



European Committee for Standardization
Comité Européen de Normalisation
Europäisches Komitee für Normung



TC 278 Road Transport and Traffic Telematics

N1843

Title : Guidance on the implications of the ISO Global Relevance policy for CEN Standardisation

Source : CEN/BT

Date : 2006-06-20

Status : For information

Work item :

Note :

The enclosed guidance document (BT N7529) was approved by the CEN/BT in the following resolution:

Resolution BT 59/2005:

Subject: BT/WG 152 – Global relevance of standards – Guidance document

BT approves the document 'Guidance on the implications of the ISO Global Relevance policy for CEN standardization' as included in document BT N 7529 and asks its Members to make it available to the CEN/TC Secretaries in their organization as wells to the experts in their country who take part in ISO activities, thanks BT/WG 152 for its work and disbands it, agrees to include the document on the CEN BOSS.

Later, Mr. Stephen Russell, Director of Standards in CEN provided additional information on the reservations expressed by the European Commission on the use of "options" in (EN) ISO standards. I have included this information on the following page.

This guidance document is of obvious relevance to CEN/TC 278 which is developing standards under the Vienna Agreement and in support of a European Directive.

n1843 Guidance on implications of the ISO Global Relevance policy.doc

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Dear BT Colleagues,

You will recall that, during the 58th CEN/BT meeting (13th/14th December 2005), the BT adopted the guidance document (BT N 7529) prepared by CEN/BT WG 152 on the consequences for CEN of the ISO Global Relevance policy.

The CEN guidance document offers a sequence of 'Routes' for use by CEN technical bodies, and European experts active in ISO, in the application of the ISO policy. In accordance with the ISO policy, two of the Routes recognise that an (EN) ISO standard can contain a limited number of alternative (or additional) requirements in order for the product or service to overcome differences in the global market if these differences are believed not to be permanent. These alternative (or additional) requirements - known as 'options' - may be presented in parallel normative clauses of the (EN) ISO standard ('Route B1') or separate normative annexes to the standard ('Route B2').

During discussions in BT WG 152 and elsewhere, the European Commission advised CEN that it would be unwilling to accept an EN ISO standard containing options as a harmonized standard because a 'legal uncertainty' would be created if not all options met the essential requirements of the related Directive(s). The Commission did not believe that the use of the Annex ZA in a harmonized standard presented a sufficient reassurance that the requirements applicable to the EEA would be used in the manufacture of the product or the delivery of the service.

In order to reflect the Commission position, BT N 7529 includes Warning Notes to Routes B1 and B2 which read:

WARNING - the European Commission has indicated to CEN that it is unlikely to recognise (EN) ISO standards containing options as harmonized standards providing a presumption of conformity. Until the position of the European Commission is clarified, 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.

Following discussions in the Senior Officials Group on Standardization (SOGS), the European Commission has now clarified its position to CEN.

In emphasising that it is of the utmost importance that the implementation of international standards as European documents is in compliance with EU legislation, the Commission advises that the use of options can be accepted provided all options provide an acceptable means of meeting EU legal requirements. The Commission urges that CEN and its members exercise caution in their approach to international standardization activities when the outcome of such activities could be EN ISO standards, featuring options, not in compliance with the legal requirements of the European Union.

This clarification from the Commission is welcome and should be reflected in an amendment to BT N 7529 in its implementation in the CEN BOSS and ISOTC portal (as reported to the 59th BT meeting, the ISO/TMB decided at its February 2006 meeting to make the CEN guidance document available to standards developers through the ISO website).

In order to avoid potential problems in the recognition of an EN ISO standard featuring options as a harmonized standard, the BT Secretariat is of the firm view that this amendment should be limited to the Warning Notes for Route B1 and Route B2 and, furthermore, that the Warning Notes should recommend that Route C be preferred unless there is absolute certainty in the drafting of the ISO standard that all options meet the essential requirements of related Directive(s) (if the intention is for an EN ISO adoption of the standard to be communicated to the Commission as a harmonized standard).

