

Webinar of 2022-10-06

Webinar: Informative Annex ZA/ZZ for Machinery Directive

Questions & Answers

1	Are the names of HAS-consultants according to MD, Noise and ATEX?	As regards this aspect, some issues relating to the protection of data need to be clarified first by the EC. EY (HAS Contractor) has launched the call to contract one machinery consultant.
2	When the new contract for the HAS-system will end? Will this again create a long period of stand-still?	The tender for the HAS-contracts - which is still publicly available - foresees a duration of 24 months with the possibility of prolongation for another 24 months (so 4 years in total - similar like the previous contract). As to the question of a potential standstill period in 4 years from now: Of course there is no guarantee to this: But I very much hope that with the experience that has been gathered with this transition one can avoid - or at least significantly reduce - such a standstill period in the future.
3	Please provide the link to BOSS in electronic form.	Dear Martin, the link to the Annex ZA (CEN) is https://boss.cen.eu/reference-material/formstemplates/pages/ . The link to Annex ZZ (CENELEC) is: https://boss.cenelec.eu/reference-material/FormsTemplates/Pages/ When you access that page and click on "Annex ZZ" the line expands and you'll find the relevant documents for the Machinery Directive.
4	If a EHSR is not applicable (different from not covered), is it possible to specify "non applicable"?	The template for informative Annex Z under Machinery Directive foresees only to mention 'the relevant' EHSRs. The mention 'not applicable' was not agreed with the EC neither approved by CEN and CENLEEC Technical Boards, so it shall not be used in the Annex Z for Machinery Directive If an EHSR is "not applicable" and "not relevant" it shouldn't be included in the Annex Z table.
5	Are non-EU market authorities involved or do they have observers in the development of the new MD?	EEA and EFTA countries apply the Machinery Directive and will also apply the new Machinery Regulation. They are not directly involved in the

		development of the new legislation, but they are consulted according to the agreements that exist between the EU and those countries. When these countries request it, they join relevant meetings linked to Notified Bodies as well as on market surveillance and also the Machinery Expert Group.
6	What is the basis to decide whether an essential requirement is relevant?	This is of course very much dependent on the product and on the knowledge of the experts in the TC or WG, respectively. They are the ones who have to decide which EHSRs are relevant. Of course, this might in principle be challenged by experts, HAS Consultants or the Commission. But it really depends on the know-how of the people.
7	What are the consequences of the Annex Z not being fully in line with the rules you have explained?	<p>This may result in the lack of compliance assessment and/or in the non-citation of the standard in the OJEU.</p> <p>As a matter of fact, in most cases where an Annex Z is not in line with the rules the HAS Consultant - who is in charge of checking the correctness of the Annex Z - will give a negative assessment to the standard. The European Commission in turn very strongly relies on these assessments as they constitute the main "test" for checking whether a standard is compliant with the legal requirements. So, it is very likely that - without a correction to the negative assessment - the harmonization will be rejected for citation in the OJEU.</p>
8	Very often Notified Bodies use the IEC technical report templates when reporting. Not all notified Bodies cover the annexes Z when they issue the report. Is that acceptable if the report also is used as evidence for compliance with an EU directive?	If such reports are used as a 'service item' by manufacturers, it is still the end-responsibility for those manufacturers to declare compliance with the requirements. It is not allowed to omit essential information that the Notified Body did not include in their report. In formal legal terms, the report has no legal value, although helpful for the manufacturer. If it is an EC type-examination procedure, however, the Notified Body has to comply with all requirements in Annex IX of the Machinery Directive without derogations.

9	<p>Is there a numbering convention for annexes when a standard is harmonized against multiple directives, eg. PED and MD? I.e. which directive "belongs" to Annex ZA, ZB etc.</p>	<p>Each directive needs to be covered by a separate Annex Z, starting from Annex ZA, then Annex ZB, etc.... It is up to the TC to decide which ones comes first</p>
10	<p>Can we assume that much of what is discussed today applies to Annex ZA/ZB for standards under other regulations and directives e.g. PED, CPR? It would not make sense to me if we have different formats?</p>	<p>Many aspects are in common as are based on the generic template for the Annex Z as agreed with the European Commission. However, there can be still some specificities dedicated to a given EU legislation. This webinar is dedicated specifically to the Annex Z under Machinery Directive.</p>
11	<p>Please excuse me, the ISO 12100 Standard does not cover all requirements in relation to the MD 21006/42/EC, which also requires protection of health and safety for domestic animals and the environment. ISO 12100 states in its Scope, that it does not cover such requirements. SO how do you handle this fact?</p>	<p>The EHSRs of the Machinery Directive refer mostly to the safety of machines and their operators and but indeed also to protection of environment, as covered by the EHSRs 2.4. The last ones are dealt with by some harmonised standards of <u>CEN/TC 144</u>. The TCs aim to cover all the relevant EHSRs. However, if it happens that a given standard does not cover certain EHSR which is relevant for the product then a manufacturer needs to prove the conformity with the Machinery Directive without referring to a hEN.</p>
12	<p>"Not Relevant" could help HAS consultant to understand that point has been considered by the Wg.</p>	<p>In principle you are right. I believe it was decided in the past to leave out the term ""not relevant"" from the informative Annex Z in order to avoid that in every Annex Z the full set of EHSRs is listed. Don't forget that the B-standards often cover only a small fraction. I agree: One could easily carry it out in the way you proposed. However, it was decided by CEN-CENELEC Sector Forum on Machinery and the CEN and CENELEC BTs to not indicate them.</p>
13	<p>For what does EHRS stand?</p>	<p>Essential Health and Safety Requirements. These Essential Health and Safety Requirements are all those listed in Annex I to the Machinery Directive 2006/42/EC</p>
14	<p>Materials used or produced: Agricultural machinery often uses hydraulic fluid which is dangerous so it should be covered?</p>	<p>If during the risk assessment this comes up as a hazard that needs to be dealt with ("relevant"), then the TC ideally should write a clause in the text describing a solution to avoid any risks. If this</p>

