



TEXTS ADOPTED

P9_TA(2024)0138

Artificial Intelligence Act

European Parliament legislative resolution of 13 March 2024 on the proposal for a regulation of the European Parliament and of the Council on laying down harmonised rules on Artificial Intelligence (Artificial Intelligence Act) and amending certain Union Legislative Acts (COM(2021)0206 – C9-0146/2021 – 2021/0106(COD))

(Ordinary legislative procedure: first reading)

The European Parliament,

- having regard to the Commission proposal to Parliament and the Council (COM(2021)0206),
- having regard to Article 294(2) and Articles 16 and 114 of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C9-0146/2021),
- having regard to Article 294(3) of the Treaty on the Functioning of the European Union,
- having regard to the opinion of the European Central Bank of 29 December 2021¹,
- having regard to the opinion of the European Economic and Social Committee of 22 September 2021²,
- having regard to the provisional agreement approved by the committees responsible under Rule 74(4) of its Rules of Procedure and the undertaking given by the Council representative by letter of 2 February 2024 to approve Parliament's position, in accordance with Article 294(4) of the Treaty on the Functioning of the European Union,
- having regard to Rule 59 of its Rules of Procedure,
- having regard to the joint deliberations of the Committee on Internal Market and Consumer Protection and the Committee on Civil Liberties, Justice and Home Affairs under Rule 58 of the Rules of Procedure,
- having regard to the opinion of the Committee on Industry, Research and Energy, the Committee on Culture and Education, the Committee on Legal Affairs, the Committee

¹ OJ C 115, 11.3.2022, p. 5.

² OJ C 517, 22.12.2021, p. 56.

on the Environment, Public Health and Food Safety and the Committee on Transport and Tourism,

- having regard to the report of the Committee on Internal Market and Consumer Protection and the Committee on Civil Liberties, Justice and Home Affairs (A9-0188/2023),
1. Adopts its position at first reading hereinafter set out³;
 2. Calls on the Commission to refer the matter to Parliament again if it replaces, substantially amends or intends to substantially amend its proposal;
 3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

³ This position replaces the amendments adopted on 14 June 2023 (Texts adopted, P9_TA(2023)0236).

Position of the European Parliament adopted at first reading on 13 March 2024 with a view to the adoption of Regulation (EU) 2024/... of the European Parliament and of the Council 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)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Articles 16 and 114 thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee¹,

Having regard to the opinion of the European Central Bank²,

Having regard to the opinion of the Committee of the Regions³,

Acting in accordance with the ordinary legislative procedure⁴,

¹ OJ C 517, 22.12.2021, p. 56.

² ***OJ C 115, 11.3.2022, p. 5.***

³ OJ C 97, 28.2.2022, p. 60.

⁴ Position of the European Parliament of 13 March 2024.

Whereas:

- (1) The purpose of this Regulation is to improve the functioning of the internal market by laying down a uniform legal framework in particular for the development, the ***placing on the market, the putting into service and the*** use of artificial intelligence ***systems (AI systems)*** ***in the Union***, in accordance with Union values, ***to promote the uptake of human centric and trustworthy artificial intelligence (AI) while ensuring*** a high level of protection of health, safety, fundamental rights as ***enshrined in the Charter of Fundamental Rights of the European Union (the ‘Charter’)***, ***including democracy, the rule of law and environmental protection, to protect against the harmful effects of AI systems in the Union, and to support innovation. This Regulation*** ensures the free movement, cross-border, of AI-based goods and services, thus preventing Member States from imposing restrictions on the development, marketing and use of ***AI systems***, unless explicitly authorised by this Regulation.
- (2) ***This Regulation should be applied in accordance with the values of the Union enshrined as in the Charter, facilitating the protection of natural persons, undertakings, democracy, the rule of law and environmental protection, while boosting innovation and employment and making the Union a leader in the uptake of trustworthy AI.***

- (3) ■ AI systems ■ can be easily deployed in a large variety of sectors of the economy and many parts of society, including across borders, and can easily circulate throughout the Union. Certain Member States have already explored the adoption of national rules to ensure that AI is **trustworthy and** safe and is developed and used in accordance with fundamental rights obligations. Diverging national rules may lead to the fragmentation of the internal market and may decrease legal certainty for operators that develop, **import** or use AI systems. A consistent and high level of protection throughout the Union should therefore be ensured **in order to achieve trustworthy AI**, while divergences hampering the free circulation, **innovation, deployment and the uptake** of AI systems and related products and services within the internal market should be prevented by laying down uniform obligations for operators and guaranteeing the uniform protection of overriding reasons of public interest and of rights of persons throughout the internal market on the basis of Article 114 of the Treaty on the Functioning of the European Union (TFEU). To the extent that this Regulation contains specific rules on the protection of individuals with regard to the processing of personal data concerning restrictions of the use of AI systems for remote biometric identification **for the purpose of law enforcement, of the use of AI systems for risk assessments of natural persons for the purpose of law enforcement and of the use of AI systems of biometric categorisation** for the purpose of law enforcement, it is appropriate to base this Regulation, in so far as those specific rules are concerned, on Article 16 TFEU. In light of those specific rules and the recourse to Article 16 TFEU, it is appropriate to consult the European Data Protection Board.

- (4) AI is a fast evolving family of technologies that ***contributes*** to a wide array of economic, ***environmental*** and societal benefits across the entire spectrum of industries and social activities. By improving prediction, optimising operations and resource allocation, and personalising digital solutions available for individuals and organisations, the use of AI can provide key competitive advantages to undertakings and support socially and environmentally beneficial outcomes, for example in healthcare, agriculture, ***food safety***, education and training, ***media, sports, culture***, infrastructure management, energy, transport and logistics, public services, security, justice, resource and energy efficiency, ***environmental monitoring, the conservation and restoration of biodiversity and ecosystems*** and climate change mitigation and adaptation.
- (5) At the same time, depending on the circumstances regarding its specific application, ***use, and level of technological development***, AI may generate risks and cause harm to public interests and ***fundamental*** rights that are protected by Union law. Such harm might be material or immaterial, ***including physical, psychological, societal or economic harm***.

- (6) *Given the major impact that AI can have on society and the need to build trust, it is vital for AI and its regulatory framework to be developed in accordance with Union values as enshrined in Article 2 of the Treaty on European Union (TEU), the fundamental rights and freedoms enshrined in the Treaties and, pursuant to Article 6 TEU, the Charter. As a pre-requisite, AI should be a human-centric technology. It should serve as a tool for people, with the ultimate aim of increasing human well-being.*
- (7) *In order to ensure a consistent and high level of protection of public interests as regards health, safety and fundamental rights, common rules for high-risk AI systems should be established. Those rules should be consistent with the Charter, non-discriminatory and in line with the Union's international trade commitments. They should also take into account the European Declaration on Digital Rights and Principles for the Digital Decade and the Ethics guidelines for trustworthy AI of the High-Level Expert Group on Artificial Intelligence (AI HLEG).*

- (8) A Union legal framework laying down harmonised rules on AI is therefore needed to foster the development, use and uptake of AI in the internal market that at the same time meets a high level of protection of public interests, such as health and safety and the protection of fundamental rights, ***including democracy, the rule of law and environmental protection*** as recognised and protected by Union law. To achieve that objective, rules regulating the placing on the market, the putting into service ***and the use*** of certain AI systems should be laid down, thus ensuring the smooth functioning of the internal market and allowing those systems to benefit from the principle of free movement of goods and services. ***Those rules should be clear and robust in protecting fundamental rights, supportive of new innovative solutions, enabling a European ecosystem of public and private actors creating AI systems in line with Union values and unlocking the potential of the digital transformation across all regions of the Union.*** By laying down those rules ***as well as measures in support of innovation with a particular focus on small and medium enterprises (SMEs), including startups***, this Regulation supports the objective of ***promoting the European human-centric approach to AI and*** being a global leader in the development of secure, trustworthy and ethical AI ■ as stated by the European Council⁵, and it ensures the protection of ethical principles, as specifically requested by ***the*** European Parliament⁶.

