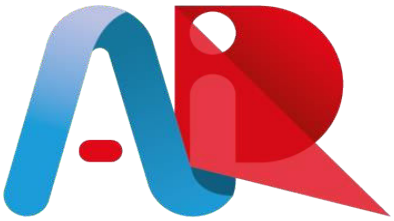

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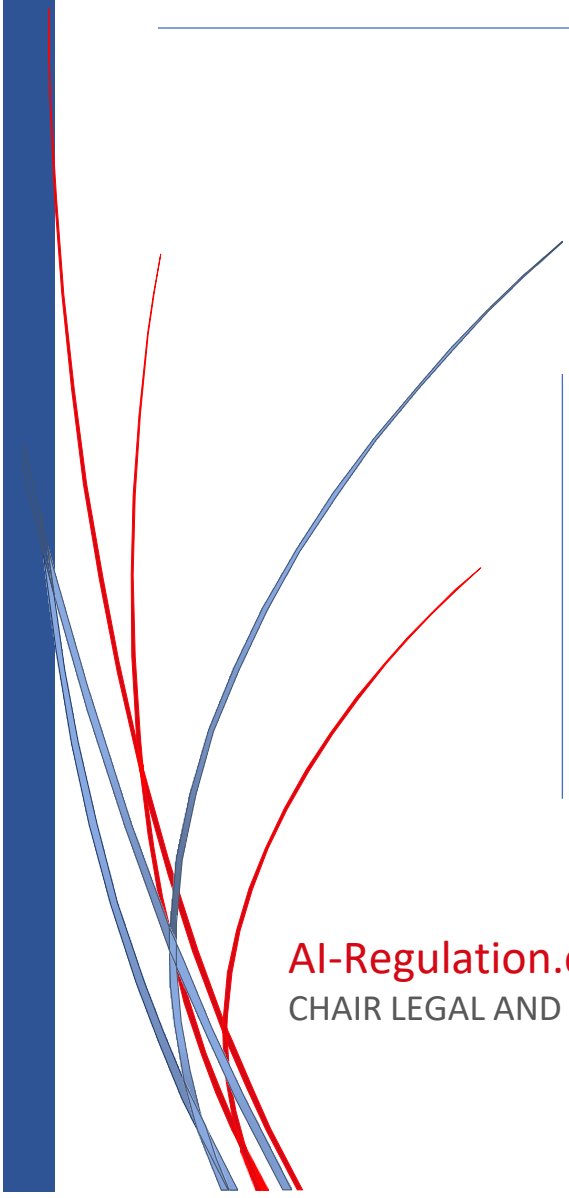
By Theodoros Karathanasis



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CHAIR LEGAL AND REGULATORY IMPLICATIONS OF ARTIFICIAL INTELLIGENCE

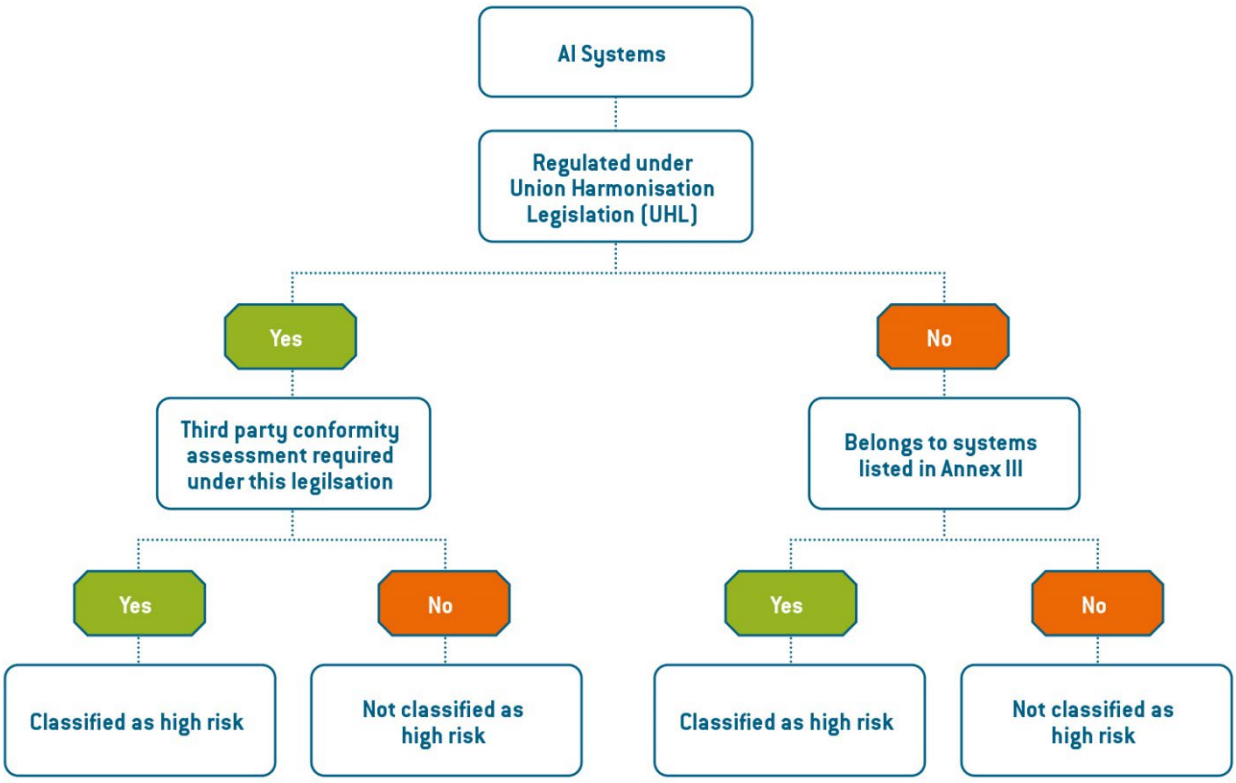
Guidance on Classification and Conformity Assessments for High-Risk AI Systems under EU AI Act

The adoption by the European Commission (Commission) of a proposal for a Regulation Laying Down Harmonised Rules On Artificial Intelligence (known as the "AI Act") in 2021 has been widely debated, in particular Article 6, according to which AI systems that could potentially harm fundamental rights are classified as high risk. Despite its value in terms of classifying AI systems as 'high risk' and imposing a requirement for third-party conformity assessments, Annex II of the AI Act seems to have attracted less interest mostly because of the technical nature of the debate around this issue. Considering the wide scope of the products covered by the AI Act, as well as the complexity involved in classifying AI systems intended to be used in the areas covered as high risk, the objective of this paper is therefore to provide guidance on the classification of high-risk AI systems as well as the conformity assessments that are required.