		isn't possible then the TC must indicate this EHSR in the list and indicate it as "not covered".
15	When doing the Annex Z, how is known / ensured, that the respective EHSR is covered complete but not just partially?	The EHSR will be covered when the TC completely eliminating any risk connected to it. This is usually done by means of a technical solution. If even after the proposed technical solution the risk still exists (even if minimized) then it should be set as "not covered".
16	We know that CE marking on machines the most important thing in conformity assessment process is to meet ESHR of the Directive. Some manufacturers can only use Type-A and Type-B standards, although the product has a Type-C standard. My questions are: 1- In this case, can we push, the manufacturer to use of C-Type standard for the product? 2- If the Type -C standard is not used, how can we understand whether the ESHR has been met?	In general, standards are voluntary. But, indeed, for the purpose of the presumption of conformity with the Machinery Directive it is not sufficient to use only the type-A and type-B standard.
17	Why should I add "not covered" in the third row - Question before it was wrong to indicate "not covered" in the third column?	The Annex Z for machinery needs to indicate the EHSRs) which are relevant for the product addressed in the standard and if applicable the EHSR(s) which is (are) relevant but is (are) not covered by the standard.
18	If one Essential Requirement is not covered the standard will not listed?	No, if one EHSR that was set as relevant (therefore included in the list) but was "not covered" doesn't mean that the standard can't be cited in the OJEU.
19	When it is not relevant, we have to do nothing, nevertheless on the working draft it could be interesting to mention it initially because we know this has been taken into account and it is not an oversight.	If an EHSR isn't relevant, it shouldn't be listed in the Annex Z. The analysis which ones are not relevant can be kept as a separate TC document but not in the standard.
20	With the changes planned to the machine directive how long do you think sessions like this will take to develop to support the new changes and exploitation of them etc	The changes in the machinery directive which impact standards are to large extent known and are being communicated to Technical Bodies e.g. in their meetings. The timeframe for the adaptation of standards to the Machinery Regulation is under discussion with the European

		Commission. Once the matters are clarified, CEN and CENELEC will prepare guidance. CEN and CENELEC will inform all the interested parts
21	I believe that the question about "not applicable" requirements has not been answered. Are they to be excluded from Annex ZA as it happens for those "not relevant"?	If a requirement is "not applicable" it shouldn't be listed in the Annex Z.
22	Do CEN and CENELEC crosscheck ESHR's quoted in Annex Z of a standard before publication?	No, the editing team only checks the editorial part of the document and not the content itself.
23	Some EHSR are self-explanatory without the need for further requirement in the EN (for example advertising literature must match technical data). For this I assume it is "not covered" even though it never will be covered?	The EHSRs should not be repeated in the standard unless the standard provides some added value. In the case where for a given EHSR (e.g. EHSR 1.7.4.3 on sales literature) the standard does not provide any added content it seems to be the only option indeed to state 'not covered'.
24	Not relevant = applicable but does not need risk reduction measure Not applicable = it does not make sense to apply it to the machine, for example the seating position for a standing operator machine	The template for informative Annex Z under Machinery Directive foresees only to mention 'the relevant' EHSRs. The mention 'not applicable' was not agreed with the EC neither approved by CEN and CENLEEC Technical Boards, so it shall not be used in the Annex Z for Machinery Directive
25	What about requirements which are relevant but not significant?	Not-significant hazards shall not be addressed in the Annex Z.
26	What about a requirement that is included in the standard due to the risk assessment for the machinery, but which is not an ESHR in the MD?	If there's no EHSR to be covered then it doesn't need to be mentioned in the Annex Z.
27	Maybe I've not well understood, but if an EHSR has several requirements e.g. indents) and for instance one of them is not covered shall be written NOT COVERED in the 3rd column?	In this case it may be advisable to "sub-divide" the EHSR into sub-sections (for example "EHSR 1.4.3.3 1st indent" etc.) and address them item by item.

28	Can the relevant EHSRs of a product be covered by different hENs?	Yes, through Normative References. In this case they have to be normatively mentioned in the Clause 2 and in the body of the standard. Then, these clauses can be indicated in the lines corresponding to the EHSR that they are covering.
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