

#### **EUROPEAN COMMISSION**

Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs

Single Market Policy, Regulation and Implementation Standards for Growth

Brussels, 16 November 2016 GROW/B3

## Verification of conditions for the publication of references of harmonised standards in the Official Journal

## 1. Introduction

The references of a harmonised standard<sup>1</sup> are not automatically published in the *Official Journal of the European Union (OJ)*. Before publication<sup>2</sup> can take place, the Commission must verify<sup>3</sup> and, where relevant, assess various aspects to ascertain that the conditions in Article 10(6) of Regulation (EU) No 1025/2012 and in relevant sectorial provisions are met.

## Article 10(6) of the Regulation

Where a harmonised standard satisfies the requirements which it aims to cover and which are set out in the corresponding Union harmonisation legislation,<sup>4</sup> the Commission shall publish a reference of such harmonised standard without delay ...

The references of a harmonised standard are published in the *OJ* only where the standard actually satisfies the relevant legal requirements. Once they have been published, there is a **presumption of conformity**, but only with the legal requirements (e.g. 'essential' requirements) actually covered by the harmonised standard or parts thereof <u>and</u> set out in relevant legislation (see model in Article R8 of Decision No 768/2008/EC). Also, the presumption of conformity does not apply to other provisions of a standard that have nothing to do with those legal requirements. There is no presumption of conformity with requirements that are <u>not</u> set out in relevant legislation and the standard must not imply that there is.

#### Article R8 of Decision No 768/2008/EC (Presumption of conformity)

Products which are in conformity with harmonised standards or parts thereof the references of which have been published in the Official Journal of the European Union shall be presumed to be in conformity with the requirements covered by those standards or parts thereof, set out in ... [reference to the relevant part of the legislation].

Standardisation requests always indicate the legal requirements to be addressed ('supported') by harmonised

A 'harmonised standard' is a European standard adopted on the basis of a request made by the Commission for the application of Union harmonisation legislation (point (1)(c) in Article 2 of Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council (OJ L 316, 14.11.2012, p. 12–33).

See SWD(2015) 205 Part 1, section 4.2.4; http://ec.europa.eu/growth/single-market/european-standards/vademecum/index\_en.htm

See 'Blue Guide' on the implementation of EU product rules, section 4.1.2.3 (Process to harmonised standards providing presumption of conformity); http://ec.europa.eu/DocsRoom/documents/18027/attachments/1/translations/

In the context of legislation for products, 'Union harmonisation legislation' means any Union legislation harmonising the conditions for the marketing of products.

Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC (OJ L 218, 13.8.2008, p. 82–128). The Decision provides model articles for harmonisation legislation for products.

standards. To identify those requirements and consequently the limits of the presumption of conformity, each harmonised standard should contain, in addition to its main normative text (which should always remain a neutral technical specification), a statement as to which requirements it is intended to cover.<sup>7</sup>

On the basis of the two articles referred to above, it is clear that, before deciding to publish the references of a harmonised standard in the OJ, the Commission must:

- ascertain whether the standard qualifies as a harmonised standard under point (1)(c) in Article 2 of the Regulation;
- 2. verify which legal requirements the standard is intended to cover;
- 3 assess whether the standard sufficiently satisfies those requirements;
- 4. check whether the scope of the standard goes beyond the scope of the relevant standardisation request and legal requirements aimed to be supported (i.e. whether there is also 'non-harmonised content' and only 'parts thereof' cover the legal requirements); and
- if so, establish that the 'non-harmonised content', which goes beyond the scope of relevant legal requirements, is not incorrectly or inappropriately associated with any legal requirements.

This verification contributes to the proper functioning of the single market by ensuring that the scope of harmonised standards or parts thereof correctly reflects, and is limited to, the supported legal requirements and that the harmonised standards are not used to suggest that provisions not supporting any legal requirements have to be applied to obtain presumption of conformity. The verification also ensures that the Commission has final control over any assessment work done during the drafting of a harmonised standard in the context of Article 10(5) of the Regulation.<sup>8</sup>

Since European standards can be used to confer presumption of conformity, they should be drafted and adopted according to established drafting and adoption rules for European standards — otherwise, the Commission will not recognise them as harmonised standards within the meaning of point (1)(c) in Article 2 of the Regulation.