The Commission's proposal for an EU AI Act has been debated since April 2021 following an ordinary legislative procedure (co-decision)[1] at both the Council of the EU (Council) and the European Parliament (Parliament); as a result of this debate, it is likely to be amended. On December 6th, 2022, the Council firstly adopted its amendments to the AI act proposal under the Council Approach, while the AI Act is still under consideration at the Parliament (Parliament approach). The developments provided in this paper are based principally on the Commission's draft. The Council and Parliament approaches will be briefly invoked whenever its proposal has an impact on the classification and the conformity assessment of high-risk AI systems.

I. The High-Risk AI Systems' Classification procedure under Article 6 of the AI Act

Irrespective of whether an AI system is intended to be used as a safety component of a product,[2] or is itself a product, Article 6 of the AI Act provides that whenever the AI system is intended to be used in areas regulated by the legal acts listed in Annex II or Annex III of the AI Act, it shall be considered high risk. While AI systems that are intended to be used in areas covered by Annex III of the AI Act are automatically classified as high risk (Article 6§2 of the AI Act), the classification that falls within the scope of Annex II of the AI Act is characterised by having certain conditions (Article 6§1 of the AI Act).



[1] Article 294 of the Treaty on the Functioning of the European Union (TFEU)

[2] Irrespective of whether an AI system is placed on the market or put into service independently

1. The Conditions involved in the Classification of High-Risk AI Systems for Areas Covered under Annex II

Two conditions have to be fulfilled in order that an AI system that is intended to be used as a safety component of a product, or is itself a product, can be classified as high risk, in areas regulated by the legal acts listed in Annex II. First, the intended use of the AI system should fall within the Union harmonisation legislation listed in Annex II and second, it should be required to undergo a third-party conformity assessment with a view to placing it on the market or putting it into service pursuant to the aforementioned legislation.

a. The First Condition: That it be Regulated Under the Union Harmonisation Legislation listed in Annex II

Union harmonisation legislation covers a large range of manufactured products. It sets out common requirements on how a product has to be manufactured, including rules on its size and composition. Its aim is not only to eliminate barriers in terms of the free movement of goods in the single market, but also to ensure that only safe and compliant products are sold in the EU. Non-compliant and unsafe products put people at risk and might distort competition with economic operators that sell compliant products within the Union. Against this background, the Commissions states in recital 28 of the AI Act that "the safety risks eventually generated by a product as a whole due to its digital components, including AI systems", should be "duly prevented and mitigated".

Annex II of the AI Act therefore lists a number of directives and regulations that originate from Union harmonisation legislation and that cover products that include AI systems that may be intended to be used either as a safety component or as a product. However, the Commission makes a distinction between the legal acts that are based on the New Legislative Framework approach (Section A of Annex II) and those that are based on the Old approach (Section B of Annex II). The table, which is presented at the end of this paper, provides details on the two sections as well as the products concerned.

What is the New Legislative Framework (NLF) ?

The combination of Regulation (EC) 765/2008 and Decision (EC) 768/2008 has resulted in the New Legislative Framework (NLF), which includes all of the elements required for a comprehensive regulatory framework to operate effectively in order that industrial products may be safe and compliant. This framework is intended to cope with the requirements adopted to protect the various public interests and for the proper functioning of the single market. According to the Commission's evaluation of the NLF in late 2022, the technologically neutral regulatory framework is "perfectly suited to cope with the higher speed of technical innovation"[3].

This distinction relies on the interplay between the conformity assessment procedure provided by these legal instruments, and the AI Act, since additional requirements will become directly applicable and checked against the conformity assessment system that already exists under these two approaches.[4]

A conformity assessment procedure takes place before the product can be put on the market. The objective is to demonstrate that a product placed on the market complies with all legislative requirements and that it secures the confidence of consumers, public authorities and manufacturers.

Most of the legal acts detailed in section A provide detailed and exhaustive provisions on the conformity assessment requirements imposed on the products that they cover. According to Article 43§3 of the AI Act, providers of AI systems classified as high risk will have to comply not only with the relevant conformity assessment as required under these legal acts, but also with the requirements set out in Chapter 2, Title III of the AI Act and in points 4.3., 4.4., 4.5., 4.6§5 of Annex VII of the AI Act. At the same time, the Commission will amend the Union harmonisation legislation using the old approach (Section B, Annex II) throughout Articles 75-80 of the AI Act in order to ensure that "the mandatory requirements for high-risk AI systems, laid down in the AI Act, are considered when adopting any relevant future delegated or implementing acts on the basis of those acts".[5]

[3] See European Commission, "Staff Working Document Evaluation of the New Legislative Framework", Brussels, 11.11.2022 SWD(2022) 364 final, available at https://ec.europa.eu/transparency/documents-register/api/files/SWD(2022)364?ersIds=090166e5f3ae58d6

[4] See the requirements set out in Chapter 2, Title III of the AI Act, as well as points 4.3., 4.4., 4.5. and the fifth paragraph of point 4.6 of Annex VII

[5] Recital 29 of the AI Act

This brings us to the second criteria involved in classifying high-risk AI systems that fall within the scope of Annex II of the AI Act: the third-party conformity assessment criteria.

b. The Third-Party Conformity Assessment Criteria

Whenever AI systems undergo a conformity assessment procedure via a third-party conformity assessment body pursuant to the relevant Union harmonisation legislation, they have to be classified as high-risk AI systems (Article 6§1 of the AI Act).

