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When AI meets machinery – the role of the notified body

Håkan Burden, Susanne Stenberg and Kristian Flink

RISE Report : 2024:56

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Please cite as:
H. Burden, S. Stenberg and K. Flink, ” When AI meets machinery – the role of the notified body”, 2024.

Key words: AI Act, Machinery regulation, New legislative framework, CE-marking, AI certification, Policy development.

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RISE Research Institutes of Sweden AB

RISE Report : 2024:56
ISBN: 978-91-89971-16-5

Abstract

Our ambition is to give an overview of the mandatory involvement of notified bodies according to the AI Act and the Machinery Regulation. Specifically, we are interested in the cases when both acts are applicable for the same product.

That said, our analysis is not to be taken as legal advice but as policy research and we recommend the reader to cross-examine our conclusions by assessing the acts in relation to the products at hand. It is also worth remembering that the focus of the analysis is when a notified body is mandatory for CE-marking a product – we do not describe what is needed to meet requirements on technology and organisation, and it is always possible to opt to include a notified body in the conformity assessment even if it is not mandatory.

Another limitation is that we do not explore the full interaction between the AI Act and the Machinery Regulation, or how they interact with other policies relevant for CE-marking products intended for EU's internal market.

Our main conclusions of the analysis are that:

- We should not focus on how the definition of Artificial Intelligence in the AI Act relates to the concept of "fully or partially self-evolving behaviour using machine learning approaches" as introduced by the Machinery Regulation; but instead
- We should focus on when the Machinery Regulation mandates the involvement of a notified body and how that relates to the AI Act.

We also foresee an up-coming bottleneck in the availability of notified bodies capable of performing the duties in relation to both the AI Act and the Machinery Regulation, something that can have an effect on access to the internal market.

Håkan Burden, Susanne Stenberg and Kristian Flink,
Sweden, October 2024

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1 Overview

The purpose of this report is to address the topic of the involvement of notified bodies when CE-marking products according to both the Machinery Regulation[1] and the AI Act[2]. In general, the Machinery Regulation comes into force on January 14th, 2027, but the articles defining the requirements on, and responsibilities of the notified body are applicable from January 14th 2024. The AI Act comes into force on August 2nd, 2026. However, article 6(1) that has an effect on when a notified body is obligatory in the conformity assessment process does not come into force until a year later. That means that the Machinery Regulation comes into force seven months before the AI Act is applicable for machinery. The requirements on and responsibilities of the notified body, according to the AI Act, are applicable from August 2nd, 2025.

The report starts off with a short summary of the AI Act, then a similar summary of the Machinery Regulation before we give a concrete example of how the two interact.

2 The AI Act

We cherry pick what we think are the most important aspects of the AI Act to consider in relation to the role of the notified body. We start with some definitions before we show how the relevant articles combine to determine if a notified body shall be part of the conformity assessment process, or not.

2.1 Defining Artificial Intelligence

The following definitions are verbatim from the AI Act, article 3.

AI system "means a machine-based system designed to operate with varying levels of autonomy, 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".[3]

Safety component "means 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".

[1] Regulation (EU) 2023/1230 of the European Parliament and of the Council of 14 June 2023 on machinery and repealing Directive 2006/42/EC of the European Parliament and of the Council and Council Directive 73/361/EEC, https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32023R1230

[2] Regulation (EU) 2024/1689 of the European Parliament and of the Council of the 13 June 2024 laying down harmonised rules on artificial intelligence and amending Regulations (EC) No 300/2008, (EU) No 167/2013, (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1139 and (EU) 2019/2144 and Directives 2014/90/EU, (EU) 2016/797 and (EU) 2020/1828 (Artificial Intelligence Act), https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32024R1689.

[3] Guidance for how the definition is to be interpreted and implemented will be supplied by the AI Office before the act is applicable.

Risk "means the combination of the probability of an occurrence of harm and the severity of that harm".

Here it is worth pointing out that the AI Act does not have its own definition of "safety function", nor is there a general definition in the foundational acts of the New legislative framework, the EU regiment for product safety.[4] Some of the product-specific acts building upon the New legislative framework have a definition, some do not.[5]

2.2 Conformity assessment of AI

From now on, when we write AI-system, we assume that the AI system fits the definition given by the AI Act and is within the scope of the act. A schematic representation showing when the involvement of a notified body is mandatory, is provided in Figure 1.

