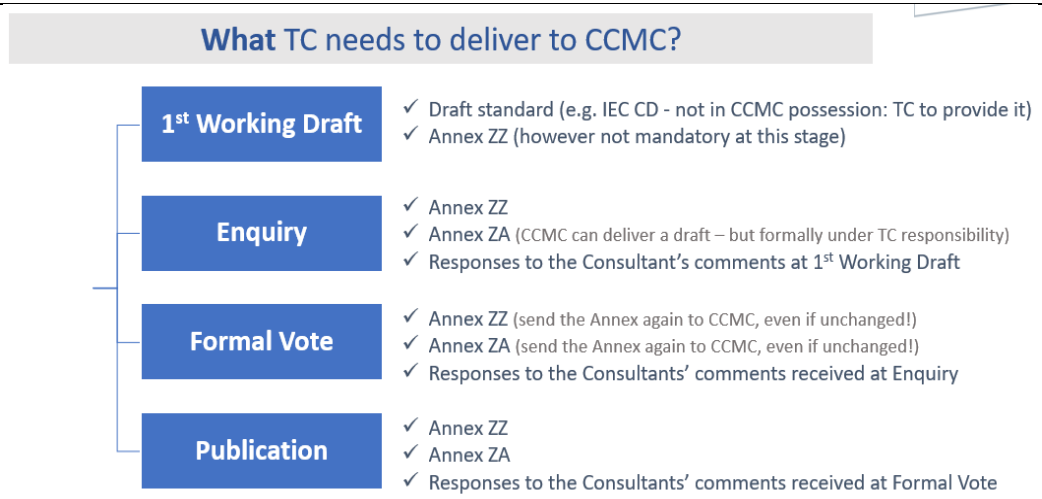
Webinar on EMC – Q&A

See the slides of the Webinar here: https://ftp.cencenelec.eu/EN/AboutUs/OurServices/Training/Others/2021-05-04_Webinar_EMC_Matters.pdf

topic	Question	Answer
General	What is the definition of a *harmonized* standard?	A harmonized standard (hEN) is a European Standard developed by a recognised European Standards Organisation: CEN, CENELEC, or ETSI. It is created following a request from the European Commission (e.g. Mandate M/552 for EMC) to one of these organisations. Manufacturers, other economic operators, or conformity assessment bodies can use harmonised standards to demonstrate that products, services, or processes comply with relevant EU legislation (i.e. presumption of conformity). Presumption of conformity is given when the hEN is cited in the Official Journal of the European Union (OJEU) only.
OJEU Citation	Is it the citation of an EN in the OJEU that gives it the status of an harmonized standard?	From a formal perspective, and as defined in Regulation 1025/2012, a harmonized standard is a EN developed in the frame of a mandate/standardization request (whether it is cited or not). Harmonized standards provide presumption of conformity only when cited in the OJEU (Commission decision, following a compliant HAS assessment).
OJEU Citation	Where can I find the lists of standards that are cited in the OJEU?	See here: https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/electromagnetic-compatibility_en Since 1 December 2018 the references of harmonised standards are published in and withdrawn from the Official Journal of the European Union, by means of 'Commission implementing decisions'. The references published under Directive 2014/30/EU on electromagnetic compatibility are found in the Commission communication published in OJ C 246 of 13 July 2018, in the Commission implementing decision OJ L 206 of 6 August 2019, and subsequent amendments (15 May 2020, 3 November 2020, 15 March 2021). These documents need to be read together, taking into account that the later decisions may modify references published in previous references. The summary list (PDF or XLS) gives a consolidated overview of all publications in the Official Journal.
OJEU Citation / EC	- what are the criteria used by the	By default, the European Commission now provides a transitional period of 18 months

