Webinar of 2021-10-18

Webinar: 'Harmonized Standards under the Machinery Directive''

Questions & Answers

1	What applies when a harmonised standard makes normative references to non-harmonised standards?	Harmonized standards can contain normative references that are: (1) Non-harmonized standards and/or (2) Harmonized standards. This remains a technical choice for the TC. However, if a normative reference is also a hEN, it is important that these have not been rejected by the EC for citation.
2	Will the non-harmonized standards mentioned be assessed by the has consultant?	The EC considers that harmonized standards are part of a legal system and normative references are integral part of hENs. Therefore, when the HAS consultant is assessing a harmonized standard, he/she will also check if the normative reference, regardless if it's harmonized or not, is relevant for the clauses of the hEN giving presumption of conformity.
3	Which formal aspects for a Risk Assessment are existing for a WG developing a type C Standard?	In order to write a Type-C standard under the Machinery Directive according to CEN Guide 414 it's necessary to: - identify significant hazards. - specify necessary risk reduction measures. According to ISO/TR 22100-1 "Safety of machinery - Relationship with ISO 12100 - Part 1: How ISO 12100 relates to type-B and type-C standards" *"Type-C standards are written by a team of technical experts (in particular, from machine manufacturers and representatives from health and safety bodies) knowledgeable in the machine design (intended use), the practical use of the machine, the accident history and health records, available risk reduction techniques, and the legal frameworks in which the machine is intended to be used (placed on the market)."* If you wish to perform the risk assessment, please refer to ISO/TR 14121-2 "Safety of machinery -

		Risk assessment - Part 2: Practical guidance and examples of methods".
4	How do you look to lowering working coefficients of lifting accessories in case the risk assessment has been executed in most detailed possible way?	If the lowering of existing safety coefficients or any other risk reduction measure can be justified by facts (e. g. via the results of a risk assessment) by the WG this should be accepted by HAS-consultants, EC representatives or representatives from member states.
5	Is there a list of HAS consultants we can consult in case of questions?	HAS contractor (currently Ernst & Young) manages the pool of 'HAS Consultants' which means it is their responsibility to allocate the work. However, Consultants are allocated per specific sector in line with their expertise. Normally, consultants are allocated to a given TC. CCMC and TC's get information which consultant was allocated to a given assessment only after the assessment and only then these consultants can be contacted concerning this specific assessment.
6	What about references to TS or TR documents? Are these allowed?	The use of TRs should be avoided as they are only informative documents with no requirements. The use of TSs as normative references in hENs is currently under discussion with the EC.
7	Can a harmonized standard set aside an EHSR of the Directive?	Yes, it can If a harmonised standard under Machinery Directive does not cover a relevant EHSR it needs to be addressed as "Not Covered" in the 3rd column of the table in Annex Z. See the template of informative Annex Z in CEN (here) and in CENELEC (here). See also the presentation Drafting a detailed informative Annex ZA/ZZ under the Machinery Directive. ".
8	Participating to the development of some type C standards, I noticed that, since the comments from the HAS consultant were "too difficult to implement", the standard was removed from the list of harmonised standards in order to be published as EN. Is that a common trend? What do you think about that position?	Indeed, this has already happened when the comments couldn't be completely addressed and there was strong need for the standard to be published. But these are exceptional cases and most of the times the Technical Committees resolve the issues raised in the comments and propose the standard for citation. In case, the TC decides to publish a non-harmonised standard, a harmonised version can be achieved via a future amendment or revision

