

# DRAFT LAW FOR THE PROPER USE AND GOVERNANCE OF ARTIFICIAL INTELLIGENCE

## EXPLANATORY STATEMENT

I

Artificial intelligence (hereinafter, AI) is a key element in the current technological revolution, with enormous potential for growth and transformation, both in economic relations and in social behavioural habits. The capacity and capillarity of this technology make it a transversal instrument, with an impact on a wide spectrum of sectors, multiplying the penetration and positive impact on the productivity of the economy at a global level.

AI systems can operate with a high degree of autonomy and self-learning. Once trained, these systems can infer recommendations, decisions, predictions or content on their own, without it being necessary to know and program beforehand what data and what assessments originated those results offered by the system.

This autonomy can, on the other hand, pose a challenge in terms of transparency and traceability. In the execution of many AI systems, it is difficult to establish a correlation between input and output data, which the system determines autonomously. This lack of traceability carries risks when the use of these systems has an impact on people, society or the economy. Therefore, it is necessary to define a regulatory framework for the use of this technology that promotes the adoption of reliable and human-centered AI.

Many States and supranational entities, in particular the European Union, have addressed the development of these conceptual normative frameworks. The "Declaration of Principles on AI" that the OECD published in 2019, and updated in 2024, addressing recent technological developments, in particular, generative AI, highlights the principle that technology must respect human rights and democratic values, also including in its principle of responsibility in the development of AI aspects related to security, protection and privacy, as well as labor and intellectual property rights. Also in 2019, the European Commission created the High-Level Expert Group on Artificial Intelligence, which published its cornerstone document, "Ethical Guidelines for Trustworthy AI" in the same year, shaping the increasingly universal concept of trustworthy AI. On this basis, the Expert Group published in 2020 the "White Paper on Artificial Intelligence", a strategic document that sets out a European approach to promote the development of AI, based on two pillars, technical excellence and trust in AI, to be underpinned by binding legal instruments. This trajectory makes the European Union a pioneer of a regulation that was already considered essential to address the new technological reality.

Since then, there have been many efforts by States, supra-state or international entities, or business associations, to reach consensus on the ethical issues surrounding the use of AI, while protecting the promotion of innovation. Thus, the "Recommendation on the Ethics of Artificial Intelligence" published by UNESCO in 2021, and adopted by 193 States, focuses on how AI can affect vulnerable groups, environmental sustainability and digital literacy. On the other hand, the "Betchley Declaration" of the 2023 AI Security Summit focuses on the need for collaboration among



participating states to detect common AI security risks, as well as the joint development of policies to mitigate them. In 2023, generative AI is also making a strong comeback, and the "Hiroshima AI Process", based on OECD principles, focuses its efforts on it, introducing a code of conduct with monitoring mechanisms and promoting international collaboration. In May 2024, the Council of Europe's Committee on Artificial Intelligence adopted the "Framework Convention on Artificial Intelligence, Human Rights, Democracy and the Rule of Law", which is the first legally binding international treaty aimed at ensuring respect for human rights, the rule of law and democratic legal standards in the use of AI systems.

The United Nations also continues its momentum: Following its 2021 UNESCO recommendation, it creates the "United Nations High-Level Advisory Body on Artificial Intelligence" in 2023; in March 2024, a US-led resolution calling on states to refrain from using artificial intelligence systems that do not comply with international human rights standards or put them at risk is passed by acclamation, and in September of the same year, the Advisory Body on AI publishes its report "AI Governance for the Benefit of Humanity", proposing the creation of an international group of scientists, international forums on AI governance standards and policies, a network of AI capacity building hubs, a global data framework, and a funding fund to bridge the gap. Along these lines, during the Future Summit, held on September 22, 2022 in New York, the Global Digital Compact was adopted, which advocates safe and reliable artificial intelligence and promotes the international governance of international intelligence for the benefit of humanity.

The activity of many States to reach international consensus on the protection of people and their fundamental rights and to agree on ethical values in the use of AI that should not be questioned is evident. The European Union, for its part, has been a pioneer in regulating the use of AI with the approval of Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 establishing harmonised standards in the field of artificial intelligence (hereinafter, Regulation (EU) 2024/1689 of 13 June).

## II

Regulation (EU) 2024/1689 of 13 June follows a risk-based approach to the use of technology and establishes prohibited uses of AI as a result of these uses. For permitted uses, and according to their level of risk on the effects it has on people, measures are established to ensure that AI is used ethically and reliably. Regulation (EU) 2024/1689, of 13 June, has a universal scope, and any AI system placed on the market or used in the European Union is subject to compliance, even for those systems that have not been developed within it. As a Union Regulation, it is directly applicable in all Member States, although it delegates to them the development of some of its aspects, which are addressed in this Law.

Thus, Chapter XII of the Regulation sets out a framework for penalties and mandates Member States to develop the system of penalties and other enforcement measures, such as warnings or non-pecuniary measures, applicable to possible infringements. This sanctioning regime is essential



to ensure compliance with the obligations established by the Regulation to suppliers, those responsible for deployment, importers and distributors, authorised representatives, potential suppliers in test spaces and people affected by AI systems established or located in the European Union.

In compliance with this obligation, and within this framework, this Law establishes a sanctioning regime and a scheme of sanctions that are proposed as effective, proportionate and dissuasive. Specific conditions of SMEs and start-ups are taken into account, thereby seeking to ensure a balance between compliance with the obligations laid down by the Regulation and the protection of scientific and technical innovation.

The Regulation also introduces governance mechanisms at Union level, which are supported by newly established Community bodies, in order to harmonise the application of legislation. Thus, the AI Office is the Commission's body responsible for the development of the Union's knowledge and capabilities in the field of AI; the European AI Committee, made up of representatives of the States, assists and advises the Commission and the States in the consistent application of the Regulation; and the Consultative Forum, made up of representatives of stakeholders, including industry, academia and society, together with the Group of Independent Experts, contribute their technical expertise.

For governance at national level, the Regulation defines the national competent authorities, which include notifying authorities and market surveillance authorities, and mandates Member States to establish or designate at least one of each type, and to regulate their tasks in accordance with the Regulation.

In compliance with this obligation, this Law defines what these authorities will be, and what their national governance mechanisms will be. In this scheme, the creation in Spain of the Spanish Agency for the Supervision of Artificial Intelligence, whose statute is approved by Royal Decree 729/2023, of 22 August, is particularly relevant.

In addition, the attribution of competences in the field of supervision of AI systems by the administrative authorities in the regulated sectors requires the regulatory provision of coordination mechanisms that make it possible to avoid a differentiated or even contradictory application of the applicable sanctions by the different Spanish Market Surveillance Authorities. Therefore, in order to guarantee uniform, coordinated and effective action in the performance of the functions attributed to them by this Law, the Joint Commission for the Coordination of Market Surveillance Authorities is created, attributing to the Spanish Agency for the Supervision of Artificial Intelligence its presidency, secretariat and management.

The Ministry for Digital Transformation and Public Administration, and specifically the Secretary of State for Digitalisation and Artificial Intelligence, through its Directorate-General for Artificial Intelligence, is the department of the General State Administration in charge, among other powers,

of regulatory development in the field of AI, in accordance with article 4.1.c) of Royal Decree 210/2024, of 27 February, which establishes the basic organic structure of the Ministry for Digital Transformation and Public Function.

### III

The regulatory framework for AI in which this Law is integrated is part of a set of broader actions aimed at the development of AI in Spain. Through these actions, progress has been made in combining the action of the different strategic sectors, to promote the promotion and promotion of innovation, both in the Public Administration and in the private sector.

Consequently, various strategic plans have been launched following the European path to promote ethical, inclusive and beneficial development of AI for society that, in addition to strengthening economic and social growth, is carried out in line with the Charter of Digital Rights.

In 2020, the Digital Spain 2025 strategic plan was presented, later updated to Digital Spain 2026, with the aim of carrying out the country's digital transformation process. This plan included the National Artificial Intelligence Strategy (ENIA), published that same year, expanding the scope of its measures with Component 16 of the Recovery, Transformation and Resilience Plan. The ENIA already defined within its strategic objective 6 "Establish an ethical and regulatory framework that reinforces the protection of individual and collective rights, in order to guarantee inclusion and social well-being", focusing on the need to develop normative work that allows the regulation of the use of AI based on ethical principles.

The National Artificial Intelligence Strategy (ENIA) has been updated through the Artificial Intelligence Strategy 2024, approved by the Council of Ministers in May 2024, which is articulated around three fundamental axes: i) strengthening the key levers for the development of Artificial Intelligence, ii) facilitating the expansion of Artificial Intelligence in the public and private sectors by promoting innovation and cybersecurity and iii) developing Artificial Intelligence transparent, responsible and humanistic.

The third axis of this Artificial Intelligence Strategy 2024 is the basis on which to structure the supervision of the uses of AI, highlighting at the national level the Spanish Agency for the Supervision of Artificial Intelligence (AESIA), whose statutes were published through Royal Decree 729/2023, of 22 August, approving the Statute of the Spanish Agency for the Supervision of Artificial Intelligence, and the regulation of a secure AI testing framework through Royal Decree 817/2023, of 8 November, which establishes a controlled environment for the testing of compliance with the proposal for a Regulation of the European Parliament and of the Council establishing harmonised standards in the field of artificial intelligence.

The development of a sanctioning regime that contributes to the application of the regulatory framework promulgated by Regulation (EU) 2024/1689, of 13 June, is an essential tool for the proper



functioning of market surveillance authorities and other supervisory bodies in the field of AI, providing these bodies with a legal basis on which to carry out their supervisory and inspection activities.

#### IV

The penalties provided for in this Law are not limited to the imposition of a monetary fine. Regulation (EU) 2024/1689 of 13 June already warns that AI can generate unacceptable risks and undermine public interests and fundamental rights protected by Union law. Such impairment may lead to serious harm, with the Regulation itself defining what it considers to be a "serious incident" and understanding that it is necessary to prohibit AI practices and systems that pose unacceptable risks to relevant public interests of the Union (recitals 5, 26, 46 and 179).

This Law establishes the need to adapt the sanction to the act constituting the infringement, providing for the necessary mechanisms to guarantee the effectiveness of the resolution issued, especially in the most serious cases due to their importance with respect to the life and security of persons and their fundamental rights.