⁵ European Council, Special meeting of the European Council (1 and 2 October 2020) – Conclusions, EUCO 13/20, 2020, p. 6.

⁶ European Parliament resolution of 20 October 2020 with recommendations to the Commission on a framework of ethical aspects of artificial intelligence, robotics and related technologies, 2020/2012(INL).

- (9) Harmonised rules applicable to the placing on the market, the putting into service and the use of high-risk AI systems should be laid down consistently with Regulation (EC) No 765/2008 of the European Parliament and of the Council⁷, Decision No 768/2008/EC of the European Parliament and of the Council⁸ and Regulation (EU) 2019/1020 of the European Parliament and of the Council⁹ (New Legislative Framework). ***The harmonised rules laid down in this Regulation should apply across sectors and, in line with the New Legislative Framework, should be without prejudice to existing Union law, in particular on data protection, consumer protection, fundamental rights, employment, and protection of workers, and product safety, to which this Regulation is complementary.***

⁷ Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and repealing Regulation (EEC) No 339/93 (OJ L 218, 13.8.2008, p. 30).

⁸ Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC (OJ L 218, 13.8.2008, p. 82).

⁹ Regulation (EU) 2019/1020 of the European Parliament and of the Council of 20 June 2019 on market surveillance and compliance of products and amending Directive 2004/42/EC and Regulations (EC) No 765/2008 and (EU) No 305/2011 (OJ L 169, 25.6.2019, p. 1).

As a consequence, all rights and remedies provided for by such Union law to consumers, and other persons on whom AI systems may have a negative impact, including as regards the compensation of possible damages pursuant to Council Directive 85/374/EEC¹⁰ remain unaffected and fully applicable. Furthermore, in the context of employment and protection of workers, this Regulation should therefore not affect Union law on social policy and national labour law, in compliance with Union law, concerning employment and working conditions, including health and safety at work and the relationship between employers and workers. This Regulation should also not affect the exercise of fundamental rights as recognised in the Member States and at Union level, including the right or freedom to strike or to take other action covered by the specific industrial relations systems in Member States as well as the right to negotiate, to conclude and enforce collective agreements or to take collective action in accordance with national law.

¹⁰ Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products (OJ L 210, 7.8.1985, p. 29).

This Regulation should not affect the provisions aiming to improve working conditions in platform work laid down in a Directive of the European Parliament and of the Council on improving working conditions in platform work. Moreover, this Regulation aims to strengthen the effectiveness of such existing rights and remedies by establishing specific requirements and obligations, including in respect of the transparency, technical documentation and record-keeping of AI systems. Furthermore, the obligations placed on various operators involved in the AI value chain under this Regulation should apply without prejudice to national law, in compliance with Union law, having the effect of limiting the use of certain AI systems where such law falls outside the scope of this Regulation or pursues legitimate public interest objectives other than those pursued by this Regulation. For example, national labour law and law on the protection of minors, namely persons below the age of 18, taking into account the UNCRC General Comment No 25 (2021) on children's rights in relation to the digital environment, insofar as they are not specific to AI systems and pursue other legitimate public interest objectives, should not be affected by this Regulation.

- (10) *The fundamental right to the protection of personal data is safeguarded in particular by Regulations (EU) 2016/679¹¹ and (EU) 2018/1725¹² of the European Parliament and of the Council and Directive (EU) 2016/680 of the European Parliament and of the Council¹³. Directive 2002/58/EC of the European Parliament and of the Council¹⁴ additionally protects private life and the confidentiality of communications, including by way of providing conditions for any storing of personal and non-personal data in, and access from, terminal equipment. Those Union legal acts provide the basis for sustainable and responsible data processing, including where data sets include a mix of personal and non-personal data. This Regulation does not seek to affect the application of existing Union law governing the processing of personal data, including the tasks and powers of the independent supervisory authorities competent to monitor compliance with those instruments.*

¹¹ Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (OJ L 119, 4.5.2016, p. 1).

¹² Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (OJ L 295, 21.11.2018, p. 39).

¹³ Directive (EU) 2016/680 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data by competent authorities for the purposes of the prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, and on the free movement of such data, and repealing Council Framework Decision 2008/977/JHA (OJ L 119, 4.5.2016, p. 89).

¹⁴ Directive 2002/58/EC of the European Parliament and of the Council of 12 July 2002 concerning the processing of personal data and the protection of privacy in the electronic communications sector (Directive on privacy and electronic communications) (OJ L 201, 31.7.2002, p. 37).

It also does not affect the obligations of providers and deployers of AI systems in their role as data controllers or processors stemming from Union or national law on the protection of personal data in so far as the design, the development or the use of AI systems involves the processing of personal data. It is also appropriate to clarify that data subjects continue to enjoy all the rights and guarantees awarded to them by such Union law, including the rights related to solely automated individual decision-making, including profiling. Harmonised rules for the placing on the market, the putting into service and the use of AI systems established under this Regulation should facilitate the effective implementation and enable the exercise of the data subjects' rights and other remedies guaranteed under Union law on the protection of personal data and of other fundamental rights.

- (11) This Regulation should be without prejudice to the provisions regarding the liability of providers of intermediary services as set out in Regulation (EU) 2022/2065 of the European Parliament and of the Council¹⁵.*

¹⁵ Regulation (EU) 2022/2065 of the European Parliament and of the Council of 19 October 2022 on a Single Market For Digital Services and amending Directive 2000/31/EC (Digital Services Act) (OJ L 277, 27.10.2022, p. 1).