Article 6(1): For the involvement of a notified body to be obligatory in the conformity assessment procedure of an AI system, two conditions need to be met:

1) The AI system is in itself a product listed in Annex I(A), or is used as a safety component in such a product, and
2) The conformity assessment procedure for the product requires the involvement of a notified body.

The AI Act refers to these AI systems as high-risk AI systems, but we use the term CE-marked AI systems instead since the risks should be mitigated to a reasonable degree before the products are taken into use or put on the market. [6]

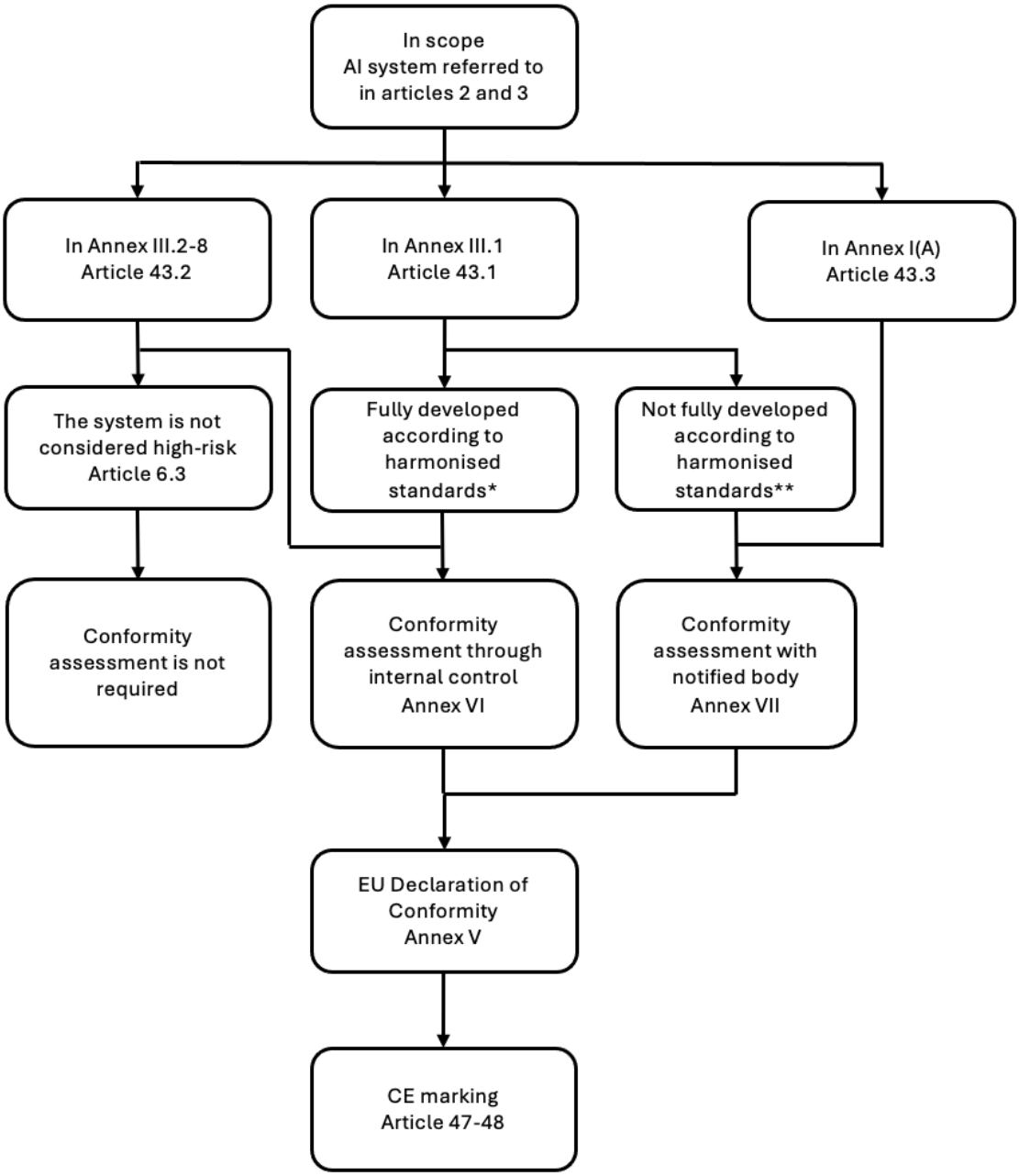
Article 43(3): The products referred to in Annex I(A) should undergo the conformity assessment procedure prescribed in the relevant regulations and directives (e.g. the Machinery Regulation for machinery, the Toy Safety Directive for toys etc). Conformity shall also be assessed in accordance with the AI Act as described in Annex VII, points 4.3 to 4.6 (see below).

