

Webinar of 2023-05-26

Webinar 'Standardization Request for the Machinery Regulation, a smooth transition from the Directive to the Regulation'

Questions & Answers

1	Why is there no voluntary application of the new MR before application date? This will make transition for companies quite rough.	This is the result of the choice of legal instrument, namely Regulation instead of Directive (which would provide for more flexibilities) and the final political agreement on the final regulation. It will require a thorough preparation by the sector - fully agreed that this will be challenging.
2	At what stage (date) can we publish a standard to the new Regulations?	The registration for a draft standard of the link to the Machinery Regulation is already possible. A harmonised standard for Machinery Regulation can be published only after the Standardization Request for machinery will be adopted by European Commission (expected in second half of 2024).
3	If a harmonized standard is revised to match new MR requirements before application date can companies utilize it as a harmonized standard even though there is no voluntary application before the end of the transition period?	This could only be done if there is an Annex Zx that contains the list for Machinery Directive in addition to an Annex Zx that contains the list for Machinery Regulation. We are working on getting a clear confirmation that future harmonised standards can be prepared with both Annexes Z.
4	Will all 800 standards be handled in one SRAHG process or will the SR be cut into separate parts based on the type of machinery for example?	At this stage, we are working towards having one Standardization Request covering all harmonised standards.
5	Does the current delay in the harmonisation of standards have anything to do with the new, upcoming machinery regulation?	No, actually not. The backlog that we are currently experiencing is rather due to the transition from the previous HAS consultant contract to the new one. In this new contract many improvements in comparison to the previous contract were introduced, but this took some time. And during this time the "regular" work was unfortunately slowed down. Should be resolved soon.

6	<p>Will the HAS assessors get more resources to unblock the current delays before all 800 MR standards are put to HAS process again?</p>	<p>The machinery sector got much more person days comparing to the previous HAS system because of the alignment of standards to the Machinery Regulation. Currently, there are several HAS Consultants for machinery. EY might hire an additional HAS Consultant. The backlog with HAS assessments for machinery is steadily reducing. Some time is needed to tackle it completely, but we are quite confident this will happen in the reasonable future. Moreover, it is rather not expected that all 800 standards will start being revised at the same time.</p>
7	<p>EN 17206:2020+AC:2021 is an EN standard for the design and test of machinery used in entertainment areas (theatres, stages, studios, etc.). The standard also covers machinery outside the scope of MD 2006 – machinery to move performers. Can the Common Specification fall back option be applied to such standard since it is not harmonised or yet harmonizable to the MD?</p>	<p>Only part of the entertainment machinery is in the scope of the Machinery Directive / Machinery Regulation and at present EN 17206 is not a harmonised standard so in principle the European Commission's common specifications could deal with these aspects which are in the scope of the Machinery Directive / Machinery Regulation. However, at present, we are not aware about any EC intention to develop such common specifications on this topic.</p>
8	<p>Will it be possible to harmonise the standards to both the Machinery Directive and Machinery Regulation at the same time?</p>	<p>Draft standards to be published (DAV) by CEN between mid-2024* and and 31 March 2026 should be developed in support of Machinery Directive and Machinery Regulation, therefore, with two Annexes ZA: one for Machinery Directive and one for Machinery Regulation</p>
9	<p>'@Peter the new Machine Safety Directive (Regulation) references AI systems should have QA Certificate of Conformance... is there a proposed detail on the expected content of the AI CoC?</p>	<p>AI systems linked to safety functions will require the EU type-examination (module B) plus internal production control (module C). There must be an EU type-examination certificate as output. The Declaration of Conformity must have the NoBo name and number that carried out the checks and issued the certificate.</p>
10	<p>Also 1.1.2 (e) has a significant change regarding the test of safety functions.</p>	<p>Yes, this is correct. As I said I was only choosing some examples. The list of changes is certainly significantly longer.</p>
11	<p>Will there be better communication from the HAS Consultants regarding work plans,</p>	<p>It is difficult to reply without knowing the details on this standard. There is still some backlog due</p>

