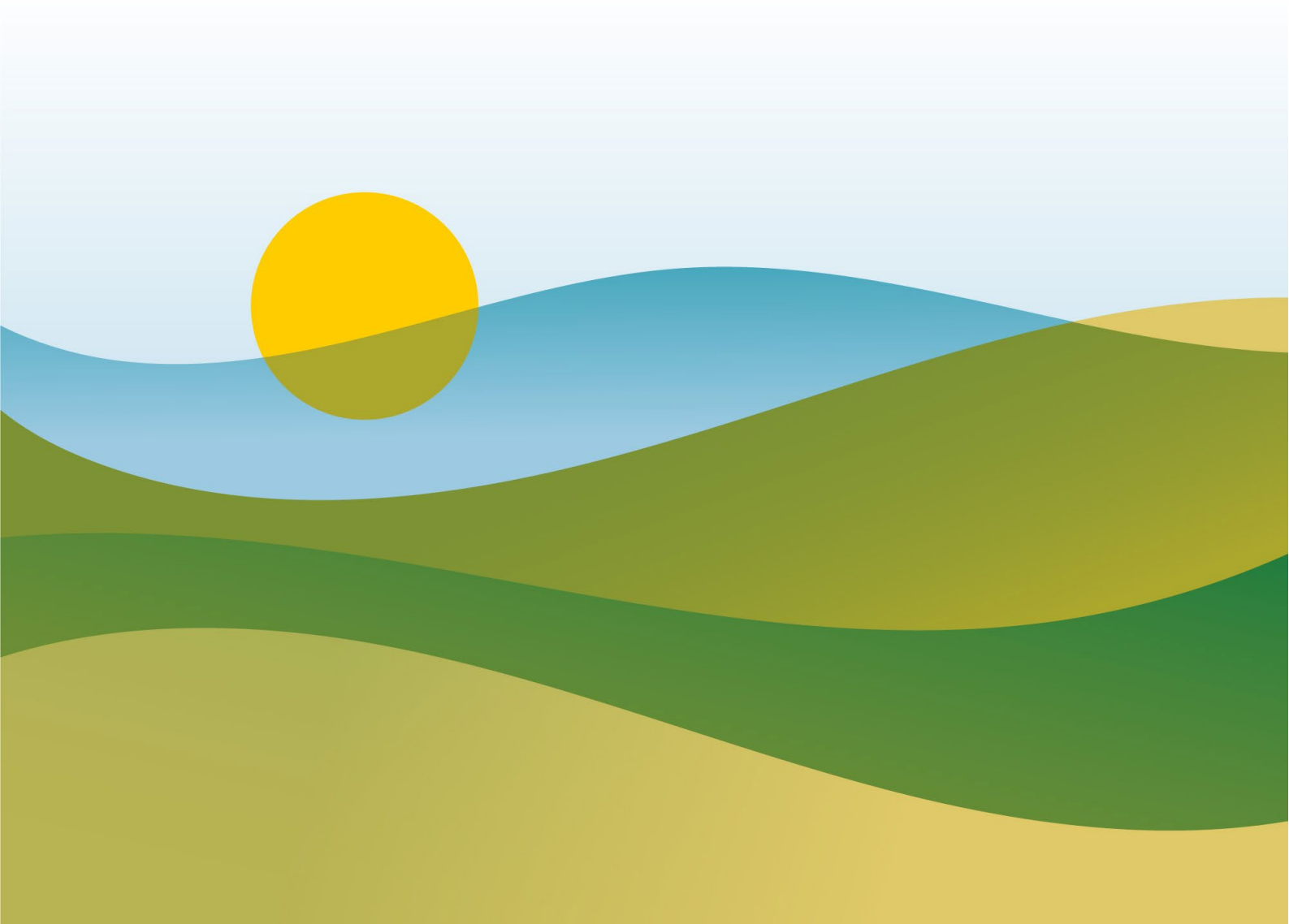


**Position Paper**

# **EU Artificial Intelligence Regulatory Framework:**

**CEMA calls on the European Commission to adapt the principles to the reality of non-road machinery**

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## Introduction

**CEMA**, representing the European agricultural machinery industry, welcomes the introduction of Artificial Intelligence (AI) in the agricultural equipment industry. This marks a revolutionary advancement in safety, sustainability, and productivity. This new era of technological innovation is defined by precision agriculture, autonomous operations, and data-driven decision-making. It brings about substantial changes in agricultural practices, offering unparalleled opportunities to minimize environmental impact, optimize resource allocation, ensure food security, and support sustainable income for farmers.

## How CEMA reads the EU AI Act and the link with product legislations

Regulators worldwide aim to minimize the risks and maximize the benefits associated with the use of AI by imposing specific requirements to protect individuals, fundamental rights, and uphold harmonious societal and ethical values<sup>1</sup>. The use of artificial intelligence in the EU will be governed by the AI Act, which is the world's first comprehensive AI law.

The EU AI Act will necessitate our industry to assess the essential risks of AI. To achieve this, the AI Act introduces various risk categories, including prohibited AI, high-risk AI, medium-risk AI (primarily general-purpose models), and low-risk AI.

The definition of AI in Art 3 of the AI Act is too wide and requires guidance:

*"a machine-based system designed to operate with varying levels of autonomy and that may exhibit adaptiveness after deployment and that, for explicit or implicit objectives, infers, from the input it receives, how to generate outputs such as predictions, content, recommendations, or decisions that can influence physical or virtual environments"*<sup>2</sup>.

CEMA acknowledges and welcomes the existence of Recital 12, which puts perspective to this meaning and calls for clear guidance from the Commission. It states that the term "levels of autonomy" in the context of AI systems generally refers to the degree to which an AI system can operate independently without human intervention, however the different "levels of autonomy" are not defined in the AI Act. Beside CEMA request for a clarification of what is to be considered automatic and what is autonomy, CEMA requires a guidance on how to understand the terms "varying levels of autonomy". The definition of AI triggers in the first-place transparency obligations. However, it is the definition as High Risk under the AI Act that provides the obligation to comply with several different requirements.