The references of harmonised standards are published in the OJ following a positive verification result. This is to be understood as an endorsement based on sufficient (but not absolute) certainty that the standard satisfies the relevant legal requirements and other requirements referred to in the relevant standardisation request(s). The Commission may choose to publish or not to publish the references, or to publish them with a notice clarifying which legal requirements the standard actually satisfies and/or covers, on the basis of reasonably coherent reasoning and recorded evidence. It usually relies on technical assistance (e.g. as provided by dedicated experts involved in the standard development process) when validating the results of standardisation.

In line with the changes introduced by Articles 10(6) and 11 of the Regulation, the Commission should use the results of compliance assessment (Article 10(5)) and take appropriate action before deciding to publish, rather than relying on the possibility of raising objections after publication (which is more for the Member States and the European Parliament). Consequently, the Commission should identify, before publication, cases where a harmonised standard fails to cover or fully satisfy the legal requirements (or the requirements referred to in the initial request(s)) and, where appropriate, publish the references with a notice.

Transparency on the Commission's action before publication also sends a signal to standardisers as regards the importance of producing clearly drafted and structured harmonised standards that simply support the legal requirements referred to in the standardisation request(s), clearly indicate which legal requirements are to be covered and avoid drafting practices that run counter to recognised ESO drafting rules. This should result in harmonised standards being not only readily verifiable by the Commission (to allow publication of the references in the OJ without delay), but also straightforward to apply and user-friendly, especially for SMEs.

See SWD(2015) 205 Part 3, section 2.8.2.

See SWD(2015) 205 Part 3, section 2.8.3.

See SWD(2015) 205 Part 3, section 7.

See 'Blue Guide' on the implementation of EU product rules, section 4.1.2.4 (Presumption of conformity).

#### 2. PROCEDURE

The verification procedure (see Table 1) contains three consecutive steps and nine main questions. It may be started already during the drafting phase of a harmonised standard, in which case it contributes directly to the objectives of Article 10(5). It also allows the Commission to have the final say over any separate compliance assessment out during or after the drafting stage, e.g. through the involvement of dedicated experts.

If a standard claims to support more than one Union harmonisation act, a separate assessment must be carried out for each act and the references are published separately in the OJ. Where there is a need to assess other Commission-requested European standards (under Article 10(5) of the Regulation) that are also intended to support application of Union legislation, but without the references being published in the OJ, the assessment arrangements should be adapted case by case.

## Step I: Verification of procedural formalities [Art. 2(1)(c), Art. 3(1)-(4), Art. 5, Art. 6]

<u>Purpose</u>: To verify compliance with legal and request-related requirements in order to ascertain whether further verification (Steps II and III) is possible and whether the standard qualifies as a harmonised standard.

Outcome: Where the answer is 'no', assessment is usually stopped. See also SWD(2015) 205 Part 1, sections 2.2 and 7.1, Part 2, section 3.6, Part 3, sections 2.3-2.5, 2.8.3 and 2.8.4.

# Step II: Quantitative verification as regards the legal requirements aimed to be covered on the basis of the standardisation request [Art. 10(1), Art. 10(6)]

<u>Purpose</u>: To verify (Q6) and, where necessary, assess which legal requirements are aimed to be covered (as indicated in Annex Z or equivalent informative element of a standard) in order to be able to proceed to Step III (which is not possible if this is not known) and to verify (Q7) whether the standard aims, and claims, to support relevant legal requirements only or whether it also deals with other subject matter outside the Commission's request(s).

Outcome: Assessment is stopped if a standard does not clearly (or at all) identify the legal requirements aimed to be supported and/or if it is not known which normative elements of a standard support those requirements (i.e. 'no' answer to question 6.1 and/or 6.2). The same could apply if the standard or its normative elements go beyond the standardisation request in an inappropriate way. See also SWD(2015) 205 Part 3, section 2.8.4.

## **Step III: Qualitative assessment as regards the legal requirements aimed to be covered** [Art. 10(1), Art. 10(6); Art. 11(1)]

<u>Purpose</u>: To assess (Q9) whether a standard sufficiently satisfies the relevant legal requirements aimed to be covered in the light of:

- (i) those requirements;
- (ii) requirements referred to in a relevant standardisation request (including SWD(2015) 205 Part 3); and
- (iii) the 'state of the art'.

Also where appropriate, to verify (Q8) that any 'non-harmonised content' is drafted in an acceptable way and not incorrectly associated with any supported legal requirements.

