





International standards and "private standards"

ISO in brief

ISO is the International Organization for Standardization. It has a membership of 159* national standards bodies from countries large and small, industrialized, developing and in transition, in all regions of the world. ISO's portfolio of more than 18 100* standards provides business, government and society with practical tools for all three dimensions of sustainable development: economic, environmental and societal.

ISO International Standards make a positive contribution to the world we live in. They facilitate trade, spread knowledge, disseminate innovative advances in technology, and share good management and conformity assessment practices.

ISO standards provide solutions and achieve benefits for almost all sectors of activity, including agriculture, construction, mechanical engineering, manufacturing, distribution, transport, medical devices, information and communication technologies, the environment, energy, quality management, conformity assessment and services.

ISO makes optimal use of the resources entrusted in it by its stakeholders by only developing standards for which there is a clear market requirement. This work is carried out by experts on loan from the industrial, technical and business sectors which have asked for the standards, and which subsequently put them to use. These experts may be joined by others with relevant knowledge, such as representatives of government agencies, testing laboratories, consumer associations and academia, and by international governmental and nongovernmental organizations.

ISO International Standards represent a global consensus on the state of the art in the technology or good practice concerned.

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Introduction

1.1 Purpose of this paper

Discussion and debate about "private standards" and their potential to act as actual or potential barriers to trade has increased in recent times, notably in the World Trade Organization (WTO) Technical Barriers to Trade (TBT) Committee and in the WTO Sanitary and Phytosanitary (SPS) Committee. The issue is also specifically referred to in paragraph 26 of the WTO TBT Committee's Fifth triennial review of the operation and implementation of the Agreement on Technical Barriers to Trade 1), adopted by WTO members on 13 November 2009.

But what is meant by "private standards" and what is the role of standards in supporting public policy and technical regulations that are designed to protect or enhance public health and safety and the environment?

This paper outlines the important role that ISO's international standards play in fostering trade while supporting the implementation of public policy and allowing good regulatory practice through performance-based, as opposed to prescriptive, technical regulations.

The paper also makes the important distinction between standards that are developed using the core WTO TBT principles of transparency, openness, impartiality and consensus, effectiveness and relevance, coherence, and addressing the concerns of developing countries - and standards that do not follow these principles. These principles are set out in the WTO TBT committee's second triennial review²⁾, and were reconfirmed by members of the WTO during the fifth triennial review. These principles are further complemented by compliance with the disciplines of Annex 3 of the WTO TBT agreement Code of Good Practice for the preparation, adoption and application of standards 3) (which ISO national standards bodies (NSBs) are encouraged to accept and comply with). Standards that are developed using processes which are open to worldwide participation and that use these principles are considered to be "international standards". While other standards may be developed that meet the needs of specific sectors or segments

of the population, these standards may be perfectly valid and relevant for their purpose, but they do not adhere to the above-described disciplines, nor do they share other attributes of formal international standards.

1.2 Trade, public policies and international standards

Public policies are established by governmental authorities and, in a number of cases, ISO standards support or relate to such public policy initiatives. ISO, and its sister organization, the International Electrotechnical Commission (IEC), have agreed on four principles to guide the development of such standards. The first principle is to provide market-driven international standards, based on objective information and knowledge. The second principle is to meet the needs and concerns of all relevant stakeholders, including public authorities where appropriate, without seeking to establish, drive or motivate public policy, regulations, or social and political agendas. The third principle is recognition that the development of regulation, public policy or the development and interpretation of international treaties are the role of governments or treaty organizations. Finally, such ISO and IEC standards supporting public policy are best developed within proven structures, operational approaches and participation models detailed in ISO/IEC's existing directives and development procedures 4).

Technical regulations set out legally binding technical requirements often with the aim of protecting public health and safety, and the environment. They may set out the requirements in generic terms (e.g. essential requirements), or in explicit terms, and they may incorporate, by reference or verbatim, the contents of a voluntary standard for all, or some, of the details thereby making compliance to the voluntary standard a part of, or a presumption of, compliance with a regulation.