	timetables, etc - we have 2 new harmonised Standards now held up for 3-4 years but still with no idea/communication on when assessment will be undertaken?	to the volume of the sector and because HAS Consultants were suspended for several months. But there is not any standard that waits for the HAS assessment for 3 years. We get regular reports from HAS Consultants so please ask TC Secretary to contact the relevant project manager in CEN-CENELEC Management Centre (Ardit or Joanna) and we can tell what is the status of the assessment. We hope that the assessment will be received very soon.
12	Any news regarding the type-B standard from CLC/TC 44x to cover 1.1.9? When can we expect it? The publication of this standard will likely affect the revision timetable of multiple standards.	CLC/TC 44X is already working on it and soon a New Work Item will be registered. We still don't have a publishing date, but the TC members are aware of the urgency and the importance of this standard.
13	Is there a plan to harmonize the timeline between Cyber Resilience act and Machine Regulation with regards to 1.1.9 this seems prudent since it is being communicated, that when you meet the cyber resilience act you meet 1.1.9?	This is still under negotiation between the European Parliament, Council and the Commission. We share view that this would be logical and beneficial. We have to wait however for the outcome of the negotiations of course
14	Regarding 1.1.9, should we refer in future in Annex ZA/ZB to this type B-standard?	It is not allowed to refer to other standards in an informative Annex Z. Once CLC/TC 44x will develop a type-B standard, the standards of other TCs are expected to normatively refer to this standard.
15	1.1.9 Protection against corruption is only served with a b standard hen the requirements in the cyber resilience act are finalized and understood	... indeed and we support working towards a coherent and consistent approach between CRA and MR standards
16	What is meant by "Task Force in SF"? What is "SF"?	SF = CEN-CENELEC Sector Forum on Machinery. It is a joint group, consisting of representatives of CEN and CENELEC members and horizontal/ biggest TCs, as referred to in the CEN-CENELEC Internal Regulations Part 2. It advises CEN and CENELEC Technical Boards on matters linked with standardization on machinery. Task Force is an activity within the SF dedicated to the given topic (here EHSR on power lines). All the impacted TCs (officers) have been informed about this activity and are involved.

17	<p>We don't understand why it is not foreseen a recovery period of time between the MD 2006/42 and the new Machinery Product Regulation. It has been possible between the RTTE Directive and the RED on Radio equipment for 1 year. This enables to update all docs attached to the products. Because to be ready at one day it is just impossible particularly on mass machinery products.</p>	<p>It is generally understood that this would be beneficial. However, the key difference is that both are Directives, but for machinery it is a Regulation... This choice of legal instrument was deemed as not compatible with a voluntary application. Moreover, it is the concrete outcome of the negotiations with the European Parliament and Member States.</p>
18	<p>What about if a machinery product is placed on the market with the only Declaration to the MD 2006/42 after Jan. 2027 (because the new docs are not ready yet)? We live in a concrete industrial world!</p>	<p>We believe that, from a practical viewpoint, it would not be prohibited for a manufacturer to prepare two documents (DoCs): one claiming compliance with the MD (in case the product is placed on the market BEFORE the applicability of the new MR) and one claiming compliance with the new MR if the product is placed on the market AFTER that date. The only restrictions would be that the DoC for MR could not be dated before the application date (20 January 2027) and products cannot be placed on the market from that date with (only) DoC for MD (and certainly not one that is dated 20 January 2027 or later).</p>
19	<p>What about if a machinery is placed on the market with new declaration ref. to the new Machinery Product Regulation before Jan. 2027?</p>	<p>This situation is "not possible", because the legislation in question would not yet apply in the EU. Formally, this would be an infringement with possible result of penalties</p>
20	<p>Concerning noise emission. Will noise limits be considered, if they are for a "mean value" or if the noise limits are for "upper statistical limit"? Because revisions of standards concerning noise emission is going on, it could be a good idea to clarify the text about this issue in machine directive.</p>	<p>While I do have a lot of sympathy for your point (inaccuracies around noise terminology are a an ever-recurring issue in our hENs...) I am afraid that there is no chance to have any modification to the MR text at this stage.</p>
21	<p>What about if the update hEN is not published for Jan. 2027 at the latest? or because the hEN is awaiting a decision at the HAS level?</p>	<p>. In general, this would mean that when the Machinery Regulation becomes applicable (from 20 January 2027), there will be no harmonised standard on this topic. Then the manufacturers would need to prove conformity with Machinery Regulation using conformity assessment models</p>