Date of withdrawal	European Commission to set the date of withdrawal from the OJEU of an EN? Why are they not corresponding to the CENELEC DOW (date of withdrawal) anymore? - Based upon the 18 months transitional default period for removal of standards listed in the OJEU, is the request for a different transitional period, part of the formal request process?	(which is the general default period set, subject to specific situations or exceptions cases), from the date of publication of the relevant EC Decision (i.e. date of citation of the new standard). After this date, the previously cited version of the hEN (i.e. the superseded standard) will not provide presumption of conformity anymore. It is called the DOCOPOCOSS (date of cessation of presumption of conformity of superseded standard). This approach provides a misalignment with the CENELEC DOW (date of withdrawal of the superseded standard, 36 months – date at which the superseded standard will be formally withdrawn). It has to be noted that a request, with relevant justifications, for extending this transitional period can be requested to the European Commission by the relevant TC. This request must be made available at the moment the compliant EN is published by CENELEC.
HAS assessment	An assessment can be asked on an IEC CDV. Why is there no communication with the HAS Consultant at AFDIS stage?	It is crucial to ensure regular communication with the HAS consultant. The TC can request a meeting with the HAS consultant anytime from the moment the assessment has been formally requested. It is notably recommended to contact the HAS consultant before he/she finalises the assessment report (usually 35 days max after the assessment has been requested – contact your CCMC project manager for the exact timing): it would be the opportunity to clear any misunderstandings or misinterpretation. Having an exchange with the HAS consultant is particularly important between the Enquiry (CDV) and the Formal Vote (FDIS). After the start of the Formal Vote (FDIS), it will not be possible to modify the text of the standard anymore (the Annex ZA and ZZ can be still modified only).
HAS assessment	In the past we sometimes received contradictory assessments during CD and CDV review from the same consultant. Is this issue fixed now - do we receive consistent assessments?	To prevent this issue: - After analysing the assessment at CD stage, provide written feedback on how the comments have been addressed by the TC (column 'remarks from secretariat'): e.g. clarifications, agreement to modify the standard, disagreement on the comment of the consultant… - When providing the assessment elements to CCMC for the CDV stage, make sure to include the table of the HAS comments with the TC feedback made at CD stage (together with the Annex ZA and the Annex ZZ).

		 An assessment at CD stage is highly recommended so that the Consultant can flag early in the process any compliance issue. Therefore, there will be more opportunities to address these issues in the frame of the relevant IEC Working Group. It is understood that some secretaries may not have access to the CD draft (which CCMC does not have either). Therefore, the secretary must contact the relevant National Committees to provide this draft.
HAS assessment	How can we improve communication with the HAS Consultant? In the past, we used to contact the HAS Consultant for discussing our standards and assessments. I understood that now the ESOs cannot contact the HAS consultants anymore?	It is advised that TCs interact and meet with the HAS Consultants within the frame of an assessment activity (e.g. discussion on adequately addressing the HAS Consultants comments given in their assessment report). The best practice is that the TC Secretary contacts the HAS Consultant directly for written exchanges (e.g. requiring clarifications by e-mail directly to the consultant) or for phone calls and short video calls foreseen to last less than 4 hours – as soon as the assessment is requested, to arrange exchanges before the finalization of the assessment by the HAS consultant. For other cases, the TC Secretary would use the online-form provided by the HAS Contractor and this at least 4 weeks prior to the scheduled meeting. It has to be noted that in principle - to ensure that an assessment would not fail because of missing information - the HAS Consultant is also encouraged to seek contact with the Technical Body during his assessment activities. The European Commission and EY had decided to temporarily suspend meetings between HAS consultants and TCs in order to give priority to assessments of candidate

		harmonized standards due to the limited budget of the HAS project (effective in Q2/2021). The situation is expected to come back to normal in July 2021.
HAS assessment	With the new restrictions, for clarifying minor questions, such clarification would be possible by addressing a related mail to the Consultant directly – without further administrative preconditions?	The principle is that, provided that those exchanges would last less than 4 hours, the TC secretary can contact the HAS consultant (for asking questions or providing clarifications by email – or for requesting a meeting with the Consultant). The best practice is to contact the HAS consultant as soon as the assessment is requested (check with your CCMC project manager), to arrange exchange before the finalization of the assessment.
HAS assessment	I thought the FV Consultant assessment was completed before start of FV ballot, which allows for changes to text prior to launch of FV (if assessment is negative)?	This is indeed the approach for 'homegrown' CENELEC standards. In most cases under EMC, EN are developed in parallel with IEC, which has the lead (and decides upon the timing for submitting the standard to CDV or FDIS). Therefore, CCMC receives the FDIS final draft only a few days before the FDIS will start. It does not give enough time for requesting an assessment (in due time with all other relevant documents, i.e. Annex ZA/ZZ), receiving the assessment and potentially modifying the final draft. Indeed, the IEC does not suspend the start of the FDIS if there is a negative assessment (unlike ISO which may decide to suspend the start of the FDIS). Therefore, it is important to ensure the closest coordination with the IEC counterparts – (1) for communicating the HAS consultant's comments to the IEC WG (generally through contacts between the relevant convenors in CENELEC and IEC), (2) for being aware of the IEC 'timing' for the launch of the standardization procedures so that the European elements (e.g. Annex ZA/ZZ) can be submitted on time to CCMC.
HAS assessment	How will the TC know who is the HAS consultant chosen to assess a standard?	Usually it is the same consultant that is allocated to one TC, but it may change depending on the available resources. CCMC can inform the TC asap about possible changes.
HAS assessment	If we have a positive assessment at Enquiry/CDV, why do we need a new assessment at Formal Vote/FDIS?	If a compliant assessment is provided at an earlier stage, e.g. at CD or CDV stages, it is still necessary to request a new assessment on the final draft, especially if it provides technical changes on the essential requirements. In any case, it will better facilitate the citation of the standard in the OJEU, without the need to provide justifications to the European Commission on why the assessment at Formal Vote was not requested.
HAS assessment	Does the assessment of the HAS consultant include informative annexes?	The assessment addresses the 'full' standard: the standard as such and the European elements (i.e. Annex ZA and Annex ZZ). Particular attention must be paid by CLC/TC when requesting an assessment on an amendment: it is important to ensure a close coordination with your CCMC project manager so that the appropriate elements can be provided in the assessment 'package' (i.e. in this case, also the 'mother' standard must be evaluated, if not done so already).
HAS assessment	If there is a negative result as output	When a harmonized standard is cited, it remains cited (whatever its version) - unless a

