CEN-CENELEC position on the revision of the Machinery Directive 2006/42/EC

In summer 2019, the European Commission (EC) carried out the public consultation regarding the revision of the Machinery Directive 2006/42/EC. In this context, in July 2019, CEN and CENELEC were requested to provide the replies to the targeted questionnaire. The replies, as indicated below, are the outcome of the consultations carried out in the Safety of Machinery Sector Advisory Nucleus[1] (i.e. the core-group of the CEN-CENELEC Sector Forum on Machinery Safety) and among the CEN and CENELEC Members[2]. The CEN and CENELEC replies are confined to these questions regarding the revision of the Machinery Directive which are directly related to standardization.

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1. **Please introduce yourself and your institution**->

   The CEN and CENELEC machinery sector brings together about 50 technical bodies dealing with different types of machinery for use in agriculture, industrial manufacturing, mining, construction and by consumers (see the dedicated CEN-CENELEC website on machinery). Since 30 years, CEN and CENELEC have been developing harmonized standards, which manufacturers, economic operators, or conformity assessment bodies can use to demonstrate that products comply with the Machinery Directive. Currently there are more than 800 published harmonised standards in support of the Machinery Directive and more than 300 harmonised standards under development.

2. Please shortly describe your knowledge of and involvement with the Machinery Directive.

Questions relating to the MD implementation and the legislative framework

The first section discusses specific issues identified relating to the Machinery Directive itself, and the wider legislative framework.

3. **What is the role of international standards such as ISO/IEC in contributing to the competitiveness of the European machinery sector?**-->

   European machinery manufacturers (more than 75% are SMEs) have to compete at the global market (export share outside EU is around 50%). For them harmonised market access conditions based on international standards from ISO/IEC are key for their competitiveness. The long-standing cooperation of CEN and CENELEC with ISO and IEC has allowed the alignment of European Standards with international ones, contributing to the global competitiveness of European businesses. This cooperation facilitates the development of ISO and IEC standards to support European legislative and policy needs.
4. Have you encountered situations where the implementation of the Machinery Directive differs significantly between different Member States? What are the differences?

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1 The two consultations were carried out in the Safety of Machinery Sector Advisory Nucleus from 12 July to 5 August and from 16 August to 5 September 2019.

2 The consultation was carried out in the Technical Boards of CEN (BT N 11757) and CENELEC (BT164/DG11455/DC) between 11 and 24 September 2019.

No comment

5. **Would you prefer converting the Directive into Regulation? What consequences (costs and benefits) for standardisation do you foresee for such conversion? ->**

   Yes. It facilitates uniform application across all Member States of the European Union and therefore the free movement of goods.

6. **Would you prefer aligning the Machinery Directive to the New Legislative Framework? What kind of consequences (costs and benefits) for standardisation do you foresee for such alignment? ->**

   We are in favour of aligning the Directive to the New Legislative Framework (NLF) for the purpose of consistency. In the consultation, which was held within CEN and CENELEC, the opinion was expressed that the Annex I of the Machinery Directive, which contains the technical requirements (EHSRs), is already consistent with the NLF.

Impacts of new technologies

One of our topics of study is the impact of new technologies to the safety of machinery, and how they should be addressed in the Machinery Directive. The questions in this section address issues relating to all Artificial Intelligence (AI) technologies, Internet of Things (IoT), robotics, data- and cyber-security, and future and emerging technologies, for example the Quantum Computing (QC).

7. **What are the current main international and harmonised standards relevant to these new technologies? Are you aware of any potential gaps? ->**

   Standardisation for safety of machinery has to address the state of the art existing in the sector. With the continuous involvement of experts from different stakeholders the CEN and CENELEC standards keep the pace of the technological development giving a suitable way of verification of the compliance of the given machine to the EHSRs.

