



cecimo

European Association of the Machine Tool Industries
and related Manufacturing Technologies

CECIMO PAPER ON THE ARTIFICIAL INTELLIGENCE ACT

www.cecimo.eu

www.cecimo.eu

1. Introduction and General Comments

CECIMO, representing the machine tool industry and related manufacturing technologies, welcomes the opportunity to share its position on the European Commission's "**Proposal for a Regulation on Artificial Intelligence**", hereafter referred to as the **Artificial Intelligence Act (AI Act)**, which aims to introduce a common regulatory and legal framework governing the use of Artificial Intelligence in the European Union (EU), building on the architecture of the New Legislative Framework (NLF).

In the sphere of machine tool manufacturing, the application of industrial AI has steadily increased over recent years particularly with the advent of Industry 4.0, **as machine connectivity, machine learning and industrial automation**, among others, have become fundamental elements of our production processes. Notwithstanding this rapid evolution, **the capabilities of industrial AI in our sector remain at a relatively early development stage** as compared to general AI within the domain of frontier academic research, where development efforts are geared towards building computerized systems that can perform tasks requiring human-level intelligence. As a matter of fact, **industrial AI is mostly concerned with the implementation of specific tasks that require only a limited form of intelligence, inevitably subject to a narrow set of constraints and limitations** established through man-made programs and algorithms. To this end, the increasing application of industrial AI has provided machine tool manufacturers with a highly effective tool to optimize factory operations, enhance productivity of machines and services, while significantly improving energy efficiency and resource utilization.

Ultimately, the potential for the European manufacturing industries to continue to reap these significant benefits will rely on a legislative framework that **allows manufacturers to further research, develop and test AI technologies** in their production processes, while guaranteeing safety, lawfulness and a full respect of fundamental rights. Henceforth, given the unprecedented nature of this piece of legislation, which will set the global standard in determining the extent to which the application of AI is beneficial or detrimental in its various domains, it is fundamental for our sector that the proposed legislation will strategically support the European manufacturing industries in their deployment of AI to strengthen their competitiveness and innovative capabilities at a global level.

In this regard, CECIMO has actively engaged in thorough analyses and numerous policy discussions with the aim of coordinating actions and exchanging views with the key European stakeholders involved in the AI Act. Throughout this process, we have identified **a series of major threats** in the draft legislative text that could create significant hurdles and lead to additional burdens for the machine tool manufacturing sector, clearly outlined in this position paper.

2. Scope of the AI Act

Definition of "AI system"

CECIMO believes that the current definition of "AI system" is too wide (Article 3(1)). The AI-techniques listed under Annex I that classify a software as AI include "statistical approaches, Bayesian estimation, search and optimization methods," (Annex I, part b and c) all of which are widespread and largely accepted techniques in numerous industrial domains, including but not limited to logistics and manufacturing. Although these methods can be deployed in automated decision-making processes for critical applications, there is a fundamental issue of measurability and thresholds to identify at what point the use of such techniques can effectively qualify as AI.

The AI-techniques deployed by manufacturers are almost exclusively limited to Narrow or Weak Artificial Intelligence ("Narrow AI"), a form of AI that implements specific tasks requiring only a limited form of intelligence, subject to a narrow set of constraints and limitations that are assigned from the outset by humans – Typically designers, computer specialists and plant engineers, among others.

In fact, narrow AI has been safely and effectively deployed in the manufacturing sector for many years to improve the reliability of components, implement predictive monitoring and maintenance, increase the lifespan of machinery, optimise energy efficiency, and adapt production to customer demand.

For this reason, CECIMO proposes a revision of this definition to ensure that 1) it includes a necessary element of “autonomy” and “intelligence behavior” in decision-making, and 2) that it does not include widely used statistics and optimization methods, while on the other hand 3) the definition should be future-proof and allow for the inclusion of technological approaches that cover more powerful forms of AI in the future. In particular, we recommend using the definition proposed by the High-Level Expert Group on AI, focusing on AI-techniques that display intelligent behaviour and take actions with some degree of autonomy (Annex I, part a).