	of the assessment for a future standard, what will happen with the former edition listed as harmonised standard which never has been assessed? Does it mean, that the former standard (having the same problem) will be deleted from the list of harmonised standards? Does the HAS-consultant start the deletion?	Formal Objection has been provided by a Member State to the European Commission and agreed by the Committee of Standards (CoS). A harmonized standard can be removed from the OJEU only through a formal Commission's decision. In practice, if the new standard is not cited, and if the previous edition is still cited, manufacturers could benefit from the presumption of conformity on a standard that don't not represent the state-of-the-art anymore.
HAS assessment	Is it an automatism that a standard which references a blocked standard is also blocked or does the blocking of the referencing standard depend on the requirements that are taken over from the blocked standard, e.g if ony uncritical specifications are only taken over from the referenced standard?	If the normative reference is so specific that it does not address the problematic parts, then there is no issue in terms of compliance. However, the reality is that most normative references are often referring to a complete standard. European Standards can normatively refer to problematic standards (e.g. CISPR standards that include statistical methods), while the product standard, as such (i.e. if we consider it without the normative references), is not problematic. Normative references form an integral part of the standard.
HAS assessment	We write technically good standards. Why do we receive negative assessments?	As reflected from many assessments, the standards are seldom failed on the technical requirements. The main problems have been the application of statistical methods to limits and manufacturer defined performance criteria in product standards. But a significant number of negative assessments are because of the scopes of standards being unclear as to what equipment is covered, the normative references are generic, and the requirements are unclear. In other words, the standards do not meet the requirements of the CEN-CENELEC Internal Regulations part 3 (i.e. objectively verifiable requirements). There is no doubt about the fact that the standards are good and meet the technical needs of the different stakeholders worldwide. Nevertheless, harmonized standards cited in the OJEU provide legal effects: therefore, these standards shall comply with some specific EU criteria. Therefore, the question is not as to whether the standards are good or not, but rather whether the standards fulfil the criteria for being cited in the OJEU.
HAS assessment	How can we improve our drafts?	To improve the draft from a compliance perspective, it is crucial to make the best use of the EMC checklist (see Annex 1) and to start the harmonization process as soon as possible. When facing systematic issues (i.e. with statistical methods or manufacturer-

		defined performance criteria), CLC/TC must liaise with the CCMC project manager to decide on the best way forward: use of a specific Annex ZZ or use of Common Modifications. With these specific issues, the CLC/TC can decide to develop Common Modifications to address these compliance issues – as an interim solution - pending the availability of the necessary (new) standards at European or International levels to address the above-mentioned issues (through CLC/TC 210).
Use of the checklist	Can the EMC checklist be used for the drafting of the standard?	Because a lot of shared frustrations and uncertainties, CLC/TC 210 has now proposed for the use of the EMC checklist template to be used by TCs before the submission for HAS Consultants' assessments. By doing so TCs and Consultants can be on the same page and can do early risk assessments - TCs then will be able to challenge if HAS Assessment comes back differently to TC's expectation.
HAS assessment	Would a technical editor role in CLC be helpful to pre-check annexes and standards before sending them to consultants?	The CLC/TC secretary is formally responsible for submitting to CCMC all the relevant elements for assessment (e.g. draft standard, Annexes ZZ and ZA, TC's feedback on previous assessments, etc. CCMC does not check the (technical) content of the standard. It is crucial to liaise with your CCMC project manager to agree together on the assessment 'package' that will have to be submitted.
International standards	If IEC does not take on board the European requirements, what can we do?	International Standards are subject to International consensus – this is clear. Having International Standards as ENs cited in the OJEU can have a great added value, not only for European players, but also for those from other regions willing to place products on to the European market. Therefore, there could always be an international interest to make the necessary arrangements to ensure the citation of the identical EN IEC standard in the OJEU. There are 2 main possibilities to address the HAS consultants' comments at IEC: - The CLC/TC secretary or relevant convenor can contact the IEC/TC secretary or convenor – as appropriate. - The NCs can provide inputs that address the compliance issues raised at CDV stage for instance If the IEC does not take on board the HAS consultants' comments, there are 2 possibilities: - No deviation for the international standard. The IEC standard = the European standard. In this case the EN will not be cited in the OJEU