The WTO Agreement on Technical Barriers to Trade (the "TBT Agreement"), which applies to the global trade of products, recognizes that technical regulations

¹⁾ See http://docsonline.wto.org/DDFDocuments/t/G/TBT/26.doc

²⁾ See Annex 4 on "Decision of the Committee on Principles for the Development of International Standards, Guides and Recommendations with relation to Articles 2, 5 and Annex 3 of the Agreement" contained in the Second Triennial Review of the TBT Agreement at http://docsonline.wto.org/DDFDocuments/t/G/ TBT/9.doc

³⁾ See http://www.wto.org/english/docs_e/legal_e/17-tbt_e. htm#annexIII

⁴⁾ See http://www.iso.org/iso/standards_development/ processes_and_procedures.htm

and standards may be necessary to achieve legitimate public policy objectives, but also warns against their misuse. Importantly, where regulation is necessary, the WTO TBT Agreement requires the use of relevant "international standards", or parts of them, as the basis for technical regulations whenever appropriate. The WTO TBT Committee has agreed on principles and procedures that should be observed when such "international standards" are elaborated. In these principles for "international standards", no distinction is made between standards developed by international governmental organizations, international non-governmental organizations or other "private" organizations.

In comparison, the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (the SPS Agreement)⁵⁾ takes a different approach to the use of relevant "international standards". This agreement addresses "measures" (laws, decrees, regulations, requirements, etc.) concerning the protection of human, animal or plant life, or health. In the context of this agreement, sanitary or phytosanitary "measures" which conform to "international standards" are presumed to be consistent with the relevant provisions of the SPS Agreement. As to what is an "international standard", the SPS Agreement specifically names the Codex Alimentarius Commission (CAC); the International Office of Epizootics (OIE); and the International Plant Protection Convention (IPPC) as organizations that produce "international standards" regarding food safety, animal health, and plant health respectively. These three intergovernmental organizations are commonly referred to as the "three sisters". The SPS Agreement further indicates that for matters not covered by the sisters, appropriate standards, guidelines and recommendations promulgated by other "relevant international organizations open for membership to all Members, as identified by the Committee" may also be considered as "international standards". In practice, however, the SPS Committee has yet to identify such organizations. In the context of discussions in the SPS Committee, standards promulgated by non-governmental organizations, be they international standards from organizations such as ISO and IEC, social and environmental standards from NGOs or industry/retailer standards, are sometimes referred to as "private standards". The lack of distinction between these different "private standards" has also contributed to extensive discussion and a certain amount of confusion in various fora.

1.3 Regional approaches

An established and successful example of governments' use of relevant international and regional consensus-based standards is the European Commission decision in the 1980s to take a "new approach" to European legislation. In this case, European Directives set out minimum essential

requirements that are supplemented by voluntary, consensus-based, European standards which provide "deemed-to-satisfy" solutions. This was an important recognition of the role that standards play in supporting public policy objectives (in this case, using European standards to support creation of the Single European Market). At the time, it also posed a major challenge to the formal international standardization system, since it called for a considerable expansion of European standardization activities, diverting a significant amount of interest and resource away from international standardization work. This was addressed, however, by the establishment of agreements between the international standardizing organizations of ISO and IEC and their European regional counterparts (the ISO counterpart being the European Committee for Standardization – CEN) under what is known as the "Vienna Agreement".

In other regions of the world, good regulatory practices have encouraged the use of performancebased regulation that is further complemented by standards. These standards can be international standards, but historically tended to be national standards, especially where they related to public safety and health. In recent years, the use of international standards in support of public policy and regulation has increased as countries have joined the WTO and have begun to apply the TBT and SPS Agreements' disciplines of using relevant international standards as a way of reducing barriers to trade. Other bilateral and multi-lateral trade arrangements, as well as existing and new regional free trade agreements in different parts of the world, have also been major drivers to encourage the use of international standards. Organizations or trade areas, such as the Organization for Economic Co-operation and Development (OECD), Asia-Pacific Economic Cooperation (APEC), and the Southern Common Market (MERCO-SUR), encourage the use of international standards as a way of fostering trade within their membership and with the rest of the world.

