

# QUESTIONS AND ANSWERS

## REGARDING

### THE EUROPEAN STANDARDIZATION SYSTEM

*In support of continued education and awareness of the standards systems supporting the US and the EU, ANSI and the European Standardization Organizations (CEN, CENELEC and ETSI) offered to answer questions posed by the other side on their respective systems. This document contains those Questions and Answers.*

*The intent of this initiative is to facilitate a better understanding of the workings of each system, in particular the main principles and policies underpinning market-led standardization in Europe and the US, and to help guide the reader to sources of additional information. Accordingly, it will be a "living document," with new questions being added if and when they are posed by the constituents in one region or the other. Please note, however, that this material is not intended to provide a comprehensive overview of the respective systems, nor are the questions posed by one side necessarily the same as those posed by the other. Additionally, the inclusion of an answer to a question does not imply that said answer is a complete or comprehensive explanation or response to the intended question. This document shall not be regarded as containing any policy statement, opinion or position of any of the organizations or people that have contributed to its development. No reliance should be placed on the information provided. As always, the respective staffs of the above organizations remain the best source for further elucidation on any of the included information.*

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**Preamble:**

Most links introduced in replies to US questions for the three European Standardization Organizations (ESOs) are directing to documents publicly available on their respective website (See [CEN website](#), [CENELEC website](#) and [ETSI website](#)), or on the [CEN BOSS \(Business Operations Support System\)](#), or on websites of the [European Commission](#).

1. Do you have written procedures for:
  - a. How the committees work?

Written procedures on the work of CEN and CENELEC technical committees can be found in [CEN-CENELEC Internal Regulations, Part 2, section 3](#).

ETSI Directives are publicly accessible at <http://portal.etsi.org/Resources/ETSIDirectives.aspx>

- b. How a TC is created?

In CEN and CENELEC, any interested party can propose the creation of a technical committee. Decision will then be taken by the Technical Board (BT). See [CEN-CENELEC Internal Regulations Part 2, section 3](#).

ETSI membership drives the proposal and ETSI Board approves the creation of a Technical body. All information pertaining to the creation of a TC or any other type of technical group is contained in ETSI Technical Working Procedures, chapter 1, Operation of the Technical Organization (see url above)

- c. How you decide to undertake a particular standard (other than mandates)?

New Work Item (NWI) proposals can come from business/industry and other stakeholders via CEN and CENELEC Members, Partners, liaison organizations. ISO and IEC also undertake standardization work of interest for Europe. The standardization work is undertaken by CEN and/or CENELEC when there is sufficient support from the Members for the NWI and enough expertise available. It is essential to note that most of CENELEC deliverables are identical to (72%) or based on (6%) IEC standards<sup>1</sup>, following the extensive application of the Dresden Agreement between CENELEC and the IEC (see the [CENELEC Guide 13](#) and [CENELEC Guide 8](#), detailing the principles and practical arrangements framing the cooperation between the IEC and CENELEC).

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<sup>1</sup> See the [CEN-CENELEC Statistical Pack for Q4 2014](#)

In CENELEC, the decision to approve a NWI is taken by the BT. In CEN, [Technical Committees can take the decision to launch a NWI](#), based on the principle of [delegated decision](#).

For CEN and CENELEC, General information in this respect can be found in [CEN-CENELEC Internal Regulations Part 2, section 11](#).

Please note that the wording "mandates" is not used anymore. The applicable terminology now is "standardization request", as stated in [EU Regulation 1025/2012](#) (see also the response to question 6).

With regards to its work programme and the creation of work items, ETSI Members propose and make the decision through the governing bodies (Board/OCG) and/or Technical Bodies. A proposal for a new ETSI work item shall be supported by at least four ETSI full and/or associate members, which shall be recorded in the ETSI work item definition prepared by the Technical Body. The supporting members should contribute to the new work ([http://portal.etsi.org/Directives/33\\_directives\\_may\\_2014.pdf](http://portal.etsi.org/Directives/33_directives_may_2014.pdf) TWP, 1.6.2).

