

ACTION PLAN

Structural solutions to decrease the stock of non-cited harmonised standards

Over the past three decades European standardisation has successfully contributed to the implementation of EU policies and legislation in a wide range of areas.

In particular, European standardisation has been extremely successful and one of the driving factors of the creation of the internal market for goods, in particular due to the New Approach legislative technique¹.

The Union harmonisation legislation under the New Approach promotes harmonised standards as a tool offering a guaranteed level of protection. Products manufactured in compliance with harmonised standards benefit from a presumption of conformity with the corresponding essential requirements of the applicable Union harmonisation legislation.

In recent years, certain issues appeared with the publication of references to harmonised standards in the OJEU which resulted in an increased number of non-cited references. The current stock of non-cited references to harmonised standards is relatively high and joint efforts of all participants are needed to address the situation effectively.

In order to address the current stock of non-cited harmonised standards and to make the process more transparent and accountable leading to a seamless citation, the following two short-term and two mid-term joint actions are considered of particular importance by both the Commission and the European Standardisation Organisations (ESOs):

Short-term (Q3/2017)

1. Proceeding with currently non-cited harmonised standards

In order to enable the citation of as many as possible currently non-cited harmonised standards, the ESOs and the Commission will together draw up a prioritised list of harmonised standards in the most relevant sectors (tentatively agreed sectors are: medical devices, construction, EMC, RED, Railways):

- with those harmonised standards which comply with the requirements in the corresponding Union legislation and display only minor (mainly formal) shortcomings, in exchange for the ESOs' commitment² to deliver revised versions within a defined period.
- with harmonised standards which can be addressed in the framework of short term pilot projects, with the participation of technical experts and management on both sides, leading to their possible conditional approval in view of their speedy referencing. A plan with pilot projects should be agreed between the EC and the ESOs.

The ESOs will clearly identify the re-submissions of previously rejected standards including the modifications made.

The re-valuation will be made within a timeframe to be agreed and in case of acceptance the standard will be cited in the OJEU without delay.

2. Improving the support from the New Approach Consultants

¹ Resolution of the Council of Ministers of 7 May 1985 on a new approach to technical harmonisation and standards, OJ C 136, 4.6.1985, p. 1.

² Subject to approval by the CEN and/or CENELEC Technical Boards or the relevant ETSI Technical Committee .

The main role of the New Approach Consultants (NAC) is to check the compliance of the harmonised standards with the standardisation request and the requirements of the corresponding Union legislation, during the development process.

In principle, the activity of the New Approach Consultants is covered by a specific agreement that the Commission has concluded with CEN and CENELEC until the end of 2017.

In this system, the potential of New Approach Consultants is not fully utilised. There is a room for improvement in several areas, in particular when it comes to communication of the New Approach Consultants with the Commission and technical bodies of the ESOs. Experience shows that it is important that Technical Committees of the ESOs have a correct understanding of the content of the standardisation request and its legal objectives from the earliest stage of drafting harmonised standards. An early and effective communication between Technical Committees and the NAC is a central element supporting the process of joint assessment (Article 10(5) of the Standardisation Regulation 1025/2012) of the compliance of the documents drafted by the European standardisation organisations with the standardisation request.

The Commission will thus propose a new framework for the activity of the New Approach Consultants, with the aim to relieve the European standardisation organisations of the administrative burden related to their management, as well as to improve the overall involvement of the New Approach consultants in the process of the drafting of harmonised standards.

CEN, CENELEC and ETSI are prepared to engage with the revamped system of NAC representing the Commission in the process of harmonised standards development. The NAC are intended to facilitate transparency of the process by providing guidance and clarification within the confines of the standardisation request adopted in consultation with the ESOs and the Member States. Their assistance to the ESOs in addressing legal, technical and formal requirements in time during the development of harmonised standards will be essential to speed up the final verification process by the Commission defined in the Article 10(6) of the Standardisation Regulation 1025/2012.

Taking into account that the current specific agreement to cover the support from New Approach Consultants will conclude in December 2017, and that the role of the NAC has been identified as an essential element in the joint assessment process, it is important to ensure the continuity of their services.

The European Commission will conclude the contractual arrangements for the continuation of the NACs ideally before end of 2017. In the case that this new framework cannot be finalised timely and the activity of the consultants could be disrupted as a result, the current specific agreement managed by CEN and CENELEC might be extended.