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<sup>1</sup> President Biden's Executive Order (USA)

<sup>2</sup> Definition of AI proposed by the OECD and adopted with minor modifications in Art. 3. of the AI Act

Most of the functions driven by an AI on agricultural machinery might be classified as low risk. However, we cannot exclude that some AI driven functions could be classified as high-risk as outlined in Art. 6.1 of the AI act, compelling to fulfil the regulatory requirement .

#### *Article 6 Classification rules for high-risk AI systems*

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

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

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

Art. 6 of the AI Act defines a **high-risk AI** system based on specific classification rules that are cumulative. However, the concept of risk is to be interpreted as

*"The combination of the probability of an occurrence of harm and the severity of that harm"*

what calls for a differentiation of the risk depending on the environment of use. The AI act already focusses on a specific use of AI, but without further considering the actual use context.

The definition of "safety component" and "safety function" in Article 6 is unclear and requires guidance in the interpretation: Art. 6 provides the definition of "An AI System that is intended to be used as a safety component or is itself a product,"<sup>3</sup>. 'Safety component' on the other hand is defined in Art. 2 of the AI Act as:

*"a component of a product or of a system which fulfils a safety function for that product or system, or the failure or malfunctioning of which endangers the health and safety of persons or property;"<sup>4</sup>*

This definition differs from the definition of safety component in the Machinery Regulation that defines "safety component" as a

*"physical or digital component, including software, of a product within the scope of (the Machinery) Regulation, which is designed or intended to fulfil a safety function and which is independently placed on the market, the failure or malfunction of which endanger the safety of persons, but which is not necessary in order for that product to function or for which normal components may be substituted in order for that product to function" <sup>5</sup>*