A third-party conformity assessment should be understood, under the AI Act, as meaning the conformity assessment activities, which include testing, certification and inspection, that are conducted by a designated conformity assessment body on behalf of the national notifying authority. This therefore excludes any "in-house" conformity assessments.

While all[6] of the legal acts listed in section A of Annex II of the AI Act, which are also based on the NLF, clearly provide for third-party conformity assessments, the other legal acts listed in section B do not, for the most part, mention such assessments. This means that the fulfilment of this criteria is open to interpretation.

Indeed, with the exception of Directive 2014/90/EU on marine equipment, and Directive (EU) 2016/797 on the interoperability of the rail system within the EU, of which it is possible to find references to third-party conformity assessments, all of the other legal acts mentioned in section B, Annex II of the AI Act make no reference to "third-party conformity assessments". It is therefore unlikely that an AI system that is intended to be used in areas covered by these legal acts will be classified, since not all products are specifically required to undergo such a third-party conformity assessment. This is understandable since the third-party conformity assessment criteria under the AI Act has to be fulfilled, but it is not applicable in all situations.

However, Regulation (EU) 167/2013, Regulation (EU) 168/2013 and Regulation (EU) 2018/858 make reference to the term "technical service", which is worth analysing. Following the definition provided by these three legal acts, a "technical service" means "an organisation or body designated by the approval authority as a testing laboratory to carry out tests, or as a conformity assessment body to carry out the initial assessment and other tests or inspections". A definition that is quite similar to that of the third-party conformity assessment under the AI Act.

This leaves us with three legal acts: Regulation (EC) No 300/2008, Regulation (EU) 2018/1139 and Regulation (EU) 2019/2144. While they do not make explicit reference to third-party conformity assessments, the final two regulations refer to a certificate of conformity. It is clearly mentioned in Regulation (EU) 2018/1139 regarding common rules in the field of civil aviation, for example, that in order to be safe and environmentally compatible, the design of individual aircraft should comply with a certificate that is delivered by organisations responsible for the design and manufacture of products, parts and non-installed equipment. This is a procedure that one can reasonably imply is a third-party conformity assessment. Regarding the Regulation (EC) No 300/2008, no reference to a (third-party) conformity assessment is clearly stated.

The planned amendments to these legal acts under articles 75-80 of the AI Act will therefore ensure that the mandatory requirements for high-risk AI systems will be considered, when the Commission adopts "any relevant future delegated or implementing acts on the basis of those acts". It will also be important however to clarify the issues concerning the term "third-party conformity assessment".

2. The "Automatic" Classification of High-Risk AI Systems for Areas Covered under Annex III

In contrast to the procedure presented above that involves conditions, the procedure laid down in annex III is automatic since it does not involve any third-party conformity assessment criteria. In other words, each time an AI system is used in accordance with the areas listed under Annex III of the AI Act – either because it poses a health and safety risk or poses a risk to people's fundamental rights – it will be automatically considered "high risk".

However, it should be mentioned that the Council introduced an exception to this rule in its compromise text of December 6th, 2022. In cases where "the output of the system is purely accessory in respect of the relevant action or decision to be taken and is

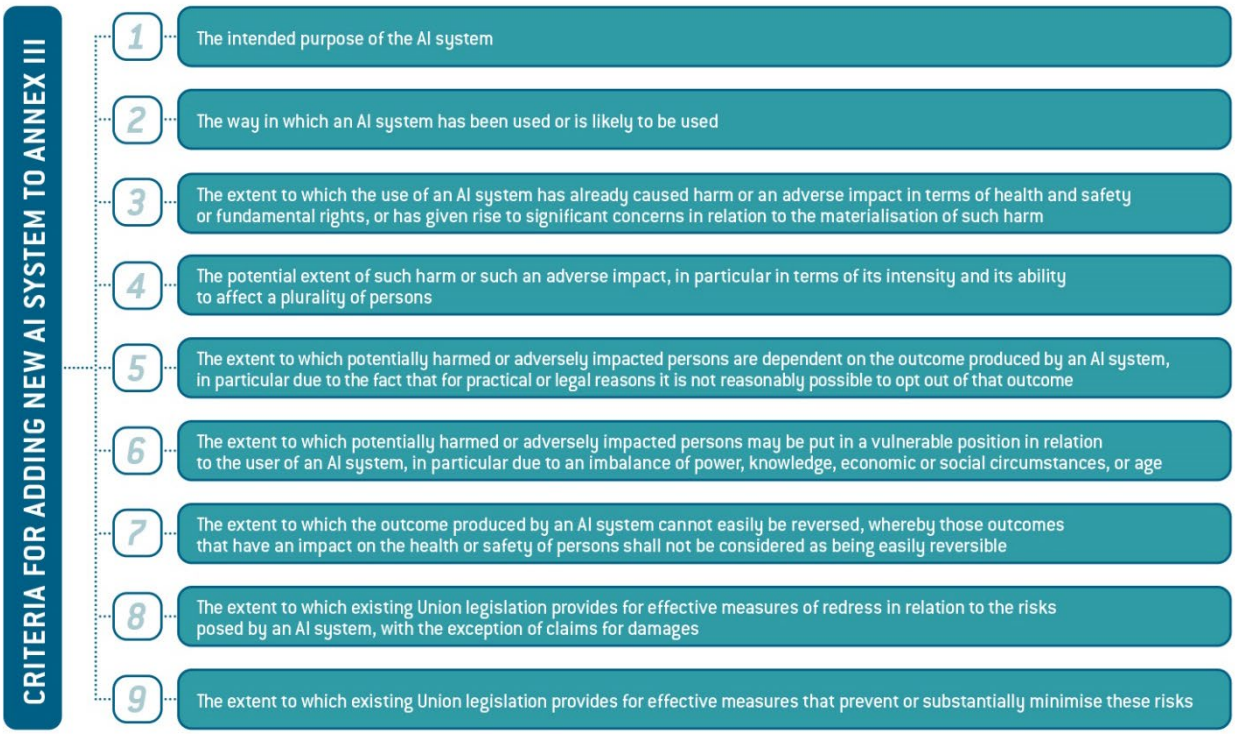
[6] Concerning Directive 2006/42/EC (known as the Machinery directive), which is listed in section A of Annex II, there is no mention of a third-party conformity assessment. However, a new draft Regulation (COM/2021/202 final), which is mentioned in the AI Act under the name of 'Machinery Regulation' and which is intended to replace Directive 2006/42/EC, was proposed by the Commission in 2021. This 'Machinery Regulation' mentions third-party conformity assessments.

