Article 6(2), with the exception of high-risk AI systems intended to be used in the area listed in point 2 of Annex III, deployers that are bodies governed by public law, or are private entities providing public services, and deployers of high-risk AI systems referred to in points 5 (b) and (c) of Annex III, shall perform an assessment of the impact on fundamental rights that the use of such system may produce. For that purpose, deployers shall perform an assessment consisting of:

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

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

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

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

(e)

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

(f)
the measures to be taken in the case of the materialisation of those risks, including the arrangements for internal governance and complaint mechanisms.

2.
The obligation laid down in paragraph 1 applies to the first use of the high-risk AI system. The deployer may, in similar cases, rely on previously conducted fundamental rights impact assessments or existing impact assessments carried out by provider. If, during the use of the high-risk AI system, the deployer considers that any of the elements listed in paragraph 1 has changed or is no longer up to date, the deployer shall take the necessary steps to update the information.
3.
Once the assessment referred to in paragraph 1 of this Article has been performed, the deployer shall notify the market surveillance authority of its results, submitting the filled-out template referred to in paragraph 5 of this Article as part of the notification. In the case referred to in Article 46(1), deployers may be exempt from that obligation to notify.
▼M1

4.
If any of the obligations laid down in this Article is already met through the data protection impact assessment conducted pursuant to Article 35 of Regulation (EU) 2016/679 or Article 27 of Directive (EU) 2016/680, the deployer may, when conducting the fundamental rights impact assessment referred to in paragraph 1 of this Article, include cross-references to the relevant sections of that data protection impact assessment or include relevant parts thereof in the fundamental rights impact assessment.
5.
The AI Office shall develop a template for a questionnaire, including through an automated tool, to facilitate deployers in complying with their obligations under this Article in a simplified manner. This template shall, where relevant, give deployers the possibility to include cross-references to the relevant sections of the data protection impact assessment or include relevant parts thereof in the fundamental rights impact assessment pursuant to paragraph 4.
▼B

SECTION 4

Notifying authorities and notified bodies

Article 28

Notifying authorities

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.
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.
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.
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.

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.
6.
Notifying authorities shall safeguard the confidentiality of the information that they obtain, in accordance with Article 78.
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.
▼M1

8.
Notifying authorities designated pursuant to this Regulation that are responsible for AI systems covered by the Union harmonisation legislation listed in Section A of Annex I shall ensure that the conformity assessment body that applies for designation both pursuant to this Regulation and the Union harmonisation legislation listed in Section A of Annex I is provided with the possibility to submit a single application and undergoes a unified assessment procedure to be designated pursuant to this Regulation and Union harmonisation legislation listed in Section A of Annex I, where the relevant Union harmonisation legislation provides for such single application and unified assessment procedure. To that end, notifying authorities designated pursuant to this Regulation and those designated pursuant to the Union harmonisation legislation listed in Section A of Annex I shall cooperate in their assessments.
The single application and the unified assessment procedure referred to in this paragraph shall also be made available to notified bodies already designated pursuant to the Union harmonisation legislation listed in Section A of Annex I, when those notified bodies apply for designation pursuant to this Regulation, provided that the relevant Union harmonisation legislation provides for such a procedure.

A conformity assessment body that is designated pursuant to more than one piece of Union harmonisation legislation listed in Section A of Annex I shall have to apply only once to be designated pursuant to this Regulation. A designation pursuant to this Regulation shall be applicable for all Union harmonisation legislation listed in Section A of Annex I for which the conformity assessment body is designated.

The single application and the unified assessment procedure shall avoid any unnecessary duplications, build on the existing procedures for designation in accordance with the Union harmonisation legislation listed in Section A of Annex I and ensure compliance with the requirements relating to notified bodies both in accordance with this Regulation and the relevant Union harmonisation legislation.

9.
A notifying authority that has been designated pursuant to the Union harmonisation legislation listed in Section A of Annex I is also the notifying authority for the application of the single application and unified assessment procedure referred to in paragraph 8, unless the Member State designates another notifying authority for this Regulation.
▼B

Article 29

Application of a conformity assessment body for notification

1.
Conformity assessment bodies shall submit an application for notification to the notifying authority of the Member State in which they are established.
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.

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.
▼M1

4.
For notified bodies which are designated pursuant to any other Union harmonisation legislation, all documents and certificates linked to those designations may be used to support and expedite their designation procedure under this Regulation, as appropriate.
Notified bodies, which are designated pursuant to any of the Union harmonisation legislation listed in Section A of Annex I and which undergo the unified assessment procedure referred to in Article 28(8), shall submit the single application for assessment to the notifying authority designated pursuant to that Union harmonisation legislation.

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.

▼B

Article 30

Notification procedure

1.
Notifying authorities may notify only conformity assessment bodies which have satisfied the requirements laid down in Article 31.
▼M1

2.
Notifying authorities shall notify the Commission and the other Member States, based on the list of codes, categories, and corresponding types of AI systems referred to in Annex XIV, and using the electronic notification tool developed and managed by the Commission, of each conformity assessment body referred to in paragraph 1.
The Commission is empowered to adopt delegated acts in accordance with Article 97 in order to amend Annex XIV, in light of technical progress, advances in knowledge or new scientific evidence by adding to the list of codes, categories, and corresponding types of AI systems a new code, a category or a type of AI system, withdrawing an existing code, category or a type of AI system from that list or moving a code or type of AI system from one category to another.

▼B

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.
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).

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.

Article 31

Requirements relating to notified bodies

1.

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

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.

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.

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.

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.

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.

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.

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.

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.

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.

11.

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

12.

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

Article 32

Presumption of conformity with requirements relating to notified bodies

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.

Article 33

Subsidiaries of notified bodies and subcontracting

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.

2.

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

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.

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.

Article 34

Operational obligations of notified bodies

1.

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

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.
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.
Article 35

Identification numbers and lists of notified bodies

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.
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.
Article 36

Changes to notifications

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).
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.

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.
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.
5.
Where its designation has been suspended, restricted, or fully or partially withdrawn, the notified body shall inform the providers concerned within 10 days.
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.

7.

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

(a)

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

(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;

(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;

(d)

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

(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.

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:

(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

(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.

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:

(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

(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.

Article 37

Challenge to the competence of notified bodies

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.
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.
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.
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).

Article 38

Coordination of notified bodies

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

Article 39

Conformity assessment bodies of third countries

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

SECTION 5

Standards, conformity assessment, certificates, registration

Article 40

Harmonised standards and standardisation deliverables

1.
High-risk AI systems or general-purpose AI models which are in conformity with harmonised standards or parts thereof the references of which have been published in the Official Journal of the European Union in accordance with Regulation (EU) No 1025/2012 shall be presumed to be in conformity with the requirements set out in Section 2 of this Chapter or, as applicable, with the obligations set out in of Chapter V, Sections 2 and 3, of this Regulation, to the extent that those standards cover those requirements or obligations.
2.
In accordance with Article 10 of Regulation (EU) No 1025/2012, the Commission shall issue, without undue delay, standardisation requests covering all requirements set out in Section 2 of this Chapter and, as applicable, standardisation requests covering obligations set out in Chapter V, Sections 2 and 3, of this Regulation. The standardisation request shall also ask for deliverables on reporting and documentation processes to improve AI systems' resource performance, such as reducing the high-risk AI system's consumption of energy and of other resources during its lifecycle, and on the energy-efficient development of general-purpose AI models. When preparing a standardisation request, the Commission shall consult the Board and relevant stakeholders, including the advisory forum.
When issuing a standardisation request to European standardisation organisations, the Commission shall specify that standards have to be clear, consistent, including with the standards developed in the various sectors for products covered by the existing Union harmonisation legislation listed in Annex I, and aiming to ensure that high-risk AI systems or general-purpose AI models placed on the market or put into service in the Union meet the relevant requirements or obligations laid down in this Regulation.

The Commission shall request the European standardisation organisations to provide evidence of their best efforts to fulfil the objectives referred to in the first and the second subparagraph of this paragraph in accordance with Article 24 of Regulation (EU) No 1025/2012.

▼M1

The Commission shall request, in accordance with Regulation (EU) No 1025/2012 of the European Parliament and of the Council (1) and without undue delay, the European standardisation organisations to develop standardisation deliverables, including, as appropriate, harmonised standards, to facilitate the joint compliance and presumption of conformity with the requirements or obligations set out in Chapter III, Sections 2 and 3 of this Regulation, and the relevant requirements and obligations laid down in the Union harmonisation legislation listed in Annex I to this Regulation.

▼B

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.
Article 41

Common specifications

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:

(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:

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

(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

(iii)
the relevant harmonised standards insufficiently address fundamental rights concerns; or

(iv)
the harmonised standards do not comply with the request; and

(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).

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.
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.
4.
Where a harmonised standard is adopted by a European standardisation organisation and proposed to the Commission for the publication of its reference in the Official Journal of the European Union, the Commission shall assess the harmonised standard in accordance with Regulation (EU) No 1025/2012. When reference to a harmonised standard is published in the Official Journal of the European Union, the Commission shall repeal the implementing acts referred to in paragraph 1, or parts thereof which cover the same requirements set out in Section 2 of this Chapter or, as applicable, the same obligations set out in Sections 2 and 3 of Chapter V.
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.
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.

Article 42

Presumption of conformity with certain requirements

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).
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.
▼M1

3.
Where high-risk AI systems fall within the scope of Regulation (EU) 2024/2847 and the conditions laid down in Article 12(1) of that Regulation are fulfilled, such systems shall be deemed to comply with the cybersecurity requirements set out in Article 15 of this Regulation.
▼B

Article 43

Conformity assessment

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:

(a)
the internal control referred to in Annex VI; or

(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:

(a)
harmonised standards referred to in Article 40 do not exist, and common specifications referred to in Article 41 are not available;

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

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

(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.

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.
▼M1

3.
For high-risk AI systems covered by the Union harmonisation legislation listed in Section A of Annex I, the provider of the system shall follow the relevant conformity assessment procedure as required in accordance with the relevant Union harmonisation legislation. 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. Assessment of the quality management system set out in Article 17 shall also be undertaken, and points 3, 4.3, 4.4. and 4.5, the fifth paragraph of point 4.6 and point 5 of Annex VII shall apply.
For the purposes of that conformity assessment, notified bodies which have been notified under the Union harmonisation legislation listed in Section A of Annex I shall have the power to assess the conformity of high-risk AI systems with the requirements set out in Section 2 of this Chapter, provided that the compliance of those notified bodies with the requirements laid down in Article 31(4), (5), (10) and (11) has been assessed in the context of the notification procedure in accordance with the relevant Union harmonisation legislation, which is evidenced through the assessment as part of the existing notification. Without prejudice to Article 28, such notified bodies which have been notified under the Union harmonisation legislation in Section A of Annex I, shall apply for designation in accordance with Section 4 of this Chapter by 28 January 2028.

Where Union harmonisation legislation listed in Section A of Annex I provides the product manufacturer with an option to rely on a conformity assessment that does not involve a third-party, provided that that manufacturer has applied harmonised standards to ensure compliance with 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. The classification of a product as a high-risk AI system in accordance with Article 6(1) does not affect the choice of the conformity assessment procedure provided to the manufacturers of products covered by Union harmonisation legislation listed in Section A of Annex I, including, where applicable, an option to rely on harmonised standards. The manufacturers of such products are not required to choose a conformity assessment procedure involving third-party conformity assessment only because the product includes a high-risk AI system as a safety component, if this is not required by the Union harmonisation legislation listed in Section A of Annex I.

Where a high-risk AI system is both covered by the Union harmonisation legislation listed in Section A of Annex I and it falls within one of the categories listed in Annex III, the provider of that system shall follow the relevant conformity assessment procedure as required pursuant to the relevant Union harmonisation legislation listed in Section A of Annex I.

▼B

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.

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.

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.

Article 44

Certificates

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.

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.

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.

Article 45

Information obligations of notified bodies

1.

Notified bodies shall inform the notifying authority of the following:

(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;

(b)

any refusal, restriction, suspension or withdrawal of a Union technical documentation assessment certificate or a quality management system approval issued in accordance with the requirements of Annex VII;

(c)

any circumstances affecting the scope of or conditions for notification;

(d)

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

(e)

on request, conformity assessment activities performed within the scope of their notification and any other activity performed, including cross-border activities and subcontracting.

2.
Each notified body shall inform the other notified bodies of:

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

(b)
Union technical documentation assessment certificates or any supplements thereto which it has refused, withdrawn, suspended or otherwise restricted, and, upon request, of the certificates and/or supplements thereto which it has issued.

3.
Each notified body shall provide the other notified bodies carrying out similar conformity assessment activities covering the same types of AI systems with relevant information on issues relating to negative and, on request, positive conformity assessment results.
4.
Notified bodies shall safeguard the confidentiality of the information that they obtain, in accordance with Article 78.
Article 46

Derogation from conformity assessment procedure

1.
By way of derogation from Article 43 and upon a duly justified request, any market surveillance authority may authorise the placing on the market or the putting into service of specific high-risk AI systems within the territory of the Member State concerned, for exceptional reasons of public security or the protection of life and health of persons, environmental protection or the protection of key industrial and infrastructural assets. That authorisation shall be for a limited period while the necessary conformity assessment procedures are being carried out, taking into account the exceptional reasons justifying the derogation. The completion of those procedures shall be undertaken without undue delay.
2.
In a duly justified situation of urgency for exceptional reasons of public security or in the case of specific, substantial and imminent threat to the life or physical safety of natural persons, law-enforcement authorities or civil protection authorities may put a specific high-risk AI system into service without the authorisation referred to in paragraph 1, provided that such authorisation is requested during or after the use without undue delay. If the authorisation referred to in paragraph 1 is refused, the use of the high-risk AI system shall be stopped with immediate effect and all the results and outputs of such use shall be immediately discarded.
3.
The authorisation referred to in paragraph 1 shall be issued only if the market surveillance authority concludes that the high-risk AI system complies with the requirements of Section 2. The market surveillance authority shall inform the Commission and the other Member States of any authorisation issued pursuant to paragraphs 1 and 2. This obligation shall not cover sensitive operational data in relation to the activities of law-enforcement authorities.
4.
Where, within 15 calendar days of receipt of the information referred to in paragraph 3, no objection has been raised by either a Member State or the Commission in respect of an authorisation issued by a market surveillance authority of a Member State in accordance with paragraph 1, that authorisation shall be deemed justified.
5.
Where, within 15 calendar days of receipt of the notification referred to in paragraph 3, objections are raised by a Member State against an authorisation issued by a market surveillance authority of another Member State, or where the Commission considers the authorisation to be contrary to Union law, or the conclusion of the Member

States regarding the compliance of the system as referred to in paragraph 3 to be unfounded, the Commission shall, without delay, enter into consultations with the relevant Member State. The operators concerned shall be consulted and have the possibility to present their views. Having regard thereto, the Commission shall decide whether the authorisation is justified. The Commission shall address its decision to the Member State concerned and to the relevant operators.

