

Position Paper

CEN and CENELEC comments on the proposed
revision of US OMB Circular A-119

May 2014

Background Information

The US Office of Management and Budget (OMB) is proposing [to revise Circular A-119](#), "Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities" (hereinafter, Circular A-119, or, the Circular) in light of changes that have taken place in the world of regulation, standards, and conformity assessment since the Circular was last revised in 1998. This US policy document is setting the framework for the use of standards in support of US legislation.

Following a fruitful track record of cooperation, which started 25 years ago, the three European Standardization Organizations CEN, CENELEC and ETSI are currently discussing with their US counterpart the American National Standards Institute (ANSI) about a possible formalization of their cooperation. Besides, the European Commission and the Office of the US Trade Representative are negotiating a Transatlantic Trade and Investment Partnership (TTIP). The role of standardization matters in supporting the outcomes of such a free trade agreement has been recognized on both sides of the Atlantic.

In this context, CEN and CENELEC believe that it is fundamental to provide their views and comments in the framework of the ongoing consultation on the OMB Circular A-119 revision, as this policy document is closely related to a series of topics of particular importance for their respective standardization communities and stakeholders.

To support these comments, CEN and CENELEC rely on the experience they have acquired, together with their 33 respective national members, by cooperating closely with European Regulators for 30 years. This cooperation significantly contributed to a unique

example of an integrated regional market, where free flow of goods is a reality among 28 countries, despite linguistic, economic and cultural differences. This experience fully respects the essential role of market operators in shaping the technical content of standards while ensuring a high level of safety for consumers. By emphasizing the voluntary nature of standards, it eventually preserves the fundamental freedom of manufacturers to demonstrate the compliance of their products with applicable legislation by other means than referenced standards. This approach creates an innovation-friendly playing field for industry and businesses.

CEN and CENELEC fully acknowledge that the US Standardization System and the European Standardization System, and the use of standards in support of regulations and policies, are different in many aspects, while showing commonalities in values and objectives.

Introduction

CEN and CENELEC do support the consultation exercise conducted by US authorities concerning the OMB Circular A-119 and consider it as a valuable guidance document. Additionally, it is an essential component of the US standardization system as a whole. CEN and CENELEC believe that providing their input in this process is in direct line with their wish to further deepen the links they have developed over the past decades with US standardization stakeholders.

CEN and CENELEC comments mostly address some core dimensions of the OMB Circular A-119. These comments have been grouped around a reduced number of headings to facilitate their review.

Scope of the Circular

CEN and CENELEC understand that OMB Circular is a binding policy document for federal-level executive agencies. Furthermore, we believe that standards end-users would benefit from a more coherent and structured system if this document would be used also as reference guidelines for State, County and local public authorities making use of standards and conformity assessment processes in support of technical regulations and policies. These levels could take policy contained in the Circular as useful recommendations.

Definitions used in the Circular

We understand from the definition of voluntary consensus standards bodies by the OMB that standards used in support of regulation in the US may originate from a variety of bodies, including US-domiciled organization as well as any foreign or international consensus-based standards body.

Therefore, we suggest that this definition is further aligned with the WTO TBT Committee Decision referred to in the proposal for a revised Circular A-119. For instance, the principles of coherence, impartiality, effectiveness and relevance should be further considered.

Voluntary use of standards in support of regulatory and policy objectives

The European experience shows that making mandatory the use of standards supporting regulatory objectives is not the most effective solution. From a standards user perspective, the implementation of standards should remain voluntary, even when these are referenced in regulation and support public policies. Regulation should indeed facilitate market access of products complying with the referenced standards, while offering alternative routes to demonstrate regulatory compliance for products showing an equivalent (or superior) level of fulfilment of regulatory requirements (for instance health, safety or energy efficiency). This approach would prove extremely useful in general, and in particular in the framework of emerging areas or technologies. Hence, manufacturers would have more freedom to develop innovative products or solutions, but still bear the full responsibility to demonstrate the compliance of their production with legitimate regulatory requirements.

Ways to refer to standards in support of regulatory and policy objectives

CEN and CENELEC welcome the information provided by OMB Circular A-119 concerning the variety of options available to use standards in support of US regulation. We recommend the OMB to provide additional guidance on how to prioritize the different ways to use standards as listed in section 6 a (i) of the Circular. Below is a suggested order of priority, which takes into account regulatory needs, market relevance and technology developments:

1. Indirect Reference

By indirect reference, we understand that the body of the regulation does not refer to the standard itself, nor does it include the text of the standard or parts of it. Instead, the reference to the standard is made in a separate document, which is itself referred to in the body of the regulation. Amending or updating that separate document should be easier and faster than amending the regulation itself.

CEN and CENELEC strongly suggest the OMB to favour an indirect referencing of standards as the main tool to support regulatory and/or policy objectives.

Indirect reference should be encouraged, rather than direct reference in order to facilitate the periodical updating of references. Such an approach would provide the

maximum level of flexibility to executive agencies and help avoid a disconnect between regulation on one side, technological developments and market reality on the other side.