not therefore likely to lead to a significant risk to the health, safety or fundamental rights", [7] the AI system should not be considered as high risk, even if it is intended to be used in accordance with the areas listed in Annex III. Therefore, over the first year following the entry into force of the AI Act, the Commission will have to adopt "implementing acts to specify the circumstances where the output of AI systems referred to in Annex III would be purely accessory in respect of the relevant action or decision to be taken".[8] For this purpose, the AI Act sets out an obligation for the Commission to follow the examination procedure[9] provided in Article 5 of Regulation (EU) 182/2011.

The critical areas covered by Annex III of the AI Act are as follows: (a) biometric identification and categorisation of natural persons; (b) management and operation of critical infrastructure; (c) education and vocational training; (d) employment, worker management and access to self-employment; (e) access to and enjoyment of essential public and private services and benefits; (f) law enforcement; (g) migration, asylum and border control management and (h) administration of justice and democratic processes. According to the Council and the Parliament Approaches, amendments to the critical areas and specific use cases listed in Annex III are expected to be proposed.

While the Council's Approach proposes removing the use of AI systems for the detection of deep fakes, for crime analytics and for the verification of the authenticity of travel documents and supporting documentation of natural persons, the Parliament approach is far more interventionist with regard to Annex III. The noteworthy amendments to cite are the intended use of AI systems for biometric identification and categorisation of natural persons, while a critical area concerning "other applications" was added. The Parliament is considering placing conversational and art-generating AI tools such as ChatGPT and DALL-E-2 in the high-risk category via this new critical area . "Subliminal techniques" used for therapeutic or scientific purposes may also end up in the high-risk bucket. However, the interinstitutional negotiations (known as trialogues[10]) need to be completed before the final contents of Annex III can be determined.

This list of critical areas included in Annex III of the AI Act is not set in stone; it may evolve. The Commission will be empowered to adopt delegated acts in accordance with Article 7 of the AI Act so that they may amend this list by adding high-risk AI systems, provided that certain conditions are fulfilled. Whether or not an AI system poses a health and safety risk, or a risk to people's fundamental rights, which is equivalent to or greater than the risk posed by the high-risk AI systems already referred to in Annex III, nine criteria should be taken into consideration by the Commission with regard to adding a new AI system to Annex III.[11]



[7] Article 6, para. 3 of the Councils General Approach
[8] Article 6, para. 3 of the Councils General Approach
[9] Article 6, para. 3 of the Councils General Approach and Article 74, para. 2 of the AI Act
[10] Informal tripartite meetings on legislative proposals between representatives of the Parliament, the Council and the Commission
[11] Article 7, para. 2 of the AI Act

It is worth noting here that the Commission's proposal for the AI Act does not contain any rules for removing high-risk AI systems from Annex III, once the aforementioned conditions are no longer being fulfilled. This issue is addressed in the Council's Approach and the addition of a third paragraph to Article 7 of the AI Act has been proposed. This paragraph provides the Commission with the option of removing items from Annex III if two conditions are fulfilled.[12] Firstly, the high-risk AI system concerned should no longer pose any significant risks to fundamental rights, health or safety, taking into account the criteria listed in paragraph 2 of Article 7 of the AI Act, and secondly, the removal should not decrease the overall level of protection of health, safety and fundamental rights under Union law. On February 1st, 2023, the establishment of a "regulatory dialogue with the competent authority in case the AI developers ask for their systems to be excluded from the high-risk category under Annex III" was also at the centre of the debate at the Parliament.

II. Conformity Assessment Procedure and Derogation (Articles 43 and 47 of the AI Act)

A conformity assessment procedure takes place before the product can be put on the market. The objective is to demonstrate that a product placed on the market complies with all legislative requirements and that it secures the confidence of consumers, public authorities and manufacturers. The purpose of this section is to enable understanding of the fact that the classification of high-risk AI systems under Article 6 of the AI Act affects the conformity assessment procedure that the providers will have to follow.

1. Conformity Assessment Procedure under Article 43

A distinction will be made once again in terms of whether the classification of high-risk AI systems pertains to areas covered by Annex II or Annex III of the AI Act.

a. For High-Risk AI Systems Classified Under Annex II

Most legal acts listed in Annex II provide detailed and exhaustive provisions on the conformity assessment procedure imposed on the products that they cover. However, Article 43§3 of the AI Act requires that providers of AI systems – classified as high-risk under Article 6§1 – should comply not only with the conformity assessment that concerns areas required under these legal acts but also, with the requirements set out in Chapter 2, Title III of the AI Act and in points 4.3., 4.4., 4.5., 4.6§5 of Annex VII of the AI Act. This encompasses requirements that cover the following areas : Risk Management, Data and Data Governance, Technical Documentation, Record-Keeping, Transparency and Provision of Information to Users, Human Oversight, Accuracy, Robustness and Cybersecurity.

