



CEN-CENELEC GUIDE 4

**General Guidelines for the
Cooperation between CEN,
CENELEC and ETSI and the
European Commission and the
European Free Trade
Association**

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The present edition of this Guide replaces the edition of December 2001 as a result of the signature in Nice on 28 March 2003 by the above-mentioned parties of a text describing the attached general guidelines for cooperation.



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1. GENERAL

CEN, CENELEC, and ETSI on one side and the European Commission and the European Free Trade Association (EFTA) on the other side, confirm that standardization is a voluntary, consensus-driven activity, carried out by and for the interested parties themselves, based on openness and transparency, within independent and recognized standards organizations, leading to the adoption of standards, compliance with which is voluntary. ¹They take note that because of the public recognition² of the organizations that issue them, and by compliance with specific procedures, including a public enquiry and a vote, standards (ENs) thus adopted are distinct from other technical specifications established on a voluntary basis.

CEN, CENELEC, ETSI, the European Commission and EFTA acknowledge that standards should be fit for purpose, have a high degree of acceptability as a result of the full involvement of all relevant parties in the standardization process, be coherent with each other and allow for technological innovation and competition; that therefore they should be

¹ Council Resolution of 28 October 1999 on the role of standardization in Europe, point 11, OJ C141, 19.5.2000

² Council Directive 98/34/EC laying down a procedure for the provision of information in the field of technical standards and regulations, OJ L 204, 21.7.1998

based on sound scientific research, be updated regularly, and be performance-based, where possible³.

Although standardization is a voluntary and independent activity, CEN, CENELEC, ETSI, the European Commission and EFTA recognize that it has an effect on a number of areas of public concern, such as the competitiveness of industry, the functioning of the single market and the environment. On various occasions the EU institutions and EFTA have recognized that standardization can play a role in public policy and support legislation.

This understanding was first established in 1984, and laid down in the General Guidelines for Cooperation between the European Commission and CEN and CENELEC, agreed on 13 November 1984, and published as CEN/CENELEC Memorandum N°4, Part1. Since then, however, the situation has evolved and they agree that these Guidelines should be updated in order to take account of this evolution.

Equivalent agreed guidelines were signed between EFTA and CEN and CENELEC on 30 April 1985 (published as CEN/CENELEC Memorandum No. 4, Part2). A revised version of these was adopted by the EFTA Council on 30 October 1992, taking especially into account the extended status attributed to standards in the EFTA States by the Agreement on the European Economic Area (EEA).

2. THE EVOLUTION OF EUROPEAN STANDARDIZATION

CEN, CENELEC, ETSI, the European Commission and EFTA consider that the new Guidelines should take into consideration the following elements, presenting notable changes with respect to the situation which existed in 1984 and 1985 respectively:

- Whilst in 1984 there were only two European Standards Organizations, with the recognition under Directive 98/34/EEC of the European Telecommunications Standards Institute, ETSI, there are now three European Standards Organizations, i.e., CEN, CENELEC and ETSI.
- With the EEA Agreement, the EFTA States party to the Agreement committed themselves to participating in the Single Market, with the same rights and obligations as the EU Member States. The Agreement created the same legal basis for the use of standards in the EFTA EEA States as exists in the EU.
- Standardization activities in Europe have moved substantially from the national level to the European and international level. The role of the national standards organizations has, in consequence, taken a new dimension in the context of European and international standardization. The national standards bodies will, however, continue to play an important role in international and European standardization. They contribute on a national level to consensus, in many cases provide support to the technical work, are a permanent link between market players, in particular SMEs, consumers and

³ Council Resolution of 28 October 1999 on the role of standardization in Europe, point 12, OJ C 141, 19.59.2000

environmentalists, and provide access to, and advice on, both international and European standards. The official adoption through public enquiry and formal vote on European standards (ENs) is carried out by the national standards bodies.

