1 Advantages and benefits of using and referencing ISO and IEC standards

Standards from ISO and IEC have the advantage of a **broad geographical reach**. Both of these organizations have a membership made up of national members the world over. This geographical reach is combined with a **multi-stakeholder environment** which ensures the representation of a wealth of technical views including those relating to social and economic interests. Different perspectives come from the national level and through a network of liaisons and cooperation with international governmental and non-governmental organizations. Therefore, the value of International Standards from ISO and IEC is that they are recognized, accepted and implemented around the globe.

Regulators can save time and money by choosing ISO and IEC standards as solutions to policy and technical issues — solutions which have been agreed upon by a consensus reached with the involvement of all parties, including the regulators themselves.

ISO and IEC standards:

- support the technical aspects of societal and environmental policies and contribute to sustainable development across the world;
- offer the same level of consumer protection whether applied in a mature or an evolving economy;
- allow products to be supplied and used across different markets, facilitating regulatory compliance and enhancing the market access opportunities for small enterprises;
- reflect the state of the art and serve as a vehicle for the dissemination of new technologies and innovative practices;
- can become national standards after a national public enquiry process carried out by a country's standards body, thereby helping to establish technical consensus on specific, discrete aspects of new regulatory measures in advance of the process of broader public consultations carried out by regulatory authorities; Comment: This is a "chicken and egg" type statement. This document should not attempt to provide a one-to-one correlation between voluntary international standards (and national or regional adoptions thereof) to regulations. There is no such correlation. Also, regulators (e.g., FDA or the EC) do not always carry out "broader public consultations" before recognizing standards within their regulatory schemes. We recommend either leaving the sentence as originally worded, or ending with "standards body," (i.e., recommend the deletion of text but omit the suggested additions).
- can be used as a basis for national technical regulations and may help to ensure that unnecessary technical barriers to trade are not created; Comment: This seems to water down the document significantly and makes it sound like benefits from standards for WTO compliance are almost accidental.
- offer a complete range of tools for the various modes of conformity assessment;
- are used for conformity assessment to enhance confidence in products, systems, processes, services or personnel;
- are developed using procedures which attempt to ensure that the thousands of ISO and IEC standards available avoid duplication and conflicts with each other.

For further information, visit the ISO and IEC websites:

Comment [w1]: I don't think we want to suggest that national consultations need not be held, as that would potentially run afoul of WTO Members' TBT obligations.

Deleted: which can reduce the need for the regulator to hold national consultations

Comment [w2]: The original formulation suggests that the use of ISO and IEC standards = automatic WTO compliance. The revised formulation qualifies the sentence to reflect accurately the text of the TBT Agreement and the Committee Decision: (1) not all ISO and IEC standards are necessarily "international" unless they follow the six principles; (2) not all international standards developed by ISO and IEC are going to be "relevant" for every situation; and (3) a technical regulation that is prepared, adopted, or applied for one of the legitimate objectives set out in Article 2.2 of the TBT Agreement and that is in accordance with relevant international standards only creates a rebuttable presumption that it does not create an unnecessary obstacle to trade.

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2 Introduction

This document demonstrates the potential value of using ISO and IEC standards in support of technical regulations. It explains how ISO and IEC standards can be used by governments to support good regulatory practice. This document may also be useful for those involved in ISO and IEC standardization who wish to engage better with the regulatory bodies relevant to their fields.

ISO and IEC standards are widely adopted at the regional or national level and are used by all interested stakeholders, such as manufacturers, trade organizations, purchasers, consumers, certification bodies, testing laboratories and authorities. Since these standards reflect the best experience of industry, researchers, consumers and regulators worldwide and cover common needs in a variety of countries, they constitute one of the important bases for the removal of unnecessary technical barriers to trade. The use of international standards that are developed under a process meeting Decision G/TCT/1Rev.8, 23 May 2002, has been acknowledged by the Technical Barriers to Trade Committee of the World Trade Organization (WTO/TBT) (see Chapter 3).

The incorporation of standards in legislative instruments by means of a reference constitutes a method of drafting a code or regulation in such a way that a detailed statement of technical requirements is replaced in the text of the code or regulation by a reference to one or more standards, or to the relevant parts thereof. The use of international standards in regulation, such as international standards published by ISO and IEC, may be an effective means of supporting national, regional and global policies. The use of international standards in regulation has been embraced in diverse agreements and frameworks such as the New Approach in the European Union, Good Regulatory Practice developed by the OECD and the Asia-Pacific Economic Cooperation, and the North American Free Trade Agreement.

