Webinar of 2024-02-23

Webinar 'Gap-analysis of harmonised standards for machinery against the new Machinery Regulation'

Questions & Answers

1	Could you confirm that before 2027 is possible to declare a product compliant to the Machinery Directive additionally also to the Machinery Regulation?	Yes, we confirm that it is possible to declare on the Declaration of Conformity in accordance with Machinery Directive 2006/42/EC that the product is ALSO in conformity with Machinery Regulation (EU) 2023/1230
2	Remote-controlled Machinery were already covered by the machinery directive. What is new?	Most notably in case of autonomous mobile machinery that must have a supervisory function (point 3.2.4.)
3	To Peter: Artificial intelligence in general is not dealt with in the new regulation, only systems with self-evolving behaviour. This is in my view to be a big difference, since self-evolving means e.g. further machine learning during operation. All systems based on AI, but do not have the feature of self-evolving have no special requirements.	In this case the naming is not important, but the predictability of a system reaction. If it cannot be predicted how a system will react, we should consider this self-evolving. It is relevant for MR only when this concerns a safety function
4	1.1.6 (g) - Why were specifically human traits chosen as examples how the machine has to communicate with the operator?	No specific reason, but easily comprehensible for the general public. This list is not exhaustive so other solutions may be implemented as well
5	If conformity with MD and MR is declared (and fulfilled) before Jan. 2027, is a "digital only - user manual" possible before Jan. 2027?	Unfortunately, I cannot give a yes/no reply, at this time. European Commission is working hard with stakeholders and notably Member States' market surveillance authorities to allow digital instructions before 2027 for machinery. This discussion is not yet finalised, but we are hoping for a breakthrough in the next few months... To be confirmed.
6	When can we expect to have an updated "Guide for the MR"?	The European Commission is currently working on two priorities: 1) accident data template for Member States, 2) standardisation request for MR. Once these have been completed, we will start the initial steps for updating the Guide. This

		will therefore not be before the summer of this year
7	Question to EC Policy Officer for machinery: Is the "Guide to the application of the Machinery Regulation" already in progress and, if so, who are the contacts?	The European Commission is currently working on two priorities: 1) accident data template for Member States, 2) standardisation request for MR. Once these have been completed, we will start the initial steps for updating the Guide. This will therefore not be before the summer of this year
8	We already built a group for Gap-analysis. We need ISO standards to start the work. Will we get all the relevant standards from CEN?	The need to have access to a standard can and is sometimes identified in relation to many standardization activities, e.g. in the framework of the discussion on the need for the revision of a given standard, or when any TC member wants to access the published version of the standard to reuse its content. So, such a need is not strictly related to the gap-analysis. Whatever the situation is and irrespective whether this is EN ISO, EN-IEC or purely CEN or CENELEC standard, the CEN-CENELEC Management Centre is not allowed to share these published standards. We do not possess them legally. The circulation of the documents is up to the Members. Therefore, if you think that it is necessary to circulate the drafts for the purpose of the gap-analysis, I would suggest that you contact the TC Committee Manager to discuss this matter with the member which holds the TC Secretariat.
9	To EC Policy Officer for machinery, your slide 18, what about an option 4 that delays the 20 January 2027 date to allow for interpretations to be formed and the MD guide amended to facilitate the completion of this work and allow manufacturers to design compliant product to place on the market?	Unfortunately, the 2027 date is completely fixed meaning that if we do not have a (full) list already in place, there will be no presumption of conformity at all.
10	What if the gap analysis shows no gap. Can the standard then be published in the OJ without any change, i.e. with the old informative annex ZA ?	This is indeed the idea. But it is obligatory that the responsible TC carries out the gap analysis through the dedicated tool.

