Industry calls on EU legislators to respect principles of the New Legislative Framework in the AI Act

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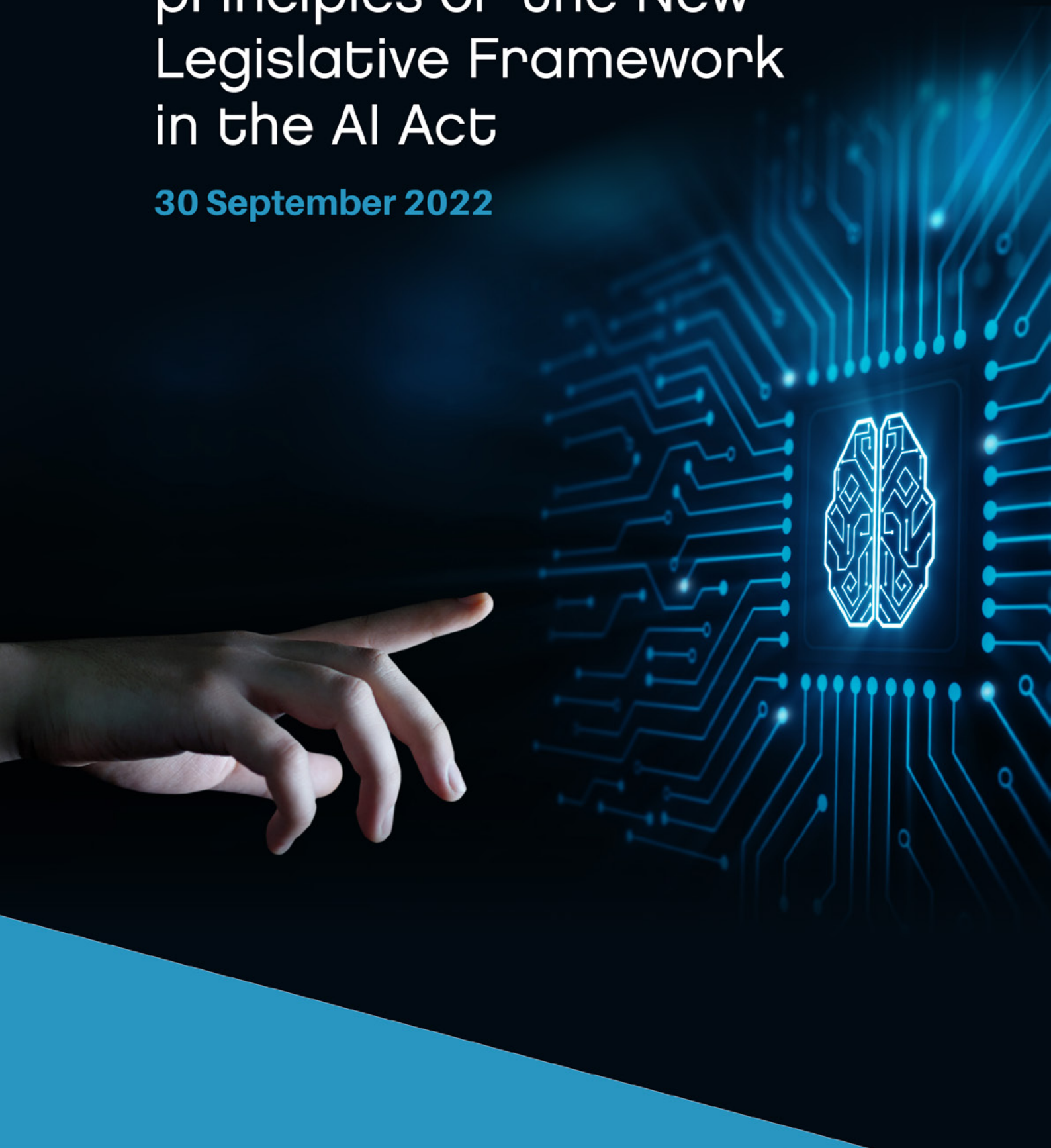

Introduction

The proposed regulation laying down harmonised rules on artificial intelligence (the Artificial Intelligence Act, henceforth called AI Act) builds on the legal architecture of the New Legislative Framework (NLF) for products. It adapts some of the well-established principles and concepts to accommodate the specificities of AI. The NLF creates a comprehensive regime for market surveillance, boosts the quality of conformity assessment, and enhances regulatory certainty and ease of compliance. It also improves safety for European consumers regarding products' safety and performance via strengthened oversight. While horizontal, the NLF represents a blueprint for a range of product legislation. Signatories support incorporating the concepts of the NLF into the AI Act. Therefore, when creating an additional layer of AI-specific requirements, it has to be ensured that the implementation of the AI Act is being done coherently in the product-specific legislation.

Questions and needs arise about how the horizontal provisions introduced in the AI Act would interact with existing requirements and obligations:

Definitions and concepts

The NLF acts as the leading framework for horizontal definitions across sector-specific legislation. As the AI Act will be applied to a broad set of products, falling under other sectoral legislation such as the Medical Devices Regulation (MDR), the *In Vitro* Diagnostic Medical Devices Regulation (IVDR), the Radio Equipment Directive (RED), the Low Voltage Directive (LVD), and the upcoming Machinery Products Regulation (MPR), it should be coherent with the NLF.