9	When the valid CEN 414 guide has an old format for the ANNEX ZA, how do persons not attending this seminar know this fact and where is then the right version public available?	CEN Guide 414 is going to be reviewed to reflect the most recent template. There are templates on the CEN and CENELEC BOSS websites: https://boss.cen.eu/reference-material/FormsTemplates/Pages/ https://boss.cenelec.eu/media/uabhjqua/annexzz_machinery_e.docx
10	The Commission presented in April 2021 a proposal for a REGULATION on machinery products in document COM(2021) 202 final. What happens if the regulation comes into force and does the standard/guidance already consider possible legal changes?	The Commission's proposal is currently subject of the "ordinary legislative procedure" as foreseen by the EU law for the adoption of the legal acts in this area. Co-legislators (European Parliament and the Council) can change the legal text. At the same time, CEN-CENELEC Sector Forum on Machinery aims to anticipate the future Regulation and will provide guidance to Technical Bodies in advance of the adoption of the Regulation. Technical Bodies are invited to anticipate the changes but on the other hand the text they can develop the respective standards only when the text of the Regulation will be stable.
11	How and when the user's contribution and experience is collected to improve the risk assessment process?	Ideally the user´s contribution can be brought in by a user representative within the WG. Often representatives from Health and Safety institutions being members of the WG have also good knowledge about the real machine use.
12	How easily can an existing ISO Standard become an ISO EN Standard?	The adoption of an ISO Standard by a CEN/TC is fairly simple process. Basically, the CEN/TC just has to propose the adoption of the existing ISO Standard as a New work Item and vote for it. If the vote is positive the process continues, and the usual steps are followed.
13	Some manufacturers want to use Type A or Type B standard, although there is a Type C standard for the product. Do you think this is the right approach?	Each standard regardless of its type (A, B or C) provides an offer for standard users (e. g. machine manufacturers). Therefore, it is up to them to decide what is appropriate for them. However, to benefit from the presumption of conformity it is strongly recommended to use existent type C standards.
14	Thank you for the presentation. ISO 12100:2010 "Machinery safety - Risk assessment and risk reduction" and EN	EN ISO 12100:2010 is a type-A standard whereas EN 60204-1:2018 is a type-B standard. CEN standards can normatively refer to EN 60204-

	60204-1:2018 “Safety of machinery - Electrical equipment of machines” are both type-A standards and both harmonised with the MD, and EN 60204-1 is harmonised with both MD and LVD.I am a national standards representative for a manufacturer of electric and electronic equipment (EEE) that can control agricultural tractors and non-road mobile machinery safety (start/stop/forward-neutral-reverse/steer/raise/lower) where EEE is >75-1500 VDC. As there are few machinery with low voltage safety standards for mobile machinery/tractors safety, should we base our standards on a hybrid between such diverse requirements?	1:2018 and to other CENELEC standards for the matters relating to electrical equipment and the other way round. CENELEC standards can have normative reference to the CEN standards.
15	Is it mandatory to link it to ISO 9001-QA requirements?	No, ISO 9001 does not play a role for the machinery safety standardisation.
16	What happens if an existing harmonized EN ISO xxx standard is changed on ISO level and thus becomes incompatible with a European Regulation?	Revisions of EN ISO standards which are started by ISO are automatically registered in CEN work programme as draft EN ISO revisions. If the EN ISO harmonized standard is being developed and is incompatible with EU regulation, it is very likely that the HAS consultant will provide a lack of compliance HAS assessment. The TC will have to assess all the comments from the consultant and consider whether they should be integrated in the EN ISO. Communication/exchanges between both CEN and ISO TCs is crucial to find consensus and try to have the standard modified to be compliant with the machinery directive.
17	There is a big goal for all standardization to make standards easier to understand for no experts.	Noted.
18	I would be interested to know what experience has been gained with the approach of feeding the comments of the HAS consultant into the international technical committee (i.e. ISO/IEC TC) with the aim that the ISO or IEC standard can be harmonized (as far as possible) unchanged with the MD. Is there a 'best practice'?	About 30% of the harmonised standards under MD were developed together with ISO or IEC. These harmonised standards need to comply with the same rules as purely CEN or CENELEC standards – being in line with the principles of the MD (2006/42/EC) the associated mandate M/396 and the cross-sectoral requirements for harmonised standards (see the dedicated CEN BOSS website here and the CENELEC BOSS