<u>Outcome</u>: Assessment is stopped if 'non-harmonised content' is associated inappropriately with legal requirements or if a standard is used for other interpretation purposes which the Commission may not confirm or endorse (i.e. 'no' answer to Q8).

References are published in the OJ on the basis of overall recorded results after qualitative assessment against all the legal requirements that the standard aims and claims to cover or after verifying previous assessments. References may be published also with an accompanying explanatory notice.

In the event of a 'no' answer to Q9, new assessment is possible only after the standard has been amended. See also SWD(2015) 205 Part 1, section 7.1; Part 3, sections 2.8.2 and 2.8.4.

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<sup>&</sup>lt;sup>10</sup> See also SWD(2015) 205 Part 1, section 7.

Table 1 — Procedure before deciding to publish references of a harmonised standard in the OJ

N:o	Verified issue	Remarks	Yes	No
Step	I: Verification of procedural formalities			
1 Cov	verage by a relevant standardisation request and Union harmonisation legislation (Art. 2(1)(c), Art. 10(1))			
1.1	Is the standard covered by the requested-work programme of a relevant standardisation request made by the Commission?			
1.2	Does the subject matter deal (at least partly) with a product, service or other aspect regulated by relevant Union harmonisation legislation <u>and/or</u> can the standard, on the basis of its actual content, be used to support application of legal requirements under Union harmonisation legislation (e.g. terminology and definitions alone cannot confer any presumption of conformity)? (see also corresponding act)			
1.3	Is the title of the standard translated into all official languages?			
1.4	In cases of a family of standards or multiple parts only: Is there a meaningful set of different parts which could be cited in the <i>OJ</i> at the same time <u>or</u> is there absence of other reasons for citing only a single part?			
1.5	In cases of revised versions of harmonised standards already cited in the <i>OJ</i> only: Are significant changes clearly indicated in the revised or amended standard? (see SWD(2015) 205 Part 2, section 3.5; model Article 5 and the relevant request; SWD(2015) 205 Part 3, section 2.10.4)			
2 Tra	nsparency and inclusiveness during requested standardisation work (Art. 3(1)-(4), Art. 5, Art. 6)			
2.1	Was the work item for the standard included appropriately in the requested-work programme? (see SWD(2015) 205 Part 3, sections 2.3 to 2.5)			
2.2	Absence of any concerns as regards inclusiveness during drafting and adoption?			
	sence of a formal objection or any information on a possible objection (including other objected harmonised standards to which there are normative references, e relevant)? (Art. 11)			
	gal requirements aimed to be covered are indicated (Annex Z or equivalent informative element is available) and, where relevant, expressed separately for relevant Union harmonisation act to be supported? (Art. 10(6); SWD(2015) 205 Part 2, section 3.6; Part 3, section 2.8.4)			
5 Nor	rmative references made in clauses or sub-clauses which support legal requirements (SWD(2015) 205 Part 3, section 2.8.3)			
5.1	Are all standards to which there are normative references publicly available, i.e. normative references have been adopted and/or standards are still valid, and are there no references to draft standards (relevant during the final assessment of an adopted standard only)?			
5.2	Is it possible to have access in all official EU languages to the most relevant standards to which there are normative references? [1]			
5.3	Is there an absence of undated normative references?			
5.4	Complete <u>normative reference chains</u> (i.e. further normative references contained in a normative reference) need to be followed and each level verified according to 5.1 to 5.3. Is there absence of any concerns on these other levels of normative references?			
Step	II: Quantitative verification as regards the legal requirements aimed to be covered on the basis of the standardisation request (Art. 10(1), 10(6)	)		
6 Cla	rity and transparency of normative parts of the standard which aim to support the legal requirements aimed to be covered (SWD(2015) 205 Part 3, section 2.8	3.4)		
6.1	Are the legal requirements (e.g. 'essential' requirements) aimed to be covered indicated clearly, transparently and in a structured way, so that Step III qualitative assessment can be carried out for each (in the case of Annex Z or equivalent informative element, this includes legally sound statements, references only to normative elements of the relevant standard, no reference to other standards) <u>and</u> do the normative elements of the standard contain no references to legal acts [2]?			

