

Machinery Working Group – Revision of the Machinery Directive 2006/42/EC (Doc. WG-2020.91.1)

CEN-CENELEC Response

General comments

At the meeting of the Machinery Working Group, held on 9-10 November 2020, the European Commission (EC) shared the indication of their future legislative proposal on the revision of the Machinery Directive (2006/42/EC)¹. With this document, CEN and CENELEC provide their initial input on this proposal.

Consultations in CEN-CENELEC

This paper is the outcome of the consultations which were carried out in the CEN-CENELEC Sector Forum on Machinery, in the CEN and CENELEC Technical Boards and among the TCs in charge of harmonised standards under the Machinery Directive². It reflects the position of the vast majority of the above-mentioned respondents on the major items which are relevant for the standardization.

We have received more than 120 pages of comments from the members of the CEN and CENELEC Technical Boards, from the members of the CEN-CENELEC Sector Forum on Machinery and from the TCs. Due to the limited time we were not able to provide a consolidated version on all aspects raised by our respondents. Nevertheless, these comments are available in a structured format (allocation to individual slides of the EC presentation) and can be used by the EC, if required.

We would like to highlight that because of the importance of this revision for CEN-CENELEC, we would wish to be given more time to analyse the EC proposal and to provide the response. Therefore, we would like to reserve the right to provide in the future further comments on the proposal.

Impact on standards

Whilst it has not been possible to carry out an exhaustive analysis in the limited time available, it is clear that the modifications introduced with the current proposal text are likely to have a high impact on the majority of our standards if not on all of them. The

¹ EC Doc. WG-2020.91.1 circulated in the Machinery Working Group

² The consultations were carried out from 10 November to 3 December in the CEN-CENELEC Sector Forum on Machinery and among CEN-CENELEC TCs which develop harmonised 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 regarding the proposal for the EC empowerment to adopt technical specifications (slide 41).

elements of the EC proposal which have the direct relevance for CEN-CENELEC are the EC empowerment to develop technical specifications (slide 41), the change in the conformity assessment procedure for Annex IV machinery – i.e. the proposal to remove the internal check option (slide 65) and all the changes in the Essential Health and Safety Requirements (EHSRs) (slides 9 – 27, 42-58 and slide 61).

Request for adequate time to adapt to the new provisions

As a consequence, it is fundamental to give CEN and CENELEC the adequate time for the review of the whole portfolio of 780 harmonised standards under the Machinery Directive and for the adaptation of the concerned standards. We would need at least 3 years or more from the moment of the adoption of the new legislative act, depending on the amount and complexity of new/modified ESHRs in the final Annex I.

Specific comments

1. Empowerment of the European Commission for adoption of implementing acts establishing technical specifications as substitute for harmonised standards (slide 41)

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 essential requirements and ESOs translate them into detailed technical requirements. This system and the standardization in this sector has proven to be successful and efficient. The indicated alternative approach towards presumption of conformity by means of technical specifications challenges the current system and would mean return to the Old Approach. This could be a “thin edge of the wedge” in the relationship between the EC and ESOs. 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 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.

Slide 41 indicates that this procedure may be used when there are undue delays in the standardisation procedure. What is the meaning of " undue delays "? An implementing act

will also take time to be elaborated. Standards take time to be written when there is no initial draft on which the standard can be based. It will be exactly the same for an implementing act. The reasons for all current delays, if relevant, have to be evaluated and can be solved operationally. EC and CEN-CENELEC must work hand in hand to find the corresponding solutions. The European Commission has a direct control on the citation of standards.

Our members also have highlighted that CEN-CENELEC need to be given the right conditions to deliver without delay. For example, allowing sufficient time between the adoption of a Standardization Request and the deadlines to develop standards. Furthermore, the Standardization Requests must be flexible enough to ensure that CEN-CENELEC can attract the relevant expertise to draft the standards.

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

Therefore, we request to not introduce the concerned provisions on the EC empowerment to develop technical specifications.

2. Conformity assessment for Annex IV machinery (slide 65)

There is no evidence of safety related shortcomings or problems of harmonised standards dealing with machines listed in the 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 harmonised standards for Annex IV machinery. Such an opinion was expressed by several Technical Committees responsible for the development of harmonised standards for Annex IV machinery.

One of our TCs expressed the opinion that the EC proposal could be driven by an insufficient market surveillance. In their opinion an insufficient market surveillance 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 relevant procedure from the Machinery Directive.

