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European “Machinery” Regulation

FOCUS on

The draft regulation intended to supersede Directive 2006/42/EC

The current directive[1] establishes a regulatory framework with a view to ensuring the free movement of machinery in the European internal market and a high level of protection of the users and other exposed persons.

Various impact studies initiated in 2016 with the interested parties concluded that there was a need to improve, simplify and adapt the text to the market's needs. Accordingly, on 21 April 2021 the European Commission published a proposal for a regulation[2] on machinery and related products. By proposing a regulation, it avoids the complexity involved in the transposition of a directive. All aspects of the new machinery regulation, once adopted, will become applicable in each European Union Member State.

This focus study analyses the major changes that would be created by this new regulation for various economic operators.

It is important to note that the points mentioned could evolve by the time the final version of the regulation is published. The discussions now being held on the level of the European Council and the European Parliament are expected to continue until the second half of 2022.

1 Directive 2006/42/EC: https://eurogip.fr/wp-content/uploads/2019/11/Directive%20200642EC.pdf

2 Proposal for a regulation: https://eurogip.fr/wp-content/uploads/2021/04/Proposal-for-a-Regulation-on-machinery-products-April-2021.pdf

Frequently used abbreviations

AI: Artificial Intelligence

EHSR: Essential Health and Safety Requirement(s)

NLF: New Legislative Framework

NB: Notified Body/Bodies

EU: European Union

Content

Introduction

The proposal for a "machinery" regulation incorporates the provisions of the "New Legislative Framework"[3] (see box) established by the European authorities since 2008.

It aims to clarify aspects that are key for an understanding of the regulations relating to machinery, concerning either certain definitions or else the links between the requirements and other sectoral regulations.

Finally, it includes issues related to new technologies in order to provide optimum support for economic and institutional actors in taking into account the innovations and the digital transition necessary for the European economy of the future.

What impact for manufacturers?

The concept of manufacturer remains very similar to the definition given in the directive. However, it should now be taken in its strict sense, i.e. the designer of the machine, whereas the concept of manufacturer was previously extended to the operator in charge of placing the machine on the market or placing it in service.

The obligations incumbent on the manufacturer will therefore be different from those of other economic operators such as importers and distributors. They remain generally similar to what was laid down in the Machinery Directive, but are better specified and condensed into a single article (Article 10).

However, **major changes** can be seen in the procedure for assessing the conformity of machinery considered as high-risk (formerly the machinery of Annex IV of the directive).

These machines may no longer be exempted from a third-party assessment (via a notified body) even if they were to comply with the requirements of a harmonized standard.

This paradigm change is justified by the approach adopted by other regulations concerning high risks, and in response to very strong demand from various economic operators in the impact studies performed since 2016.

What is the New Legislative Framework (NLF)?

The NLF is the legal basis designed to align the legislation relating to product conformity in the EU. It defines the role and obligations of the various economic operators based on a set of fundamental documents, including:

- **Regulation (EC) 765/2008** setting out the requirements for accreditation and market surveillance relating to the marketing of products.
- **Decision 768/2008** establishing a common framework for the marketing of products. It includes references to requirements to be introduced when the various legislations on products are revised. This decision should therefore be viewed as a framework to be used for the revision of sectoral legislations.
- **Regulation 2019/515** on the mutual recognition of goods lawfully marketed in another Member State and repealing Regulation (EC) No 764/2008.

3 *New Legislative Framework* (NLF): https://ec.europa.eu/growth/single-market/goods/new-legislative-framework_en

What's new for EHSR 1.2.1 *Safety and reliability of control systems*?

Several points taking into account the risks related to software in general, including software making use of AI, have been added in the draft regulation.

- The safety functions may not go beyond the framework stipulated by the manufacturer following its risk analysis. This requirement also applies during the phases of learning about the machine and its configuration by the operator.
- Software updates or changes made following placing on the market must be able to be identified.
- The safety decision-making process shall be retained for the purpose of demonstrating the product's conformity.

There are question marks regarding the procedures for collecting this information, especially since it should be retained for one year. Should it be expected that the machines record all the decisions taken on an internal device? This subject is likely to arouse much discussion during the future consultations of the European Parliament and the European Council.

Among the new features of the draft, **extra obligations** are incumbent on the manufacturer with regard to new technologies. For example, the concept of **Artificial Intelligence** (AI) appears as of Article 9 and refers directly to another draft regulation which is specially devoted to it[4].

Although the two regulations are linked, the conformity assessment scope of one and the other will be different. Within the framework of the Machinery Regulation, the manufacturer will have to ensure the satisfactory integration of AI so as not to impair the overall safety of the machine.

This is the case when AI performs safety functions or interacts with such functions.

For this purpose, the manufacturer will have to take into account new requirements, in particular the essential health and safety requirement (EHSR) relating to control systems (see box opposite).