		- Deviate from the international standard by adding specific European elements through a European amendment (Common Modifications). This will allow the modified standard to be cited in the OJEU. It is up to the TC to decide what is the most favourable solution. Having Common modifications to address the compliance issue can be a reasonable solution, pending, for instance, the uptake of these elements in a future version of the IEC standard (e.g. a future amendment at IEC level can be the vehicle to address compliance issues found in previous versions).
International standards	CENELEC TCs are not always active at IEC CD stage. How can we ensure that TCs participate at an early stage?	The CD stage does not appear in the CENELEC standard development process (i.e. see Projex-online). Since starting the harmonization process asap with the IEC CD is crucial to ensure compliance, CLC/TC secretaries need to closely follow-up the development phases at IEC. It has to be noted that CCMC does not have the CD drafts: therefore it is up to the CLC/TC secretary to provide CCMC with the CD draft, so that CCMC can request an assessment on it (at this stage, it is not needed to provide an Annex ZA and Annex ZZ).
International standards	How can a CLC TC be informed when IEC launches a CD under their scope? There is no automatic notification.	CLC/TCs mirror the activities of IEC/TCs, which means that the members of the CLC/TCs are involved in the IEC/TCs. Therefore, they should monitor the development at IEC level in order to be informed and trigger an assessment on the CD.
International standards	Could it be considered to start the official parallel process already at CD stage?	Noted.
International standards	Is there any coordination with IEC to ensure that IEC convenors will be motivated on taking into account also the CENELEC European concerns for structure and contents of the standards?	The coordination must take place at TC level, for instance between relevant convenors.
Presumption of conformity	What is the consequence for manufacturers and market surveillance when a product has no more a listed standard?	The standards can be used even if not listed. Standards have still an important value even if not cited in the OJEU. In the case of the EN IEC standard (IEC standard adopted identically as European Standards), the first value is in the fact that one standard will apply across Europe (and any conflicting standard will be removed), which is already a significant asset to remove technical barriers to trade. Furthermore, even if not cited, the standards are used by market surveillance authorities who need to rely on commonly agreed requirements.
Presumption of conformity	If not harmonized [not cited in OJEU], CEN/CENELEC standards are on the	European Standards (from CEN, CENELEC and ETSI) have a specific status and cannot be compared to standards from other organization (see Regulation 1025/2012 on

	same level as ANSI, ITU or internal standards.	European Standardization). 1 European Standard becomes the national standard in all the countries involved in the European standardization system. https://ec.europa.eu/growth/single-market/european-standards_en
Presumption of conformity / Market surveillance	What standard will Market Surveillance use, when the latest standard is not cited in the OJEU?	A manufacturer can only place a product on the EU market when it meets all the applicable requirements. Market surveillance authorities check the compliance of the product with the legal requirements applicable at the moment of the placing on the market or, if relevant, putting into service. Union harmonisation legislation provides for two different tools that enable market surveillance authorities to receive information on the product: the EU declaration of conformity and the technical documentation. A standard can be used also if it is not listed, however, the application of the standard does not lead to the presumption of conformity with the essential requirement(s) and another conformity module of the Directive shall be used (see also the Blue Guide on the implementation of EU products rules: https://ec.europa.eu/growth/content/%E2%80%98blue-guide%E2%80%99-implementation-eu-product-rules_nn).
Presumption of conformity / Market surveillance	Do Market Surveillance Authorities participate in standardizations	Indeed, European standardization is an open, transparent and inclusive system, where all relevant stakeholders can contribute to standards' development.
EU criteria and requirements for compliance	What are the requirements European Standards shall comply to for being cited in the OJEU	The HAS consultant checks the compliance of the European Standards according to several specific criteria, decided by the European Commission. They are reproduced in the an 'Assessment report' checklist (Annex 2). The criteria articulate mainly around the following aspects: • Clear and concise scope • Objectively verifiable requirements and test methods – see CEN-CLC/IR3: *expression in the content of a document conveying **objectively verifiable criteria to be fulfilled and from which no deviation is permitted** if compliance with the document is to be claimed or Requirements shall be objectively verifiable. Only those requirements which can be verified shall be included. Phrases such as "sufficiently strong" or "of adequate strength" shall not be used because they are subjective statements.* • Normative references must be dated • Neutrality principle: the standard shall not contain clauses imposing requirements or obligations on or between certain economic operators • Annex ZA (dated) and Annex ZZ • Sector specific requirements (see below: performance criteria, measurement uncertainty, statistical methods)