- (12) The notion of ‘AI system’ *in this Regulation* should be clearly defined *and should be closely aligned with the work of international organisations working on AI* to ensure legal certainty, *facilitate international convergence and wide acceptance*, while providing the flexibility to accommodate *the rapid* technological developments *in this field*. *Moreover, the definition* should be based on *key* characteristics of *AI systems that distinguish it from simpler traditional software systems or programming approaches and should not cover systems that are based on the rules defined solely by natural persons to automatically execute operations. A key characteristic of AI systems is their capability to infer. This capability to infer refers to the process of obtaining the outputs, such as predictions, content, recommendations, or decisions, which can influence physical and virtual environments, and to a capability of AI systems to derive models or algorithms, or both, from inputs or data. The techniques that enable inference while building an AI system include machine learning approaches that learn from data how to achieve certain objectives, and logic- and knowledge-based approaches that infer from encoded knowledge or symbolic representation of the task to be solved. The capacity of an AI system to infer transcends basic data processing by enabling learning, reasoning or modelling. The term ‘machine-based’ refers to the fact that AI systems run on machines.*

The reference to explicit or implicit objectives underscores that AI systems can operate according to explicit defined objectives or to implicit objectives. The objectives of the AI system may be different from the intended purpose of the AI system in a specific context. For the purposes of this Regulation, environments should be understood to be the contexts in which the AI systems operate, whereas outputs generated by the AI system reflect different functions performed by AI systems and include predictions, content, recommendations or decisions. AI systems are designed to operate with varying levels of autonomy, meaning that they have some degree of independence of actions from human involvement and of capabilities to operate without human intervention. The adaptiveness that an AI system could exhibit after deployment, refers to self-learning capabilities, allowing the system to change while in use. AI systems can be used on a stand-alone basis or as a component of a product, irrespective of whether the system is physically integrated into the product (embedded) or serves the functionality of the product without being integrated therein (non-embedded).

- (13) *The notion of ‘deployer’ referred to in this Regulation should be interpreted as any natural or legal person, including a 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. Depending on the type of AI system, the use of the system may affect persons other than the deployer.*

- (14) The notion of ‘biometric data’ used in this Regulation ■ should be interpreted *in light of* the notion of biometric data as defined in Article 4, point (14) of Regulation (EU) 2016/679, Article 3, point (18) of Regulation (EU) 2018/1725 and Article 3, point (13) of Directive (EU) 2016/680. ***Biometric data can allow for the authentication, identification or categorisation of natural persons and for the recognition of emotions of natural persons.***
- (15) ***The notion of ‘biometric identification’ referred to in this Regulation should be defined as the automated recognition of physical, physiological and behavioural human features such as the face, eye movement, body shape, voice, prosody, gait, posture, heart rate, blood pressure, odour, keystrokes characteristics, for the purpose of establishing an individual’s identity by comparing biometric data of that individual to stored biometric data of individuals in a reference database, irrespective of whether the individual has given its consent or not. This excludes AI systems intended to be used for biometric verification, which includes authentication, whose sole purpose is to confirm that a specific natural person is the person he or she claims to be and to confirm the identity of a natural person for the sole purpose of having access to a service, unlocking a device or having security access to premises.***

- (16) *The notion of ‘biometric categorisation’ referred to in this Regulation should be defined as assigning natural persons to specific categories on the basis of their biometric data. Such specific categories can relate to aspects such as sex, age, hair colour, eye colour, tattoos, behavioural or personality traits, language, religion, membership of a national minority, sexual or political orientation. This does not include biometric categorisation systems that are a purely ancillary feature intrinsically linked to another commercial service, meaning that the feature cannot, for objective technical reasons, be used without the principal service, and the integration of that feature or functionality is not a means to circumvent the applicability of the rules of this Regulation. For example, filters categorising facial or body features used on online marketplaces could constitute such an ancillary feature as they can be used only in relation to the principal service which consists in selling a product by allowing the consumer to preview the display of the product on him or herself and help the consumer to make a purchase decision. Filters used on online social network services which categorise facial or body features to allow users to add or modify pictures or videos could also be considered to be ancillary feature as such filter cannot be used without the principal service of the social network services consisting in the sharing of content online.*

- (17) The notion of ‘remote biometric identification system’ referred to in this Regulation should be defined functionally, as an AI system intended for the identification of 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, *irrespective of the particular technology, processes or types of biometric data used. Such remote biometric identification systems are typically used to perceive multiple persons or their behaviour simultaneously in order to facilitate significantly the identification of natural persons without their active involvement. This excludes AI systems intended to be used for biometric verification, which includes authentication, the sole purpose of which is to confirm that a specific natural person is the person he or she claims to be and to confirm the identity of a natural person for the sole purpose of having access to a service, unlocking a device or having security access to premises. That exclusion is justified by the fact that such systems are likely to have a minor impact on fundamental rights of natural persons compared to the remote biometric identification systems which may be used for the processing of the biometric data of a large number of persons without their active involvement.* In the case of ‘real-time’ systems, the capturing of the biometric data, the comparison and the identification occur all instantaneously, near-instantaneously or in any event without a significant delay. In this regard, there should be no scope for circumventing the rules of this Regulation on the ‘real-time’ use of the AI systems concerned by providing for minor delays. ‘Real-time’ systems involve the use of ‘live’ or ‘near-live’ material, such as video footage, generated by a camera or other device with similar functionality. In the case of ‘post’ systems, in contrast, the biometric data has already been captured and the comparison and identification occur only after a significant delay. This involves material, such as pictures or video footage generated by closed circuit television cameras or private devices, which has been generated before the use of the system in respect of the natural persons concerned.

- (18) *The notion of ‘emotion recognition system’ referred to in this Regulation should be defined as an AI system for the purpose of identifying or inferring emotions or intentions of natural persons on the basis of their biometric data. The notion refers to emotions or intentions such as happiness, sadness, anger, surprise, disgust, embarrassment, excitement, shame, contempt, satisfaction and amusement. It does not include physical states, such as pain or fatigue, including, for example, systems used in detecting the state of fatigue of professional pilots or drivers for the purpose of preventing accidents. This does also not include the mere detection of readily apparent expressions, gestures or movements, unless they are used for identifying or inferring emotions. Those expressions can be basic facial expressions, such as a frown or a smile, or gestures such as the movement of hands, arms or head, or characteristics of a person’s voice, such as a raised voice or whispering.*

- (19) For the purposes of this Regulation the notion of ‘publicly accessible space’ should be understood as referring to any physical space that is accessible to *an undetermined number of natural persons, and* irrespective of whether the space in question is privately or publicly owned, *irrespective of the activity for which the space may be used, such as for commerce, for example, shops, restaurants, cafés; for services, for example, banks, professional activities, hospitality; for sport, for example, swimming pools, gyms, stadiums; for transport, for example, bus, metro and railway stations, airports, means of transport; for entertainment, for example, cinemas, theatres, museums, concert and conference halls; or for leisure or otherwise, for example, public roads and squares, parks, forests, playgrounds. A space should also be classified as being publicly accessible if, regardless of potential capacity or security restrictions, access is subject to certain predetermined conditions which can be fulfilled by an undetermined number of persons, such as the purchase of a ticket or title of transport, prior registration or having a certain age. In contrast, a space should not be considered to be publicly accessible if access is limited to specific and defined natural persons through either Union or national law directly related to public safety or security or through the clear manifestation of will by the person having the relevant authority over the space. The factual possibility of access alone, such as an unlocked door or an open gate in a fence, does not imply that the space is publicly accessible in the presence of indications or circumstances suggesting the contrary, such as signs prohibiting or restricting access. Company and factory premises, as well as offices and workplaces that are intended to be accessed only by relevant employees and service providers, are spaces that are not publicly accessible. Publicly accessible spaces should not include prisons or border control. Some other spaces may comprise both publicly accessible and non-publicly accessible spaces, such as the hallway of a private residential building necessary to access a doctor's office or an airport. Online spaces are not covered, as they are not physical spaces.* Whether a given space is accessible to the public should however be determined on a case-by-case basis, having regard to the specificities of the individual situation at hand.