Lastly, the conformity assessment of a software performing safety functions or of any machine containing AI performing safety functions must be performed by a notified body because it is included in the high-risk machinery category of Annex 1 (points 24 and 25).

Regarding this, with the introduction of all the software performing safety functions in the list of high-risk machinery, the draft would considerably extend the scope of third-party assessment. Indeed, all or part of the safety functions of a machine are managed by computer programming, i.e. by software. Therefore, machines incorporating programmable safety functions, which includes practically all those placed on the market, would be subject to conformity assessment by a notified body. However, it is unlikely that this is the European Commission's objective.

4 Proposal for a Regulation of the European Parliament and of the Council laying down harmonised rules on artificial intelligence (Artificial Intelligence Act) and amending certain Union legislative acts - 21 April 2021
https://eur-lex.europa.eu/legal-content/FR/TXT/PDF/?uri=CELEX:52021PC0206&from=EN

The other aspect relating to new technologies which is introduced explicitly concerns **cybersecurity**. From now on, manufacturers will have to take into account this risk, which covers both minor external influences (configuration error, protection of access to safety settings to prevent any incorrect operation, etc.) and cyberattacks. Apart from the requirements relating to the control system, EHSR 1.1.9 was added especially to cover protection against data corruption.

The need for the manufacturer to provide protection of the machine against malicious acts related to cybercrime radically changes the concept of taking into account reasonably foreseeable risk which prevailed previously. Due to the particular nature of hacking, which endeavours to exploit the system's flaws, malicious acts naturally go beyond the field of the reasonably foreseeable. It is therefore likely that the European Commission will have to soften its position, or at least specify what will be expected of the manufacturer to respond to this risk.

It is also likely that standardization work will have to take the subject of cybersecurity into consideration more systematically and thoroughly so as to have harmonized standards in support of the future regulation.

Furthermore, the draft regulation introduces the concept of **autonomous mobile machinery**. These are machines whose movement is “automatic” and not controlled by an operator. They will have to be provided with a supervision system making it possible to stop or restart the machine remotely whenever there is sufficient visibility.

Lastly, the regulation will allow the manufacturer to dematerialize the documentation accompanying the machine. The entire instruction manual would be available in digital format, and the printed format could be provided at the user's request.

What impact for importers and distributors?

The concepts of importer and distributor enter the draft regulation. Their obligations, described in detail in Articles 12 and 13 respectively, make them responsible actors in making conforming equipment available in the European market.

In particular, they must ensure that the machines have CE marking, a declaration of conformity, instructions that are understandable for the end user, or that the manufacturer has suitably compiled the technical documentation.

They shall also ensure that the transport and storage of the machine under their responsibility is performed in accordance with the manufacturer's instructions so as not to jeopardize the machine’s conformity.

If they have a doubt concerning the machine’s conformity, importers and distributors shall not make it available on the market. In the event of a proven risk, moreover, it will be incumbent on them to inform the market surveillance authorities of this. The importer, for its part, shall also implement the necessary remedial measures, which may go as far as a product recall.

In addition to these obligations, importers shall ensure that the appropriate conformity assessment procedure has indeed been carried out (i.e. that an EU type examination certificate indeed accompanies high-risk machinery). Finally, they shall indicate their name and the postal address at which they can be contacted, either on the machine or on its packaging or its instruction manual.

If an importer or a distributor makes a substantial modification to the machine or affixes its name or its brand to the machine, it will become the machinery manufacturer and will assume all the obligations incumbent on the latter.

This major change is likely to have a significant impact for certain machinery hiring firms, which

possess ranges of various machines wearing their colors.

What impact for users?

The end user of the machine, even though it is not explicitly named in the draft regulation, is also affected by the consequences of a substantial modification.

As specified in Article 15, any operator making such a modification becomes the manufacturer of the “new” altered machine and must comply with all the requirements of Article 10.

What impact for notified bodies (NBs)?

The notified bodies, which are independent organizations appointed by the Member States and notified to the European Commission, are tasked with performing conformity assessment in accordance with the relevant EU regulations.

Their obligations and tasks would remain generally the same. The draft regulation nevertheless specifies certain aspects relating to their activities or to the rules concerning their notification by the national authorities.

For example, it is planned that the national authorities may be supported by accreditation bodies to certify the NBs. This accreditation possibility is to be placed in parallel with the changes in the rules concerning notification under NANDO[5] initiated in 2015, and providing in particular for a period for objection to notification by the Member States. This period during which it was possible to object to the appointment of an organization regarded as not guaranteeing the minimum requirements to perform its tasks, was increased from two weeks for a notified body under accreditation to two months for a notified body based solely on the criteria of its supervisory authority.

The regulation also provides for the objectives of coordination of the activities of the NBs. Article 40 would endorse the obligation of coordinating the action of the NBs in appropriate working groups. Each body shall take part in this and apply the decisions resulting from the deliberations of these groups.