For the AI system to be CE-marked there needs to be technical documentation that shows how the system fulfils the technical requirements in articles 9 to 15, and that the quality management system fulfils the requirements of article 17.

[4] Regulation (EC) 765/2008, Decision 768/2008 and Regulation (EU) 2019/1020. See links on the Commission's webpage for the New legislative framework, https://single-market-economy.ec.europa.eu/single-market/goods/new-legislative-framework_en

[5] Again, see the links on the Commission's webpage for the New legislative framework.

[6] There are more AI systems that need to be CE-marked but they are out of scope for this report.



* There are relevant harmonised standards and/or common specifications for all requirements in articles 9-15, and these have been followed when developing the system.
** There is a lack of harmonised standards and/or common specifications for the requirements in article 9-15, or these have not been followed in the development of the system.

Figure 1: The mandatory involvement of notified bodies according to the AI Act.

Annex I(A): The products regulated under the New legislative framework and relevant for the AI Act are the ones covered in the following:

Directive 2006/42/EC on machinery, to be replaced by the Machinery Regulation;
Directive 2009/48/EC on the safety of toys;
Directive 2013/53/EU on recreational craft and personal watercraft;
Directive 2014/33/EU on lifts and safety components for lifts;
Directive 2014/34/EU on equipment and protective systems intended for use in potentially explosive atmospheres;
Directive 2014/53/EU on radio equipment;
Directive 2014/68/EU on pressure equipment;
Regulation (EU) 2016/424 on cableway installations;
Regulation (EU) 2016/425 on personal protective equipment;
Regulation (EU) 2016/426 on appliances burning gaseous fuels;
Regulation (EU) 2017/745 on medical devices;
Regulation (EU) 2017/746 on in vitro diagnostic medical devices.

Annex VII: For the AI system to be CE-marked a notified body shall assess if the technical documentation shows how the system fulfils the technical requirements in articles 9 to 15, and if the quality management system fulfils the requirements of article 17 (points 4.3 – 4.6).

It is now time to turn our attention to the Machinery Regulation.

3 The Machinery Regulation

Just as for the AI Act, we have chosen what we see as relevant definitions and legal grounds in relation to the obligation of involving a notified body in the conformity assessment procedure. First out are the definitions.

3.1 Defining machinery and related products

The relevant definitions can be found in article 3 of the Machinery regulation and in Annex III(A) of the same act. It is worth pointing out that the definition of safety component differs between the Machinery Regulation and the AI Act, so that the term has to be assessed depending of the object under consideration – the definition in the Machinery Regulation is applicable to machinery, the definition in the AI Act is applicable for AI systems. The same way of working has to be applied to the concept of risk as they differ between the two acts.

Machinery "means: (a) 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; (b) an assembly referred to in point (a), missing only the components to connect it on site or to sources of energy and motion; (c) an assembly referred to points (a) and (b), 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; (d) assemblies of machinery referred to in points (a), (b) and (c), or of partly completed machinery, which, in order

to achieve the same end, are arranged and controlled so that they function as an integral whole; (e) 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; (f) an assembly as referred to in points (a) to (e) missing only the uploading of the software intended for the specific application foreseen by the manufacturer".

Safety component "means a physical or digital component, including software, of a product within the scope of this 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".

Safety function "means 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".

Risk "means a combination of the probability and the degree of an injury or damage to health that can arise in a hazardous situation;".

So, the AI Act does not have a definition of a "safety function", but the Machinery Regulation does. That could be worth keeping an eye on.