Performance criteria	What are the requirements of the European Commission with regards to Performance criteria?	The European Commission requires that there are no non-specific requirements in the European Standard, i.e. undefined or manufacturer defined limits, test levels, measurement methods or performance criteria. For instance, a clause that allows manufacturers to define performance criteria for use in immunity testing – allowing an individual manufacturer to determine if equipment being tested passes or fails a test. The matter is addressed by CLC/TC 210 from a horizontal perspective.
Measurement uncertainty	How to address the topic of Measurement uncertainty and the decision of the ADCO RED?	The ADCO RED, the coordination group of the Market Surveillance Authorities of the Radio Equipment Directive 2014/53/EU (RED), have put forward a position paper on enforcement and measurement uncertainty, which has led to non-compliant assessments. Taking EN 61000-3-3+A1:2019 as an example, its clause 6.2 is considered problematic in this regard. According to the European Commission, the standard does not appear to prevent controversies if that clause is applied by manufacturers. The matter is addressed by CLC/TC 210 from a horizontal perspective. See the position of ADCO RED here: https://ec.europa.eu/docsroom/documents/32381
Statistical methods	Why statistical method cannot be accepted if, for a product family, common knowledge demonstrates that such statistical approach is correct?	The requirement of the EC is the following: “No statistical methods are described or referred to in this standard to evaluate products to be placed on the market.” It relates to requirements/information in electromagnetic emission standards, which concern the statistical assessment of mass-produced equipment (e.g. so called 80%/80% rule). CENELEC has been requested by the European Commission to fulfil the ‘long-term’ plan for the removal of the statistical methods from the harmonized standards. In accordance with the long-term plan, CLC/TC 210 experts have been working at international level (IEC/CISPR) and European level, either to remove the statistical methods from the impacted standards or to make it as part of informative Annexes. In this context, CLC/TC 210 has started to work on New Work Items for introducing Common Modifications to delete the 80/80 implication statements/sentence from the cited versions of the relevant CLC/TC 210 standards (EN 55011, EN 55014-1, EN 55015, EN 55032).
General	Who can we contact if we have more questions?	CCMC Project Manager for any question.

Annexes

HAS Consultant EMCD assessment checklist	COMPLEMENT TO ASSESSMENT FORM

Date:			

Status of the WI	☐ Indicative	☐ Enq-vote	☐ FV	☐ Approved	☐ Ratified	☐ Published
TC						
Standard number			**Work Item Project ID**			
Title			**Amdt or Rev**			
Directive or Regulation (EU or EC)[1]	EMCD (2014/30/EU)		**Standardisation Request**	M/552		

MODIFIED VERSION FOR USE BY TCs

TC	HAS OK	HAS NOK	Vademecum part III – clause 2.8	Remarks
			General	
☐	☐	☐	The standardisation request which provides the basis for the standard is referred to in the foreword.	
☐	☐	☐	Those parts of the standard related to the essential requirements of the EMC Directive are clearly identified in the ZZ annex.	
☐	☐	☐	The Scope is clearly defined giving precise limits to the products covered.	
☐	☐	☐	The normative elements in response to the standardisation request are properly separated from other normative elements.	
☐	☐	☐	Clauses in support of legal requirements under the standardisation request are normative.	
☐	☐	☐	There are no non-specific normative references, e.g. no generic references.	
☐	☐	☐	The normative references are dated and up-to-date.	
☐	☐	☐	The normative references are primary to EN or ISO/IEC standards, where these exist.	
☐	☐	☐	There are no contradictions by provisions contained in the normatively referenced clauses of a referenced standard.	
☐	☐	☐	There are no repetitions of legal requirements in the standard.	
☐	☐	☐	There are no clauses amending legislative definitions or provisions.	

[1]Only one (1) Regulation or Directive per assessment

HAS Consultant EMCD assessment checklist	COMPLEMENT TO ASSESSMENT FORM

Date:			

TC			For amended or revised standards	Remarks
☐	☐	☐	Significant changes are properly identified.	
☐	☐	☐	The scope is narrower, the Commission has been informed.	

TC	OK	NOK	Technical – Clear identification of the Essential Requirements or Safety Objectives intended to be covered	Remarks
☐	☐	☐	The Informative Annex (CLC: ZZ; CEN: ZA or ETSI: A) is in accordance with the agreed template.	
☐	☐	☐	The identification of the Essential Requirements/Safety Objectives is clear, unambiguous and reflecting the correct coverage and/or exclusions.	