Depending on policy, in some countries, national adoption may be an important element encouraging the use of the ISO or IEC standard in national technical regulation. Where it is needed, the national adoption process can give confidence that the international solution is fully acceptable to the national situation.

Standards published by other organizations may also be referenced in regulations, but this document deals only with standards published by ISO and IEC.

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Comment [w3]: The original formulation could be read as granting ISO and IEC standards an elevated or exclusive status as international standards. The proposed revision removes that implication, while making clear that ISO and IEC can develop international standards. We also propose to substitute the word "is" for "may be" because the use of an international standard that is not "relevant" will not necessarily achieve the sought-after policy objective.

Deleted: It is already widely used in several regions of the world in concepts,

Deleted: Subcommittee on Standards and Conformance,

Comment [w4]: ISO and IEC state that they develop "international standards" in other places in the document. That is fine and perfectly appropriate. Using that term in this sentence, however, could be read as suggesting that only ISO and IEC develop international standards. So we are proposing a minor tweak to clarify.

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3 International trade and standards

One of the main benefits of standards is that they facilitate trade. The World Trade Organization (WTO) is the international organization that deals with the global rules of trade between nations. Its main goal is to ensure that trade flows as smoothly, predictably and freely as possible. The use of relevant international standards to support technical regulation may help to facilitate the elimination of unnecessary technical barriers to trade. [Comment: Standards are not the "basis" for technical regulation; they provide detailed support to regulations that are typically written in general terms.] In this context, the WTO/TBT Agreement recognizes the contribution international standards can make toward improving the efficiency of production and international trade. In 2005, the WTO's World Trade Report concentrated on the theme of standards and trade and was supportive of the role of international standards.

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Comment [w5]: See comment 2.

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The basic objective of the WTO/TBT Agreement is to ensure that national technical regulations, standards and conformity assessment procedures do not constitute unnecessary technical barriers to trade. The WTO/TBT Agreement seeks to achieve a balance between allowing WTO Members to take regulatory measures to fulfill legitimate objectives and ensuring that national technical regulations, standards and conformity assessment procedures do not become unnecessary obstacles to international trade. In particular, under the TBT Agreement, WTO Members undertake obligations to:

- use relevant international standards, guides and recommendations, or relevant parts of them, as a basis for their national technical regulations and conformity assessment procedures, except when such international standards or relevant parts would be an ineffective or inappropriate means for the fulfilment of the legitimate objectives pursued; and
- play a full part, within the limits of their resources, in the preparation of international standards, guides and recommendations by participating in international standardizing bodies.

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Comment [JS6]: Makes a conclusion about the TBT Agreement. Ideas on what harmonization means, and what responsibilities WTO Members have to 'harmonize,' vary.

Deleted: Harmonization is therefore a central discipline of the TBT Agreement and is articulated in particular in two requirements[1]:

Deleted: WTO members should

Comment [w7]: See Articles 2.4 and 5.4 of the TBT Agreement.

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The WTO also has specific policy areas where international standards are being discussed: trade in services (GATS), food safety (SPS) and trade and the environment (CTE) and the Government Procurement Agreement (GPA). More information on each of these can be found on the WTO website: www.wto.org.

Comment [JS8]: The OECD document referred to doesn't have the same legal standing as the WTO Agreement, and there are many multilateral fora that produce documents supporting the use of international standards. Thus, we moved the reference to the OECD up to the third paragraph of section 2.

Deleted: The Organization for Economic Cooperation and Development (OECD) also recognizes the role of international standards in support of regulation. In June 2005, the OECD member countries adopted the Guiding Principles for Regulatory Quality and Performance, one of which specifically encourages harmonization towards international standards. It also recommends support for the development and use of internationally harmonized standards as a basis for domestic regulations.¶

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ISO and IEC and their members adhere to the requirements of the WTO

The WTO/TBT Agreement also contains a voluntary code that standards bodies should follow to ensure that their standards support the trade facilitation objectives of the WTO. This list appears in Annex 3 of the WTO/TBT Agreement and is called the *Code of good practice for the preparation, adoption and application of standards.* The majority of ISO and IEC members follow this Code and governments are encouraged to work with their national standards bodies to make sure they adhere to it.