		website here and here). It is recommended that EN ISO follow CEN/Guide 414 (which takes into account ISO/Guide 78). The interaction with the HAS-consultants should be started as early as possible (e. g. initiating the voluntary HAS-assessment at WD-stage). In addition, the cooperation between CEN and ISO/TCs or CENELEC and IEC/TCs is key to achieve harmonisation.
19	I object to "feasibility" of requirements (slide 28): Either the requirement is essential and/or health related or not. But if it IS, then feasibility must not be an argument.	Slide discusses this attribute generically, in domain-independent fashion. If a requirement is defined in the legal text (as essential), the quality of implementation should be ensured at any cost. If not possible, or decided not to cover an EHSR, the informative Annex Z offers a possibility to state "not covered".
20	Could you explain what you mean by “atomic” please	Atomic requirement refers to a single traceable element. In other words, one should focus on THIS requirement only, without seeking missing elements described in other requirements.
21	For a EN std supporting MD accepted by the HAS Consultants that was rejected by EC at the end (after publication), and TC is asked by EC to prepare an Amendment to make the EN acceptable for harmonization (without detailed comments), how the TC can ensure that the EN is acceptable prior publication of the EN + Amendment, as HAS Consultants are not supposed to check other than the amendment?	Normally a standard that received a compliant assessment by the HAS consultant should not be rejected by the EC for citation. If this happens, CCMC will follow up with the EC to request to look at the coherence and consistency of the HAS consultants to ensure alignment with the EC instructions. If the EC provides comments to be included in the standard, the TC can choose whether to prepare an amendment or revision. A revision is recommended because it will avoid to miss out something in the amendment. If the TC still prefers to proceed with an amendment, the HAS assessment will be on the amendment and in principle the HAS consultant should also take a look at some elements of the parent standard.
22	Slide 30: I know a standard which imposes an obligation to the "manufacturer", but the standard is older than the harmonization legislation, so the standard does not mean the "economic operator" "manufacturer", but simply the person who assembles the device. (this is not machinery). The next revision is	It might be an idea to contact the National Standardization Body in CEN or the National Committee in CENELEC which is relevant for this standard to propose the review of the standard if relevant.

	not to be expected soon. This already leads to misunderstandings. How to react?	
23	How is it expected to document the SOTA?	State-Of-The-Art is result of the discussions of a Technical Body during the development of a standard, it is reflected also in its documents (meeting reports, documents relating to risk assessment, if they exist, etc).
24	For many standards including harmonized standards such as EN 1005-3:2002, there is a lack of reference/support for the technical data/values presented in the standard. Is this acceptable from a CEN perspective or is it strongly advised to support technical data or values etc. with references? (This lack-of-reference might be a risk for the credibility of the standards in the longer term.)"	See above
25	In the context of 'Verifiable': if the Guide mentions that a working coefficient needs to be 'appropriate', how is this linked with the content of your slides?	The use of standards is voluntary. When the ESOs submit a standard for harmonisation, it could be decided to cite it in the OJEU or not to cite. This circumstance could be used to discuss about the opportunity to harmonise something which appears incomplete in comparison with something similar that the State Of The Art can realistically propose. This shall be subject of case-by-case analysis.
26	Appreciating that not all ESRs need to be addressed in a 'harmonised' Standard, can a technical body simply decide not to address an ESR because its perceived complexity makes it difficult to address? Are there any circumstances where there is an obligation on a 'harmonised' Standard to address an ESR (e.g. if there is no other known technical guidance and the scope of the Standard means it a reasonable expectation to address the ESR)?"	In principle, Technical Bodies aim to cover all the relevant Essential Health and Safety Requirements. But indeed, this is not mandatory.
27	The goal is to write a standard that gives legal certainty. To reach that target it is important to have the legal basis (the Machinery Directive/Regulation) written in the same,	Reply from the European Commission: The text of the MR proposal was carefully prepared by several professionals looking from different angles/views. The MR text was sent to the co-