As regards the conformity assessment procedures followed by the NB, they are defined by modules, as described in the "Blue Guide"[6]:

- The EU type examination in accordance with module B (Annex VII);
- Conformity based on full quality assurance in accordance with module H (Annex IX).

The assessment procedures in accordance with these various modules would remain the same as what is provided for by the directive. Only some clarifications have been added.

Note, in particular, for module B the rules relating to the review of an EU type examination certificate. Point 7 of Annex VII would include all the rules applicable to the certification review (see box on page 7), whether it be for a change in the state of the art, or a change in the product or in the relevant technical documentation.

This point, moreover, will require that the notified body monitor all changes in the state of the art that could have an impact on the product's conformity with the EHSR. The notified body shall inform the manufacturer of this, and the manufacturer shall itself ensure that the machine still complies with the applicable EHSR.

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5 CERTIF 2015-01 REV2 - *The functioning of NANDO with regard to providing accurate information, objection periods, notification procedures and notified bodies groups*: https://ec.europa.eu/docsroom/documents/13464?locale=en

6 Blue Guide: https://eurogip.fr/wp-content/uploads/2019/12/Blue-Guide_2016.pdf

Certification review: renewal or addition to the original EU type-examination certificate?

The proposal for a regulation introduces a review which gives rise to either a supplement to the original certification which is not presumed to lead to an extension of its period of validity, or else a renewal for a five-year period.

This distinction, which exists in other sector-specific regulations that have already been incorporated in the NLF, engendered long discussions on the regulation relating to personal protective equipment, where there are diverging interpretations.

If the European Commission has not yet done so, the French authorities, for their part, have decided: renewal for a five-year period takes place only when the application for the certification review is made between one year and six months before the date of the end of validity of the EU type-examination certificate. In all other cases, there is an addition to the original certificate.

Finally, a "simplified" certification renewal procedure is included in point 7.6, allowing renewal for a five-year period simply at the manufacturer's request when there has been no proven change in the best practice rules, the technical dossier or the product.

What impact for national authorities and for market surveillance?

The inclusion of the NLF in the regulation reinforces the obligations of the Member States with regard to market surveillance, the free movement of goods and notification of the certification bodies.

The most significant feature is the possibility given to the European Commission to produce delegated acts[7] in order to modify the list of high-risk machinery (Annex I). This corresponds to the desire of the Member States to be able to "keep alive" the list of machinery covered by the conformity assessment by a notified body. The aim is therefore to be able to keep up with technological developments by adding new machines regarded as high-risk, and be able to remove from the Annex those that might be considered now less dangerous.

However, the procedures defined by the European Commission for changes in this list remain hard to implement. If the risk is to be established on the basis of the combination of the probability of occurrence of damage and its severity, the factors for assessing the latter are hard to understand and their scope is not very clear.

As a result, in its current wording, it seems impossible to make changes to Annex I, whether by including or removing machines from it. It must be hoped that these requirements will be clarified, or that otherwise a precise protocol will be defined in the future guide to interpretation of the regulation.

What impact on standardization?

While the regulation confirms the presumption of conformity provided by the harmonized standard for machinery, it regulates it more strictly.

First, as mentioned earlier, the application of a harmonized standard will no longer enable the manufacturers of high-risk machinery (formerly the Annex IV machinery) to be exempted from a third-party assessment.

7 Delegated acts are legally binding acts that enable the Commission to supplement or amend non-essential parts of EU legislative acts, for example in order to define detailed measures.

Next, the European Commission would leave itself the possibility of adopting implementing acts (see box) in order to establish technical specifications where necessary. This would concern cases where no harmonized standard is available to cover certain EHSR, whether it be due to a delay in preparing the standard or because the standard application was not accepted by the CEN/CENELEC.

Note that this new power granted to the European Commission aroused very strong reactions, especially since the procedures relating to the establishment of these implementing acts are not clearly defined.

And in particular, the composition of the groups in charge of drafting these implementing acts has not been specified: will they consist solely of representatives of the Member States? Could representatives of industry take part?

As yet, very little information is available on the subject. It will therefore be necessary to wait for the European Commission to communicate more extensively on this point to resolve the various concerns reported by the standardizers.

In conclusion

Apart from the points highlighted in this focus study, the draft machinery regulation remains in line with the existing legislation.

It aims above all to anticipate technical and technological developments in order to ensure the stability required by the various economic operators in the coming decades.

It also enables ageing legislation to be harmonized with other sector-specific regulations, thereby limiting interpretation risks while facilitating its application by the Member States.

Why acquire the possibility of adopting implementing acts?

Implementing acts are legally binding acts that enable the European Commission – under the supervision of committees consisting of EU countries' representatives – to set conditions that ensure that EU laws are applied uniformly.

For example, in the field of construction products (Regulation 305/2011), many standards were considered inadequate. Since the standardization groups were unable to achieve the objectives laid down by the European Commission, the latter issued decisions which supplement the standards with regard to certain verification criteria.

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