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<sup>3</sup> Art. 6. 1. (a) AI Act

<sup>4</sup> Art. 2. AI Act

<sup>5</sup> Art. 2. Machinery Regulation

While the Machinery Regulation provides a definition of *safety function*,

*“As a function that serves to fulfil a protective measure designed to eliminate, or, if that is not possible, to reduce, a risk, which, if it fails, could result in an increase of that risk”*

the EU AI Act does not provide an explicit definition of 'safety function' leaving room for interpretation and highlighting the need for harmonized understanding across regulatory applications to avoid negative impact and inconsistencies in the compliance process of involved economic operators. Moreover, by including the potential endangerment of property in its definition of a safety component, the AI Act appears to broaden the scope of Article 6 beyond the Machinery Regulation, which primarily focuses on the safety of persons. This extension allows the AI Act to cover potential property damages — areas typically addressed post-incident through civil and tort law. The extensive compliance protection provided by the definition of safety component in the AI Act applies to property damages even if no person is at risk to be endangered by the AI system. It extends the protection way beyond Machinery Regulation and overlaps civil and tort law. Alignment in the interpretation of 'safety component' and 'safety function' is critical.

Article 6 of the AI Act provides the criteria for classifying a system as high-risk. Besides the requirement that the system concerns a safety component, it stipulates additional cumulative conditions. The system must also be 'covered by the EU legislation listed in Annex I of the AI Act' and be subject to third-party conformity assessment under those product legislations. Annex I lists several Regulations and Directives applicable to different sectors.

Essentially the AI Act stipulates that a high-risk AI system is defined by the requirement of being submitted to a third-party certification. However, it delegates the responsibility of defining what is to be considered in need of a third-party certification to the most relevant product legislation.

Annex I lists specific product applicable legislations. This includes the Machinery Regulation (EU) 2023/1230 and the Tractor Regulation 167/2013.

The Tractor Regulation currently submits all AI definitions to the AI Act. The Machinery Regulation (EU) 2023/1230, is not defining explicitly Artificial Intelligence however it is introducing the need of third-party conformity assessment in the following cases

*5. Safety components with fully or partially self-evolving behaviour using machine learning approaches ensuring safety functions.*

*6. Machinery that has embedded systems with fully or partially self-evolving behaviour using machine learning approaches ensuring safety functions that have not been placed independently on the market, in respect only of those systems.*

And the proper interpretation of the wording 'fully or partially self-evolving behaviour' is fundamental in order to provide the proper clarification.

Notably, the industry is already proposing for the fully or partially self-evolving definition in the Machinery Regulation a staggered approach, identifying five possible different levels:

1. Level 1: Deterministic software that ensures a safety function,

2. Level 2: AI software that ensures a safety function, is pre-trained by the OEM and does not independently learn after being placed on the market (specific release version). That includes new releases of software updates from transfer learning (aggregated information fed back to machinery for incremental improvement) and feedback loops (optimizing behaviour, but logic is predetermined - no changing behaviour),
3. Level 3: Self-evolving AI software used as a tool within deterministic software to ensure a safety function,
4. Level 4: Self-evolving AI software that ensures a safety function with a consulting function but requires the operator/driver to validate, steer, or decide to activate and override the safety function,
5. Level 5: Self-evolving AI software that ensures a safety function; it learns independently in the product from the OEM, without direct human intervention in activating the safety function.

Looking from an AI Act perspective in level 1-4 humans are always in control despite having an AI involved with a safety function however as the operator stays in control and the AI cannot be considered steering a safety function.

Finally, only the level 5 AI should fall in scope of Annex I part A of the Machinery Regulation and thus potentially fall under the high-risk systems.

Main message from the above discussions is the need for a harmonised interpretations of terms and definitions, and further common guidance for the involved legislations AI act, Machinery Regulation and tractor framework Regulation.