		<p>from the Machinery Regulation. As soon as a harmonised standard on this topic is finalised and cited by the European Commission in the Official Journal of the European Union, the manufacturers will be able to benefit from the presumption of conformity. However, it is to be highlighted that the EC has informed that they intend to carry over the hENs for Machinery Directive to the OJEU list under Machinery Regulation. In case, the hEN is affected to some extent by the new/modified EHRs but is not (sufficiently) addressing them, the EC would like to cite them in the OJEU with the restriction: i.e. there will be no presumption of conformity for the clauses / EHRs impacted by the gap. Early 2024, the TCs will be asked to carry out the gap analysis for this purpose.</p>
22	<p>What happens if CEN and CENELEC do not accept a standardisation request?</p>	<p>It is key that it is accepted as otherwise there will be no possibility to publish harmonised standards under Machinery Regulation. The reason we have this webinar today is to have a smooth work on the document in cooperation with the TCs and EC. So that it can be accepted.</p>
23	<p>There is ongoing revision of ISO 7574 concerning noise emission. In this work, there is a wish and need for harmonized definitions and noise limits. I think a machine directive should be clear and hopefully harmonized with the work of ISO 7574.</p>	<p>Thank you for your comment. It's noted.</p>
24	<p>Considering that there will be only one SRAHG for 800 standards the amount of experts in the group will likely/hopefully be huge. Any plans already on how this will be organized from the CEN-CLC side?</p>	<p>This is exactly one of the reasons of the webinar today. Some further information will come later. This is why we organise the webinar already today so that you familiarise with the process and can prepare. So that the work in the SRAHG is efficient and smooth. But admittedly this will be a challenge given the volume of the sector and number of TCs.</p>
25	<p>In the sector "Health" the Standardization Request of MDR is rechecked and amended about once a year. Will this also be the case for this SR for MR?</p>	<p>The Standardization Request for MR is not expected to change each year. This is why we need to work out in cooperation with EC a good</p>

		content of it. The standardization requests in other sectors do not change each year, either.
26	Double DoCs, so double works, because after a period of time it will be to remove the previous DoCs to the MD, so three times work and, unnecessary costs.	This might indeed cause some added burden in terms of internal processes, in view of the lack of such a real transition. It seems that with virtually all Directives and Regulations it is the same discussion.
27	Will a SReq be accepted by CEN even if the TC does not see it fit for acceptance/is not in favour of it?	The CEN and/or CENELEC Technical Board will consider the recommendation from the SRAHG, which will include the input of representatives of TCs. Then, it's up to the CEN and CENELEC Technical Boards to decide to follow or not the recommendation of the SRAHG.
28	To Jacques: the Blue Guide, 2.11, allows to have information on the DOC to state till which date it complies with the MD and from which date it complies with the Machinery Regulation (as long as the machinery complies with both). But it is good to have this confirmation from the Commission as we are moving from a Directive to a Regulation.	We are afraid that this would not be possible, subject to a further legal assessment but MD has an EC Declaration of Conformity and MR has an EU Declaration of Conformity. In legal terms these are two different documents that cannot be, somehow, combined. An EU Declaration of Conformity could possibly be added as long as the validity date on the document would be after the application date of the new MR (and of course if all new/updated ESHR are fully met).
29	Does the SReq only concern hEN?	Normally a SReq covers harmonized standards for the application of EU legislation. However, the EC could also include standards, not harmonized, to support EU policies. It's not common, but we have experience with some cases.
30	3.5.4 is mentioned as a new requirement, but we should not forget that the risk was initially addressed through point 1.1.7, par. 2, of the machinery Directive.	As a matter of fact we (i.e. the "machinery community") will probably (or at least we hope to...) benefit from the fact that this risk was already in the past addressed by some TCs. Don't worry, the experts will certainly not try to "re-invent the wheel". But the risk under 3.5.4 is in contrast to the "old" MD now formulated in a more detailed and specific manner, so one has to check whether or in how far this entails some measures that in the past were not necessarily seen as "obligatory".
31	Considering the if you want to create new harmonized standards they need to be	Yes, in fact once that the SReq is finalized it will remain largely "stable" as it is until the expiration

