

Position Paper

Proposal for a Regulation laying down harmonized rules on artificial intelligence (Artificial Intelligence Act-COM 2021/206)

October 2021

Introduction

Background information

CEN and CENELEC, two of the three European Standardization Organisations (ESO) together with ETSI, welcome the European Commission's proposal for a Regulation on Artificial Intelligence (AI), that provides a horizontal regulatory approach to AI, that is limited to the minimum necessary requirements to address the risks and problems linked to AI – while also ensuring EU's technological leadership.

CEN and CENELEC support the proposed risk-based regulatory approach to AI and recognize the efforts made to ensure consistency between the proposed regulation and other product legislations. In this context, the exact interplay between existing NLF legislation (e.g. Medical Device Regulation) and the proposed AI Regulation regarding conformity assessment procedures, notified body accreditation and scope, and competent authorities on national and European level, needs to be clarified with high priority. European Standards (ENs) will be valuable tools – voluntary and strongly founded on the WTO/TBT principles – for the development and promotion of coherent, transparent, open, and consensus-based technical requirements and specifications. European Standards, as defined by Regulation 1025/2012, are proven assets to the development of the Single Market and are used as a strategic European tool in support of legislations and public policies.

New Legislative Framework for AI systems' requirements

Therefore, CEN and CENELEC welcome the use of the New Legislative Framework (NLF) to support the development of the needed technical solutions and achieve compliance with the policy makers-defined requirements (essential requirements for high-risk AI systems). Under the NLF regime, once the harmonized standards are cited in the Official Journal of the European Union (OJEU), following compliant

assessments from the European Commission, manufacturers, economic operators, or conformity assessment bodies can use these harmonized standards to demonstrate that products, services, processes, or systems comply with EU legislation. Therefore, the use of the NLF can significantly contribute to the inclusive harmonization of the European Single Market with regards to AI, through the involvement of all relevant stakeholders in the standardization work.

Noting the role of the European Artificial Intelligence Board (EAIB) that will be established to issue opinions, recommendations or written contributions on matters related to the implementation of this Regulation, **CEN and CENELEC invite the European Commission to ensure the participation of ESOs' representatives in the EAIB and to ensure a close coordination with the European Commission's Multi-Stakeholder Platform on ICT standardization (MSP).**

Need to anticipate the development of harmonized standards

The timely availability of harmonized standards cited in the OJEU will be crucial for the implementation of the Artificial Intelligence Act. A standardization request will have to be issued by the European Commission to the ESOs to trigger the formal work on harmonized standards. Therefore, CEN and CENELEC invite the European Commission to start working on a dedicated draft standardization request that will be the basis for the development of the harmonized standards. In accordance with Article 8 of Regulation 1025/2012, **the European Commission is invited to introduce the development of harmonized standards in support of the Artificial Intelligence Act in next year's Annual Union Work Programme (AUWP).** CEN and CENELEC also recommend making available a detailed planning for these elements, to be able to anticipate standardization work as much as possible.

In this context, CEN and CENELEC also invite the European Commission to further address with the ESOs the requirements for AI systems that will be checked as part of the conformity assessment procedures under other sectorial NLF legislations. There is a need for a closer analysis on how the interaction between this proposed regulation and the sector-specific regulations should work in practice.

CEN and CENELEC's platforms for the development of harmonized standards

In 2020, CEN and CENELEC have established the Joint Technical Committee CEN-CENELEC/JTC 21 'Artificial Intelligence' to produce standardization deliverables in the field of AI and to consider for adoption at European level of those relevant international standards developed in ISO and IEC, in particular in [ISO/IEC JTC 1 SC 42](#). It is crucial to create the most relevant architecture of AI standards to support Europe's needs and to ensure a smooth alignment between the European and international standardization frameworks. To this end, CEN and CENELEC have dedicated agreements with ISO and IEC to notably ensure markets' harmonization. The high level of convergence between European and International Standards is facilitated by the technical cooperation in the frame of the Vienna (CEN-ISO) and Frankfurt Agreements (CENELEC-IEC).