Legislators must be aware of the NLF concepts and the evolution of sector-specific concepts when negotiating legislative proposals to ensure consistency and alignment between legislations.

Recommendations:

- The proposed regulation not only modifies fundamental NLF principles and definitions such as '*economic operator*' and '*provider*', 'placing on the market', putting into service, and '*importer*'. In addition, it lacks a clear definition of '*risk*', a core concept of the conformity assessment procedure. These aspects create uncertainty for EU manufacturers and developers. If the AI Act is to be efficient and workable, we recommend that consistency with the NLF is maintained.
- The category of products mentioned in Art. 6 of the AI Act should be renamed in alignment with ongoing discussions to limit the scope of AI product applications to products with evolving behaviour (as in amendments to Annex I of MPR pos. 24 and 25).

Regulatory consistency

The signatories consider that the essential safety and performance requirements set out in the NLF regulations and existing sectoral requirements are well suited to ensure the safety of an AI-enabled product when placed on the market. For the AI Act, the requirements may duplicate existing requirements, including deviations from and conflicts with similar NLF-based requirements.

According to Art. 6 of the AI Act, an AI system can be classified as high-risk on 1) it is '*used as a safety component of a product, or is itself a product covered by the Union Harmonisation Legislation listed in Annex II*' and 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 Art. 6 would force companies to abide by overlapping classifications and obligations from the AI Act and their respective sectoral legislation.

The AI Act provides that following substantial modification, a new CE marking and thus, a new conformity assessment procedure should be undertaken by the entity conducting the modification for the modified parts. The conditions and criteria for a modification to constitute a "substantial modification" often vary significantly depending on the product to which the system is applied and the sectoral legislation (e.g., MDR/IVDR, MPR, RED and LVD) under which the product is regulated.

Recommendations:

- To ensure regulatory consistency, the signatories recommend that only products for which safety criteria based on the relevant sectoral legislation dictate a third-party conformity assessment procedure should be considered high-risk (i.e., according to a risk-based approach).
- The AI Act should respect sectoral specifications, such as what qualifies as a "substantial modification" per product and sector-specific risk classifications.
- Quality Management Systems and Risk Management for AI systems need to be integrated and be compatible with established Quality Management Systems and Risk Management Systems on a product level, similarly to Art. 17 (3) of the AI Act for credit institutions.

Responsibilities in the value chain (e.g., post-market surveillance)

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 regarding the obligations of providers, users, and other parties. According to Art. 24, 26, 27, 28 and 29 of the proposal, in situations where a high-risk AI system is made available on the market by a user, manufacturer, importer, distributor or any other third-party other than the original provider itself, these shall be subject to the same obligations imposed by existing requirements on providers of AI systems (Art. 16), including the obligation to provide the relevant technical documentation, as outlined under Art. 11 and 18.

Often the obligations assigned to the users and other parties can only be fulfilled by the provider of the embedded AI system, particularly regarding the requirement to prepare technical documentation, which inevitably requires detailed technical knowledge of the AI system in place. The legal responsibility to fulfil these obligations does not always lie with the legal or natural entity manufacturing the AI systems that controls its purpose, although it is the best-placed actor to ensure compliance. The NLF sets clear obligations and requirements for economic operators, which are the basis for establishing clear contractual relationships between product suppliers and manufacturers.

Recommendation:

The AI Act should allow economic operators in the AI value chain the freedom to allocate responsibilities through contractual agreements, following the actual conditions for AI-enabled product use. In all cases, responsibility should be allocated to the best-placed actors to ensure compliance. Should any obligations be moved from providers onto other parties by contractual agreements between the involved parties, detailed clarification, ensuring full product compliance under the AI Act would have to be established in those agreements.

Harmonised European standards aligned with international standards

One of the fundamental principles of the NLF is to avoid legislation providing technical details in the essential requirements and instead request European

Standardisation Organisations (ESOs) to develop and revise harmonised European standards. Through these, it supports practical implementation and enables a presumption of conformity. Harmonised European standards remain the best tool to reflect the fast-changing state-of-the-art, applications, and business models. ESOs often participate in standardisation activity at an international level and then transpose the work into harmonised European standards.

The signatories believe that legislation without the support of internationally recognised standards will create a barrier to the free movement of products and drive legal uncertainty. The introduction of common specifications (Art. 41 of the AI Act) in cases where relevant international standards exist is contrary to the principles of *the New Approach*, risking the creation of parallel and conflicting systems.

Recommendations:

- Harmonised standards should be preferred over common specifications to prevent Europe's decoupling from multilateral trading instruments. Following standardisation work already done at the international level is essential for European industry to be competitive.
- Common specifications should only be developed under strict and unambiguous conditions, including a proper *ex-ante* impact assessment. They should be seen as a temporary and exceptional 'fallback option' where harmonised standards do not exist and are not expected to be published within a reasonable time.
- Developing common specifications requires the industry's early involvement, consultation, and direct engagement. This engagement is key to ensuring market relevance, alignment with the technological state-of-the-art and application to various technologies, applications, and business models. Binding and transparent criteria for the commissioning or applying of these specifications should be created.

