

**Guidance document for technical bodies**  
**on practical measures when dealing with a negative assessment at Formal vote stage**

*Decisions BT C148/2019 (CEN) & D163/C064 (CENELEC)*

This guidance document contains some practical measures to help technical bodies officers to deal with draft candidate harmonised standards receiving a negative (i.e. "non-compliant" or "lack of compliance") assessment at Formal vote stage - before or after the formal vote is launched – that therefore need to be carefully reviewed to solve the pending issues preventing citation in the OJEU in due time.

The document is part of the CEN and CENELEC follow up – as decided by the Technical Boards - to the EC proposed measures aiming to facilitate citation of European standards in the OJEU, such as *'reinforcing links between the relevant Commission services in charge of harmonised legislation and the technical committees in charge of developing harmonised standards'* (see COM(2018) 764, par. 3).

NOTE: this document is to be considered as a good practice for Technical Bodies and does not imply a commitment from the EC to participate in meetings.

## **1. Harmonised standards receiving a negative assessment: practical measures**

When draft candidate harmonised standards receive a negative assessment at Formal vote stage, before or after the formal vote is launched, two cases can be distinguished:

- a. When several harmonised standards from a sector encounter the same kind of issues related to the Standardisation Request or the EU legislation, a dedicated **workshop** with the European Commission and the Technical committees concerned could be organised to tackle those recurring difficulties.
- b. When a harmonised standard encounters a specific difficulty (for instance, linked to the different interpretations of a specific part of the standardisation request, to an issue related to market access of a product or service covered by the standard, or to a different vision between stakeholders and the European Commission), a direct discussion during a **(web)meeting** on the most critical items from the HAS assessment report will allow the issues raised by the assessment to be understood by all. The TC can best decide how to address them.

This document lays down basic principles for the organisation of **(web)meeting** as proposed under point b), which could solve specific remaining issue for a harmonised standard under development.

## **2. Organization of the (web)meeting**

### **2.1. Persons to be involved in the (web)meeting**

The TC secretary systematically invite the following participants:

1. The delegates appointed by the national members of the Technical Body;
2. The convenor of the responsible working group and, if different, the project leader;
3. If needed, any expert of the responsible WG with specific knowledge relevant to the issue at hand, appointed by the TC;
4. DG GROW Unit B/3 – Standardization;

5. A Representative of the European Commission sectoral services in charge of harmonised legislation; it is stressed that this person is never obliged to participate, but is invited to provide guidance and direction to the HAS Consultant ;
6. The relevant HAS Consultant(s).

The CCMC programme manager and the BT member of the TC secretariat should be informed of the meeting and may take part to it.

Whenever relevant and applicable, also members of the relevant Standing Committee should be informed of the meeting and may take part to it as well, e.g. when a hEN project in the context of EU Regulation 305/2011 for construction products encounters specific difficulties.

*NOTE: the HAS consultant is the designated channel of communication between Commission services in charge of harmonised legislation and the technical committees in charge of developing harmonised standards. However, the mission of the HAS Consultant is now explicitly focused on assessment of the standard's compliance with the Standardisation Request and the relevant EU Directive/Regulation. Therefore, in particular when the issue at stake is to decide on the future of a harmonised standard developed under the ISO/CEN Vienna agreement, involvement of the Commission services in charge of harmonised legislation before the harmonised standard is published will enhance transparency, reinforce legal certainty and speed of the adoption.*

## **2.2. Elements to be duly taken into account**

Finding the right balance between excessively formal and excessively informal rules is needed. It is therefore suggested to draw attention of all participants of the (web)meeting on the following items:

- ✓ Availability of HAS Consultant should be checked and sought by the TC secretary when organizing the (web)meeting;
- ✓ Relevant documentation to be available to all persons involved in due time for a decision to be made; 3 weeks is the timeframe recommended, in particular to enable nomination of delegates of the CEN-CENELEC technical body<sup>1</sup>;
- ✓ The documentation provides information enabling quick identification of the remaining issues (nature of the obstacle, alternative proposals, observations, track-changed version of the amended draft, etc.);
- ✓ Participants to the meeting, all TC members and the BT are informed of the outcomes and, if any, of the action plan within an appropriate period of time (e.g. 2 weeks);
- ✓ The meeting should preferably be hosted online; in case of a meeting in presence, it is recommended to locate the venue in Brussels to make participation simpler for EC officials, should they decide to attend.

## **2.3. Specific issues with harmonised standards developed by CEN in cooperation with an ISO/TC<sup>2</sup>**

Reinforcing the link with the relevant European Commission services is even more critical when the negative assessment is about a European standard developed under the Vienna agreement (ISO/CEN), especially under ISO lead. Then, the CEN Technical Committee does not have the authority to change the ISO standard as such.

---

<sup>1</sup> In the very exceptional case of a physical meeting the notice should be given 6 weeks beforehand.