Hence the revised wording of the Warning Notes proposed is:

WARNING - the European Commission will not recognise EN ISO standards containing options as harmonized standards 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.

Noting that this proposed change to the CEN guidance document reflects the clarification received from the Commission and does not change the policy adopted at the 58th BT meeting through Resolution BT 59/2005, the BT secretariat does not believe that there is need for a formal BT decision on this amendment. However, should you have a fundamental disagreement with the proposal, please contact me no later than Friday 30th June 2006.

Best wishes

Stephen Russell



BT - TECHNICAL BOARD

1 TO DECIDE

2 SUBJECT: CEN/BT WG 152 'Global relevance' – Guidance on the implications of the ISO Global Relevance policy for CEN standardization

3 BACKGROUND :

At its 57th meeting, BT took Resolution BT 11/2005:

RESOLUTION BT 11/2005 (57th BT item: 3.1)

Subject: BT/WG 152 'Global Relevance'– report and proposed guidance

BT endorses the principles and 'routes' presented in document BT N 7372 and the related presentation and asks BT WG 152 to share its thinking with the ISO/TMB through the ISO/CEN JCG.

BT WG 152 is asked to develop a guidance document for BT approval, which reflects the principles and routes, and should be addressed to European experts taking part in ISO activities and the CEN/TCs.

In accordance with the BT resolution, a progress report on development of the CEN guidance was made to the ISO/CEN JCG meeting held on 13th June 2005. ISO/CEN JCG welcomed the report and 'routes' established by BT WG 152.

BT WG 152 then met on 10th October 2005 to finalise the detail of the guidance document. Noting the reservations expressed by the European Commission on the use of 'options' in (EN) ISO standards, the morning session of the meeting was attended by Mr Michel Jeanson (DG ENTR C/2) and Mr Martin Eifel (DG ENTR H/5).

4 PROPOSAL :

BT to decide on the draft guidance document.

5 RESP : Ruggero Lensi/BT WG 152



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

2nd December 2005

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 (of the two technical boards), before its approval by the CEN Technical Board.

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).

4.1 Consequences for CEN

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 such cases, it is essential to identify in the ISO text the clauses which support the legislative requirements and to compare their means of their implementation against the available options. CEN/TCs are advised to seek the help the CEN Consultants in this task.

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.

In principle, this route can be followed even in cases where the EN ISO is intended to support European legislation and hence where it is important to identify in the ISO text the relevant clause which supports the legislative requirement³.

This means that, in Annex ZA, the EN ISO indicates that requirements not in line with an EU Directive shall be excluded providing presumption of conformity, by the following wording: *“Once this standard is cited in the Official Journal of the European Communities under that Directive and has been implemented as a national standard in at least one Member State, compliance with the normative clauses of this standard **except clause n** confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.”*

WARNING – the European Commission has indicated to CEN that it is unlikely to recognise (EN) ISO standards containing options as harmonized standards providing a presumption of conformity. Until the position of the European Commission is clarified, 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.

³ Compliance with a Directive is essential if a product is to be traded legally within the European Economic Area. CE marking should imply that the European option has been chosen.

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

When the EN ISO is intended to support European legislation, this route could be useful, for example, for an additional characteristic not considered in the ISO standard that could be specified in the Annex.

Annex X provides the additional European requirements and this should then be indicated by the following Note in the main text of the ISO standard: *“Annex X is applicable in markets regulated by EU Directives and associated EFTA regulations.”*⁴

In Annex ZA of the EN ISO standard, the usual text on the presumption of conformity to the Directive is included.

WARNING – the European Commission has indicated to CEN that it is unlikely to recognise (EN) ISO standards containing options as harmonized standards providing a presumption of conformity. Until the position of the European Commission is clarified, 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.

⁴ Compliance with a Directive is essential if a product is to be traded legally within the European Economic Area. CE marking should imply that the European option has been chosen.

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/TSs). 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/TSs 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/TSs.

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

“I. 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.

