

Technical Note

Draft Organic Law on the Good Use and Governance of AI

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Issuing agencies

Congress of Deputies

Primary applicability

Technology, Risk, Data Protection,
Compliance and Business.

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The Organic Draft Law establishes the Spanish framework for governance, market supervision, AI regulatory sandboxes, the responsible use of AI in the State public sector and the enforcement regime

Context	Objectives	Next steps
- Regulation (EU) 2024/1689 on Artificial Intelligence (AI Act) establishes harmonised rules on the development, placing on the market, putting into service and use of AI systems. - As a directly applicable Regulation, it delegates the development of certain aspects to the Member States, including the designation of national competent authorities and certain elements of the enforcement regime. - In this context, the Congress of Deputies has published the Organic Draft Law on the Responsible Use and Governance of Artificial Intelligence, which specifies the national competent authorities, the national governance mechanisms, the regulation of AI regulatory sandboxes, and measures to promote the responsible use of AI in the State public sector.	Establish the national governance framework for the implementation of Regulation (EU) 2024/1689. Regulate the enforcement regime applicable to AI systems in Spain. Regulate the governance of AI regulatory sandboxes provided for in Article 57 of the Regulation. Provide for measures to promote the responsible use of AI in the State public sector. Designate the national competent authorities, including notifying authorities and market surveillance authorities.	30 June 2026. End of the deadline for submitting amendments. Currently. The parliamentary process is continuing until the final adoption of the legislation.

Key aspects of the publication

Governance and Supervision	The Draft Law designates the notifying authority and the market surveillance authorities, assigning to AESIA the functions of market surveillance authority in certain areas, the single point of contact, and the general coordination body.
AI Regulatory Sandboxes	AESIA is entrusted with responsibility for the mandatory AI regulatory sandbox, while allowing competent authorities to establish additional regulatory sandboxes within their respective areas of competence, subject to reporting obligations, adequate resources and annual reporting requirements.
Responsible Use of AI in the State Public Sector	The Draft Law provides for awareness-raising initiatives, the establishment of an inventory of AI systems, the promotion of training, and the designation of an AI officer within State public sector entities.
Infringements and Penalties	The Draft Law classifies very serious, serious and minor infringements, establishes financial penalties, and provides for additional corrective measures, including product withdrawal, disconnection of AI systems, or prohibition.

The Draft Law establishes a distributed governance and supervision model, with market surveillance authorities specialised by area of competence and AESIA acting as the single point of contact and general coordination body

Notifying Authority	• The Directorate-General for Artificial Intelligence is designated as the notifying authority for AI systems covered by Annex III of the Regulation. • It will be responsible for establishing and carrying out the procedures for the assessment, designation, notification, supervision and sanctioning of conformity assessment bodies. • To that end, it will be supported by ENAC in the assessment and supervision of those bodies.
Market surveillance authorities	• The market surveillance authorities will exercise market surveillance, inspection and enforcement powers over AI systems. • Different authorities are designated according to the subject matter of the AI system, including AESIA, the Spanish Data Protection Agency (AEPD), the regional data protection authorities, the General Council of the Judiciary (CGPJ), the Bank of Spain, the National Securities Market Commission (CNMV), and the Directorate-General for Insurance and Pension Funds (DGSFP). • AESIA will act as the market surveillance authority in the areas assigned to it under the Draft Law and, where appropriate, in respect of AI systems whose supervision has not been specifically assigned to another authority.
AESIA as the sole point of contact	• AESIA is designated as the single point of contact for institutional coordination and liaison with the European Commission, the AI Office, the AI Board and the authorities of other Member States. • It will coordinate the submission of the biennial report on financial and human resources, the annual report on prohibited practices, and the annual report on administrative fines and litigation. It will also provide a single contact channel and maintain publicly accessible contact information for the national competent authorities.
Coordination and Market Surveillance Activities	• A joint cooperation committee of the market surveillance authorities is established, chaired and managed by AESIA, to facilitate the exchange of information and best practices. • The committee will promote consistent enforcement criteria, although these will not be binding on the CGPJ or on the independent administrative authorities. • Market surveillance authorities may carry out analysis, verification, inspection and corrective actions, require corrective measures and, where appropriate, initiate enforcement proceedings.
Complaints and Whistleblower Protection	• Any natural or legal person may lodge a complaint with the competent market surveillance authority where they consider that the Regulation has been infringed. • AESIA will establish a single-entry complaint portal, through which complaints must be forwarded to the competent authority within 10 working days. • The Draft Law recognises protection for whistleblowers who report potential infringements of the Regulation or the Law in the context of an employment or professional relationship.

