

# Assessment report under service contract SI2.876921 <sup>1</sup>

<b>Date of the report</b>	<b>XX/XX/20XX</b>
<b>Nature of the report</b>	<input type="checkbox"/> Initial report <input type="checkbox"/> Reviewed report after the initial report was challenged by ESO
<b>Internal reference</b>	Indicate the reference of the work order from EY
<b>Assessed document</b> standard reference and full title including date or version of the document	
<b>ESO work item reference</b>	
<b>Main objective and purpose of the assessed document, including its relation to other standards within the 'harmonised context'</b> describe briefly to set the context under which the assessment was carried out	
<b>Relevant normative references partly or fully verified and assessed</b> give actual dated reference numbers of those standards checked or assessed as part of this assessment	
<b>Nature of the assessed document</b>	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
<b>ESO technical body</b>	Reference of the Technical Body
<b>ISO/IEC in lead</b>	<input type="checkbox"/> No <input type="checkbox"/> Yes
<b>Assessment phase</b>	Phase at which the draft is assessed
<b>Regulated aspects covered by this assessment report</b>	(1) <input type="checkbox"/> All aspects (2) <input type="checkbox"/> All other aspects except (give those excluded) _____ (3) <input type="checkbox"/> Only (give the aspect(s) assessed) _____
<b>Legislation supported</b> 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
<b>Standardisation request(s)</b> 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)
<b>Consultant(s) involved</b>	Name of the consultant
<b>Commission service(s) DG/Unit</b>	DG GROW/Unit XX or DG SANTE/Unit YY

<sup>1</sup> **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)

**Conditional compliance** - only in case of problems related to the dates of normative references to other inter-linked standards

**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

<b>3. Information on possible self-initiative ESO reports for the purposes of assessing or proving compliance -</b> attach such documents as an annex to Part C where relevant)
N/a
<b>4. Information on meetings or other dialogues with relevant ESO's technical bodies before or during this assessment -</b> attach such details as an annex to Part C where relevant
<input type="checkbox"/> <b>The Consultant attended a meeting previous to the assessment having an impact on this assessment report</b> <input type="checkbox"/> Meeting report sent to EY and Desk Officer <input type="checkbox"/> <b>The Consultant has contacted and exchanged information with the ESO's technical body</b> <input type="checkbox"/> <b>The Consultant has contacted and exchanged information with DG GROW / Unit B3 'Standardisation'</b> <input type="checkbox"/> <b>The Consultant has contacted and exchanged information with the corresponding Desk Officer on reported issues</b>
<b>5. Information on ESO responses to earlier assessments -</b> 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	<input type="checkbox"/> Not fulfilled <input type="checkbox"/> N/A <input type="checkbox"/> Fulfilled	
1.2 ‘Annex Z’ or equivalent is provided	<input type="checkbox"/> Not fulfilled <input type="checkbox"/> N/A <input type="checkbox"/> Fulfilled	
1.3 In ‘Annex Z’ a clear and precise description of the relationship is given	<input type="checkbox"/> Not fulfilled <input type="checkbox"/> N/A <input type="checkbox"/> 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	<input type="checkbox"/> Not fulfilled <input type="checkbox"/> N/A <input type="checkbox"/> 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 .	<input type="checkbox"/> Not fulfilled <input type="checkbox"/> N/A <input type="checkbox"/> 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’	<input type="checkbox"/> Not fulfilled <input type="checkbox"/> N/A <input type="checkbox"/> Fulfilled	
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### 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	<input type="checkbox"/> Not fulfilled <input type="checkbox"/> N/A <input type="checkbox"/> 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	<input type="checkbox"/> Not fulfilled <input type="checkbox"/> N/A <input type="checkbox"/> 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)	<input type="checkbox"/> Not fulfilled <input type="checkbox"/> N/A <input type="checkbox"/> 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	<input type="checkbox"/> Not fulfilled <input type="checkbox"/> N/A <input type="checkbox"/> 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	<input type="checkbox"/> Not fulfilled <input type="checkbox"/> N/A <input type="checkbox"/> Fulfilled	
4.4 No legal text is repeated without providing any added value or it is not repeated in slightly modified form	<input type="checkbox"/> Not fulfilled <input type="checkbox"/> N/A <input type="checkbox"/> 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	<input type="checkbox"/> Not fulfilled <input type="checkbox"/> N/A <input type="checkbox"/> 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’)	<input type="checkbox"/> Not fulfilled <input type="checkbox"/> N/A <input type="checkbox"/> 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)]