ISO and IEC are among the observers in the WTO/TBT Committee and contribute regularly to its work. Many ISO and IEC national members work closely with their WTO representatives and can be included in national delegations to the WTO/TBT Committee meetings. For further information, see www.iso.org/wtocode.

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4 Global applicability of ISO and IEC standards

At first sight, it would appear that countries in all stages of development have identical needs for technical regulations. Any goods and services that have the potential to cause serious harm to the health or safety of the population, or to the environment, would seem to be obvious candidates for technical regulation. However, the differences between countries mean that this concept can be applied differently.

Most developed countries are, in general, characterized by:

- fully fledged market economies;
- large, diversified domestic manufacturing and service bases;
- a culture of competition in industry and commerce;
- consumer protection entrenched in law with organized and influential consumer organizations and special interest groups;
- efficient and functioning standards systems, quality assurance infrastructure, accreditation and legal metrology systems;
- a growing demand for harmonization through regulation which is kept light and market forces that take care of quality-related issues;
- developed systems of civil litigation that support, when necessary, the application of sanctions.

In some countries, these elements exist to varying degrees. For example, some may:

- have subsistence economies and little domestic manufacturing capacity for finished products;
- rely heavily for their subsistence on agriculture or the extraction and exportation of raw materials;
- be highly dependent on the quality of imported products, which is often outside their control;
- lack a consumer infrastructure;
- have an under-developed quality assurance, accreditation and legal metrology infrastructure — even basic legal metrology "weights and measures" may not exist;
- not have implementation systems developed to a degree that would facilitate an efficient regime of technical regulation;
- depend on a command and control regulatory regime.

In some countries, for example, the response by authorities to a specific need for technical regulation may be a general declaration that certain standards in a subject area must be mandatory. It is therefore vital that international standards exist to help such countries. These countries can benefit from the savings they make when applying a wide range of relevant international standards. They are encouraged to make use of and, where necessary, adopt relevant international standards that address their needs.

Comment [w9]: See comment 3.

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ISO and IEC standards have an important role to play across the range of diversity and development in the world. Therefore, both organizations have programmes to raise awareness, increase capacity and promote the participation of all countries in international standardization. More information is available at the following URLs:

www.iso.org/devco
http://www.iec.ch/affiliates

Such a list of recognized references needs to be kept up to date and made easily available to users through a website or other means. This model has been applied in Europe where it is referred to as the "New Approach"[2] (see www.newapproach.org).

Comment [O10]: Delete reference to the EU. The model has been applied by others as well and this reference is not significantly helpful enough to single out Europe as an example.

Example:
Where the product complies with the relevant ISO or IEC standard whose reference number has been published in [refer to relevant official listing here], the relevant authorities shall presume compliance with the requirements of this law.

Example:
A product shall be presumed safe, as far as the risks are concerned, when it conforms to voluntary ISO and IEC standards, the references of which have been registered on [refer to relevant official listing here].

6.4 Actions by regulators/authorities to encourage the use of ISO and IEC standards

In some cases, it may be adequate merely to encourage the use of ISO and IEC standards on the assumption that their voluntary take-up by the market means that regulators' objectives are met — for example, enhancing the quality of products or services in a particular sector. Such measures would not imply the creation of legal instruments, but could rather be achieved through, for example, government policy in targeted areas such as procurement. In cases were this occurs, the standard may become the *de facto* tool for market access.

[2] Where ISO or IEC standards are to be used to support the New Approach Directives, they are first formally adopted as European Standards.

7 Other considerations when choosing to use and reference ISO and IEC standards for technical regulations

7.1 Ensuring no delegation of legislative responsibility

Using ISO and IEC standards for technical regulation does not imply that regulators have reduced power or that they delegate responsibility to other parties. Regulators still have the power to change or update their legislation at any time, or to delete a reference if the standard loses its validity for the relevant legislation. Referencing ISO and IEC standards in technical regulation simply means that regulators make use of the existing consensus at international level.

The ISO and IEC processes benefit from a broad range of expertise and all standards are subjected to a period of public consultation before publication. This helps to ensure that they represent viable solutions which are the fruit of broad consultation.