2. In these procedures, is it clear that before starting the development of a standard, other existing documents should be given full consideration?

This is the case in CEN and CENELEC, as indicated in [CEN-CENELEC Internal Regulations Part 2, section 11.2.1.:](#)

*"11.2.1.2 As the basis for the European Standard, it shall first be established whether a) there is published international work in the field and that international work would be acceptable as a European Standard; b) the work can be developed within the framework of the international agreements that CEN and CENELEC have with ISO and IEC respectively. For case a) The "Questionnaire procedure" allows a published international document to be assessed for suitability for progressing to a formal vote as a European Standard. For case b) the work may be offered to the international organisations for work to be carried out within the international organisation with parallel approval conducted by the European organisation under the terms of the Vienna Agreement (for CEN and ISO) or the Dresden agreement (for CENELEC and IEC)."*

Please see online the template [Questionnaire](#) to be filled out by the proposer of a NWI.

3. Is there a policy easily available on the CEN/CENELEC website explaining to CEN/CENELEC technical committees the process for normative referencing to existing standards developed by standards bodies operating in the United States and accredited by ANSI?

Does CEN/CENELEC consult with the relevant standards body during the normative reference process?

Principles governing the inclusion of normative references in CEN and CENELEC standards are detailed [in CEN-CENELEC Internal Regulations Part 3, section 6.2.2](#):

*“This conditional element shall give a list of the referenced documents cited (see 6.6.7.5) in the document in such a way as to make them indispensable for the application of the document. For dated references, each shall be given with its year of publication, or, in the case of enquiry with its year of issue, and full title. The year of publication or year of issue shall not be given for undated references. When an undated reference is to all parts of a document, the publication number shall be followed by the indication —(all parts) and the general title of the series of parts (i. e. the introductory and main elements, see Annex E).*

*NOTE References to enquiry drafts are discouraged.*

*In principle, the referenced documents shall be documents published by ISO and/or IEC. Documents published by other bodies may be referred to in a normative manner provided that*

*a) the referenced document is recognized by the ISO and/or IEC committee concerned as having wide acceptance and authoritative status as well as being publicly available,*

*b) the ISO and/or IEC committee concerned has obtained the agreement of the authors or publishers (where known) of the referenced document to its inclusion and to its being made available as required — the authors or publishers will be expected to make available such documents on request,*

*c) the authors or publishers (where known) have also agreed to inform the ISO and/or IEC committee concerned of their intention to revise the referenced document and of the points the revision will concern, and*

*d) the ISO and/or IEC committee concerned undertakes to review the situation in the light of any changes in the referenced document.*

*The list shall be introduced by the following wording:*

*—The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.”*

In addition, for CEN, if no suitable CEN, CENELEC, ETSI, ISO or IEC documents are available and that there is a necessity to refer to a document other than those developed by CEN, CENELEC, ETSI, ISO and IEC, see the [applicable form](#).

For CENELEC, the CENELEC Guide 10 *Normative references to documents other than those from CEN, CENELEC, ETSI, ISO or IEC* details the process to be followed in such situations. It is publicly available on a [dedicated webpage of the CENELEC website](#).

4. Is it mandatory for all CEN and CENELEC NSBs to vote in the ESO's technical committees at some or all stages? Is it mandatory to vote even though the member has not participated in the work, at the formal vote stage?

All CEN and CENELEC Members are called on to vote on European standards, in particular at the enquiry and final voting stages. Active engagement in that process is expected, given the obligation for all members to identically adopt at national level standards adopted at European level.

However, there is no concept of mandatory voting in CEN and CENELEC. Respective Members can either vote yes, no, abstain, or not vote.

In CEN, depending on the situation, abstentions may need to be justified (see the applicable [CEN BOSS guidance](#)). The absence of vote shall not be justified. See [CEN and CENELEC Internal Regulations Part 2, section 6 and section 11.2.4.2](#) for more detailed information.