Effectively all regions of the world, whilst having specific regional issues to deal with, have strong incentives to use international standards. These incentives range from obligations if they are members of the WTO, to the pragmatic need to ensure that products and materials from their country can be sold with as few barriers to trade as possible. Having these products and materials conform to international standards is a key element in ensuring such trade.

⁵⁾ See http://www.wto.org/english/tratop_E/sps_e/spsagr_e.htm

2 Formal international standardization

2.1 ISO and other international standardizing organizations

ISO is a worldwide federation currently comprising 159 members on the basis of one member per country. The ISO member is a "national standards body" (NSB) expected to be the organization most representative of standardization in its country and typically with a formal national remit from their government for voluntary standardization.

In the ISO membership, there is a good deal of diversity among NSBs that make up the formal ISO standardization system. In developing countries, for example, NSBs are often government departments with a formal remit for membership in ISO, whereas in developed countries, NSBs are often non-governmental organizations recognized by their government as the entity responsible for such voluntary standardization.

In some countries, there may be numerous standards bodies, each responding to the needs of one or more industry sectors, but with one national standards body coordinating their activities and responsible for membership in ISO. In some of these cases, the ISO member may not itself develop standards, but has the responsibility to coordinate national standardization activities and the authority to impart the status of "national standard" to standards developed by other bodies in their country.

Effectively all ISO members comply with the principles set out in annex 3 of the WTO TBT agreement Code of Good Practice for the preparation, adoption and application of standards. In accepting the TBT Agreement, WTO Members agree to ensure that their central government standardizing bodies accept and comply with the Code of Good Practice and agree also to take reasonable measures to ensure that local government, non-governmental and regional standardizing bodies do the same. The Code is open to acceptance by all such bodies. Obligations by these NSBs having adopted the Code include conducting public consultations on draft national, regional and international standards, making their

work programme and catalogue publicly available and appropriately addressing comments and complaints.

Features such as ISO NSB national coordination and representation; NSBs' associated remits from their governments; NSB disciplines of the TBT Code of Good Practice, and ISO's adherence to the principles of international standards set out in the TBT Agreement's second triennial review, all contribute to ISO's broad recognition as a developer of "formal" international standards.

ISO also collaborates extensively with two other formal international standardizing organizations, namely the International Electrotechnical Commission (IEC) and the ITU (International Telecommunication Union). In 2001, the three organizations established the World Standards Cooperation (WSC) as a means to coordinate policies and shared objectives, and to provide direction on converging areas of technology. In addition to the WSC partners, there are also a number of intergovernmental bodies setting their own standards, usually in very specific fields. Some of these include United Nations agencies such as the World Meteorological Organization (WMO), the International Labour Organization (ILO) and the Codex Alimentarius Commission (CAC) (as previously mentioned). ISO systematically coordinates with these organizations to avoid overlap and to ensure complementarity of standardization efforts (e.g., through Memoranda of Understanding).

Finally, there are other standards developing organizations (SDOs) that develop standards having important global reach and relevance. ISO endeavors to collaborate with these organizations through, for example, partnership arrangements (e.g., with the Institute of Electrical and Electronics Engineers (IEEE) in the areas of health informatics (e-health) and information and communication technologies.



2.2 ISO's standards development process

ISO standards are developed in response to needs recognized by market players whether they are industry, government, consumers or others. The first step in the process seeks to verify that an ISO standard on a specific subject will bring added value. The process involves broad consultations to ascertain that there is indeed support for the proposed development of an ISO standard on a particular topic and, in particular, that the market players and other stakeholders will commit appropriate resources to the development of the standard.