(20) *In order to obtain the greatest benefits from AI systems while protecting fundamental rights, health and safety and to enable democratic control, AI literacy should equip providers, deployers and affected persons with the necessary notions to make informed decisions regarding AI systems. Those notions may vary with regard to the relevant context and can include understanding the correct application of technical elements during the AI system's development phase, the measures to be applied during its use, the suitable ways in which to interpret the AI system's output, and, in the case of affected persons, the knowledge necessary to understand how decisions taken with the assistance of AI will have an impact on them. In the context of the application this Regulation, AI literacy should provide all relevant actors in the AI value chain with the insights required to ensure the appropriate compliance and its correct enforcement. Furthermore, the wide implementation of AI literacy measures and the introduction of appropriate follow-up actions could contribute to improving working conditions and ultimately sustain the consolidation, and innovation path of trustworthy AI in the Union. The European Artificial Intelligence Board (the 'Board') should support the Commission, to promote AI literacy tools, public awareness and understanding of the benefits, risks, safeguards, rights and obligations in relation to the use of AI systems. In cooperation with the relevant stakeholders, the Commission and the Member States should facilitate the drawing up of voluntary codes of conduct to advance AI literacy among persons dealing with the development, operation and use of AI.*

- (21) In order to ensure a level playing field and an effective protection of rights and freedoms of individuals across the Union, the rules established by this Regulation should apply to providers of AI systems in a non-discriminatory manner, irrespective of whether they are established within the Union or in a third country, and to **deployers** of AI systems established within the Union.
- (22) In light of their digital nature, certain AI systems should fall within the scope of this Regulation even when they are not placed on the market, put into service, or used in the Union. This is the case, for example, where an operator established in the Union contracts certain services to an operator established in a third country in relation to an activity to be performed by an AI system that would qualify as high-risk **■**. In those circumstances, the AI system used in a third country by the operator could process data lawfully collected in and transferred from the Union, and provide to the contracting operator in the Union the output of that AI system resulting from that processing, without that AI system being placed on the market, put into service or used in the Union. To prevent the circumvention of this Regulation and to ensure an effective protection of natural persons located in the Union, this Regulation should also apply to providers and **deployers** of AI systems that are established in a third country, to the extent the output produced by those systems is **intended to be** used in the Union.

Nonetheless, to take into account existing arrangements and special needs for **future** cooperation with foreign partners with whom information and evidence is exchanged, this Regulation should not apply to public authorities of a third country and international organisations when acting in the framework of **cooperation or** international agreements concluded at Union or national level for law enforcement and judicial cooperation with the Union or the Member States, ***provided that the relevant third country or international organisation provides adequate safeguards with respect to the protection of fundamental rights and freedoms of individuals. Where relevant, this may cover activities of entities entrusted by the third countries to carry out specific tasks in support of such law enforcement and judicial cooperation. Such framework for cooperation or*** agreements have been ***established*** bilaterally between Member States and third countries or between the European Union, Europol and other Union agencies and third countries and international organisations. ***The authorities competent for supervision of the law enforcement and judicial authorities under this Regulation should assess whether those frameworks for cooperation or international agreements include adequate safeguards with respect to the protection of fundamental rights and freedoms of individuals. Recipient national authorities and Union institutions, bodies, offices and agencies making use of such outputs in the Union remain accountable to ensure their use complies with Union law. When those international agreements are revised or new ones are concluded in the future, the contracting parties should make utmost efforts to align those agreements with the requirements of this Regulation.***

- (23) This Regulation should also apply to Union institutions, bodies, offices and agencies when acting as a provider or *deployer* of an AI system. ■
- (24) *If, and insofar as, AI systems are placed on the market, put into service, or used with or without modification of such systems for military, defence or national security purposes, those should be excluded from the scope of this Regulation regardless of which type of entity is carrying out those activities, such as whether it is a public or private entity. As regards military and defence purposes, such exclusion is justified both by Article 4(2) TEU and by the specificities of the Member States' and the common Union defence policy covered by Chapter 2 of Title V TEU that are subject to public international law, which is therefore the more appropriate legal framework for the regulation of AI systems in the context of the use of lethal force and other AI systems in the context of military and defence activities. As regards national security purposes, the exclusion is justified both by the fact that national security remains the sole responsibility of Member States in accordance with Article 4(2) TEU and by the specific nature and operational needs of national security activities and specific national rules applicable to those activities. Nonetheless, if an AI system developed, placed on the market, put into service or used for military, defence or national security purposes is used outside those temporarily or permanently for other purposes, for example, civilian or humanitarian purposes, law enforcement or public security purposes, such a system would fall within the scope of this Regulation.*

In that case, the entity using the AI system for other than military, defence or national security purposes should ensure the compliance of the AI system with this Regulation, unless the system is already compliant with this Regulation. AI systems placed on the market or put into service for an excluded purpose, namely military, defence or national security, and one or more non-excluded purposes, such as civilian purposes or law enforcement, fall within the scope of this Regulation and providers of those systems should ensure compliance with this Regulation. In those cases, the fact that an AI system may fall within the scope of this Regulation should not affect the possibility of entities carrying out national security, defence and military activities, regardless of the type of entity carrying out those activities, to use AI systems for national security, military and defence purposes, the use of which is excluded from the scope of this Regulation. An AI system placed on the market for civilian or law enforcement purposes which is used with or without modification for military, defence or national security purposes should not fall within the scope of this Regulation, regardless of the type of entity carrying out those activities.

- (25) *This Regulation should support innovation, should respect freedom of science, and should not undermine research and development activity. It is therefore necessary to exclude from its scope AI systems and models specifically developed and put into service for the sole purpose of scientific research and development. Moreover, it is necessary to ensure that this Regulation does not otherwise affect scientific research and development activity on AI systems or models prior to being placed on the market or put into service. As regards product-oriented research, testing and development activity regarding AI systems or models, the provisions of this Regulation should also not apply prior to those systems and models being put into service or placed on the market. That exclusion is without prejudice to the obligation to comply with this Regulation where an AI system falling into the scope of this Regulation is placed on the market or put into service as a result of such research and development activity and to the application of provisions on AI regulatory sandboxes and testing in real world conditions. Furthermore, without prejudice to the exclusion of AI systems specifically developed and put into service for the sole purpose of scientific research and development, any other AI system that may be used for the conduct of any research and development activity should remain subject to the provisions of this Regulation. In any event, any research and development activity should be carried out in accordance with recognised ethical and professional standards for scientific research and should be conducted in accordance with applicable Union law.*

- (26) In order to introduce a proportionate and effective set of binding rules for AI systems, a clearly defined risk-based approach should be followed. That approach should tailor the type and content of such rules to the intensity and scope of the risks that AI systems can generate. It is therefore necessary to prohibit certain **unacceptable** AI practices, to lay down requirements for high-risk AI systems and obligations for the relevant operators, and to lay down transparency obligations for certain AI systems.
- (27) *While the risk-based approach is the basis for a proportionate and effective set of binding rules, it is important to recall the 2019 Ethics guidelines for trustworthy AI developed by the independent AI HLEG appointed by the Commission. In those guidelines, the AI HLEG developed seven non-binding ethical principles for AI which are intended to help ensure that AI is trustworthy and ethically sound. The seven principles include human agency and oversight; technical robustness and safety; privacy and data governance; transparency; diversity, non-discrimination and fairness; societal and environmental well-being and accountability. Without prejudice to the legally binding requirements of this Regulation and any other applicable Union law, those guidelines contribute to the design of coherent, trustworthy and human-centric AI, in line with the Charter and with the values on which the Union is founded. According to the guidelines of the AI HLEG, human agency and oversight means that AI systems are developed and used as a tool that serves people, respects human dignity and personal autonomy, and that is functioning in a way that can be appropriately controlled and overseen by humans.*

Technical robustness and safety means that AI systems are developed and used in a way that allows robustness in the case of problems and resilience against attempts to alter the use or performance of the AI system so as to allow unlawful use by third parties, and minimise unintended harm. Privacy and data governance means that AI systems are developed and used in accordance with privacy and data protection rules, while processing data that meets high standards in terms of quality and integrity.