The Draft Law regulates the governance of AI regulatory sandboxes and introduces measures on information, inventory, training and the designation of an AI officer in the state public sector

AI Regulatory Sandboxes

- AI regulatory sandboxes will be governed by Regulation (EU) 2024/1689, the European Commission's implementing acts, and the provisions of the Draft Law
- **AESIA** will be the **competent authority** responsible for the mandatory AI regulatory sandbox.
- Additional AI regulatory sandboxes may be established by at least one competent authority designated as a **notifying authority** or **market surveillance authority**, within its area of competence. Market surveillance authorities may also establish additional regulatory sandboxes for high-risk AI systems associated with products regulated under certain Union harmonisation legislation.

Governance of AI Regulatory Sandboxes

- The competent authority must notify the **AI Office** and the **AI Board** of the establishment of the sandbox through the **single point of contact**. It must demonstrate **sufficient resources**, submit **annual reports**, and make them publicly available from the time the sandbox becomes operational.
- Coordination must involve the authorities responsible for **public policies** in the affected sectors and, where appropriate, for the **protection of fundamental rights**.

Information and Inventory of AI Systems

- State public sector entities must provide **relevant and up-to-date information** on the use of AI systems in the performance of their functions.
- An **inventory of AI systems** for the State public sector will be established, interoperable with the **EU register of high-risk AI systems**.
- The inventory will include AI systems used in **electronic administrative procedures**, without replacing the registration obligations established by the Regulation.
- The authority responsible for the inventory, its content, format and interoperability will be specified through **implementing regulation**.

Scope and Exemptions of the Inventory

- The obligation to provide information **will not apply** to AI systems used for **military purposes, defence, national security**, or the management and maintenance of critical infrastructure.
- AI systems in the **research, testing or development** phase, prior to being placed on the market or put into service, are also excluded.
- Systems related to **cybersecurity**, restrictions on the **right of access to public information**, or the **prevention, detection and investigation of fraud** are excluded where disclosure could increase the risk of attacks or misuse of the service.

Training and AI Officer

- State public sector entities will promote **awareness-raising, dissemination and training activities** on the **responsible, sustainable and trustworthy** development and use of AI.
- Each entity must designate an **AI Officer** responsible for developing **internal policies** and ensuring compliance with the standards applicable to AI systems.
- Where appropriate, the **AI Officer** will provide advice on **impact assessments, discriminatory bias and fundamental rights**. Their specific functions will be further defined through **implementing regulation**.

4. Infringements and Penalties

The Draft Law develops the enforcement regime applicable in Spain to infringements of the AI Act, classifying infringements as very serious, serious and minor, and providing for financial penalties, additional corrective measures and interim measures

Type of infringement	Examples of infringements	Financial penalties	Additional measures
Very serious	- Placing on the market, putting into service or using AI systems that constitute prohibited AI practices under the Regulation. - Failure by providers of high-risk AI systems, or, where applicable, by deployers, to notify serious incidents.	- Up to €35 million or 7% of total worldwide annual turnover for infringements involving prohibited AI practices. - Up to €15 million or 3% of total worldwide annual turnover for other very serious infringements.	Product withdrawal, disconnection or prohibition of the AI system in the event of prohibited practices or a serious incident.
Serious	- Failure to comply with the registration obligations for high-risk AI systems. Resistance, obstruction or refusal to cooperate with evaluation, verification or inspection activities carried out by a market surveillance authority. - Failure to comply with interim or corrective measures imposed by a market surveillance authority. - Significant breaches of obligations applicable to providers, deployers, importers, distributors, authorised representatives and notified bodies. - Failures relating to transparency, human oversight, documentation, information provision and post-market monitoring.	Up to €7.5 million or 1% of total worldwide annual turnover.	Interim or corrective measures and, where appropriate, restrictions or prohibitions on marketing, or withdrawal from the market.
Minor	- Submission of inaccurate or incomplete information where this does not constitute a serious infringement. - Formal or remediable breaches of obligations applicable to providers, importers, distributors, deployers, authorised representatives and notified bodies. - Breaches relating to contact details, documentation, marking, accessibility, storage and transport, or commercial information.	Up to €500,000 or 0.5% of total worldwide annual turnover.	Rectification of formal breaches; where non-compliance persists, possible restrictive measures or market withdrawal.