5. Do CEN, CENELEC and/or ETSI have weighted voting? How does that work, and when?

CEN and CENELEC do apply a weighted voting policy (the spread of votes per country is based on the [Treaty of Nice](#) covering that amended the institutional structure of the European Union in 2001) and further detailed in [CEN and CENELEC Internal Regulations Part 2, Annex D](#)). It is applicable during the formal vote on European Standards they develop (see [CEN and CENELEC Internal Regulations Part 2, Section 11.2.4](#)).

ETSI Weighted voting in ETSI is in RoP – national weighted voting (when voting on ENs) and membership weighted voting (on governance issues). See Directives for more detail.

6. What is a mandate? What entity issues it and how do the ESOs respond? We find the word "mandate" in the European context to be very confusing.

The terminology "mandate" is not applicable anymore. It has been replaced by the terminology "standardization request". Please refer to [EU Regulation 1025/2012, Chapter III, Article 10 in general and Article 10.3](#) specifically. A standardization

request is an invitation from the European public authorities, specifically the European Commission, to one or more ESO to develop standards to support public policy objectives, while still remaining market-driven.

ETSI same answer. As a way of illustration, a standardization request in Europe can be compared to what the USG tasks NIST to perform when national strategic initiatives have standards implications (eg "Cloud First").

7. What are some recent instances when CEN/CENELEC has declined to accept a mandate received from the European Commission for the creation of a standard or standardization activity?

The following standardization requests were rejected by either CEN, CENELEC, or both of them (this is a non-exhaustive list):

M/524 on ATM interoperability, M/517 on Horizontal Service Standards, M/514 on Emissions of volatile organic compounds, M/515 on Eurocodes, M/511 on the alignment of LVD to the New Legislative Framework, M/501 on Equipment used in the offshore oil and gas industry.

Further details on each of these standardization requests (including the full text of the request) can be found on the [European Commission online public database of standardization requests](#).

8. When a mandate directs CEN/CENELEC to take into consideration an existing standard developed by standards body operating in the United States and accredited by ANSI, does CEN/CENELEC consult that standards body during the development process?

First, it shall be noted that standardization requests (cf. response to question 6 above) do not "direct" as these are not instructions. These requests are usually formulated as terms of reference, i.e. the expression of a regulatory need, for which ESOs are invited to propose a standardization solution. When accepted, then CEN and CENELEC are (under their own processes) required to consider any relevant reference document or standard.

Nevertheless, we can state the example of European Commission mandate M/425 (issued in 2008) on fire safety requirements for cigarettes, which clearly referred to a test method developed by a US SDO. As a result of its acceptance, the EN ISO 12863 (based on the test method mentioned in the mandate) was referenced by the European Commission in support of EU legislation.

In general, should there be a decision by CEN or CENELEC to adopt a deliverable developed by a US SDO accredited by ANSI, then consultation would be organized. The standard in question would have to follow the usual official approval process to

become an EN (Unique Acceptance Procedure or Enquiry and Formal Vote), as per internal [CEN and CENELEC Internal Regulations Part 2](#), Section 11.2 *Preparation of European Standards* and in line with the [CEN-CENELEC Guide 23 "Consortium bridge – Adoption of third-party specifications as European Standardization Publications"](#) (see the reply to question 11). We foresee this to happen especially in the context of current discussions with ANSI, noting however the European preference for international (i.e. ISO or IEC) solutions, whenever possible.

9. What is a mandatory standard in the context of the ESOs?

European Standards are voluntary in nature. Nevertheless, regulators sometimes make the use of standards mandatory. There is no reference to mandatory standards in EU Regulation 1025/2012. [See EU Regulation 1025/2012, Chapter 1, Article 2](#) "Definitions": "*standard* means a technical specification, adopted by a recognised standardisation body, for repeated or continuous application, with which compliance is not compulsory[...]".

Same answer for ETSI.