If the acceptance conditions are met, the proposal formally becomes a standards project assigned to a relevant ISO technical body, which will have been established with a defined scope and sector, through an open and consensus-based process.

ISO standards are developed through a hierarchy of technical committees and subcommittees (currently more than 700) and their associated working groups (currently more than 2200). The "participating" members of technical committees and subcommittees are those ISO members that have expressed the wish to participate actively in the work. These participating members typically form national mirror committees bringing together representatives of all interested parties at the national level, including industry, government, consumers, academia and others as appropriate. ISO members may also opt to be observers or non-members of committees according to their national interests.

ISO's procedures provide mechanisms by which other international and broad regional organizations may participate in the work and some 700 organizations, including most of the United Nations agencies, are engaged with relevant ISO committees in the development of ISO standards.

The initial drafting work on a standard is usually carried out in a working group comprising experts nominated by the participating ISO members and interested liaison organizations. The experts discuss and agree amongst themselves on what elements they believe the standard should contain. Once they have reached agreement, the draft standard is then reviewed by the members of the parent committee. During this phase of the work, the national mirror committees referred to above reach national consensus positions and these positions are then negotiated within the ISO committee to reach an international consensus. Once consensus has been reached in the committee, the draft is issued as a Draft International Standard (DIS) for voting by all ISO member

bodies, and during this phase many ISO members make the document available for public review within their country. Comments received during this process are then reviewed and if the DIS has achieved the required level of approval, the final text is agreed for publication as an International Standard. The standard is made available to any interested party for their application in processes, products or services and without constraint for such purposes as implementation, training and certification.

An ISO standard consequently reflects a double level of consensus - between market players, and between countries.



3 The advent of "private standards"

3.1 Introduction

Although so-called "private" standards may be viewed to encompass any standard developed by an entity outside of government, the characterization may be misleading. In many fora, the term "private" may be perceived as somehow "lesser", "self-serving" or "not in the interest of the public". There is a vast range of non-governmental standards (and growing in number) and there are significant differences in the bodies/organizations that develop these standards related to such aspects as governance, development approach, stakeholder engagement, etc. In this paper, a distinction is made between "formal" international standardizing organizations as described above and other "private" standards setters. In the context of ISO's work, at least three important categories of private standards (described below) have evolved and have lead to efforts of harmonization or coordination with the ISO standards development system.

3.2 Private standards in the ICT sector (consortia and fora)

In addition to a hierarchy of formal international, regional and national standards, it has long been recognized that another layer exists in the form of industry or company standards, used within or between companies or in contractual arrangements with suppliers.

In response to such industry interest to set its own standards, a phenomenon emerged in the late 1980s and early 1990s of "consortia" and "fora", principally in the field of information and communication technologies (ICT), to develop industry specifications.

In many instances, the first consortia and fora were closed groups formed by a number of ICT companies to develop specifications that the participants could then implement principally to compete with rival approaches in the marketplace. Such groups were not necessarily seeking to engage with all interested parties, nor were the specifications they produced

systematically made available for public enquiry. Over time however, many of these groups have become more open, have achieved levels of recognition in the ICT industry and certain specifications they have developed are widely recognized as market *de facto* international standards.

In the mid-1990s, the ISO Council established an ad hoc study group to consider the potential consequences of the establishment of this de facto international standardization system in parallel with the formal system, the main finding being that the formal system should not be overly concerned about the complementary establishment of such bodies this was the inevitable consequence of the strategic interests of ICT companies – but the formal system should look for ways to interact with such bodies. One result was that the ISO/IEC joint technical committee on information technology (ISO/IEC JTC1) introduced a special procedure whereby specifications developed by consortia and fora could be processed through the formal standardization system in order to be transformed into international standards from ISO and IEC.

This procedure initially had modest success but has taken on increased significance in recent years as a result of policies by some governments to favour open, international voluntary standards of the kind produced by the formal standardization system. This has resulted in standards such as the Linux operating system and the OASIS open document format (ODF) being transformed into formal ISO/IEC international standards, as well as the adoption of previously proprietary standards, such as Adobe's portable document format (PDF), as a formal international standard in ISO.