	unambiguous way. As far as I know this is often not the case. Will the new Machinery Regulation be checked using the same criteria?	legislators (European Parliament and the Council).
29	What about the references to the always actual version of a standards (references to standards without giving the version)? Is this no more possible?	In harmonised standards the normative references which are linked with the presumption of conformity should be dated. See details in the last presentation 'Dating of normative references on harmonized standards'.
30	I object that "measurement methods" should be considered: If the requirement is justified by arguments of safety or essentiality, then the requirement is valid and must be verified by ANY method available. The methods available at any time must not affect the consideration and wording of a requirement.	"Making measurable" could be supported by different tools. Experts can select a method available (it means ANY), but the choice should be also feasible and necessary. Case-by-case.
31	I might be taking your text too literally. The conclusion stated that WHO should be doing something - but I thought the guidance was not to specify an actor?	The European Commission representative explained that he was trying to say that ALL POSSIBLE uses/interactions need to be analysed and that is not necessary tospecify who is THAT actor because ideally the testing/verification refers to ANY use at ANY time.
32	Many thanks for this clear presentation. Moreover, could you please give us more precisions on the requirements linked to "foreseeable misuse"? How can we approach and address them with respect to the user's point of view?	Do consider ALL possible interactions between users and the machine. The property allowed/not allowed/prohibited/shall be avoided.. Any use (and misuse) shall be part of the collection of all possible interaction. It is the property of the interaction. Check the book on requirement engineering. See also CEN Guide 414
33	In case there is a dispute about the State-Of-The-Art. Is there any arbitrator available eg. HAS Consultant or Commission?	State-Of-The-Art is result of the discussions of a Technical Body during the development of a standard in line with the CEN-CENELEC rules. The ESOs are autonomous and independent. It is always possible to convey to the relevant Technical Body the opinion about the need to improve the content of a given standard This can be done for example via the National Standardization Body in CEN or the National Committee in CENELEC which is relevant for the

		standard.
34	You told us that the verification by inspection is related to the human senses (seeing, hearing, sensing, tasting, smelling) and hard to be implemented by digital systems. What about image processing algorithms for example? I see this differently.	Thank you for this question. One day indeed, we will discuss about AI robots deputed to inspect quality automatically (a kind of machine-verification). A challenging aspect indeed.
35	What about 50% covered requirements, are they to be stated as “not covered” or what?	This should be indeed marked as "not covered".
37	If a type C standard does not cover all the requirement of the MD (by indicating "not covered" in annex Z), can the standard still become a harmonized standard which gives you presumption of conformity to the MD?	Yes, it can be harmonized and give presumption of conformity but not for that particular Essential Health and Safety Requirement.
38	Regarding the Annex ZA. Can the TC decide which of the requirements are relevant for the product in question or who decides this? (It seems that my impression that all Essential Requirements have to be listed in an Annex ZA of a Type C standard was not correct.)	First, the TC must identify the significant hazards being associated with the machinery. Then the necessary risk reduction measures must be specified in the clauses of the standard. These risk reduction measures must correspond to the relevant essential requirements of the MD See the template of informative Annex Z in CEN (here) and in CENELEC (here).
40	When we developed the Annex ZA's for EN ISO 10218-1 and -2, we added all text from the MD into the Excel fil and cut the different requirements into pieces, one at each row in the work sheet. This made it easier to work and to compare that we had covered all relevant EHSRs.	Thank you for sharing your experience.
41	(For ESHR 1.1.2) How is the reference to guide 414 to be handled in CENELEC?	Indeed, Guide 414 is currently the CEN Guide. CENELEC TCs are invited, in an analogous way, to indicate in relation to EHSR 1.1.2 the number of these clauses which deal with safety requirements and/or protective/risk reduction measures, verification of those and with the information for use
43	What is advised when an international standard is to be harmonized with the MD,	The National Committee, which holds the secretariat of the SR, will be responsible to decide