N:o	Verified issue	Remarks	Yes	No
	[Where covered legal requirements and/or relevant clauses and sub-clauses cannot be identified, consider giving a 'no' answer and move on to question 6.2]			
	['Yes' answer: consider each 'requirement aimed to be covered' in Step III and skip question 6.2]			
6.2	Does the standard itself otherwise make clear to the reader which legal requirements it is intended to cover, through clearly identifiable clauses and sub-clauses (to allow for continued verification in justified cases, even where a specific Annex Z or equivalent informative element is missing)?			
	[If 'yes', consider each 'requirement aimed to be covered' in Step III <u>and</u> , where references are published in the <i>OJ</i> , publish a notice listing these requirements; if 'no', stop the process here — the standard must be amended to indicate which legal requirements are actually aimed to be covered]. [2]			
7 The standard does not contain normative elements outside the scope of supported legal requirements addressed in the relevant request(s) (whether or not clearly indicated in Annex Z or elsewhere)?				
[A 'no'	answer means that normative elements are not restricted to supporting legal requirements only; move on to question 8 in Step III — otherwise skip question 8].			
Step	III: Qualitative assessment as regards the legal requirements aimed to be covered (Art. 10(1), 10(6))			
8 Abs	sence of specifications (in 'non-harmonised content') which:			
(a)	are incorrectly or inappropriately linked to supported legal requirements despite having nothing to do with such requirements; or			
(b	aim to provide interpretations regarding other regulated issues outside the scope of the relevant standardisation request (absence of unaccepted interference with other EU legislation)? (SWD(2015) 205 Part 1, section 7.1; Part 3, sections 2.8.2 and 2.8.4)			
[If 'no'	, consider stopping the process here — the standard must be amended to reflect the scope of the initial request] [3]			
9 Absence of concerns about insufficient coverage regarding actually covered legal requirement? (see Annex on 'principal assessment criteria' and 'horizontal assessment questions' and how to assess and record all this first separately)				
[If 'yes	', tick also 1 or 2 below. If 'no', refuse publication in the OJ on the basis that the harmonised standard does not satisfy the requirements it aims to cover.]			
1.Pu	blication of the references in the OJ			
(b) aim to provide interpretations regarding other regulated issues outside the scope of the relevant standardisation request (absence of unaccepted interference with other EU legislation)? (SWD(2015) 205 Part 1, section 7.1; Part 3, sections 2.8.2 and 2.8.4)  [If 'no', consider stopping the process here — the standard must be amended to reflect the scope of the initial request] [3]  9 Absence of concerns about insufficient coverage regarding actually covered legal requirement? (see Annex on 'principal assessment criteria' and 'horizontal				

#### **Notes**

- [1] Acceptable use, as normative references, of non-European or non-international standards which cannot be translated by national standardisation bodies because of copyrights and exploitation rights should be assessed case by case (see also SWD(2015) 205 Part 1, section 2.2).
- [2] Without knowing the legal requirements, it would be impossible to find out in Step III whether 'a harmonised standard satisfies with the requirements it aims to cover and which are set out in the corresponding Union harmonisation legislation' on the basis of Art. 10(6).
- [3] Standards containing interpretations that relate to legal acts or legal requirements other than those addressed in the relevant request(s) and are outside the standardiser's field of competence should not normally be published. In harmonised standards for products, this could involve, for example, setting out provisions or conditions for 'placing on the market', 'marketing', 'exporting', 'national marking', 'language of documents', 'contractual or other responsibilities between economic operators', 'design requirements and/or related responsibilities addressed to end users of a product or other third parties', 'competence requirements addressed to economic operators or employees', 'interpretations concerning conformity assessment and related marking' (when not addressed in a request) or 'modified legal definitions'.

#### Annex

### Qualitative assessment as regards the legal requirements aimed to be covered (Step III)

#### 1. Purpose

The purpose of Q9 in Step III is to allow and record an overall assessment as to whether the standard, including all relevant provisions laid down through normative references, *sufficiently satisfies the relevant legal requirements aimed to be covered*, as identified in Step II (Q6), and thus to be able to decide whether references should be published in the OJ in accordance with Article 10(6) of the Regulation.

Where the Commission or dedicated experts have already carried out comparable verification and assessment within the meaning of SWD(2015) 205 Part 1, section 7.2 (through Step I to III) in the drafting phase, this assessment step can focus on verifying the completeness and correctness of previously recorded assessments and how conclusions were implemented in the final standard. In such cases, full records of the previous assessments must be available and the assessments should be based on an approach equivalent to that described in this document. See also SWD(2015) 205 Part 1, section 7.3.