The NLF going forward

The NLF provides robust rules for state-of-the-art products reaching European businesses and consumers. It is also an innovation-friendly way to ensure safety and compliance.

On the other hand, AI is not just a technological tool embedded in products (i.e., software) but also a stand-alone product in specific sectors. Hence, in the development of the AI Act, it is paramount that the fundamental concepts of the NLF be preserved while considering the nature of AI. Changing NLF concepts would only result in regulatory distortion and misapplication of baseline requirements for manufacturers, exacerbating already existing economic and administrative burdens on Member States and responsible national authorities, but most importantly, adversely impacting European citizens.

Recommendation:

When creating an additional layer of AI-specific requirements, it must be ensured that the implementation of the AI Act is being done coherently in the product-specific legislation.

APPLiA, Home Appliance Europe is a Brussels-based trade association that provides a single, consensual voice for the home appliance industry in Europe. By promoting innovative, sustainable policies and solutions for EU homes, APPLiA, in conjunction with its 24 direct member companies and 26 National Associations, has helped build the sector into an economic powerhouse, with an annual turnover of €67 billion, investing over €1.4 billion in R&D activities and creating nearly 1 million jobs." www.applia-europe.eu/

CAPIEL is the European Coordinating Committee of Manufacturers of Electrical Switchgear and Controlgear. CAPIEL represents 9 national associations from 8 European countries. CAPIEL member associations include small, medium and large-sized companies representing more than 100,000 direct jobs across the EU. CAPIEL membership includes global players. www.capiel.eu

CECIMO represents globally the common position of European Machine Tool Industries and related Manufacturing Technologies, and promotes co-operation with other organisations worldwide. www.cecimo.eu

CECIP is the European association representing the weighing instrument industry. Founded in 1958, CECIP has currently members in 14 countries. The weighing instrument industry in Europe is world leader and consists of around 700 companies that are mostly SMEs. The total turnover is approximately 3 billion euro and the industry employs about 50.000 persons. www.cecip.eu

COCIR is the European Trade Association representing the medical imaging, radiotherapy, health ICT, and electromedical industries. Founded in 1959, COCIR is a non-profit association headquartered in Brussels (Belgium) with a China Desk based in Beijing since 2007. COCIR is unique as it brings together the healthcare, IT and telecommunications industries. We provide a wide range of services on regulatory, technical, market intelligence, environmental, standardisation, international and legal affairs. COCIR is also a founding member of DITTA, the Global Diagnostic Imaging, Healthcare IT and Radiation Therapy Trade Association. www.cocir.org

EFIC is the European Furniture Industries Confederation, representing over 70% of the total turnover of the European Furniture Industries, a sector employing 1 million people in about 120.000 enterprises across the EU and generating a turnover of over 100 billion Euros. The EFIC membership is composed of 17 national associations, one individual company member and several clusters. www.efic.eu

The European Garden Machinery industry Federation – EGMF – has been the voice of the garden machinery industry in Europe since 1977. With 30 European corporate members and 7 national associations representing manufacturers for garden, landscaping, forestry and turf maintenance equipment, we are the most powerful network in this sector in Europe. Our members are responsible for employing 120,000 people in the EU, and in 2021 sold over 23 million units on the European Market. www.egmf.org

EUnited, the European Engineering Industries Association, is the voice of machinery and equipment suppliers in Europe. EUnited connects machinery and equipment companies in one association to improve awareness and understanding among decision-makers and policy actors in the European Union institutions and to articulate the role of equipment suppliers in technical standards development, policy formulation, trade issues and legislation. Equipment suppliers are the mainstay of advanced manufacturing, increasingly recognized as indispensable for basic needs. www.eu-nited.net

Euralarm represents the electronic fire and security industry, providing leadership and expertise for industry, market, policy makers and standards bodies. Our members make society safer and secure through systems and services for fire detection and extinguishing, intrusion detection, access control, video monitoring, alarm transmission and alarm receiving centres. Founded in 1970, Euralarm represents over 5000 companies within the fire safety and security industry valued at 67 billion Euros. Euralarm Members are national associations and individual companies from across Europe www.euralarm.org

Europgen promotes the interests of the European generating set industry in its relations with customer, suppliers, European regulatory authorities, and government organizations. www.europgen.eu

MedTech Europe is the European trade association for the medical technology industry including diagnostics, medical devices, and digital health. Our members are national, European, and multinational companies as well as a network of national medical technology associations who research, develop, manufacture, distribute and supply health-related technologies, services, and solutions. www.medtecheurope.org

Orgalim represents Europe's technology industries, comprised of 770,000 innovative companies spanning the mechanical engineering, electrical engineering, electronics, ICT and metal technology branches. Together they represent the EU's largest manufacturing sector, generating annual turnover of over €2,480 billion, manufacturing one-third of all European exports and providing 10.97 million direct jobs. www.orgalim.eu