3.2 Conformity assessment of machinery

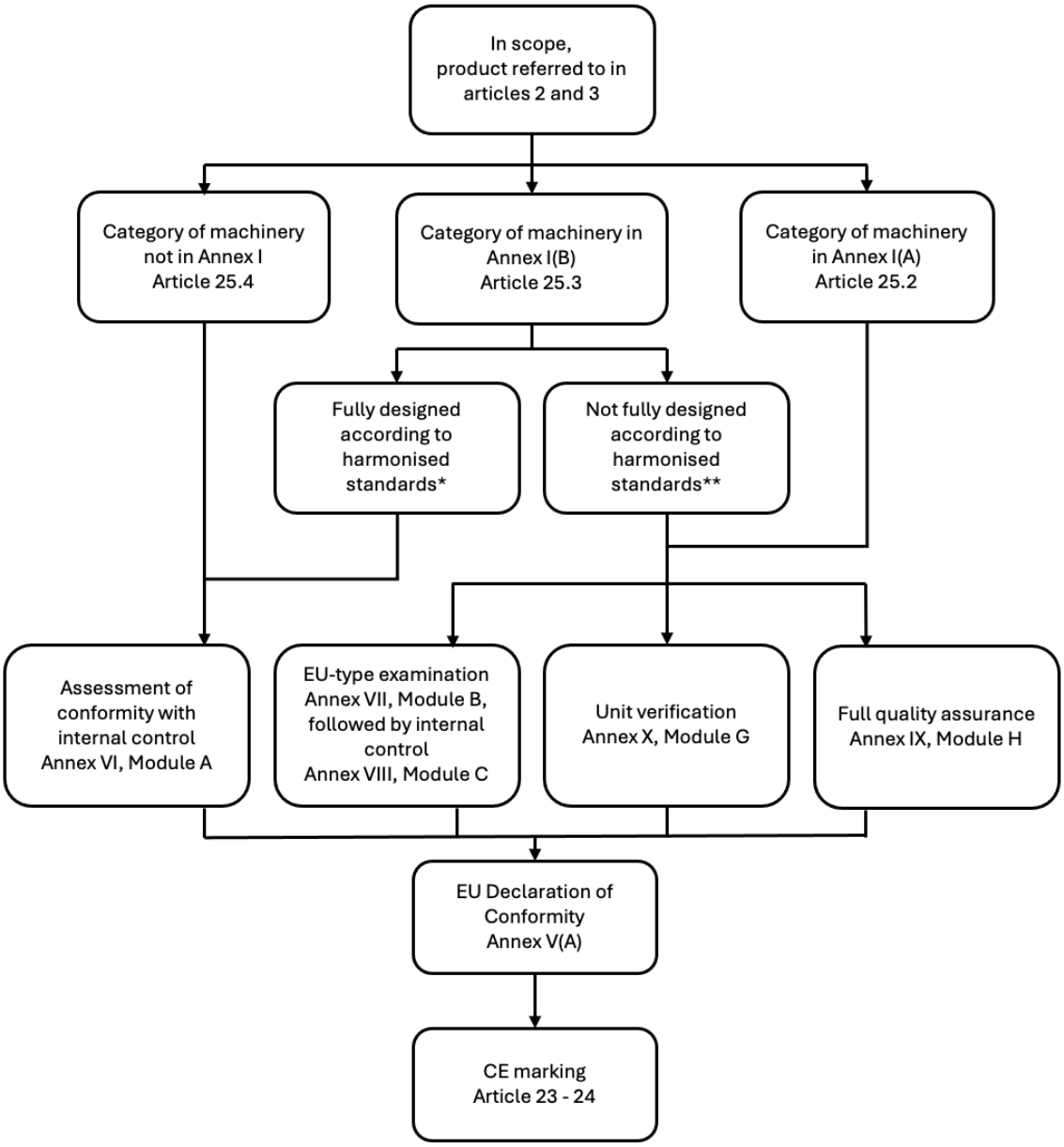
From now on, when we write machinery or machine, we refer to a product that is regulated by the Machinery Regulation and fulfils the definition of machinery. The different paths that lead to the obligatory involvement of a notified body is illustrated in Figure 2.

Article 25(2): The machinery listed in Annex I(A) shall undergo the conformity assessment procedure described in Module B followed by Module C, Module G or Module H.