	<p>noted in the SR-document. If the goal is not to review the SR in the future to add new standards I guess experts will need to guess what harmonized standards are needed in the future??</p>	<p>of its validity. As I indicated: Theoretically, additions to it are possible, but require a lot of formal work and take a lot of time. Hence, the SReq which will be developed now should be as complete as possible. It should encompass ALL existing hENs (be it via their explicit mentioning in the SReq or be it by generally grouping certain machine types) and it will of course try to identify/describe fields of activity where very likely new standards will be developed in the subsequent years.</p> <p>Note: We are well aware that it will not be realistic to have ALL hENs revised within the next 5 or 7 years. So, if a standard is mentioned in the SReq as a potential candidate for revision, but the experts simply do not manage to achieve this during the SReq validity period (due to workload etc) this should be justified. In any case, its mentioning is vital to at least have the "possibility"/allowance to become active.</p>
<p>32</p>	<p>The new machine directive (regulation) also references the EU Cyber Act and also a comment on need for a 'CyberSecurity Certificate' or CoC, has it been defined what will be expected?</p>	<p>The new Machinery Regulation was revised in the process of negotiations with the European Parliament and Member States. As a result, the references to CRA (and AI) have been removed. Machinery that has been certified or for which a statement of conformity has been issued under a cybersecurity certification scheme adopted in accordance with Regulation (EU) 2019/881, the references of which have been published in the Official Journal of the European Union, shall be presumed to be in conformity with the essential health and safety requirements.</p>
<p>33</p>	<p>Will there be also a standardisation request to update standards harmonized to the Lifts Directive which have references to modified EHSRs of the Machinery Directive? Is it clear that the link from the Lifts Directive to the EHSRs of the Machinery Directive shall point to the Annex III of the Machinery Regulation?</p>	<p>This question of course refers to the fact that the Lifts Directive calls sometimes for the application of the Machinery Directive. The Standardization Request for Lifts is under finalisation [remark from November 2023: SReq M/599 for lifts was accepted by CEN in October 2023). The draft refers to the Machinery Directive. The hENs in support of the Lifts Directive which will be published after April 2026 should in the Annex ZA table refer to the Machinery Regulation.</p>