It is acknowledged that, when a standard is to be used for regulatory purposes, the regulator will wish to ensure that it is fit for that regulatory purpose. In particular, this will depend on the risks associated with the product, the national/regional situation and the purpose of the regulation.

Regulatory procedures are therefore required when approving references to standards regardless of which method of referencing is used. There is a range of regulatory procedures which can be followed to ensure regulators' confidence. The extent and type of the procedure chosen will depend on the risk posed by the product or service.

To summarize, regulators have a choice of techniques to assess and ensure the suitability of an ISO or IEC standard. They have at their disposal a broad range of methods for making reference to, and use of, the standard.

Comment [O11]: ADD: "The methods and examples here are not intended to be exhaustive of the choices that regulators have at their disposal.

7.2 National and regional adoptions of ISO and IEC standards

ISO and IEC standards, as well as being stand-alone documents (with the designation ISO and IEC), can be formally adopted as national or regional standards and given designations combined with the ISO or IEC reference[3]. National and regional adoptions of an ISO or IEC standard may involve a separate consultation process at national or regional level.

Example:
ISO 14971, *Medical devices — Application of risk management to medical devices*, is:
- adopted as ANSI/AAMI/ISO 14971 in the U.S.A.;
- adopted as EN ISO 14971 in Europe;
- adopted as JIS T 14971 in Japan.

In some countries or regions, adoption may be an important and sometimes necessary element for the use of the ISO or IEC standard in technical regulation or public procurement. In other countries, ISO or IEC standards may be used or referenced directly in national technical regulation, based on an assessment of their suitability, without the need for them to be recognized as national standards for the country. What is common to both approaches is that the ISO or IEC standards have been assessed and judged by national stakeholders to suit needs and be fit for purpose in that country or region.

[3] See ISO/IEC Guide 21-1, *Regional or national adoption of International Standards and other International Deliverables – Part 1: Adoption of International Standards*

In some cases, regulators may wish to have a further level of confidence in conformity assessment results. This may involve the particular technical regulation requiring that the competence of conformity assessment bodies be formally recognized. Such competence may be demonstrated, amongst other means, through accreditation by an independent accreditation body — often established by the government.

ISO and IEC have developed a series of standards and guides to ensure the international comparability and credibility of conformity assessment. The voluntary criteria these documents contain represent an international consensus on what constitutes best practice in conformity assessment. Regulators who need to include conformity assessment requirements in their technical regulations can use these documents as elements for the specific requirements in those regulations. Using these documents means international compatibility is fostered and can help to ensure that unnecessary technical barriers to trade are avoided.

Comment [w10]: See comment 2 Also, we wanted to clarify that Members only need to avoid "unnecessary" TBTs. All technical regulations create TBTs to some extent. The TBT Agreement provides disciplines with respect to determining which TBTs are unnecessary.

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Examples of relevant conformity assessment documents from ISO and IEC are provided in the following table:

ISO/IEC 17000	*Conformity assessment — Vocabulary and general principles*
ISO/IEC 17011	*Conformity assessment — General requirements for accreditation bodies accrediting conformity assessment bodies*
ISO/IEC 17020	*General criteria for the operation of various types of bodies performing inspection*
ISO/IEC 17021	*Conformity assessment — Requirements for bodies providing audit and certification of management systems*
ISO/IEC 17024	*Conformity assessment — General requirements for bodies operating certification of persons*
ISO/IEC 17025	*General requirements for the competence of testing and calibration laboratories*
ISO/IEC 17040	*Conformity assessment — General requirements for peer assessment of conformity assessment bodies and accreditation bodies*
ISO/IEC 17050-1	*Conformity assessment — Supplier's declaration of conformity — Part 1: General requirements*
ISO/IEC 17050-2	*Conformity assessment — Supplier's declaration of conformity — Part 2: Supporting documentation*
ISO/IEC Guide 65	*General requirements for bodies operating product certification systems*

The following URL provides further information and a complete, regularly updated list of conformity assessment documents: www.iso.org/casco

7.6 Market surveillance

Market surveillance is a key component of the safety and quality infrastructure of a country. This may be accomplished through pre-market assessment and approval systems, or post-market surveillance programmes. ISO and IEC standards can facilitate market surveillance by providing a common, well-known set of requirements which are known to all the market participants.