Module B (EU type-examination): The notified body assesses the technical documentation and examines a specimen that is representative of the product to be put on the market (Annex VII). This is then followed by conformity assessment according to Module C (Conformity to type based on internal production control) so that all measures necessary are taken to ensure conformity of the product with the type described in the EU type-examination certificate (Annex VIII).

Module G (Conformity based on unit verification): The notified body assesses the technical documentation and examines an example of the product (Annex X).

Module H (Conformity based on full quality assurance): The notified body assesses the quality management system and makes observations on the premises where the product is manufactured (Annex IX).



* There are harmonised standards and/or common specifications for all relevant essential health and safety requirements in Annex III, and these have been followed in the design and construction of the product.
** There is a lack of harmonised standards and/or common specifications for relevant essential health and safety requirements in Annex III, or these have not been followed in the design and construction of the product.

Figure 2: The mandatory involvement of notified bodies according to the Machinery Regulation.

Article 25(3): The machinery listed in Annex I(B) shall also undergo conformity assessment according to Module B followed by Module C, Module G or Module H if one of the following hold for true:

1) There is a lack of harmonised standards or common specifications for relevant requirements on health and safety in relation to the product at hand, or
2) There are harmonised standards and/or common specifications covering relevant health and safety requirements, but these have not been applied.

Or, in other words, if the products listed in Annex I(B) have been fully designed according to harmonised standards and/or common specifications for all relevant essential health and safety requirements in Annex III (of the Machinery Regulation), there is no obligation to involve a notified body in the conformity assessment.

Annex I(A): The following list is verbatim from the Machinery Regulation:

1) Removable mechanical transmission devices including their guards.
2) Guards for removable mechanical transmission devices.
3) Vehicle servicing lifts.
4) Portable cartridge-operated fixing and other impact machinery.
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.

The term "self-evolving behaviour" is not defined in the Machinery Regulation nor in the AI Act. It seems it should be interpreted as behaviour that is not fully defined at the time the safety component is placed on the market or taken into use, but rather as behaviour that is defined at run-time when the safety component is activated.[7]

Annex I(B): The following is our summary of machinery or related products found in Annex I(B):

Circular saws, band-saws with manual loading and portable chainsaws.
Handheld planning machinery and thicknessers.
Hand-fed tenoning machinery and vertical spindle moulding machinery.
Presses.
Injection or compression machinery used for plastics or rubber.
Machinery used for working underground, including locomotives.
Manually loaded trucks used for collecting household refuse that incorporate a compression mechanism.
Devices for the lifting of persons and goods.
Protective devices designed to detect persons.

[7] See responses from a Q&A organised by the Commission together with CEN och CENELEC, https://www.cencenelec.eu/media/CEN-CENELEC/Events/Webinars/2024/q-a_report_machinery_webinar_2024-02-23.pdf.

Logic units to ensure safety functions.
Roll-over and falling object protective structures, abbreviated ROPS and FOPS respectively.

Before we give an example of the AI Act and Machinery Regulation interact, we will pay some attention to the red herring of how AI relates to “self-evolving behaviour using machine learning approaches”.

4 Artificial Intelligence and machine-learning approaches

The used definitions of the AI Act means that the act can cover a broader scope of products that fulfil being AI-based safety components, compared to the Machinery Regulation. The latter’s approach focuses on machine learning approaches while the former emphasises how input is used to infer how to generate output, where inference can include logic- and knowledge-based approaches besides machine-learning approaches.

In fact, the Machinery Regulation does not use the concept of AI in the articles so trying to understand the interaction between the two regulations has to be based on what the articles state, not the idea of both referring to the same concept or idea with different words. We will try to do that next by looking at examples of products that trigger the mandatory involvement of a notified body in the conformity assessment.