Even if a product, or its safety component, is considered high risk under the relevant legal act listed in Annex II of the AI Act, it does not mean that this same system will automatically be considered a high-risk AI system under the AI Act (Recital 31). Regulations (EU) 2017/745 on medical devices and (EU) 2017/746[13] on *in vitro* diagnostic medical devices provide, for example, a third-party conformity assessment for medium risk and high-risk products. An AI-enabled medical device that is therefore considered a high-risk product under Regulation (EU) 2017/745 does not automatically mean that it is also a high-risk AI system in terms of the meaning provided by the AI Act. In order to be considered as such, the requirements set out in Article 43§3 of the AI Act have to be followed.

The same applies for opting out of a third-party conformity assessment.[14] Where a legal act – listed in section A, Annex II of the AI Act – allows a manufacturer to opt out of a third-party conformity assessment, the manufacturer may also make use of this option under the AI Act provided two conditions are fulfilled:

a) the manufacturer has applied all of the harmonised standards that cover all the relevant requirements specified in the legal act under the scope of which its product falls;
b) the manufacturer has applied harmonised standards or, where applicable, common specifications referred to in Article 41, covering the requirements set out in Chapter 2, Title III of the AI Act.

[12] Article 7, para. 3 of the Council General Approach
[13] Concerning Regulations (EU) 2017/745 and (EU) 2017/746 exclusively, Article 47 of the AI Act states that conformity assessment procedure derogations provided by these regulations "shall apply also with regard to the derogation from the conformity assessment of the compliance with the requirements set out in Chapter 2 of this Title [of the AI Act]"
[14] Article 43, para. 3 of the AI Act

b. For High-Risk AI Systems Classified Under Annex III

The AI Act also requires that conformity assessments be carried out for high-risk AI systems that are intended to be used in the areas listed in Annex III. However, a distinction is made between the providers that have to follow the conformity assessment procedure based on internal control, as required under Annex VI of the AI Act, and those that have to follow the conformity assessment procedure based on a quality management system and an assessment of their technical documentation, as required under Annex VII of the AI Act.

Two categories can be distinguished according to the areas listed in Annex III: the providers of AI systems that are intended to be used in biometric identification and categorisation of natural persons and those that are intended to be used in the other areas.

Regarding remote biometric identification systems, it should be noted that the AI Act provides for a choice of two procedures defined in Annex VI and Annex VII of the AI Act. If a provider demonstrates that a high-risk AI system complies with the requirements set out in Chapter 2, Title III of the AI Act, but it has not applied or has only partially applied the harmonised standards[15], or if such harmonised standards do not exist and common specifications[16] are not available, the provider will be forced to observe the conformity assessment procedure set out in Annex VII of the AI Act. Otherwise, Annex VI should apply.

According to the Parliament approach, amendments were proposed that have a direct impact on the providers of AI systems that involve biometric identification and categorisation of natural persons. Indeed, according to these amendments, a provider of AI systems that are intended to be used for biometric identification and categorisation of natural persons is also required to follow the conformity assessment procedure set out in Annex VII: "where one or more of the harmonised standards referred to in Article 40 has been published with a restriction; when the provider considers that the nature, design, construction or purpose of the AI system necessitate third party verification, regardless of its risk level". The long-awaited start of the interinstitutional negotiations will however be an opportunity to see if these proposed amendments will be retained or not.

For the rest of the areas provided for in points 2-8 of Annex III, the provider will have to follow the conformity assessment procedure set out in Annex VI in all cases.

2. Derogation

Article 47 of the AI Act provides that "any market surveillance authority may authorise [for a limited period] the placing on the market or putting into service of specific high-risk AI systems within the territory of the Member State concerned, for exceptional reasons of public security or the protection of life and health of persons, environmental protection and the protection of key industrial and infrastructural assets". In terms of the Parliamentary Approach, an amendment has been proposed to Article 47 of the AI Act in order to include the judicial authority in this procedure. Removing the term "public security" from the exceptional reasons listed in Article 47 of the AI Act has also been proposed.

Such an authorisation should only be issued if the market surveillance authority concludes that the high-risk AI system complies with the requirements set out in Chapter 2, Title III of the AI Act. The market surveillance authority may issue such an authorisation if the high-risk AI system complies with these requirements. With regard to high-risk AI systems that are intended to be used as safety components in devices, or which are themselves devices, they must abide by Regulation (EU) 2017/745 and Regulation (EU) 2017/746, in which case Article 59 of Regulation (EU) 2017/745 and Article 54 of Regulation (EU) 2017/746 should also apply.

Once the authorisation has been issued, the market surveillance authority is required to notify the Commission and the other Member States. Article 47 does not provide any legal redress mechanism for those providers willing to place on the market or put into service specific high-risk AI systems within the territory of the Member State concerned. A redress mechanism is however only available to the Commission or the Member States in order that they may object to the authorisation in the event that the system is found to not be compliant with the requirements set out in Chapter 2, Title III of the AI Act. In this case, the provider should be consulted and should only be afforded the option of presenting its views. Whenever the authorisation is considered unjustified, it should be withdrawn by the market surveillance authority of the Member State concerned. In terms of the Council Approach, it has been proposed to remove the paragraphs that provide the framework for this redress mechanism. Once again, the trialogues that involve the Commission, the Council and the Parliament should clarify this issue.

[15] As referred to in Article 40 of the AI Act
[16] As referred to in Article 41 of the AI Act

III. Conclusion

It should be understood from the aforementioned developments that the AI Act will certainly have a considerable impact on a wide range of products on the EU market, especially when one considers the number of areas and products that fall under the scope of the legal acts listed in Annex II, as well as the "dual" requirement of following both the conformity assessment procedures defined in the relevant legal act listed in Annex II, and in the AI Act.

As far as high-risk AI systems are concerned, the breadth of the scope of the AI Act, but also the exhaustiveness of the conformity assessment requirements and procedures, entail risks for consumer protection; especially when one considers the burdens on SMEs and start-ups willing to use AI technology in applications that are considered – or may in future be considered – high risk under the proposed AI Act.

