

## Position Paper

# CEN-CENELEC response to the European Commission's Public Consultation on the draft Machinery Regulation

July 2021

## Introduction

### Background information

On 21 April 2021, the European Commission (EC) adopted [its proposal for the Machinery Regulation](#) which will replace the Machinery Directive 2006/42/EC.

At the same time, the EC launched a [public consultation](#) for feedback on the draft Machinery Regulation. With this document, CEN and CENELEC provide its position on this proposal.

This paper is the outcome of the consultations which were carried out in the CEN-CENELEC Sector Forum on Machinery and in the CEN and CENELEC Technical Boards and among the TCs in charge of harmonized standards under the Machinery Directive<sup>1</sup>.

### CEN-CENELEC input on the Machinery Regulation from December 2020

In December 2020, CEN-CENELEC provided its [response](#) to the first EC consultation on the Machinery Regulation which had been presented at the meeting of the EC Machinery Working Group, held on 9-10 November 2020.

CEN and CENELEC regret that most of our requests were not taken into account and thus are not reflected in the EC proposal from 21 April 2021 (COM(2021) 202 final).

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<sup>1</sup> The first consultations were carried out from 10 November to 3 December 2020 in the CEN-CENELEC Sector Forum on Machinery and among CEN-CENELEC TCs which develop harmonized standards under the Machinery Directive. Out of around 50 TCs which were consulted, the replies were received from 21 TCs. Furthermore, a dedicated consultation was carried out in CEN and CENELEC Technical Boards. The second consultations were carried out from 17 to 26 May 2021 in the CEN-CENELEC Sector Forum on Machinery as well as in the CEN-CENELEC European Policy Hub. This paper was approved by the CEN-CENELEC Sector Forum on Machinery on 2021-05-27 and by the CEN and CENELEC Technical Boards on 2021-06-30.

## Impact on standards

The elements of the EC proposal which will create an immediate impact for CEN-CENELEC are the following:

- EC implementing powers to develop technical specifications (Article 17.3 of the proposed Machinery Regulation), see also specific comment 1.;
- the change in the conformity assessment procedure for high-risk machinery covered by the current Annex IV – i.e. the proposal to remove the internal check option in case of application of harmonized standards (Article 21.2), see also specific comment 3.;
- the link between the Annex III of the proposed Machinery regulation and the “high risk AI system” in the AI regulation, see also specific comment 4.;
- the multitude of changes in the Essential Health and Safety Requirements (EHSRs) (Annex III) see also specific comment 5. & 6.;

**Considering the last aspect it is expected that the changes introduced by the EC proposal will have a high impact on the majority of harmonized standards if not on all of them.**

## Request for adequate time to adapt to the new provisions

For the system of harmonized standards that confer a presumption of conformity to work well, it is fundamental to give CEN and CENELEC the adequate time for the review of the whole portfolio of 780 harmonized standards under the Machinery Directive and for the adaptation of the concerned standards. To adapt these standards, **we would need as a minimum 3 years** (36 months) from the moment of the adoption of the new legislative act, **but surely more time** (especially for standards developed in parallel with ISO for which it will be necessary to coordinate with the non-European countries to revise the standard), depending on the amount and complexity of new/modified EHSRs in the final text of the Machinery Regulation. However, Article 52 of the proposed Machinery Regulation foresees that the new legislation will become applicable already within 30 months from the date of its entry into force. Thus, we request **to extend this date to at least 3 years (36 months)**.

## Specific comments

### 1. Empowerment of the European Commission for adoption of implementing acts establishing technical specifications as substitute for harmonized standards (Article 17.3 of the proposed Machinery Regulation)

Over the last 25 years, the European industry has shown a strong commitment in the sector of machinery standardisation under CEN - CENELEC leadership. This strong commitment resulted in the development and maintenance of a consistent standardisation framework in the area of machinery safety, with about 780 standards supporting the Machinery Directive.

The machinery sector relies on the New Approach and New Legislative Framework (NLF), i.e. EC sets the legal frame with EHSRs and ESOs translate them into detailed technical requirements. This system and the standardization in this sector have proven to be successful and efficient. The indicated alternative approach towards presumption of conformity by means of technical specifications challenges the current system, if the ESOs are not given the right conditions to develop harmonized standards. The flexibility offered by the New Approach and NLF system presents many benefits: **openness, transparency, diversity, the integration of the state of the art, contribution of all stakeholders, proximity to SME's, easiness to update the documents.**

The European Standardization System ensures the participation of all relevant and interested stakeholders representing the widest possible technical expertise and the environmental and consumers' interests and offers a right balance of participation among all stakeholders. Moreover, standards also reflect the positions of experts of all Member States and are under public survey in the whole ESOs' community. The European Standardization System is based on **consensus**. It would be very difficult to gain the participation of the relevant parties and qualified experts in such a parallel process for developing technical specifications, especially considering the international dimension of the CEN-CENELEC standardization for machinery, i.e.: currently more than 40 % of standards are developed together with ISO and IEC. Consequently, those technical specifications may lack the necessary technical practicability and be therefore not suitable for the application by the addressed machine manufacturers, might not **meet the market needs** and involve additional costs for players.