TC	OK	NOK	Technical – Sector Specific – Sufficient coverage of E.R/S.O. intended to be covered	Remarks
☐	☐	☐	All relevant (significant) essential or other legal requirements have been identified (after consideration of possible limitations in the scope).	
☐	☐	☐	Where appropriate, for the identified relevant (significant) requirements, appropriate and verifiable measures for reduction of uncertainty or risk have been specified (as far as possible performance based).	
☐	☐	☐	Harmonised generic EMC standards together with state of the art and more comprehensive standards, e.g. EN 55032 and EN 55035 (which deal with all types of ports except exotic variants) have been used to establish an appropriate reference for assessment.	
☐	☐	☐	Older versions of harmonised product standards for the same equipment and current harmonised product standards for similar types of equipment have been used to establish another appropriate reference for the assessment.	
☐	☐	☐	The emission requirements, if relevant, are equivalent to or more appropriate than those in the reference standards for assessment.	
☐	☐	☐	The immunity requirements, if relevant, including performance criteria, are equivalent to or more appropriate than those the reference standards.	
☐	☐	☐	The requirements are compatible with good EMC engineering practice, state of the art EMC expertise or appropriate reference standards.	
☐	☐	☐	No statistical methods are described or referred to in this standard to evaluate products to be placed on the market.	
☐	☐	☐	There are no non-specific requirements, i.e. undefined or manufacturer defined limits, test levels, measurement methods or performance criteria.	

HAS Consultant EMCD assessment checklist	COMPLEMENT TO ASSESSMENT FORM

Date:			

Remarks and justifications

Outcome of the assessment	
☐ POSITIVE	☐ NEGATIVE

Assessment report under service contract SI2.770800[1]

Date of the report	**XX/XX/20XX**
Nature of the report	☐ Initial report ☐ Reviewed report after the initial report was challenged by ESO
Internal reference	Indicate the reference of the work order from EY

Assessed document standard reference and full title including date or version of the document	
ESO work item reference	
Main objective and purpose of the assessed document, including its relation to other standards within the 'harmonised context' describe briefly to set the context under which the assessment was carried out	
Relevant normative references partly or fully verified and assessed give actual dated reference numbers of those standards checked or assessed as part of this assessment	
Nature of the assessed document	New project / Revision of Harmonised standard or a standard that was cited under GPSD / Revision of a standard that was not cited If the draft amends a standard that was cited or non-cited under the relevant Union legislation, please provide information on this, in particular when Lack of Compliance is based on this situation
ESO technical body	Reference of the Technical Body
ISO/IEC in lead	☐ No ☐ Yes
Assessment phase	Phase at which the draft is assessed
Regulated aspects covered by this assessment report	(1) ☐ All aspects (2) ☐ All other aspects except (give those excluded)____ (3) ☐ Only (give the aspect(s) assessed) ____

Legislation supported indicate legal act reference(s), its short title (or acronym) and relevant articles and/or annexes supported	Indicate which is the legislation that is being assessed here (e.g. Directive/Regulation xxxx/xxxxx, Short title, Article X/Annex X) If the aspects assessed have a link with another legislation (e.g. electrical safety for LVD and RED) indicate whether a coordination took place or not
Standardisation request(s) give reference number and relevant point of a request	Indicate the Standardisation Requests corresponding to the legislation above (i.e. the one that is being considered in this assessment,) [e.g M/xxx, Annex I point 3 of Table 1)
Consultant(s) involved	Name of the consultant
Commission service(s) DG/Unit	DG GROW/Unit XX or DG SANTE/Unit YY

[1] **Disclaimer**: This assessment report contains the overall opinion of the relevant consultant(s) on the document's sufficient compliance with the Commission's standardisation request(s) and suitability to support relevant Union legislation on the basis of those findings reported in it. This report is without prejudice to other findings which could be identified at later stages by the Commission, the consultant(s) or any other parties or individuals. The report does not establish any rights or obligations for any parties or individuals; it does not represent the opinion of the Commission and is not binding on the Commission.

Part A: Summary of the assessment

1. Consultant's opinion

1.1 On the document's compliance with the standardisation request(s) and suitability to support relevant EU legislation - i.e. sufficiency and suitability to initiate the intended 'legal effect' in relevant context based on a full verification and assessment as summarised below in 1.2 and 1.3 covering 'Critical findings' and on Part B

☐ **Compliance** - no 'critical findings' are reported

☐ **Good or sufficient quality for a compliant document** - no changes required and no critical findings

☐ **Minor or limited number of changes not affecting compliance –** please indicate those changes in section 2 (other findings)

☐ **Lack of compliance** - quality not sufficient for a harmonised standard

☐ **Minor or limited number of changes are required – e.g. Annex Z –** please see sections 1.2 and 1.3, Part B and template

☐ **Redrafting required** - need for substantial changes to the document are reported – please see sections 1.2 and 1.3, Part B and template

1.2 Critical findings leading to a Lack of compliance - Tick relevant boxes for the Critical findings that have been found in the document (and provide details in 1.3 'Additional information on the critical findings', Part B and template of comments)