With pre-market assessment, regulators have the opportunity to assess in advance the data provided by the party responsible for the product and to determine whether or not the product complies with the standards or conformity assessment procedures referenced in a regulation.

Post-market surveillance can be carried out through a variety of mechanisms. These could include

- inspection and testing of products on the market,
- inspection of the requested marking on products and/or accompanying documents,
- validation of conformity assessment procedures followed by the supplier,

- verification of quality systems of the supplier's manufacturing processes,
- examination of the supplier's electronic and paper records,
- mandatory reporting of adverse incidents to the regulators, and
- corrective actions for non-conforming products.

8 Conclusion

Regulators can make use of ISO and IEC standards in a variety of ways. Choosing to use them to support their regulations and policies affords numerous benefits: ISO and IEC standards support trade, can be used as a basis for technical regulations, and can help to ensure that unnecessary technical barriers to trade are not created. They are widely recognized across the world and offer the same benefits whether applied in developed or developing countries. There is a full portfolio of different types of ISO and IEC standards on offer, and they cover all major subjects from product specifications to management procedures. Regulators can chose from a range of techniques for referencing ISO and IEC standards and decide for themselves the appropriate level of use and conformity assessment that should be applied. This ensures that they retain full control over their legal requirements.

The participation of regulators in the standards process can take on many different forms, ranging from basic information exchange as a means of highlighting their priorities through to acting as a member of a delegation to an ISO or IEC meeting. Where regulatory participation takes place, it fosters coordination and communication between the regulatory and technical levels. In publishing this document, ISO and IEC are making an offer to assist regulators who wish to use international standards to support their work or who are interested in finding out more.

Annexes A, B and C provide practical examples of the key themes contained within this document.

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Comment [w13]: See comment 2

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Comment [O14]: Delete this statement as gratuitous and non-measurable.

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A.4 Food products

ISO standards play an important role in the food industry, both for trade purposes and in order to ensure that food is safe for consumption. Food safety is a well-regulated area, so there is a long history of collaboration between the Codex (the international forum for food regulators) and ISO/TC 34, *Food products*.

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Who is involved?

Codex and ISO activities are complementary. Codex, as an intergovernmental organization, prepares standards and guidelines to assist governments in their statutory and regulatory task of protecting the health of consumers. Codex also is charged with ensuring fair practices in the food trade. ISO, as a non-governmental organization, prepares standards on test methods to assist stakeholders along the whole food chain to fulfil both the statutory and regulatory requirements, as well as the requirements of consumers of these products.

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How is regulatory cooperation in this field achieved?

The Codex Committee on Methods of Analysis and Sampling endorses analytical and test methods from various standards writing bodies, following recommendations from the relevant Codex Commodity Committee. In the field of milk and milk products, ISO/TC 34/SC 5, *Food products — Milk and milk products*, and the International Dairy Federation (IDF) work together to prepare analysis methods that are published jointly. Most of these analysis methods are endorsed by the Codex Committee on Methods of Analysis and Sampling. Several analysis methods from ISO/TC 34/SC 9, *Food products — Microbiology*, have also been endorsed by this committee as have standards from ISO/TC 34/SC 4, *Food products — Cereals and pulses*, and ISO/TC 34/SC 11, *Food products — Animal and vegetable fats and oils*. More than 100 standards by ISO/TC 34 have now been endorsed by Codex as the official test method.

In 2005, ISO/TC 34 published ISO 22000, *Food safety management systems — Requirements for any organization in the food chain*, which is based on a management systems approach similar to that detailed in ISO 9001:2000 as well as on the Codex hazard analysis and critical control point (HACCP) system. The HACCP system is widely accepted worldwide, but it has been implemented in different ways in different countries. In addition, retailer organizations have prepared documents (British Retail Consortium and International Food Standard) for the establishment and auditing of food safety systems, possibly including HACCP requirements. ISO 22000 should help to clarify and harmonize the present situation. Codex played an active role in the development of ISO 22000.

In 2007, ISO/TC 34 published ISO 22005, *Traceability in the feed and food chain — General principles and basic requirements for system design and implementation*. The traceability of food products "from the farm to the fork" is an important requirement. This standard is intended to complement the Codex work on traceability, as it explains the design of a suitable system.

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A.5 Radio services

reduction of time-to-market for some medical devices while still ensuring that fundamental regulatory health and safety responsibilities are met.