This Law introduces, in a novel way in the European Union, a new digital right that guarantees the basic fundamental rights of citizens, which is the right to disconnect or withdraw from the market AI systems that have caused serious incidents. By regulating the initiation of the sanctioning procedure by means of a complaint, the application of the right set out in Article 85 of the Regulations is anticipated as of 2026. This will therefore determine a right to disconnect or withdraw AI systems in those cases in which it is reported that a system has caused a serious incident, such as the death of a family member. Article 14 of Regulation (EU) 2019/1020, of 20 June, allows Market Surveillance Authorities in such cases to prohibit or restrict the marketing of an AI system, or its withdrawal if it is integrated into a product. The Kingdom of Spain therefore continues to lead the incorporation of digital rights for the benefit of citizens, as happened with the recognition of the "right to be forgotten", at the request of the State Attorney General's Office and the Spanish Data Protection Agency, by the Court of Justice of the European Union.

In relation to the sanctioning procedure, specialities are introduced to the general procedure. The first is the one already mentioned, relating to the initiation of the file through the right to claim, which will be established by Regulation (EU) 2024/1689, of 13 June, in its article 85 in favour of any natural or legal person as of 2 August 2026. In this sense, in order to promote compliance with European Union law, it is made easier for any citizen, through anonymous information, to initiate the sanctioning proceedings, articulating the mechanisms for receiving such information centrally through the Spanish Agency for the Supervision of Artificial Intelligence.

It also highlights the possibility of adopting the precautionary measures that are necessary to guarantee the effectiveness of the sanctioning decision as long as it is not enforceable, including

the possible precautionary withdrawal of the product or the disconnection or prohibition of the AI system within the territorial scope of the sanctioning market surveillance authority when the continuity of the AI system in the market during the processing of the file implies an unacceptable risk. This measure is based on Article 73.8 of Regulation (EU) 2024/1689, of 13 June, which allows the adoption of appropriate measures for the recall of products for which a serious incident has been reported. For this reason, a generic regulation of the measures that can be adopted is accepted, to adapt in the future to any AI systems that may be introduced into the market, put into service or used in national territory.

Finally, as a specialty, a specific mechanism is established for SMEs in cases of commission of a minor infringement, allowing the acting entity to be warned, and establishing the relevant measures to cease the conduct or correct the effects of the infringement that has been committed, excluding the imposition of administrative fines, in accordance with Article 99.8 of Regulation (EU) 2024/1689, of 13 June.

## V

The Law consists of thirty-seven articles, grouped into four chapters, two additional provisions, four final provisions, and an annex.

The first chapter contains the general provisions, including the object, definitions and subjective scope. The purpose of this Law is, in compliance with the European Regulation on Artificial Intelligence, to regulate the sanctioning regime applicable in Spain to AI systems, as well as the legal regime for authorising the use of biometric identification systems "in real time" in spaces of public access, in order to guarantee compliance with the Law. This law applies to legal persons and public sector entities that act as operators, as defined by the Regulations themselves.

The second chapter regulates the governance established in Regulation (EU) 2024/1689, of 13 June, to adapt the different mentions that this Regulation establishes in terms of the functions attributed to the Member States in the field of AI. This regulation complements the powers in sanctioning matters set out in Articles 4 to 6 with respect to the designation, establishing the competent bodies to make the designation of market surveillance authorities and their communication to the European Commission. Similarly, the assumption of powers by the Spanish Agency for the Supervision of Artificial Intelligence in the temporary absence of the exercise of such powers by a market surveillance authority in a harmonised sector listed in Section A of Annex I of the Regulation is regulated. Likewise, the possible establishment of tests in controlled environments and in real conditions is regulated, in order to guarantee the necessary coherence and cooperation in the performance of the practices in the national territory. Finally, it is possible for the Spanish Agency for the Supervision of Artificial Intelligence to assist the other market surveillance authorities through collaboration agreements.



The third chapter establishes the cases of use of AI for remote biometric identification "in real time" in spaces of public access, in order to guarantee compliance with the Law that may be authorised, granting the contentious-administrative courts the power to grant authorisations, and introducing an administrative procedure for the application, Concession and report of use. Likewise, Regulation (EU) 2024/1689, of 13 June, considers a framework limited to the use of this technology, always with prior authorisation by a competent authority, authorisation that will be restricted to the identification of specific people, for specific reasons that fit the aforementioned objectives, and with geographical and temporal limitations. This chapter also includes the regulation of these exceptions in national territory.

The fourth chapter includes the classification of infringements, and establishes the sanctioning regime for Regulation (EU) 2024/1689, of 13 June, by virtue of the obligation imposed on Member States in Article 99. Firstly, upper and lower limits are established for the penalties for minor, serious and very serious infringements, which allow for proportionate, dissuasive and effective application, and which are within the limits imposed by the Regulation. It also sets out the circumstances in which the restriction or withdrawal from the system may be imposed. Since the maximum penalties may be limited by the annual turnover of the infringing entity, it is considered that, when the company directly responsible for the infringement is part of a group of companies, it will be the turnover of the group that sets the upper limit, thus preventing large companies, acting through small companies in their group, from may receive sanctions that, due to their low amount, do not meet the criteria of proportionality, deterrent effect and effectiveness.

Secondly, all the infringements are classified. Given the variety of types of subjective scope, the difference between the obligations imposed on each one, and the number of these, the infringements are divided between several articles, according to their classification and the nature of the subject to whom they apply, with the aim of greater clarity of the text.

Infringements relating to prohibited practices, including those relating to remote "real-time" biometric identification that may be authorised from time to time as regulated in Chapter III of this Law, are considered to be very serious, in view of the maximum limit of the sanction imposed on them by the Regulation. Failure to notify serious incidents to the supervisory authorities, and failure to comply with the corrective measures imposed by the latter, are also considered very serious by operators, because they ignore the controls that the surveillance system can impose to stop the spread of damage.

Most infringements of the obligations imposed on operators are considered serious, in view of the maximum penalty limit imposed on them by Regulation (EU) 2024/1689, of 13 June. Some of these obligations, which can be considered administrative faults with limited consequences and easily remedied, are considered minor.

The graduation of the penalties is then addressed, introducing criteria that must be assessed when they are applicable, and which are mostly established in Regulation (EU) 2024/1689, of 13 June, being almost identical to those established in Regulation (EU) 2016/679 of the European Parliament and of the Council, of 27 April 2016, relating to data protection. Given the general nature of the criteria, the possibility of their regulatory development is established, in accordance with the principle of typicity established in Article 27 of Law 40/2015, of 1 October, on the Legal Regime of the Public Sector.

The sanctioning power for an infringement is granted to the competent market surveillance authority, which will be the one designated to supervise the market sector in which the AI system with which the alleged infringement is committed operates, and an administrative procedure is established for the processing and possible imposition of sanctions.

A regime of preliminary actions is established necessary for the competent authority to gather information on the facts, and provisional measures to ensure the effectiveness of the resolution and avoid the continuation of the risks or damage that may be caused to fundamental rights, safety or health. The limitation periods are also defined.

In the event that the infringing party is an SME, and the infringement is not very serious, an injunction regime is established by which the resolution may end the sanctioning procedure with the adoption by the responsible party, within the time and form, of the relevant corrective measures and full compensation for the damages caused. if applicable.

Likewise, in the event that the infringing party is a public sector entity, it is established that the resolution may warn the offender and impose corrective measures, excluding the imposition of fines, as provided for in Article 99.8 of Regulation (EU) 2024/1689, of 13 June. The market surveillance authority may also initiate disciplinary actions, following the disciplinary or sanctioning regime applicable to the case.

The penalty applied may be reduced, by acknowledgment of responsibility and by voluntary payment. In any case, and without prejudice to the sanction that may be imposed, the restoration of the situation prior to the infringement will be mandatory, as well as compensation for damages. The application of coercive fines, until this restoration takes place, and the subsidiary enforcement of the same, is foreseen.

The first additional provision establishes when the first annual reports that the Regulation establishes as mandatory for Member States will be prepared.

The second additional provision provides for the creation and regulation of a national database in Spain where AI systems dedicated to the management of critical infrastructures can be registered,





which, due to their importance for safety, have been established as exceptions in the Regulation for their European registration, which will be published.

The first final provision includes the amendment of Law 29/1998, of 13 July, regulating the Contentious-Administrative Jurisdiction, to attribute to the contentious-administrative courts the competence to grant authorisations for prohibited practices regulated by Chapter II.

The second final provision includes the title of competence protected by law.

The third final provision enables the regulatory development of the Law and its annexes.

The fourth final provision includes the entry into force of the Law.

As for the annexes to the regulation, the annex contains the objectives, of those contemplated in Regulation (EU) 2024/1689, of 13 June, for which this Law considers it acceptable to make exceptions to the general prohibition. All the objectives and offences contemplated in this Regulation are set out from the outset, with the aim of eliminating those that are considered unacceptable in Spain.

This Law meets the principles of good regulation established in Article 129 of Law 39/2015, of 1 October, on the Common Administrative Procedure of Public Administrations.

By virtue of this, at the proposal of the Minister for Digital Transformation and the Civil Service, following a report from the Minister of Finance, in agreement with the Council of State and after deliberation by the Council of Ministers, at its meeting on XX XXXXX day 2025.

## **I ORDER**

### **CHAPTER I: GENERAL PROVISIONS**

#### **Article 1. *Object***

This Law establishes the legal sanctioning regime applicable to AI systems introduced, put into service, marketed or tested in real conditions, in Spanish territory, for non-compliance with Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 establishing 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. It also regulates the legal regime for authorising the use of "real-time" remote biometric identification systems in publicly accessible

spaces for the purpose of ensuring compliance with the Law, in compliance with Article 5 of the same Regulation.

## **Article 2. Definitions**

1. For the purposes of this Law, the definitions in Article 3 of Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 shall apply.
2. SME: For the purposes of this Law, an SME is considered to be an entity that meets the definition of small and medium-sized enterprises established in Annex I of Commission Regulation (EU) 651/2014 of 17 June 2014 declaring certain categories of aid compatible with the internal market in application of Articles 107 and 108 of the Treaty.
3. Public Sector: For the purposes of this Law, the entities considered in Articles 2.1 and 2.2 of Law 40/2015, of 1 October, on the Legal Regime of the Public Sector, are considered to be the public sector.
4. Regulation (EU) 2024/1689 of 13 June: Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised standards 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.
5. Product Safety Regulation: Regulation (EU) 2023/988 of the European Parliament and of the Council of 10 May 2023 on general product safety, amending Regulation (EU) No 1025/2012 of the European Parliament and of the Council and Directive (EU) 2020/1828 of the European Parliament and of the Council, and repealing Directive 2001/95/EC of the European Parliament and of the Council and Council Directive 87/357/EEC.
6. Market Surveillance and Product Conformity Regulation: Regulation (EU) 2019/1020 of the European Parliament and of the Council of 20 June 2019 on market surveillance and conformity of products and amending Directive 2004/42/EC and Regulations (EC) No 765/2008 and (EU) No 305/2011.
7. General Data Protection Regulation: 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.
8. Directive on the processing of personal data in criminal matters: 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 to the free movement of such data and repealing Council Framework Decision 2008/977/JHA.
9. Public access space: For the purposes of this Law, public access spaces are considered to be those defined through recital 19 of Regulation (EU) 2024/1689, of 13 June.