In the case of Union harmonisation legislation for products and harmonising health and safety, this assessment does not replace proper risk assessment; it can only generally review how it is proposed that the results of a risk assessment (in the course of the standardisation process) are to be implemented, by means of risk reduction measures set out in the standard itself under assessment.

#### 2. Principal assessment criteria and recording conclusions

The 'sufficient satisfaction' of each legal requirement aimed to be covered should be assessed on the basis of the following **principal assessment criteria**:

- 1. **actual legal requirements** (e.g. 'essential' requirements) under relevant legislation, taking into account any restrictions, exemptions or specific conditions found or allowed in these requirements;
- 2. **specific requirements referred to in a relevant standardisation request** as to the content of the standard (e.g. legislation may regulate certain physical parameters, but the standardisation request sets out requirements for a harmonised measurement method); and
- 3. **generally acknowledgeable 'state of the art'** as regards particular products, sub-systems, components, materials, technologies, procedures, methods, etc.

In addition, **assessment questions** in section 3 of this Annex should be used when recording the conclusions for each legal requirement claimed to be covered. These are presented as statements and are mainly based on section 2.8 of SWD(2015) 205 Part 3. Where a statement is 'true', a 'no' answer may be given as regards the 'legal requirement in question. The questions are not exhaustive and may need to be complemented by sector- or issue-specific questions.

Table 2 — Template for recording the assessment and conclusions

Legal requirement <sup>11</sup> claimed to be covered (from Step II)  (If the standard covers several products, etc., it might be necessary to consider each product separately)	Clause, sub-clause, annex of the standard (including relevant normative references)	Remarks	sat	ufficient isfaction <sup>12</sup> ith legal uirements	
			yes	no	n/a
Overall conclusion (Q9)	•				

Where relevant, one row may deal with 'one particular essential requirement', 'one aspect of a legal requirement', 'an aspect of a requirement addressed in the relevant standardisation request', 'a group of several essential requirements', 'a requirement for a testing method (possibly given in a request) to assess regulated performance or a limit value set by legislation', 'a requirement to measure a physical parameter X', 'need for interoperability'.

<sup>12</sup> In relation to principal assessment criteria (see section 2) and assessment questions (see section 3).

Table 2 presents a template for recording the assessment and related conclusions. The conclusion regarding each legal requirement should be marked in one of three categories:

- 'yes': it is clear that the **relevant legal requirement has been sufficiently satisfied**;
- 'no': it is clear that the relevant legal requirement has not been entirely satisfied; or
- 'n/a' (not applicable): the **relevant legal requirement is not covered at all**, although it is claimed that it is.

The **overall conclusion** regarding Q9 'Absence of concerns about insufficient coverage regarding actually covered legal requirement?' is then deducted and recorded as 'yes' or 'no' on the basis of the individual conclusions.

## 3. Assessment questions

#### Horizontal assessment questions

- 1. The standard contains internally contradictory provisions or provisions which cannot be complied with.
- 2. The provisions are not drafted in accordance with the prescriptions and requirements of the relevant standardisation request (including relevant chapters of SWD(2015) 205 Part 3).
- 3. The standard contains provisions which unfairly privilege one economic operator or a group of economic operators by not being technically neutral enough (e.g. IPRs are included or a specification arbitrarily matches the products of one/a few manufacturers only).
- 4. For a revised version of a standard previously cited in the *OJ*: the level of safety, interoperability, repeatability, reproducibility, etc. has deteriorated and disregards developments in the 'state of the art' or the actual legal obligation.
- 5. There are problems with the claimed and actual coverage of the legal requirement(s), e.g. the standard claims to cover a certain legal requirement but actually does not, or it claims to cover all regulated aspects and all product sub-groups or the entire product while:
  - only one aspect (e.g. electro-magnetic compatibility) of several (all regulated aspects) is actually covered;
     or
  - only one or a limited sub-group of several products is actually covered; or
  - only a component or sub-part is covered, but not the entire product; or
  - only an assessment method is provided, but not the result to be achieved.
- 6. The standard claims to cover a certain legal requirement while giving the economic operator a choice that is not provided for by the legislator and thus suggesting that it is permissible to circumvent the requirement.
- 7. The standard claims to cover a certain legal requirement, but deviates from the requirement itself in such a way that application of the respective clause(s) or sub-clause(s) does not guarantee compliance.
- 8. The standard contains legal interpretations which are outside the scope of supported legal requirements and thus also outside the scope of the standardisation request (e.g. interpretations of legal definitions, CE-marking, conformity assessment, other legislation) (complements Q8).
- 9. The specifications given in the standard do not comply with the recognised drafting rules for European and international standards (SWD(2015) 205 Part 1, section 7.1).<sup>13</sup>

#### **Assessment questions specific to normative references**

10. The standard contains a normative reference to another standard, the application of which requires further risk assessment or other subjective decision-making, i.e. 'sufficient satisfaction' of legal requirements is not possible because the standard does not set any specification.