The German Federal Council (Bundesrat) expressed, in its Resolution 488/21 of September 17th, 2021, the concern that "the capacities and competences of conformity assessment bodies can also be a bottleneck for the authorisation of certain high-risk applications". The significant negative impact on companies and on patient care, which resulted from the lack of designated conformity assessment bodies in the case of the implementation of Regulation (EU) 2017/745 (Medical Devices Regulation) and Regulation (EU) 2017/746 (In Vitro Diagnostic Medical Devices Regulation), is cited as an example.

Consideration should be given to the fact that this requirement relies on Member States, and that significant gaps in terms of fees for conformity assessments may appear across the EU, increasing the risk of non-compliance with the conformity assessment requirements. This is an issue that has also been considered in the Parliament, since it has been proposed that the following passage should be added to Article 43 of the AI Act: "the specific interests and needs of small suppliers must be taken into account when setting the fees for third-party conformity assessment, reducing those fees proportionately to their size and market share".

This amendment is difficult to understand since Article 55§2 of the AI Act contains almost the same statement: "the specific interests and needs of the SME providers, including start-ups, shall be taken into account by the Member States when setting the fees for **conformity assessment** under Article 43, reducing those fees proportionately to their size, market size **and other relevant indicators**". The additional intention of the Parliament Approach may be to reduce fees for third-party conformity assessments conducted under the legal acts listed in Annex II. However, this remains an important issue that should be clarified once the trialogues are initiated.

SCOPE OF UNION HARMONISATION LEGISLATION LISTED IN ANNEX II

A. Union harmonisation legislation based on the New Legislative Framework (New approach)

(a) Directive 2006/48/EC

Machinery[1]; Interchangeable equipment[2]; Safety components[3]; Lifting accessories[4]; Removable mechanical transmission devices[5]; Partly completed machinery[6]

(b) Directive 2009/48/EC

Products (toys[7]) designed or intended, whether or not exclusively, for use in play by children under 14 years of age

(c) Directive 2013/53/EU

Recreational craft[8]; Personal watercraft[9] and partly completed personal watercraft; Components[10]; Propulsion engines[11]; Propulsion engines installed on or in watercraft[12]; Watercraft that are subject to major craft conversion[13]

(d) Directive 2014/33/EU

Lifts permanently serving buildings and constructions[14]; Safety components for lifts listed in Annex III[15]

(e) Directive 2014/34/EU

Equipment[16] and protective systems[17] intended for use in potentially explosive atmospheres[18]; safety devices, controlling devices and regulating devices intended for use outside potentially explosive atmospheres[19]

(f) Directive 2014/53/EU

Radio equipment[20]

(g) Directive 2014/68/EU

Pressure equipment[21] and assemblies[22] with a maximum allowable pressure PS greater than 0,5 bar

(h) Regulation (EU) 2016/424

New cableway installations[23] designed to transport persons, to modifications of cableway installations requiring a new authorisation, and to subsystems[24] and safety components[25] for cableway installations

(i) Regulation (EU) 2016/425

Personal protective equipment (PPE)[26]

(j) Regulation (EU) 2016/426

Appliances[27] and fittings[28]

(k) Regulation (EU) 2017/745

Medical devices[29] for human use and accessories[30] for such devices; Groups of products without an intended medical purpose[31]

(l) Regulation (EU) 2017/746

In vitro diagnostic medical devices for human use and accessories for such devices

B. Union harmonisation legislation based on the Old approach

(a) Regulation (EC) No 300/2008

All airports or parts of airports located in the territory of a Member State[32]; all operators, including air carriers, providing services at airports[33]; all entities applying aviation security standards that operate from premises located inside or outside airport premises and provide goods and/or services to or through airports[34]

(b) Regulation (EU) No 168/2013

Wheeled tractors (Category T)[35]; Track-laying tractors propelled by endless tracks or by a combination of wheels and endless tracks (Category C)[36]; Trailers (Category R)[37]; Interchangeable towed equipment (Category S)[38]

(c) Regulation (EU) No 167/2013

Categories: L1e[39] light two-wheel powered vehicle; L2e[40] three-wheel moped; L3e[41] two-wheel motorcycle; L4e two-wheel motorcycle with side-car; L5e[42] powered tricycle; L6e[43] light quadricycle; L7e[44] heavy quadricycles

(d) Directive 2014/90/EU

Equipment placed or to be placed on board an EU ship[45], regardless of whether the ship is situated in the Union at the time when it is fitted with the equipment[46]

(e) Directive (EU) 2016/797

Union rail system

(f) Regulation (EU) 2018/858

Motor vehicles[47] of categories M and N and their trailers[48] of category O, that are intended to be used on public roads[49] and to systems[50], components[51] and separate technical units[52]; Parts[53] and equipment[54], designed and constructed for such vehicles and their trailers

(g) Regulation (EU) 2018/1139

Products, parts and equipment to control aircraft remotely by a natural or legal person[55]; The design, production, maintenance and operation of aircraft, as well as their engines, propellers, parts, non-installed equipment and equipment to control aircraft remotely; Safety-related aerodrome equipment[56]; The design, maintenance and operation of aerodromes, including the safety-related equipment used at those aerodromes[57]; The design, production, maintenance and operation of systems and constituents used in the provision of the ATM/ANS in the Single European Sky airspace

(h) Regulation (EU) 2019/2144

Vehicles of categories M, N and O[58]