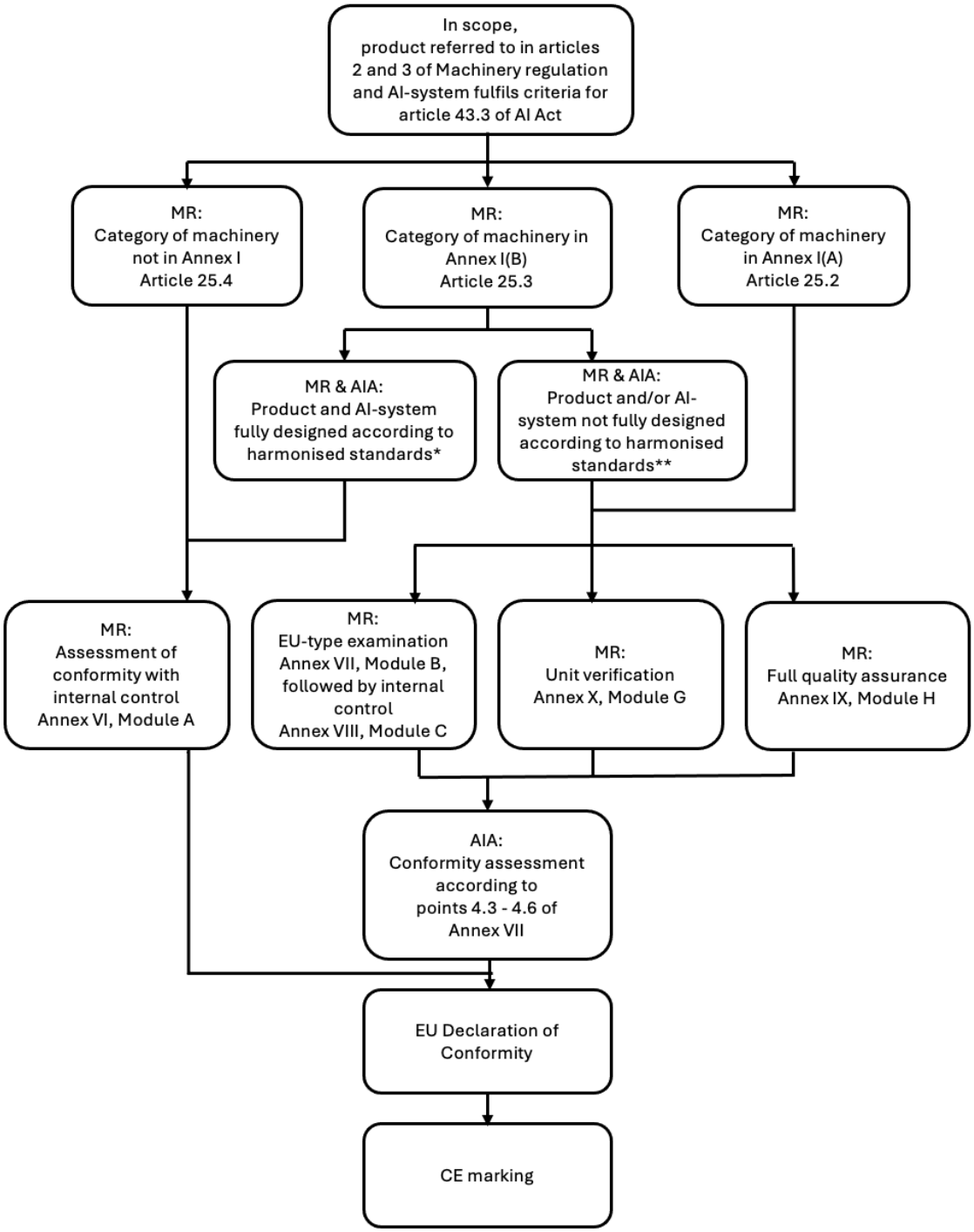
5 Examples of AI meeting machinery

This section provides an example of how the two regulations interact when examining a machine with an AI-based safety component, from the perspective of involving notified bodies in the conformity assessment procedure. A schematic overview is presented in Figure 3.

5.1 The Machinery Regulation mandates the involvement of a notified body

For the involvement of a notified body to be mandatory the machine either needs to be listed in Annex I(A) or Annex I(B) without all relevant health and safety requirements covered by a harmonised standard. Let’s consider three examples of such products:

1. A vehicle servicing lift,
2. A logic unit to ensure safety functions that was not manufactured in accordance to harmonised standards for a relevant safety requirement, or
3. A safety component “with fully or partially self-evolving behaviour using machine learning approaches ensuring safety functions”



* There are harmonised standards and/or common specifications for all relevant essential health and safety requirements in Annex III of the Machinery regulation and the requirements in articles 9-15 of the AI Act, and these have been followed in the design and construction of the product.
** There is a lack of harmonised standards and/or common specifications for relevant essential health and safety requirements in Annex III of the Machinery regulation and/or for the requirements in articles 9-15 of the AI Act, or these have not been followed in the design and construction of the product.