11	Can be the difference between self-evolving behaviour and partially self-evolving behaviour clarified? Can examples be provided?	This wording has not been chosen to create a threshold of any kind, but only to avoid the loophole that if a (tiny) manual adjustment could be made, the product category would then be exempted. In other words, with any level of self-evolving behaviour is in scope.
12	Is it still possible to add standards to the gap analysis tool, it seems that some of our standards are missing. Thank you.	The tool contains the references of all active published standards which are currently cited in OJEU in support of the Machinery Directive. The gap-analysis in the tool shall be made only for these standards which are cited. Upon future citations in OJEU of new editions of standards, the new editions will be added to the tool. This will be also explained further in the webinar by CEN-CENELEC Sector Rapporteur for Machinery.
13	Is also TR and TS in scope of the gap analysis, for example security in context of machinery safety and functional safety?	No, the gap-analysis should only be carried out on the standards.
14	What if you have a revised standard that indeed closes a gap, but is yet not published in the OJ, shall this not be considered in the gap analysis?	Once this new edition of the standard will be cited, this new edition of a standard will be added to the tool and then the TC shall make a gap-analysis for this new edition. In the meantime, it is possible to make a gap-analysis for the current edition of the standard. This might be especially valid if it is not certain whether the new edition will be cited before the application date of the Machinery Regulation. The gap analysis on the previous edition will be replaced by the gap-analysis of the new edition. Waiting for the citation in the OJEU of the new edition, the TC can make a gap-analysis already in the PDF file.
15	Is it possible to do the gap analysis and still to revise the standard at the same time?	Yes, this may actually be very useful. Consider the case where a standard from e.g. 2016 is currently cited in the OJEU, the TC decides to revise it for the MR, but publication (and listing) of the revised version can be expected only in 2027/2028. Then a gap analysis for the "old" standard will enable the Commission to list the old one (temporarily, so-to-speak) with restrictions under the new MR, and the

		new/revised one would then replace it once it gets cited.
16	What about standards under the Lifts Directive referring also to MD/MR EHSR. It seems to be forgotten. Will there be an update of the standardisation request for lifts?	This exercise is primarily linked to the standards listed as hEN under the MD. Standards listed as hEN under other Directives/Regulations are not considered. The revision of the Standardization Request for lifts is not planned. The Standardization request for lifts has its own target dates to revise the standards.
17	I'm participating in development of coming hEN type-C standard (DIS state). The informative Annex ZA refers to former EU Machinery Directive (2006/42/EC), not to the new Machinery Regulation (2023/1230/EU). We're currently addressing HAS consultant feedback based on the MD. It's my understanding that we should update Annex ZA according to Machinery Regulation (2023/1230/EU) only. It's ok?	For projects that have been newly started or which are still at a stage where technical changes can be made (e.g. in the comments resolution phase shortly after CEN enquiry or even before CEN enquiry) it is strongly recommended to draw up two Annexes Z: one (ZA in CEN, ZZA in CENELEC) for the MD and another one (ZB in CEN and ZZB in CENELEC) for the MR. The additional work for the TC will be very limited as the MR largely encompasses the MD, so it is more a formal issue. In other words and in practical terms: One draws up an Annex Z for the new MR and then uses this one as the basis for the Annex Z for MD (so that only few EHSR-elements such as 1.1.9 or 3.2.4 need to be removed). In this way, after its citation in the OJEU the standard would give presumption of conformity independently under which regulation (MD or MR) it is being used.
18	To access the tool " https://gap-analysis.unm.fr/ a password is requested. How we require it?	The password was provided to Secretaries / Committee Managers of European Technical Bodies. They will decide together with Technical Bodies Chair who shall carry out a gap analysis in a given TC and hence with whom share the password
19	Regarding the tool: Is it possible to work in parallel within one TC, that means more than one user at the same time?	For the PDF file, more than one person can use this file at the same time e.g. during a WG meeting. For the tool, only one person can fill in the answers for a given standard. But it can be that the different standards of a given TC are dealt with by different persons (usually a TC