6.

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

7.

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

Article 47

EU declaration of conformity

1.

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

2.

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

3.

Where high-risk AI systems are subject to other Union harmonisation legislation which also requires an EU declaration of conformity, a single EU declaration of conformity shall be drawn up in respect of all Union law applicable to the high-risk AI system. The declaration shall contain all the information required to identify the Union harmonisation legislation to which the declaration relates.

4.

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

5.

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

Article 48

CE marking

1.

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

2.

For high-risk AI systems provided digitally, a digital CE marking shall be used, only if it can easily be accessed via the interface from which that system is accessed or via an easily accessible machine-readable code or other electronic means.

3.

The CE marking shall be affixed visibly, legibly and indelibly for high-risk AI systems. Where that is not possible or not warranted on account of the nature of the high-risk AI system, it shall be affixed to the packaging or to the accompanying documentation, as appropriate.

4.
Where applicable, the CE marking shall be followed by the identification number of the notified body responsible for the conformity assessment procedures set out in Article 43. The identification number of the notified body shall be affixed by the body itself or, under its instructions, by the provider or by the provider's authorised representative. The identification number shall also be indicated in any promotional material which mentions that the high-risk AI system fulfils the requirements for CE marking.
5.
Where high-risk AI systems are subject to other Union law which also provides for the affixing of the CE marking, the CE marking shall indicate that the high-risk AI system also fulfil the requirements of that other law.
Article 49

Registration

1.
Before placing on the market or putting into service a high-risk AI system listed in Annex III, with the exception of high-risk AI systems referred to in point 2 of Annex III, the provider or, where applicable, the authorised representative shall register themselves and their system in the EU database referred to in Article 71.
2.
Before placing on the market or putting into service an AI system for which the provider has concluded that it is not high-risk according to Article 6(3), that provider or, where applicable, the authorised representative shall register themselves and that system in the EU database referred to in Article 71.
3.
Before putting into service or using a high-risk AI system listed in Annex III, with the exception of high-risk AI systems listed in point 2 of Annex III, deployers that are public authorities, Union institutions, bodies, offices or agencies or persons acting on their behalf shall register themselves, select the system and register its use in the EU database referred to in Article 71.
4.
For high-risk AI systems referred to in points 1, 6 and 7 of Annex III, in the areas of law enforcement, migration, asylum and border control management, the registration referred to in paragraphs 1, 2 and 3 of this Article shall be in a secure non-public section of the EU database referred to in Article 71 and shall include only the following information, as applicable, referred to in:

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

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

(c)
Section C, points 1 to 3, of Annex VIII;

(d)
points 1, 2, 3 and 5, of Annex IX.

Only the Commission and national authorities referred to in Article 74(8) shall have access to the respective restricted sections of the EU database listed in the first subparagraph of this paragraph.

5.
High-risk AI systems referred to in point 2 of Annex III shall be registered at national level.
CHAPTER IV

TRANSPARENCY OBLIGATIONS FOR PROVIDERS AND DEPLOYERS OF CERTAIN AI SYSTEMS

Article 50

Transparency obligations for providers and deployers of certain AI systems

1.

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

2.

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

3.

Deployers of an emotion recognition system or a biometric categorisation system shall inform the natural persons exposed thereto of the operation of the system, and shall process the personal data in accordance with Regulations (EU) 2016/679 and (EU) 2018/1725 and Directive (EU) 2016/680, as applicable. This obligation shall not apply to AI systems used for biometric categorisation and emotion recognition, which are permitted by law to detect, prevent or investigate criminal offences, subject to appropriate safeguards for the rights and freedoms of third parties, and in accordance with Union law.

4.

Deployers of an AI system that generates or manipulates image, audio or video content constituting a deep fake, shall disclose that the content has been artificially generated or manipulated. This obligation shall not apply where the use is authorised by law to detect, prevent, investigate or prosecute criminal offence. Where the content forms part of an evidently artistic, creative, satirical, fictional or analogous work or programme, the transparency obligations set out in this paragraph are limited to disclosure of the existence of such generated or manipulated content in an appropriate manner that does not hamper the display or enjoyment of the work.

Deployers of an AI system that generates or manipulates text which is published with the purpose of informing the public on matters of public interest shall disclose that the text has been artificially generated or manipulated. This obligation shall not apply where the use is authorised by law to detect, prevent, investigate or prosecute criminal offences or where the AI-generated content has undergone a process of human review or editorial control and where a natural or legal person holds editorial responsibility for the publication of the content.

5.

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

6.

Paragraphs 1 to 4 shall not affect the requirements and obligations set out in Chapter III, and shall be without prejudice to other transparency obligations laid down in Union or national law for deployers of AI systems.

▼M1

7.

The Commission shall encourage and facilitate the drawing up of codes of practice at Union level to facilitate the effective implementation of the obligations regarding the detection, marking and labelling of artificially generated or manipulated content. The Commission, taking utmost account of the opinion of the Board, shall assess whether adherence to those codes of practice is adequate to ensure compliance with the obligations laid down in paragraphs 2 and 4 of this Article, in accordance with the procedure laid down in Article 56(6). If it deems the code of practice to be inadequate, the Commission may adopt an implementing act specifying

common rules for the implementation of those obligations in accordance with the examination procedure laid down in Article 98(2).

▼B

CHAPTER V

GENERAL-PURPOSE AI MODELS

SECTION 1

Classification rules

Article 51

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

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:

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

(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.

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.

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.

Article 52

Procedure

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.

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.

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.

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.

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.

6.

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

SECTION 2

Obligations for providers of general-purpose AI models

Article 53

Obligations for providers of general-purpose AI models

1.

Providers of general-purpose AI models shall:

(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;

(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:

(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

(ii)

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

(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;

(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.

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.
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.
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.
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.
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.
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.
Article 54

Authorised representatives of providers of general-purpose AI models

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.
2.
The provider shall enable its authorised representative to perform the tasks specified in the mandate received from the provider.
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:

(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;

(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;

(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;

(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.

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.

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.

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.

SECTION 3

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

Article 55

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

1.
In addition to the obligations listed in Articles 53 and 54, providers of general-purpose AI models with systemic risk shall:

(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;

(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;

(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;

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

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.

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.

SECTION 4

Codes of practice

Article 56

Codes of practice

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.

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:

(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;

(b)

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

(c)

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

(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.

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.

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.

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.

▼M1

6.

The Commission 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 Commission, taking utmost account of the opinion of 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. The Commission shall publish its assessment of the adequacy of the codes of practice.
▼B

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.
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.
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).

CHAPTER VI

MEASURES IN SUPPORT OF INNOVATION

Article 57

AI regulatory sandboxes

▼M1

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 2027. 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.
▼B

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.

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.
▼M1

3.
The European Data Protection Supervisor may establish an AI regulatory sandbox for Union institutions, bodies, offices and agencies. For this purpose, references to national competent authorities in this Chapter shall be construed as references to the European Data Protection Supervisor.
▼M1

3a.

The AI Office may establish an AI regulatory sandbox at Union level for AI systems covered by Article 75(1). For this purpose, references to national competent authorities in this Chapter shall be construed, where relevant, as references to the AI Office. That AI regulatory sandbox shall be implemented in close cooperation with relevant competent authorities, in particular where compliance with Union legislation other than this Regulation is supervised in the AI regulatory sandbox, and shall provide priority access to SMEs, including start-ups, and SMCs.
The establishment of a Union level AI regulatory sandbox by the AI Office shall be without prejudice to the competences of Member States to establish and supervise AI regulatory sandboxes for AI systems under their supervision.

▼B

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.
▼M1

5.
AI regulatory sandboxes established under this Article 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 authorities, ensuring that appropriate safeguards are in place. Such sandboxes may include testing in real world conditions supervised therein. Where applicable, the sandbox plan shall incorporate the real-world testing plan referred to in Articles 60 and 60a.
▼B

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.
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.

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.

9.
The establishment of AI regulatory sandboxes shall aim to contribute to the following objectives:

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

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

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

(d)
contributing to evidence-based regulatory learning;

▼M1

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

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

11.
The AI regulatory sandboxes shall not affect the supervisory or corrective powers of the competent authorities supervising the sandboxes, including at regional or local level. Any significant risks to health and safety and fundamental rights identified during the development and testing of such AI systems shall result in an adequate mitigation. National competent authorities shall have the power to temporarily or permanently suspend the testing process, or the participation in the sandbox if no effective mitigation is possible, and shall inform the AI Office of such decision. National competent authorities shall exercise their supervisory powers within the limits of the relevant law, using their discretionary powers when implementing legal provisions in respect of a specific AI regulatory sandbox project, with the objective of supporting innovation in AI in the Union.
12.
Providers and prospective providers participating in the AI regulatory sandbox shall remain liable under applicable Union and national liability law for any damage inflicted on third parties as a result of the experimentation taking place in the sandbox. However, provided that the prospective providers observe the specific plan and the terms and conditions for their participation and follow in good faith the guidance given by the national competent authority, no administrative fines shall be imposed by the authorities for infringements of this Regulation. Where other competent authorities responsible for other Union and national law were actively involved in the supervision of the AI system in the sandbox and provided guidance for compliance, no administrative fines shall be imposed regarding that law.
13.
The AI regulatory sandboxes shall be designed and implemented in such a way that, where relevant, they facilitate cross-border cooperation between national competent authorities.
▼M1

14.

National competent authorities, the European Data Protection Supervisor and the AI Office, shall, as appropriate and within their respective competences, coordinate their activities and cooperate within the framework of the Board. They may support the joint establishment and operation of AI regulatory sandboxes, including in different sectors, and exchange best practices on related matters.

▼B

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

16.
National competent authorities shall submit annual reports to the AI Office and to the Board, from one year after the establishment of the AI regulatory sandbox and every year thereafter until its termination, and a final report. Those reports shall provide information on the progress and results of the implementation of those sandboxes, including best practices, incidents, lessons learnt and recommendations on their setup and, where relevant, on the application and possible revision of this Regulation, including its delegated and implementing acts, and on the application of other Union law supervised by the competent authorities within the sandbox. The national competent authorities shall make those annual reports or abstracts thereof available to the public, online. The Commission shall, where appropriate, take the annual reports into account when exercising its tasks under this Regulation.

17.
The Commission shall develop a single and dedicated interface containing all relevant information related to AI regulatory sandboxes to allow stakeholders to interact with AI regulatory sandboxes and to raise enquiries with competent authorities, and to seek non-binding guidance on the conformity of innovative products, services, business models embedding AI technologies, in accordance with Article 62(1), point (c). The Commission shall proactively coordinate with national competent authorities, where relevant.

Article 58

Detailed arrangements for, and functioning of, AI regulatory sandboxes

▼M1

1.
In order to avoid fragmentation across the Union, the Commission shall adopt implementing acts specifying the detailed arrangements for the establishment, development, implementation, operation, governance, and supervision of the AI regulatory sandboxes. Those implementing acts shall include common principles on the following issues:

▼B

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

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

(c)
the terms and conditions applicable to the participants;

▼M1

(d)
the detailed rules applicable to the governance of AI regulatory sandboxes covered pursuant to Article 57, including as regards the involvement of and supervision by the competent data protection authorities, where relevant, and the coordination and cooperation at national and Union level.

▼B

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

2.
The implementing acts referred to in paragraph 1 shall ensure:

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

(b)
that AI regulatory sandboxes allow broad and equal access and keep up with demand for participation; providers and prospective providers may also submit applications in partnerships with deployers and other relevant third parties;

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

(d)
that access to the AI regulatory sandboxes is free of charge for SMEs, including start-ups, without prejudice to exceptional costs that national competent authorities may recover in a fair and proportionate manner;

(e)
that they facilitate providers and prospective providers, by means of the learning outcomes of the AI regulatory sandboxes, in complying with conformity assessment obligations under this Regulation and the voluntary application of the codes of conduct referred to in Article 95;

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

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

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

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

3.
Prospective providers in the AI regulatory sandboxes, in particular SMEs and start-ups, shall be directed, where relevant, to pre-deployment services such as guidance on the implementation of this Regulation, to other value-

adding services such as help with standardisation documents and certification, testing and experimentation facilities, European Digital Innovation Hubs and centres of excellence.

4.

Where national competent authorities consider authorising testing in real world conditions supervised within the framework of an AI regulatory sandbox to be established under this Article, they shall specifically agree the terms and conditions of such testing and, in particular, the appropriate safeguards with the participants, with a view to protecting fundamental rights, health and safety. Where appropriate, they shall cooperate with other national competent authorities with a view to ensuring consistent practices across the Union.

Article 59

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

1.

