

**Guidance on the implications of the ISO Global Relevance policy
for CEN standardization**

Edition 2 - 25th August 2006

This document is intended to provide guidance to CEN/TC secretaries and European experts taking part in CEN and ISO activities. It has been prepared by CEN/BT WG 152 "Global relevance", under the Convenorship of UNI (Italy), and its principles were discussed within the ISO Technical Management Board and agreed by ISO/CEN Joint Co-ordination Group before its approval by the CEN Technical Board (Resolution BT 59/2005).

This is Edition 2 of the guidance. Paragraphs where text has been modified (added, changed or deleted) from the previous edition are shown by a vertical mark in the left margin.

1. ISO Global Relevance policy

ISO/TMB Resolution 1/2003 committed ISO to ensuring the "Global relevance" of its standards.

Global Relevance is the characteristic of an ISO standard through which "it can be used/implemented as broadly as possible by affected industries and other stakeholders in markets around the world". Ideally, an ISO standard should represent a single international solution that applies to all countries and can be applied by all countries. At European level, the application of the Global Relevance approach is intended to lead to ISO standards which can be adopted as identical European standards. This is in line with the commitment of CEN to adopt common EN ISO standards whenever possible.

If a single international solution cannot be found for certain elements of the ISO standard at the time of drafting, the ISO policy allows an ISO/TC or SC to include 'options' in the standard in order to achieve its global relevance. These 'options' are intended to reflect market differences. However, such differences should not be permanent and so should be expected to disappear over time. If the elimination of market differences cannot be foreseen at the start of drafting, the ISO/TC or SC should not attempt to develop an ISO standard but should use another deliverable instead (such as the ISO Technical Specification).

ISO/TMB has drafted a policy document (see Annex 1), a guidance as a collection of FAQs and a presentation, which explain the implementation of the "global relevance of standards" principles and the involvement of P-Members in the handling of market differences¹ and essential differences² in the procedure for new work item proposals and standards drafting. ISO also recommends recurring to other deliverables as an interim step, rather than definitely giving up the publication of an ISO standard.

2. Europe in the global market

Acknowledging that, in the global market, the impact of European standardisation and its relationship to European Union legislation can become a source of market differences, the CEN/BT accepted the need to study the effects of the ISO Global Relevance policy on the CEN system and the European market. CEN acknowledges that, in the past, it has not always been possible for the European members of ISO to support the parallel development of EN ISO standards which were not in line with the requirements of European legislation (i.e. New Approach directives).

Hence CEN/BT WG 152 examined the possibilities that could be explored in cases where the existence of European legislation does not allow a single technical solution in an ISO standard to be applicable to Europe. The evaluation of the possibilities was carried out taking into account the following elements:

- the application of ISO Global Relevance policy;
- the simplicity for the CEN and ISO parties involved in the drafting process;
- the clarity and transparency for the standard user;
- the user-friendliness for the market;
- the reference to conformity assessment;
- the risk of proliferation of national exemptions.

¹ Defined by ISO as "as those current and potentially changeable differences in markets that are based on factors such as legislation, economies, social conditions, trade patterns, market needs, scientific theories, and design philosophies".

² Defined by ISO as the "differences that are not expected to change over time, such as imbedded technological infrastructures, climatic, geographical or anthropological differences".

3. General application of ISO Global Relevance policy

In developing an ISO standard, consideration should be given as to whether the single technical solution proposed is applicable to all countries and can be applied by all countries. Committees are encouraged whenever possible to use a performance-based approach in the development of the standard and to ensure that all interested parties have opportunity to contribute to its development.

Where a single technical solution is not possible because of market differences, options can be included in the ISO standard, with a note specifying the market for which the options are intended. These options can appear:

- either in the main body of the standard;
- or in normative Annex A.

If this is not possible, the largest common denominators should be reflected in an ISO standard with the market differences addressed through two or more ISO/TSs.

If the market differences are believed to be permanent, an ISO standard should not be developed. The ISO committee should instead consider developing an alternative deliverable (e.g. ISO/TS).

4 Consequences for CEN

4.1 Principles

The opportunities to apply ISO Global Relevance policy at CEN level should be a matter of discussion within the CEN Technical Committees, in order to allow the European market to express its needs. If the choice is to pursue the development of a common CEN and ISO standard in parallel under the Vienna Agreement, whenever possible, the aim should be to prepare a common ISO/CEN standard representing a single technical solution (Route A).

If this is not possible due to existing market differences at European level, options can be included in the ISO standard, with a note specifying the market(s) to which the options apply (i.e. Europe). The EN ISO standard should also draw the attention of the user to the option that is applicable in Europe through explanation in the European foreword.

These options can appear:

- either in the main body of the standard (Route B1);
- or in normative Annex A (Route B2).

If this is not possible, the largest common denominators should be reflected in the ISO standard and an ISO/TS developed to address the European market difference. This ISO/TS could be adopted as an EN in the CEN collection in order to support the core EN ISO standard (Route C).

Alternatively, an EN could be developed in CEN to support the core EN ISO standard (Route D).