   Several aspects relevant to safety of machinery for new technologies have been addressed via the international standardization. The main standardisation deliverables are the following:

ISO documents:

- 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' ; adoption as identical CEN/TR planned by CEN/TC 114;

- ISO/TS 15066 'Robots and robotic devices -- Collaborative robots' (ISO/TC 299)

Harmonised standards:

- EN ISO 20607 'Safety of machinery – Instruction handbook – General drafting principles' containing a reference to ISO/TR 22100-4 regarding information for use on IT security aspects which can have relevance for machinery safety (CEN/TC 114 and ISO/TC 199);
- EN ISO 13482 'Robots and robotic devices -- Safety requirements for personal care robots' (CEN/TC 310 and ISO/TC 184);
- EN ISO 10218-1 'Robots and robotic devices - Safety requirements for industrial robots - Part 1: Robots' and EN ISO 10218-2 'Robots and robotic devices - Safety requirements for industrial robots - Part 2: Robot systems and integration'.

Draft harmonised standards and future work:

- EN ISO/DIS 21260 'Safety of Machinery - Mechanical safety data for physical contacts between moving machinery and people' (co-operation with ISO/TC299 'Robotics'); specification of maximum levels for forces, pressure, speed of movements etc (CEN/TC 114 and ISO/TC 199 in cooperation with ISO/TC 299);
- forthcoming revision of ENISO 11161 'Safety of machinery -- Integrated manufacturing systems -- Basic requirements' to cover among other aspects the autonomous re-configuration of manufacturing systems during use (CEN/TC 114 and ISO/TC 199);
- forthcoming new study project “Possible implications of KI for safety of machinery” in WG 5 of ISO/TC199.

8. **To what extent can challenges introduced by new technologies be addressed through standards instead of changing the legislative text? →**

   Challenges relevant for safety of machinery in relation to new technologies can be addressed by standards in a much quicker way compared to legislation. In addition, standards allow to specify related requirements in a much more transparent/practicable way. This would be especially important with regard to the complexity of those new technologies.

9. **New generation machinery is empowered by different kinds of software. A newly proposed machinery system that includes a machinery, some software, and the networking connectivity, forms a so-called cyber-physical machinery system. For example, robots that are empowered by AI software. Do you believe a better definition of the next generation machinery that reflects the cyber-physical nature of the assembly could be advantageous? →**

   The explanation given for the newly created term “next generation machinery” is mixing many different attributes. Provided this new term will become relevant in the context of the revised Machinery Directive it should be clearly defined because it has to be expected that it will have implications for standardisation, too.

10. **Would you like to see the General Principles and Essential Health and Safety Requirements (EHSR) of the Machinery Directive more explicitly addressing AI, IoT and/or robotics, in the context of:**

    - **Control systems (including accountability requirements and algorithm transparency)**
    - **New safety hazards of collaborative or mobile robots**
    - **Autonomous behaviour of machines (including principles of safety integration and the concept of ‘reasonable foreseeable misuse’)**
    - **Any other aspects ->**

   In the consultation, which was carried out within CEN and CENELEC, different opinions were expressed: on the one hand that the existing set of EHSRs duly covers any type of risk that can be envisaged, because all possible implications on safety which may result from emerging digital or new technologies are already addressed by the current set of EHSRs. In addition, it is believed that together with the continuous involvement of experts from different stakeholders we can ensure that the standards keep the pace of the technological development giving a suitable way of verification of the compliance of the given machine to the EHSRs. The comment was made that as new technologies are covered by the existing publications and standardisation projects, they should not change

the existing generic approach of the directive. The directive should remain technology neutral. For example, the possible implications which can result from cyber threats are already addressed implicitly as part of the risk assessment specified in item 1 in Annex I of the Directive.

On the other hand, the other views were also shared in the consultation which was carried out in CEN and CENELEC, i.e. that the EHSRs should be reviewed to address aspects relating to emerging digital technologies.

- **What adjustments would you like to see? What would be the consequences (costs and benefits) on standardisation of these adjustments? →**

A potential extension of EHSRs as prescribed above would result in the need for a review of the whole portfolio of the existing harmonised standards (more than 800) in order to evaluate the necessary adaptations. As a final consequence, the revision of the whole portfolio of standards or part of it can be necessary. This exercise would require significant resources, therefore a necessary transition period of at least 3 years or more would be necessary in order to give CEN and CENELEC time to adapt.