Medium-term (2018)

3. Developing a common understanding of the process for joint assessment and citation of harmonised standards

The Standardisation Regulation, Regulation (EU) No 1025/2012, provides for a cooperative model for a joint assessment of draft harmonised standards by the Commission and the ESOs, prior to the publication of references to harmonised standards in the OJEU in the Article 10(5). However, neither the way how this cooperative model should function in detail, nor the process of the publication in the OJEU, have yet been formalised. The new improved system of NACs (see point 2) will be the basis to implement the cooperative model for joint assessment of harmonised standards.

In addition, the Commission and the ESOs have agreed on a mechanism for the verification and publication process for harmonized European Standards (hEN) with a clear division of roles and responsibilities and strict deadlines. The main elements of the agreed process are outlined in some detail in the Annex.

4. Modernisation of the Harmonised standards database

The Harmonised standards database (HAS database), hosted by the EC, aims at facilitating the delivery of ESO's data required to allow the publication of the titles of harmonised standards in the OJEU in all official languages of the EU.

The HAS database is used to generate the lists of harmonised standards to be published in the OJEU in the format of Commission communications. It is also used to generate/update content about harmonised standards on the [EC European standards website](#).

The Commission and the European standardisation organisations consider it necessary to agree upon steps improving the functionality of the HAS database to better serve its purpose, in particular to facilitate the verification of references and related data (e.g. date of withdrawal) of harmonised standards and to provide an accurate overview of the outcome of the verification, as well as the follow-up steps.

With respect to the above, the following action plan is jointly proposed by the Commission and the ESOs:

Task	Who	Timetable
To agree on a list of harmonised standards to be cited or re-valuated	EC, ESO	<i>Q3 2017</i>
To agree on plan for pilot meetings on the harmonised standards to be re-valuated	EC, ESO	<i>Q3/2017</i>
Organise pilot meetings on specific agreed standards	EC, ESO	<i>Q4/2017 Q1-Q2/2018</i>
To streamline the process for joint assessment and publication of harmonised standards	EC, ESOs	End of 2017/early 2018
To set up a new framework for the activity of the New Approach consultants	EC	2017
To improve the functionality of the HAS database and the interface with the ESOs	EC with the input of the ESO	2017/2018

ANNEX: The verification and publication processes for hENs

1. ESO:

- a. Submits at pre-agreed dates following the conclusion of the joint assessment (Article 10(5)) a formal note to the EC annexing lists of references to new, amended or resubmitted hENs per sector, with full reference of data available in HAS database.
- b. Provides
 - i) the text of the harmonised standards (including, where relevant, the adopted international standard, including access to texts of its relevant normative references) through electronic format
 - ii) the date of the formal note for each reference to new, amended or resubmitted hENs as a part of the HAS upload together with any additional information possibly needed for the OJ publication and as agreed with the EC services.

2. EC (GROW B 3):

- a. Acknowledges the receipt of the note (and registers in ARES) within 15 working days
- b. Sets 4-6 weeks deadline for operational units to verify each new hEN (through ARES)

3. EC (sector unit):

- a. Verifies the contents of each hEN in accordance with Article 10(6) on the basis of consultants assessment reports and/or other available evidence criteria (such as the essential requirements, mandate, work programme)
- b. Records the results (positive/negative) in HAS database within the given timeframe (up to 6 weeks)
- c. Informs (ARES) GROW B3 on the results of the verification. For hENs rejected for citation provides in-depth explanation of the reasons, clearly identifying the relevant parts of the standard after its entire assessment
- d. Where additional time is needed to complete the verification, informs the ESO accordingly within the given timeframe

4. EC (GROW B 3):

- a. Submits a formal note to ESO (ARES) informing on the results of the assessment. For rejected hENs, provides in-depth reasons and asks for information within 15 working days on remedial actions within a timeframe to be mutually agreed
- b. Finalises the "publication decision" to be signed by the corresponding Director General, and the lists (per sector) of new hENs accepted for citation in the OJ.

5. EC (Director General of DG GROW or the corresponding DG)

- a. Signs the decision

6. EC (GROW B3):

- a. Produces consolidated lists (Communications) from HAS database and sends to SecGen together with the publication decision for submission to the Publication Office

7. ESO

- a. Revises the standard on the basis of a negative assessment (point 4.a) provided by the Commission and re-submits within a timeframe to be mutually agreed. The timeframe will normally be agreed within 15 working days after the notification.
- b. In case of a resubmission of a rejected standard, indicates clearly changes made to the standard on the basis of reasons provided by the Commission (point 4.a)

8. EC

- a. Establishes a publication decision when the revised standard satisfies the outcome of the original assessment.