In the AI regulatory sandbox, personal data lawfully collected for other purposes may be processed solely for the purpose of developing, training and testing certain AI systems in the sandbox when all of the following conditions are met:

(a)

AI systems shall be developed for safeguarding substantial public interest by a public authority or another natural or legal person and in one or more of the following areas:

(i)

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

(ii)

a high level of protection and improvement of the quality of the environment, protection of biodiversity, protection against pollution, green transition measures, climate change mitigation and adaptation measures;

(iii)

energy sustainability;

(iv)

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

(v)

efficiency and quality of public administration and public services;

(b)

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

(c)

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

(d)

any personal data to be processed in the context of the sandbox are in a functionally separate, isolated and protected data processing environment under the control of the prospective provider and only authorised persons have access to those data;

(e)

providers can further share the originally collected data only in accordance with Union data protection law; any personal data created in the sandbox cannot be shared outside the sandbox;

(f)
any processing of personal data in the context of the sandbox neither leads to measures or decisions affecting the data subjects nor does it affect the application of their rights laid down in Union law on the protection of personal data;

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

(h)
the logs of the processing of personal data in the context of the sandbox are kept for the duration of the participation in the sandbox, unless provided otherwise by Union or national law;

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

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

2.
For the purposes of the prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, including safeguarding against and preventing threats to public security, under the control and responsibility of law enforcement authorities, the processing of personal data in AI regulatory sandboxes shall be based on a specific Union or national law and subject to the same cumulative conditions as referred to in paragraph 1.
3.
Paragraph 1 is without prejudice to Union or national law which excludes processing of personal data for other purposes than those explicitly mentioned in that law, as well as to Union or national law laying down the basis for the processing of personal data which is necessary for the purpose of developing, testing or training of innovative AI systems or any other legal basis, in compliance with Union law on the protection of personal data.
Article 60

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

▼M1

1.
Testing of high-risk AI systems in real world conditions outside AI regulatory sandboxes may be conducted by providers or prospective providers of high-risk AI systems listed in Annex III or covered by Union harmonisation legislation listed in Section A of Annex I, in accordance with this Article and the real-world testing plan referred to in this Article, without prejudice to the prohibitions under Article 5.
▼B

The Commission shall, by means of implementing acts, specify the detailed elements of the real-world testing plan. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 98(2).

This paragraph shall be without prejudice to Union or national law on the testing in real world conditions of high-risk AI systems related to products covered by Union harmonisation legislation listed in Annex I.

▼M1

2.

Providers or prospective providers may conduct testing of high-risk AI systems referred to in Annex III or covered by Union harmonisation legislation listed in Section A of Annex I in real world conditions at any time before the placing on the market or the putting into service of the high-risk AI system on their own or in partnership with one or more deployers or prospective deployers.
▼B

3.
The testing of high-risk AI systems in real world conditions under this Article shall be without prejudice to any ethical review that is required by Union or national law.
4.
Providers or prospective providers may conduct the testing in real world conditions only where all of the following conditions are met:

(a)
the provider or prospective provider has drawn up a real-world testing plan and submitted it to the market surveillance authority in the Member State where the testing in real world conditions is to be conducted;

(b)
the market surveillance authority in the Member State where the testing in real world conditions is to be conducted has approved the testing in real world conditions and the real-world testing plan; where the market surveillance authority has not provided an answer within 30 days, the testing in real world conditions and the real-world testing plan shall be understood to have been approved; where national law does not provide for a tacit approval, the testing in real world conditions shall remain subject to an authorisation;

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

(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;

(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;

(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;

(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;

(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;

(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;

(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;

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

5.
Any subjects of the testing in real world conditions, or their legally designated representative, as appropriate, may, without any resulting detriment and without having to provide any justification, withdraw from the testing at any time by revoking their informed consent and may request the immediate and permanent deletion of their personal data. The withdrawal of the informed consent shall not affect the activities already carried out.
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.
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.
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.
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.
▼M1

Article 60a

Testing of high-risk AI systems covered by Union harmonisation legislation listed in Section B of Annex I in real-world conditions outside AI regulatory sandboxes

1.
Member States may allow, in accordance with this Article, the testing of high-risk AI systems in real world conditions outside AI regulatory sandboxes by providers or prospective providers of AI enabled products

covered by the Union harmonisation legislation listed in Section B of Annex I, with a view to assessing and verifying the conformity of those systems with the requirements laid down in Articles 8 to 15.

2.

Member States that choose to allow testing as referred to in paragraph 1 shall, individually or jointly, adopt frameworks for real-world testing.

3.

Each Member State shall notify the Commission of any real-world testing framework it adopts before implementing it. This shall not affect the competences of the Commission under the Union harmonisation legislation listed in Section B of Annex I.

4.

Member States that have adopted real-world testing frameworks shall ensure that the relevant national competent authorities, relevant authorities and public authorities responsible for the management and operation of infrastructure and products covered by Union harmonisation legislation listed in Section B of Annex I cooperate closely with each other in good faith and remove any practical obstacles, including on procedural rules providing access to physical public infrastructure, where this is necessary, to successfully implement those real-world testing frameworks and test AI-enabled products covered by Union harmonisation legislation listed in Section B of Annex I.

5.

The frameworks for real-world testing shall lay down the requirements under which testing in real-world conditions shall occur. Those frameworks shall:

(a)

include the provision of a mandatory real-world testing plan to be agreed between the provider or prospective provider and the national competent authority or relevant authority in accordance with the Union harmonisation legislation listed in Section B of Annex I;

(b)

ensure compliance with the requirements laid down in Article 60(2), (3), (4)(d)-(j) and (5)-(9), where any reference to market surveillance authorities in those provisions shall be read as a reference to the national competent authority or relevant authority, as appropriate in accordance with the Union harmonisation legislation listed in Section B of Annex I;

(c)

include effective governance and accountability arrangements;

(d)

ensure a high level of protection of health safety and fundamental rights.

6.

The real-world testing shall comply with the applicable provisions laid down in the Union harmonisation legislation listed in Section B of Annex I. Any requirements laid down in those provisions shall not affect the application of this Article to the extent necessary to enable the testing referred to in paragraph 1.

▼B

Article 61

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

1.

For the purpose of testing in real world conditions under Article 60, freely-given informed consent shall be obtained from the subjects of testing prior to their participation in such testing and after their having been duly informed with concise, clear, relevant, and understandable information regarding:

(a)

the nature and objectives of the testing in real world conditions and the possible inconvenience that may be linked to their participation;

(b)
the conditions under which the testing in real world conditions is to be conducted, including the expected duration of the subject or subjects' participation;

(c)
their rights, and the guarantees regarding their participation, in particular their right to refuse to participate in, and the right to withdraw from, testing in real world conditions at any time without any resulting detriment and without having to provide any justification;

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

(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.

2.
The informed consent shall be dated and documented and a copy shall be given to the subjects of testing or their legal representative.

Article 62

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

1.
Member States shall undertake the following actions:

(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;

(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;

(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;

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

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.

3.
The AI Office shall undertake the following actions:

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

(b)

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

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

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

Article 63

Derogations for specific operators

▼M1

1.
SMEs, including start-ups, may comply with certain elements of the quality management system required by Article 17 in a simplified manner, provided that they do not have partner enterprises or linked enterprises within the meaning of Recommendation 2003/361/EC. 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 SMEs, without affecting the level of protection or the need for compliance with the requirements in respect of high-risk AI systems.
▼B

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.
CHAPTER VII

GOVERNANCE

SECTION 1

Governance at Union level

Article 64

AI Office

1.
The Commission shall develop Union expertise and capabilities in the field of AI through the AI Office.
2.
Member States shall facilitate the tasks entrusted to the AI Office, as reflected in this Regulation.
▼M1

3.
Without prejudice to the budgetary procedure, the AI Office shall be allocated adequate resources to effectively perform its duties and exercise its powers in relation to the enforcement of this Regulation.
▼B

Article 65

Establishment and structure of the European Artificial Intelligence Board

1.
A European Artificial Intelligence Board (the ‘Board’) is hereby established.
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.
3.
Each representative shall be designated by their Member State for a period of three years, renewable once.
4.
Member States shall ensure that their representatives on the Board:

(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;

(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;

(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.

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.
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.

7.
The Board shall be organised and operated so as to safeguard the objectivity and impartiality of its activities.
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.
Article 66

Tasks of the Board

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:

(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);

(b)

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

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

(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;

(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:

(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;

(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;

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

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

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

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

(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;

(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;

(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;

(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;

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

(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;

(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;

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

(m)
advise the Commission in relation to international matters on AI;

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

(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.

Article 67

Advisory forum

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

8.
The advisory forum may prepare opinions, recommendations and written contributions at the request of the Board or the Commission.
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.
10.
The advisory forum shall prepare an annual report on its activities. That report shall be made publicly available.
Article 68

Scientific panel of independent experts

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).
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:

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

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

(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.

3.
The scientific panel shall advise and support the AI Office, in particular with regard to the following tasks:

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

(i)
alerting the AI Office of possible systemic risks at Union level of general-purpose AI models, in accordance with Article 90;

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

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

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

(v)
contributing to the development of tools and templates;

(b)

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

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

(d)
supporting the AI Office in carrying out its duties in the context of the Union safeguard procedure pursuant to Article 81.

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.
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.
Article 69

Access to the pool of experts by the Member States

1.
Member States may call upon experts of the scientific panel to support their enforcement activities under this Regulation.
▼M1

2.
The Member States may be required to pay fees for the advice and support provided by the experts at a rate equivalent to the remuneration fees applicable to the Commission pursuant to the implementing act referred to in Article 68(1).
▼B

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.
SECTION 2

National competent authorities

Article 70

Designation of national competent authorities and single points of contact

1.
Each Member State shall establish or designate as national competent authorities at least one notifying authority and at least one market surveillance authority for the purposes of this Regulation. Those national competent authorities shall exercise their powers independently, impartially and without bias so as to safeguard the objectivity of their activities and tasks, and to ensure the application and implementation of this Regulation. The members of those authorities shall refrain from any action incompatible with their duties. Provided that those principles are observed, such activities and tasks may be performed by one or more designated authorities, in accordance with the organisational needs of the Member State.
2.

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.

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.

4.

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

5.

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

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.

7.

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

▼M1

8.

National competent authorities may provide guidance and advice on the implementation of this Regulation, in particular to SMEs, including start-ups, and SMCs, 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.

▼B

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.

CHAPTER VIII

EU DATABASE FOR HIGH-RISK AI SYSTEMS

Article 71

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

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.

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

CHAPTER IX

POST-MARKET MONITORING, INFORMATION SHARING AND MARKET SURVEILLANCE

SECTION 1

Post-market monitoring

Article 72

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

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.
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.

▼M1

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, taking utmost account of the opinion of the Board, shall adopt guidance, including a template, on the post-market monitoring plan by 2 September 2027.

▼B

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.

SECTION 2

Sharing of information on serious incidents

Article 73

Reporting of serious incidents

1.
Providers of high-risk AI systems placed on the Union market shall report any serious incident to the market surveillance authorities of the Member States where that incident occurred.
2.
The report referred to in paragraph 1 shall be made immediately after the provider has established a causal link between the AI system and the serious incident or the reasonable likelihood of such a link, and, in any event, not later than 15 days after the provider or, where applicable, the deployer, becomes aware of the serious incident.
The period for the reporting referred to in the first subparagraph shall take account of the severity of the serious incident.

3.
Notwithstanding paragraph 2 of this Article, in the event of a widespread infringement or a serious incident as defined in Article 3, point (49)(b), the report referred to in paragraph 1 of this Article shall be provided immediately, and not later than two days after the provider or, where applicable, the deployer becomes aware of that incident.
4.
Notwithstanding paragraph 2, in the event of the death of a person, the report shall be provided immediately after the provider or the deployer has established, or as soon as it suspects, a causal relationship between the high-risk AI system and the serious incident, but not later than 10 days after the date on which the provider or, where applicable, the deployer becomes aware of the serious incident.
5.
Where necessary to ensure timely reporting, the provider or, where applicable, the deployer, may submit an initial report that is incomplete, followed by a complete report.
6.
Following the reporting of a serious incident pursuant to paragraph 1, the provider shall, without delay, perform the necessary investigations in relation to the serious incident and the AI system concerned. This shall include a risk assessment of the incident, and corrective action.
The provider shall cooperate with the competent authorities, and where relevant with the notified body concerned, during the investigations referred to in the first subparagraph, and shall not perform any investigation which involves altering the AI system concerned in a way which may affect any subsequent evaluation of the causes of the incident, prior to informing the competent authorities of such action.

7.
Upon receiving a notification related to a serious incident referred to in Article 3, point (49)(c), the relevant market surveillance authority shall inform the national public authorities or bodies referred to in Article 77(1).
The Commission shall develop dedicated guidance to facilitate compliance with the obligations set out in paragraph 1 of this Article. That guidance shall be issued by 2 August 2025, and shall be assessed regularly.
8.

The market surveillance authority shall take appropriate measures, as provided for in Article 19 of Regulation (EU) 2019/1020, within seven days from the date it received the notification referred to in paragraph 1 of this Article, and shall follow the notification procedures as provided in that Regulation.

9.

For high-risk AI systems referred to in Annex III that are placed on the market or put into service by providers that are subject to Union legislative instruments laying down reporting obligations equivalent to those set out in this Regulation, the notification of serious incidents shall be limited to those referred to in Article 3, point (49)(c).

10.

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

11.

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

SECTION 3

Enforcement

Article 74

Market surveillance and control of AI systems in the Union market

1.

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

(a)

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

(b)

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

2.

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

3.

For high-risk AI systems related to products covered by the Union harmonisation legislation listed in Section A of Annex I, the market surveillance authority for the purposes of this Regulation shall be the authority responsible for market surveillance activities designated under those legal acts.

By derogation from the first subparagraph, and in appropriate circumstances, Member States may designate another relevant authority to act as a market surveillance authority, provided they ensure coordination with the relevant sectoral market surveillance authorities responsible for the enforcement of the Union harmonisation legislation listed in Annex I.

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.

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.
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.
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.

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

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:

(a)
access to source code is necessary to assess the conformity of a high-risk AI system with the requirements set out in Chapter III, Section 2; and

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

14.
Any information or documentation obtained by market surveillance authorities shall be treated in accordance with the confidentiality obligations set out in Article 78.
Article 75

▼M1

Market surveillance and control of AI systems and mutual assistance

1.
The AI Office shall be exclusively competent for the supervision and enforcement of the obligations under this Regulation in relation to the following AI systems:

(a)
AI systems based on general-purpose AI models where the model and the system are developed by the same provider, or by providers forming part of the same undertaking as that provider, with the exception of:

(i)
AI systems related to products covered by the Union harmonisation legislation listed in Annex I;

(ii)
AI systems referred to in point 2 of Annex III;

(iii)
AI systems provided by law enforcement authorities, border management authorities and financial institutions, insofar as those AI systems fall under Article 74(6); and

(iv)
AI systems referred to in point 8 of Annex III as regards the administration of justice;

(b)
AI systems that constitute or that are integrated into a very large online platform or very large online search engine designated in accordance with Regulation (EU) 2022/2065.