<sup>2</sup> Under the Frankfurt Agreement (IEC-CENELEC), the CENELEC publishes European standard modifying the IEC standard.

The CEN members cannot always convince the ISO committee to stop the approval process of the International standard, to wait for a new proposal to be drafted, to review this proposal and, if needed, to re-launch a final vote on a modified EN-ISO standard.

During a dedicated **(web)meeting**, the CEN TC should then make a decision, 3 choices being possible:

1. Approval of the EN ISO standard, in full knowledge of the risk that it will be cited in the OJEU with a notice (i.e. restrictions to the presumption of conformity).
2. Approval of the EN ISO, in full knowledge of the risk that it will not be cited at all in the OJEU.
3. Decoupling from the Vienna Agreement, i.e. referring the project to a CEN/TC in view of developing and adopting an EN different from the International Standard.

All three outcomes have significant downsides: the first two outcomes mean that the standardization request will not be completely fulfilled and that the market cannot fully benefit from presumption of conformity; the third one can have the undesirable effect of creating technical barriers to trade.

Furthermore, it is to be noted that, in order to choose between the first two outcomes, participants must have a clear view of the Commission's intention regarding the standard as it stand (i.e. can it be cited with a notice or will the citation be refused altogether).

It is therefore recommended that all participants in the process, including the European Commission, be involved in the decision making process among the 3 possibilities, in consideration of their impact on policy and for frictionless market conditions.

In concrete terms, the implementation of the decision taken by the participants may lead to revision or removal of Annexes Z; in these cases, BT approval is necessary.

#### **2.4. Specific issues with harmonised standards developed by CENELEC in parallel to IEC<sup>3</sup>**

Similar critical issues may happen when the negative assessment is about a European standard developed under the Frankfurt Agreement (IEC - CENELEC).

The CENELEC Technical Committee should, in first instance, ensure the necessary steps are taken during development of the IEC Standards to allow a maximal identical adoption, without common modifications and without undue delays. These steps include (but are not limited to):

- ✓ undertaking, from the earliest stages, the necessary steps for the drafting of the common modifications that are possibly needed, **promote their acceptance at international level**, and inform CCMC accordingly. To that extent, the NC holding the secretariat of the CENELEC Technical Body is allowed to convey two types of comments to the IEC :
  - Their own NC comments as national position
  - A separate set of '*EU harmonization comments*', highlighting that the latter do not represent a veto on consensus, but an input for compliance to EU legislation.
- ✓ organizing the proper involvement of Harmonized Standards Consultants and/or other experts to ensure compliance with requirements of the European Commission

When despite all efforts a negative assessment is received when the formal vote under the FA is about to start,

---

<sup>3</sup> Under the Frankfurt Agreement (IEC-CENELEC), CENELEC may make available a European amendment modifying the IEC standard.

- ✓ The start of the Vote on the EN IEC without common modifications is not delayed. However, the implementation dates will not be automatic following IEC publication, but depending on the outcome of the process for Common Modifications or non-modifying Amendment, as described below.
- ✓ The start of the vote on the Common Modifications or non-modifying Amendment necessary to allow citation in the OJEU, is suspended **for maximum 12 weeks** after reception of the assessment, to allow for the following actions to be initiated:
  - The Technical Body **Secretariat** and the BT Member/Permanent Delegate of the NSB/NC holding the secretariat shall immediately be informed.
  - The Technical Body shall do its utmost to resolve any issues and ensure that the CCMC Project Manager/Editor is properly informed should any changes to the text be necessary.
  - Within 4 weeks of reception of an assessment with partial or lack of compliance, the Technical Body needs to decide, duly justified, whether it will challenge the assessment and request a review of the assessment to CCMC Project Manager. CCMC will then submit the request in the relevant section of Livelink/eCommittees. In case of such a challenge, in principle, the HAS Contractor has 21 days to reply with a reviewed assessment by uploading the assessment results in the relevant section of Livelink/eCommittees.

Regardless whether the Technical body decides to challenge the Assessment or not, two possibilities exist:

- ✓ **Issues can be resolved by the Technical Body within 7 weeks after reception of the original assessment at FV:** BT is informed and the Formal Vote is started.
- ✓ **Issues cannot be resolved by the Technical Body within 7 weeks after reception of the original assessment at FV** a proposal on the way forward is circulated to BT. This can range from reverting to a Second Enquiry to proceeding with a (temporary) de-harmonized project.

In all cases due attention shall be given to correctly defining the implementation dates of the resulting EN IEC standard (main + amendment).

The input is sent by the Technical Body to the CCMC Programme Manager who will take care of submitting it to BT. In case no input from the Technical Body reaches CCMC 7 weeks after the original assessment at FV, CCMC shall trigger the BT Member/Permanent Delegate of the NSB/NC holding the secretariat for due action: a proposal to BT within one week after being triggered.