This includes relevant ESO drafting guides such as the CEN/Cenelec Internal Regulations, Part 3 (ISO/IEC Directives – Part 2, as amended). Important drafting issues include 'compliance with rules for drafting technical normative elements', 'absence of competence or certification requirements for economic operators', 'absence of management system requirements' (when not addressed in a request), 'absence of accreditation requirements', 'absence of contractual requirements for economic operators' and 'not defining who should perform tests'.

- 11. The standard contains normative references to:
  - (a) substantially outdated standards, which do not represent the generally acknowledgeable 'state of the art' anymore; or
  - (b) formally outdated standards, which have lost validity due to their withdrawal or adoption of a superseding standard.
- 12. The standard contains normative references to standards which themselves refer to other standards so as to create contradictory normative reference chains (e.g. implying that different versions of the same standards should be applied in parallel).
- 13. The standard contains normative references to so many standards or pages that it is virtually impossible for SMEs to acquire and apply all the normative specifications in question.
- 14. The standard contains normative references to standards the references of which have been removed from the *OJ* following a formal objection.
- 15. Legal acts are used as normative references. As legislation has direct force, it is inappropriate for compliance with a standard to 'require' compliance with legislation.
- 16. Any of the deficiencies listed in 1 to 15 are found in the standards to which there are normative references.

## 4. Guidance on setting the overall conclusion mark and publication of the references in the OJ

A 'yes' mark (for an individual conclusion) is given in cases of <u>sufficient satisfaction</u> allowing appropriate tolerance during assessment because thorough technical assessment is not always appropriate. Where all individual conclusion marks are 'yes', the references are published normally in the OJ.

A 'no' mark (for an individual conclusion) must always be followed by a recorded justification and a reference to the relevant assessment question(s) (1 to 16) or sector-specific assessment questions or criteria. Before giving the final mark, it is essential to consult relevant risk assessment documents, completed check lists, annual or other reports (see SWD(2015) 205 Part 3, section 2.6), work programmes, etc. submitted by the ESO(s).

Any single 'no' mark (for an individual conclusion) should normally lead to a 'no' for the overall conclusion, which would result in non-publication in the *OJ*. 'No' marks should be given where insufficient satisfaction (non-compliance with the relevant legal requirement(s)) is clearly evident and critically when taking into account all **principal** assessment criteria in section 2 of this Annex.

In duly justified cases, a 'yes' mark may be given for the overall conclusion despite a 'no' mark having been given for an individual conclusion, thus allowing publication of the references in the OJ; in such cases, however, a notice must be published in the OJ, clearly stating that the standard <u>does not sufficiently satisfy</u> the legal requirement(s) listed in the notice and thus excluding a presumption of conformity in respect of those requirements.

In the event of an 'n/a' mark being given (for an individual conclusion), there are two possibilities:

- the overall conclusion mark could be 'yes', allowing publication of the references in the *OJ*; in such cases, however, a notice must be published in the *OJ*, clearly stating that (despite its claims) the standard <u>does not cover certain legal requirement(s) at all</u>; or
- the overall conclusion mark 'no' is given and the ESO is invited to amend the standard as necessary.

Publication with a notice should be considered in cases where it is feasible to draft a short understandable notice and where the non-satisfaction and/or non-coverage can be explained in technical and legal terms in the light of the context.

Situations should be avoided where the references of a standard are published in the *OJ* despite evident and critical deficiencies in the standard, without also publishing a notice, and inviting the ESO only informally to correct the deficiencies. With such an arrangement, there is no guarantee that the required corrections will be made in an acceptable timeframe or that the corrections will correct the deficiencies. Publication without an appropriate notice may actually create more uncertainty and removing or restricting the publication at a later stage is much more cumbersome, given the Commission's limited ability to raise objections subsequently.