		Secretary or WG Secretary or WG Convenor or Project leader)
20	To Peter: Many thanks for the answer. There is a lot of confusion on the market related to that question. It needs an official interpretation soon.	
21	Have we officially received the standardization request for 2023/1230/EU? Asking because I would like to submit the FprEN with Annex ZA (for 2006/42/EC) and ZB (for 2023/1230/EU).	
22	For standards that you know have a gap, but which is closed by a revised version with DAV during the first ½ of 2024, it then makes sense to await their OJ publication and do the gap analysis in 2025, right ?	That's correct. There is a deadline of October 2024 to do the gap analysis for standards that are already cited in Spring 2024.
23	To ?: As an authority, if we disagree during the construction of the gap analysis or with the result, how can we proceed?	This is to be resolved within the respective TC's as it is the TC's that reply and their understanding on the status of the standards under their responsibility.
24	Is the pdf version available without having to access the tool ?	Yes, it was shared with all Secretaries of European Technical Bodies
25	Who will check the quality of the gap-analysis?	In the end the final decision if the standards will be published as hEN under the MR is with the EU Commission. If they have doubts they may reach out to CEN/CLC. Hence, why we are already involved and committed to this very important project!
26	Can I assume all 800+ harmonised standards are registered in the gap analysis tool? Will there by notification from the tool that someone else has already carried out the analysis for a standard I want to work on?	While we can never exclude minor mistakes: Yes, all 800+ harmonised standards were registered in the gap analysis tool. And once a standard has undergone the gap analysis exercise this will in fact be indicated in the tool (including the answers that have been given). But I would strongly recommend that within the TC the tasks are coordinated at the beginning of the analysis for each standard, so that no contradictory or double work is done.

27	To Mr. Broertjes 10:52 The GUIDE is of most importance for the industry, rather than any administrative issues. I want to encourage priority and timely finalisation of the work on the revised GUIDE. There are lot of unclear clauses and even some mistakes in the MR. Also, it is highly important that everyone in the entire EAR gets the same understanding of the MR, which should be achieved by the GUIDE. The experience with the Guide from the MD is that is a very large help in the application of the MD. This means, that all efforts spent are very valuable.	This is a well understood position of our stakeholders
28	Why 3.1.1 is covered in the list of 26 items even if this clause does not specify an ESHR?	This clause indeed does not include ESHR's, but are to help the reader to understand the relevant ESHR because new definitions have been added.
29	To Catherine: Many thanks for the presentation of the tool. For some new/modified EHSRs, there are some indents a), b)... What is the answer, if only one of these indents is relevant/covered?	
30	Question to Catherine & Joanna: how shall we do the gap analysis having in mind we are not sure on the interpretation of some EHSR like 3.5.4 for the overhead power lines? Is the gap analysis now reliable having in mind the work on the Guide hasn't started officially (with/by EU COM) yet?	There is no interpretation in the gap-analysis. We only ask if the Requirement is covered or not and what is the number of subclauses.
31	Seems to me that this tool replace what is today the content of annex Z , you have to say if relevant and find the proper clause(s) that cover the ESR. Why not to use annex Z process to provide it? Or alternatively is foreseeable that this will tool going to replace the annex Z writing in future?	Is s true that the gap-analysis is a good tool to prepare annex Z. We will investigate.
32	to ? : what is the procedure for standards to which a formal objection has been lodged	From our perspective they can still be included. What we try to achieve is that we can publish the