☐ 1.2.1 The terminology (including definitions of terms) is not in line or consistent with relevant EU legislation

☐ 1.2.2 The Foreword or the introduction contains inappropriate information not belonging there or misleads document users on its role and scope as a harmonised standard (e.g. contains requirements, legal or technical interpretations, information outside of the scope of a document)

☐ 1.2.3 The Scope covers products not considered by the relevant legal requirements of EU legislation or standardisation request and organisation/subdivision of technical content or Annex Z mislead users of a document on its support on EU legislation

☐ 1.2.4 The Scope sets requirements or covers aspects which cannot be subject to harmonised standards on the basis of relevant EU legislations or standardisation request

☐ 1.2.5 The Scope excludes products or aspects that are expected to be covered by the standard according to its title or Annex Z in order to support relevant EU legislation or standardisation Request. This means that there is not consistence between the title, the scope and Annex Z; as a result, products that are expected to be covered are excluded.

☐ 1.2.6 One or several Normative references that are essential for the assessment of harmonised elements are not available at the time of the assessment

☐ 1.2.7 The document contains undated normative references without proper justification (and assessment) or the justification is not acceptable

☐ 1.2.8 The document contains too long chains of normative references that are needed to comply with or to follow (in the case of CPR) when applying the harmonised part of the document

☐ 1.2.9 The normative references need updating or reconsideration, i.e.

- one or more do not reflect the state of the art and have an impact on compliance with EU legislation,
- one or more normative references, in particular references to other harmonised standards should be informative (to avoid later contradictions because of different update cycles of referring and referenced documents)

☐ 1.2.10 The technical content of the document contains requirements that do not align with or contradict relevant EU legislation (e.g. are out of scope from supporting proper or any legal requirements, fails to specify 'technical solutions', allows users of a document to decide on the specification)

☐ 1.2.11 The technical content of the document unsuitably repeats legal requirements as part of its normative requirements (e.g. without any added value or modifying them, suggesting that only some legal requirements are valid)

☐ 1.2.12 Absence of reproducible tests or assessment methods (or lack of reference to standards containing such tests or assessment methods) to demonstrate in a objectively verifiable manner the technical specifications in support of the Essential Requirements and indicated in Annex ZA/ZZ, or the foreseen assessment methods are not suitable

☐ 1.2.13 Neutrality principle is not respected: the document contains clauses imposing requirements or obligations on or between certain economic operators (e.g. requirements are set to an economic operator and its competence or resources instead of to product design and product properties)

☐ 1.2.14 Neutrality principle is not respected in requirements for verifications, sampling and testing (e.g. clauses imposing first, second- or third-party testing)

☐ 1.2.15 Risk assessment or identification of relevant risks is missing or not complete and/or there is no evidence that certain risks were considered

☐ 1.2.16 The Annex Z is not sufficiently detailed (need for more granularity) in describing which clauses and sub-clauses support relevant EU legislation

☐ 1.2.17 The Annex Z does not properly refer to the relevant legal requirements of EU legislation in question

☐ 1.2.18 The document is not aligned with the guidance documents or checklist of the relevant EU legislation

☐ 1.2.19 Other comments as indicated in 1.3 'Additional information on the critical findings', Part B and in the template for comments

1.3 Additional information on the critical findings leading to Lack of Compliance - issues concerning legal clarity of the draft, level of safety/interoperability/protection/performance or coverage of essential requirements/characteristics on the basis of reported results in Part B and template of comments

2 Other findings -coherence, consistency, quality and clarity of drafting on the basis of reported results in Part B not leading by themselves to a lack of compliance

3. Information on possible self-initiative ESO reports for the purposes of assessing or proving compliance - attach such documents as an annex to Part C where relevant)
N/a
4. Information on meetings or other dialogues with relevant ESO's technical bodies before or during this assessment - attach such details as an annex to Part C where relevant
☐ **The Consultant attended a meeting previous to the assessment having an impact on this assessment report** ☐ **Meeting report sent to EY and Desk Officer** ☐ **The Consultant has contacted and exchanged information with the ESO's technical body** ☐ **The Consultant has contacted and exchanged information with DG GROW / Unit B3 'Standardisation'** ☐ **The Consultant has contacted and exchanged information with the corresponding Desk Officer on reported issues**
5. Information on ESO responses to earlier assessments - attach such details as an annex to Part C where relevant
5.1 To what extent was the earlier assessment followed-up (in terms of improvements made) and what are the possible major remaining issues (which were reported already in an earlier report) which have an adverse impact on compliance? - attach details as an annex to Part C where relevant
N/a
5.2 If the previous assessment report was challenged, are there still critical or other remaining issues where the intervention of the relevant Commission service could be needed? - indicate the issues challenged and possible remaining issues; attach details as an annex to Part C where relevant
N/a