## AI integrated into future agricultural equipment represents an opportunity

In the rapidly advancing agricultural technology landscape, the incorporation of Artificial Intelligence (AI) into upcoming equipment signifies a substantial advancement in operational safety and efficiency. CEMA firmly believes that through the utilization of AI, our industry's equipment will not only enhance safety but also deliver unparalleled precision and automation in the field. This is crucial as the complexity of tasks and the environment necessitate the highest standards of reliability and performance.

Compared to other industries, the human safety risks associated with AI in agriculture are significantly limited, mainly because the operations take place in rural or forestry areas with little to no human presence. The adoption of AI technologies marks a profound shift in the landscape of farming and food production. AI in agriculture is not merely an incremental advancement but a game changer that will transform agricultural practices.

Scalable AI solutions in agriculture offer a promising opportunity to support both large-scale farms and small-scale agricultural businesses. By harnessing AI-driven data, analysis, automation, and precision agriculture, this technology has the potential to greatly enhance the efficiency of the whole sector.

AI-driven autonomous operations will help address and improve labour processes in the sector. The adoption of AI-driven autonomous operations, along with advanced predictive analytics of terrain conditions and weather, can optimize the use of machinery equipment, enabling efficient hazard detection. Thus, the risk to operators is significantly reduced in ways that cannot be achieved with other safety measures.

Furthermore, precision agriculture powered by AI can optimize Plant Protection products applications, minimizing chemical use and exposure for farmers.

## **More coherence with existing legislations, already addressing risks associated with equipment use**

The Machinery Regulation (EU) 2023/1230 and the Agricultural and Forestry Vehicles Regulation (EU) 167/2013 already addresses the inherent risks of machinery and vehicles, many of which can be drastically reduced or even eliminated by the introduction of AI systems. AI applications in agricultural equipment have the potential to mitigate risks associated with human errors and enhance sustainable production.

CEMA strongly supports the EU institutions' vision for legal consistency in AI applications. This consistency is not just a regulatory milestone; it is a foundational pillar that will ensure the smooth and safe integration of AI into agricultural and forestry equipment. It establishes a harmonized legal framework that encourages innovation while safeguarding public and environmental well-being. Failing to achieve this harmonization would lead to increased, and in some cases doubled, requirements such as additional documentation and reporting, multiple certifications by different bodies (e.g. certification under the Machinery Regulation and certification for AI for the same product), resulting in a practical obstacle to innovation and potentially raising machinery costs, thereby neutralizing the economic benefits for farmers gained through the adoption of the technology.

Our industry pledges to certify our AI-equipped machinery in accordance with the Machinery Regulation, with specific considerations for the integrated AI systems. The Machinery Regulation's clear identification of high-risk functions serves as a crucial guide for integrating AI into our equipment. This identification not only aligns with our industry's safety objectives but also reinforces our dedication to compliance and best practices within the EU's regulatory framework.

Furthermore, failing to achieve harmonization could lead to deviating requirements depending on the product legislation for example with the 167/2013 agricultural vehicles EU type approval framework Regulation ending up with a different interpretation than the Machinery Regulation.

## **Self-certification as an option based on AI risk assessment**

The potential for conflicting guidelines or requirements between the AI Act and specific product legislation is causing confusion and complicating efforts to comply. It is important to work towards greater harmonization, through official EU Commission AI Act Guidelines, industry dedicated

Guidelines and harmonized international standards, between these legal frameworks to make the compliance processes as efficient as possible. Consistency and legal certainty are crucial for encouraging innovation and practical use of AI in machinery while ensuring safety and ethical standards are upheld. In the changing landscape of regulatory compliance for AI systems, especially those possibly regarded as high risk under the current AI Act, it is essential to reassess, based on new insights, the certification process and improve efficiency while maintaining the highest safety and compliance standards. **In this context, carefully examining the potential integration of self-certification processes, in addition to third-party certification requirements, is necessary.**

The current requirement in the AI Act for third-party certifications of high-risk AI systems, while intended to provide independent oversight, also introduces potential redundancies and inefficiencies. These issues can arise in the form of conflicting opinions on certification methods among certifying bodies, unnecessary duplication of certification efforts, and a resulting strain on resources for AI system providers.