## **Article 3. Subjective scope.**

1. This Law applies, under the terms established in Article 2 of Regulation (EU) 2024/1689 of 13 June, to **both legal persons and public sector entities**, when they act as operators, specifically:
  - a) Providers of AI systems and general-purpose AI models.
  - b) Potential suppliers of AI systems and general-purpose AI models that perform real-world testing prior to market introduction or commissioning.
  - c) The ones responsible for the deployment of AI systems.
  - d) Manufacturers of products that place an AI system on the market or put into service together with their product and with their own name or brand.
  - e) Authorised representatives of suppliers who are not established in the Union.
  - f) Importers and distributors of AI systems.
2. This Law also applies to notified bodies.
3. The infringements and penalties provided for in this Law shall not apply to the cases excluded from Article 2(3) to (8) of Regulation (EU) 2024/1689 of 13 June.

## CHAPTER II: GOVERNANCE AND OVERSIGHT

### **Article 4. Notifying authority**

1. The notifying authority designated in this Article shall be competent to exercise the sanctioning power of the notified bodies referred to in Article 99.4, section e).
2. The Secretary of State for Digitalisation and Artificial Intelligence, through the Directorate-General for Artificial Intelligence, is designated as the notifying authority for the purposes of Article 28.1 of Regulation (EU) 2024/1689, of 13 June, as the body responsible for establishing the necessary procedures for the assessment, designation and notification of conformity assessment bodies, as well as their supervision.
3. However, the assessment and supervision of notified bodies shall be carried out by the national accreditation body in accordance with Royal Decree 1715/2010 of 17 December 2010 designating the National Accreditation Entity (ENAC) as the national accreditation body in accordance with the provisions of Regulation (EC) No 765/2008 of the European Parliament and of the Council, of 9 July 2008 laying down the requirements for accreditation and market surveillance relating to the placing on the market of products and repealing Regulation (EEC) No 339/93 pursuant to Article 28(2) of Regulation (EU) 2024/1689 of 13 June.
4. When it is found that a previously designated notified body no longer meets the requirements laid down in Article 31 of Regulation (EU) 2024/1689 of 13 June, the designated notifying authority or the national accreditation body, as the case may be, shall withdraw the designation, after carrying out the corresponding administrative procedure, with a hearing of the interested party, and shall inform the European Commission and the other Member States thereof in accordance with the provisions of Article 36 of said Regulations.

## **Article 5. *European Committee on Artificial Intelligence***

The Secretary of State for Digitalisation and Artificial Intelligence is responsible for appointing the representative on the AI Council established in Article 65.3 of Regulation (EU) 2024/1689, of 13 June.

## **Article 6. *Market surveillance authorities***

1. The competent market surveillance authority designated in accordance with this Article shall be competent to exercise the power to impose penalties in respect of the persons referred to in Article 3(1).
2. The Spanish Agency for the Supervision of Artificial Intelligence is designated as the Single Point of Contact in accordance with the provisions of Article 70.2 of Regulation (EU) 2024/1689, of 13 June, and as the market surveillance authority for the following AI systems:
  - a) Those who carry out prohibited AI practices included in paragraphs a), b), c), e) and f) of article 5.1 of Regulation (EU) 2024/1689, of 13 June, provided that the systems are not used for the purposes of ensuring compliance with the law, border management, and justice or democratic processes.
  - b) High-risk AI systems as described in Annex III to Regulation (EU) 2024/1689 of 13 June(1) in the field of biometrics, provided that the systems are not used for the purposes of law enforcement, border management, justice or democratic processes, and excluding, in line with Annex III.1(a) of that Regulation, systems for remote biometric identification whose sole purpose is to confirm that a specific natural person is the person they claim to be.
  - c) The high-risk AI systems described in Annex III of Regulation (EU) 2024/1689 of 13 June, paragraph 2, on the field of critical infrastructures.
  - d) The high-risk AI systems described in Annex III to Regulation (EU) 2024/1689 of 13 June, paragraph 3, on the field of vocational education and training.
  - e) The high-risk AI systems described in Annex III of Regulation (EU) 2024/1689, of 13 June, paragraph 4, on the field of employment and management of workers.
  - f) High-risk AI systems described in Annex III to Regulation (EU) 2024/1689 of 13 June, paragraph 5, on the scope of essential services and benefits, with the exception of those described in points (b) and (c), relating to systems for the assessment of solvency or credit rating and those for risk assessment and pricing in relation to natural persons in the case of insurance of life and health, respectively.
  - g) AI systems that are not categorized as prohibited or high-risk, when they may breach the duty of transparency or other obligation established in the applicable regulations on AI.
3. The Spanish Data Protection Agency and the regional data protection authorities, within the scope of their respective competences, are designated as market surveillance authorities for the following AI systems:
  - a) Those who carry out prohibited AI practices included in paragraphs d), g) and h) of the article 5.1 of Regulation (EU) 2024/1689, of 13 June.

- b) High-risk AI systems described in Annex III.1 to Regulation (EU) 2024/1689 of 13 June on the field of biometrics, when the systems are used for the purposes of law enforcement or border management, excluding, in line with Annex III.1 a) of that Regulation, systems for remote biometric identification whose sole purpose is to confirm that a specific natural person is the person they claim to be.
  - c) The high-risk AI systems described in Annex III.6 of Regulation (EU) 2024/1689, of 13 June, on the scope of enforcement of the law, and the prohibited AI practices that fall within this area.
  - d) The high-risk AI systems described in Annex III.7 of Regulation (EU) 2024/1689 of 13 June on the area of migration, asylum and border control management, and the prohibited AI practices that fall under this scope.
4. The Bank of Spain and the National Securities and Exchange Commission (CNMV) are designated as market surveillance authorities, in the area of competence that each holds in relation to the financial supervision of financial institutions in accordance with the legislation on the supervision of financial services, of the high-risk AI systems described in Annex III.5 b) of Regulation (EU) 2024/1689, of 13 June, relating to systems in the field of solvency assessment or credit rating.
5. The Directorate-General for Insurance and Pension Funds, in its area of competence under the legislation on the supervision of life and health insurance, is designated as the market surveillance authority for the high-risk AI systems described in Annex III.5 (c) to Regulation (EU) 2024/1689, of 13 June on AI systems intended to be used for risk assessment and pricing in relation to natural persons in the case of life and health insurance.
6. The Directorate for Data Protection Supervision and Control of the General Council of the Judiciary is designated as the market surveillance authority for high-risk AI systems described in Annex III.8.a) of Regulation (EU) 2024/1689, of 13 June, on the areas of the administration of justice, and prohibited AI practices that fall within this field. Likewise, the Central Electoral Board is designated as the market surveillance authority for the high-risk AI systems described in Annex III.8.b) of said Regulation, relating to democratic processes, as well as the prohibited AI practices that fall within this area.
7. The market surveillance authorities designated under the legislative acts listed in Section A of Annex I to Regulation (EU) 2024/1689 of 13 June shall act as market surveillance authorities for the high-risk AI systems associated with the products covered by those harmonisation legislation. When one of these market surveillance authorities notifies the Spanish Agency for the Supervision of Artificial Intelligence of the lack of suitable technical, financial and human resources for the supervision, inspection and sanctioning of AI systems, the Agency shall assume such functions, ensuring coordination with the relevant sectoral market surveillance authority. until said authority communicates that it has the appropriate means to exercise the functions of surveillance, inspection and sanction.
8. For the rest of the cases not contemplated in this Law, or in the case of new areas of artificial intelligence supervision established by the Commission through delegated acts in accordance with Article 7.1 thereof, the Secretary of State for Digitalisation and Artificial Intelligence, by Resolution of the person in charge, shall be responsible for the designation of other market surveillance

authorities other than those established in this Article. including the case provided for in paragraph 2 of Article 74.3 of the Regulations. Such designation shall require a prior assessment of the suitability of the financial and human resources allocated.

9. The Secretary of State for Digitalisation and Artificial Intelligence is responsible for communicating to the Commission on the identities and functions of the market surveillance authorities established in Article 70.2 of Regulation (EU) 2024/1689, of 13 June.

10. The market surveillance authorities are responsible for all the functions of surveillance, inspection and sanctioning of artificial intelligence systems established in Chapter IX of Regulation (EU) 2024/1689, of 13 June.

11. In any case in which the decisions or actions of a supervisory authority may affect the interests or powers of others, the latter must obtain a report from those authorities before making a decision.

12. On an exceptional basis and when necessary to avoid or mitigate the consequences arising from serious incidents caused by AI systems, the Spanish Agency for the Supervision of Artificial Intelligence will promote, coordinate or adopt as many measures as necessary, with the collaboration of the authorities described above, with the European Commission and in accordance with their respective competences.

13. The Spanish Agency for the Supervision of Artificial Intelligence shall submit to the Commission the report provided for in Article 70.6 of Regulation (EU) 2024/1689, of 13 June, on the state of the financial and human resources of the competent authorities, which shall include an assessment of their suitability.

14. The market surveillance authorities shall submit to the Spanish Agency for the Supervision of Artificial Intelligence, on an annual basis or at the request of the Agency, a report on the state of their financial and human resources, including an assessment of their suitability.

15. The Spanish Agency for the Supervision of Artificial Intelligence may provide, within the scope of Regulation (EU) 2024/1689, of 13 June, technical assistance to the competent market surveillance authorities, including the processing of files and the possible exercise of public or administrative powers, under the terms established in the appropriate collaboration agreements.

## **Article 7. *Inspection actions***

1. The market surveillance authorities shall carry out the inspection actions necessary for the exercise of their supervisory and control function. The civil servants assigned to the competent administrative units that carry out the inspection shall be considered as public authorities in the instruction of the sanctioning procedures provided for in this Law.