3.3 Private standards from the retail and agri-food industry

In many respects, the emergence of private standards in the agri-food and retail sectors has many parallels with earlier experiences in the ICT sector, even if motivations are not the same. For example the Global Food Safety Initiative (GFSI) was formed in 2000 at the request of food retailer CEOs to promote continuous improvement in food safety systems and to ensure confidence and consistency in the delivery of safe food to consumers. The initiatives tend to be managed by groups of leading companies. While such standards may benefit from a high level of expert industry input, they do not necessarily adhere to the same principles as a formal international standardizing organization (i.e., WTO TBT principles of transparency, openness, impartiality and consensus, etc.), nor are disciplines of the WTO TBT Annex 3 Code of Good Practice necessarily utilized.

Some concerns have been expressed, especially in developing countries, that certain agri-food private standards (e.g., GlobalGAP – previously EurepGAP) may at times exceed requirements (e.g. for certain minimum pesticide residue limits) which are established in regulations or "international standards". In this area, these are typically international standards developed by the intergovernmental Codex Alimentarius Commission (CAC). Again, with no formal international standardization process adhering to accepted principles and no particular national disciplines, private industry standards must take extra measures to gain a level of support from regulators and other stakeholders, especially in developing countries, to be effectively accepted and implemented.

In this sector, ISO and the formal standardization system have made progress in recent years to facilitate the evaluation and harmonization of basic food safety management systems, inherent in all of the various retailer/industry food safety and good agricultural practice standards, by introducing the ISO 22000 series on food safety management systems. Additional ISO prerequisite programme standards are being developed to complement the main management system standard and to address inconsistencies that can be detrimental to producers (large and small), manufacturers and ultimately, the consumer.

A number of issues related to private standards in the agri-food sector were also presented in a paper⁶⁾ at the May 2009 meeting of the Codex Alimentarius Commission.

3.4 Private standards related to social and environmental aspects

The latest and perhaps most diverse landscape of private standards relates to social and environmental aspects, often with associated claims, certification and labeling programmes. These standards address such subjects as carbon footprint, eco-labeling, sustainable management of natural resources (forests, fisheries, biofuels), fair trade practices, organizational accountability and social responsibility. These standards are also produced by an array of private standards developers, from retailer consortia (e.g., private-label schemes) to social and environmental NGO movements promoting specific social and environmental change through their standards and certification activities. The standards development practices of these organizations also vary widely. Certain efforts have been made in recent years to improve the consistency of principles and criteria supporting such development activities, as well as any associated conformity assessment programmes (certification, labelling). One such private organization, called the International Social and Environmental Accreditation

and Labelling Alliance (ISEAL), is a global association for social and environmental standards systems. Together, ISEAL and its members seek to "contribute to a world where ecological sustainability and social justice are the normal conditions of business".

In a number of cases, private standards initiatives in the social and environmental field could be reconciled and, in some cases, merged to avoid confusion, fragmentation of the marketplace and potential dilution of their intended effects. The formal international standardization system is a platform that can potentially complement, or help to harmonize various private standards, and help provide coherent global solutions. This could lead to a greater level of marketplace and regulatory acceptance and, ultimately, to the intended social and environmental impact.

As examples, the formal standardization system has helped to consolidate a number of subjects by providing some important international standards on key social and environmental subjects. In the environment and related areas, ISO provides international standards addressing such subjects as environmental management (ISO 14001/4); environmental labelling (ISO 14020/21/24/25), lifecycle assessment (ISO 14040/44); greenhouse gas measurement, verification and validation (ISO 14064/65); and drinking water and wastewater services (ISO 24510/11/12).