- Economic and social interest groups and relevant organizations, namely NGO's have shown an increased interest in European standardization, and, organized at the European level, they now have increased possibilities of access to the European standards-making process and various structures with CEN, CENELEC and ETSI. However, this does not diminish the need for their involvement at national level.
- High levels of environmental and consumer protection have become fundamental objectives under the EC-Treaty. Subsequently, environmental and consumer considerations need to be systematically integrated into other policy areas and sectors of society. This development also concerns European standardization.
- European standardization is acknowledged as playing a key role for the economic and political integration of the candidate countries into the European Union; and conversely, these countries are increasingly participating in the work of the European Standards Organizations.
- With the globalization of the economy, international standards have become a major factor for Europe. The importance to be attributed to international standards has been confirmed by the WTO, notably the Agreement on Technical Barriers to Trade and the WTO decision on principles for the development of international standards used under the Agreement⁴, as well as by the Commission's services in the staff working paper SEC (2001) 1296 on European policy principles on International Standardization of 26 July 2001.
- The needs of the market for technical specifications have been subject to change and they differ by sector. In addition, industrial sectors are becoming more inter-related, and the traditional boundaries between them are becoming less distinct, thus reinforcing the need for a strong cooperation between the European Standards Organizations and the way in which standards are made.
- The use of standards in public policy has evolved. Apart from the continuing need to complete the internal market, encouraging competitiveness and information technology, there are new areas in which policy makes increasing use of standards, such as safety in the work place, consumers and the environment, transfer of research results to the market, and the establishment of Trans-European networks.
- The rapid development of technologies and processes in the Information and Communication Technology (ICT) has led to a need for the equally rapid elaboration of new types of publications. Taking account of these developments, the European Standards Organizations have developed new deliverables which do not have the status of formal standards (ENs).

⁴ Annex 4 of G/TBT/9, 10.11.2000

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- With regard to the possible restrictions to competition caused by horizontal cooperation agreements between companies operating on the same market level(s), the Commission published a notice on the applicability of Article 81 of the EC Treaty⁵. In this notice, standardization agreements are considered to be a type of horizontal cooperation agreement, either concluded between private undertakings or determined under the aegis of public bodies or bodies entrusted with the operation of services of general economic interest, such as the standards organizations recognized under Directive 98/34/EC. The notice also states that, in principle, standardization agreements do not restrict competition if the standards are adopted by the recognized standard organizations, based on non-discriminatory, open and transparent procedures.
 - Standardization has acquired a high political profile. This reflects the unique position of standards in contrast to other forms of specification and creates a correspondingly enhanced obligation to observe the principles of transparency, openness, consensus, independence, efficiency and coherence.

For these reasons, CEN, CENELEC, ETSI, the European Commission and EFTA wish to confirm their mutual understanding on a number of policy objectives and the role of standards in that context, on the principles of their relationship and cooperation, and on their present intentions for the attainment of these objectives.

3. COMMON POLICY OBJECTIVES

CEN, CENELEC, ETSI, the European Commission and EFTA have a common understanding that standardization plays an important role for the European market, for the competitiveness of enterprises and that it constitutes an important instrument in support of European policy reflecting the public interest. European Standardization policy objectives are, therefore as follows:

- To play a role in the completion of the internal market, facilitating the free movement of goods and services and ensure sustainable development, having a high level of safety and quality and taking into account all economic, social and environmental aspects. Under the New Approach, harmonized European standards provide technical solutions for presumption of conformity with legal requirements; they constitute a common and transparent reference for public procurement; they contribute to the elimination of technical trade barriers; they encourage environmentally sound development of products; and they provide a source of common reference for trade and national and European legislation, thus promoting European technical integration.
- To help attain the goal of high environmental protection.

⁵ OJ C 3 of 6.1.2001, p. 2-30.