Figure 3: The mandatory involvement of notified bodies when both the AI Act and the Machinery Regulation are applicable.

All three examples of machinery or related products should then be assessed according to the conformity processes described in Modules B and then Module C, Module G or Module H. And remember, it is the definition of safety component found in the Machinery Regulation that is applicable.

5.2 The AI Act mandates the involvement of a notified body

Considering the three examples of machinery above we can have the following coupling of AI and machinery:

1. A vehicle serving lift – with an AI-based safety component,
2. A logic unit to ensure safety functions that was not manufactured in accordance to harmonised standards for a relevant safety requirement – with an AI-based safety component.

In case 1 and 2, the AI system is a safety component of a product listed in Annex I(A) of the AI Act. That product shall be assessed following a procedure that involves a notified body, according to the relevant act (i.e. the Machinery Regulation).

3. A safety component "with fully or partially self-evolving behaviour using machine learning approaches ensuring safety functions".

In case 3, the product can both fulfil the requirement of being an AI-based safety component and in itself be a product covered by the acts listed in Annex I(A) of the AI Act – and should be assessed through a Module requiring the involvement of a notified body.

Thereby the requirements in article 6(1) of the AI Act are fulfilled for all three examples – the example products need to be assessed according to Module B and then Module C, Module H or Module G of the Machinery Regulation, and subsequently they also need to be assessed according to the procedure described in points 4.3 to 4.6 of Annex VII of the AI Act. Or in other words,

- We should not focus on how the definition of Artificial Intelligence in the AI Act relates to the concept of "fully or partially self-evolving behaviour using machine learning approaches" as introduced by the Machinery Regulation; but instead
- We should focus on when the Machinery Regulation mandates the involvement of a notified body and how that relates to the AI Act.

Remember, we are now assuming that the safety components adhere with the definitions given by the AI Act. It is also worth pointing out that in case 1 and 2 it was not necessary for the safety component to have "fully or partially self-evolving behaviour using machine learning approaches ensuring safety functions" to trigger the mandatory involvement of a notified body, according to the Machinery Regulation. Since the product in scope required a notified body in the conformity assessment, the AI Act comes into force as long as the definitions of AI and safety component are met, as defined in the AI Act.

Regarding the possibility to opt out from involving a notified body (mentioned in article 25(3) of the Machinery Regulation and in section 3.2 of this report), the AI Act states that it is only possible to opt out from involving a notified body if there are corresponding harmonised standards or common specifications for the requirements regarding the AI system (article 43).

5.3 The Declaration of Conformity

Depending on the applicability of the legal acts, the content of the EU Declaration of Conformity and the scope of the CE-mark in terms of product safety will vary. Seen in terms of Figure 3 the meaning of the last and penultimate steps will depend on the path that took you through the diagram. Since the scope of our analysis is the Machinery Regulation and the AI Act:

- if taking the left path through internal control, the Declaration of Conformity is based solely on the Machinery Regulation; else
- if taking the central route via Module B followed by Module C, Module G or Module H, the Declaration of Conformity covers both the Machinery Regulation and the AI Act.

5.4 The responsibility of the notified body

Given that we focus on the combination of the Machinery Regulation and the AI Act, a notified body shall perform the tasks described in Module B and then Module C, Module G or Module H of the Machinery Regulation as well as those in point 4.3 to 4.6 of Annex VII in the AI Act.

Module B followed by Module C: The notified body assesses the technical documentation and examines a specimen that is representative of the product to be put on the market as well as assessing the quality management system and technical documentation in relation to the AI system.

Module G: The notified body assesses the technical documentation and examines an example of the product as well as assessing the quality management system and technical documentation in relation to the AI system.

Module H: The notified body assesses the quality management system and makes observations on the premises where the product is manufactured as well as assessing the quality management system[8] and technical documentation in relation to the AI system.

[8] As can be seen in the case of Module H there is a quality management system in place for both the machinery and the AI system. The obligations related to both quality management systems can be fulfilled in one quality management system if this makes sense for the provider of the product with an AI-based safety component.