We believe harmonized standards **offer a valid and successful alternative to legislative options such as technical specifications** and that the EC should take into account the essence of article 3.2 of the NLF Decision (No 768/2008/EC)<sup>2</sup>, which specifies that:

*"Where Community harmonisation legislation sets out essential requirements, it shall provide for recourse to be had to harmonised standards, adopted in accordance with Directive 98/34/EC, which shall express those requirements in technical terms and which shall, alone or in conjunction with other harmonised standards, provide for the presumption of conformity with those requirements, while maintaining the possibility of setting the level of protection by other means".*

We also note that such implementing powers were not envisaged by the NLF-decisions, which in its reference provisions for harmonized legislation only refers to the option of harmonized standards<sup>3</sup>, not technical specifications.

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<sup>2</sup> See Decision No 768/2008/EC <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32008D0768> on a common framework for the marketing of products Article R8 Presumption of conformity simply states that "Products which are in conformity with harmonised standards or parts thereof the references of which have been published in the Official Journal of the European Union shall be presumed to be in conformity with the requirements covered by those standards or parts thereof, set out in ... [reference to the relevant part of the legislation]."

<sup>3</sup> See Note 2.

An implementing act will take time to be elaborated and will need to take into account the views of various stakeholders. Thus, it is unlikely that technical specification will be a faster route than harmonized standards.

Taking into account several statements from European Commission representatives, that ensuring the function of the NLF does not require a harmonized standard for each machine type, such an empowerment is not necessary.

As a consequence, we ask to **delete the Article 17.3 which introduces the concerned EC empowerment as well as the references to the technical specifications developed on the basis of this empowerment which are contained in Articles 10.4, 17.4, 41.5 b) and in the following Annexes:**

- Annex III in EHSRs 1.7.4.2. u), 2.2.1.1., 3.6.3.1.,
- Annex IV in A f),
- Annex V 'EU Declaration of conformity of machinery products except for partly completed machinery' in item 7, 'EU Declaration of incorporation of partly completed machinery' in item 6,
- Annex VII in items 4 c) and e), 6.2. e), 7.6 b),
- Annex IX in items 3.1 b) (iv) and 3.2. b).

## 2. Retain existing language on voluntary use of standards

The modifications which have been made in EHSRs 1.7.4.2. u), 2.2.1.1., 3.6.3.1. in relation to the concerned empowerment, compared to the current text of the Machinery Directive, seem to be against the **principle of the voluntary application of harmonized standards** which must be ensured as one of the basic principles of the NLF:

*"Where the harmonised standards are not or technical specifications adopted by the Commission in accordance with Article 17(3) **cannot be applied** (...),*

These modifications provide the impression that the technical specifications in accordance with Article 17(3) will have a mandatory character which would be against the principles of the NLF, as well.

Therefore, we request to reinstate the wording used in the current Machinery Directive:

*"Where the harmonised standards **are not applied**"*

## 3. Conformity assessment for high-risk machinery (Articles 5.1 and 21.2)

There is no evidence of safety related shortcomings or problems of harmonized standards dealing with high-risk machines listed in the current Annex IV neither with the widely used corresponding conformity assessment procedure as prescribed in Article 12 (3a) of the Machinery Directive (2006/42/EC), i.e. the internal check option. Therefore, deleting this procedure seems to be not justified nor proportionate. Furthermore, a deletion of this procedure is expected to negatively influence the motivation of the stakeholders to develop and maintain harmonized standards for Annex IV machinery. Such an opinion was expressed

by several Technical Committees responsible for the development of harmonized standards for Annex IV machinery.

An additional opinion was that the EC proposal could be driven by an insufficient market surveillance which cannot be replaced by adding to the manufacturers of machines listed in the Annex IV the burden of a European Type Examination.

Therefore, we recommend **abstaining from the deletion of the internal check option.**

Consequently, **we request to delete the concerned provisions Articles 5.1 and 21.2 from the draft Machinery Regulation.**

#### **4. Link between the Annex III of the proposed Machinery Regulation and the “high risk AI system” in the AI regulation**

A number of new requirements for high-risk AI systems arising from the AI Regulation will have to be taken into account by standardisers in order to help manufacturers comply with all relevant requirements of the Machinery Regulation for their products.