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- To constitute a tool for the advancement of European competitiveness and to allow for technological innovation. European standards provide a common, yet flexible, technical environment across the single market and constitute accepted references for quality, certification, and regulatory compliance; they encourage technical cooperation and the exchange of expertise and provide entrepreneurs with an opportunity to exploit economies of scale.
 - To provide a graduated range of types of deliverables that respond to different market needs.
 - To provide a flexible and transparent mechanism for consensus building on identified issues in Europe. The basis of consensus necessary to meet the needs of the parties concerned (including the public authorities) varies according to the industrial sector, the relationship to the regulatory environment and factors such as safety and the potential for harm to the environment.
 - Through participation by their respective members in the international work, to promote Europe's interests in the global economy and create conditions for access to world markets; standards provide a means of reference for technical cooperation, assistance and Mutual Recognition Agreements (MRAs) with third countries. It is of utmost interest that international standards be uniformly adopted and applied when legitimate objectives can be ensured, i.e. the protection of human health and safety, animals or plant life and/or the environment.
 - To provide candidate countries and neighboring countries with a major tool for the facilitation of adaptation of their economies to the Community market and to promote sustainable development, economic and technological integration or cooperation.
 - To provide a mechanism for economic and social partners in Europe and other relevant interest groups, namely NGO's, that might not otherwise be involved but who have a legitimate interest in the outcome, to be involved in the process of standardization. This constitutes a means for them to play an active role in relation to public interests such as protection of the environment, workers, and consumers. It allows them to contribute to sustainable development and to safeguard the public interest in areas where co-regulation or self-regulation is considered preferable to outright regulation.

4. PRINCIPLES OF RELATIONSHIP AND COOPERATION

In order to attain these objectives, CEN, CENELEC, ETSI, the European Commission and EFTA have a common understanding that:

- Relations between the European Standards Organizations and the public authorities at a European level should be based on their acknowledgement of the common objectives set out in detail in section 3 above, bearing in mind their distinct responsibilities and

competencies. They emphasize that a permanent, open and transparent dialogue between them is a fundamental basis for cooperation.

- The national member bodies of CEN and CENELEC and the members of ETSI have a vital role in the cooperation between the European Standards Organizations, the European Commission and EFTA. Cooperation between all the relevant bodies and common understanding of the objectives set out in section 3 above is essential for these guidelines to be successful.
- The institutional rules of the European Standards Organizations should ensure that European standardization, in particular where it supports European policies and Community regulation, remains fully accountable to all the interested parties in Europe, that is, that the standardizers take into account the broadest possible range of views in drawing up standards and other documents and that the procedures (during development, inquiry and voting) are open and transparent.
- The European standardization system has a broad responsibility to all interests, including industry, workers, consumers, environmental interests, public authorities, and in consequence must not act on the basis of vested interests.
- Coherence, at all levels and between the three European Standards Organizations, should be ensured in the planning, execution and implementation of standardization programs and activities carried out by the European Standards Organizations, where applicable through the approval and implementation activities at national level.
- It is essential that the European standardization system should respond readily and appropriately to differing market needs in different sectors, with due respect for the fundamental principles of European standardization set out in section 3 above. In particular, different market needs may call for different types of deliverables. However, for all types of deliverables the principles of transparency, access, openness, efficiency, coherence and voluntary work and application should still be followed.
- International standardization should be reinforced and Europe's interests safeguarded within it; international standards should be uniformly applied except where, this would be ineffective or inappropriate for the objectives pursued.
- Efforts shall be made to support the integration of the economies of the candidate countries into the Community.
- The use of European standards should be further encouraged as an instrument of economic and technological integration within and outside the European market and as an instrument in order to work with the market and as a technical basis for legislation, in particular in defining technical specifications for products and services and for testing methods.

5. IMPLEMENTATION

Against the background of the previous sections, the European Standards Organizations expect the European Commission and EFTA to:

- Maintain a transparent legal and political framework for European standardization as an independent, consensus-oriented and voluntary activity.
- Make use of European standards where they are appropriate in support of European regulations and other policies, and continue to pursue a policy of broader use of standards.
- In accordance with the provisions of Directive 98/34/EC, indicate legal and political requirements for standards.
- Refrain from drawing up technical regulations on subjects covered by mandates assigned to the European Standards organizations, except where considered necessary in the public interest. Request, to the extent feasible, the opinion of the European Standards Organizations, and possibly their members, on matters relating to standardization and, where appropriate, technical barriers to trade at the European and global levels.
- Intend to continue to provide targeted financial support to the European standards Organizations, subject to the limits imposed by available budgetary assets, towards the maintenance of an appropriate European standardization infrastructure and towards the improvement of the quality of efficiency and visibility of the European Standards Organizations.
- Invite the advice of the European Standards Organizations on the needs for pre-normative research and development, and stimulate the exploitation of Community and/or EFTA funded pre-normative research, arising both from the direct and indirect research actions, into European standards.
- Encourage those participating in the European R&D programs to feed back their results into European Standards Organizations, as appropriate.
- Seek, where appropriate, the advice and active cooperation of the European Standards Organizations in the establishment and implementation of European programs of technical assistance to, and cooperation with, third countries.
- Promote the use of standards by Europe's trading partners in their policy and regulations.