The exclusive competence referred to in the first subparagraph shall apply to the providers of those systems. It shall apply to the deployers of those systems only when they are also the provider or form part of the same undertaking as the provider.

▼M1

1a.
By way of derogation from Article 73, providers of high-risk AI systems subject to the competence of the AI Office pursuant to paragraph 1 of this Article shall report any serious incidents to the AI Office. Article 73 (2) to (9), shall apply mutatis mutandis. The AI Office shall promptly transmit the relevant information to the market surveillance authority of the Member State in the territory of which the provider or its legal representative is situated.
1b.

The authorities involved in the application of this Regulation shall cooperate actively with the AI Office and provide the AI Office the necessary assistance for the exercise of its powers, including, where necessary, in connection with inspections or other enforcement measures carried out in the territory of a Member State. To that end, those authorities shall enjoy the powers provided for pursuant to this Regulation and Regulation (EU) 2019/1020, and where relevant and limited to what is necessary to fulfil their tasks under this paragraph, in accordance with the applicable national procedures.

1c.

When taking investigatory or enforcement action in the territory of a Member State that involves access to a public authority's data or AI system, the AI Office shall be assisted by the relevant market surveillance authority.

1d.

Before taking a decision that would have the effect of prohibiting or restricting the AI system being made available or put into service on a national market, or a decision to withdraw or recall the AI system from such market, the AI Office shall, without undue delay, notify the market surveillance authority competent for that market of its intention to take such a decision. The AI Office shall consult the authorities involved in the application of this Regulation, where appropriate, on any matter relating to the application and enforcement of this Regulation.

1e.

The AI Office shall be responsible for conformity assessments and tests of AI systems referred to in paragraph 1 of this Article that are classified as high-risk and subject to a third-party conformity assessment pursuant to Article 43 before such AI systems are placed on the market or put into service. Those tests and assessments shall verify that the systems comply with the relevant requirements of this Regulation and may be placed on the market or put into service in the Union in accordance with this Regulation. The Commission shall entrust the performance of those tests or assessments to notified bodies designated in accordance with this Regulation, in which case the notified body shall act on behalf of the Commission. If a notified body to which the Commission has delegated tasks under this paragraph does not perform those tasks adequately, the Commission may withdraw the delegation with immediate effect.

The fees for testing and assessment activities shall be levied on the provider of a high-risk AI system who has applied for a third-party conformity assessment to the Commission. The provider shall pay the costs related to the services entrusted by the Commission to the notified bodies in accordance with this Article directly to the notified body.

▼B

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.

▼M1

2a.

Where a market surveillance authority has well-founded and sufficient reasons to suspect that a provider or a deployer of an AI system referred to in paragraph 1 of this Article has infringed this Regulation, it may request, through the relevant single point of contact designated in accordance with Article 70(2), the AI Office to assess the matter in order to take the necessary supervisory and enforcement measures to ensure prompt compliance with this Regulation. Such a request shall be duly reasoned and shall include at least:

(a)

the name of the provider or the deployer concerned;

(b)

a description of the relevant facts, the provisions of this Regulation that have allegedly been infringed, and any well-founded and sufficient reasons for suspecting an infringement, including, where applicable, the description of the negative effects of the alleged infringement;

(c)
the market surveillance authority making the request.

The AI Office shall take utmost account of the request and the market surveillance authority shall cooperate actively and provide the AI Office the necessary assistance for the exercise of its powers in accordance with paragraph 1a.

The AI Office shall, without undue delay and in any event no later than four months following receipt of the request, inform the single point of contact of its intention to exercise its powers in accordance with Article 75a or of its reasons for not exercising its powers. If the AI Office decides to exercise its powers in accordance with Article 75a, it shall periodically inform that single point of contact about major developments in the proceedings and the outcome of such proceedings, without disclosing any confidential information.

▼B

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.
▼M1

Article 75a

Supervisory and enforcement powers of the AI Office

1.
When exercising its tasks of supervision and enforcement laid down in Article 75(1) of this Regulation, the AI Office shall have all the powers of a market surveillance authority provided for in this Section and in Article 14(4) and Article 16(3) of Regulation (EU) 2019/1020. The AI Office shall be authorised to fully reclaim from the relevant operator the totality of the costs of its supervision and enforcement activities with respect to instances of non-compliance, including costs for human and technical resources, in accordance with Article 15 of Regulation (EU) 2019/1020. Article 17 of Regulation (EU) 2019/1020 shall apply mutatis mutandis.
2.
Where the AI Office has reasonable grounds to suspect non-compliance with this Regulation by a provider or a deployer of an AI system referred to in Article 75(1) of this Regulation, it may adopt a decision to start an investigation into that non-compliance in accordance with Article 14(4), point (f) of Regulation (EU) 2019/1020. Upon starting such an investigation, the AI Office shall notify the operator of the AI system concerned. The AI Office may exercise the powers referred to in paragraph 1 of this Article on its own initiative or following a complaint received pursuant to Article 85 of this Regulation, even before starting an investigation pursuant to Article 14(4), point (f) of Regulation (EU) 2019/1020.
Where a market surveillance authority has reason to suspect non-compliance with this Regulation by a provider or a deployer of an AI system referred to in Article 75(1), it may send a request to the AI Office to assess the matter.

3.
The AI Office may exercise the powers listed in Article 14(4), points (a), (b) and (c) of Regulation (EU) 2019/1020 and Article 74(12) and (13) of this Regulation by simple request or by decision.

When requesting information, the AI Office shall state the legal basis and the purpose of the request, specify what information is required, and set the period within which the information is to be provided. Where the request is a simple request, the AI Office shall additionally indicate that although there is no obligation to provide the information requested, in the case of a voluntary reply, the information must be correct and not misleading, and indicate the potential fines provided for in Article 99(5) for supplying incorrect or misleading information. Where the request is made by decision, the AI Office shall additionally indicate the fines provided for in Article 99(5) for supplying incorrect, incomplete or misleading information and indicate the right to have the decision reviewed by the Court of Justice of the European Union. The AI Office shall send a copy of the request to the market surveillance authority of the Member State in the territory of which the operator or its legal representative is situated.

4.
In order to carry out the tasks assigned to it under this Section, the AI Office may conduct all necessary remote or on-site inspections pursuant to the powers laid down in Article 14(4), points (d) and (e) of Regulation (EU) 2019/1020 and Article 74(5) of this Regulation. When conducting an inspection, the AI Office shall inform the provider concerned of the subject matter and purpose of the investigation, the relevant fines referred to in Article 99(5) of this Regulation, and the right to have the decision reviewed by the Court of Justice of the European Union. Prior to conducting an inspection, the AI Office shall inform the market surveillance authority of the Member State in the territory of which the operator or its legal representative is situated.
During such an inspection, the officials of the AI Office shall be empowered to:

(a)
enter any of the business premises, land or property located in the Union of the operator concerned;

(b)
examine the books, data and other material relevant to the execution of their tasks, irrespective of the medium on which they are stored;

(c)
take or obtain in any form copies of or extracts from books, data and other records;

(d)
ask any of the persons subject to the inspection, or their representatives, or staff, for oral or written explanations on factors or documents relating to the subject matter and purpose of the inspection, and to record the answers;

(e)
seal any business premises and books or records for the duration of, and to the extent necessary for, the inspection.

Where the AI Office finds that a natural or legal person opposes or obstructs an inspection, the national competent authority of the Member State concerned shall afford it the necessary assistance, requesting, where appropriate, the assistance of the police or an equivalent enforcement authority, to enable it to conduct its on-site inspection.

Where an on-site inspection of business premises, land or property requires authorisation by a judicial authority in accordance with national law, the AI Office shall apply for such an authorisation. The AI Office may also apply for such authorisation as a precautionary measure. Where such an authorisation is applied for, the national judicial authority shall promptly verify that the coercive measures envisaged are neither arbitrary nor excessive having regard to the subject matter of the investigation or inspection and the documents provided by the AI Office with the decision. In its verification of the proportionality of coercive measures, the national judicial authority may ask the AI Office for detailed explanations, in particular relating to the grounds the AI Office has for suspecting that an infringement of this Regulation has taken place and the seriousness of the suspected infringement and, where relevant, the nature of the involvement of the person subject to the coercive measures. The national judicial authority shall not review the necessity of the investigation or inspection nor demand information from the case file of the AI Office. In accordance with the Treaties, the legality of the decision of the AI Office is subject to review only by the Court of Justice of the European Union.

5.
At the request of the AI Office, the competent market surveillance authority of a Member State may in its own territory carry out any investigation, inspection or other fact-finding measure on behalf and for the account of the AI Office in order to establish whether there has been an infringement of this Regulation. The officials of the competent authorities of the Member States who are responsible for conducting such investigations, inspections, or fact-finding measures, as well as those authorised or appointed by them, shall exercise their powers in accordance with their national law.
6.
In addition to the powers set out in paragraph 1 of this Article, the AI Office, in the exercise of its competences referred to in Article 75(1), may:

(a)
order operators to provide access to, and explanations relating to, their AI systems;

(b)
impose an obligation on an operator to retain all data and documents deemed to be necessary to assess the implementation of and compliance with the obligations under this Regulation.

7.
To assist it in monitoring the effective implementation and compliance with the relevant provisions of this Regulation and to provide it with specific expertise or knowledge in the exercise of its competences under Article 75(1), the AI Office may appoint independent external experts and auditors, as well as experts, investigative teams and auditors from the Member State's competent authorities with the agreement of the authority concerned. Information obtained as a result of such monitoring actions shall be shared with the relevant competent authorities of the Member States.
8.
Information collected pursuant to this Article shall be used only for the purpose of this Regulation.
Article 75b

Commitments

If, during proceedings under Article 75a(2), the operator concerned offers commitments to ensure compliance with the relevant provisions of this Regulation, the AI Office may, by decision, make those commitments binding on the operator concerned and declare that there are no further grounds for action. The AI Office may, upon request or on its own initiative, reopen the proceedings where:

(a)
there has been a material change in any of the facts on which the decision was based;

(b)
the operator acts contrary to its commitments; or

(c)
the decision was based on incomplete, incorrect or misleading information provided by the operator concerned.

Where the AI Office considers that the commitments offered by the operator concerned are unable to ensure effective compliance with the relevant provisions of this Regulation, it shall reject those commitments in a reasoned decision when concluding the proceedings.

Article 75c

Non-compliance, fines and periodic penalty payments

1.
Where the AI Office finds that an operator falling within the scope of Article 75(1) does not comply with the relevant provisions of this Regulation or with commitments made binding pursuant to Article 75b, it shall adopt a decision establishing such non-compliance.
2.

Before adopting a decision pursuant to paragraph 1, the AI Office shall communicate its preliminary findings to the operator concerned. In the preliminary findings, the AI Office shall explain the measures that it is considering taking, or that it considers that the operator concerned should take, in order to effectively address the preliminary findings.

3.

In the decision pursuant to paragraph 1 of this Article, the AI Office shall, where relevant, order the operator concerned to take the necessary measures to ensure compliance with the relevant provisions of this Regulation within a reasonable period specified therein and to provide information on the measures that that operator intends to take to comply with the decision. The operator concerned shall provide the AI Office with a description of the measures it has taken to ensure compliance with the decision upon their implementation. Prior to requesting any measure, the AI Office may engage in a structured dialogue with the operator of the AI system in question. During this dialogue, the operator may propose commitments in accordance with Article 75b.

4.

A decision adopted pursuant to paragraph 1 of this Article may be accompanied by the imposition of penalties in accordance with Article 99(3) to (7), which provisions shall apply mutatis mutandis to the AI Office in the execution of its supervision and enforcement tasks referred to in Article 75(1).

In particular, the following shall be subject to administrative fines as referred to in Article 99(4):

(a)
infringement of any applicable provision of this Regulation, including those not listed in Article 99(4);

(b)
failure to comply with decisions or measures adopted pursuant to the powers listed in Article 14(4) or Article 16(3) of Regulation (EU) 2019/1020, as well as those specified in Article 75a of this Regulation;

(c)
failure to comply with a commitment made binding by a decision pursuant to Article 75b.

The supply of incorrect, incomplete or misleading information to the AI Office in reply to a request shall be subject to administrative fines as referred to in Article 99(5).

5.

The AI Office may adopt a decision imposing periodic penalty payments to compel the operators subject to its competence pursuant to Article 75(1) to the following:

(a)
to submit to an investigation;

(b)
to comply with an information request ordered by a decision adopted under Article 75a(3);

(c)
to submit to an inspection ordered by a decision pursuant to Article 75a(4);

(d)
to provide correct or complete answers or explanations in the context of an inspection ordered by a decision pursuant to Article 75a(4);

(e)
to comply with corrective actions ordered pursuant to the power listed in Article 16 of Regulation (EU) 2019/1020;

(f)
to comply with commitments made legally binding by a decision pursuant to Article 75b; or

(g)
to comply with a decision pursuant to the paragraph (1) of this Article.

Those penalty payments shall be effective and proportionate, and, where applicable, shall not exceed 5 % of the average daily income or worldwide annual turnover in the preceding financial year per day, calculated from the date appointed by the decision.

6.
The Court of Justice of the European Union shall have unlimited jurisdiction to review decisions of the AI Office fixing a fine or periodic penalty payment pursuant to this Article. It may cancel, reduce or increase the fine or periodic penalty payment imposed.
7.
Funds collected through the imposition of fines or periodic penalty payments pursuant to this Article shall contribute to the general budget of the Union.
8.
The powers conferred on the AI Office by this Article shall be subject to a limitation period of five years. The limitation period shall begin to run on the day on which the infringement is committed. However, in the case of continuing or repeated infringements, the limitation period shall begin to run on the day on which the infringement ceases.
The power of the AI Office to enforce decisions taken pursuant to this Article shall be subject to a limitation period of five years. The limitation period shall begin to run on the day on which the decision becomes final.