C.5.4 Procurement reform

In addition, the U.S. Government has increased its reliance on private sector standards in its procurement activities. In 1994, Secretary of Defence, William Perry, announced that one of the Department of Defence's (DoD's) top priorities would be to move away from military-unique specifications and standards (milspecs) and toward reliance upon private sector standards to ensure that DoD continued to meet its military, economic and policy objectives in the future in a cost-effective manner.

C.5.5 Summary

The United States considers standards to be a fundamental factor in the nation's economy and vital to world commerce. Within the United States, voluntary consensus standards are developed through a decentralized but effective system administered by the private sector, with the participation of industry, academia, consumers and government. The U.S. system has evolved over the last 100 years to meet the needs of U.S. industry and society in general. Rooted in the private sector, the voluntary standards system has successfully met domestic marketplace needs on a sector-by-sector basis. Responsibility for coordination of the U.S. private sector standards system rests with the American National Standards Institute (ANSI). ANSI is also the U.S. member body within ISO and IEC. Organizations that are accredited by ANSI to develop American National Standards (ANSs) or to serve as U.S. Technical Advisory Groups (U.S. TAGs) to the International Organization for Standardization (ISO), or organizations that are approved by ANSI's U.S. National Committee (USNC) of the International Electrotechnical Commission (IEC) to serve as U.S. TAGs to IEC committees, are required to adhere to a set of essential requirements that are aligned with the WTO principles. These principles include transparency, openness, impartiality, effectiveness and relevance, consensus, performance-based coherence, due process, and the provision of technical assistance where appropriate. The U.S. system, both domestically and internationally, benefits from strong industry support and participation of both government and private sector technical experts as equals at all levels in the process.

Comment [O15]: these are distinct from regulatory standards that are legitimately developed by government agenices.

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Comment [O16]: Delete "it"

1. Request: Delete the reference to the 2005 WTO Trade Report on page 4 (section 3). Rationale: The USTR sent a strong letter to the WTO Secretariat on June 23, 2006, calling the standards section of the 2005 WTO Trade Report “subjective, confusing and otherwise troublesome”. The Secretariat acknowledged that the WTO report was not reviewed by the WTO TBT Committee and that it should not be construed as official policy of the WTO. Accordingly, it is inappropriate and misguiding to reference the report.

2. Request and Rational: Add a sentence to page 4 (section 3) to clarify that it is not just ISO/IEC that have accepted the WTO/TBT Annex 3 Code of Good Practice. “The majority of ISO and IEC members follow this Code and governments are encouraged to work with their national standards bodies to make sure they adhere to it”.

   Add: “In addition, certain ISO members such as the American National Standards Institute (ANSI) have accepted the code on behalf of other international standards developing organizations domiciled in their territory”.

   3.Request and Rationale: Add language to make the following statement about EU New Approach more factual9page 37,sectionC.2.3) “ The policies of the European Standards Bodies demand that International Standards are used wherever they exist and are suitable” , add: “ but European lawmakers are under no obligation to attribute a special role to such international standards in technical legislation”.

Comment

On page 3, Introduction, 3rd paragraph, the 3rd sentence, as proposed by USTR/ITA, reads:

The use of international standards in regulation has been embraced in diverse agreements and frameworks such as the New Approach in the European Union, Good Regulatory Practice developed by the OECD and the Asia-Pacific Economic Cooperation, and the North American Free Trade Agreement.

We suggest

The use of standards in regulation has been embraced in diverse frameworks such as the New Approach in the European Union, Good Regulatory Practice developed by the OECD and the Asia-Pacific Economic Cooperation, and the North American Free Trade Agreement.

Reasons for deleting "international" -- (1) The EU's New Approach does not use international standards. The NA requires the use of European Standards (EN) in directives to the exclusion of any other standards, international or otherwise. At times, ENs used in NA directives may be based on ISO and IEC standards but they can never be referrenced directly. (2) In APEC, while there are a number of GRP guidance documents, to our knowledge, there are no published principles to specifically encourage the use of international standards in the regulatory regimes of APEC economies.

This 3rd paragraph starts by mentioning the use of standards in regulation (not international standards) and this, in itself, is a significant point that merits being emphasized. This sentence expands on that opening sentence.

Reason for deleting "agreements" -- of those mentioned, only NAFTA is an agreement.