2. Market surveillance authorities may be assisted by the Spanish Agency for the Supervision of Artificial Intelligence, as well as, in accordance with the delegated acts of the Commission, by the experts described in Article 69 of Regulation (EU) 2024/1689, of 13 June, in the supervision and control tasks assigned to them by said Regulation (EU) 2024/1689, of 13 June and this Law

3. Tests may be required to be carried out in laboratories or specialised entities to prove compliance with certain requirements. In this case, the sanctioned suppliers must assume all the expenses caused by this evaluation.
4. In all these cases, the confidentiality duties required in Article 78 of Regulation (EU) 2024/1689, of 13 June, must be guaranteed.

#### **Article 8. Coordination of market surveillance authorities**

1. In order to guarantee uniform, coordinated and effective action in the development of the actions attributed to them by this Law, the market surveillance authorities shall supply and exchange any operational information that ensures adequate coordination in the exercise of their functions. In the inspection, surveillance and control actions of the provisions of Regulation (EU) 2024/1689, of 13 June, the market surveillance authorities shall take particular account of the findings and exchanges produced in the context of the European Committee on Artificial Intelligence and, in any case, the guidelines on the application of the aforementioned Regulation which, as described in Article 96, the Commission should draw up.
2. In accordance with the provisions of the previous section, the market surveillance authorities:
  - a) They will report on serious incidents, in accordance with Articles 73 and 76 of Regulation (EU) 2024/1689, of 13 June.
  - b) Upon the identification of a risk presented by an AI system, when the market surveillance authority considers that the infringement exceeds the national territory, they shall report on the evaluation of the system, the corrective measures issued to the operator and, where appropriate, the provisional measures adopted, in accordance with Article 79 of Regulation (EU) 2024/1689, of 13 June.
  - c) Where the market surveillance authority considers that an AI system that the operator classified as not high-risk, and that the use of the system is not limited to the national territory, is high-risk, it shall report on the evaluation of the system, the corrective measures issued to the operator and, where appropriate, the provisional measures adopted; in accordance with Article 80 of Regulation (EU) 2024/1689, of 13 June.
  - d) Where the market surveillance authority concludes that a high-risk AI system that complies with Regulation (EU) 2024/1689 of 13 June presents risks to the health or safety of persons, fundamental rights or other aspects of protection of the public interest, it shall report in detail on the conclusions reached, in accordance with Article 82 of Regulation (EU) 2024/1689, of 13 June. This information will be sent within a period of no more than 72 hours through the Safety Gate system contemplated in the Product Safety Regulations, or any other that replaces it.
3. Market surveillance authorities shall make use of the information and communication system provided for in Article 34 of the Market Surveillance and Product Conformity Regulation in order to exchange data on matters relating to the application of Regulation (EU) 2024/1689 of 13 June and other product safety legislation that may be applicable in the exercise of their duties.
4. The Spanish Agency for the Supervision of Artificial Intelligence may implement the most appropriate measures to achieve the effective coordination of actions aimed at risk prevention and

the application of the supervisory regime for artificial intelligence systems established in Regulation (EU) 2024/1689, of 13 June.

5. In order to guarantee such coordination, the Joint Commission for the Coordination of Market Surveillance Authorities is created for the purpose of ensuring the application of the powers defined in this Law. The Spanish Agency for the Supervision of Artificial Intelligence will hold its presidency, secretariat and management of the body.

6. Without prejudice to the coordination and collaboration measures established by regulation, the market surveillance authorities designated under this Law shall exchange annual information on the activities they carry out to ensure the preparation of the annual report established as an obligation in Articles 5 and 6 of Regulation (EU) 2024/1689, of 13 June.

### **Article 9. Governance of Controlled Testing Spaces for AI**

1. The Spanish Agency for the Supervision of Artificial Intelligence will be the competent national authority responsible for establishing the controlled testing space for AI that must be created by virtue of Article 57.1 of Regulation (EU) 2024/1689, of 13 June. This controlled testing space shall be subject to the provisions of Chapter VI of that Regulation, in addition to the implementing acts adopted by the Union, as provided for in Article 58(1) of that Regulation.

2. The creation of a controlled testing space within the scope of Chapter VI of Regulation (EU) 2024/1689, of 13 June, in addition to that required by Article 57.1 thereof, must be proposed by a competent national authority with national competences, in order to provide, in a homogeneous manner, the guidance, supervision and support within the controlled testing space for AI determined in paragraphs 6 and 7 of Article 57 of said Regulation (EU) 2024/1689 Regulation.

The proposing national competent authority must obtain a mandatory report from the Spanish Agency for the Supervision of Artificial Intelligence prior to the establishment of the additional controlled testing space. This report shall assess the allocation of sufficient resources and ensure the level of cooperation required by Article 57.4 of Regulation (EU) 2024/1689 of 13 June.

3. The creation of controlled test environments within the scope of Chapter VI of Regulation (EU) 2024/1689, of 13 June, additional at regional or local level, or at sectoral level, referred to in Article 57.2 of Regulation (EU) 2024/1689, of 13 June, will be possible provided that it is subject to the provisions of this article, in order to guarantee the coordination and reporting obligations to the European authorities on the development of controlled test environments set out in Articles 57.4 and 57.15 of said Regulation.

## **CHAPTER III: PROHIBITIONS AND EXCEPTIONS**

### **Article 10. Prohibited practices**



1. The placing on the market, commissioning or use of an AI system whose practice is defined as prohibited as set out in Article 5.1, paragraphs a), b), c), d), e), f) and g) of Regulation (EU) 2024/1689, of 13 June, is prohibited.
2. The placing on the market, commissioning or use of a 'real-time' remote biometric identification AI system in publicly accessible spaces for the purpose of ensuring compliance with the Law is prohibited, unless its use is strictly necessary for the fulfilment of the purposes described in Annex II to Regulation (EU) 2024/1689, of 13 June, and in that case in the terms described in Article 5 of this Law and in Article 5 of said Regulations.

**Article 11. Authorisations for the use of remote biometric identification "in real time" in publicly accessible spaces for the purpose of ensuring compliance with the Law**

1. Each use of a 'real-time' biometric identification AI system in publicly accessible spaces for the purpose of ensuring compliance with the law, by an interested legal authority, shall be limited to one of the purposes described in Annex II to Regulation (EU) 2024/1689 of 13 June, it shall be aimed at identifying specific persons, and shall be subject to judicial authorisation, in compliance with Article 5 of said Regulation.  
Data on persons other than those specified in the authorisation may not be processed. The person responsible for the deployment of the AI system shall ensure that data of persons other than those specified that are obtained in the authorised use are discarded and deleted without undue delay. Likewise, the data obtained during the authorised use may not be used outside the scope of the investigation of the facts in which the authorisation is justified, and their existence will not have a place outside the body of evidence corresponding to that investigation. The person responsible for the deployment of the AI system will ensure that the data obtained are discarded and deleted without undue delay once they have been sent to the interested legal authority concerned, which will be responsible for its custody as evidence in the terms established by Law.
2. The granting of the aforementioned authorisations will correspond to the Contentious-Administrative Courts.
3. The legal authority concerned shall make an application for authorisation for each use, in writing containing the following details:
  - a) URL or unambiguous reference of the AI system registry entry in the EU database, in accordance with Article 5.2 of Regulation (EU) 2024/1689 of 13 June.
  - b) If reasons of urgency have so far prevented registration in the database referred to in the previous paragraph, justification of the reasons of urgency, date of commencement of the first use of the system by the authority requesting the permit, and the data on the system described in Annex VIII, section C, paragraphs 1, 2, 4, 5, and section A, paragraphs 1, 2, 3, 4, 8 of Regulation (EU) 2024/1689 of 13 June.
  - c) If, for reasons of urgency, use has begun before requesting judicial authorisation, justification for these reasons, and the time at which use has begun.
  - d) Specification of the specific measures requested. These measures must mention the conservation, destruction or, where appropriate, blocking of the data once the authorisation

for the use of biometric identification has ended, and must establish the way to proceed with the data once the authorisation has ended.

- e) Identification of the person or persons affected by the measures.
  - f) Geographical area where the requested measures are to be carried out.
  - g) Temporal scope of the measures requested, which may not exceed one month, extendable for successive equal periods if necessary.
  - h) A case, among those listed in Annex I of this Law, in which the need for use is justified.
  - i) Facts on which the request is based, purposes that motivate it and reasons that make it necessary to authorize the measures requested.
4. The application must be resolved, by means of a reasoned decision upholding or rejecting it, within a maximum period of 48 hours, silence being understood as rejecting.
5. The resolution will detail, at least:
- a) The meaning of the resolution.
  - b) The assessment of the declared objective, the justification for its necessity, the adequacy and proportionality of the measures requested to achieve it and, where appropriate, the reasons for urgency adduced.
  - c) The personal, temporal and geographical limitations imposed, if estimated.
  - d) The obligation to discard and delete any biometric data that, during the processing of the authorisation for the use of identification, are unrelated to the purpose of the authorisation, in the event of an estimate.
  - e) The obligation to immediately discontinue use and to immediately discard and delete the data and information obtained up to that point, in the event of rejection.
6. In the event of an express or presumed resolution of the request, the authority guaranteeing compliance with the Law shall notify the Spanish Data Protection Agency of the following aspects thereof:
- a) Number of persons affected.
  - b) Geographical area where the requested measures are to be carried out.
  - c) Temporal scope of the measures requested.
  - d) Case, among those listed in Annex I of this Law, in which the request is justified.
  - e) Contentious-administrative court where the application was filed.
  - f) Date and time of the request.
  - g) Date and time of the resolution.
  - h) Date and time of start of use.
  - i) Meaning of the resolution.
6. If, for reasons of urgency, use has been initiated before judicial authorisation has been obtained, in the event of the express or implied rejection of the application, the law enforcement authority shall immediately cease use and immediately discard and delete all results obtained so far, in accordance with Article 5(3) of Regulation (EU) 2024/1689, of 13 June.

## CHAPTER IV: INFRACTIONS AND PENALTIES

### Article 12. *Infringements*

Actions or omissions not classified as an offence that contravene the provisions of Regulation (EU) 2024/1689, of 13 June or the provisions of this Law will have the character of administrative offences.