Transparency means that AI systems are developed and used in a way that allows appropriate traceability and explainability, while making humans aware that they communicate or interact with an AI system, as well as duly informing deployers of the capabilities and limitations of that AI system and affected persons about their rights.

Diversity, non-discrimination and fairness means that AI systems are developed and used in a way that includes diverse actors and promotes equal access, gender equality and cultural diversity, while avoiding discriminatory impacts and unfair biases that are prohibited by Union or national law. Social and environmental well-being means that AI systems are developed and used in a sustainable and environmentally friendly manner as well as in a way to benefit all human beings, while monitoring and assessing the long-term impacts on the individual, society and democracy. The application of those principles should be translated, when possible, in the design and use of AI models. They should in any case serve as a basis for the drafting of codes of conduct under this Regulation. All stakeholders, including industry, academia, civil society and standardisation organisations, are encouraged to take into account, as appropriate, the ethical principles for the development of voluntary best practices and standards.

- (28) Aside from the many beneficial uses of AI, it can also be misused and provide novel and powerful tools for manipulative, exploitative and social control practices. Such practices are particularly harmful and ***abusive and*** should be prohibited because they contradict Union values of respect for human dignity, freedom, equality, democracy and the rule of law and fundamental rights enshrined in the Charter, including the right to non-discrimination, to data protection and to privacy and the rights of the child.
- (29) ***AI-enabled manipulative techniques can be used to persuade persons to engage in unwanted behaviours, or to deceive them by nudging them into decisions in a way that subverts and impairs their autonomy, decision-making and free choices.*** The placing on the market, the putting into service or the use of certain AI systems ***with the objective to or the effect of materially distorting*** human behaviour, whereby ***significant harms, in particular having sufficiently important adverse impacts on physical, psychological health or financial interests*** are likely to occur, ***are particularly dangerous and*** should ***therefore*** be prohibited. Such AI systems deploy subliminal components ***such as audio, image, video stimuli that persons*** cannot perceive, ***as those stimuli are beyond human perception, or other manipulative or deceptive techniques that subvert or impair person's autonomy, decision-making or free choice in ways that people are not consciously aware of those techniques or, where they are aware of them, can still be deceived or are not able to control or resist them.*** This could be facilitated, for example, by machine-brain interfaces or virtual reality as they allow for a higher degree of control of what stimuli are presented to persons, insofar as they may materially distort their behaviour in a significantly harmful manner. In addition, AI systems may also otherwise exploit the vulnerabilities of ***a person or a specific group of persons*** due to their age, ***disability within the meaning of Directive (EU) 2019/882 of the European Parliament and of the Council***¹⁶, or a specific social or economic situation that is likely to make those persons more vulnerable to exploitation such as persons living in extreme poverty, ethnic or religious minorities.

¹⁶ Directive (EU) 2019/882 of the European Parliament and of the Council of 17 April 2019 on the accessibility requirements for products and services (OJ L 151, 7.6.2019, p. 70).

*Such AI systems can be placed on the market, put into service or used with the objective to or the effect of materially **distorting** the behaviour of a person and in a manner that causes or is **reasonably** likely to cause **significant** harm to that or another person **or groups of persons, including harms that may be accumulated over time and should therefore be prohibited**. It may not be possible to assume that there is an intention **to distort behaviour** where the distortion ■ results from factors external to the AI system which are outside the control of the provider or the **deployer, namely factors that may not be reasonably foreseeable and therefore not possible for the provider or the deployer of the AI system to mitigate**. In any case, it is not necessary for the provider or the deployer to have the intention to cause significant harm, provided that such harm results from the **manipulative or exploitative AI-enabled practices**. The prohibitions for such AI practices are complementary to the provisions contained in Directive 2005/29/EC of the European Parliament and of the Council¹⁷, in particular unfair commercial practices leading to economic or financial harms to consumers are prohibited under all circumstances, irrespective of whether they are put in place through AI systems or otherwise. The prohibitions of manipulative and exploitative practices in this Regulation should not affect lawful practices in the context of medical treatment such as psychological treatment of a mental disease or physical rehabilitation, when those practices are carried out in accordance with **the applicable law and medical standards, for example explicit consent of the individuals or their legal representatives**. In addition, common and legitimate commercial practices, for example in the field of advertising, that comply with the applicable law should not, in themselves, be regarded as constituting harmful manipulative AI-enabled practices.*

¹⁷ Directive 2005/29/EC of the European Parliament and of the Council of 11 May 2005 concerning unfair business-to-consumer commercial practices in the internal market and amending Council Directive 84/450/EEC, Directives 97/7/EC, 98/27/EC and 2002/65/EC of the European Parliament and of the Council and Regulation (EC) No 2006/2004 of the European Parliament and of the Council ('Unfair Commercial Practices Directive') (OJ L 149, 11.6.2005, p. 22).

- (30) *Biometric categorisation systems that are based on natural persons' biometric data, such as an individual person's face or fingerprint, to deduce or infer an individuals' political opinions, trade union membership, religious or philosophical beliefs, race, sex life or sexual orientation should be prohibited. That prohibition should not cover the lawful labelling, filtering or categorisation of biometric data sets acquired in line with Union or national law according to biometric data, such as the sorting of images according to hair colour or eye colour, which can for example be used in the area of law enforcement.*
- (31) AI systems providing social scoring of natural persons ■ by public *or private actors* may lead to discriminatory outcomes and the exclusion of certain groups. They may violate the right to dignity and non-discrimination and the values of equality and justice. Such AI systems evaluate or classify *natural persons or groups thereof* on the basis of *multiple data points related to* their social behaviour in multiple contexts or known, *inferred* or predicted personal or personality characteristics *over certain periods of time*. The social score obtained from such AI systems may lead to the detrimental or unfavourable treatment of natural persons or whole groups thereof in social contexts, which are unrelated to the context in which the data was originally generated or collected or to a detrimental treatment that is disproportionate or unjustified to the gravity of their social behaviour. *AI systems entailing such unacceptable scoring practices and leading to such detrimental or unfavourable outcomes* should therefore be prohibited. *That prohibition should not affect lawful evaluation practices of natural persons that are carried out for a specific purpose in accordance with Union and national law.*