11. By extensively using any connectivity technology (wired, wireless, optical or other) to network the machinery, the temporary failure of the communication channel could change the behaviour of the machine by isolating it from the network. Do you believe it could negatively impact on safety? Should additional requirements for networking be considered? →No comment

12. Machinery empowered by software components can receive software updates done after the machine has been put into service. The extent of such changes could range from the security patches only, bug fixes, some minor updates, up to major software upgrades that might also require higher computational power in hardware. Do you believe that there should be essential requirements to protect a machinery against major updates of the intended behaviour? →No comment

13. Would you prefer to see new horizontal legislation to address issues relating to AI, IoT and robotics in addition to or instead of the Machinery Directive? →No comment

14. **Should the Machinery Directive explicitly address data protection and cybersecurity?**
If the answer is positive: How would you prefer this to be done? What would be the impacts on standardisation? →
Data protection and cybersecurity have implications on many different sectors.

    If both aspects would be in the future covered by the Machinery Directive, this probably would imply the need to extend the current field of expertise of the machinery-TCs. We would like to refer to the sub-clause 5.2 of 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' which is planned to be transposed by CEN in 2020. We would also like to refer to the CEN and CENELEC activities regarding cybersecurity (see the dedicated CEN-CENELEC website on cybersecurity) and to the CEN and CENELEC position on the Cybersecurity Act.

15. **Should data- and cyber- security be addressed against hazards going beyond the list of health and safety hazards? To what extent? →** See answer to question 14.

16. **Would you prefer to see new horizontal legislation to address cybersecurity in addition to or instead of the Machinery Directive?** → See answer to question 14.

17. **Should other new essential safety requirements be added, for example to reflect the impacts brought by networking and/or by newly introduced or emerging technologies?**
    If yes, which new essential safety requirements would you suggest? → See answer to question 10.

18. Concerning the safety of the Machinery that uses AI software or other forms of differently-predictable forms of soft computing, do you believe the process of verification of conformity needs to be better defined? → No comment

Digital documentation

While the Directive does not explicitly specify the format of Declaration of Conformity and user manual, they are currently produced in paper format under the Machinery Directive. This section discusses the possibility of switching to digital formats for some or all of the documentation.

19. What would be the costs and benefits for your organisation of such switch? → no comment

20. What regulatory issues do you foresee for switching to digital documentation? → no comment

21. Do you believe that users can perceive the replacement of the paper-based documentation by the digital one as an obstacle to usability of the machinery? Could it become a disadvantage? → no comment

22. If digital documentation was to be used, do you believe that some essential information should remain on paper while more complete documentation can be delivered in electronic form? For example, a leaflet explaining how to install the printing equipment and more detailed user manual consultable in a digital format → no comment

Definitions

This section includes questions about definitions used or to be used in the Directive.

23. According to Article 2 (a) 'machinery' means— 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. This definition applies also to machines which stock energy after the human effort is applied. With regards to machines able to stock energy (e.g. exoskeletons), should the stocked energy be higher than the energy of any directly applied human effort so that the machine is considered as machinery for the purposes of the directive? → no comment

24. Should the definition of 'safety component' in Article 2 (c) be revised so that it explicitly covers active safety? In particular, should passive safety systems (e.g. alarms) be excluded from the definition? What would be the costs and benefits of such change? → no comment

25. Should the concept of partly competed machinery (PCM) be removed from the directive? What would be the costs and benefits of such change? Alternatively, should PCM comply with certain relevant essential health and safety requirements?--> no comment

26. **Certain Machinery requires an installation by a third party different from the manufacturer. Do you believe that the role of an "installer" should be added? For example, a lift being supplied as a kit of components that needs an installation to adapt to the peculiarities of a building**.

    → We would like to highlight that such a change in the Machinery Directive can trigger the need for an adaptation exercise for the whole portfolio of harmonised standards.

Specific equipment

This section includes questions covering aspects applying to specific types of machinery. These questions are intended for stakeholders who have specific knowledge of these types of equipment.