### Article 13. *Classification of offences*

1. **Infringements are classified as very serious, serious or minor** in Articles 8 to 21 of this Law, and shall give rise to the imposition of the following penalties:

a) **Very serious infringements of prohibited AI systems will be punished with a fine of from €7,500,001 to €35,000,000 or, if the offender is a company or group of companies, from 2% to 7% of the total global turnover corresponding to the previous year, if this upper limit is higher than the previous one.**

b) **Very serious infringements in high-risk AI systems will be punished with a fine of from 7,500,001 euros to 15,000,000 euros or, if the offender is a company or group of companies, from 2% to 3% of the total global turnover corresponding to the previous year, if this upper limit is higher than the previous one.**

c) **Serious infringements shall be punishable by a fine of between EUR 500 001 and EUR 7 500 000 or, if the offender is a company or group of companies, from 1% to 2 per cent of the total worldwide turnover for the previous financial year, if this upper limit is higher than the previous one.**

d) **Minor infringements will be punished with a fine of between 6,000 euros and 500,000 euros or, if the offender is a company or group of companies, from 0.5% to 1% of the total worldwide turnover corresponding to the previous year, if this upper limit is higher than the previous one.**

**In the case of SMEs, including start-ups, each of the fines referred to in this Article may be for the percentage or amount referred to in paragraphs a), b), c) and d), depending on which of them is the least, as established in Article 99.6 of Regulation (EU) 2024/1689, of 13 June.**

2. **In very serious infringements of prohibited AI practices and in infringements in which an AI system has caused a serious incident, under the terms of Article 3.49 of Regulation (EU) 2024/1689, of 13 June, the sanction will additionally impose the withdrawal of the product or the disconnection or prohibition of the AI system, within the territorial scope of the sanctioning market surveillance authority.**

3. **In the event of persistent non-compliance with the duty to remedy the formal obligations referred to in Article 83 of Regulation (EU) 2024/1689 of 13 June, the market surveillance authority shall adopt in the sanctioning decision the necessary measures to restrict or prohibit the placing on the market of the high-risk AI system or to ensure that it is recovered or withdrawn from the market without delay.**

4. For the purposes of the provisions of this article, a group of companies is considered when a company holds or may hold, directly or indirectly, the control of another or others, in accordance with the provisions of article 42 of the Royal Decree, of 22 August 1885, which publishes the Commercial Code.

Likewise, when an infringing company belongs to a group of companies, the turnover of the group of companies will be considered, for the purposes of calculating penalty limits.

5. The sanctions must be proportionate to the economic and business activity of the infringing company, and may not, in any case, lose their effective and dissuasive nature.

#### **Article 14. Very serious infringements**

1. For the purposes of this Law, the following shall be considered to be very serious infringements, relating to the prohibited AI practices set out in Article 5 of Regulation (EU) 2024/1689, of 13 June:

a) The introduction, commissioning or use of an AI system whose practice is defined as prohibited as set out in Article 5.1 paragraphs a), b), c), d), e), f) and g) of the aforementioned Regulation (EU) 2024/1689, of 13 June 2024.

b) The use of a "real-time" remote biometric identification system in publicly accessible spaces for the purpose of ensuring compliance with the Law, except in the cases set out in Article 5.1.h) of the aforementioned Regulation (EU) 2024/1689, of 13 June 2024.

c) The use of a "real-time" remote biometric identification system in publicly accessible spaces for the purpose of ensuring compliance with the Law without first having the authorisation referred to in Article 5.3 of the aforementioned Regulation (EU) 2024/1689, of 13 June 2024, except in duly justified cases of urgency.

d) The use of a "real-time" remote biometric identification system in publicly accessible spaces for the purpose of ensuring compliance with the law when, in the event of a duly justified emergency, the use will begin before requesting authorisation, and this request does not take place within 24 hours of the start of its use, in accordance with Article 5.3 of Regulation (EU) 2024/1689, of 13 June 2024.

e) The use of a "real-time" remote biometric identification system in publicly accessible spaces for the purpose of ensuring compliance with the Law, without respecting the temporal, geographical or personal limitations, provided for in the authorisation of use of the same, in accordance with Article 5.3 of Regulation (EU) 2024/1689, of 13 June 2024.

f) Failure to comply with the obligation to delete the data, results and output information generated by a remote biometric identification system "in real time" in publicly accessible spaces for the purpose of ensuring compliance with the Law, when for emergency reasons the use had begun before the resolution of the application for its authorisation, and this application was rejected, in accordance with Article 5.3 of Regulation (EU) 2024/1689, of 13 June 2024.

g) Failure to comply with the obligation to notify each use of a remote biometric identification system "in real time" in publicly accessible spaces for the purpose of ensuring compliance with the Law, in accordance with Article 5.4 of Regulation (EU) 2024/1689, of 13 June 2024.

2. For the purposes of this Law, the following shall be considered very serious infringements, relating to operators of high-risk systems:

a) The absence of notification by a provider of high-risk AI systems, or by the person responsible for the deployment in its absence, to the competent market surveillance authority, in the terms established in Article 73 of Regulation (EU) 2024/1689, of 13 June 2024.

b) Total or partial non-compliance by an operator with the definitive measures imposed by a market surveillance authority, within the period required in any of the procedures provided for in Articles 79 and 80 of Regulation (EU) 2024/1689 of 13 June 2024, without due justification.

3. The commission of a serious infringement within two years of being sanctioned for a serious infringement of the same nature, counted from the date of notification of the final sanctioning decision, except those arising from the application of Article 99.5 of Regulation (EU) 2024/1689, of 13 June 2024.

#### **Article 15. Serious infringements applicable to any operator**

1. For the purposes of this Law, the following shall be considered serious infringements by any operator:

a) Resistance, obstruction or refusal to an evaluation, verification or inspection action by a market surveillance authority in any of the procedures established in Articles 79 and 80 of Regulation (EU) 2024/1689, of 13 June.

b) Total or partial non-compliance by an operator with the provisional measures imposed by a market surveillance authority, after the expiry of the period established for the adoption of the measures, in any of the procedures provided for in Articles 79 and 80 of Regulation (EU) 2024/1689, of 13 June 2024.

c) Unjustified resistance or obstruction by an operator to the exercise by a market surveillance authority of any of the powers recognised in Article 74 of Regulation (EU) 2024/1689 of 13 June 2024.

d) Total or partial non-compliance by an operator, within the required period, with the measures imposed by a market surveillance authority in the procedure provided for in Article 82 of Regulation (EU) 2024/1689, of 13 June 2024, without due justification.

e) The lack of information, or its deficient presentation, when required by a market surveillance authority, from the expiration of the period established by the second request for such information.

2. The commission of a minor infringement within two years of having been sanctioned for a minor infringement of the same nature, counted from the date of notification of the final sanctioning decision, shall be considered a serious infringement.

#### **Article 16. Serious breaches by suppliers and potential suppliers of AI systems**

1. For the purposes of this Law, the following shall be considered serious infringements by providers of AI systems:

- a) Failure to comply with the documentation and registration obligations set out in Article 6(4) of Regulation (EU) 2024/1689 of 13 June for providers of AI systems of any category in Annex III that consider, pursuant to paragraph 3 of the same Article, that the system is not high-risk.
  - b) Failure to comply with the obligation, where AI systems are intended to interact with natural persons, to inform those persons that they are interacting with an AI system, in accordance with Article 50(1) and (5) of Regulation (EU) 2024/1689 of 13 June 2024.
  - c) Failure to comply with the obligation, where AI systems generate synthetic audio, image, video or text content, to mark output results in such a way that their artificial nature can be detected, in accordance with Article 50(2) and (5) of Regulation (EU) 2024/1689 of 13 June 2024.
2. For the purposes of this Law, the following are considered serious infringements by providers of high-risk AI systems:
- a) The placing on the market or the commissioning of high-risk AI systems that do not comply, by error or omission, with the requirements defined in Chapter III, Section 2 of Regulation (EU) 2024/1689, of 13 June 2024.
  - b) Failure to comply with the obligation laid down in Article 16(k) of Regulation (EU) 2024/1689 of 13 June to demonstrate, upon a reasoned request from the competent authority, the conformity of the high-risk AI system with the requirements defined in Section 2 of Chapter III of that Regulation.
  - c) The placing on the market or commissioning of high-risk AI systems without having established and integrated a quality management system in accordance with Article 17 of Regulation (EU) 2024/1689 of 13 June 2024.
  - d) Failure to comply with any of the obligations to draft or keep documentation referred to in Article 18 of Regulation (EU) 2024/1689, of 13 June 2024.
  - e) Failure to comply with the obligation to retain log files automatically generated by high-risk AI systems when these files are under the control of the provider, in accordance with Article 19 of Regulation (EU) 2024/1689 of 13 June 2024.
  - f) Failure to adopt the necessary corrective measures or failure to provide the required information, in accordance with Article 20 of Regulation (EU) 2024/1689, of 13 June 2024, on the adoption of corrective measures in the event of indications of non-conformity or detection of risks, and the resulting reporting obligations.
  - g) placing on the market or putting into service high-risk AI systems without appointing an authorised representative by providers established in third countries or, having appointed one, obstructing the performance of the tasks specified in the mandate, in accordance with Article 22 of Regulation (EU) 2024/1689; of 13 June 2024.
  - h) The placing on the market or the commissioning of high-risk AI systems that have not passed a conformity assessment as established in Article 43 of Regulation (EU) 2024/1689, of 13 June 2024.
  - i) Failure to comply with the obligations to register in the national database for high-risk AI systems listed in Annex III of Regulation (EU) 2024/1689, of 13 June, paragraph 2, on AI systems for critical infrastructures, including cases of non-compliance in the event of substantial modification of the AI system. An exception is made in the case where the provider has appointed the authorised

representative to comply with them, in particular if the provider has concluded that the AI system is not high risk under Article 6.3 of the aforementioned Regulation.

3. For the purposes of this Law, the following actions relating to the testing of high-risk AI systems in real conditions shall be considered serious infringements by a supplier or potential supplier:

- a) Failure to comply, during tests in real conditions, with any of the conditions that Regulation (EU) 2024/1689, of 13 June 2024, in its article 60.4, establishes as necessary for their performance.
- b) Failure to comply with any of the measures referred to in Article 76.3 of Regulation (EU) 2024/1689 of 13 June 2024, which may be imposed by a market surveillance authority in the supervision of tests in real conditions.

#### **Article 17. Serious violations by authorized representatives of AI systems**

For the purposes of this Law, the following are considered serious infringements by authorised representatives of high-risk AI systems:

- a) Failure to comply with the obligations to register in the national database established by Regulation (EU) 2024/1689 of 13 June for AI systems listed in Annex III, paragraph 2, on AI systems for critical infrastructures, including cases of non-compliance in the event of substantial modification of the AI system, where the provider has appointed the authorised representative to comply with them, in particular if the provider has concluded that the AI system is not high risk under Article 6.3 of Regulation (EU) 2024/1689 of 13 June.
- b) Failure to comply with the obligations of authorised representatives established in Article 22.3 of Regulation (EU) 2024/1689, of 13 June 2024.
- c) Failure to terminate the mandate received from the supplier and to report thereon in accordance with Article 22.4 of Regulation (EU) 2024/1689 of 13 June 2024, when the authorised representative considers or has reason to consider that the supplier is in breach of its obligations.