The implementing act referred to in Article 75d(3) shall specify the first and second subparagraphs of this paragraph, including the circumstances in which the limitation periods shall be interrupted.

9.
Where the AI Office determines that there are no grounds to adopt a decision of non-compliance, it shall close the proceeding by a decision. That decision shall apply with immediate effect.
Article 75d

Safeguards and further specification

1.
Article 18 of Regulation (EU) 2019/1020 shall apply mutatis mutandis to operators subject to the AI Office's competence pursuant to Article 75(1) of this Regulation, without prejudice to more specific procedural rights provided for in this Regulation.
2.
The rights of defence and of access to the file of operators falling within the scope of Article 75(1) shall be fully respected in proceedings. In view of the possible adoption of decisions on the basis of Article 75c(1), those operators shall be entitled to have access to the AI Office file under the terms of a negotiated disclosure, subject to the legitimate interest of the operator or other person concerned in the protection of their business secrets. The AI Office shall have the power to adopt decisions setting out such terms of disclosure in the case of disagreement between the parties. The right of access to the file shall not extend to confidential information and internal documents of the AI Office, the Board, competent market surveillance authorities or other public authorities of the Member States. In particular, the right of access shall not extend to correspondence between the AI Office and those authorities. Nothing in this paragraph shall prevent the AI Office from disclosing and using information necessary to prove an infringement.
3.
The Commission may adopt implementing acts concerning the practical arrangements for access to the file and the negotiated disclosure of information provided for in paragraph 2.
4.
The AI Office shall publish the decisions it adopts pursuant to Articles 75b and 75c. Such publication shall state the names of the parties and the main content of the decision, including any penalties imposed. The publication shall have regard to the rights and legitimate interests of any person concerned in the protection of their confidential information.
▼B

Article 76

Supervision of testing in real world conditions by market surveillance authorities

1.
Market surveillance authorities shall have competences and powers to ensure that testing in real world conditions is in accordance with this Regulation.
▼M1

Where testing in real world conditions is based on Article 60a, any reference to a market surveillance authority in this Article shall be construed as a reference to the national competent authority or appropriate authority under the Union harmonisation legislation listed in Section B of Annex I, and references to Article 60 shall be construed as references to Article 60a, as appropriate.

▼B

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).
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:

(a)
to suspend or terminate the testing in real world conditions;

(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.

4.
Where a market surveillance authority has taken a decision referred to in paragraph 3 of this Article, or has issued an objection within the meaning of Article 60(4), point (b), the decision or the objection shall indicate the grounds therefor and how the provider or prospective provider can challenge the decision or objection.
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.
Article 77

▼M1

Powers of authorities protecting fundamental rights and cooperation with market surveillance authorities

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, shall have the power to request and access any information or documentation created or maintained from the relevant market surveillance authority pursuant to this Regulation in accessible language and machine-readable format by electronic means where access to that information or documentation is necessary for effectively fulfilling their mandates within the limits of their jurisdiction. This Article is without prejudice to the competences, tasks, powers and independence of the relevant national public authorities or bodies under their mandates.
▼M1

1a.

Subject to the conditions specified in this Article, the market surveillance authority shall grant the relevant public authority or body referred to in paragraph 1 access to such information or documentation, including by requesting such information or documentation from the provider or the deployer, where necessary and without undue delay.

1b.

Market surveillance authorities and public authorities or bodies referred to in paragraph 1 shall cooperate closely and provide each other with the mutual assistance necessary to fulfil their respective mandates, with a view to ensuring the coherent application of this Regulation and Union law protecting fundamental rights and streamlining procedures, while respecting their respective competences, tasks, powers and independence. This shall include, in particular, exchange of information where necessary for the effective supervision or enforcement of this Regulation and the respective other Union legislation.

▼B

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.

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.

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.

Article 78

Confidentiality

1.

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

(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 (2);

(b)

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

(c)

public and national security interests;

(d)

the conduct of criminal or administrative proceedings;

(e)

information classified pursuant to Union or national law.

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.

3.

Without prejudice to paragraphs 1 and 2, information exchanged on a confidential basis between the national competent authorities or between national competent authorities and the Commission shall not be disclosed without prior consultation of the originating national competent authority and the deployer when high-risk AI systems referred to in point 1, 6 or 7 of Annex III are used by law enforcement, border control, immigration or asylum authorities and when such disclosure would jeopardise public and national security interests. This exchange of information shall not cover sensitive operational data in relation to the activities of law enforcement, border control, immigration or asylum authorities.

When the law enforcement, immigration or asylum authorities are providers of high-risk AI systems referred to in point 1, 6 or 7 of Annex III, the technical documentation referred to in Annex IV shall remain within the premises of those authorities. Those authorities shall ensure that the market surveillance authorities referred to in Article 74(8) and (9), as applicable, can, upon request, immediately access the documentation or obtain a copy thereof. Only staff of the market surveillance authority holding the appropriate level of security clearance shall be allowed to access that documentation or any copy thereof.

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.

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.

Article 79

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

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.

2.

Where the market surveillance authority of a Member State has sufficient reason to consider an AI system to present a risk as referred to in paragraph 1 of this Article, it shall carry out an evaluation of the AI system concerned in respect of its compliance with all the requirements and obligations laid down in this Regulation. Particular attention shall be given to AI systems presenting a risk to vulnerable groups. Where risks to fundamental rights are identified, the market surveillance authority shall also inform and fully cooperate with the relevant national public authorities or bodies referred to in Article 77(1). The relevant operators shall cooperate as necessary with the market surveillance authority and with the other national public authorities or bodies referred to in Article 77(1).

Where, in the course of that evaluation, the market surveillance authority or, where applicable the market surveillance authority in cooperation with the national public authority referred to in Article 77(1), finds that the AI system does not comply with the requirements and obligations laid down in this Regulation, it shall without undue delay require the relevant operator to take all appropriate corrective actions to bring the AI system into compliance, to withdraw the AI system from the market, or to recall it within a period the market surveillance

authority may prescribe, and in any event within the shorter of 15 working days, or as provided for in the relevant Union harmonisation legislation.

The market surveillance authority shall inform the relevant notified body accordingly. Article 18 of Regulation (EU) 2019/1020 shall apply to the measures referred to in the second subparagraph of this paragraph.

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.
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.
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.
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:

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

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

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

(d)
non-compliance with Article 50.

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.
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.
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.

Article 80

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

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.
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.
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.
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.
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.
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.
7.
Where, in the course of the evaluation pursuant to paragraph 1 of this Article, the market surveillance authority establishes that the AI system was misclassified by the provider as non-high-risk in order to circumvent the application of requirements in Chapter III, Section 2, the provider shall be subject to fines in accordance with Article 99.
8.
In exercising their power to monitor the application of this Article, and in accordance with Article 11 of Regulation (EU) 2019/1020, market surveillance authorities may perform appropriate checks, taking into account in particular information stored in the EU database referred to in Article 71 of this Regulation.

Article 81

Union safeguard procedure

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.

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.
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.
Article 82

Compliant AI systems which present a risk

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.
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.
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.
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.
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

Formal non-compliance

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:

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

(b)
the CE marking has not been affixed;

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

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

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

(f)
where applicable, no authorised representative has been appointed;

(g)
technical documentation is not available.

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.
Article 84

Union AI testing support structures

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.
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.
SECTION 4

Remedies

Article 85

Right to lodge a complaint with a market surveillance authority

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.

Article 86

Right to explanation of individual decision-making

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.
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.
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

Reporting of infringements and protection of reporting persons

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

SECTION 5

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

Article 88

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

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.

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.

Article 89

Monitoring actions

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.

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:

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

(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;

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

Article 90

Alerts of systemic risks by the scientific panel

1.
The scientific panel may provide a qualified alert to the AI Office where it has reason to suspect that:

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

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

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.
3.
A qualified alert shall be duly reasoned and indicate at least:

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

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

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

Article 91

Power to request documentation and information

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.
2.
Before sending the request for information, the AI Office may initiate a structured dialogue with the provider of the general-purpose AI model.
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).
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.
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.
Article 92

Power to conduct evaluations

1.
The AI Office, after consulting the Board, may conduct evaluations of the general-purpose AI model concerned:

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

(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).

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).
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.
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.
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.
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).
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.
Article 93

Power to request measures

1.
Where necessary and appropriate, the Commission may request providers to:

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

(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;

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

2.
Before a measure is requested, the AI Office may initiate a structured dialogue with the provider of the general-purpose AI model.
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.
Article 94

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

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.

CHAPTER X

CODES OF CONDUCT AND GUIDELINES

Article 95

Codes of conduct for voluntary application of specific requirements

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.
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:

(a)
applicable elements provided for in Union ethical guidelines for trustworthy AI;

(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;

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

(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;

(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.

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.
▼M1

4.
The AI Office and the Member States shall take into account the specific interests and needs of SMEs, including start-ups, and SMCs, when encouraging and facilitating the drawing up of codes of conduct.
▼B

Article 96

Guidelines from the Commission on the implementation of this Regulation

1.

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

▼M1

(a)
the application of the requirements and obligations referred to in Articles 8 to 15 and in Articles 25 and 26;

▼B

(b)
the prohibited practices referred to in Article 5;

(c)
the practical implementation of the provisions related to substantial modification;

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

(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;

(f)
the application of the definition of an AI system as set out in Article 3, point (1);

▼M1

(g)
the practical implementation of Article 8(2), Article 9(10) and Article 17(3) in accordance with the principle of complementarity and proportionality, with a view to ensuring consistency, avoiding duplication and minimising additional burdens when complying with the requirements of this Regulation and the requirements of the Union harmonisation legislation listed in Section A of Annex I; such guidelines shall be published by 1 August 2027.

▼M1

When issuing such guidelines, the Commission shall involve the Board and pay particular attention to the needs of SMEs, including start-ups, and SMCs, of local public authorities and of the sectors most likely to be affected by this Regulation.

▼B

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.

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.

CHAPTER XI

DELEGATION OF POWER AND COMMITTEE PROCEDURE

Article 97

Exercise of the delegation

1.
The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

▼M1

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 power to adopt delegated acts referred to in Article 2(13) and Article 30(2) shall be conferred on the Commission for a period of five years from 27 July 2026. 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 no later than three months before the end of each period.
3.
The delegation of power referred to in Article 2(13), Article 6(6) and (7), Article 7(1) and (3), Article 11(3), Article 30(2), 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.
▼B

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.
5.
As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.
▼M1

6.
Any delegated act adopted pursuant to Article 2(13), Article 6(6) or (7), Article 7(1) or (3), Article 11(3), Article 30(2), 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.
▼B

Article 98

Committee procedure

1.
The Commission shall be assisted by a committee. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.
2.
Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.
CHAPTER XII

PENALTIES

Article 99

Penalties

▼M1

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 administrative fines, warnings and non-monetary measures, applicable to any infringement 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. The Member States shall take into account the interests of SMEs, including start-ups, and SMCs, and their economic viability when imposing penalties.
▼B

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.
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.
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:

(a)
obligations of providers pursuant to Article 16;

(b)
obligations of authorised representatives pursuant to Article 22;

(c)
obligations of importers pursuant to Article 23;

(d)
obligations of distributors pursuant to Article 24;

▼M1

(da)
obligations of providers and operators pursuant to Article 25(2) and (4);

▼B

(e)
obligations of deployers pursuant to Article 26;

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

(g)
transparency obligations for providers and deployers pursuant to Article 50.

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.
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.

▼M1

6a.

In the case of SMCs, each fine referred to in paragraphs 4 and 5 shall be up to the percentages or amount referred therein, whichever is lower.

▼B

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:

(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;

(b)

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

(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;

(d)

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

(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;

(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;

(g)

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

(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;

(i)

the intentional or negligent character of the infringement;

(j)

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

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.

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.

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.

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.

Article 100

Administrative fines on Union institutions, bodies, offices and agencies

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:

(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;

(b)

the degree of responsibility of the Union institution, body, office or agency, taking into account technical and organisational measures implemented by them;

(c)

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

(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;

(e)

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

(f)

the manner in which the infringement became known to the European Data Protection Supervisor, in particular whether, and if so to what extent, the Union institution, body, office or agency notified the infringement;

(g)

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

2.

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

3.

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

4.

Before taking decisions pursuant to this Article, the European Data Protection Supervisor shall give the Union institution, body, office or agency which is the subject of the proceedings conducted by the European Data

Protection Supervisor the opportunity of being heard on the matter regarding the possible infringement. The European Data Protection Supervisor shall base his or her decisions only on elements and circumstances on which the parties concerned have been able to comment. Complainants, if any, shall be associated closely with the proceedings.

5.

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

6.

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

7.

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

Article 101

Fines for providers of general-purpose AI models

1.

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

(a)

infringed the relevant provisions of this Regulation;

(b)

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

(c)

failed to comply with a measure requested under Article 93;

(d)

failed to make available to the Commission access to the general-purpose AI model or general-purpose AI model with systemic risk with a view to conducting an evaluation pursuant to Article 92.

In fixing the amount of the fine or periodic penalty payment, regard shall be had to the nature, gravity and duration of the infringement, taking due account of the principles of proportionality and appropriateness. The Commission shall also into account commitments made in accordance with Article 93(3) or made in relevant codes of practice in accordance with Article 56.

2.

Before adopting the decision pursuant to paragraph 1, the Commission shall communicate its preliminary findings to the provider of the general-purpose AI model and give it an opportunity to be heard.

3.

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

4.

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

5.

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

6.

The Commission shall adopt implementing acts containing detailed arrangements and procedural safeguards for proceedings in view of the possible adoption of decisions pursuant to paragraph 1 of this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 98(2).

CHAPTER XIII

FINAL PROVISIONS

Article 102

Amendment to Regulation (EC) No 300/2008

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.

Article 103

Amendment to Regulation (EU) No 167/2013

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.

Article 104

Amendment to Regulation (EU) No 168/2013

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.

Article 105

Amendment to Directive 2014/90/EU

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.

Article 106

Amendment to Directive (EU) 2016/797

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.

Article 107

Amendment to Regulation (EU) 2018/858

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.
Article 108

Amendments to Regulation (EU) 2018/1139

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

(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.
(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.’
;

(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.’
;

(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.’
;

(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.’

