

## Report of the International Conference “Standards and Regulatory Systems”

19 November 2013, Geneva, Palais des Nations

### Opening session

Ms. Elisabeth Stampfl-Blaha, ISO Vice-President said that both regulators and business faced the challenge of creating a future, respectively for society and for their customers. Companies responded to this challenge through open innovation, and regulators can do the same by referencing to standards in regulations. They could do so because the underlying principles of good standardization practice and good regulatory practice were similar, so regulators could use standards with confidence. IEC and ISO had published a comprehensive guide to this practice in 2007 and were ready to offer further support to interested parties. Other existing cooperation efforts could be strengthened, starting from cooperation between national standards bodies and regulators, and including: discussing the possibility of creating a platform for citizens to access the content of standards referenced in regulations, helping protect the copyright of referenced standards, and join forces to fight pirated standards.

Dr. Rob McFarlane, UK Cabinet Office, commented on one specific role of standards in public administration, i.e. in the context of civil contingencies, defined as the activities designed to prepare for, respond to and recover from emergencies and in building the resilience of communities. Standards were crucial in two ways: in promoting innovative ways of managing risks and in preserving coherence across diverse geographical areas and diverse challenges. Good practice in this area of work was available in many different forms, so standards competed for attention with other available tools – including government issued guidance and case studies. Many local organizations were therefore not sufficiently aware of standards and faced difficulties in finding and implementing them. The UK Government was – instead - enthusiastically taking up standards as an alternative to regulations in this and other areas.

Answering questions from the floor, he said that statutory guidance from government was the primary framework for balancing innovation, local practice and coherence in responding to an emergency. This statutory guidance explained *what* was required but not *how* to put it in place. This was an area where standards could find their place. He added that standards could promote convergence across jurisdictions and administrations because they were a form of transferable knowledge that each organization could adapt to the specifics of its area of work.

Speaking from the floor, Mr. Daniel Mansfield of BSI observed that as standards were revised through an iterative process, which both reflected and helped bring up the general baseline in the marketplace. Dr. Stampfl-Blaha added that in standards development there was a tension between the unaffordable and the mediocre, and that at their best, standards could also allow for different levels of achievement, walking organizations up step by step. Answering a question from the floor she emphasized that the standards development process was balanced and did not unduly favor industry or administrations.

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## Global best practice in the use of standards in regulatory work

Ms. Mary McKiel, of the United States Environmental Protection Agency, said that US federal government used voluntary standards for a wide range of activities ranging from regulations and compliance to partnership programs and collaborations with academia. One of the many benefits of using, and participating in the development of, voluntary standards was the improved ease with which technical, testing, materials, and other requirements can be adopted and harmonized across various authorities. In recent years the federal community, under the direction of a 1995 law on the use of standards, had begun looking at new ways to work with the private sector to help escalate the development of improved buildings, green procurement, and energy efficiency among other areas. She also provided examples of various private-sector developed standards that drive and support sustainable construction.

A speaker from the floor raised the concern of how regulators choose among multiple product standards that coexist in sectors like organizational resilience and environmental protection. Ms. McKiel replied that nothing prevented federal agencies from making reference more than one standard. In practice, the speaker from the floor observed, this could lead to situations where businesses would go “standards-shopping” for the standards of “least resistance”.

Answering more questions, Ms. McKiel added that in some areas, federal regulators had been working with the industry and other stakeholders within standardization bodies in view of developing standards that would respond to policy-makers’ objectives, so that there would be no need to regulate. She also explained that in US Government practice, any standard could be referenced, so long as it was voluntary and consensus-based and it fed the need of the regulation. Administrations did not need to prove that the standard of choice was consensus based, so long as the standardization body adhered to the Code of Good Standardization Practice. In evaluating whether the standard was consistent with the regulatory objective, federal administrations could request standardization bodies for background material, for example on testing methods. Additionally, administrations could discuss with standardization bodies proposals for revising a particular standard, so it was better suited to their requirements, or make reference to only a part of a standard. A standard could even be used to only partially satisfy the requirements of a regulation. As regards the voluntary nature of standards, Ms. McKiel explained that in cases in which regulations made exclusive reference to a standard, the standard indeed became compulsory in the context of the regulation, but was still voluntary if used outside its scope (firms could use it beyond statutory requirements).

Ms. Norma McCormick, Chair, ISO/COPOLCO explained that ISO/COPOLCO did not itself produce standards but instead developed best practice to ensure that the consumers’ perspective was reflected in standards development. This was important, as it was one way how consumers could be heard in the regulatory development process, even when standards were not referenced in regulations, but only used as background information or as the basis for co-operation among governments (disseminating best practices, sharing information resources such as international databases etc). Consumers’ involvement was important not just in the development of standards and regulations but also in their implementation: for example, consumers could act as watchdogs against fraud and counterfeit. Ways in which both businesses and governments could increase cooperation with consumers were: seeking consumer feedback on suspicious products and services through hotlines, investing in public education to raise consumers’ awareness on resulting consumer detriment, etc. Questions directed to Ms. McCormick related to the possible inclusion of the subject of services to the elderly to the future work program of ISO/COPOLCO, to which she answered that there had been

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preliminary discussion on the issue at the national level; and to the challenge of identifying appropriate representatives for consumers’ interest and facilitating their participation in the standards-making process, especially at an international level. Increasingly, she observed, consumers are seen not just as stakeholders, but as experts, so there is a perceived value in their participation and for this reason national standards bodies are willing to support it.