For their part, the European Commission and EFTA expect the European Standards Organizations CEN, CENELEC and ETSI to:

- Maintain the standardization infrastructure and procedures to meet legitimate needs (including safety, health, consumer and environmental protection) in Europe, and actively cooperate to ensure that stakeholders gain the maximum benefit of the European standardization infrastructure and its links with other standards organizations.
- Ensure that structures and procedures allow for the highest possible degree of openness, transparency and representativeness. Procedures should be transparent and ensure independence from vested interests. Further efforts should be made to increase the participation of interested circles, especially public authorities, manufacturers, small and medium-sized enterprises, consumers, workers and environmental interest groups, at the national and European level in the drafting of standards and other deliverables and in ensuring their views are adequately taken into account.
- Ensure that all interested parties participating in the development process have access to documents in order to effectively participate.
- Take the public interest into account, in particular, safety and health, the protection of workers, consumers and environment.
- Maintain a dialogue with the Commission and EFTA while carrying out standardization work.
- Ensure that the environment is fully considered and where relevant taken into account in the development of standards in order to contribute to a high level of environmental protection.
- Pro-actively support participation of relevant stakeholders in standardization work on national European, and international level.
- Establish and maintain institutional rules and procedures that ensure coherence, speed and quality in the establishment, elaboration and implementation of the programs, standards, other deliverables and activities carried out in order to meet the needs of evolving markets. This specifically includes coherent rules for standstill, notification of activities, uniform transposition and withdrawal of conflicting national standards (as far as ENs are concerned).
- Ensure that when common mandates are issued by the Commission and the EFTA side a consistent approach is taken in accepting and executing or in rejecting the mandate.
- Ensure that rules in decision-making procedures continue to preserve accountability to European Community, EFTA members and the economic and social partners concerned

in work undertaken under a mandate from the European Commission and the EFTA side.

- Carry out their tasks with the highest efficiency and quality, including the use of modern methods and technologies for the elaboration and distribution of their work.
- Keep their corpus of publications up to date and in line with technological evolution by means of regular reviews leading to their confirmation, amendment, revision or withdrawal, as appropriate.
- Together with their members, adapt their structures, procedures, and publications to meet developments in the legitimate needs of interested parties. Develop appropriate mechanisms to accept documents originating from interest groups and other parties, and transform them, if appropriate, into deliverables of the European Standards Organizations.
- Ensure that all interested parties have access to standards, by broad provision of information on their availability, and by ensuring that standards – including any intellectual property rights (IPRs) they might contain – can be used by market operators on fair, reasonable and non-discriminatory conditions.
- Undertake and support actions to improve the visibility of European standardization.
- Work towards the development and widespread use of a single mark of conformity with European standards, as appropriate.
- Provide support to the progress of standards organizations in the countries that have applied for EU or EFTA membership, to full participation in, and membership of the European Standards Organizations. Grant full membership once the appropriate and approved conditions have been met.
- Cooperate actively with international standardization structures; observe the terms of the WTO Code of Good Practice for the Preparation, Adoption and Application of Standards; promote the international standard organizations, promote the use of international standards in their own work and at the global level when legitimate objectives can be ensured, i.e. the protection of human health and safety, animals or plant life and/or the environment. Use best efforts to support access by interested circles to standardization processes at the international level.
- Cooperate with the European Commission and EFTA in the development and implementation of Community and EFTA programs of technical assistance and cooperation with third countries, and ensure where possible that related policies of their member organizations are coherent.
- Maintain and develop a dialogue with the European Commission and EFTA on all issues of strategic, political or technical importance of common interest.