	but there is "only" a Reporting Secretariat (SR) at the European level? Does the SR have to be transformed into a TC for the development of the Annexes ZA/ZZ? Is it sufficient to create a task force?	whether the EN IEC is relevant for becoming a harmonized standard, in consultation with the European experts involved in the IEC TC. If it is the case, the National Committee will be responsible to assess the resources that are needed to perform the harmonization work. If the work requires the preparation of Annexes, the European experts in the IEC TC can be invited to come together to prepare such Annexes, which will go through the CENELEC processes (Enquiry and Formal Vote - giving the possibility to all National Committees to have their say). If the work requires further technical work (e.g. common modifications), it may be relevant to consider the creation of a TC. Nevertheless, it has to be noted that the CEN-CENELEC Internal Regulations don't prevent the development of Common Modifications by a SR
44	With regard to the use of part 1's in conjunction with part X's. The EU Comm are withdrawing the part 1 for electric power tools in December 2021 however some part 2's of the replaced standards already have been given a DoW into 2023, how does that leave these part 2s?	In order to apply a standard B in conjunction with the standard A, both A and B need to be valid. The withdrawal of a reference to a standard is about the presumption of conformity. Technically speaking, this case suggests a case-by-case discussion.
45	Very nice guide in relation of multi part standards. How much of those rules are aligned also for other relevant directives like RED, LVD, PED, ATEX which also concerns safety?	The referred here guidance on multi-part standards was in principle agreed for the machinery sector only for the time being.
46	How are the General Principles of Annex I to be understood in this context? (The EHSRs are a mix of general principal requirements and specific requirements, where the risk assessment may reveal for example that an EHSR is not applicable or that the risk may be mitigated in another way)	Not fully clear what is meant by "General Principles of Annex I". When a hazard identification (part of risk assessment) shows that a hazard corresponding to a particular EHSR does not exist or is not considered significant than the hEN must not address such an EHRS (see Annex I clause 2 of "General principles": *The obligations laid down by the essential health and safety requirements* ***only apply when the corresponding hazard exists*** *for the machinery in question ...*

47	Are SAE test codes commonly used on a product type allowed in an EN standard?	The principle is that normative references should be EN/ISO/IEC published standards. On case by case, the EC may accept the use of non-EN/ISO/IEC standards and a detailed justification needs to be provided. CCMC PM can provide support on this matter.
48	It is important for the future to ask that the consulting firms managing the HAS consultants provide a sufficient number of days for the working group managing the EN standard to discuss the critical points related to its harmonization	Indeed, CEN-CENELEC keep on highlighting this important point.
49	What happens in the case of standards developed under the Vienna Agreement / Frankfurt Agreement? In the ISO/IEC Directives, there is also the rule that dated references have to be made when referring to a specific part of a standard. However undated references are made to whole standards. Is there guidance how to work under these conditions with the requirement from the EC related to date all references? (e.g. by adding information in the European Foreword or similar to state which edition applies in the EU?)	For standards developed together with IEC, the normative Annex ZA is used to date the normative references. For standards developed together with ISO - the same EC request applies for harmonised standards as for the standards which are CEN only. This means that in principle, the normative references need to be dated in EN ISO standards.
50	Dated normative references. In CLC standards originating in IEC we use a normative annex ZA to translate IEC standards into EN standards. Is that sufficient since it will not be dated in the body of the standard.	Yes, if the normative reference is undated in the body of the standard, it is the normative Annex ZA that indicates the publication date of the normative reference.
51	What does the end user of the standard do if the normative references are no longer valid?	If a normative reference is no longer valid, the TC should consider revising/amending the harmonized standard to update the normative references. The end user could contact the national standardization organization for consideration.
52	What is the situation if the referenced EN Standard become withdrawn but is referenced in an EN standard listed under the	In general, at the time of adoption of hEN all the normative references should be active and published. If a standard cited in the OJEU contains

	MD in the OJ? Please explain this in comparison to a withdrawn part 1 connected to a part x which is not withdrawn?	a normative reference that becomes outdated, this requires consideration when the TC is revising the harmonized standard in the future.
53	Referring (older) ISO-Standards to become EN ISO standards, when not in Vienna Agreement process. Is there a need or process to change the original ISO regarding undated references or rather a general "dropping" the candidate for "hEN" to EN, when dealing only the undated reference of ISO standards? Especially when dealing with committees without working groups on CEN level.	No, there is no process for dating the normative references of ISO standards. The CEN/TC should contact the ISO TC for considering dating them within the next revision.
54	Therefore, only harmonized standards shall be referenced.	Harmonized standards can contain normative references that are: (1) Non-harmonized standards and/or (2) Harmonized standards. This remains a technical choice for the TC. However, if a normative reference is also a hEN, it is important that these have not been rejected by the EC for citation.
57	It was stated earlier that it is possible to have a non-harmonised standard as a normative reference in a harmonised standard. If that is the case, why is a non-cited standard not allowed? (and how does WG know that it is not cited?)	If the EC rejects a hEN for citation, it means that the standard is not compliant with EU legislation and other EC requirements. Therefore, the EC considers inappropriate its inclusion as normative references in hEN. When the harmonized standard includes non-harmonized standards as normative references, they are also checked by the HAS consultant/EC when assessing the hEN. The list of cited standards is available on the EC website dedicated to the relevant legislation.
58	There used to be a possibility for Medical Devices to add a Table of Standards in the Foreword which gave the clear reference of which dated European standards apply and which was accepted for harmonization with the MDD in the past. It would be very helpful to have such a solution for Machinery as well.	According to Internal Regulations Part 3 the Foreword is not dedicated to such aspects. However, as mentioned, the possible solution is being discussed now with the CEN BT members and EC.
59	But the problem is still pending when you give a dated reference to a standard which contains undated references to other standards. Thus, this matter does not end with clause 2 of a hEN. Shouldn't it be	Normative references included in clauses of the harmonized standard giving presumption of conformity should be dated. The question is valid and is under discussion with the EC.