Part B: Structured verification and assessment results on the basis of a full assessment of the entire document

1. Clarity and transparency of elements that aim to support legal requirements – Any box ticked as 'Not fulfilled' shall necessarily be explained and lead to a Lack of Compliance		**Assessment of the impact on compliance / lack of compliance and evidences**
1.1 Significant changes in a draft revision or a draft amendment to a harmonised standard are clearly flagged	☐ **Not fulfilled** ☐ **N/A** ☐ **Fulfilled**	
1.2 'Annex Z' or equivalent is provided	☐ **Not fulfilled** ☐ **N/A** ☐ **Fulfilled**	
1.3 In 'Annex Z' a clear and precise description of the relationship is given	☐ **Not fulfilled** ☐ **N/A** ☐ **Fulfilled**	
1.4 'Annex Z' only refers to clauses or normative references contained in the document. Annex Z' does not refer to another standard or to another document (including a legal act) not supported by the document	☐ **Not fulfilled** ☐ **N/A** ☐ **Fulfilled**	
1.5 'Annex Z' claims a relationship only with elements of a document supporting relevant legal requirements. 'Annex Z' does not claim any relationship with elements of a document not supporting relevant legal requirements .	☐ **Not fulfilled** ☐ **N/A** ☐ **Fulfilled**	
2. Normative references		
2.1 Document contains normative references the suitability and availability of which have been verified, assessed and reported in the 'harmonised context'	☐ **Not fulfilled** ☐ **N/A** ☐ **Fulfilled**	
3. Scope of the document		
3.1 The scope indicates that the document provides on its own for **(i)** a verifiable compliance of a product against legal requirements, OR **(ii)** a method or criteria for declaring or assessing performance of a product	☐ **Not fulfilled** ☐ **N/A** ☐ **Fulfilled**	
3.2 The scope corresponds with the one initially requested by the standardisation request. No additional category of products are included and no category of products is excluded against the requirements in the standardisation request	☐ **Not fulfilled** ☐ **N/A** ☐ **Fulfilled**	
4. Requirements, provisions and guidance addressed by clauses and annexes including relevant normative references and informative elements		
4.1 **(i)** There are no requirements, provisions or pieces of guidance specifically addressed to 'economic operators', **(ii)** the 'neutrality principle' is respected, OR **(iii)** There are no inappropriate requirement, provisions or pieces of guidance limiting the placing on the market (or service provision)	☐ **Not fulfilled** ☐ **N/A** ☐ **Fulfilled**	
4.2 No requirement, provision or pieces of guidance (although dealing with a regulated product/service) goes beyond the scope of the legal requirements	☐ **Not fulfilled** ☐ **N/A** ☐ **Fulfilled**	
4.3 The structure of a normative element (when a document goes beyond the scope of legal requirements) makes it evident to distinguish between 'harmonised elements' and other content	☐ **Not fulfilled** ☐ **N/A** ☐ **Fulfilled**	
4.4 No legal text is repeated without providing any added value or it is not repeated in slightly modified form	☐ **Not fulfilled** ☐ **N/A** ☐ **Fulfilled**	

4.5 It does not contain non-specific or non-verifiable requirements, provisions or piece of guidance, leaving it to a manufacturer or another standard user to decide how to apply	☐ **Not fulfilled** ☐ **N/A** ☐ **Fulfilled**	
4.6 No legal requirement is **(i)** insufficiently or inappropriately covered, satisfied or dealt with, OR **(ii)** is not covered at all in cases where 'coverage' is claimed (in 'Annex Z')	☐ **Not fulfilled** ☐ **N/A** ☐ **Fulfilled**	

Part C: Documents annexed and relevant for the assessment

The Assessment Report contains (tick the appropriate boxes):

1. Detailed assessment documents annexed

☐ template of comments on ESO commenting form (including assessment of the relevant normative references), duly numbered and identifying clearly the HAS Consultant
☐ noise assessment
☐ risk assessment file
☐ checklist as required by the corresponding EC sector unit
☐ assessed document with track changes (where relevant)
☐ previous assessment report or parts of it (where relevant)
☐ TC's answers to previous comments
☐ other (please indicate) _____

2. Other information given by the consultant and relevant for this report

☐ information on meetings or other communication with ESO before or during this assessment (where relevant)
☐ information on literature, other standards, studies etc. used during assessment to deliver this report (where relevant)]

3. Supporting documents produced by ESO and relevant for this report

☐ self-initiative ESO reports for the purposes of assessing or proving compliance (where relevant)
☐ extract(s) of a risk assessment (where relevant)
☐ documents describing ESO response on earlier assessment report(s) including challenged issues (where relevant)]