In addition, embedded AI cannot be separated from the machine itself. The complex interactions between machine AI interfaces require a comprehensive approach to certification. A unified certification process administered by a single body, the manufacturer, offers a practical solution to ensure the safety, reliability, and compliance of the entire system.

It is important to recognize the challenges posed by the early stage of AI standardization. While the evaluation of AI output can be standardized, interfering with the fundamental neural activation processes may reduce AI to deterministic software. Therefore, in the absence of specific standards, the industry should be empowered to employ its methodologies for risk evaluation. This flexibility will enable a more dynamic and responsive approach to safety and efficiency, ensuring that AI integration into agricultural equipment remains both innovative and secure.

**Arguably, the most suitable option is a well-structured self-certification process underpinned by rigorous legal and regulatory-compliant standards as well as robust internal compliance mechanisms integrating the already existing certification methods in place for agricultural and non-road mobile machinery.**

Manufacturers of AI systems possess in-depth knowledge and an understanding of their products. This includes AI algorithm details, data usage, operational parameters and potential risks associated with their use. Their expertise placed them in a unique position to evaluate whether the AI system meets regulatory requirements. Providing self-certification allows manufacturers to utilize and maximize this expertise to ensure compliance effectively and efficiently.

Manufacturers directly involved in the development of AI systems can adapt and respond more quickly to technological changes, enabling a faster pace of technology adoption. This agility ensures that AI products are brought to market without unnecessary delays while still complying with regulatory standards.

## Conclusions and Recommendations

AI has the potential to enhance the sustainability and economic viability of agriculture for farms of all sizes by boosting productivity and lowering costs. However, these benefits may be overshadowed



by unnecessary burdens on machinery manufacturers linked to being classified as high-risk under the AI Act, as well as the additional requirements and time-consuming certification processes.

**Self-certification** places the responsibility directly on manufacturers, incentivizing them to conduct thorough assessments of their AI systems to ensure compliance. This approach also fosters a culture of accountability, requiring manufacturers to stand behind the compliance and safety of their products. This approach can be especially effective in industries where brand reputation is critical. It is essential for agricultural applications to operate in a dynamic and innovation-friendly environment, enabling producers and farmers to access AI technologies and realize the benefits in a balanced and risk-conscious manner. The introduction of self-certification as an option, contingent upon a risk assessment will ensure that it is only allowed under appropriate conditions. Over time, with harmonised standards, touching on all relevant aspects related to data quality, record keeping, transparency, human oversight, accuracy, robustness, cybersecurity, quality management, conformity assessment, etc., such risk assessment can be practically implemented. CEMA emphasizes the need for the EU Commission to develop clear, actionable guidelines addressing the issues outlined above. These clarifications are essential to empower the industry to navigate the regulatory landscape confidently. The guidelines should specify how the rules under the AI Act can be adapted, based on risk assessments under the relevant product legislation as mentioned in Annex I, to the specific use cases and capacities of a particular industry. This will ensure that the integration of AI into agricultural machinery complies with current regulatory standards and is prepared for future developments and challenges.

## ABOUT CEMA

**CEMA aisbl** ([www.cema-agri.org](http://www.cema-agri.org)) is the association representing the European agricultural machinery industry. With 11 national member associations, the CEMA network represents both large multinational companies and numerous European SMEs active in this sector.

The industry comprises about 7,000 manufacturers, producing more than 500 different types of machines with an annual turnover of about €60 billion and 150,000 direct employees. CEMA companies produce a large range of machines that cover any activity in the field from seeding to harvesting, as well as equipment for livestock management.

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