The CEN Technical Committee should pay careful attention to those cases where the EN ISO standard is intended to support European legislation. In addition to the guidance in this document, CEN/TCs are advised to seek the help of the CEN Consultant(s).

4.2 The Routes to follow

See also the flowchart attached as Annex 2.

Route A

Single technical solution

Every effort shall be made to develop a globally relevant ISO standard representing a single technical solution in order for the EN ISO standard to be identical to the ISO standard in content and application.

If this result is not possible, the following Routes may be considered.

The order in which the Routes appear reflects the order in which they should be considered.

Route B1

Diverging requirements addressed through different normative clauses

In this case, the text of the ISO standard addresses the diverging requirements through parallel normative clauses. Each clause should be accompanied by a note specifying the market(s) to which the clause applies (e.g. Europe).

This will allow the adoption by CEN of an EN standard identical to the ISO standard (i.e. an EN ISO standard), either after publication of the ISO standard or in parallel with the adoption of the ISO standard.

WARNING - the European Commission will not recognise an EN ISO standard containing options as a harmonized standard, providing a presumption of conformity, unless ALL options comply with the essential requirements of the related Directive(s).

Unless there is absolute certainty during the DRAFTING of the ISO standard that ALL options do comply, it is recommended that Route C is considered as the first alternative to Route A if the EN ISO standard is intended to support a New Approach Directive.

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Route B2

Additional requirements addressed through a normative Annex

In this case, the text of the ISO standard addresses the additional requirements through the use of a normative Annex. Reference to the Annex is made in a normative clause in the main text of the standard using the following wording: *“In some markets, the additional requirements listed in the normative Annex X apply.”*

This will allow the adoption by CEN of an EN identical to the ISO standard (i.e. an EN ISO standard), either after publication of the ISO standard or in parallel with the adoption of the ISO standard.

WARNING - the European Commission will not recognise an EN ISO standard containing options as a harmonized standard, providing a presumption of conformity, unless ALL options comply with the essential requirements of the related Directive(s).

Unless there is absolute certainty during the DRAFTING of the ISO standard that ALL options do comply, it is recommended that Route C is considered as the first alternative to Route A if the EN ISO standard is intended to support a New Approach Directive.

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Route C

Diverging requirements addressed through separate ISO Technical Specifications

In this case, the text of the ISO standard contains only core requirements that are applicable to all regions.

Diverging market requirements are dealt with in separate ISO Technical Specifications (ISO/Ts). One ISO/TS should address the particular requirements of the European market.

In cases where the EN ISO standard is intended to support European legislation, the ISO/TS addressing the particular requirements of the European market should be adopted as an EN to complement the core EN ISO standard.

Note: the ISO/Ts should add few requirements to the core ISO standard. Hence the ISO standard must not be an “empty shell”, acting simply as a ‘bridge’ for the different ISO/Ts.

Route D

Additional requirements addressed through a separate EN

If particular European requirements cannot be addressed in ISO in accordance with Route C, it is possible to publish a separate EN in support of the core ISO standard. But, noting the commitment of CEN to the primacy of international standardisation, this Route is not preferred or recommended.

4.3 Failure to agree at ISO level

If, after all alternatives have been considered and after exhaustive efforts, no agreement is possible at the ISO level on the development of an ISO standard that is globally relevant, the ISO/TC should abandon development of an ISO standard and consider the development of an alternative deliverable (e.g. ISO/TS, ISO/TR).

If development of an ISO alternative deliverable is not pursued – or if it does not meet the needs of the European market - CEN is free to pursue the development of its own deliverable (EN, CEN/TS, CEN/TR or – in the case of a CEN Workshop – a CWA).

However, the CEN technical body should keep developments at the ISO level under regular review in order to use future opportunities that may be presented to achieve a common ISO and CEN deliverable.

The primacy of international standardization must be respected at all times.

ANNEX 1

1. ISO/TMB POLICY AND PRINCIPLES STATEMENT

2. GLOBAL RELEVANCE OF ISO TECHNICAL WORK AND PUBLICATIONS

2.1 1 Introduction

The formation of the WTO and the subsequent adoption of the WTO Technical Barriers to Trade Agreement (WTO/TBT), placed an obligation on ISO to ensure that the International Standards it develops, adopts and publishes are globally relevant. In Annex 4, paragraph 10 of the Second Triennial Review of the Agreement, the following criteria state that a globally relevant standard should:

- Effectively respond to regulatory and market needs (in the global marketplace)
- Respond to scientific and technical developments in various countries
- Not distort the market
- Have no adverse effects on fair competition
- Not stifle innovation and technological development
- Not give preference to characteristics or requirements of specific countries or regions when different needs or interests exist in other countries or regions
- Be performance based as opposed to design prescriptive

Hence the development and adoption of an International Standard that fails to meet these requirements is open to being challenged as creating a barrier to free trade.

Noting the need to provide fuller advice to committees on global relevance, and following a request from the ISO Council, the ISO/TMB established a Global Relevance Task Force. This task force and, subsequently, the ISO/TMB have agreed on the set of principles that follows.