10. What is a harmonized standard in the context of the ESOs? What is harmonized with what?

There are different concepts of "harmonization" in the context of the ESOs:

1. As per the [EU Regulation 1025/2012, Chapter I, Article 2](#), a 'harmonised standard' "means a European standard adopted on the basis of a request made by the Commission for the application of European Union harmonisation legislation". These harmonized standards are therefore ENs that support specific EU regulation. This is the first type of "harmonization";

*Same answer for ETSI*

2. In addition, all other ENs (not called "harmonized standards") also imply harmonization in Europe, due to the identical implementation by all Members of CEN and CENELEC, and the withdrawal of conflicting standards;

*Same for ETSI in that the EN becomes national standards (AP process)*

Finally, a high proportion of CEN and CENELEC standards are aligned to ISO and IEC standards respectively. CEN and CENELEC enjoy close cooperation with their international counterparts. Under the cooperation agreements they have established, both the adoption by one organization of standards developed by the other organization and the mutually agreed allocation of work with parallel approval of

standards are possible, and even encouraged. This enables European standards to be in many cases identical to ISO or IEC standards. Please see the [CEN-CENELEC quarterly statistical pack, Part 4 "International Relations"](#) for precise figures in this respect.

*This last paragraph is not applicable to ETSI*

11. What is the process for standards developed by standards bodies (such as those operating in the United States and accredited by ANSI) other than ESOs and ISO, IEC, and ITU to become a European harmonized standard? Are there recent examples that we can learn from?

First, it can be noted that several CEN and CENELEC standards include normative references to standards developed by standards bodies operating in the US and accredited by ANSI.

An example of a US standard that became a harmonized EN can be seen in the response to question 8 above.

The initial condition is the existence of a standardization request issued by the European Commission for the application of European Union harmonization legislation. On that basis, European Standardization Organizations may find among standards developed by an ANSI-accredited standard developer a deliverable likely to fulfil regulatory expectations as per the standardization request, based on the understanding that there is no suitable ISO, IEC or ITU deliverable or activity likely to meet the need.

The [CEN-CENELEC Guide 23 "Consortium bridge — Adoption of third-party specifications as European Standardization Publications"](#) details the applicable principles and existing process that would be followed, in the event that CEN or CENELEC decides to adopt a standard developed by a standards body operating in the US and accredited by ANSI. Such a process may be used more often in the context of ongoing ESOs-ANSI discussion on ways and means to enhance their cooperation, in areas where no international (i.e. ISO or IEC) solution is available or applicable.

Basically, in order for such a standard to become a European harmonized standard, following steps should be taken:

- The proposal should be evaluated against cooperation principles and criteria respectively listed under clause 2 and 3.1 of the CEN-CENELEC Guide 23;
- Based on positive outcomes of this evaluation and following the signature of an agreement between the concerned standards body and CEN-CENELEC Director General (respecting the guidelines available in the Annex A of the CEN-CENELEC Guide 23), the text would be proposed for endorsement (either via the Unique



Acceptance Procedure (UAP) for a fast-track process or via the Enquiry and Formal Vote). Another route allows the specification to become a reference document. These possibilities are detailed, including the applicable timeframe, under clause 3.2 of the CEN-CENELEC Guide 23.

The standard should eventually be accepted by the European Commission and cited in the Official Journal of the European Union, in line with [EU Regulation 1025/2012](#).

ETSI standards make use of normative and informative references that may point at work being developed in any other standards organizations. For ENs, it has been the case for e.g. referenced EUROCAE specifications which then became Community Specifications under the Single European Sky interoperability regulation.

12. How does CEN approve a National Adoption of an ISO Standard? If so, for what nation?

CEN, as a membership-based organization relying on the national delegation principle, does not interfere with the adoption process of ISO standards by its Members. However, CEN Members are intensively involved in ISO work and committed to the adoption and implementation of resulting international standards, be it at European or national level. This certainly explains the high level of harmonization of ENs with ISO (and IEC) standards.