34	<p>The new machine directive (regulation) also references the EU Cyber Act but does not reference the EU Cyber Resilience Act (CRC). CENELEC EU have asked Technical panel to map CRA to IEC62443 for its relevance. Does the machine directive (regulation) plan to also reference the EU CRC ?</p>	<p>There are no cross-references to AIA and CRA in the new MR. So far, any reference to new MR in the AIA and CRA appear to have also been removed (but subject to final agreements). The lack of a reference does not however mean that there is no interplay when the final CRA and AI legislation is agreed and concluded</p>
35	<p>how to ensure a smooth transition from one standardisation request to a new one? and avoid to have some gaps in time?</p>	<p>We are discussing with the EC the possibility that the new SReq will not replace immediately M/396 and we will see if a transition period is possible.</p>
36	<p>If the Sreq has a time limit does that mean hEN published under the Sreq is invalid after the end date of the Sreq?</p>	<p>If the SReq has expired, there is no legal basis for the development of hEN. It is not possible to publish a hEN after the expiry date of the Standardization Request. However, the EC must ensure that an amended or revised SReq is published before the expiration of the SReq and it's very important to avoid a gap between SReqs. If a given hEN was published before the expiry date and is accepted by the European Commission for the citation in the OJEU it is not invalidated only because the expiry date of the Standardization Request has passed.</p>
37	<p>Is there a list available, which EHSR is referenced in which EN standard?</p>	<p>No, not that I knew of. The difficulty is that among the > 850 hENs under the Machinery Directive we probably have more than 700 product-specific C-standards (just an estimate from my side). The majority of these C-standards claims to cover most EHSRs of each specific product type. Hence there has never been - to my knowledge - an attempt to make such a list because one would obtain for some EHSRs up to 700 - albeit very specific - standard entries.</p>
38	<p>I asked: If a harmonized standard is revised to match new MR requirements before application date can companies utilize it as a harmonized standard even though there is no voluntary application before the end of the transition period? Peter replied: This could only be done if there is an Annex Zx that contains the list</p>	<p>It is possible, even recommended to start working on harmonised standards for MR very soon and before the applicability date of the MR. so that they are ready when MR becomes applicable. Because the development of a harmonised standard as you know usually takes a few years.</p>

	<p>for Machinery Directive in addition to an Annex Zx that contains the list for Machinery Regulation. We are working on getting a clear confirmation that future harmonised standards can be prepared with both Annexes Z.</p> <p>Follow-up: Does this mean that we cannot revise standards currently to match the new MR until after the application date without adding another Annex?</p>	
39	<p>To get a good effect of harmonization, I would suggest it could be a good idea to make most of annexes "normative" and not "informative". With annexes normative, I think it will simplify similar practise across the countries.</p>	<p>In principle, it is a TC which decides whether an annex is normative or informative. The choice needs to be based on the rules on the annexes which are in CEN and CENELEC Internal Regulations, Part 3.</p>
40	<p>Currently as a WG secretary I have 2-3 revisions of harmonized MD standards ongoing. Should we just stop the processes and wait for the SRAHG or how should we move forward?</p>	<p>In general, the TCs should keep on working.. But it also depends at which stage the standard is. If the standard is at an advanced stage, it can be finalised under Machinery Directive and then it will be possible to produce an amendment in support of Machinery Regulation We can discuss in detail in the sperate dedicated call as we need to know the status of the standards and how they are impacted by the changes in EHSRs.</p>
41	<p>The explanation of the procedure is very clear, thank you Hugo and Joanna. But, what is not clear is the need or benefit for what seems a rigid and complicated procedure to get a well-working SReq. In the recent years, technical experts in TCs have experienced a skyrocketing increase of complication (list of harmonised standards published as a puzzle, detailed Annex ZA, HAS consultant contract break, compliance checklist ...). If all this is done to achieve full legal certainty, maybe different ways need to be found. EU COMM and CEN are doing their best, thanks again for this, but please be aware that life of a standard writer today is really hard.</p>	<p>Thank you for your comment. We note your comment. We will do everything we can to have it as clear and easy to TCs as possible.</p>