27. Annex IV machines: do you see advantages in removing the self-assessment option when the product is manufactured in accordance with harmonised standards? What would be the costs and benefits of such change?--> no comment

28. Annex IV machines: should the list of Annex IV products be updated? What categories should be added /removed? What would be the costs and benefits of such changes?--> no comment

29. Annex IV machines: do you see advantages in removing the Annex IV? What would be the costs and benefits of such change?--> no comment

30. The Machinery Directive excludes machinery specially designed or put into service for nuclear purposes which, in the event of failure, may result in an emission of radioactivity. Do you agree that the **exclusion should refer only to machinery** specially designed or put into service for nuclear purposes which, in the event of failure, **may result in a direct emission of radioactivity or any other ionizing emission?** What would be the costs and benefits of such change?--> no comment

31. The Machinery Directive excludes seagoing vessels and mobile offshore units and machinery installed on board of such vessels and/or units. With respect to the machinery installed on board of such vessels, should this exclusion be limited to machines aimed at safety in the sea (floatability, etc.) hence those machines used on ships for other purposes not related with safety at sea are covered by the Machinery Directive? If yes, what would be the costs and benefits of such change? → no comment

32. **Do you consider that the exclusion of Category I pressure equipment from the Pressure Equipment Directive (which has specific essential safety requirements to address hazards due to pressure) leads to increased safety concerns (such as risk of explosion due to pressure)? If yes, would you agree to include Category I pressure equipment in the scope of Pressure Equipment Directive? If yes, what would be the costs and benefits of such change?**

    → What is important is to ensure clarity under which piece of legislation a given product falls and that there is a coherence between the requirements of the Machinery Directive and of the other legislations. There should be no inconsistences.

33. **Do you see any advantages in removing the exclusion of low voltage * machinery in Art. 1.2 (k) of Machinery Directive so that the machinery whose risks are mainly of electrical origin are covered exclusively by the Low Voltage Directive? What would be the costs and benefits of such change?**

→ What is important is to ensure clarity under which piece of legislation a given product falls and that there is a coherence between the requirements of the Machinery Directive and of the other legislations. There should be no inconsistences.

34. Should the exclusion on specific equipment for use in fairgrounds and/or amusement parks be removed, so that equipment for use in fairgrounds and/or amusement parks falls under the Machinery Directive, including a possible new section in EHSRs (for instance on Safety Factors, limit G Forces, seating/containment requirements)? What would be the costs and benefits of such change?--> no comment

35. An increase of the maximum speed for lifting appliance/platforms under the Machinery Directive from 0.15 m/s to 0.50 m/s would result in relevant products that could be self-assessed by the manufacturer instead of involving a third-party conformity assessment body to certify them (as required by the Lifts Directive). Do you think that such change leads to safety concerns? If not, what would be the costs and benefits of such speed limit increase → no comment

Essential Health and Safety Requirements (eHSR)

This section includes questions related to essential health and safety requirements included in the directive.

36. Should the Directive address the protection against exposure of workers to hazardous substances since the initial design phase (through principles of safety integration)? If yes, what new essential safety requirements should be added? For example, should a handheld machine be designed to measure the amounts of hazardous substances during operation? → no comment

37. Should the directive take better into account the use of the machine and the risks derived from maintenance activities? Is yes, in which way?--> no comment

38. Should the essential safety requirements related to seating (eHSR 3.2.2.) be updated in order to allow innovation to mitigate the risk of ejection? For example, in case of machines designed or equipped with a restraint system to keep the persons in their operating positions, should the machine start be disallowed until the restraint system is activated? → no comment

39. Should a new eHSR 3.5.4. be added to ensure that machinery must be designed and constructed so as to minimise the risk of contact with overhead power lines? → no comment

40. Given the technical progress in the sector, it has been suggested to revise the safety requirements for lifting platforms with carrier which is not completely enclosed to allow innovative technologies to be used, such as for example light barrier curtains.

    What would be the costs and benefits of such revision? --> no comment

Policy options

On the last page of this document, you will find the policy options considered for this Impact Assessment. There are five main options (including the "no change" option 0), with several sub-options for options 1, 2 and 3.