2. Direct reference

By direct reference, we understand that the body of the regulation refers to a standard or a list of standards.

Although a system of direct references has a lower level of convenience and flexibility than the use of indirect references, it remains preferable than incorporation of the content of the standard in the regulation. Should this approach be used, CEN and CENELEC would recommend that the relevant Agency recognizes that future revisions or amendments of the standards grant legal compliance, unless otherwise explicitly specified by the Agency. This should allow keeping pace with technological developments.

Transparency in the use of published standards in support of technical regulations and public policies

From our experience, standards users highly appreciate to have a central and up-to-date source of information containing references of all standards listed to support regulatory requirements, be it standards incorporated by reference or standards used via other regulatory means. It notably seems essential to avoid duplication of the information in different repositories, as well as to ensure the completeness and accuracy of the information provided. We note that there are existing tools aiming to increase transparency, but that they could be improved in terms of clarity, completeness and coherence of the information they contain.

Those tools should be completed with information on standards used to support US regulation at sub-federal levels.

CEN and CENELEC are concerned with the fact that today still, many references of standards used in support of US Regulation are not up-to-date. Additionally, agencies are likely to refer to several versions of the same standard to support different regulatory requirements. We note that it may result in complex liability issues for manufacturers, consumers and authorities. For instance, there are cases of distortion between legal references to a standard, and the state of the art as reflected by the latest version of the same standard. Eventually, the latest version of a standard normally is the only available version of the document.

Transparency and inclusiveness in the choice of standards likely to support regulation

When executive agencies are faced with regulatory needs that may require the support of standards, CEN and CENELEC would suggest to increase the transparency and openness of the selection process. It could take the format of an open call published on the Federal Register, for any relevant standards developing organization to notify potentially relevant existing standards or ongoing/planned standardization activities that may be fit for purpose.

Such a format would facilitate the work of executive agencies exploring a particular field, and may maximize the array of options that they could choose from. Additionally, it would foster equal access and fair competition between SDOs that meet the definition of a voluntary consensus standards body.

The results of this call should be made public. Any agency's intention to use the outcomes of an ongoing standardization work to support regulatory requirements should be clearly and centrally announced (e.g. on the Federal Register), in order to enable all relevant and interested stakeholders to be timely informed and to be able to contribute.

Conformity assessment practices in relation to standards

The OMB Circular A-119 covers conformity assessment matters, which are intrinsically related to standardization issues. In this context, CEN and CENELEC would like to make some suggestions based on international good practices, as a means to enhance the effectiveness of the OMB guidance in this domain, as follows:

- Recognize / authorize accredited conformity assessment bodies following ISO/IEC standards and guides, developed under ISO/CASCO structure or recognized by IEC CA system(s);
- Avoid prescribing a single conformity assessment body, or to require that products are "listed" under a single, or a reduced number of, conformity assessment body(ies);
- Avoid referring to recognized / authorized conformity assessment bodies in the body of the regulation itself, but rather mandate the relevant authority to publish and regularly maintain a list of recognized / authorized conformity assessment bodies. In line with our comments on methods used to reference standards in regulation, we recommend that the list of specific conformity

assessment bodies that are recognized / authorized by each specific Agency for each regulation is listed in a separate document, which is publicly available;

- Facilitate the establishment of mutual recognition agreements of recognized / authorized conformity assessment bodies with third-countries' conformity assessment bodies, provided that they are also accredited or recognized under international procedures, and in the context of trade agreements and negotiations;
- Consider as a general principle to use self-declaration of conformity as a preferred option, unless the nature of the associated risks calls for third-party certification. Self-declaration combined with a sound and effective market surveillance framework has proven to be an effective tool in the European Single Market, allowing easy market access while maintaining the responsibility of the manufacturer. Where it is not needed due to the level of risk, third-party certification can play the role of a voluntary, market-driven tool fostering differentiation and competitiveness, independent from regulatory compliance aspects.

About CEN and CENELEC

CEN (European Committee for Standardization) and **CENELEC (European Committee for Electrotechnical Standardization)** are recognized by the European Union (EU) and by the European Free Trade Association (EFTA) as European Standardization Organizations responsible for developing and defining standards at European level. These standards set out specifications and procedures in relation to a wide range of products and services.

The members of CEN and CENELEC are the National Standards Bodies and National Electrotechnical Committees of 33 European countries including all of the EU member states plus Iceland, Norway, Switzerland, Turkey and the former Yugoslav Republic of Macedonia.

European Standards (ENs) are developed through a process of collaboration among technical experts nominated by business and industry, research institutes, consumer and environmental organizations and other societal stakeholders. Once adopted, these standards are implemented and published in all of the 33 countries covered by CEN and CENELEC.

CEN and CENELEC also work to promote the international harmonization of standards in the framework of technical cooperation agreements with ISO (International Organization for Standardization) and IEC (International Electrotechnical Commission).

For more information, please see: www.cencenelec.eu