42	<p>Following the Vienna Agreement most work on developing harmonised European Standards for crop protection equipment (EN ISO 16119 and 16122 series and associated Standards) has taken place within a corresponding ISO Committee, which is now well established (and with the benefit of global experience). How is the (major) future work required to update these Standards, and develop required new ones, therefore likely to be assessed and carried out?</p>	<p>We are now referring only to standards under Machinery Regulation (and not the one in support of Directive on Sustainable Use of Pesticides). The general answer is that the TC needs to assess the impact of changes in EHRS on the dedicated standards and, if there is an impact, soon, they need to start working on the changes.</p>
43	<p>In the future hEN could be included also NON mandated characteristics, clearly identified as voluntary characteristics or referring to other EU regulation ?</p>	<p>A hEN in support of the Machinery Directive/Regulation can include clauses that are not linked with the requirements of the machinery directive or regulation. In this case, these clauses need to be very well separated from the clauses of the standard that give legal effect with the Machinery Directive/Regulation</p>
44	<p>We are working already on the possible revision a standard (type C) according to the New Machinery Product Regulation. There are ref. to standards type A (e.g. EN ISO 12100) or type B. Is it necessary to wait for the final revision of them (type A & B) before to take some positions in our standards? This could add a delay to work correctly on the standard type C, could not it?</p>	<p>No. I would say that - while it is very likely that the B-standard-TCs will also revise (or potentially formally adapt) many of their standards - we should not wait for the finalization of the revision of B-standards.</p> <p>1.) Actually, many B-standards are only weakly affected by new or modified EHSRs.</p> <p>2.) Each C-standard is harmonized by itself. Consequently - strictly speaking - a B-standard would not need to be harmonized in order to make use of a technical solution therein in a C-standard. If the experts of a C-standard consider a solution in a relatively ""old"" B-standard as appropriate to comply with an EHSR of the new MR (in the context of their own C-standard) this is perfectly in line with the system.</p> <p>So again: No, revisions of C-standard do not need to wait for the revision of B-standards (which by the way are often on ISO-level and can easily take more than 4 years...).</p>
45	<p>if there is no technical modification to be provided (no impact from the Machinery Regulation), what will need to be done.</p>	<p>According to the current feedback from the European Commission, it will be possible to cite such a standard. The TC will be asked by</p>

		European Commission via CEN and CENELEC to provide a gap-analysis in this respect.
46	Thank you for your answers Joanna BUT all of the EN ISO 16119 series require compliance with, and cite requirements from, EN ISO 4254-6 which depends on the MR, and which is also being revised by ISO, not CEN. I will write further separately on the issues.	In case the standards are impacted by changes in EHSRs, they will need to be reviewed by the TC. All these standards are within CEN/TC 144 (ISO/TC 23), so we would recommend liaising with the leadership responsible for (EN) ISO 4254-6 to discuss what needs to be done and what is the timeframe. In case of general questions on the alignment of standards to Machinery Regulation, if you are in ISO please contact ISO Committee Manager and if CEN - please contact CEN/TC Secretary - he/she can arrange for the call with CCMC Project Manager for machinery if this is useful. We are available to discuss.
47	Who would benefit from the funding? TC and WG Chairs? Task Force Experts?	The EU funding can be for both the staff of National Standardization Bodies / National Committees as well as for the experts.
48	Why do you think we need harmonized Standards to build safe Machines. International Standards do suffice	Of course it is not mandatory to follow harmonized standards when one wants to build safe machines. The main advantage of CEN standards that are harmonised in support of EU legislation is the presumption of conformity. This concept constitutes a sort of "reversal of proof" for the manufacturer. In other words (and slightly simplified): If member state authorities are of the opinion that a "harmonized" technical solution is not compliant with European law, they have to prove this non-compliance while without a harmonized standard the manufacturer would have to prove the compliance of his product.
49	The answer to my question is not satisfactory. What happens when the standardisation request is rejected by CEN and CENELEC?	It will not be possible to publish harmonised standards in support of the Machinery Regulation.
50	If there are two Annex Zs do we only need two significant risk assessment Annexes?	We expect to see only one such annex that lists the significant risks. Anything else would be a doubling of work. The only "additional" element would be a second Annex Z. The experts in the SF are currently in intensive