41. **What would be impacts (positive and negative) of each option for your own institution? →**
    Impacts for standardisation would in particular occur for those options addressing Changes/additions of EHSRs in Annex I of the Machinery Directive.

42. **How would the different options impact standardisation →**
    Any changes/additions of EHSRs in Annex I of Machinery Directive, would result in the need for a review of a part or even the whole portfolio of existing harmonised standards (more than 800) in order to evaluate the necessary adaptations. As a final consequence, the revision of the whole portfolio of standards or part of it can be necessary. The real impact depends on the amount and on the nature of these changes. Taking into account the recent demands from the European Commission regarding a detailed specification of an informative Annex ZA/ZZ this work is expected to require more resources than the challenging adaptation of the standards to the current version of Machinery Directive 2006/42/EC. We would also suggest not to increase the complexity of the existing set of essential health and safety requirements further, for example by transferring the elements already specified in harmonised standards into Annex I with the EHSRs which had been the case for some provisions of Machinery Directive 2006/42/EC. Therefore, it is of key importance to thoroughly consider the positive and negative impact of the changes of these provisions. Moreover, it would be important to give CEN and CENELEC the adequate time for the adaptation of the concerned standards of at least 3 years or more.

43. **Unless otherwise specified, the options are not mutually exclusive, and can be combined with each other. What would be your preferred option or combination of options? ->**

    We are in favour of aligning the Machinery Directive of the New Legislative Framework (NLF) for the purpose of consistency. However, in the consultation, which had been carried within CEN and CENELEC, the opinion was expressed that the Annex I of the Machinery Directive, which contains the technical requirements (EHSR), is already consistent with the NLF. In the above-mentioned consultation, different opinions were expressed regarding the potential change of EHSRs: on the one hand that the existing set of EHSRs duly covers any type of risk that can be envisaged, because all possible implications on safety which may result from emerging digital or new technologies are already addressed by the current set of EHSRs. In addition, it is believed that together with the continuous involvement of experts from different stakeholders we can ensure that the standards keep the pace of the technological development giving a suitable way of verification of the compliance of the given machine to the essential health and safety requirements. The comment was made that as new technologies are covered by existing publications and standardisation projects, they should not change the existing generic approach of the directive. The directive should remain technology neutral. For example, the possible implications which can result from cyber threats are already addressed implicitly as part of the risk assessment specified in item 1 in Annex I of the Directive.
    On the other hand, the other views were also shared in this consultation, i.e. that the EHSRs should be reviewed to address aspects relating to emerging digital technologies.

44. Are there changes you would like to see to the Machinery Directive that are currently not covered by the policy options?--> No

Concluding questions

45. **Do you know of any studies/reports/other documents that support your views or would otherwise provide valuable information for this study?**
    → Our feedback takes into account the experiences made for the adaptation of existing harmonised standards at the last revision of the Machinery Directives (98/37/EC → 2006/42/EC) in the years 2006 to 2009.
46. **Can you provide any data (cost data, accidents data or any other data) that support your views or would otherwise provide valuable information for this study?**
    --> No
47. **Are there any aspects that we have not discussed that you would like to bring up?**
    --> Yes. The link between the EHSR of the Machinery Directive and the Outdoor Noise Directive (OND) is not fully beneficial for the standardization under Machinery Directive. The OND is not a New Approach legislation and it contains fixed references to standards as well as to the noise test codes which became outdated over the course of time. At the same time EHSR 1.7.4.2 (u) of the Machinery Directive foresees the application of the OND. The number of products which fall within the scope if the OND and are at the same time within the scope of MD is considerable and there are identified cases where there is a conflict between certain standards under Machinery Directive and the outdated content of the OND. Therefore, we kindly invite the European Commission to propose solutions to overcome the above-mentioned problem.

Thank you for taking the time to participate in this study. We would also like to take the opportunity to draw your attention to the public consultation on the impact assessment, available on the Commission website.

Prepared in September 2019, Brussels

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	3.3 Removing Annex IV
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