#### **Article 18. Serious infringements by importers of AI systems**

For the purposes of this Law, the following are considered serious infringements by importers of high-risk AI systems:

- a) Failure to comply with the obligation to verify the conformity of the system with Regulation (EU) 2024/1689, of 13 June, in accordance with Article 23.1 of the same Regulation.
- b) The placing on the market of the system with reason to doubt its authenticity or its conformity with Regulation (EU) 2024/1689, of 13 June, in accordance with Article 23.2 of the same Regulation.
- c) The failure to indicate their registered name, trademark or name and contact details, in accordance with Article 23.3 of Regulation (EU) 2024/1689, of 13 June.
- d) Failure to comply with the obligation to ensure, while they are responsible for the system, that during storage or transport the requirements established in Chapter III, section 2, of Regulation (EU) 2024/1689, of 13 June, in accordance with Article 23.4 of said Regulation, are not compromised.



- e) Failure to comply with the obligation to provide the competent authorities with the information necessary to demonstrate the conformity of the system with Regulation (EU) 2024/1689 of 13 June 1689, in accordance with Article 23.6 of that Regulation.

#### **Article 19. Serious violations by AI system distributors**

For the purposes of this Law, the following are considered serious infringements by distributors of high-risk AI systems:

- a) Failure to comply with Article 24.1 of Regulation (EU) 2024/1689, of 13 June, on the verification that the product is properly marked and accompanied by the necessary documents and information.
- b) Failure to comply with Article 24(2) and (4) of Regulation (EU) 2024/1689 of 13 June on actions to be taken by distributors when they have reason to consider that the system does not comply with the requirements set out in Chapter III, Section 2.
- c) Failure to comply with Article 24.3 of Regulation (EU) 2024/1689 of 13 June on the need to ensure storage and transport conditions of the system that do not compromise compliance with the requirements set out in Chapter III, Section 2 thereof Regulation
- d) Failure to comply with Article 24.6 of Regulation (EU) 2024/1689, of 13 June, on cooperation with the competent authorities in the measures they adopt for the system.

#### **Article 20. Serious breaches by those responsible for deploying AI systems**

1. For the purposes of this Law, the following are considered serious infringements by those responsible for the deployment of AI systems:

- a) Failure to comply with Article 50.3 of Regulation (EU) 2024/1689, of 13 June, on the obligation to inform natural persons, in the terms established in paragraph 5 of the same article, of their exposure to the use of the system when it is an emotion recognition or biometric categorisation system.
- b) Failure to comply with Article 50.4 of Regulation (EU) 2024/1689 of 13 June on the obligation to make public, in the terms established in paragraph 5 of the same article, the artificial nature of the output results of a system that generates or manipulates images or audio or video content that constitute ultra-impersonation, or that generates or manipulates text intended to inform the public about matters of public interest.

2. For the purposes of this Law, the following are considered serious infringements by those responsible for the deployment of high-risk AI systems:

- a) Failure to comply with Article 26.1 of Regulation (EU) 2024/1689, of 13 June, on the need to adopt appropriate technical and organisational measures to ensure that the use of the system is carried out in accordance with the instructions accompanying it.



- b) Failure to comply with Article 26.2 of Regulation (EU) 2024/1689, of 13 June, on the need to entrust the human supervision of the system to persons with appropriate competence, training and authority.
- c) Failure to comply with Article 26.4 of Regulation (EU) 2024/1689 of 13 June on the obligation to ensure that input data is relevant and representative in view of the purpose of the system.
- d) Failure to comply with Article 26.5 of Regulation (EU) 2024/1689 of 13 June on the obligation of post-market surveillance of AI systems based on the accompanying instructions, risk and incident information to other operators and to the market surveillance authority, and the possible need to suspend the use of the system in the event of the occurrence of risks.
- e) Failure to comply with Article 26.6 of Regulation (EU) 2024/1689 of 13 June on the obligation of the deployant to retain log files automatically generated by its high-risk AI systems, when these files are under its control.
- f) Failure to comply with Article 26.7 of Regulation (EU) 2024/1689, of 13 June, on the obligation, when a high-risk AI system is deployed in a workplace, to inform the representatives of the workers and the workers concerned that they will be exposed to the use of it.
- g) Failure to comply with Article 26.9 of Regulation (EU) 2024/1689, of 13 June, on the obligation to use information on the system provided by the provider, in accordance with Article 13 of the same Regulation, when those responsible for the system carry out an impact assessment relating to data protection in compliance with the General Data Protection Regulation or the Directive on the processing of personal data in criminal matters.
- h) Failure to comply with Article 26.10 of Regulation (EU) 2024/1689, of 13 June, on the obligations and limitations on the use of a deferred remote biometric identification AI system in the search for a person suspected of having committed a crime or convicted of it, by incurring a delay of more than 72 hours in the application for permission, or failing to comply with any other of the obligations and limitations imposed by the aforementioned article.
- i) Failure to comply with Article 26.11 of Regulation (EU) 2024/1689 of 13 June on the obligation to inform natural persons of their exposure to the use of the system in the case of a high-risk system described in Annex III of said Regulation that participates in decisions relating to these persons.
- j) Failure to comply with Article 26.12 of Regulation (EU) 2024/1689 of 13 June on the obligation to cooperate with the relevant competent authorities in the measures they adopt in relation to the system to implement the Regulation.
- k) Failure to comply with Article 27 of Regulation (EU) 2024/1689 of 13 June 1689 regulating the obligation to carry out a fundamental rights impact assessment when those responsible for the deployment are bodies governed by public law, or private entities providing public services, and those responsible for the deployment of high-risk AI systems referred to in Annex III to that Regulation, point 5(b) and (c) of that regulation.

#### **Article 21. Serious *infringements by notified bodies***

For the purposes of this Law, the following are considered to be serious infringements:

- a) Perform the functions of a provider of AI systems when carrying out conformity assessment activities with respect to those systems, or the absence of independence of the notified body from any other operator with an economic interest in the high-risk AI systems being assessed, as well as from any competitor of the provider, in accordance with the provisions of Article 31.4 of Regulation (EU) 2024/1689, of 13 June.
- b) The involvement of management staff or staff responsible for the assessments of conformity assessment tasks of a notified body in the design, development, commercialisation or use of high-risk AI systems, or the representation of the parties carrying out such activities, as well as the performance of any activity that may conflict with their independence of judgement or their integrity in relation to the activities conformity assessment for which they were notified, in accordance with the provisions of Article 31.5 of Regulation (EU) 2024/1689, of 13 June.
- c) The absence or alteration, in a negative sense, of the structure and procedures by notified bodies that guarantee the independence, objectivity and impartiality of their activities, in accordance with Article 31.6 of Regulation (EU) 2024/1689, of 13 June.
- d) The absence or lack of respect for documented procedures that ensure that staff, committees, subsidiaries, subcontractors and associated bodies or staff of external bodies maintain the confidentiality of the information in their possession by the notified bodies, in accordance with Article 31.7 of Regulation (EU) 2024/1689, of 13 June.
- e) Failure to comply with the obligations of notified bodies to cease conformity assessment activities, as described in Article 36.3 of Regulation (EU) 2024/1689, of 13 June.
- f) The failure to take out adequate liability insurance for the conformity assessment activities of notified bodies, in accordance with Article 31.9 of Regulation (EU) 2024/1689, of 13 June.

## **Article 22. *Minor infractions by any operator***

For the purposes of this Law, it will be considered minor infringements by any operator not to provide any information required by the market surveillance authorities in the exercise of their powers or to provide it in an incomplete, inaccurate or misleading manner by an operator, in accordance with Article 99.5 of Regulation (EU) 2024/1689, of 13 June, provided that it does not constitute a more serious offence.

Likewise, non-compliance with the obligations imposed on any operator determined by Regulation (EU) 2024/1689, of 13 June, which do not constitute a serious or very serious infringement in accordance with the provisions of the eight previous articles, shall constitute minor infringements.

## **Article 23. *Minor violations by AI system providers***

For the purposes of this Law, the following are considered minor infringements by providers of AI systems:

- a) Failing to indicate commercial and contact information on high-risk AI systems on the packaging of the system or accompanying documentation, as applicable, in accordance with Article 16(b) of Regulation (EU) 2024/1689 of 13 June 2024.

- b) Failure to remedy within the period established by the market surveillance authority the formal breaches relating to the marking obligations of the high-risk AI system in accordance with Articles 16 h) and 83 of Regulation (EU) 2024/1689, of 13 June 2024.
- c) Failure to comply with the obligation to draw up the EU declaration of conformity, in accordance with Article 47 of Regulation (EU) 2024/1689, of 13 June.
- d) The placing on the market or the commissioning of high-risk AI systems without having carried out the appropriate CE marking, in accordance with Article 48 of Regulation (EU) 2024/1689, of 13 June.
- e) Non-compliance by the high-risk AI system with the requirements set out in Article 16(l) of Regulation (EU) 2024/1689 of 13 June on accessibility in accordance with Directives (EU) 2016/2102 of 26 October 2016 on the accessibility of websites and mobile applications of public sector bodies, and (EU) 2019/882 of 17 April 2019 on accessibility requirements for products and services.
- f) Failure to comply with the registration obligations referred to in Article 49(1) of Regulation (EU) 2024/1689 of 13 June.

**Article 24. *Minor infringements by importers of AI systems***

For the purposes of this Law, failure to comply with the obligation to keep system documentation in accordance with Article 23.5 of Regulation (EU) 2024/1689, of 13 June, is considered a minor infringement by importers.

**Article 25. *Minor infractions by those responsible for deploying AI systems***

For the purposes of this Law, the following are considered minor infractions by those responsible for deployment:

- a) Failure by those responsible for deployment who are public authorities, or institutions, bodies, offices and agencies of the Union, to comply with Article 26.8 of Regulation (EU) 2024/1689 of 13 June on the registration obligations referred to in Article 49 of that Regulation.
- b) Failure to comply with Article 26.10 of Regulation (EU) 2024/1689, of 13 June, on the obligations and limitations on the use of a deferred remote biometric identification AI system in the search for a person suspected of having committed a crime or convicted of it, due to a delay of more than 48 hours and less than 72 hours in the application.