1. An assembly, fitted with or intended to be fitted with a drive system other than directly applied human or animal effort, consisting of linked parts or components, at least one of which moves, and which are joined together for a specific application ; an assembly referred to in the first indent, missing only the components to connect it on site or to sources of energy and motion ; an assembly referred to in the first and second indents, ready to be installed and able to function as it stands only if mounted on a means of transport, or installed in a building or a structure ; assemblies of machinery referred to in the first, second and third indents or partly completed machinery referred to in point (g) which, in order to achieve the same end, are arranged and controlled so that they function as an integral whole; an assembly of linked parts or components, at least one of which moves and which are joined together, intended for lifting loads and whose only power source is directly applied human effort (Art. 2, point a, of Directive 2006/42/EC)
2. A device which, after the putting into service of machinery or of a tractor, is assembled with that machinery or tractor by the operator himself in order to change its function or attribute a new function, in so far as this equipment is not a tool (Art. 2, point b, of Directive 2006/42/EC)
3. A component which serves to fulfil a safety function ; which is independently placed on the market ; the failure and/or malfunction of which endangers the safety of persons, and; which is not necessary in order for the machinery to function, or for which normal components may be substituted in order for the machinery to function (Art. 2, point c, of Directive 2006/42/EC)
4. A component or equipment not attached to the lifting machinery, allowing the load to be held, which is placed between the machinery and the load or on the load itself, or which is intended to constitute an integral part of the load and which is independently placed on the market; slings and their components are also regarded as lifting accessories (Art. 2, point d, of Directive 2006/42/EC)
5. A removable component for transmitting power between self-propelled machinery or a tractor and another machine by joining them at the first fixed bearing. When it is placed on the market with the guard it shall be regarded as one product (Art. 2, point f, of Directive 2006/42/EC)
6. An assembly which is almost machinery, but which cannot in itself perform a specific application. A drive system is partly completed machinery. Partly completed machinery is only intended to be incorporated into or assembled with other machinery or other partly completed machinery or equipment, thereby forming machinery to which this Directive applies (Art. 2, point g, of Directive 2006/42/EC)
7. The products listed in Annex I shall not be considered as toys within the meaning of this Directive (Art. 2§1 of the Directive 2009/48/EC)
8. Any watercraft of any type, excluding personal watercraft, intended for sports and leisure purposes of hull length from 2,5 m to 24 m, regardless of the means of propulsion (Art. 3, point 2, of the Directive 2013/53/EU)
9. A watercraft intended for sports and leisure purposes of less than 4 m in hull length which uses a propulsion engine having a water jet pump as its primary source of propulsion and designed to be operated by a person or persons sitting, standing or kneeling on, rather than within the confines of, a hull (Art. 3, point 3, of the Directive 2013/53/EU)
10. As listed in Annex II of Directive 2013/53/EU
11. Any spark or compression ignition, internal combustion engine used directly or indirectly for propulsion purposes (Art. 3, point 5, of the Directive 2013/53/EU) and which is installed or specifically intended for installation on or in watercraft.
12. Major modification of a propulsion engine which could potentially cause the engine to exceed the emission limits set out in Part B of Annex I or increases the rated power of the engine by more than 15 % (Art. 3, point 6, of the Directive 2013/53/EU);
13. A conversion of a watercraft which changes the means of propulsion of the watercraft, involves a major engine modification, or alters the watercraft to such an extent that it may not meet the applicable essential safety and environmental requirements laid down in this Directive (Art. 3, point 7, of the Directive 2013/53/EU)
14. Intended for the transport of: persons; persons and goods; goods alone if the carrier is accessible, that is to say a person may enter it without difficulty, and fitted with controls situated inside the carrier or within reach of a person inside the carrier.
15. Devices for locking landing doors. devices to prevent falls referred to in point 3.2 of Annex I to prevent the car from falling or uncontrolled movements, overspeed limitation devices, energy-accumulating buffers (non-linear, or with damping of the return movement), energy-dissipating buffers, safety devices fitted to jacks of hydraulic power circuits where these are used as devices to prevent falls, electric safety devices in the form of safety circuits containing electronic components
16. Machines, apparatus, fixed or mobile devices, control components and instrumentation thereof and detection or prevention systems which, separately or jointly, are intended for the generation, transfer, storage, measurement, control and conversion of energy and/or the processing of material and which are capable of causing an explosion through their own potential sources of ignition (Art. 2, point 1, of the Directive 2014/34/EU)
17. Devices other than components of equipment which are intended to halt incipient explosions immediately and/or to limit the effective range of an explosion and which are separately made available on the market for use as autonomous systems (Art. 2, point 2, of the Directive 2014/34/EU)
18. A mixture with air, under atmospheric conditions, of flammable substances in the form of gases, vapours, mists or dusts in which, after ignition has occurred, combustion spreads to the entire unburned mixture (Art. 2, point 4, of the Directive 2014/34/EU)
19. But required for or contributing to the safe functioning of equipment and protective systems with respect to the risks of explosion due to local and operational conditions (Art. 2, point 5, of the Directive 2014/34/EU)
20. An electrical or electronic product, which intentionally emits and/or receives radio waves for the purpose of radio communication and/or radiodetermination, or an electrical or electronic product which must be completed with an accessory, such as antenna, so as to intentionally emit and/or receive radio waves for the purpose of radio communication and/or radio determination (Art. 2, point 1, of the Directive 2014/53/EU)
21. Vessels, piping, safety accessories and pressure accessories, including, where applicable, elements attached to pressurised parts, such as flanges, nozzles, couplings, supports, lifting lugs (Art. 2, point 1, of Directive 2014/68/EU)
22. Several pieces of pressure equipment assembled by a manufacturer to constitute an integrated and functional whole (Art. 2, point 6, of Directive 2014/68/EU)
23. A whole on-site system, consisting of infrastructure and subsystems, which is designed, constructed, assembled and put into service with the objective of transporting persons, where the traction is provided by cables positioned along the line of travel (Art. 3, point 1, Regulation (EU) 2016/424)
24. A system listed in Annex I, or a combination thereof, intended to be incorporated into a cableway installation (Art. 3, point 2, Regulation (EU) 2016/424)
25. Any component of equipment or any device intended to be incorporated into a subsystem or a cableway installation for the purpose of ensuring a safety function, the failure of which endangers the safety or health of passengers, operating personnel or third parties (Art. 3, point 4, Regulation (EU) 2016/424)
26. Equipment designed and manufactured to be worn or held by a person for protection against one or more risks to that person's health or safety; interchangeable components for equipment referred to in point (a) which are essential for its protective function; connexion systems for equipment referred to in point (a) that are not held or worn by a person, that are designed to connect that equipment to an external device or to a reliable anchorage point, that are not designed to be permanently fixed and that do not require fastening works before use (Art. 3, point 1, of Regulation (EU) 2016/425)
27. Appliances burning gaseous fuels used for cooking, refrigeration, air-conditioning, space heating, hot water production, lighting or washing, and also forced draught burners and heating bodies to be equipped with such burners (Art. 2, point 1, of Regulation (EU) 2016/426)
28. Safety devices, controlling devices or regulating devices and sub-assemblies thereof, designed to be incorporated into an appliance or to be assembled to constitute an appliance (Art. 2, point 2, of Regulation (EU) 2016/426)
29. Any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes: diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease; diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability; investigation, replacement or modification of the anatomy or of a physiological or pathological process or state; providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations; and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means. The following products shall also be deemed to be medical devices: devices for the control or support of conception; products specifically intended for the cleaning, disinfection or sterilisation of devices as referred to in Article 1(4) and of those referred to in the first paragraph of this point (Art. 2, point 1, of Regulation (EU) 2017/745)
30. An article which, whilst not being itself a medical device, is intended by its manufacturer to be used together with one or several particular medical device(s) to specifically enable the medical device(s) to be used in accordance with its/their intended purpose(s) or to specifically and directly assist the medical functionality of the medical device(s) in terms of its/their intended purpose(s) (Art. 2, point 2, of Regulation (EU) 2017/745)
31. That are listed in Annex XVI of the Regulation (EU) 2017/745