3. Classification rules for “high-risk” AI systems

CECIMO welcomes the risk-based approach outlined in the AI Act as an attempt to achieve trust and excellence without hampering the early development stages of AI-techniques. Nonetheless, **the current classification rules for high-risk AI** applications outlined under Article 6 would lead to legal uncertainty and likely limit the uptake of innovative and beneficial AI-techniques, particularly in the manufacturing sphere.

According to Article 6, an AI system can be classified as high-risk on the basis that it is 1) “used as a safety component of a product, or is itself a product covered by the Union legislation listed in Annex II” and that 2) “the product whose safety component is the AI system, or the AI system itself as a product, is required to undergo a third-party conformity assessment pursuant to the Union legislation listed in Annex II,” thereby extending the classification beyond safety components and safety-relevant software products. Although this risk-based approach may seem purposeful and pragmatic, **it creates significant ambiguities in the interplay between the AI Act and the legal acts listed under Annex II**, which already provide for comprehensive safety requirements covering most industrial applications of AI. The current classification rules in Article 6 would force EU manufacturers to abide by overlapping classification and obligations from both the AI Act and their respective sectoral legislation.

According to CECIMO, the proposed classification rules for High-risk AI should be redefined to ensure consistency with sectoral legislation in Annex II, thus regulating only high-risk AI applications in areas where a clear regulatory gap has been demonstrated, without extending beyond safety components and safety-relevant software products. Furthermore, the provisions of Article 6 should not hold the third-party conformity assessment as a criterion for high-risk classification, given that this would undermine the development of innovative and beneficial AI-techniques that grant EU manufacturers a competitive edge, particularly in our sector where highly customized solutions are often commercialized.

4. Duplication of Conformity Assessments (AI Act vs. Machinery Regulation)

The European Commission’s “**Proposal for a Regulation on Machinery Products**” is the core legislation regulating the machine tool manufacturing sector, and it was first released in April 2021 in a legislative package together with the AI Act. Since these proposals have been following separate legislative procedures, and considering the interplay between them, it is essential for our sector to **ensure coherence to maintain a stable and harmonized legislative framework.**

CECIMO’s main concern in this regard is **the inclusion of AI systems under the Annex I (High-risk machinery products)** of the Machinery Regulation, which could potentially lead to **a duplication of conformity assessments.** According to Article 43 (3) of the AI Act, “for high-risk AI systems, to which the legal acts listed in Annex II, section A, apply (the Machinery Regulation), the provider shall follow the relevant conformity assessment as required under those legal acts.”

Henceforth, a duplication of conformity assessments could arise in cases of safety-relevant AI systems (Item 24 of Annex I) or machinery embedding safety-relevant AI systems (Item 25 of Annex I), where the conformity assessment carried out by the AI system provider would need to be repeated by the machinery manufacturer under the AI Act and the Machinery Regulation respectively.

Therefore, CECIMO believes that to ensure coherence between the AI Act and the Machinery Regulation, there need to be clear provisions that prevent the duplication of conformity assessments and the imposition of excessive compliance costs on manufacturers. Such a duplication of efforts would highly contradict the good functioning of the internal market, by adding to the manufacturers' burden without effectively enhancing the safety of the machines.

5. Compliance Costs

The current draft AI Act foresees the **obligation of third-party conformity assessments** for all machinery embedding high-risk AI systems, thus requiring those machinery manufacturers to undertake **significant compliance costs**. This would represent **a strong economic barrier** for all the small and medium sized manufacturers in our sector that invest in the deployment of AI systems, as well as **a major limitation on their long-term competitiveness and technological capabilities**.

According to the EC Impact Assessment of the AI Act, compliance costs for manufacturers deploying high-risk AI systems are estimated at around 6k€ / 7k€, with additional conformity assessment costs estimated at around 3.5k€ to 7.5k€, thereby leading to a total estimated costs of 9.5k€ to 14.5k€. This calculation excludes all additional expenditures arising from external consultancy + internal costs (Human effort to complete the conformity assessment, internal legal advice and external auditing) and the setting up of a new Quality Management System (Article 17), with total estimated costs of 193k€ to 330k€.

Taking into consideration the estimated costs of third-party conformity assessments, and their detrimental effect on manufacturers' long-term competitiveness and technological capabilities, CECIMO recommends carefully addressing all potentially unwanted consequences and administrative burden for industry that could discourage investment in the development of AI systems.