;
(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.’.
Article 109

Amendment to Regulation (EU) 2019/2144

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.
Article 110

Amendment to Directive (EU) 2020/1828

In Annex I to Directive (EU) 2020/1828 of the European Parliament and of the Council (3), the following point is added:

‘(68)
Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence and amending Regulations (EC) No 300/2008, (EU) No 167/2013, (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1139 and (EU) 2019/2144 and Directives 2014/90/EU, (EU) 2016/797 and (EU) 2020/1828 (Artificial Intelligence Act) (OJ L, 2024/1689, 12.7.2024, ELI: http://data.europa.eu/eli/reg/2024/1689/oj).’.

Article 111

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

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.

▼M1

2.
Without prejudice to the application of Article 5 as referred to in Article 113, third paragraph, 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 the date of application of Chapter III referred to in Article 113, 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 laid down in this Regulation by 2 August 2030.
▼B

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.
▼M1

4.
Providers of AI systems, including general-purpose AI systems, generating synthetic audio, image, video or text content, that have been placed on the market before 2 August 2026 shall take the necessary steps in order to comply with Article 50(2) by 2 December 2026.
▼B

Article 112

Evaluation and review

1.
The Commission shall assess the need for amendment of the list set out in Annex III and of the list of prohibited AI practices laid down in Article 5, once a year following the entry into force of this Regulation, and until the end of the period of the delegation of power laid down in Article 97. The Commission shall submit the findings of that assessment to the European Parliament and the Council.
2.
By 2 August 2028 and every four years thereafter, the Commission shall evaluate and report to the European Parliament and to the Council on the following:

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

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

(c)
amendments enhancing the effectiveness of the supervision and governance system.

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.
4.
The reports referred to in paragraph 2 shall pay specific attention to the following:

(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;

(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;

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

(d)
the number of undertakings that enter the market after the entry into application of this Regulation, and how many of them are SMEs.

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.

6.
By 2 August 2028 and every four years thereafter, the Commission shall submit a report on the review of the progress on the development of standardisation deliverables on the energy-efficient development of general-purpose AI models, and asses the need for further measures or actions, including binding measures or actions. The report shall be submitted to the European Parliament and to the Council, and it shall be made public.
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.
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.
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.
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.
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:

(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;

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

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

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.
13.
By 2 August 2031, the Commission shall carry out an assessment of the enforcement of this Regulation and shall report on it to the European Parliament, the Council and the European Economic and Social Committee, taking into account the first years of application of this Regulation. On the basis of the findings, that report shall, where appropriate, be accompanied by a proposal for amendment of this Regulation with regard to the structure of enforcement and the need for a Union agency to resolve any identified shortcomings.
Article 113

Entry into force and application

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:

▼M1

(a)
Chapters I and II shall apply from 2 February 2025, with the exception of Article 5(1), first subparagraph, points (ba) and (bb), and Article 5(1a) and (1b) which shall apply from 2 December 2026;

▼B

(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;

▼M1

(c)
Chapter III, Sections 1, 2, and 3, with the exception of Article 6(5), shall apply from:

(i)
2 December 2027 as regards AI systems classified as high-risk pursuant to Article 6(2) and Annex III; and

(ii)
2 August 2028 as regards AI systems classified as high-risk pursuant to Article 6(1) and Annex I;

▼M1

(d)
Articles 102 to 110 shall apply from 27 July 2026.

▼B

This Regulation shall be binding in its entirety and directly applicable in all Member States.

ANNEX I

List of Union harmonisation legislation

Section A. List of Union harmonisation legislation based on the New Legislative Framework

▼M1 ——————

▼B

2. Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys (OJ L 170, 30.6.2009, p. 1);

3. Directive 2013/53/EU of the European Parliament and of the Council of 20 November 2013 on recreational craft and personal watercraft and repealing Directive 94/25/EC (OJ L 354, 28.12.2013, p. 90);

4. Directive 2014/33/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to lifts and safety components for lifts (OJ L 96, 29.3.2014, p. 251);

5. Directive 2014/34/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to equipment and protective systems intended for use in potentially explosive atmospheres (OJ L 96, 29.3.2014, p. 309);

6. Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC (OJ L 153, 22.5.2014, p. 62);

7. Directive 2014/68/EU of the European Parliament and of the Council of 15 May 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of pressure equipment (OJ L 189, 27.6.2014, p. 164);

8. Regulation (EU) 2016/424 of the European Parliament and of the Council of 9 March 2016 on cableway installations and repealing Directive 2000/9/EC (OJ L 81, 31.3.2016, p. 1);

9. Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC (OJ L 81, 31.3.2016, p. 51);

10. Regulation (EU) 2016/426 of the European Parliament and of the Council of 9 March 2016 on appliances burning gaseous fuels and repealing Directive 2009/142/EC (OJ L 81, 31.3.2016, p. 99);

11. Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1);

12. Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (OJ L 117, 5.5.2017, p. 176).

Section B. List of other Union harmonisation legislation

13. Regulation (EC) No 300/2008 of the European Parliament and of the Council of 11 March 2008 on common rules in the field of civil aviation security and repealing Regulation (EC) No 2320/2002 (OJ L 97, 9.4.2008, p. 72);

14. Regulation (EU) No 168/2013 of the European Parliament and of the Council of 15 January 2013 on the approval and market surveillance of two- or three-wheel vehicles and quadricycles (OJ L 60, 2.3.2013, p. 52);

15. Regulation (EU) No 167/2013 of the European Parliament and of the Council of 5 February 2013 on the approval and market surveillance of agricultural and forestry vehicles (OJ L 60, 2.3.2013, p. 1);

16. Directive 2014/90/EU of the European Parliament and of the Council of 23 July 2014 on marine equipment and repealing Council Directive 96/98/EC (OJ L 257, 28.8.2014, p. 146);

17. Directive (EU) 2016/797 of the European Parliament and of the Council of 11 May 2016 on the interoperability of the rail system within the European Union (OJ L 138, 26.5.2016, p. 44);

18. Regulation (EU) 2018/858 of the European Parliament and of the Council of 30 May 2018 on the approval and market surveillance of motor vehicles and their trailers, and of systems, components and separate technical units intended for such vehicles, amending Regulations (EC) No 715/2007 and (EC) No 595/2009 and repealing Directive 2007/46/EC (OJ L 151, 14.6.2018, p. 1);

19. Regulation (EU) 2019/2144 of the European Parliament and of the Council of 27 November 2019 on type-approval requirements for motor vehicles and their trailers, and systems, components and separate technical units intended for such vehicles, as regards their general safety and the protection of vehicle occupants and vulnerable road users, amending Regulation (EU) 2018/858 of the European Parliament and of the Council and repealing Regulations (EC) No 78/2009, (EC) No 79/2009 and (EC) No 661/2009 of the European Parliament and of the Council and Commission Regulations (EC) No 631/2009, (EU) No 406/2010, (EU) No 672/2010, (EU) No 1003/2010, (EU) No 1005/2010, (EU) No 1008/2010, (EU) No 1009/2010, (EU) No 19/2011, (EU) No 109/2011, (EU) No 458/2011, (EU) No 65/2012, (EU) No 130/2012, (EU) No 347/2012, (EU) No 351/2012, (EU) No 1230/2012 and (EU) 2015/166 (OJ L 325, 16.12.2019, p. 1);

20. Regulation (EU) 2018/1139 of the European Parliament and of the Council of 4 July 2018 on common rules in the field of civil aviation and establishing a European Union Aviation Safety Agency, and amending Regulations (EC) No 2111/2005, (EC) No 1008/2008, (EU) No 996/2010, (EU) No 376/2014 and Directives 2014/30/EU and 2014/53/EU of the European Parliament and of the Council, and repealing Regulations (EC) No 552/2004 and (EC) No 216/2008 of the European Parliament and of the Council and Council Regulation (EEC) No 3922/91 (OJ L 212, 22.8.2018, p. 1), in so far as the design, production and placing on the market of aircrafts referred to in Article 2(1), points (a) and (b) thereof, where it concerns unmanned aircraft and their engines, propellers, parts and equipment to control them remotely, are concerned;

▼M1

21. Regulation (EU) 2023/1230 of the European Parliament and of the Council of 14 June 2023 on machinery and repealing Directive 2006/42/EC of the European Parliament and of the Council and Council Directive 73/361/EEC (OJ L 165, 29.6.2023, p. 1, ELI: http://data.europa.eu/eli/reg/2023/1230/oj).

▼B

ANNEX II

List of criminal offences referred to in Article 5(1), first subparagraph, point (h)(iii)

Criminal offences referred to in Article 5(1), first subparagraph, point (h)(iii):

—
terrorism,
—
trafficking in human beings,
—
sexual exploitation of children, and child pornography,
—
illicit trafficking in narcotic drugs or psychotropic substances,
—
illicit trafficking in weapons, munitions or explosives,
—
murder, grievous bodily injury,
—
illicit trade in human organs or tissue,
—
illicit trafficking in nuclear or radioactive materials,
—
kidnapping, illegal restraint or hostage-taking,
—
crimes within the jurisdiction of the International Criminal Court,
—
unlawful seizure of aircraft or ships,
—
rape,
—
environmental crime,
—
organised or armed robbery,

—
sabotage,
—
participation in a criminal organisation involved in one or more of the offences listed above.

ANNEX III

High-risk AI systems referred to in Article 6(2)

High-risk AI systems pursuant to Article 6(2) are the AI systems listed in any of the following areas:

1.
Biometrics, in so far as their use is permitted under relevant Union or national law:

(a)
remote biometric identification systems.

This shall not include AI systems intended to be used for biometric verification the sole purpose of which is to confirm that a specific natural person is the person he or she claims to be;

(b)
AI systems intended to be used for biometric categorisation, according to sensitive or protected attributes or characteristics based on the inference of those attributes or characteristics;

(c)
AI systems intended to be used for emotion recognition.

2.
Critical infrastructure: AI systems intended to be used as safety components in the management and operation of critical digital infrastructure, road traffic, or in the supply of water, gas, heating or electricity.

3.
Education and vocational training:

(a)
AI systems intended to be used to determine access or admission or to assign natural persons to educational and vocational training institutions at all levels;

(b)
AI systems intended to be used to evaluate learning outcomes, including when those outcomes are used to steer the learning process of natural persons in educational and vocational training institutions at all levels;

(c)
AI systems intended to be used for the purpose of assessing the appropriate level of education that an individual will receive or will be able to access, in the context of or within educational and vocational training institutions at all levels;

(d)
AI systems intended to be used for monitoring and detecting prohibited behaviour of students during tests in the context of or within educational and vocational training institutions at all levels.

4.
Employment, workers' management and access to self-employment:

(a)
AI systems intended to be used for the recruitment or selection of natural persons, in particular to place targeted job advertisements, to analyse and filter job applications, and to evaluate candidates;

(b)
AI systems intended to be used to make decisions affecting terms of work-related relationships, the promotion or termination of work-related contractual relationships, to allocate tasks based on individual behaviour or personal traits or characteristics or to monitor and evaluate the performance and behaviour of persons in such relationships.

5.
Access to and enjoyment of essential private services and essential public services and benefits:

(a)
AI systems intended to be used by public authorities or on behalf of public authorities to evaluate the eligibility of natural persons for essential public assistance benefits and services, including healthcare services, as well as to grant, reduce, revoke, or reclaim such benefits and services;

(b)
AI systems intended to be used to evaluate the creditworthiness of natural persons or establish their credit score, with the exception of AI systems used for the purpose of detecting financial fraud;

(c)
AI systems intended to be used for risk assessment and pricing in relation to natural persons in the case of life and health insurance;

(d)
AI systems intended to evaluate and classify emergency calls by natural persons or to be used to dispatch, or to establish priority in the dispatching of, emergency first response services, including by police, firefighters and medical aid, as well as of emergency healthcare patient triage systems.

6.
Law enforcement, in so far as their use is permitted under relevant Union or national law:

(a)
AI systems intended to be used by or on behalf of law enforcement authorities, or by Union institutions, bodies, offices or agencies in support of law enforcement authorities or on their behalf to assess the risk of a natural person becoming the victim of criminal offences;

(b)
AI systems intended to be used by or on behalf of law enforcement authorities or by Union institutions, bodies, offices or agencies in support of law enforcement authorities as polygraphs or similar tools;

(c)
AI systems intended to be used by or on behalf of law enforcement authorities, or by Union institutions, bodies, offices or agencies, in support of law enforcement authorities to evaluate the reliability of evidence in the course of the investigation or prosecution of criminal offences;

(d)
AI systems intended to be used by law enforcement authorities or on their behalf or by Union institutions, bodies, offices or agencies in support of law enforcement authorities for assessing the risk of a natural person offending or re-offending not solely on the basis of the profiling of natural persons as referred to in Article 3(4) of Directive (EU) 2016/680, or to assess personality traits and characteristics or past criminal behaviour of natural persons or groups;

(e)
AI systems intended to be used by or on behalf of law enforcement authorities or by Union institutions, bodies, offices or agencies in support of law enforcement authorities for the profiling of natural persons as referred to in Article 3(4) of Directive (EU) 2016/680 in the course of the detection, investigation or prosecution of criminal offences.

7.

Migration, asylum and border control management, in so far as their use is permitted under relevant Union or national law:

(a)
AI systems intended to be used by or on behalf of competent public authorities or by Union institutions, bodies, offices or agencies as polygraphs or similar tools;

(b)
AI systems intended to be used by or on behalf of competent public authorities or by Union institutions, bodies, offices or agencies to assess a risk, including a security risk, a risk of irregular migration, or a health risk, posed by a natural person who intends to enter or who has entered into the territory of a Member State;

(c)
AI systems intended to be used by or on behalf of competent public authorities or by Union institutions, bodies, offices or agencies to assist competent public authorities for the examination of applications for asylum, visa or residence permits and for associated complaints with regard to the eligibility of the natural persons applying for a status, including related assessments of the reliability of evidence;

(d)
AI systems intended to be used by or on behalf of competent public authorities, or by Union institutions, bodies, offices or agencies, in the context of migration, asylum or border control management, for the purpose of detecting, recognising or identifying natural persons, with the exception of the verification of travel documents.