2.2 2 Definitions

2.2.1.1 standard

document, established by consensus and approved by a recognized body, that provides, for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context.

NOTE Standards should be based on the consolidated results of science, technology and experience, and aimed at the promotion of optimum community benefits.

(ISO/IEC Guide 2:1996, ISO/IEC Directives, Part 2: 2001)

2.2.1.2 international standard

standard that is adopted by an international standardizing/standards organization and made available to the public.

(ISO/IEC Guide 2 :1996, ISO/IEC Directives, Part 2:2001)

2.2.1.3 International Standard

international standard where the international standards organization is ISO or IEC.

(ISO/IEC Guide 2:1996, ISO/IEC Directives, Part 2:2001)

2.2.1.4 global relevance

required characteristic of an International Standard that it can be used/implemented as broadly as possible by affected industries and other stakeholders in markets around the world.

(TMB agreed definition)

2.3 3 Principles

2.3.1.1 3.1 The status and meaning of an International Standard shall be respected.

Any International Standard shall respect the above definitions and shall to the extent possible represent a unique international solution. In cases where unique international solutions are not possible for specific provisions of an International Standard at the current time due to legitimate market and essential differences, International Standards may present options to accommodate these differences where justified.

2.3.1.2 3.2 The commitment to participate in the development of and the feasibility of preparing International Standards shall be demonstrated at the outset of a standards development project.

It is recognized that in some instances various solutions exist to meet unique aspects of the local markets in different regions and countries. With globalization and the unification of markets, these market differences should be minimized over time and evolve into one global market. Simply projecting one solution that accommodates one market (but not others) as the International Standard will not force markets to evolve and coalesce. In such cases, the markets and their related industries will look elsewhere for standards that better accommodate their needs, and ISO will lose its relevance for those markets and industries. Rather than force such a situation, ISO committees should ascertain at the outset of a project whether:

a globally relevant International Standard presenting one unique international solution in all of its provisions is feasible;

an International Standard is feasible that presents options in specific provisions to accommodate existing and legitimate market differences where justified; or

the preparation of a globally relevant International Standard is not feasible and work should not be undertaken in such circumstances.

Additional practical guidance for committee leaders and delegates/experts may be found in the ISO/TMB's Global Relevance Implementation Guidance document.

2.3.1.3 3.3 Preference shall be given to preparing performance rather than prescriptive standards.

Please note the following:

Annex 3 of the WTO/TBT Agreement

“1. Wherever appropriate, the standardizing body shall specify standards based on product requirements in terms of performance rather than design or descriptive characteristics.”

ISO/IEC Directives, Part 2, Clause 4.2 Performance approach (Excerpt)

“Whenever possible, requirements shall be expressed in terms of performance rather than design or descriptive characteristics. This approach leaves maximum freedom to technical development. Primarily those characteristics shall be included that are suitable for world wide (universal) acceptance. Where necessary, owing to differences in legislation, climate, environment, economies, social conditions, trade patterns, etc., several opinions may be indicated.”

Given these quotations, the use of the performance-based approach is widely recognized as supporting the development of globally relevant ISO standards. In the case of design-based standards, the freedom for further technical innovation is most limited, while performance-based standards provide for maximum freedom for further innovation. However, in practice, there may be cases where inclusion of design requirements for some provisions within a performance-based standard is appropriate. There may also be other cases where development of a completely design-based standard may be appropriate and will result in a globally relevant ISO standard. Thus, which approach is most appropriate depends on the technical matter in question.

Additional practical guidance for committee leaders and delegates/experts may be found in the ISO/TMB’s Global Relevance Implementation Guidance document.

2.3.1.4 3.4 Given existing and legitimate market differences, an International Standard may pass through an evolutionary process, with the ultimate objective being to publish, at a later point, an International Standard that presents one unique international solution in all of its provisions.

Under this principle, a committee may wish to consider how it addresses current and potentially changeable differences in markets (based on factors such as legislation, economies, social conditions, trade patterns, market needs, scientific theories, design philosophies, etc.) in the ISO deliverables it produces.

Additional practical guidance for committee leaders and delegates/experts may be found in the ISO/TMB’s Global Relevance Implementation Guidance document.

2.3.1.5 3.5 Essential differences consistent with Annex 3 to the WTO Agreement on Technical Barriers to Trade can be included in International Standards, but specific rules shall be applied if a committee wishes to introduce such differences and special authorization needs to be given by the TMB in instances not covered by these rules.

Under this principle, a committee may wish to consider how it addresses essential differences in markets around the world, that is, factors that are not expected to change over time, such as imbedded technological infrastructures, climatic, geographical or anthropological differences.

Additional practical guidance for committee leaders and delegates/experts may be found in the ISO/TMB’s Global Relevance Implementation Guidance document.

2.3.1.6 3.6 Committees can only ensure the global relevance of the International Standards they produce if they are aware of all the factors that may affect a particular standard's global relevance.

Additional practical guidance for committee leaders and delegates/experts may be found in the ISO/TMB's Global Relevance Implementation Guidance document.