		discussions with the EC how to implement this concept in detail. It is clearly everybody's goal to keep the formal effort for the standard writers at a minimum. So while having two Annexes Z will certainly help with the practical transition from the MD to the MR, we will make sure that the creation of these two Annexes Z will be kept as simple as possible.
51	Will there be a need to update the Annex Z for the compliance with the existing Machinery Directive under a table format if it is in old template?	According to the current feedback from the European Commission, this is not necessary in the first place. But actually, in all standards that are currently being revised or created newly, we have to draw up the Annex Z in table format. So as soon as a TC "touches" an existing standard (be it for technical reasons or because one simply wants to update it formally) the new template of the Annex Z is mandatory.
52	Thanks for the feedback. I see it will be impossible to create such a list considering C-standards. It would be interesting to have such a list for B-standards.	At this moment, there is no plan to have such a list. However, the information on the development of the respective standards is available e.g. on the CEN and CENELEC websites.
53	Would be really good to have a map over all groups, committees, etc involved in this to get a helicopter view. It is not easy to understand the whole picture :-). Is there such a map available?	The list of all Technical Bodies in charge of the development of standards in 'Mechanical and machines' sector can be found on the CEN and CENELEC sectoral websites(->tab 'Technical Bodies'). In general, CEN and CENELEC are responsible for the development of standards including harmonised standards. The European Commission oversees the legislation, its interpretation and in relation to standards –the preparation of the Standardization Request and the citation of standards. CEN and European Commission cooperate regarding these last aspects. The processes for standardization can very often be found on the CEN and CENELEC so-called BOSS websites (information on the European Standardization presented in a user friendly way).
54	Considering the importance of making harmonized standards available in the	In general, it is possible to get the EU funding for translation. It will be the decision of the National

	official languages of each Member State, is funding planned for these translation processes?	Standardization Bodies / National Committees whether to apply for the dedicated EU funding.
55	AS it was presented I see a very complex process. May I propose a different view at the subject. As it is commonly known, that TC and WG Chairs do suffer under the time display the current Management of the Hass Consultants. Yet timely publication is desired. So why not use the HAS consultants differently. Task The HAs Consultants to scree the International standards and make them report to you which ones do need change or where a gap is. Should there be a need for rewrite of an existing International Standard initiate it. This should be a much faster way than the complicated process presented.	The task of the review of standards to decide on what needs to be done to align them to Machinery Regulation is technical and should be carried out by the responsible Technical Bodies in the first place.
56	I'm sorry I'm still uncertain about when we are supposed to publish hENs for product standards. If I understood correctly the new Regulations will be in force from January 2027 and that the manufacturer of machine will have no opportunity to claim compliance before that. So from February 2027 does that mean the manufacturer must comply with Regulations or can they still use Directive until a future date? On the assumption that it must be Regs, that means hENs for the Regulations need to be published before Feb 27?	As from 20 January 2027 (applicability date of the Machinery Regulation), the manufacturers will need to apply the Machinery Regulation. Indeed, first harmonised standards in support of Machinery Regulation will need to be finalised by CEN and CENELEC by quarter Q1 2026 at the latest in order to be timely offered for the citation in the Official Journal of the European Union (OJEU) and validated by the European Commission for this citation. If some harmonised standards will not be ready by then, they will be cited in the OJEU in the framework of the subsequent citations (the European Commission usually cites new references of standards twice per year)
57	Will it be necessary a new accreditation and notification for the Notified Bodies under the new MR?	The Member States first have to formally designate their notifying authority for Machinery Regulation (EU) 2023/1230. After this, the notifying authorities have to proceed with the respective notifications of the bodies authorised to carry out third-party conformity assessment tasks under the Machinery Regulation.