In any case, it is worth highlighting here the following:

- Members of CEN (all being members of ISO) may approve the adoption of ISO standards according to their own rules and processes, which are not in the remit of CEN, provided it does not conflict with CEN standstill policy (See [CEN and CENELEC Internal Regulations Part 2, Section 5](#)).
- In the case of an adoption at European level of an ISO standard (approved by CEN National Members according to CEN voting policy – see [CEN and CENELEC Internal Regulations Part 2, Section 5](#)), then the [CEN and CENELEC Internal Regulations Part 2, Section 11.2.6](#) applies and the resulting EN/ISO standard is adopted identically by all CEN Members (and conflicting standards are withdrawn).

13. Many U.S.-domiciled SDOs accredited by ANSI permit voting membership for technical experts from Europe and other parts of the world in their development of American National Standards. Does CEN/CENELEC have an equivalent reciprocal process for the development of European standards?

CEN and CENELEC do not claim to be international standardization organizations in the sense of WTO TBT Agreement, but regional organizations. However, **any interested party from any part of the world can participate in the technical work of CEN and/or CENELEC through different channels.**

As a preamble, it is to be noted that the work of CEN and CENELEC Working Groups is not based on votes but rather on consensus. For CEN and CENELEC Technical Committees and Sub-committees, delegates represent the national consensus so there is no vote of individual companies as such (it would make no sense).

Furthermore, observers have no voting right in CEN and CENELEC Technical Committees and Sub-committees. This is coherent with [CEN and CENELEC Internal Regulations Part 2, Section 11.2.6](#) (implementation of CEN and CENELEC standards): only those who will be impacted by the decision taken at European level (i.e. bound by the obligation to adopt a standard and to withdraw conflicting standards), i.e. the Members of CEN and CENELEC – via their national delegation - are allowed to vote.

Based on the above clarification, any US expert may seek participation in CEN or CENELEC technical standardization work by exploring one of the options described below:

- Via a National Member:

Non-European expert(s) can explore existing possibilities to get involved in technical work at European level by addressing CEN or CENELEC National Members (respectively listed on dedicated pages of the [CEN](#) and [CENELEC](#) websites), enquiring with them about applicable rules for involvement. The expert(s) would then be appointed by the National Member concerned, in line with rules for participation it has defined.

- Via an Affiliate of CEN or CENELEC:

Non-European expert(s) can explore existing possibilities to get involved in technical work at European level by addressing CEN and CENELEC Affiliates (respectively listed on dedicated pages of the [CEN](#) and [CENELEC](#) websites), enquiring with them about applicable rules for involvement. The expert(s) would then be appointed by the CEN or CENELEC Affiliate concerned, in line with rules for participation it has defined.

For reference, the guide covering rights and obligations of CEN and CENELEC Affiliates is available in CEN-CENELEC Guide 12 *The concept of Affiliation with CEN and CENELEC* publicly available [there on CEN-CENELEC website](#).

- Via a CEN or CENELEC Partner or Liaison organization:

Non-European expert(s) can explore existing possibilities to get involved in technical work at European level by addressing CEN and CENELEC Partners or liaison organizations (respectively listed on dedicated pages of the [CEN](#) and [CENELEC](#) websites), enquiring with them about applicable rules for involvement. The expert(s) would then be appointed by the CEN or CENELEC Partner or liaison organization, in line with rules for participation it has defined.

For reference, the guide covering rights and obligations of CEN and CENELEC Partners or liaison organizations is available in CEN-CENELEC Guide 25 *The concept of Partnership with European Organisations and other stakeholders* publicly available [there on CEN-CENELEC website](#).

For CEN, two additional possibilities exist, as presented below:

- Via an ISO/TC whose activities are related to those of a CEN/TC or CEN/TC/WG concerned:

In such an event, up to four representatives can be formally appointed by the ISO TC concerned, including from the US. The process is detailed in the *Guidelines for the implementation of the Agreement on Technical Cooperation between ISO and CEN (the Vienna Agreement)*, publicly available on a [dedicated webpage of the CEN Business Operations Support System \(BOSS\)](#) – section 5. In this situation the ISO/TC representatives will represent the views of ISO/TC that appointed them, not their views as individual experts.