5.5 The competence of the notified body

An organisation that is already notified body for (certain) machinery needs to be re-notified according to the AI Act in order to assess the machinery with an AI-based safety component:

> "For the purposes of that assessment, notified bodies which have been notified under those legal acts shall be entitled to control the conformity of the high-risk AI systems with the requirements set out in Section 2, provided that the compliance of those notified bodies with requirements laid down in Article 31(4), (10) and (11) has been assessed in the context of the notification procedure under those legal acts".[9]

Here high-risk is the terminology of the AI Act for AI systems that need to be CE-marked and Section 2 refers to the requirements in terms of technical documentation – risk management, data governance, logs, human oversight, cyber security and so forth. Article 31(4) defines what is meant by impartiality between the provider of an AI system and the notified body, article 31(10) describes how the notified body shall have the right competences needed for the assessment, and article 31(11) states that this obligation is true even if the work is carried out by a subcontractor to the notified body (as the work done by the subcontractor needs to be assessed by the notified body).

5.6 The competence of the market surveillance authorities

Just as the notified bodies need to have sufficient competences for both machinery and AI to fulfil their role and responsibility in placing products on the market, so does the market surveillance authorities in relation to products placed on the market.

6 Same procedure as last time

Recertification is a topic worth considering, i.e. when an AI system or product has been modified to such a degree that it needs to undergo a new conformity assessment procedure. For this end, both the AI Act and the Machinery Regulation introduce definitions of "substantial modification", albeit with different wordings.

The AI Act: The concept of substantial modification is defined in article 3 which also states that if the change is covered by the technical documentation submitted at the time of certification, the change is not to be seen as a substantial modification. Article 43 both states that AI systems "that have already been subject to a conformity assessment procedure shall undergo a new conformity assessment procedure in the event of a substantial modification" and that AI systems covered by Annex I(A) shall undergo the process described in Annex VII (see section 2.2 of this report). The obligation to ensure

[9] Article 43(3) of the AI Act.

that the AI system conforms to the AI Act falls on the person who made the substantial modification (article 25).

The Machinery Regulation: The definition of substantial modification can be found in article 3 while article 18 describes how the person responsible for a substantial modification shall apply the relevant conformity assessment procedure according to article 25 (see section 3.2 of this report).

In short, this means that if it was mandatory to use a conformity assessment procedure with a notified body last time, a notified body also needs to be involved for the recertification triggered by the substantial modification.

This has an impact to what extent conformity assessment involving a notified body can be automated. Remember, Module B and Module G require the inspection of a product specimen or example while Module H mandates on-premise inspections to be carried out by the notified body.

7 A bottleneck for market access

Since the requirements regarding relevant competence for a notified body to be able to partake in the conformity assessment are steep, it is not obvious that they will be able to build relevant competence in time to meet the market demand. Also, bearing in mind that the relevant accreditation is dependent on the competence of the notifying authority to be able to rightly assess the notified body, a lack of notified bodies could become a bottleneck for novel products to be placed on the internal market.

And the shortage of notified bodies can make itself known again and again when systems and products on the market need to be recertified.

But if there is a shortage of supply in relation to demand, there are also new business opportunities for those who can supply relevant services in relation to a market disrupted by new policy.

In parallel, other legal acts on product safety are being updated (see e.g. the regulation on medical devices[10]) or new acts are in the pipeline (such as the Cyber Resilience Act[11]). This means that new competences are needed both within the notifying authorities and bodies for the market surveillance system to function as certificates are required for placing the CE-mark on bespoke products.

[10] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC, https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02017R0745-20240709

[11] European Parliament legislative resolution of 12 March 2024 on the proposal for a regulation of the European Parliament and of the Council on horizontal cybersecurity requirements for products with digital elements and amending Regulation (EU) 2019/1020 (COM(2022)0454 – C9-0308/2022 – 2022/0272(COD)), https://www.europarl.europa.eu/doceo/document/TA-9-2024-0130_EN.html#ref_2_25

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RISE Research Institutes of Sweden AB
Box 857, 501 15 BORÅS, SWEDEN
Telephone: +46 10-516 50 00
E-mail: info@ri.se, Internet: www.ri.se

RISE Report : 2024:56
ISBN: 978-91-89821-87-3