Management Solutions is experienced in reviewing and developing AI systems across all industries, while ensuring regulatory compliance and meeting supervisors' expectations.

1. **Specialized team.** MS has a team of **1,000+ Data Scientists** who combine **technical and quantitative skills with strong regulatory knowledge and certifications** in leading cloud providers (AWS, Azure and Google).
2. **AI models and regulatory practice.** MS has led the **development of numerous AI models** (supervised learning, unsupervised learning, NLP techniques, deep learning models...) with application in **multiple use cases**: fraud detection, risk classification, energy prediction, AML, XAI, and reputational risk or model risk measurement, among others. At the same time, MS has been involved in the implementation of various regulatory requirements across different industries (financial, telco, insurance...).
3. **Experience with regulators and supervisors.** MS is a "**highly qualified external service provider**" to the **European Central Bank**, with which it has signed 7 framework agreements in the last 6 years, and to national authorities. For the interpretability of advanced models, **MS works under the recommendations of the EBA in its "Report on Big Data and Advanced Analytics"**, according to its 7 elements of confidence for model development and interpretability.
4. **Interpretable models.** MS has **extensive experience in the development of interpretable models** and the application of interpretability techniques in the industries in which it operates: banking, insurance, energy, telecommunications and other industries.
5. **R&D area.** MS allocates **10% of its capacity to R&D**, allowing it to be at the forefront of Artificial Intelligence. **Co-founding of the iDANAE chair** (intelligence, data, analysis and strategy) **with the UPM** (Universidad Politécnica de Madrid), focused on the development of components that form part of the value cycle of the most important assets of today's society, such as information and knowledge.
6. **Close relationship with the RAC** (Royal Academy of Sciences) and active participation in several **research projects with AI applications in areas such as sustainability** (quantification of climate risk) **and efficient training of neural networks** (training optimization and interpretability in transfer learning architectures).
7. **In-house development of proprietary tools ModelCraft™**, with advanced AI/XAI techniques covering **multiple areas of advanced modeling, including dashboards and proprietary interpretability modules**, as well as management and **definition of architectures and cloud services**; **Gamma™**, a model governance and MRM tool, incorporating inventory, workflow management, document repository and MRM reporting; **and Hatari™**, a reputational risk quantification tool based on information from media and social networks, using **innovative artificial intelligence and NLP techniques**.

A.2. Abbreviations

Abbreviation	Meaning	Abbreviation	Meaning
EBA	European Banking Authority	MS	Management Solutions
AEPD	Spanish Data Protection Agency	NLP	Natural Language Processing
AESIA	Spanish Agency for the Supervision of Artificial Intelligence	RAC	Royal Academy of Sciences
AI Act	European Artificial Intelligence Regulation / Regulation (EU) 2024/1689	EU	European Union
AML	Anti-Money Laundering	UPM	Technical University of Madrid
AWS	Amazon Web Services	XAI	Explainable Artificial Intelligence
BdE	Bank of Spain		
BCE	European Central Bank		
BOCG	Official Gazette of the Spanish Parliament		
EC	European Commission		
CGPJ	General Council of the Judiciary		
CNMV	National Securities Market Commission		
DGSFP	Directorate-General for Insurance and Pension Funds		
ENAC	National Accreditation Body		
AI	Artificial Intelligence		
R+D	Research and Development		
MRM	Model Risk Management		




International
One Firm


Multiscope
Team


Best practice
know-how


Proven
Experience


Maximum
Commitment

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