- Via a CEN Technical Committee directly:

Non-European expert(s) can explore existing possibilities to get involved in technical work at European level by addressing a CEN Technical Committee directly. This is only possible if none of the above options is achievable and if there is no ISO technical body with a scope similar to the one of the CEN technical body concerned. In such a situation, the request shall be addressed to the CEN TC Secretary. The ISO Member of the country of origin of the expert(s) would then be asked if it supports the request. Should the feedback be positive, then a consultation of the CEN TC would be organized and the request assessed by the TC. In case of acceptance, a maximum of 3 experts (per body or company having submitted the request) could be allowed to participate in a specific CEN TC meeting as observers (on an ad hoc basis, without voting rights) or in a CEN/TC/WG meeting (as experts), as stipulated in the CEN/TC Decision. The process is detailed in a Guidance document publicly available on a [dedicated webpage of the CEN Business Operations Support System \(BOSS\)](#), covering the *participation in meetings of CEN technical bodies of representatives of bodies or companies from countries outside the CEN membership*.

Outside of these possibilities, only the status of Partner Standardization Body (PSB) of CEN and or CENELEC or a formal Cooperation Agreement enable the direct appointment of observers to the work of CEN or CENELEC technical bodies. For information and reference, a guide on the PSB status is publicly available on the CEN-

CENELEC website (CEN-CENELEC Guide 13 *The concept of Partner Standardization Body with CEN and CENELEC*, available on [that webpage](#))

14. Is there a single place (publication, website, etc.) where all the work of all the technical committees of all the ESOs, including notice of new standards projects (US: PINS), call for comments on draft standards, and notice of approval of standards can be found?

Such information is made available at national level (i.e. the level at which the enquiry is carried out, close to the market) by CEN and CENELEC Members. Most of CEN and CENELEC Members, if not all, offer a single portal where all this information can be found: notice of new standardization work, call for comments, notice of approval. These portals can be found on the website of each CEN and/or CENELEC Members, respectively listed on dedicated pages of the [CEN](#) and [CENELEC](#) websites.

Besides, CEN and CENELEC publish a yearly narrative forecast called "Annual Work Programme", providing information on main areas of activity and intended standardization work for the year (See as an example [the work programme covering the year 2015](#)).

The complete work programme of all CEN and CENELEC Technical Committees can be found via the [CEN list of technical bodies](#) and [CENELEC list of technical bodies](#) respectively.

ETSI No single point for the 3 ESOs but there is easy access to ETSI – web site and portal. Directives, rules, processes and work programme are on-line.

The European Commission also publishes a yearly work programme for standardization, which provides a forecast of intended standardization requests (see as an example [the work programme covering the year 2015](#)). The European Commission also publishes a yearly work programme for standardization, which provides a forecast of intended standardization requests (see as an example [the work programme covering the year 2015](#)).

15. How does the public access European standards, and drafts for comment?

The public accesses CEN and CENELEC draft standards for commenting purposes via their national members (see the online [list of CEN members](#) and [list of CENELEC members](#)).

ETSI deliverables are available for free on the web. Standards entering the Approval process are made publicly available via the ETSI portal <http://portal.etsi.org//home.aspx>.

16. How can manufacturers that do not have a European presence provide technical comments during the development of CEN/CENELEC standards? Are these comments taken into consideration by the relevant technical committees?

See the response provided to question 13 above. Additionally, most of the CEN and/or CENELEC members have their own online platforms for public commenting on standards during the enquiry phase. These platforms are open to any interested party from all over the world.

17. How can manufacturers that do not have a European presence provide technical comments at the point where CEN/CENELEC is considering the National Adoption of an ISO or IEC standard?

See responses provided to question 12 and 13 above.

18. How can the public access European Union legislation?  
a. What is the process of implementing European legislation?

*As the question relates to issues falling outside of the strict scope of competence of ESOs, the response provided below should be verified against official European Institutions' views.*

European legislation is publicly available on the [dedicated online portal EUR-Lex](#). The process of implementing European legislation is detailed there on a dedicated [European Commission webpage](#).

ETSI This is a question for the European Commission.