32. That are not exclusively used for military purposes
33. Located in the territory of a Member State that are not exclusively used for military purposes
34. Located in the territory of a Member State that are not exclusively used for military purposes
35. Article 4 of the Regulation (EU) No 167/2013
36. *Ibidem*
37. *Ibidem*
38. *Ibidem*
39. L1e-A vehicle (powered cycle) and L1e-B vehicle (two-wheel moped)
40. L2e-P vehicle (three-wheel moped designed for passenger transport) and L2e-U vehicle (three wheel moped designed for utility purposes)
41. L3e-A1 vehicle (low-performance motorcycle), L3e-A2 vehicle (medium-performance motorcycle), L3e-A3 vehicle (high-performance motorcycle), L3e-A1E, L3e-A2E or L3e-A3E enduro motorcycle and L3e-A1T, L3e-A2T or L3e-A3T trial motorcycle
42. L5e-A vehicle (tricycle): vehicle mainly designed for passenger transport and L5e-B vehicle (commercial tricycle): utility tricycle exclusively designed for the carriage of goods
43. L6e-A vehicle (light on-road quad), L6e-BU vehicle (light quadri-mobile for utility purposes): utility vehicle exclusively designed for the carriage of goods and L6e-BP vehicle (light quadri-mobile for passenger transport): vehicle mainly designed for passenger transport
44. L7e-A1: A1 on-road quad, L7e-A2: A2 on-road quad, L7e-B1: all terrain quad, L7e-B2: side-by-side buggy, L7e-CU vehicle (heavy quadri-mobile for utility purposes): utility vehicle exclusively designed for the carriage of goods and L7e-CP vehicle (heavy quadri-mobile for passenger transport): vehicle mainly designed for passenger transport
45. For which the approval of the flag State administration is required by the international instruments
46. Notwithstanding the fact that the equipment referred to in paragraph 1 may also fall within the scope of instruments of Union law other than this Directive, that equipment shall, for the purpose set out in Article 1, be subject only to this Directive (Art. 3§2 of the Directive 2014/90/EU)
47. Any power-driven vehicle that is designed and constructed to be moved by its own means, that has at least four wheels, is complete, completed or incomplete, and has a maximum design speed exceeding 25 km/h (Art. 3, point 16, of Regulation (EU) 2018/858)
48. Any non-self-propelled vehicle on wheels designed and constructed to be towed by a motor vehicle, that can articulate at least around a horizontal axis perpendicular to the longitudinal median plane and around a vertical axis parallel to the longitudinal median plane of the towing motor vehicle (Art. 3, point 17, of Regulation (EU) 2018/858)
49. Including those designed and constructed in one or more stages
50. An assembly of devices combined to perform one or more specific functions in a vehicle and that is subject to the requirements of this Regulation or any of the regulatory acts listed in Annex II (Art. 3, point 18, of Regulation (EU) 2018/858)
51. A device that is intended to be part of a vehicle, that can be type-approved independently of a vehicle and that is subject to the requirements of this Regulation or any of the regulatory acts listed in Annex II where the specific regulatory act makes express provision to that effect (Art. 3, point 19, of Regulation (EU) 2018/858)
52. A device that is intended to be part of a vehicle that can be type-approved separately, but only in relation to one or more specified types of vehicle and that is subject to the requirements of this Regulation or any of the regulatory acts listed in Annex II where the specific regulatory act makes express provisions to that effect (Art. 3, point 20, of Regulation (EU) 2018/858)
53. Goods used for the assembly, repair and maintenance of a vehicle, as well as spare parts (Art. 3, point 21, of Regulation (EU) 2018/858)
54. Goods other than parts that can be added to or installed on a vehicle (Art. 3, point 22, of Regulation (EU) 2018/858)
55. Under the oversight of the Agency or a Member State (Art. 2§1, point a, of the Regulation (EU) 2018/1139)
56. Aerodromes, located in the territory to which the Treaties apply, , which: (i) are open to public use; (ii) serve commercial air transport; and (iii) have a paved instrument runway of 800 metres or more, or exclusively serve helicopters using instrument approach or departure procedures; (Art. 2§1, point d and e, of the Regulation (EU) 2018/1139)
57. Located in the territory to which the Treaties apply
58. As defined in Article 4 of Regulation (EU) 2018/858

These statements are attributable only to the author, and their publication here does not necessarily reflect the view of the other members of the AI-Regulation Chair or any partner organizations.

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