Eurogip, which is the member of the CEN-CENELEC Sector Forum on Machinery, expressed the opinion which is different from the opinion of other respondents to the consultations. Eurogip stated that there are examples of problems linked with self-certification that have not necessarily led to accidents but demonstrate non-compliance with the regulations. Eurogip provided some examples to illustrate this statement. In

addition, Eurogip claims that some manufacturers of Annex IV machinery tend to misunderstand the possibility to carry out conformity assessment without a Notified Body when a harmonized standard exists by complying with only some relevant requirements of the standard.

3. Compliance 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*”.

This foundational principle which is very important for the correct comprehension and the application of the Essential Health and Safety Requirements of the Machinery Directive as well as for the development of harmonised standards 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". Several TCs expressed a strong doubt whether it will be possible to merge those two concepts within their standards. Safety is about protecting men against machinery hazards, security is about protecting machinery against men attack. Therefore, additional thoughts seem necessary in order to define achievable limits in the sense of "reasonably foreseeable".

Consequently, the following modifications seems to be required:

slide 11: Delete all idents except the 1st one.

slide 12, 2nd indent: Delete following text “, *including those coming from malicious third parties leading to a hazardous situation,*”

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 harmonised standards.

However, in their comments TCs often expressed the opinion that the proposed EHSRs are too prescriptive. As one TC explained these new EHSRs are "challenging for standardization because of the conflict that may exist between the General principles of Annex I, part 1, and the specific new EHSRs. The CEN Guide 414 requires the standardization processes to follow the principles of EN ISO 12100, but several new

ESHRs of the Machinery Directive are prescriptive requirements regardless of the individual risk assessment. On the one hand, the new provisions inform of new risks and set requirements, but on the other hand, the risk assessment shall identify the risks, and, if applicable and significant for the specific machinery in question, determine requirements to mitigate each risk (...). Technology develops faster and faster and EHSRs describing technical solutions will always lag behind."

Consequently, it seems necessary to check whether to review or delete the following proposed new EHSRs :

- slide 21: first paragraph of new EHSR 3.2.4
- slide 23: first two paragraphs of the proposed EHSR 3.3.3
- slide 51: EHSR 1.7.4.2 should be restricted to the essential content of the safety manual. There is no need to insert several new details which come from the harmonised standard EN ISO 20607:2019 'Safety of machinery — Instruction handbook — General drafting principles'. (Eurogip, which is the member of the CEN-CENELEC Sector Forum on Machinery, is of a different opinion).
- slide 55: the proposed addition; the last sentence of the existing EHSR 3.5.3. sufficiently addresses the risk.

4. Ensuring consistency of the specified Essential Requirements (Machinery Directive, Annex I)

The consistency of the Annex I to Machinery Directive, is fundamental for the correct comprehension and application of the EHSRs as well as for the development of harmonised 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 harmonised standards in OJEU) will become even more critical. Some of these new proposed EHSRs, especially those relating to new and emerging technologies, could be better covered by the Guide to the application of the new Machinery Regulation.

Whereas, very often in their comments the TCs noted that many aspects in the EC proposal are already covered by the existing EHSRs of the Machinery Directive. Moreover, many new proposed or amended EHSRs are not clear for the TCs which will have a negative impact on the development of harmonised standards.

Consequently, the following aspects should be reconsidered by the EC:

- slide 19: the proposed additions to the existing EHSR 1.3.7
- slide 27: new Essential Requirement under 3.5.1 for batteries as it is not clear at all what kind of hazards/risks for an automatic charging process (where no person would be involved) should be addressed by this new EHSR.

- slide 44: new paragraph; duplication of existing EHSR 1.2.4.3 Emergency stop. The details already exist in the harmonized standard EN ISO 13850.
- slide 45: all proposed modifications for EHSR 1.5.13; existing text “*hazardous materials and substances*” covers the additionally mentioned examples in the first paragraph (new sentence might be suitable for integration in the Guide to the Machinery Directive); added words “*capture*” and “*filtration (separation)*” in 2nd and 3rd paragraph are basically covered in existing text by words “*contained*” and “*evacuated*”.
- slide 48: the proposed addition to EHSR 1.7.4.2 r) is already covered by the existing EHSR 1.1.2 a) and the details are given by the harmonised standard EN ISO 20607.
- slide 49: new EHSR 1.7.4.2 w); are much too detailed requirements in the NLF context and already covered by the existing EHSR 1.7.4.2 l) (new text might be suitable for integration in the Guide to the Machinery Directive).
- slide 52: the proposed addition to EHSR 2.2.1; is already covered by the existing EHSR 1.5.13.

On the principle the modifications of Annex I on EHSRs as proposed by the EC suits Eurogip, the member of the CEN-CENELEC Sector Forum on Machinery.