19. What are the priority markets (including non-traditional areas) for Europe and do you see any of these as potential areas of cooperation with the US?

*European standardization is bottom-up and market-driven, each sector may have their own priority areas. Examples of areas of focus, which will call for coordination at international level (ISO and IEC), are services, cybersecurity, consumer products, energy management and smart initiatives, among others.*

Based on the understanding that this question refers to priority areas of CEN and CENELEC standardization work, information can be found in [CEN-CENELEC Annual Work Programme 2015](#).

Some potential areas for possible cooperation in standardization matters with the US were identified by CEN and CENELEC Members in January 2014, following a dedicated consultation: automotive (including tires, EV issues - charging, road infrastructure and connecting infrastructures), PPE, textiles and textile products, Medical Devices,

playground equipment and amusement park machinery. The railway sector came up at a later stage as an additional possible area for cooperation. In February 2015, female body armour and synthetic biology were jointly identified by ESOs and ANSI as areas deserving further exploration.

This question does not apply to ETSI, who is anyhow in continuous cooperation with the US in most of its work areas – actually, US companies are contributing to the work often in their capacity of full members of ETSI.

20. How do you address and prevent technical barriers to trade within the European system, and in taking account of third countries?

Ex-ante elimination of Technical Barriers to Trade (TBTs):

The three ESOs respect and comply with Annex 3 of the WTO Agreement on Technical Barriers to Trade, and so do all their respective national Members individually. Such compliance is encouraged by the [EU Regulation 1025/2012](#).

[EU Regulation 1025/2012](#) also requires ESOs and their national members to take certain measures to ensure transparency in their activities and thus avoid technical barriers to trade, such as publication of work programmes, permitting the involvement of other European standards bodies in standards development and sharing the text of draft standards.

In addition, for CENELEC, the Vilamoura procedure imposes to CENELEC members an additional notification of new draft standards at national level, with the competence to move national work to the European or International (IEC) level if sufficient interest from the other members of these organizations (see [CENELEC Guide 8](#) for further details).

Ex-post elimination of Technical Barriers to Trade (TBTs):

- Within Europe: European standards are implemented identically by all the CEN and CENELEC national members, which also remove any conflicting national standard. This ensures a coherent internal market.
- With third countries: CEN and CENELEC European standards are increasingly harmonized with international standards (ISO and IEC), removing barriers to trade with non-European countries.

Concerning the role played by public authorities in removing TBTs at regional level in Europe, see the European Commission [DG GROW webpage dedicated to the EU Single Market](#)).

ETSI Same response as above §1 : ETSI checks compliance of its rules with WTO-TBT (and TRIPS) on a regular basis.

21. How are the EU standards and CE marking related?

*As the question relates to issues falling outside of the strict scope of competence of the ESOs, the response provided below should be verified against official European Institutions' views.*

Please note first that the CE marking only applies to some Directives and Regulations.

The CE marking is an indicator of a product's compliance with EU legislation and enables the free movement of products within the European market. By affixing the CE marking on a product, a manufacturer is declaring, on his sole responsibility, conformity with all of the relevant legal requirements and therefore ensuring free circulation for that product throughout the European Economic Area (EEA, the 28 Member States of the EU and EFTA countries Iceland, Norway, Liechtenstein), as well as Turkey.

Full compliance of a product with harmonized standards cited in the Official Journal of the European Union in support of EU harmonization legislation (cf. response to question 10 above) that applies to it may give the product "presumption of conformity" with the relevant essential regulatory requirements, depending on the type of product. For further information, please see the [dedicated European Commission DG GROW webpage](#) as well as the [European Commission 2014 Blue Guide on the implementation of EU product rules](#). However, the manufacturer has the liberty to apply other standards and choose other means to comply with European legislation.

Same answer for ETSI. ENs if complied with (therefore presumption conformity) allows manufacturer to use CE mark – but again the legislation concerned gives the information and it is not our role to make any specification of marking.