- (32) The use of AI systems for ‘real-time’ remote biometric identification of natural persons in publicly accessible spaces for the purpose of law enforcement is particularly intrusive **to** the rights and freedoms of the concerned persons, to the extent that it may affect the private life of a large part of the population, evoke a feeling of constant surveillance and indirectly dissuade the exercise of the freedom of assembly and other fundamental rights. ***Technical inaccuracies of AI systems intended for the remote biometric identification of natural persons can lead to biased results and entail discriminatory effects. Such possible biased results and discriminatory effects are particularly relevant with regard to age, ethnicity, race, sex or disabilities.*** In addition, the immediacy of the impact and the limited opportunities for further checks or corrections in relation to the use of such systems operating in real-time carry heightened risks for the rights and freedoms of the persons concerned in the context of, or impacted by, law enforcement activities.
- (33) The use of those systems for the purpose of law enforcement should therefore be prohibited, except in exhaustively listed and narrowly defined situations, where the use is strictly necessary to achieve a substantial public interest, the importance of which outweighs the risks. Those situations involve the search for ***certain*** victims of crime **■** including missing ***persons***; certain threats to the life or to the physical safety of natural persons or of a terrorist attack; and the localisation ***or identification*** of perpetrators or suspects of the criminal offences listed in an annex to this Regulation, ***where*** those criminal offences are punishable in the Member State concerned by a custodial sentence or a detention order for a maximum period of at least ***four*** years and as they are defined in the law of that Member State. Such a threshold for the custodial sentence or detention order in accordance with national law contributes to ensuring that the offence should be serious enough to potentially justify the use of ‘real-time’ remote biometric identification systems.

Moreover, ***the list of criminal offences provided in an annex to this Regulation is based on the 32 criminal offences listed in the Council Framework Decision 2002/584/JHA¹⁸, taking into account that some of those offences are, in practice, likely to be more relevant than others, in that the recourse to ‘real-time’ remote biometric identification could, foreseeably, be necessary and proportionate to highly varying degrees for the practical pursuit of the localisation or identification of a perpetrator or suspect of the different criminal offences listed and having regard to the likely differences in the seriousness, probability and scale of the harm or possible negative consequences. An imminent threat to life or the physical safety of natural persons could also result from a serious disruption of critical infrastructure, as defined in Article 2, point (4) of Directive (EU) 2022/2557 of the European Parliament and of the Council¹⁹, where the disruption or destruction of such critical infrastructure would result in an imminent threat to life or the physical safety of a person, including through serious harm to the provision of basic supplies to the population or to the exercise of the core function of the State. In addition, this Regulation should preserve the ability for law enforcement, border control, immigration or asylum authorities to carry out identity checks in the presence of the person concerned in accordance with the conditions set out in Union and national law for such checks. In particular, law enforcement, border control, immigration or asylum authorities should be able to use information systems, in accordance with Union or national law, to identify persons who, during an identity check, either refuse to be identified or are unable to state or prove their identity, without being required by this Regulation to obtain prior authorisation. This could be, for example, a person involved in a crime, being unwilling, or unable due to an accident or a medical condition, to disclose their identity to law enforcement authorities.***

¹⁸ Council Framework Decision 2002/584/JHA of 13 June 2002 on the European arrest warrant and the surrender procedures between Member States (OJ L 190, 18.7.2002, p. 1).

¹⁹ Directive (EU) 2022/2557 of the European Parliament and of the Council of 14 December 2022 on the resilience of critical entities and repealing Council Directive 2008/114/EC (OJ L 333, 27.12.2022, p. 164).

- (34) In order to ensure that those systems are used in a responsible and proportionate manner, it is also important to establish that, in each of those exhaustively listed and narrowly defined situations, certain elements should be taken into account, in particular as regards the nature of the situation giving rise to the request and the consequences of the use for the rights and freedoms of all persons concerned and the safeguards and conditions provided for with the use. In addition, the use of ‘real-time’ remote biometric identification systems in publicly accessible spaces for the purpose of law enforcement should ***be deployed only to confirm the specifically targeted individual’s identity and should be limited to what is strictly necessary concerning the period of time, as well as the geographic and personal scope,*** having regard in particular to the evidence or indications regarding the threats, the victims or perpetrator. The ***use of the real-time remote biometric identification system in publicly accessible spaces should be authorised only if the relevant law enforcement authority has completed a fundamental rights impact assessment and, unless provided otherwise in this Regulation, has registered the system in the database as set out in this Regulation.*** The reference database of persons should be appropriate for each use case in each of the situations mentioned above.

- (35) Each use of a ‘real-time’ remote biometric identification system in publicly accessible spaces for the purpose of law enforcement should be subject to an express and specific authorisation by a judicial authority or by an independent administrative authority of a Member State ***whose decision is binding***. Such authorisation should, in principle, be obtained prior to the use ***of the AI system with a view to identifying a person or persons***. ***Exceptions to that rule should be allowed*** in duly justified situations on grounds of urgency, namely in situations where the need to use the systems concerned is such as to make it effectively and objectively impossible to obtain an authorisation before commencing the use of the AI system. In such situations of urgency, the use of the AI system should be restricted to the absolute minimum necessary and should be subject to appropriate safeguards and conditions, as determined in national law and specified in the context of each individual urgent use case by the law enforcement authority itself. In addition, the law enforcement authority should in such situations ***request such*** authorisation ■ while providing the reasons for not having been able to request it earlier, ***without undue delay and at the latest within 24 hours***. ***If such an authorisation is rejected, the use of real-time biometric identification systems linked to that authorisation should cease with immediate effect and all the data related to such use should be discarded and deleted. Such data includes input data directly acquired by an AI system in the course of the use of such system as well as the results and outputs of the use linked to that authorisation. It should not include input that is legally acquired in accordance with another Union or national law. In any case, no decision producing an adverse legal effect on a person should be taken based solely on the output of the remote biometric identification system.***

- (36) ***In order to carry out their tasks in accordance with the requirements set out in this Regulation as well as in national rules, the relevant market surveillance authority and the national data protection authority should be notified of each use of the real-time biometric identification system. Market surveillance authorities and the national data protection authorities that have been notified should submit to the Commission an annual report on the use of real-time biometric identification systems.***
- (37) Furthermore, it is appropriate to provide, within the exhaustive framework set by this Regulation that such use in the territory of a Member State in accordance with this Regulation should only be possible where and in as far as the Member State concerned has decided to expressly provide for the possibility to authorise such use in its detailed rules of national law. Consequently, Member States remain free under this Regulation not to provide for such a possibility at all or to only provide for such a possibility in respect of some of the objectives capable of justifying authorised use identified in this Regulation. ***Such national rules should be notified to the Commission within 30 days of their adoption.***

- (38) The use of AI systems for real-time remote biometric identification of natural persons in publicly accessible spaces for the purpose of law enforcement necessarily involves the processing of biometric data. The rules of this Regulation that prohibit, subject to certain exceptions, such use, which are based on Article 16 TFEU, should apply as *lex specialis* in respect of the rules on the processing of biometric data contained in Article 10 of Directive (EU) 2016/680, thus regulating such use and the processing of biometric data involved in an exhaustive manner. Therefore, such use and processing should be possible only in as far as it is compatible with the framework set by this Regulation, without there being scope, outside that framework, for the competent authorities, where they act for purpose of law enforcement, to use such systems and process such data in connection thereto on the grounds listed in Article 10 of Directive (EU) 2016/680. In that context, this Regulation is not intended to provide the legal basis for the processing of personal data under Article 8 of Directive (EU) 2016/680. However, the use of real-time remote biometric identification systems in publicly accessible spaces for purposes other than law enforcement, including by competent authorities, should not be covered by the specific framework regarding such use for the purpose of law enforcement set by this Regulation. Such use for purposes other than law enforcement should therefore not be subject to the requirement of an authorisation under this Regulation and the applicable detailed rules of national law that may give effect to that authorisation.