6. Allocation of Responsibilities

Within the framework of the AI Act, it is important to adjust and clarify **the balance of responsibilities between the different actors** present in the value chains of AI systems, particularly with regards to the obligations of product manufacturers. According to Article 24 of the draft text, the manufacturer of a product in which a high-risk AI system is installed "takes responsibility of the compliance of the AI system with this Regulation" and has the **same obligations imposed by the present Regulation** on the provider, including the obligation to provide the relevant technical documentation (Article 11).

Nevertheless, CECIMO contests the aforementioned obligations on the basis that **in most cases product manufacturers do not necessarily possess a detailed technical knowledge of the AI system in place**. In the machine tool manufacturing sector, where there is a rising number of machines embedding AI systems, the assembly and maintenance of these AI systems are typically carried out by the AI software providers directly, in most cases FANUC and Siemens, who preserve an **exclusive technical knowledge** of their systems in protection of their technological leadership. As the information required to prepare technical documentation usually remains with the AI system providers and is not passed on, machine tool manufacturers do not have the ability to realistically fulfil this obligation.

Consequently, in these cases product manufacturers should be exempted from obligations that can realistically only be fulfilled by the provider of the embedded AI system, particularly regarding the requirement to prepare technical documentation. In fact, CECIMO holds that the legal responsibility to fulfil these obligations should lie with the legal or natural entity building the AI system that actually controls its purpose and use, as it is the best-placed actor to ensure compliance.

7. Harmonized Standards vs. Common Specifications

Under Article 41 of the draft AI Act, **the Commission would be given the possibility to develop common specifications** via implementing acts in cases where harmonized standards do not exist or where the Commission considers that the relevant harmonised standards are insufficient or that there is a need to address specific safety or fundamental rights' concerns.

This provision risks **undermining the inclusiveness and technical quality of standard-setting processes** and disincentivizing the participation of companies, particularly manufacturing SMEs, and thereby **weakening the legal and technical status of standards**. Standard-setting processes are and must remain inclusive and market-driven processes drawing on the expertise of a wide range of stakeholders including users, market surveillance authorities, notified bodies, academia, and industry.

From CECIMO's perspective, the implementation of common specifications should be seen as a **time-limited "fall-back" option in the absence of harmonized standards** rather than a replacement, whose use should only be permitted under the strict, finite and clear conditions outlined below:

- No reference to harmonized standards published in the Official Journal of the European Union (OJEU) according to Regulation (EU) No 1025/2012;
- Submitted request by the Commission to one or more Standardization Bodies to draft a harmonized standard subject to undue delays or to rejection;
- Repeal of common specifications when references of a harmonized standard are published in the Official Journal of the European Union (OJEU).

On these grounds, CECIMO strongly recommends that harmonized standards should be formulated with the active participation of industry, particularly SMEs, to ensure market relevance, technical quality and to avoid a "one-size-fits-all" approach. Ultimately, the powers of the European Commission to introduce common specifications via implementing acts should be on the basis of strict and unambiguous conditionality.

8. Financial Support for Innovation in AI

CECIMO welcomes the Commission's intention to support a thriving and innovative AI ecosystem in Europe through the creation of AI Regulatory Sandboxes at the national level overseen by their designated national competent authorities (Article 53 and 59). Regulatory sandboxes can greatly improve framework conditions for innovation in the field of AI, by providing controlled environments that **"facilitate the development, testing and validation" of innovative AI systems** before their placement on the market.

For an effective sandboxing scheme, the national competent authorities referred to in Article 59 that will oversee the regulatory sandboxes will require **a sound infrastructure, good organization, adequate legal powers and skilled staff** – this will inevitably require sizeable financial resources from national governments, which are currently lacking and largely unbalanced across EU Member States. From a legal perspective, to ensure uniform application across the EU, **we recommend converting the voluntary nature of setting up the sandbox scheme into an obligation for national governments**, with well-established criteria that guarantee an effective and smooth access to small-scale manufacturers wishing to deploy AI systems.

Besides the provisions on regulatory sandboxes, the AI Act foresees a set of measures for small-scale providers and users of AI (Article 55) that CECIMO fully supports. In this regard, it is fundamental that small-scale businesses are provided with **priority access to AI regulatory sandboxes and comprehensive guidance** on the AI Act's regulatory framework, with their compliance costs kept to a strict minimum.