8.
Administration of justice and democratic processes:

(a)
AI systems intended to be used by a judicial authority or on their behalf to assist a judicial authority in researching and interpreting facts and the law and in applying the law to a concrete set of facts, or to be used in a similar way in alternative dispute resolution;

(b)
AI systems intended to be used for influencing the outcome of an election or referendum or the voting behaviour of natural persons in the exercise of their vote in elections or referenda. This does not include AI systems to the output of which natural persons are not directly exposed, such as tools used to organise, optimise or structure political campaigns from an administrative or logistical point of view.

ANNEX IV

Technical documentation referred to in Article 11(1)

The technical documentation referred to in Article 11(1) shall contain at least the following information, as applicable to the relevant AI system:

1.
A general description of the AI system including:

(a)
its intended purpose, the name of the provider and the version of the system reflecting its relation to previous versions;

(b)
how the AI system interacts with, or can be used to interact with, hardware or software, including with other AI systems, that are not part of the AI system itself, where applicable;

(c)
the versions of relevant software or firmware, and any requirements related to version updates;

(d)
the description of all the forms in which the AI system is placed on the market or put into service, such as software packages embedded into hardware, downloads, or APIs;

(e)
the description of the hardware on which the AI system is intended to run;

(f)
where the AI system is a component of products, photographs or illustrations showing external features, the marking and internal layout of those products;

(g)
a basic description of the user-interface provided to the deployer;

(h)
instructions for use for the deployer, and a basic description of the user-interface provided to the deployer, where applicable;

2.
A detailed description of the elements of the AI system and of the process for its development, including:

(a)
the methods and steps performed for the development of the AI system, including, where relevant, recourse to pre-trained systems or tools provided by third parties and how those were used, integrated or modified by the provider;

(b)
the design specifications of the system, namely the general logic of the AI system and of the algorithms; the key design choices including the rationale and assumptions made, including with regard to persons or groups of persons in respect of who, the system is intended to be used; the main classification choices; what the system is designed to optimise for, and the relevance of the different parameters; the description of the expected output and output quality of the system; the decisions about any possible trade-off made regarding the technical solutions adopted to comply with the requirements set out in Chapter III, Section 2;

(c)
the description of the system architecture explaining how software components build on or feed into each other and integrate into the overall processing; the computational resources used to develop, train, test and validate the AI system;

(d)
where relevant, the data requirements in terms of datasheets describing the training methodologies and techniques and the training data sets used, including a general description of these data sets, information about their provenance, scope and main characteristics; how the data was obtained and selected; labelling procedures (e.g. for supervised learning), data cleaning methodologies (e.g. outliers detection);

(e)
assessment of the human oversight measures needed in accordance with Article 14, including an assessment of the technical measures needed to facilitate the interpretation of the outputs of AI systems by the deployers, in accordance with Article 13(3), point (d);

(f)
where applicable, a detailed description of pre-determined changes to the AI system and its performance, together with all the relevant information related to the technical solutions adopted to ensure continuous compliance of the AI system with the relevant requirements set out in Chapter III, Section 2;

(g)
the validation and testing procedures used, including information about the validation and testing data used and their main characteristics; metrics used to measure accuracy, robustness and compliance with other relevant requirements set out in Chapter III, Section 2, as well as potentially discriminatory impacts; test logs and all test reports dated and signed by the responsible persons, including with regard to pre-determined changes as referred to under point (f);

(h)
cybersecurity measures put in place;

3.
Detailed information about the monitoring, functioning and control of the AI system, in particular with regard to: its capabilities and limitations in performance, including the degrees of accuracy for specific persons or groups of persons on which the system is intended to be used and the overall expected level of accuracy in relation to its intended purpose; the foreseeable unintended outcomes and sources of risks to health and safety, fundamental rights and discrimination in view of the intended purpose of the AI system; the human oversight measures needed in accordance with Article 14, including the technical measures put in place to facilitate the interpretation of the outputs of AI systems by the deployers; specifications on input data, as appropriate;

4.
A description of the appropriateness of the performance metrics for the specific AI system;

5.
A detailed description of the risk management system in accordance with Article 9;

6.
A description of relevant changes made by the provider to the system through its lifecycle;

7.
A list of the harmonised standards applied in full or in part the references of which have been published in the Official Journal of the European Union; where no such harmonised standards have been applied, a detailed description of the solutions adopted to meet the requirements set out in Chapter III, Section 2, including a list of other relevant standards and technical specifications applied;

8.
A copy of the EU declaration of conformity referred to in Article 47;

9.
A detailed description of the system in place to evaluate the AI system performance in the post-market phase in accordance with Article 72, including the post-market monitoring plan referred to in Article 72(3).

ANNEX V

EU declaration of conformity

The EU declaration of conformity referred to in Article 47, shall contain all of the following information:

1.
AI system name and type and any additional unambiguous reference allowing the identification and traceability of the AI system;

2.
The name and address of the provider or, where applicable, of their authorised representative;

3.

A statement that the EU declaration of conformity referred to in Article 47 is issued under the sole responsibility of the provider;

4.
A statement that the AI system is in conformity with this Regulation and, if applicable, with any other relevant Union law that provides for the issuing of the EU declaration of conformity referred to in Article 47;

5.
Where an AI system involves the processing of personal data, a statement that that AI system complies with Regulations (EU) 2016/679 and (EU) 2018/1725 and Directive (EU) 2016/680;

6.
References to any relevant harmonised standards used or any other common specification in relation to which conformity is declared;

7.
Where applicable, the name and identification number of the notified body, a description of the conformity assessment procedure performed, and identification of the certificate issued;

8.
The place and date of issue of the declaration, the name and function of the person who signed it, as well as an indication for, or on behalf of whom, that person signed, a signature.

ANNEX VI

Conformity assessment procedure based on internal control

1. The conformity assessment procedure based on internal control is the conformity assessment procedure based on points 2, 3 and 4.

2. The provider verifies that the established quality management system is in compliance with the requirements of Article 17.

3. The provider examines the information contained in the technical documentation in order to assess the compliance of the AI system with the relevant essential requirements set out in Chapter III, Section 2.

4. The provider also verifies that the design and development process of the AI system and its post-market monitoring as referred to in Article 72 is consistent with the technical documentation.

ANNEX VII

Conformity based on an assessment of the quality management system and an assessment of the technical documentation

1. Introduction

Conformity based on an assessment of the quality management system and an assessment of the technical documentation is the conformity assessment procedure based on points 2 to 5.

2. Overview

The approved quality management system for the design, development and testing of AI systems pursuant to Article 17 shall be examined in accordance with point 3 and shall be subject to surveillance as specified in point

5. The technical documentation of the AI system shall be examined in accordance with point 4.

3. Quality management system

3.1. The application of the provider shall include:

(a)
the name and address of the provider and, if the application is lodged by an authorised representative, also their name and address;

(b)
the list of AI systems covered under the same quality management system;

(c)
the technical documentation for each AI system covered under the same quality management system;

(d)
the documentation concerning the quality management system which shall cover all the aspects listed under Article 17;

(e)
a description of the procedures in place to ensure that the quality management system remains adequate and effective;

(f)
a written declaration that the same application has not been lodged with any other notified body.

3.2. The quality management system shall be assessed by the notified body, which shall determine whether it satisfies the requirements referred to in Article 17.

The decision shall be notified to the provider or its authorised representative.

The notification shall contain the conclusions of the assessment of the quality management system and the reasoned assessment decision.

3.3. The quality management system as approved shall continue to be implemented and maintained by the provider so that it remains adequate and efficient.

3.4. Any intended change to the approved quality management system or the list of AI systems covered by the latter shall be brought to the attention of the notified body by the provider.

The proposed changes shall be examined by the notified body, which shall decide whether the modified quality management system continues to satisfy the requirements referred to in point 3.2 or whether a reassessment is necessary.

The notified body shall notify the provider of its decision. The notification shall contain the conclusions of the examination of the changes and the reasoned assessment decision.

4. Control of the technical documentation.

4.1. In addition to the application referred to in point 3, an application with a notified body of their choice shall be lodged by the provider for the assessment of the technical documentation relating to the AI system which the provider intends to place on the market or put into service and which is covered by the quality management system referred to under point 3.

4.2. The application shall include:

(a)
the name and address of the provider;

(b)
a written declaration that the same application has not been lodged with any other notified body;

(c)
the technical documentation referred to in Annex IV.

4.3. The technical documentation shall be examined by the notified body. Where relevant, and limited to what is necessary to fulfil its tasks, the notified body shall be granted full access to the training, validation, and testing data sets used, including, where appropriate and subject to security safeguards, through API or other relevant technical means and tools enabling remote access.

4.4. In examining the technical documentation, the notified body may require that the provider supply further evidence or carry out further tests so as to enable a proper assessment of the conformity of the AI system with the requirements set out in Chapter III, Section 2. Where the notified body is not satisfied with the tests carried out by the provider, the notified body shall itself directly carry out adequate tests, as appropriate.

4.5. Where necessary to assess the conformity of the high-risk AI system with the requirements set out in Chapter III, Section 2, after all other reasonable means to verify conformity have been exhausted and have proven to be insufficient, and upon a reasoned request, the notified body shall also be granted access to the training and trained models of the AI system, including its relevant parameters. Such access shall be subject to existing Union law on the protection of intellectual property and trade secrets.

4.6. The decision of the notified body shall be notified to the provider or its authorised representative. The notification shall contain the conclusions of the assessment of the technical documentation and the reasoned assessment decision.

Where the AI system is in conformity with the requirements set out in Chapter III, Section 2, the notified body shall issue a Union technical documentation assessment certificate. The certificate shall indicate the name and address of the provider, the conclusions of the examination, the conditions (if any) for its validity and the data necessary for the identification of the AI system.

The certificate and its annexes shall contain all relevant information to allow the conformity of the AI system to be evaluated, and to allow for control of the AI system while in use, where applicable.

Where the AI system is not in conformity with the requirements set out in Chapter III, Section 2, the notified body shall refuse to issue a Union technical documentation assessment certificate and shall inform the applicant accordingly, giving detailed reasons for its refusal.

Where the AI system does not meet the requirement relating to the data used to train it, re-training of the AI system will be needed prior to the application for a new conformity assessment. In this case, the reasoned assessment decision of the notified body refusing to issue the Union technical documentation assessment certificate shall contain specific considerations on the quality data used to train the AI system, in particular on the reasons for non-compliance.

4.7. Any change to the AI system that could affect the compliance of the AI system with the requirements or its intended purpose shall be assessed by the notified body which issued the Union technical documentation assessment certificate. The provider shall inform such notified body of its intention to introduce any of the abovementioned changes, or if it otherwise becomes aware of the occurrence of such changes. The intended changes shall be assessed by the notified body, which shall decide whether those changes require a new conformity assessment in accordance with Article 43(4) or whether they could be addressed by means of a supplement to the Union technical documentation assessment certificate. In the latter case, the notified body shall assess the changes, notify the provider of its decision and, where the changes are approved, issue to the provider a supplement to the Union technical documentation assessment certificate.

5. Surveillance of the approved quality management system.

5.1. The purpose of the surveillance carried out by the notified body referred to in Point 3 is to make sure that the provider duly complies with the terms and conditions of the approved quality management

system.

5.2. For assessment purposes, the provider shall allow the notified body to access the premises where the design, development, testing of the AI systems is taking place. The provider shall further share with the notified body all necessary information.

5.3. The notified body shall carry out periodic audits to make sure that the provider maintains and applies the quality management system and shall provide the provider with an audit report. In the context of those audits, the notified body may carry out additional tests of the AI systems for which a Union technical documentation assessment certificate was issued.

ANNEX VIII

Information to be submitted upon the registration of high-risk AI systems in accordance with Article 49

Section A — Information to be submitted by providers of high-risk AI systems in accordance with Article 49(1)

The following information shall be provided and thereafter kept up to date with regard to high-risk AI systems to be registered in accordance with Article 49(1):

1.
The name, address and contact details of the provider;

2.
Where submission of information is carried out by another person on behalf of the provider, the name, address and contact details of that person;

3.
The name, address and contact details of the authorised representative, where applicable;

4.
The AI system trade name and any additional unambiguous reference allowing the identification and traceability of the AI system;

5.
A description of the intended purpose of the AI system and of the components and functions supported through this AI system;

6.
A basic and concise description of the information used by the system (data, inputs) and its operating logic;

7.
The status of the AI system (on the market, or in service; no longer placed on the market/in service, recalled);

8.
The type, number and expiry date of the certificate issued by the notified body and the name or identification number of that notified body, where applicable;

9.
A scanned copy of the certificate referred to in point 8, where applicable;

10.
Any Member States in which the AI system has been placed on the market, put into service or made available in the Union;

11.
A copy of the EU declaration of conformity referred to in Article 47;

12.
Electronic instructions for use; this information shall not be provided for high-risk AI systems in the areas of law enforcement or migration, asylum and border control management referred to in Annex III, points 1, 6 and 7;

13.
A URL for additional information (optional).

Section B — Information to be submitted by providers of high-risk AI systems in accordance with Article 49(2)

The following information shall be provided and thereafter kept up to date with regard to AI systems to be registered in accordance with Article 49(2):

1.
The name, address and contact details of the provider;

2.
Where submission of information is carried out by another person on behalf of the provider, the name, address and contact details of that person;

3.
The name, address and contact details of the authorised representative, where applicable;

4.
The AI system trade name and any additional unambiguous reference allowing the identification and traceability of the AI system;

5.
A description of the intended purpose of the AI system;

6.
The condition or conditions under Article 6(3)based on which the AI system is considered to be not-high-risk;

▼M1 ——————

▼B

8.
The status of the AI system (on the market, or in service; no longer placed on the market/in service, recalled).

▼M1 ——————

▼B

Section C — Information to be submitted by deployers of high-risk AI systems in accordance with Article 49(3)

The following information shall be provided and thereafter kept up to date with regard to high-risk AI systems to be registered in accordance with Article 49(3):

1.
The name, address and contact details of the deployer;

2.
The name, address and contact details of the person submitting information on behalf of the deployer;

3.
The URL of the entry of the AI system in the EU database by its provider;

4.
A summary of the findings of the fundamental rights impact assessment conducted in accordance with Article 27;

5.