- (39) Any processing of biometric data and other personal data involved in the use of AI systems for biometric identification, other than in connection to the use of real-time remote biometric identification systems in publicly accessible spaces for the purpose of law enforcement as regulated by this Regulation, ***should continue to comply with all requirements resulting from Article 10 of Directive (EU) 2016/680. For purposes other than law enforcement, Article 9(1) of Regulation (EU) 2016/679 and Article 10(1) of Regulation (EU) 2018/1725 prohibit the processing of biometric data subject to limited exceptions as provided in those Articles. In the application of Article 9(1) of Regulation (EU) 2016/679, the use of remote biometric identification for purposes other than law enforcement has already been subject to prohibition decisions by national data protection authorities.***

- (40) In accordance with Article 6a of Protocol No 21 on the position of the United Kingdom and Ireland in respect of the area of freedom, security and justice, as annexed to the TEU and to the TFEU, Ireland is not bound by the rules laid down in ***Article 5(1), first subparagraph, point (g), to the extent it applies to the use of biometric categorisation systems for activities in the field of police cooperation and judicial cooperation in criminal matters, Article 5(1), first subparagraph, point (d), to the extent it applies to the use of AI systems covered by that provision***, Article 5(1), first subparagraph, point (h), Article 5(2) to (6) and Article 26(10) of this Regulation adopted on the basis of Article 16 TFEU which relate to the processing of personal data by the Member States when carrying out activities falling within the scope of Chapter 4 or Chapter 5 of Title V of Part Three of the TFEU, where Ireland is not bound by the rules governing the forms of judicial cooperation in criminal matters or police cooperation which require compliance with the provisions laid down on the basis of Article 16 TFEU.
- (41) In accordance with Articles 2 and 2a of Protocol No 22 on the position of Denmark, annexed to the TEU and to the TFEU, Denmark is not bound by rules laid down in ***Article 5(1), first subparagraph, point (g), to the extent it applies to the use of biometric categorisation systems for activities in the field of police cooperation and judicial cooperation in criminal matters, Article 5(1), first subparagraph, point (d), to the extent it applies to the use of AI systems covered by that provision***, Article 5(1), first subparagraph, point (h), (2) to (6) and Article 26(10) of this Regulation adopted on the basis of Article 16 TFEU, or subject to their application, which relate to the processing of personal data by the Member States when carrying out activities falling within the scope of Chapter 4 or Chapter 5 of Title V of Part Three of the TFEU.

- (42) *In line with the presumption of innocence, natural persons in the Union should always be judged on their actual behaviour. Natural persons should never be judged on AI-predicted behaviour based solely on their profiling, personality traits or characteristics, such as nationality, place of birth, place of residence, number of children, level of debt or type of car, without a reasonable suspicion of that person being involved in a criminal activity based on objective verifiable facts and without human assessment thereof. Therefore, risk assessments carried out with regard to natural persons in order to assess the likelihood of their offending or to predict the occurrence of an actual or potential criminal offence based solely on profiling them or on assessing their personality traits and characteristics should be prohibited. In any case, that prohibition does not refer to or touch upon risk analytics that are not based on the profiling of individuals or on the personality traits and characteristics of individuals, such as AI systems using risk analytics to assess the likelihood of financial fraud by undertakings on the basis of suspicious transactions or risk analytic tools to predict the likelihood of the localisation of narcotics or illicit goods by customs authorities, for example on the basis of known trafficking routes.*
- (43) *The placing on the market, the putting into service for that 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, should be prohibited because that practice adds to the feeling of mass surveillance and can lead to gross violations of fundamental rights, including the right to privacy.*

- (44) *There are serious concerns about the scientific basis of AI systems aiming to identify or infer emotions, particularly as expression of emotions vary considerably across cultures and situations, and even within a single individual. Among the key shortcomings of such systems are the limited reliability, the lack of specificity and the limited generalisability. Therefore, AI systems identifying or inferring emotions or intentions of natural persons on the basis of their biometric data may lead to discriminatory outcomes and can be intrusive to the rights and freedoms of the concerned persons. Considering the imbalance of power in the context of work or education, combined with the intrusive nature of these systems, such systems could lead to detrimental or unfavourable treatment of certain natural persons or whole groups thereof. Therefore, the placing on the market, the putting into service, or the use of AI systems intended to be used to detect the emotional state of individuals in situations related to the workplace and education should be prohibited. That prohibition should not cover AI systems placed on the market strictly for medical or safety reasons, such as systems intended for therapeutical use.*
- (45) *Practices that are prohibited by Union law, including data protection law, non-discrimination law, consumer protection law, and competition law, should not be affected by this Regulation.*

- (46) High-risk AI systems should only be placed on the Union market, put into service *or used* if they comply with certain mandatory requirements. Those requirements should ensure that high-risk AI systems available in the Union or whose output is otherwise used in the Union do not pose unacceptable risks to important Union public interests as recognised and protected by Union law. ***On the basis of the New Legislative Framework, as clarified in the Commission notice “The ‘Blue Guide’ on the implementation of EU product rules 2022”²⁰, the general rule is that more than one legal act of Union harmonisation legislation, such as Regulations (EU) 2017/745²¹ and (EU) 2017/746²² of the European Parliament and of the Council or Directive 2006/42/EC of the European Parliament and of the Council²³, may be applicable to one product, since the making available or putting into service can take place only when the product complies with all applicable Union harmonisation legislation. To ensure consistency and avoid unnecessary administrative burdens or costs, providers of a product that contains one or more high-risk AI systems, to which the requirements of this Regulation and of the Union harmonisation legislation listed in an annex to this Regulation apply, should have flexibility with regard to operational decisions on how to ensure compliance of a product that contains one or more AI systems with all applicable requirements of the Union harmonisation legislation in an optimal manner.*** AI systems identified as high-risk should be limited to those that have a significant harmful impact on the health, safety and fundamental rights of persons in the Union and such limitation should minimise any potential restriction to international trade.

²⁰ ***OJ C 247, 29.6.2022, p. 1.***

²¹ 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).

²² 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).

²³ Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC (OJ L 157, 9.6.2006, p. 24).