	extended to all CEN / CENELEC deliverables?	
60	The way to improve the proportion of standards that receive positive assessment is to increase the participation of the HAS Consultants in the development process. Are there any plans to implement this?	The EC decided to temporarily suspend meetings with the HAS consultants due to issues with the budget of the HAS project. CEN-CENELEC is in constant dialogue with the EC to highlight the need to have meetings with the HAS consultants to clarify comments and agree on a way forward.
61	How should eg. ISO 7010 be dated? It is a database.	ISO 7010:2019/AMD 3:2021, just put the date of the version being used.
62	What about the usage of the hEN check list for parallel work under VA ISO Lead?	It is strongly recommended that the checklist is also used for EN ISO under VA lead. The CEN/TC should liaise with the ISO/TC to ensure that the checklist elements are covered in the standard.
	What is WG Qualified support??	The WG qualified support is provided by a national standardization body to ensure that the candidate hEN is aligned with the EC requirements.
63	In general, the work on standards is supposed to go faster and faster, how does this fit in with more and more additional requirements on the part of the Commission? Will the time frame for the standardisation work be adjusted, especially if one is not allowed to contact the HAS consultant?	There is no plan to adjust the timeframe to develop a hEN. The flexible standards development process allows to make modifications in the timeframe (e.g. 'one change' option or 9-months tolerance). TCs are also encouraged to request first working draft assessments of candidate harmonized standards to identify from early stage potential non-compliant issues. This will increase the chances that at FV stage all the EC requirements will be covered in the hEN.
64	Whose task is it to fill out the checklist WG? Convenor?	Please refer to the Matrix of Responsibilities.
65	At the stage of WD, we received a negative HAS assessment because of a reference to a FprEN (draft under ballot EN 620 now published). How to avoid such feedback?	The TC correctly used the FprEN normative reference. Since this is a first working draft HAS assessment, it is not critical. It is important that when the hEN is being summitted to ENQ that EN 620 is published.
66	Is CCMC able to provide a tool that monitors and reports on the development status of standard normatively referenced by a standard under development? Surely, this	A TC has a technical task to verify if the normative references are appropriate. The existing tools like Projex, which are available to the TC Officers, give the possibility to check the status of a normatively

	should be automatic within a database rather than a manual task for the WG subject to human error?	referenced document. In case a clarification is needed, a TC is invited to contact the other TC about the status of the normative reference. If additional support is needed, CCMC can also be contacted.
67	What happens when a normative reference is withdrawn from the list of harmonized standards? Is it necessary to produce an updated annex ZZ in a standard that refers to it?	It depends when the normative reference became withdrawn. It is important that at the time of publication of hEN the normative references are dated and published. The CCMC Project Manager can provide support.
68	If a standard is intended to address EHSR 1.5.1 (electrical safety) of the MD, should this requirement broken into the details given in CENELEC Guide 32, Annex D or is it sufficient to 'only" mention EHSR 1.5.1 in Annex ZZ?	When elaborating Annex ZA/ZZ concerning the Machinery Directive you must identify the relevant EHSRs and identify the clauses that cover them. In the case of being relevant but not being covered this should also be stated by indicating 'not covered'. Guide 32, Annex D isn't applicable for Machinery Directive.