The establishment of CEN-CENELEC/JTC 21 further expands the activities of the CEN-CENELEC Focus Group on AI, which has notably made available a response to the European Commission's White Paper on AI (see [here](#)), as well as the CEN-CENELEC standardization roadmap for AI (see [here](#)). These two documents have been developed in coordination with the European Commission and put forward a framework for the activities of CEN-CENELEC/JTC 21.

The risk of developing Common specifications

The proposal allows for the European Commission to develop and adopt its own common specifications if standards are not available, or if existing standards are deemed insufficient or if there is a need to address specific safety or fundamental rights concerns (Article 41). Regulation 1025/2012 establishes a clear separation between legislation, standardization, and conformity assessment. The European Single Market depends on voluntary and consensus-based standards, which involve all relevant stakeholders and ensure the availability of products in the European market that are compliant with the EU legislation. **The addition of article 41 in the AI regulation could lead to the substitution of harmonized standards with common specification creating a confusion in the marketplace and reducing the impact of European Standardization. CEN and CENELEC would like to underscore the benefits of the European Standardization System and the values that it is known for as the bedrock of a strong European industry that operates within our European values, without being limited in its development of new technologies.**

CEN and CENELEC, as European Standardization Organisations, ensure transparency in the standards' development process and guarantee openness and inclusiveness to all relevant stakeholders. ENs are developed through a consensus-based process, which ensures the interests of all stakeholders are taken into account. These aspects may not be met with the development of Common specifications by the European Commission.

Role of European Standards for the European digital society

European Standards play an important role in support of new technologies and in the trust, consumers place therein, e.g., with regards to the safety and security of products, services, systems, processes, the trustworthiness of providers, the accuracy of results and the privacy of the personal data being processed. They play an important role in enhancing the ethical reasoning and the ethical skills of developers and managers. The European Technical Committees that develop European Standards are made up of experts coming from the CEN and CENELEC members (which are recognized by national authorities), from 34 different countries. The work in European Technical Committees also relies on the contributions from the CEN and CENELEC partner and liaison organisations, and on the involvement of the Annex III organisations (representing consumers, workers, SMEs, and environmental interests). When a European standard is made available by CEN and/or CENELEC, it becomes the national standard of 34 countries and any conflicting standards are withdrawn, whether this standard concerns the adoption of an international standard as EN or

whether it concerns a specific 'homegrown' EN. **It is a cornerstone in the consolidation of the European Single Market and an important tool to ensure the technical implementation of the requirements set out in EU NLF legislations while making sure that no organisation, territory, or individual is left behind.**

For more information about the activities of CEN and CENELEC, please consult the [CEN and CENELEC's Work Programme for 2021](#).

About CEN and CENELEC

CEN (European Committee for Standardization) and CENELEC (European Committee for Electrotechnical Standardization) are recognized by the European Union (EU) and by the European Free Trade Association (EFTA) as European Standardization Organizations responsible for developing and defining standards at European level. These standards set out specifications and procedures in relation to a wide range of products and services. The members of CEN and CENELEC are the National Standards Bodies and National Electrotechnical Committees of 34 European countries including all of the EU member states plus Iceland, Norway, Switzerland, United Kingdom, Turkey and the former Yugoslav Republic of Macedonia. European Standards (ENs) are developed through a process of collaboration among technical experts nominated by business and industry, research institutes, consumer and environmental organizations and other societal stakeholders. Once adopted, these standards are implemented and published in all of the 34 countries covered by CEN and CENELEC. CEN and CENELEC also work to promote the international harmonization of standards in the framework of technical cooperation agreements with ISO (International Organization for Standardization) and IEC (International Electrotechnical Commission).

For more information, please visit: www.cencenelec.eu