- (47) AI systems could *have an* adverse *impact* on the health and safety of persons, in particular when such systems operate as *safety* components of products. Consistent with the objectives of Union harmonisation legislation to facilitate the free movement of products in the internal market and to ensure that only safe and otherwise compliant products find their way into the market, it is important that the safety risks that may be generated by a product as a whole due to its digital components, including AI systems, are duly prevented and mitigated. For instance, increasingly autonomous robots, whether in the context of manufacturing or personal assistance and care should be able to safely operate and performs their functions in complex environments. Similarly, in the health sector where the stakes for life and health are particularly high, increasingly sophisticated diagnostics systems and systems supporting human decisions should be reliable and accurate. ■

(48) *The extent of the adverse impact caused by the AI system on the fundamental rights protected by the Charter is of particular relevance when classifying an AI system as high risk. Those rights include the right to human dignity, respect for private and family life, protection of personal data, freedom of expression and information, freedom of assembly and of association, the right to non-discrimination, the right to education, consumer protection, workers' rights, the rights of persons with disabilities, gender equality, intellectual property rights, the right to an effective remedy and to a fair trial, the right of defence and the presumption of innocence, and the right to good administration. In addition to those rights, it is important to highlight the fact that children have specific rights as enshrined in Article 24 of the Charter and in the United Nations Convention on the Rights of the Child, further developed in the UNCRC General Comment No 25 as regards the digital environment, both of which require consideration of the children's vulnerabilities and provision of such protection and care as necessary for their well-being. The fundamental right to a high level of environmental protection enshrined in the Charter and implemented in Union policies should also be considered when assessing the severity of the harm that an AI system can cause, including in relation to the health and safety of persons.*

- (49) As regards high-risk AI systems that are safety components of products or systems, or which are themselves products or systems falling within the scope of Regulation (EC) No 300/2008 of the European Parliament and of the Council²⁴, Regulation (EU) No 167/2013 of the European Parliament and of the Council²⁵, Regulation (EU) No 168/2013 of the European Parliament and of the Council²⁶, Directive 2014/90/EU of the European Parliament and of the Council²⁷, Directive (EU) 2016/797 of the European Parliament and of the Council²⁸, Regulation (EU) 2018/858 of the European Parliament and of the Council²⁹, Regulation (EU) 2018/1139 of the European Parliament and of the Council³⁰, and Regulation (EU) 2019/2144 of the European Parliament and of the Council³¹, it is

²⁴ 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).

²⁵ 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).

²⁶ 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).

²⁷ 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).

²⁸ 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).

²⁹ 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).

³⁰ 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).

³¹ 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).

appropriate to amend those acts to ensure that the Commission takes into account, on the basis of the technical and regulatory specificities of each sector, and without interfering with existing governance, conformity assessment and enforcement mechanisms and authorities established therein, the mandatory requirements for high-risk AI systems laid down in this Regulation when adopting any relevant delegated or implementing acts on the basis of those acts.

- (50) As regards AI systems that are safety components of products, or which are themselves products, falling within the scope of certain Union harmonisation legislation listed in an annex to this Regulation, it is appropriate to classify them as high-risk under this Regulation if the product concerned undergoes the conformity assessment procedure with a third-party conformity assessment body pursuant to that relevant Union harmonisation legislation. In particular, such products are machinery, toys, lifts, equipment and protective systems intended for use in potentially explosive atmospheres, radio equipment, pressure equipment, recreational craft equipment, cableway installations, appliances burning gaseous fuels, medical devices, *in vitro* diagnostic medical devices, automotive and aviation.
- (51) The classification of an AI system as high-risk pursuant to this Regulation should not necessarily mean that the product whose safety component is the AI system, or the AI system itself as a product, is considered to be high-risk under the criteria established in the relevant Union harmonisation legislation that applies to the product. This is, in particular, the case for Regulations (EU) 2017/745 and (EU) 2017/746, where a third-party conformity assessment is provided for medium-risk and high-risk products.

- (52) As regards stand-alone AI systems, namely high-risk AI systems other than those that are safety components of products, or that are themselves products, it is appropriate to classify them as high-risk if, in light of their intended purpose, they pose a high risk of harm to the health and safety or the fundamental rights of persons, taking into account both the severity of the possible harm and its probability of occurrence and they are used in a number of specifically pre-defined areas specified in this Regulation. The identification of those systems is based on the same methodology and criteria envisaged also for any future amendments of the list of high-risk AI systems ***that the Commission should be empowered to adopt, via delegated acts, to take into account the rapid pace of technological development, as well as the potential changes in the use of AI systems.***

(53) *It is also important to clarify that there may be specific cases in which AI systems referred to in pre-defined areas specified in this Regulation do not lead to a significant risk of harm to the legal interests protected under those areas because they do not materially influence the decision-making or do not harm those interests substantially. For the purposes of this Regulation, an AI system that does not materially influence the outcome of decision-making should be understood to be an AI system that does not have an impact on the substance, and thereby the outcome, of decision-making, whether human or automated. An AI system that does not materially influence the outcome of decision-making could include situations in which one or more of the following conditions are fulfilled. The first such condition should be that the AI system is intended to perform a narrow procedural task, such as an AI system that transforms unstructured data into structured data, an AI system that classifies incoming documents into categories or an AI system that is used to detect duplicates among a large number of applications. Those tasks are of such narrow and limited nature that they pose only limited risks which are not increased through the use of an AI system in a context that is listed as a high-risk use in an annex to this Regulation. The second condition should be that the task performed by the AI system is intended to improve the result of a previously completed human activity that may be relevant for the purposes of the high-risk uses listed in an annex to this Regulation. Considering those characteristics, the AI system provides only an additional layer to a human activity with consequently lowered risk. That condition would, for example, apply to AI systems that are intended to improve the language used in previously drafted documents, for example in relation to professional tone, academic style of language or by aligning text to a certain brand messaging.*

The third condition should be that the AI system is intended to detect decision-making patterns or deviations from prior decision-making patterns. The risk would be lowered because the use of the AI system follows a previously completed human assessment which it is not meant to replace or influence, without proper human review. Such AI systems include for instance those that, given a certain grading pattern of a teacher, can be used to check ex post whether the teacher may have deviated from the grading pattern so as to flag potential inconsistencies or anomalies. The fourth condition should be that the AI system is intended to perform a task that is only preparatory to an assessment relevant for the purposes of the AI systems listed in an annex to this Regulation, thus making the possible impact of the output of the system very low in terms of representing a risk for the assessment to follow. That condition covers, inter alia, smart solutions for file handling, which include various functions from indexing, searching, text and speech processing or linking data to other data sources, or AI systems used for translation of initial documents. In any case, AI systems used in high-risk use-cases listed in an annex to this Regulation should be considered to pose significant risks of harm to the health, safety or fundamental rights if the AI system implies profiling within the meaning of Article 4, point (4) of Regulation (EU) 2016/679 or Article 3, point (4) of Directive (EU) 2016/680 or Article 3, point (5) of Regulation (EU) 2018/1725. To ensure traceability and transparency, a provider who considers that an AI system is not high-risk on the basis of the conditions referred to above should draw up documentation of the assessment before that system is placed on the market or put into service and should provide that documentation to national competent authorities upon request. Such a provider should be obliged to register the AI system in the EU database established under this Regulation. With a view to providing further guidance for the practical implementation of the conditions under which the AI systems listed in an annex to this Regulation are, on an exceptional basis, non-high-risk, the Commission should, after consulting the Board, provide guidelines specifying that practical implementation, completed by a comprehensive list of practical examples of use cases of AI systems that are high-risk and use cases that are not.