	or which are currently being examined by the Commission?	hEN with restrictions relevant for the MR. But any previous restriction (due to the F.O.) relevant for both the MD and MR can be taken on board as relevant restrictions on our side at the time of publication in the Official Journal under MR.
33	Regarding the conversation Thomas Bömer/Peter Broetjes (10:20/1043): when "self-evolving" acually means "predictable", I think it should be named like that, along with a sound interpretation. I'll be very curious to see the definition of "predictable", as it could include human factors/knowledge as well.	The HAS consultant will the first stop in this journey. But ultimately, the market surveillance authorities of EU countries are the ones taking the legal decision what is meant and what not (e.g. when a product is on the market with self-evolving safety feature, but captured incorrectly in its conformity assessment process). If there is disagreement even on that level, it will be up to the EU Court of Justice to decide. So rather than to find 'room' in the definition to skim the rules, it would, in my personal view, be more logical to use a pragmatic approach in terms of the definition and the standard's safety perspective.
34	Who is responsible for the answers in the tool?	The respective TC's are responsible
35	It is possible to have a read mode, just to see what has been answered for other standards?	Yes - click on view TCs previous answers
36	Do you have to cover all new or modified clauses for example in 1.1.6 b, f and g or can it be partially covered?	If it is partially covered, we recommend to answer "yes it is covered" and to provide explanation in the box where you will indicate the number of subclause
37	Which of the three options for the Annex Z to apply in which cases?	1. Please prepare two Annexes Z (one for MD and second for MR) for ongoing projects 2. Standards ready for submission to formal vote: at this moment shall have only Annex Z for MD 3. New projects shall be linked only with MR
38	What version of the standards can be found in the Gap analysis tool? If TC has published a new version during Q1/2024 is the new version referenced in the gap analysis or will the tool have the older version?	As the carry-over process is a step that has the sole purpose to list hENs from MD under the MR, the gap analysis can only be carried out on standards that are listed under the MD in the OJEU. In your example: As soon as the new version is cited in the OJ, the standards will replace the "old" one in the tool.

39	The modified EHSR 1.1.2 refers to the entire standard according to instructions in CEN BOSS. What is expected to be done because of the change? Why is it changed?	
40	It is possible to add Annex Z for MR after formal vote to avoid an amendment?	This depends on the status of the standardization request. Formally it's possible via another vote via the Technical Board and only if the std request is adopted by then.
41	If a new or modified EHSR is not sufficiently covered by the assessed current standard, do we agree that the answer has to be "not covered" ?	The gap analysis does not provide any interpretation. In this case, the answer is "covered" and indicate the number of subclauses. The EC may decide on this basis to cite the standard with a restriction
42	Will there be in the SREQ requests for Type B standards to cover the cybersecurity and AI aspects of machinery that could help TC to tackle those EHSR?	Yes.
43	My understanding was so far that an Annex ZA for MR is allowed to be included in a draft hEN for ENQ after the SRequest has been officially approved. Do I understand Joanna correctly that this is allowed already right now?	No, you can draw up two Annexes Z already today. The template for MR is available on CEN BOSS. Of course it does NOT contain the number for the new SReq yet. But nothing speaks against drawing up that new Annex ZA already now. Remember: The processing of the standard will take considerable time and in most cases the standard will be published AFTER publication of the new SReq, so the necessary correction in the foreword of the Annex can be easily done on short notice.
44	Sorry I am confused, seems the work on gap analysis is duplicated with the Annex Z here we are talking about? Hope it's just my misconception.	Gap analysis applies on published standards. Annexes Z for MR are for future standards. Of course, the gap analysis will be a good tool the create annex Z of revised standards.
45	Is there a website or place where I can search for all Standards mandates, as I found a website but it only shows current Mandates and not old ones?	We provide online database with standardisation requests adopted by the Commission from 2014...
46	To change a WI that exists currently for MD to now also include MR is that an email to Joanna or submission of new NWIP?	If the WI is active and under drafting stage, then please inform Ardit (for CLC and CEN standards)