ISO has also established a comprehensive stakeholder engagement effort to develop the new ISO 26000 standard on social responsibility. This highprofile project, involving more than 400 global experts, from 91 countries and 42 international governmental and non-governmental organizations, also demonstrates how the ISO standards development process can address complex societal and sustainability issues. Other examples under development in ISO include the carbon footprint of products and services; sustainability criteria for biofuels; sustainability in event management, and the water footprint of organizations.

6) See ftp://ftp.fao.org/Codex/CAC/CAC32/al329Dbe.pdf



4 Claims, labels, certification and compliance

Given the broad array of claims, labels and certificates in the marketplace, it is more important than ever that users and consumers have confidence in the integrity of such assessments. The WTO TBT Agreement recognizes the importance of using relevant guides and recommendations issued by international standardizing bodies to support globally harmonized approaches to conformity assessment. Without such harmonized approaches, it is impossible to have common recognition and acceptance of test reports and certificates, potentially resulting in a restriction of trade. The ISO policy development committee on conformity assessment (ISO/CASCO) provides a forum for developing these consistent and harmonized practices. ISO/CASCO's so-called "toolbox" of international standards and guides gives confidence to the user that the product, process or service conforms to specified requirements. It should be noted that although ISO develops the international standards that support globally-harmonized conformity assessment, ISO itself does not carry out any activities related to testing, certification or accreditation to its standards, or any other standards.

This need for harmonized conformity assessment approaches has also been recognized by private standards developers. ISO/CASCO cooperates with a number of such organizations and provides a forum, through its "Strategic Alliance and Regulatory Group (STAR)", for sectoral and subject organizations (both public and private) to participate in conformity assessment policy issues and to review best use and evolution of ISO/CASCO's toolbox of standards, in the context of their own schemes.

Although the ISO/CASCO toolbox is a generic set of standards and guides, there is sometimes a need for additional specific requirements in a sector or subject (e.g. food safety considerations, information security issues). Where this occurs, the development of any such additional sector-specific requirements within ISO for auditing, testing, sampling, etc. are always based on the relevant generic ISO/CASCO standard, supplemented with specific subject/sector requirements. This approach ensures a harmonized and coherent approach to conformity assessment across sectors and globally.

5 Conclusions and way forward

Formal international standards, at the national, regional and international levels, are an established and proven approach to address technological and emerging global challenges. In addition, however, it is a modern reality that private standards in such areas as the ICT sector, from the retail and agri-food industry and those dealing with social and environmental issues are in some cases successfully addressing a multitude of stakeholder-driven priorities.

Any organization may claim to have developed a "standard" and, even further, may subsequently establish a certification/marking/labeling scheme that demonstrates conformance to such a "standard". However, not all standards are created equal. WTO disciplines for use of standards as the basis for regulatory measures demand that "international standards" be developed by designated organizations in the case of the SPS Agreement or according principles for international standards development - in the case of the TBT Agreement. Formal international standards, such as those from ISO and IEC, follow such principles and are conventionally not considered "private standards". It is therefore urged that a distinction be made between international standards which use principles for international standards set out in the WTO agreements and disciplines established through acceptance of the Code of Good Practice, from other standards that may be described as private standards, not having adhered to these WTO principles and disciplines.

The existence of a growing multitude of private standards in such fields as ICT, agri-food and on social and environmental issues, may ultimately confuse users and consumers, thereby diminishing their important market, safety, social or environmental effect. In addition, claims of conformity, using potentially inconsistent methodologies for their assessment, may also undermine the intended impacts of such private standards.

In the end, coherence, harmonization and a closer level of cooperation between the developers of private standards and the formal international standards system needs to occur. Sessions organized by the WTO have addressed the issue of private standards7) and have recognized the need to promote dialogue and strengthen linkages between private standards schemes and formal international standard-setting organizations. Ultimately, the goal of "one international standard, one test, and one certificate" should be pursued in these domains in order to achieve global acceptance as well as their intended impacts.

⁷⁾ The WTO Standards and Trade Development Facility in June 2008 and the WTO CTE session on environment-related private standards and certification in July 2009.

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