5. Other comments on the proposed changes in EHSRs:

- slide 53: Some TCs asked to delete the proposed addition to the EHSR 2.2.1.1. CLC/TC 116 'Safety and environmental aspects of motor-operated electric tools' noted that the current proposal requires measurement and declaration of both continuous vibrations and repeated shock vibrations, regardless whether they are generated by the machine concerned or not. The TC believes that the requirement should be clarified so that only existing phenomena are to be tested and declared. This TC highlighted that there are currently no standards available for the measurement of shock vibrations

Moreover, the question was made why the proposal does not cover anymore the following requirement of the current EHSR 2.2.1.1, which restricts the declaration (detailed measurement) of vibration values to levels which are considered dangerous:

“— the vibration total value to which the hand-arm system is subjected, if it exceeds 2,5 m/s². Where this value does not exceed 2,5 m/s², this must be mentioned,”?

- Slide 56
One of our members made the following comment: "This induces constraints on the design of the machine, whereas safety measures could be taken elsewhere (by training, by using PPE...) in order to mitigate the electrical risk.

For working on or around live conductors, wouldn't there be a risk of being prevented to make use of any machine designed, even slightly, with conductive materials?

When stating that all high mobile vehicles that are due to pass under or near power lines should be equipped with insulation systems, this can be conceived for specific machines (e.g. insulating arm elevators, machines for tree pruning under the lines) that are intended to be used predominantly in the electrical environment. However, if extending that rationale further on, what would this lead to for machines such as excavators, trucks with a dump body, concrete pumps, etc.? Would it therefore be economically reasonable to imagine that all these machines that may at some point be in operation near an overhead line will have to be designed with this requirement in mind?"

- Slide 58 This proposal is in particular relevant for CEN/TC 10 'Lifts, escalators and moving walks' as well as for CEN/TC 98 'Lifting platforms'

CEN/TC 10 provided the following comment:

"EHSR 6.2) From the standardization point of view, the current requirement of "hold-to-run" control is clear with no room for interpretation. Removing and replacing this requirement with "manned at all times" (option 1) or adding second sentence related to identification of risks (option 2) makes the requirements ambiguous, leading to difficulties in formulating specification of standards in fulfilling this EHSR. More detail given below:

Regarding the option 1:

The term "Manned at all times" is open to many interpretations or understandings. In an industrial environment, such as a factory or a warehouse, the person who is "manning" the control station may have been trained and have instructions to use the device. On the other hand, lifting appliances for lifting persons are widely used by general public, including children, elderly as well as persons with disabilities. These persons have no training or instructions for using the lifting appliances or take necessary actions in case of malfunction or emergencies.

Replacing hold-to-run control with "manned at all times" basically means that the requirements for product design is replaced by the requirements of who is using the product and how the person may behave.

One understanding of "manned at all times" may be that a person must be present, but the control device may be automatic, which only needs to be activated. If after activation of the control device, e.g. a landing call station in a lifting platform, the person walks away, would the requirement of "manned at all times" be fulfilled?

Considering above, the option 1 creates severe difficulty for standardization experts, especially considering that hENs may not define the type of the users (passengers) on or around the carrier or their expected behaviour.

Regarding the option 2:

This is becoming a very confusing EHSR. From the Directive point of view, the first sentence is clear in indicating that there are risks which should be mitigated by providing a fully enclosed carrier. But the newly added second sentence overrides the first, indicating that there may be no risks.

There is a strong link between EHSR 6.2 and EHSR 6.4.1. In the proposed changes to EHSR 6.2, no references or proposal has been made for EHSR 6.4.1. The proposed changes to EHSR 6.2 will create confusion on application of EHSR 6.4.1. These contradictions cause difficulties in standardization work, as the EHSRs and their relationship becomes uncertain."

CEN/TC 98 'Lifting platforms' asked to delete the proposed additions to the EHSR.

Conclusions

First, we plead to continue the cooperation with the EC "hand in hand" and in confidence. CEN-CENELEC need to be given the right conditions to deliver without delay. Therefore, we do not support the concerned provisions on the EC empowerment to develop technical specifications (slide 41).

Secondly, we ask the EC to ensure the compliance of the future legislative act with the NLF concept as specified in the Blue Guide whereas, as explained above, several parts of the EC proposal are not in line with the concept of the intended use and of the reasonably foreseeable misuse of a product. Furthermore, NLF legal acts shall specify *“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). They shall not be prescriptive. Therefore, we ask the EC to review the relevant new/modified EHSRs.