		or Joanna (CEN standards) to make the link to the MR.
47	On the gap analysis tool is it possible to save a partially completed review of a standard without submitting it, so that you can return to it at a later time?	It is not possible to partially complete the answers on the tool
48	To Catherine/Frank. Frank said that we can also inform whether an ER is ""sufficiently"" covered. Any detail about what “sufficiently” means and how we can communicate this via the gap-analysis tool?	As a matter of fact, this is of course a decision from the TC. Personally, I would say that this will probably mainly concern scenarios where a TC explicitly addressed such an additional EHSR in the past (as in the example of Catherine for the power lines in one particular case). So, the TC should really know what they ""talk about"". It would NOT be a good idea in my view to just ""blindly assume"" that one covers a new EHSR just because one is convince of the standard's quality in general. The communication via gap analysis tool is then quite straightforward: If a TC responds ""yes, our standard is affected"" and ""Yes we are covering this issue sufficiently" you are then asked to indicate where in your standard (i.e. in which Clause) you are covering it.
49	Since the deadline of the gap analysis is in October and should be made with version cited in the OJEU, is there information when last OJEU will be published before the gap analysis DL?	
50	If the gap analysis shows that there are too many "not covered" by an EN ISO standard, TC could decide to break the Vienna agreement ?	The gap analysis applies only to published standards.
51	To Peter Broertjes, what is the web address of " We provide online database with standardisation requests adopted by the Commission from 2014..."	https://ec.europa.eu/growth/tools-databases/enorm/
52	With interoperability required many new technologies will be integrated into machinery. When it comes to standards for	

	the RED in relationship with the MR, is CENELEC in charge or still ETSI?	
53	Why is it not possible to save without submitting in the gap analysis tool?	It’s because the saving appears only when you click on "submit".
54	what is the expected timeline to publish all of those 800+ hENs in the OJEU?	I believe this question was also addressed when I took the floor, but for clarity the target, as currently in mind, is mid-2026
55	Does the GAP analysis also take into account the fact that there are multi-part standards or series of standards? Are there reasons that restrict the application of the GAP analysis to such series of standards?	Normally the gap analysis is for all standards cited in the OJEU.
56	For a WI that exists currently, and the standard is currently being drafted for harmonisation to MD, how do I get the Projex changed to now also include MR?	I believe the best would be to send a message to Joanna or Ardit, so that they can make the necessary change.
57	When will EN 13849-1 be published in OJEU and will it be published with ZA annex for MD or MR or Both?	The OJ list according to the information we have from the EC is under preparation and should be published soon. However, it will only have Annex Z for the MD.
58	We have WI's that ran out of time and would have to be restarted in due time. Currently they are registered to be under the MD. What’s your recommendation for the restart?	Depending on whether you think it's a quick task, certainly register them already under the MR.
59	With respect to Gaps, my understanding with AI Act still WIP but getting closer and New Machine directive reference, how will the compliance requirements be measured such as 'AI System Certificate of Compliance' and what this means with respect to information needed for compliance etc.	This gap analysis is strictly between current Machinery Directive 2006/42/EC vs. Machinery Regulation (EU) 2023/1230. Any 'additional' requirements in the AIA or CRA should not be taken into consideration for this exercise.
60	From a standardization point of view, I feel reasonably clear about the steps we have to take, my question is how to deal with these issues from the manufacturers' point of view. How are we going to explain to manufacturers who until now have a	In my view, it's the other way around. They will still have presumption of conformity for all aspects covered previously by MD, and on top have a pretty clear outline what new requirements are not covered. This will enable for each manufacturer to identify what needs to

	harmonized standard that confers presumption of conformity and based on which they can issue a Declaration of Conformity, for a new realization in which the standard has several "gaps" and does not cover all the new requirements of the MR. What steps does the manufacturer have to take to be able to issue the Declaration of Conformity while the standard is not harmonized for the new Regulation?	be (still)addressed. For this reason, I personally believe that the gap analysis will provide a tool that goes quite beyond the standardisation community level. Of course, to add, HOW they address is up to their own ingenuity, until the new hEN is finalised.
61	to Peter: what about machinery related to Annex I A?"	
62	You wrote: Yes, we confirm that it is possible to declare on the Declaration of Conformity in accordance with Machinery Directive 2006/42/EC that the product is ALSO in conformity with Machinery Regulation (EU) 2023/1230.	