Nevertheless, in addition to the aforementioned provisions, CECIMO believes that **the EU would need to maximize its available resources and coordinate investments in the field of AI**. Through the Digital Europe and Horizon Europe programmes, the Commission plans to invest €1 billion per year in AI, with additional investments leveraged through the private sector. While this certainly represents a step in the right direction, we would advocate for increased EU funding towards the development of AI, especially considering that the United States and China have undertaken much higher investments in this field.

With regards to the AI Regulatory Sandbox scheme, CECIMO calls for the introduction of obligations for EU Member States to establish functioning regulatory sandboxes and to provide them with adequate levels of funding, while preserving the support measures foreseen for small-scale businesses. To further support the development of AI in Europe, we foresee the need for the EU to maximize available resources and coordinate investments, beyond the current commitment of €1 billion invested per year.

9. Conclusion: CECIMO Key Messages

While the objectives and core principles guiding the Artificial Intelligence Act are fundamentally correct in principle, some of the provisions outlined in the draft text could potentially undermine our sector's ability to compete and maintain technological leadership in the long-term, particularly for the small-scale manufacturers. Henceforth, CECIMO firmly believes that the recommendations advanced in this position paper would significantly contribute to establish a clearer regulatory framework for this key emerging technology. Please find below a summary of our key set of recommendations to improve the current legislative text:

- **Narrow definition of AI in Annex I:** The definition of AI should be narrowed to the range of AI-techniques listed under Annex I, part a, to clarify the scope of the AI Act and to eliminate unnecessary ambiguities.
- **Insert “autonomy” and “intelligent behaviour” in AI definition:** To avoid regulation of non-decision-making AI-techniques, the definition of AI must include a necessary element of “autonomy” and “intelligent behaviour” in decision-making.
- **Limit “high-risk” classification of embedded AI systems to safety-relevant components:** If industrial machinery embedding AI systems remains within the scope of the AI Act, the high-risk classification should remain limited to safety-relevant components.
- **Simplify classification rules for high-risk AI systems under Annex II:** The criterion of “third-party conformity assessment” is an insufficient categorization of high-risk that would undermine the development of innovative and beneficial AI-techniques.
- **Exclude already regulated AI systems from the scope:** Industrial AI applications that are already subject to product-specific safety legislation and do not have a relevance for human rights should be excluded from the scope.
- **Limit the use of the third-party conformity assessment:** Third-party conformity assessment is a costly procedure that can inhibit innovation, and thus the possibility of internal production controls (Manufacturers' self-declaration) should be expanded in accordance with Annex II.

- **Strengthen existing standard-setting processes:** Standard-setting processes are and must remain inclusive and market-driven processes drawing on the expertise of a wide range of stakeholders including users, market surveillance authorities, notified bodies, academia, and industry.
- **Common specifications as limited “fall-back” option:** The power to introduce common specifications via implementing acts should be applicable on a temporary basis, and subject to strict and unambiguous conditions.
- **Strengthen the AI Regulatory Sandbox scheme:** Introduce obligations for EU Member States to establish functioning regulatory sandboxes with adequate financial resources to ensure sound infrastructure, good organization, adequate legal powers and skilled staff.
- **Financial support for development of AI in Europe:** To support a thriving AI ecosystem beyond the current commitment of €1 billion per year, maximizing available resources and coordinating investments across Member States.

For more information please contact:

✉ Vincenzo BELLETTI, Director of EU Public Affairs, vincenzo.belletti@cecimo.eu

✉ Stefano RAMUNDO ORLANDO, Technical Regulations Officer, stefano.ramundo@cecimo.eu

CECIMO is the European Association of the Machine Tool Industries and related Manufacturing Technologies. We bring together 15 national associations of machine tool builders, which represent approximately 1500 industrial enterprises in Europe (EU + UK+ EFTA + Turkey), over 80% of which are SMEs. CECIMO covers 98% of the total machine tool production in Europe and about 33% worldwide. It accounts for approximately 150,000 employees and a turnover of around 22.5 billion euros in 2021. More than three quarters of CECIMO production is shipped abroad, whereas half of it is exported outside Europe.