Thirdly, as we explained above, many aspects in the EC proposal are already covered by the existing EHSRs of the Machinery Directive. Moreover, many new proposed EHSRs or their additions are not clear for the TCs which is expected to have a negative impact on the development of harmonised standards. The consistency and the clarity of the Annex I to Machinery Directive is fundamental for the smooth development of harmonised standards in this field. Therefore, we request the EC to eliminate the duplications and ensure clear requirements.

Finally, it is fundamental to give CEN and CENELEC the adequate time for the review of the whole portfolio of 780 harmonised standards under the Machinery Directive and for the adaptation of the concerned standards. We would need at least 3 years or more from the moment of the adoption of the new legislative act, depending on the amount and complexity of new/modified ESHRs in the final Annex I.



Annexes:

1. CEN-CENELEC Sector Forum machinery explanation regarding AI based on ISO TR 22100-5
2. 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](#).

CEN-CENELEC Sector Forum on Machinery – Contribution how to cover safety related implications of AI (machine learning) use in machinery

At the web-meeting held on 2020-06-18 the representatives from the CEN-CENELEC Sector Forum on Machinery informed the EC desk officer responsible for the Machinery Directive 2006/42/EC about the general risk assessment and risk reduction methodology for safety of machinery as specified in EN ISO 12100 'Safety of machinery - General principles for design – Risk assessment and risk reduction' especially in relation to upcoming new digital technologies (see document **WG.2020-84** circulated at the Machinery Working Group). This technology neutral methodology is fully compatible with the general principles of the Machinery Directive and is therefore the basis for a large majority of harmonised standards in support of this Directive.

With regard to the possible safety related implications of AI (machine learning) use in machinery the upcoming CEN/ISO Technical Report ISO/TR 22100-5 'Safety of machinery - Relationship with ISO 12100 - Part 5: Implications of Artificial Intelligence-machine learning' was presented at this meeting.

This document considers actual existing AI (machine learning) use cases for machinery and contains an analysis under which conditions safety related implications are at stake. Based on the comparison between two different design concepts for driverless industrial trucks (AGVs) with and without AI (machine learning) the document comes finally to the following conclusion:

“The risk(s) introduced by AI in machinery applications can be completely addressed by the methodology for risk assessment and risk reduction as prescribed in EN ISO 12100 where risks of the AI are addressed according to the intended use and limits (predetermined boundaries) specified by the machine manufacturer.”

In conjunction with ISO/TR 22100-5, the machine specific standard EN ISO 3691-4 for safety of automated industrial trucks was presented, which considers among other design features also the use of embedded AI for this type of equipment.

In view of the EC presentation at the last meeting of the Machinery Working Group meeting (2020-11-09/10) the above conclusion from ISO/TR 221100-5 would imply **to restrict the new EHSRs on AI to the aspect covered by slide 13.**

New technologies – Annex I

1.2. CONTROL SYSTEMS

1.2.1. Safety and reliability of control systems

Control systems must be designed and constructed in such a way as to prevent hazardous situations from arising. Above all, they must be designed and constructed in such a way that:

– the safety functions cannot change outside the limits of the machinery as defined by the manufacturer in the risk assessment. This must be part of guaranteed-in-the risk assessment performed by the machine manufacturer, regardless of any modifications to the settings or rules generated by the machinery or by operators in charge of the learning phases.

13



Consequently, the additional foreseen EHSRs (addressing under the term “*machinery with fully or partially evolving behavior or logic*” obviously AI aspects, too) on slides 10, 14, 15 and 19 (last sentence) of the EC presentation (Doc. WG-2020.91.1) are not necessary and would lead to misunderstandings in the Technical Committees because of the inconsistency of EHSRs in Annex I of the Machinery Directive.

As the autonomous behavior of machinery is normally the result of an AI application, we may question the necessity of the proposed EHSRs related to “*autonomous mobile machines*” (slides 16, 20 to 27 of the EC presentation), too.

Certain aspects mentioned in these slides which seem to be not necessary in the legal text can be suitable for further explanations in the Guide on the new Machinery Regulation.

A restriction of safety related AI aspects on the amended EHSR 1.2.1 as covered in slide 13 would address comments from several TCs and members of the CEN-CENELEC Sector Forum on Machinery highlighting that the definition of artificial intelligence is not clear in the EC proposal. For example, one TC stated “the subject of AI seems to be



insufficiently considered and, by treating the whole concept as a single item, existing standards which satisfactorily address so called “weak AI/machine learning” might be severely and unnecessarily impacted by an approach attempting to account for so called “strong AI” which is not the state of the art.”