22. How does the European system support SME growth and make the single market work for its citizens?

The European Standardization System supports SMEs competitiveness and growth firstly by offering coherence in the European market. The European standardization model, as described above, ensures that there is no fragmentation in the European market. This in turn fosters the global competitiveness of SMEs that have got easy access to a broad market of 33 countries. Moreover, the system places great emphasis on ensuring easy access for SMEs to standardization work (based on [CEN-CENELEC Guide 17 Guidance for writing standards taking into account micro, small and medium-sized enterprises \(SMEs\) needs](#)) and easy use of the resulting standards. CEN and CENELEC guarantee one clear entry point for standards and standardization work.

In their [Ambitions to 2020](#), CEN and CENELEC have detailed the way they intend to support SME growth and meet the needs and expectations of European stakeholders and citizens in the coming years, in full support of the European Union Single Market.

A variety of CEN and CENELEC initiatives targeting SMEs can be found on a [dedicated webpage](#) of their common website. Comparable information covering initiatives targeting “societal stakeholders” (understood in the context of [EU Regulation 1025/2012](#) as representatives of consumers’, workers’ and environmental interests) is also available on a [dedicated webpage](#) of the common CEN-CENELEC website.

ETSI This is more of a question for the European Commission; However ETSI encourages SMEs - 25% of its membership to actively participate in standardization. Whatever their size, all members have equal rights of direct participation in standards-making activities and access to other ETSI services. SMEs can keep up to date with the latest standards – and influence their development. They can also network with the leading players in the field. Through participating in the standards-making process, SMEs increase their visibility and enhance their reputation. They gain insights into the latest developments which can improve their competitiveness. They can increase their knowledge of international best practices, create beneficial partnerships and gain access to new customers

From a different perspective, the [European Commission DG GROW webpage dedicated to SMEs](#) can provide complementary information on regulatory initiatives supporting SME growth.

The European Union “Europe 2020” Strategy provides the broader strategic framework aiming to support sustainable growth and jobs in the European Union. A [specific website](#) is available and provides very detailed information in this respect. CEN and CENELEC are developing a paper highlighting how they can continue to contribute to those objectives, in response to the EC consultation on the review of Europe 2020 strategy. The document will soon be submitted and may be shared with ANSI for further reference.

23. How does the European system support jobs and economic growth and what is the action plan in order to increase growth after the recent economic crisis?

See the response provided to question 22 above.

ETSI This is a question for the European Commission.

24. Is it true that in the context of New Approach directives, a presumption of compliance with essential technical requirements can only attach to European harmonized standards? When manufacturers do not rely on ENs for the presumption of conformity in the context of New Approach directives, a notified body must assess whether the solutions adopted by the



## Questions for CEN, CENELEC and ETSI regarding the European Standardization System

manufacturer meet the essential requirements of the directive. Does CEN/CENELEC provide any additional technical insight to notified bodies, particularly when the essential requirements of a directive lack enough rigor for the notified body to guarantee conformance outside of the use of ENs?

*As the question relates to issues falling outside of the strict scope of competence of the ESOs, the response provided below should be verified against official European Institutions' views.*

Indeed, presumption of conformity with essential health and safety requirements of European Union harmonization legislation can only be given by compliance with applicable harmonized European Standards. However, manufacturers remain free to demonstrate the compliance of their products with applicable regulatory requirements via alternative means. See the [European Commission 2014 Blue Guide on the implementation of EU product rules](#).

CEN and CENELEC publications remain neutral regarding conformity assessment. As stated in [CEN-CENELEC Internal Regulations Part 3, Section 6.7.1](#), "All documents containing requirements for products, processes, services, persons, systems and bodies shall be written in accordance with the "neutrality principle", such that conformity can be assessed by a manufacturer or supplier (first party), a user or purchaser (second party), or an independent body (third party)". CEN and CENELEC do not have the competence, nor the ambition, to address instructions to Notified Bodies or to assess whether the information available in European Union harmonization legislation enables them to perform their mission outside the use of European Standards.

In addition, conformity assessment by a notified body is only mandatory when European Union legislation so requires.

ETSI question not directed at ETSI