A summary of the data protection impact assessment carried out in accordance with Article 35 of Regulation (EU) 2016/679 or Article 27 of Directive (EU) 2016/680 as specified in Article 26(8) of this Regulation, where applicable.

ANNEX IX

Information to be submitted upon the registration of high-risk AI systems listed in Annex III in relation to testing in real world conditions in accordance with Article 60

The following information shall be provided and thereafter kept up to date with regard to testing in real world conditions to be registered in accordance with Article 60:

1.
A Union-wide unique single identification number of the testing in real world conditions;

2.
The name and contact details of the provider or prospective provider and of the deployers involved in the testing in real world conditions;

3.
A brief description of the AI system, its intended purpose, and other information necessary for the identification of the system;

4.
A summary of the main characteristics of the plan for testing in real world conditions;

5.
Information on the suspension or termination of the testing in real world conditions.

ANNEX X

Union legislative acts on large-scale IT systems in the area of Freedom, Security and Justice

1. Schengen Information System

(a)
Regulation (EU) 2018/1860 of the European Parliament and of the Council of 28 November 2018 on the use of the Schengen Information System for the return of illegally staying third-country nationals (OJ L 312, 7.12.2018, p. 1).

(b)
Regulation (EU) 2018/1861 of the European Parliament and of the Council of 28 November 2018 on the establishment, operation and use of the Schengen Information System (SIS) in the field of border checks, and amending the Convention implementing the Schengen Agreement, and amending and repealing Regulation (EC) No 1987/2006 (OJ L 312, 7.12.2018, p. 14).

(c)
Regulation (EU) 2018/1862 of the European Parliament and of the Council of 28 November 2018 on the establishment, operation and use of the Schengen Information System (SIS) in the field of police cooperation and judicial cooperation in criminal matters, amending and repealing Council Decision 2007/533/JHA, and repealing Regulation (EC) No 1986/2006 of the European Parliament and of the Council and Commission Decision 2010/261/EU (OJ L 312, 7.12.2018, p. 56).

2. Visa Information System

(a)
Regulation (EU) 2021/1133 of the European Parliament and of the Council of 7 July 2021 amending Regulations (EU) No 603/2013, (EU) 2016/794, (EU) 2018/1862, (EU) 2019/816 and (EU) 2019/818 as regards the establishment of the conditions for accessing other EU information systems for the purposes of the Visa Information System (OJ L 248, 13.7.2021, p. 1).

(b)
Regulation (EU) 2021/1134 of the European Parliament and of the Council of 7 July 2021 amending Regulations (EC) No 767/2008, (EC) No 810/2009, (EU) 2016/399, (EU) 2017/2226, (EU) 2018/1240, (EU) 2018/1860, (EU) 2018/1861, (EU) 2019/817 and (EU) 2019/1896 of the European Parliament and of the Council and repealing Council Decisions 2004/512/EC and 2008/633/JHA, for the purpose of reforming the Visa Information System (OJ L 248, 13.7.2021, p. 11).

3. Eurodac

Regulation (EU) 2024/1358 of the European Parliament and of the Council of 14 May 2024 on the establishment of 'Eurodac' for the comparison of biometric data in order to effectively apply Regulations (EU) 2024/1315 and (EU) 2024/1350 of the European Parliament and of the Council and Council Directive 2001/55/EC and to identify illegally staying third-country nationals and stateless persons and on requests for the comparison with Eurodac data by Member States' law enforcement authorities and Europol for law enforcement purposes, amending Regulations (EU) 2018/1240 and (EU) 2019/818 of the European Parliament and of the Council and repealing Regulation (EU) No 603/2013 of the European Parliament and of the Council (OJ L, 2024/1358, 22.5.2024, ELI: http://data.europa.eu/eli/reg/2024/1358/oj).

4. Entry/Exit System

Regulation (EU) 2017/2226 of the European Parliament and of the Council of 30 November 2017 establishing an Entry/Exit System (EES) to register entry and exit data and refusal of entry data of third-country nationals crossing the external borders of the Member States and determining the conditions for access to the EES for law enforcement purposes, and amending the Convention implementing the Schengen Agreement and Regulations (EC) No 767/2008 and (EU) No 1077/2011 (OJ L 327, 9.12.2017, p. 20).

5. European Travel Information and Authorisation System

(a)
Regulation (EU) 2018/1240 of the European Parliament and of the Council of 12 September 2018 establishing a European Travel Information and Authorisation System (ETIAS) and amending Regulations (EU) No 1077/2011, (EU) No 515/2014, (EU) 2016/399, (EU) 2016/1624 and (EU) 2017/2226 (OJ L 236, 19.9.2018, p. 1).

(b)
Regulation (EU) 2018/1241 of the European Parliament and of the Council of 12 September 2018 amending Regulation (EU) 2016/794 for the purpose of establishing a European Travel Information and Authorisation System (ETIAS) (OJ L 236, 19.9.2018, p. 72).

6. European Criminal Records Information System on third-country nationals and stateless persons

Regulation (EU) 2019/816 of the European Parliament and of the Council of 17 April 2019 establishing a centralised system for the identification of Member States holding conviction information on third-country nationals and stateless persons (ECRIS-TCN) to supplement the European Criminal Records Information System and amending Regulation (EU) 2018/1726 (OJ L 135, 22.5.2019, p. 1).

7. Interoperability

(a)

Regulation (EU) 2019/817 of the European Parliament and of the Council of 20 May 2019 on establishing a framework for interoperability between EU information systems in the field of borders and visa and amending Regulations (EC) No 767/2008, (EU) 2016/399, (EU) 2017/2226, (EU) 2018/1240, (EU) 2018/1726 and (EU) 2018/1861 of the European Parliament and of the Council and Council Decisions 2004/512/EC and 2008/633/JHA (OJ L 135, 22.5.2019, p. 27).

(b)
Regulation (EU) 2019/818 of the European Parliament and of the Council of 20 May 2019 on establishing a framework for interoperability between EU information systems in the field of police and judicial cooperation, asylum and migration and amending Regulations (EU) 2018/1726, (EU) 2018/1862 and (EU) 2019/816 (OJ L 135, 22.5.2019, p. 85).

ANNEX XI

Technical documentation referred to in Article 53(1), point (a) — technical documentation for providers of general-purpose AI models

Section 1

Information to be provided by all providers of general-purpose AI models

The technical documentation referred to in Article 53(1), point (a) shall contain at least the following information as appropriate to the size and risk profile of the model:

1.
A general description of the general-purpose AI model including:

(a)
the tasks that the model is intended to perform and the type and nature of AI systems in which it can be integrated;

(b)
the acceptable use policies applicable;

(c)
the date of release and methods of distribution;

(d)
the architecture and number of parameters;

(e)
the modality (e.g. text, image) and format of inputs and outputs;

(f)
the licence.

2.
A detailed description of the elements of the model referred to in point 1, and relevant information of the process for the development, including the following elements:

(a)
the technical means (e.g. instructions of use, infrastructure, tools) required for the general-purpose AI model to be integrated in AI systems;

(b)

the design specifications of the model and training process, including training methodologies and techniques, the key design choices including the rationale and assumptions made; what the model is designed to optimise for and the relevance of the different parameters, as applicable;

(c)
information on the data used for training, testing and validation, where applicable, including the type and provenance of data and curation methodologies (e.g. cleaning, filtering, etc.), the number of data points, their scope and main characteristics; how the data was obtained and selected as well as all other measures to detect the unsuitability of data sources and methods to detect identifiable biases, where applicable;

(d)
the computational resources used to train the model (e.g. number of floating point operations), training time, and other relevant details related to the training;

(e)
known or estimated energy consumption of the model.

With regard to point (e), where the energy consumption of the model is unknown, the energy consumption may be based on information about computational resources used.

Section 2

Additional information to be provided by providers of general-purpose AI models with systemic risk

1. A detailed description of the evaluation strategies, including evaluation results, on the basis of available public evaluation protocols and tools or otherwise of other evaluation methodologies. Evaluation strategies shall include evaluation criteria, metrics and the methodology on the identification of limitations.

2. Where applicable, a detailed description of the measures put in place for the purpose of conducting internal and/or external adversarial testing (e.g. red teaming), model adaptations, including alignment and fine-tuning.

3. Where applicable, a detailed description of the system architecture explaining how software components build or feed into each other and integrate into the overall processing.

ANNEX XII

Transparency information referred to in Article 53(1), point (b) — technical documentation for providers of general-purpose AI models to downstream providers that integrate the model into their AI system

The information referred to in Article 53(1), point (b) shall contain at least the following:

1.
A general description of the general-purpose AI model including:

(a)
the tasks that the model is intended to perform and the type and nature of AI systems into which it can be integrated;

(b)
the acceptable use policies applicable;

(c)
the date of release and methods of distribution;

(d)

how the model interacts, or can be used to interact, with hardware or software that is not part of the model itself, where applicable;

(e)
the versions of relevant software related to the use of the general-purpose AI model, where applicable;

(f)
the architecture and number of parameters;

(g)
the modality (e.g. text, image) and format of inputs and outputs;

(h)
the licence for the model.

2.
A description of the elements of the model and of the process for its development, including:

(a)
the technical means (e.g. instructions for use, infrastructure, tools) required for the general-purpose AI model to be integrated into AI systems;

(b)
the modality (e.g. text, image, etc.) and format of the inputs and outputs and their maximum size (e.g. context window length, etc.);

(c)
information on the data used for training, testing and validation, where applicable, including the type and provenance of data and curation methodologies.

ANNEX XIII

Criteria for the designation of general-purpose AI models with systemic risk referred to in Article 51

For the purpose of determining that a general-purpose AI model has capabilities or an impact equivalent to those set out in Article 51(1), point (a), the Commission shall take into account the following criteria:

(a)
the number of parameters of the model;

(b)
the quality or size of the data set, for example measured through tokens;

(c)
the amount of computation used for training the model, measured in floating point operations or indicated by a combination of other variables such as estimated cost of training, estimated time required for the training, or estimated energy consumption for the training;

(d)
the input and output modalities of the model, such as text to text (large language models), text to image, multi-modality, and the state of the art thresholds for determining high-impact capabilities for each modality, and the specific type of inputs and outputs (e.g. biological sequences);

(e)
the benchmarks and evaluations of capabilities of the model, including considering the number of tasks without additional training, adaptability to learn new, distinct tasks, its level of autonomy and scalability, the tools it has

access to;

(f)
whether it has a high impact on the internal market due to its reach, which shall be presumed when it has been made available to at least 10 000 registered business users established in the Union;

(g)
the number of registered end-users.

▼M1

ANNEX XIV

The list of codes, categories and corresponding types of AI systems for the purpose of the notification procedure referred to in Article 30 specifying the scope of the designation as notified bodies

1. Introduction

Conformity assessment of high-risk AI systems pursuant to this Regulation may require the involvement of conformity assessment bodies. Only conformity assessment bodies that have been designated in accordance with this Regulation may carry out conformity assessments and only for the activities related to the types of AI systems concerned. The list of codes, categories, and corresponding types of AI systems sets the scope of the designation of conformity assessment bodies notified under Article 30.

2. List of Codes, categories, and corresponding AI systems

a. AI systems subject to Annex I

AIA Code	
AIP 0102	AI systems subject to point 2 of Section A of Annex I
AIP 0103	AI systems subject to point 3 of Section A of Annex I
AIP 0104	AI systems subject to point 4 of Section A of Annex I
AIP 0105	AI systems subject to point 5 of Section A of Annex I
AIP 0106	AI systems subject to point 6 of Section A of Annex I
AIP 0107	AI systems subject to point 7 of Section A of Annex I
AIP 0108	AI systems subject to point 8 of Section A of Annex I
AIP 0109	AI systems subject to point 9 of Section A of Annex I
AIP 0110	AI systems subject to point 10 of Section A of Annex I
AIP 0111	AI systems subject to point 11 of Section A of Annex I

AIP 0112	AI systems subject to point 12 of Section A of Annex I

b. AI systems subject to point 1 of Annex III

AIA Code	
AIB 0201	Remote biometric identification systems
AIB 0202	Biometric categorisation AI systems
AIB 0203	Emotion recognition AI systems

3. AI technology-specific codes

a. Symbolic AI and expert systems

AIA Code	
AIH 0101	AI systems based on symbolic AI, expert and knowledge-based systems, and AI systems based on search and optimisation

b. Machine learning, excluding generative AI and general-purpose AI systems

AIA Code	
AIH 0201	AI systems that process structured data
AIH 0202	AI systems that process signal and audio data
AIH 0203	AI systems that process text data
AIH 0204	AI systems that process image and video
AIH 0205	AI systems that learn from their environment, excluding AI systems covered under AIH 0401

c. AI systems based on general-purpose AI models or generative AI

AIA Code	

AIH 0301	generative AI systems, including AI systems based on general-purpose AI models

d. Emerging AI technologies

AIA Code	
AIH 0401	AI systems based on other emerging AI technologies not covered by other codes, including Agentic AI

4. Application for designation

Conformity assessment bodies shall use the lists of codes, categories and corresponding types of AI systems set out in this Annex when specifying the types of AI systems in the application for designation referred to in Article 29.

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(1) Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council (OJ L 316, 14.11.2012, p. 12, ELI: http://data.europa.eu/eli/reg/2012/1025/oj).

(1) Directive (EU) 2016/943 of the European Parliament and of the Council of 8 June 2016 on the protection of undisclosed know-how and business information (trade secrets) against their unlawful acquisition, use and disclosure (OJ L 157, 15.6.2016, p. 1).

(*1) 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).’.

(*2) 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).’.

(*3) 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).’.

(*4) 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).’.

(*5) 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).’.

(*6) 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).’.

(*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).’;

(*8) 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).’.

(1) Directive (EU) 2020/1828 of the European Parliament and of the Council of 25 November 2020 on representative actions for the protection of the collective interests of consumers and repealing Directive 2009/22/EC (OJ L 409, 4.12.2020, p. 1).