This will imply the involvement of AI specialists willing to participate in the standardisation process which will be enabled through the open and inclusive process of CEN and CENELEC work. This will take time and attracting industry experts will be challenging as Module A will no longer be allowed for the certification of high-risk machinery products. Therefore, we highlight again the importance of giving to CEN-CENELEC sufficient time to adapt to the new Machinery Regulation which will also support SMEs in this new field of AI.

#### **5. Compliance of the EHSRs with the NLF concept as specified in the Blue Guide**

a) One of the basic principles of the NLF is that legal acts under this framework specify essential requirements within the limit of the “**intended use**” and the “**reasonably foreseeable misuse**” of a product. The 2016 edition of the Blue Guide clearly states in Section 2.7 that this consideration shall result from “*lawful and readily predictable human behaviour*”. Hence intentional unlawful human behavior should thus not fall under the “intended use” or “reasonably foreseeable misuse” under any NLF-legal acts, such as the proposed regulation.

This foundational principle is very important for the correct comprehension and the application of the EHSRs of the Machinery Directive as well as for the development of harmonized standards and must be observed as well for the consideration of the possible safety implications as result of cybersecurity attacks. Every kind of intentional violation (sabotage/spying) of a machine is de facto a criminal act.

CEN/ISO/TR 22100-4 'Safety of machinery — Relationship with ISO 12100 — Part 4: Guidance to machinery manufacturers for consideration of related IT-security (cyber security) aspects', developed by CEN/TC 114 'Safety of machinery' and ISO/TC 199, indicates "the principle objectives and conditions of IT-security are very much different from machinery safety". Safety is about protecting humans against machinery hazards, security is about protecting machinery against humans attack. Therefore, the new EHSR 1.1.9 "*Protection against*

*corruption*" which is in contradiction with the above-mentioned basic principle of the NLF as stated in the Blue Guide should be deleted. The same applies for EHRS 1.2.1 1<sup>st</sup>. para (a) where the added text "*...including malicious attempts from third parties to create a hazardous situation*" should be deleted.

Instead, the objectives covered by this additional EHSRs would be suitable for the envisaged horizontal legal act regarding cybersecurity.

b) Another foundational NLF principles is that NLF legal acts are specifying "*Essential requirements defining the results to be attained, or the hazards to be dealt with, but **do not specify the technical solutions for doing so.***" (see clause 4.1.1 of Blue Guide, Edition 2016). The specification of the technical solutions is the task of harmonized standards.

However, in their comments TCs often expressed the opinion that **the proposed EHSRs are too prescriptive, undermining the possibility to draft technology neutral standards.**

Consequently, we ask to review the proposed new EHSRs so that they are not prescriptive as the solution sought.

## **6. Ensuring consistency of the specified EHSRs (Annex III of the proposed Machinery Regulation)**

The consistency of the specified EHSRs (current Annex I, Annex III in the proposed Machinery Regulation), is fundamental for its correct comprehension and application as well as for the development of harmonized standards. Therefore, duplications and alterations of EHSRs must be avoided. Otherwise, the elaboration of detailed Annexes ZA/ZZ (which is already challenging and being one of the main reasons for non-citation of harmonized standards in OJEU) will become even more critical. Unfortunately, some of these new proposed EHSRs, especially those relating to new and emerging technologies are not in line with this consistency aspect. Either they are already covered by the existing EHSRs or new EHSRs are basically repeated at different sections of Annex III.

Consequently, we ask to reconsider the integrated new EHSRs so that **they are consistent.**

### **Additional supporting documents :**

1. CEN-CENELEC general position on the revision of Machinery Directive from 2019 (i.e. the input to the EC public consultation) is available here: [link](#).
2. CEN-CENELEC response to the EC indication on the revision of Machinery Directive (2020) is available here: [link](#).

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## About CEN and CENELEC

**CEN (European Committee for Standardization)** and **CENELEC (European Committee for Electrotechnical Standardization)** are recognized by the European Union (EU) and by the European Free Trade Association (EFTA) as European Standardization Organizations responsible for developing and defining standards at European level. These standards set out specifications and procedures in relation to a wide range of products and services.

The members of CEN and CENELEC are the National Standards Bodies and National Electrotechnical Committees of 34 European countries including all of the EU member states plus Iceland, Norway, Switzerland, United Kingdom, Turkey and the former Yugoslav Republic of Macedonia.

European Standards (ENs) are developed through a process of collaboration among technical experts nominated by business and industry, research institutes, consumer and environmental organizations and other societal stakeholders. Once adopted, these standards are implemented and published in all of the 34 countries covered by CEN and CENELEC.

CEN and CENELEC also work to promote the international harmonization of standards in the framework of technical cooperation agreements with ISO (International Organization for Standardization) and IEC (International Electrotechnical Commission).

For more information, please see: [www.cencenelec.eu](http://www.cencenelec.eu)

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