58	<p>If there will be two separate Annex Z (and list of significant hazards), does that increase HAS assessment delays? Transparency to HAS assessment process would be highly preferred.</p>	<p>Very good point. In fact, this is one of the aspects that will have to be considered very diligently when setting up this process. Of course, we need to make sure that the "framework" for writing two separate Annexes is appropriate and does not unintentionally lead to delays. But I think the idea as such (to have these two annexes) is very good and in fact was accomplished in the past (during the last transition from 98/37EC to 2006/42/EC).</p>
59	<p>Thanks for the explanation, but still not very clear how the transition will work from standards harmonized to MD to new revision of them for MR.</p>	<p>Noted. CCMC project manager is available in case a dedicated meeting with the Technical Body is useful on this topic (please contact the TC Secretary to arrange such a call). Further clarifications and guidance is expected to be provided to the Technical Bodies over the course of time.</p>
60	<p>There is a lack of a single comprehensive guide to the process and requirements for development of harmonised standards in accordance with the machinery directive. Could the SReq include development of such a guide to the MR? and could there be funding for this?</p>	<p>There is CEN Guide 414 Safety of machinery – Rules for the drafting and presentation of safety standards within responsibility of CEN/TC 114. Its update has been waiting the adoption of Machinery Regulation. The associated National Standardization Body probably will be able to ask for the EU funding for this purpose, if it wishes so and if such an EU funding will be available.</p>
61	<p>How about standards are awaiting publication/ harmonisation now?</p>	<p>They are part of the regular standardization process. They will be harmonized under the "old" MD as the MD will be applicable until January 2027. It is not intended to stop or interrupt their schedule now.</p>
62	<p>Which is the task TC secretaries have to comply with concerning the thematic list and which is the deadline? Thank you.</p>	<p>CCMC will send out the dedicated email to Technical Bodies next week (DONE).</p>
63	<p>OK, assumed HS for MR will be ready - before jan27. but no adaptation time is left to manufacturer. Right?</p>	<p>The text of the Machinery Regulation is already known. The date of the first list of harmonised standards under Machinery Regulation is under the discussion with the EC: expected in 2026.</p>
64	<p>Normally, this is why there would be two Annexes Z, one for the compliance with the</p>	<p>Indeed, but this matter needs to be confirmed by CEN and CENELEC Technical Boards.</p>

	Machinery Directive, one with the Machinery Regulation	
65	About 12100 and the work with amendment, is that in context of the Machinery Regulation?	Among others, yes to our knowledge. Please contact the responsible CEN/TC 114 or its national committee for more information.
66	So my question regarding two Annexes was in regards to the current Annex 1 that needs to be in machinery standards that contains the list of significant hazards. If we have two annex Z parts one for MD and one for MR, do we also need to add to Annexes that contain two separate tables named "List of Significant Hazards for MD" and "List of Significant Hazards for MR" since the updated MR has new hazards compared to current MD?	As pointed out under Question 51, we'd consider it highly unlikely that two tables with significant hazards will be required. It should be possible to set up one list of significant hazards that forms the basis for the consideration under both MD and MR. Again: The introduction of two Annexes Z does NOT aim at adding unnecessary complexity for the standard writers. Still, the details and prerequisites for creating two Annexes Z are still under discussion.
67	So, did I understand that correctly, the general application date for the Machine Directive is Jan27, 2027, Correct?	The application date for the Machinery Regulation is 20 January 2027.
68	Other regulation, ex. CPR, permit a transition time - for the CE marking - indicating starting date on voluntary bases - and a compulsory date.	Indeed, different EU legislation can have different approaches regarding the transition time, which is the case of CPR and Machinery Regulation.
69	Thanks for the explanations, Peter. I understand we will have to work on that. Assuming a regulation is willing to get a material modification of products. Is just impossible that all products (of all product families of all the manufacturer) in just one day will be changed. This is the reason to allow manufacturer to apply new requirements before those requirements will becomes mandatory by law.	We believe that none of the new requirements are incompatible with the current Directive in the sense that the technical solutions to address the new MR EHSRs would be in conflict with the MD EHSRs. So products can be produced anticipating MR compliance, while declaring MD compliance before Jan 2027. We believe that is possible for all product categories, but please flag to us if you would discover any different information!
70	Please could Peter answer if a machine is produced in February 2027 can it still be harmonised to Directive or must it go straight to Regs?	If it is placed on the market on or after the application date of the Machinery Regulation (January 2027) this is only allowed if it is in full compliance with the Machinery Regulation.

71	Right, the other way round is to allow placing on market of MD machine after January 2027.	This not allowed. They have to be placed on the market before Jan 2027.
72	Is it then the task of TCs to check 1st draft of SReq and to provide CCMC (SRAHG) by September 2023? Will there be a request sent out by CCMC what is further expected from TCs?	Yes, we will send out the dedicated messages for most of the actions. Except that the analysis of the impact of MR on standards should be already ongoing as it was already requested by emails