**Article 26. *Minor infringements by notified bodies***

For the purposes of this Law, the following are considered minor infringements by notified bodies:

- a) The cessation or omission of the requirements established by the notified bodies in organisational matters, quality management, resources and processes necessary for the performance of their functions, as well as in matters of cybersecurity, and which do not constitute a serious infringement.

- b) The lack of respect or omission in the design of the procedures to carry out the procedures of the notified bodies that must take into account the size of the operators, the sector in which they operate, their structure and the degree of complexity of the AI system in question.
- c) The absence of sufficient internal technical competences to assess the tasks carried out by external agents on its behalf or the lack of adequate staff as described in Article 31.11 of Regulation (EU) 2024/1689, of 13 June.
- d) Failure to participate in the coordination activities referred to in Article 38 of Regulation (EU) 2024/1689 of 13 June.
- e) Failure to comply with any of the operational obligations to which they are subject in accordance with Article 34 of Regulation (EU) 2024/1689, of 13 June.

#### **Article 27. Graduation of sanctions**

1. The public administrations must ensure that the sanction is duly appropriate and the act constituting the infringement, especially considering its impact and its significance with regard to the health and safety of people and their fundamental rights. In particular, the following should be assessed on a case-by-case basis:

- a) The nature, gravity and duration of the infringement and its consequences, taking into account the purpose of the AI system and, where applicable, the number of persons affected and the level of harm they have suffered.
- b) If other market surveillance authorities, both at national and European Union level, have already imposed administrative fines on the same operator for the same type of infringement.
- c) If other authorities have already imposed administrative fines on the same operator for infringements of other Union or national legislative acts, where those infringements result from the same activity or omission constituting a relevant infringement of this Regulation.
- d) The size, annual turnover and market share of the infringing operator.
- e) Any other aggravating or mitigating factor applicable to the circumstances of the case, such as financial benefits obtained or losses avoided, directly or indirectly, through the infringement.
- f) The degree of cooperation with the competent national authorities in order to remedy the infringement and mitigate its possible adverse effects.
- g) The degree of responsibility of the operator, taking into account the technical and organisational measures applied by the operator.
- h) The manner in which the national competent authorities became aware of the infringement, in particular whether the operator notified the infringement and, if so, to what extent it revealed and established all relevant facts.
- i) The intentionality or negligence in the infringement.

- j) Actions taken by the operator to mitigate or repair the damage suffered by the affected persons before the supervision, assessment or inspection procedure by the competent authority is initiated.
  - k) Previous infringements committed by the same operator in the past or the fact that an SME has previously been required for the same type of infringement.
  - l) The existence of a succession of companies or the application of the doctrine of lifting the veil in abusive or fraudulent situations.
2. The graduation criteria may be developed by regulation.

#### **Article 28. *Publicity of sanctions***

1. The market surveillance authorities and, where appropriate, the corresponding notifying authority, shall publish, once they have become final in administrative proceedings, the penalties imposed for infringements committed against the Law, the facts constituting such infringements, as well as the identity of the infringer, and shall communicate these details to the Spanish Agency for the Supervision of Artificial Intelligence, safeguarding the confidentiality of the information and data obtained in accordance with Article 78 of Regulation (EU) 2024/1689, of 13 June.
2. The Spanish Agency for the Supervision of Artificial Intelligence shall publish within a period of no more than 15 working days from the date of administrative finality, and shall notify the European Commission of the administrative sanctions that have been imposed during that year by virtue of this Law, in compliance with Article 99.11 of Regulation (EU) 2024/1689, of 13 June.
3. Any published resolution shall exclude any data of a personal nature or that requires confidentiality.

#### **Article 29. *Procedure***

1. The corresponding sanctions will be imposed by reasoned resolution of the market surveillance authority, after examining the corresponding file and in accordance with the provisions of Title IV of Law 39/2015, of 1 October, on the Common Administrative Procedure of Public Administrations, with the particularities established in this article.
2. Sanctioning procedures for the administrative offences described in this Law shall always be initiated ex officio, by reasoned request from other administrative bodies or by virtue of a complaint from a third party, in accordance with the procedure established in Article 85 of Regulation (EU) 2024/1689, of 13 June, which shall be applicable from the entry into force of this Law.
3. Complaints must state the identity of the person or persons who file them and the account of the facts that are brought to the attention of the Authority. If the complainant has expressed a desire for confidentiality or the need to guarantee the confidentiality of the complainant's identity is understood, access to the complainant's data may be refused by means of a reasoned decision of the body that must decide, except for the judicial authority, the Public Prosecutor's Office in the framework of a criminal investigation. The complaint does not, in itself, confer on the third party the status of interested party in the proceedings.

4. The Spanish Agency for the Supervision of Artificial Intelligence will establish a mailbox or external information channel, by electronic means, through which any natural person may anonymously report the facts that have led to the commission of any infringement included in the scope of application of this law. Once the information has been submitted anonymously, the Authority will proceed to register it, deciding within 10 working days, in a reasoned manner, whether or not to initiate a sanctioning procedure ex officio or whether to send said information to the market surveillance authority that it considers competent for its processing.

5. In sanctioning proceedings, the market surveillance authority must guarantee the confidentiality of the information and data obtained in the exercise of its inspection and sanctioning functions, in accordance with the obligations established in Article 78 of Regulation (EU) 2024/1689, of 13 June. 5. The period for resolving and notifying in these proceedings shall be eighteen months in the case of very serious and serious infringements, and nine months in the case of minor infringements. If this period has elapsed without an express resolution, the expiration of the procedure will be declared ex officio.

6. The resolution will be enforceable when it puts an end to the administrative procedure. The resolution may adopt the necessary precautionary provisions to guarantee its effectiveness as long as it is not enforceable, including the possible precautionary withdrawal of the product or the disconnection or prohibition of the AI system, within the territorial scope of the sanctioning market surveillance authority.

### **Article 30. Preliminary actions.**

1. Prior to the commencement of the procedure and in accordance with Article 55.2 of Law 39/2015, of 1 October, the bodies with sanctioning powers may open a period of information or preliminary actions to determine, as precisely as possible, the facts likely to motivate the initiation of the procedure, the identification of the person or persons who may be responsible and the relevant circumstances that occur in both of them. without prejudice to the powers attributed to them in terms of requesting information, supervision and inspection, in accordance with Chapter IX of Regulation (EU) 2024/1689, of 13 June and Chapter V of the Regulation on Market Surveillance and Product Conformity.

2. Within the framework of the preliminary investigation actions, the competent market surveillance authority may request from those responsible for the conduct that could constitute an infringement of Regulation (EU) 2024/1689, of 13 June 2024, and of this law, any information that it deems necessary to determine the facts likely to motivate the initiation of the procedure.

Likewise, and within the same framework, the competent market surveillance authority may, when it has not been able to carry out the identification by other means, collect from the Public Administrations, including tax and Social Security Administrations, the information and data that are essential for the sole purpose of achieving the identification of those responsible for the conduct that could constitute an infringement of Regulation (EU) 2024/1689, of 13 June 2024, and of this law.

3. The bodies with sanctioning powers, taking into account the nature of the facts in the event that the infringing party is an SME, may agree to suspend the processing of the sanctioning procedure, requiring the responsible party, so that, within the period determined by the sanctioning body, it certifies the adoption of the corrective measures that, in each case, are relevant, provided that the facts do not constitute a very serious infringement in accordance with the provisions of this Law, and compensation is paid for all the damages caused, if any.

The notification of the requirement to the infringing party will suspend the maximum period for resolving the sanctioning procedure.

In the event that all the corrective measures and the compensation established by the injunction are complied with within the period established by the responsible party, the termination of the procedure will be agreed by means of a resolution by the competent sanctioning body.

If the request is not complied with within the period determined by the sanctioning body, the sanctioning procedure for such non-compliance will be resumed.

4. When a Public Sector entity commits any of the infringements set out in this Law, the competent market surveillance authority shall issue a resolution declaring the infringement, warning the acting entity, and establishing, where appropriate, the measures to be adopted to cease the conduct or correct the effects of the infringement that has been committed. excluding the imposition of administrative fines in accordance with Article 99.8 of Regulation (EU) 2024/1689, of 13 June.

The resolution will be notified to the entity responsible for the AI system, to the body to which it reports hierarchically, where appropriate, and to the affected parties who hold the status of interested parties, where appropriate.

The competent market surveillance authority shall also propose the initiation of disciplinary proceedings where there are sufficient indications to do so. In this case, the procedure and sanctions to be applied will be those established in the applicable legislation on disciplinary or sanctioning regime.

Likewise, when the infractions are attributable to authorities and management personnel, and the existence of technical reports or requirements that have not been duly attended to is accredited, the resolution imposing the sanction shall include a reprimand with the name of the responsible position and shall order its publication in the Official State Gazette. as well as in the regional bulletin, where appropriate.

#### **Article 31. *Prescription.***

1. Minor infringements shall be time-barred after one year, serious infringements after three years and very serious infringements after five years.

2. The limitation period for infringements shall begin to run from the day on which the infringement was committed.

3. In the event of continuous infringements, the limitation period will begin to run from the moment of the end of the activity or the last act with which the infringement is consummated. In the event that the facts or activities constituting the infringement are unknown because they lack

external signs, this period will be calculated from the introduction on the market, their marketing or their putting into service.

4. The limitation period will be interrupted by the initiation, with the knowledge of the interested party, of the sanctioning procedure, and the limitation period will be restarted if the sanctioning file is paralyzed for more than six months for reasons not attributable to the alleged perpetrator. An exception is made in the case in which the alleged responsible party has been summoned in accordance with the provisions of Article 29, in which case the limitation period shall not be interrupted during the period granted for the adoption of the relevant corrective measures and to compensate for the damages caused.

5. The penalties imposed for the commission of minor offences shall expire after one year, those imposed for serious offences after three years and those imposed for very serious offences after five years.

6. The limitation period for penalties shall begin to run from the day following the day on which the decision imposing the penalty becomes enforceable or the period for appealing against it has elapsed.

7. The limitation period of the sanction shall be interrupted by the initiation, with the knowledge of the interested party, of the enforcement procedure, and the period shall elapse again if it is paralyzed for more than one month for reasons not attributable to the offender.

8. If, in the course of the preliminary proceedings or during the investigation of the procedure, it is noticed that the infringement has expired, the body with sanctioning powers shall decide ex officio and without delay to terminate the preliminary proceedings or to conclude the sanctioning procedure, notifying the interested party.

### **Article 32. *Concurrence of sanctions***

1. Acts that have been criminally or administratively sanctioned may not be punished, in cases in which the identity of the subject, fact and basis is established.

2. In cases where the facts that give rise to the initiation of the sanctioning procedure could constitute a crime or misdemeanour, the competent administration will pass the blame to the competent court and will refrain from continuing the sanctioning procedure until the judicial authority has issued a final judgment or resolution that ends the procedure. If the existence of a crime or misdemeanour has not been found, the competent administration may continue the disciplinary proceedings, being bound by the facts declared proven in a final judicial decision.

3. When a single act constitutes two or more infractions in accordance with this Law, and other applicable laws, the offender shall be imposed the penalty corresponding to the most serious infraction.

### **Article 33. *Provisional measures***

1. Once the sanctioning procedure has been initiated, the competent market surveillance authority may at any time, by means of a reasoned agreement, adopt the provisional measures it



deems necessary to ensure the effectiveness of the resolution that may be issued and to avoid the continuation of the risks or damage to safety, health or fundamental rights.

Such measures must be proportionate to the nature and seriousness of the alleged infringements.

2. For the same purpose, the competent market surveillance authority, in cases of urgent need and for the provisional protection of the interests involved, may adopt the essential provisional measures in a reasoned manner, prior to the initiation of the procedure, within the limits and conditions established in Article 56.2 of Law 39/2015. of 1 October, and other applicable regulations, but in no case may they exceed the three-month period.

3. These provisional measures aimed at preventing the spread of damage, without constituting an exclusive or limiting list, may be the following:

- a) Require the adaptation of the AI system to make it compliant, including for formal breaches;
- b) Prevent the AI system from being commercialized;
- c) Withdraw the AI system immediately and alert the public of the risk it presents;
- d) Destroy the AI system or otherwise disable it;
- e) Publish appropriate, clearly and understandably worded warnings about the risks in the language or languages to be determined;
- f) Adequately alert end-users of the risk, including by publishing warnings in the AI system itself in the language(s) to be determined.

4. The measures described in this Article shall apply without prejudice to any others that may be taken by the market surveillance authorities, in accordance with Chapter IX of Regulation (EU) 2024/1689 of 13 June and Chapters IV and V of the Market Surveillance and Product Conformity Regulation.

#### **Article 34. *Reparation of damage and compensation.***

1. Without prejudice to the sanction that may be imposed, the offender shall be obliged to restore the situation altered by him to its original state, as well as to compensate for the damages caused, which may be determined by the competent authority, in which case the offender must be notified for satisfaction within the period determined for that purpose.

2. When the damage is difficult to assess, the theoretical cost of restitution and replacement, and the value of the damaged goods or rights, shall be taken into account in determining the compensation, and the value of the damaged goods or rights shall be applied, whichever provides the highest value shall be applied.

#### **Article 35. *Voluntary Payment***

1. Once a sanctioning procedure has been initiated, if the offender acknowledges his responsibility, the procedure may be resolved with the imposition of the appropriate sanction. In this case, the competent sanctioning body will apply a reduction of 20% on the amount of the proposed penalty.

2. When the proposed sanction is only pecuniary, the voluntary payment by the alleged perpetrator, at any time prior to the resolution, will also imply the termination of the procedure, except in relation to the restoration of the altered situation or the determination of compensation for the damages caused by the commission of the infringement. In this case, the competent sanctioning body will apply a 20% reduction on the amount of the proposed penalty.

In these cases, the infringement may be classified according to the degree resulting from the economic amount of the penalty

3. In the event that the offending entity is considered an SME, the sanctioning body will increase the reduction percentages to 25% in the event of acknowledgement of liability and to 25% in the case of voluntary payment prior to resolution.

4. The aforementioned reductions will be cumulative with each other, must be determined in the notification of initiation of the procedure and their effectiveness will be conditional on the withdrawal or waiver of any action or appeal in administrative proceedings against the sanction.

#### **Article 36. *Coercive fines and subsidiary enforcement.***

1. If the offenders do not proceed with restoration or compensation, in accordance with the provisions of Article 29, and once the period indicated in the corresponding request has elapsed, the competent market surveillance authority may decide to impose periodic penalty payments or subsidiary enforcement. The amount of each of the fines will not exceed 10% of the fine set for the infringement committed.

2. The imposition of periodic penalty payments shall require that the request indicate the period available for compliance with the obligation, which in no case may be less than one month, and the amount of the fine that may be imposed. In any case, the period must be sufficient to comply with the obligation. In the event that, once the coercive fine has been imposed, the non-compliance that has motivated it is maintained, it may be repeated for periods of time that are sufficient to comply with the order.

3. Periodic penalty payments are independent of and compatible with those that may be imposed by way of sanction.

4. The periodic penalty payments imposed, like the pecuniary penalties, shall be in the nature of a public law claim owned by the sanctioning entity or body and their amount may be demanded through the administrative enforcement procedure.

#### **Article 37. *Successors of legal persons.***

1. The penalties that may be applicable for the infringements committed by the companies and entities referred to in Article 3 shall be enforceable against their successors in the terms set out in the following section and, where appropriate, up to the limit of the value determined in accordance with the provisions of Article 40.1 of Law 58/2003. of 17 December, General Taxation.

2. In the event of extinction or dissolution without liquidation of companies and entities with legal personality, the pecuniary penalties and periodic penalty payments pending thereon shall be

transferred to the persons or entities that succeed or are beneficiaries of the corresponding operation. This rule will also be applicable to any case of global transfer of the assets and liabilities of a company and entity with legal personality.

**First additional provision.** *First reports and data required under Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024.*

1. Annual reports on the use of 'real-time' remote biometric identification systems in publicly accessible spaces for the purposes of ensuring compliance with the law that must be published in accordance with Article 5 of Regulation (EU) 2024/1689 of 13 June shall have their first publication date before 31 December 2025 and shall be published annually thereafter.
2. The annual reports on the use of deferred remote biometric identification systems to be prepared by those responsible for the deployment in accordance with Article 26 of Regulation (EU) 2024/1689, of 13 June, will have their first publication date before 31 December 2026 and will be published annually thereafter.
3. The annual reports relating to the information on progress and results of the controlled test spaces referred to in Article 57.16 of Regulation (EU) 2024/1689 of 13 June shall be published for the first time before 2 August 2027 and shall be published annually thereafter.
4. The Spanish Agency for the Supervision of Artificial Intelligence will publish a first report before 2 August 2025 on the state of the financial and human resources of the competent national authorities, which will include an assessment of their adequacy. This report will be published every two years thereafter.

**Second additional provision.** *National Database for Registration of High-Risk Systems*

The national database for the registry referred to in Annex III of Regulation (EU) 2024/1689, of 13 June, point 2, on AI systems for critical infrastructures, will be regulated by regulation, in accordance with the provisions of Article 49.5 of said Regulation. First final provision. Amendment of Law 29/1998, regulating the contentious-administrative jurisdiction

A new paragraph is added to paragraph 6 of Article 8, with the following wording:

'In addition, the Administrative Courts shall be responsible for authorising prohibited practices of real-time remote biometric recognition AI systems, which the competent administrative authorities consider urgent and necessary, adopted in accordance with Article 5 of Regulation (EU) 2024/1689 of 13 June 1689 laying down harmonised standards in the field of artificial intelligence.'

**Second final provision.** *Title of competence.*

This Law is enacted under Article 149.1, 1, 6 and 13 of the Constitution, which attributes to the State the competences over the basic conditions that guarantee the equality of all Spaniards in the exercise of rights and in the fulfilment of constitutional duties, procedural legislation and the bases and coordination of the general planning of economic activity. respectively.



**Third final provision. Authorization for regulatory development.**

The Government is empowered to issue any provisions necessary for the development and application of this Law, within the scope of its powers, as well as to update its annex.

**Fourth final provision. Entry into force.**

1. This Law shall enter into force on the day following its publication in the Official State Gazette.
2. The sanctioning regime contained in this Law, relating to prohibited artificial intelligence systems, will be applicable from 2 August 2025.
3. The sanctioning regime applicable to notified bodies will be applicable from 2 August 2025.
4. The sanctioning regime applicable to operators related to high-risk AI systems contained in Annex III of Regulation (EU) 2024/1689, of 13 June, will be applicable from 2 August 2026.
5. The sanctioning regime applicable to operators related to high-risk AI systems contained in Annex I of Regulation (EU) 2024/1689, of 13 June, will be applicable from 2 August 2027.
6. The sanctioning regime applicable to operators related to high-risk AI systems contained in Annex III of Regulation (EU) 2024/1689, of 13 June, will be applicable from 2 August 2026.

Therefore

I command all Spaniards, individuals and authorities, to observe and ensure that this Law is observed.

**ANNEX I: CASES IN WHICH THE USE OF "REAL-TIME" BIOMETRIC RECOGNITION AI SYSTEMS IN PUBLICLY ACCESSIBLE SPACES MAY BE AUTHORISED FOR THE PURPOSE OF ENSURING COMPLIANCE WITH THE RIGHT**

Objectives for which the use of "real-time" remote biometric identification systems in publicly accessible spaces may be authorised for the purpose of ensuring compliance with the Law:

1. 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,
2. The prevention of a specific, significant and imminent threat to the life or physical safety of natural persons or of a real and present or actual and foreseeable threat of a terrorist attack,
3. The location or identification of a person suspected of having committed a crime in order to carry out a criminal investigation or prosecution or to execute a criminal sanction, for any of the following crimes that in Spain are punishable by a custodial sentence or security measure whose maximum duration reaches or exceeds four years: a) Terrorism  
b) Trafficking in human beings,



- c) Sexual exploitation of minors and child pornography,
- d) Illicit trafficking in narcotic drugs or psychotropic substances,
- e) Illicit trafficking in arms, ammunition and explosives;
- f) Voluntary manslaughter, assault with serious injury,
- g) Illicit trafficking in human organs or tissues,
- h) Illicit trafficking in nuclear or radioactive materials,
- i) Kidnapping, false imprisonment or hostage-taking,
- j) Offences within the jurisdiction of the International Criminal Court,
- k) Hijacking of aircraft or ships,
- l) Rape
- m) Crimes against the environment,
- n) Organized or armed robbery,
- ñ) Sabotage
- o) Participation in a criminal organization involved in one or more of the crimes listed in this list.

BE SUBMITTED TO THE COUNCIL OF MINISTERS

Madrid, 2025

THE MINISTER FOR DIGITAL TRANSFORMATION AND THE CIVIL SERVICE

Oscar López Águeda