Mr. Devin McDaniels of the WTO TBT Secretariat commented on the implications of different methods of reference to standards for the purpose of the TBT Agreement, in three contexts: harmonization, unnecessary barriers to trade and transparency. As regards harmonization, the TBT Agreement contained a requirement to follow relevant international standards as a basis for technical regulations and conformity assessment procedures, but also provided room for flexibility (Article 2.4 and 5.4). Additionally, the specific method of reference to standards used by the regulator influenced the degree of regulatory convergence which was achieved (for example, if reference was only partial). He emphasized that there was a presumption in the TBT agreement that reference to standards was itself not only a way of avoiding technical barriers to trade, especially when international standards were used, but also a key component of good regulatory practice, throughout the regulatory life-cycle. Finally, different methods of reference could influence what is notified, and had an impact on the ability to comment on draft regulations. Transparency could possibly be impaired under certain methods of reference, depending on the accessibility of referenced standards. Answering a question from the floor he clarified that the WTO TBT agreement promotes reference to international standards as a means of addressing technical barriers to trade, but does not explicitly encourage reference to international regulations, such as those developed by the World Forum.

Mr. Francois Guichard, of the UNECE secretariat, representing the World Forum for Harmonization of Vehicle Regulations (WP.29), shared the experience of the World Forum with incorporation by reference of standards into regulations. He stressed the need for cooperation between standardization organizations and regulatory bodies to ensure regulatory transparency. He said that one possible solution to the challenges faced by the regulator when referencing to standards in regulations was "read-only" access to standards through "reading rooms". One example was the American National Standard Institute "Incorporation by Reference" internet portal ([ibr.ansi.org](http://ibr.ansi.org)). Mr. Juan Ramos, UNECE Secretary to WP.29, added that the World Forum was seeking to strengthen cooperation with standardization bodies as regards in particular: the accessibility of standards to regulators during the regulatory process; the accessibility of standards referenced in regulations not just to producers, but also to other stakeholders and ordinary citizens; and the continued accessibility of norms that had been revised and withdrawn.

Ms. Silvia Vaccaro of the European Commission said that the EU internal market had been a success, and that standardization had been a key cornerstone of its success. By efficiently applying the simple principle of 'one product, one standard' in all 28 EU member states, most national standards had been replaced by European standards granting access to the internal market and allowing free circulation of products between all EU member States. Recently the European legislation on standardization had been updated – the fundamentals remained the same, but the system had been modernized – so as to improve stakeholders’ participation, speed up the process, and recognize services standardization as well as better deal with the ICT sector. A speaker from the floor emphasized the importance of the New Approach in the success of the internal market and asked to which extent the same experience could be replicated at a broader level in groups such as WP. 6.

Mr. Trevor Vyze of the ISO Secretariat explained that the sales of standards helped finance the standardization bodies that served the purpose of organizing the standardization process and

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making standards widely available. Each participant in the standardization process was still responsible for financing its own participation costs. ISO was looking at innovative ways to facilitate interaction with regulators and emphasized that the ANSI reading room was an ISO Council approved pilot project. Financing the standardization system through the sale of standards had several advantages including: that it was a fair and users-paid system and it ensured that standards were available, including to regulators. Ms. McKormick added that another advantage of the sales system was that it maintained participation costs reasonably low (avoiding dues that were for example collected by some consortia).

The representative of the Russian Federation lamented the insufficient clarity in the reference to standards in the field of transport, both as regards the rules and the instruments used in verifying these rules, in the UNECE World Forum as well as in other UNECE conventions including in the field of dangerous goods. He encouraged WP. 6 to further discuss the legal scope of the different references, in particular how to differentiate reference to voluntary standards from reference that created legal obligations. This pointed to a need for increased participation by other UNECE bodies in the work of WP. 6.

## Opening of the afternoon session

Mr. Frans Vreeswijk, General Secretary and CEO of the IEC expressed his support for the revision of Recommendation D and more generally for the use of indicative reference to standards in regulations. This practice made optimal use of expertise and know-how and eliminated the need for rigid and soon outdated specifications in regulations. The General Secretary recalled that most of world trade was in electric and electronic products that relied on IEC International Standards to function effectively and safely with one another. For this reason close cooperation between standardization bodies, regulators and other stakeholders was essential and had been very fruitful. Recent examples included the contribution of IEC to the World Bank Group project “Lighting Global” and to the UN “Sustainable Energy for All” initiative. He concluded by saying that IEC conformity assessment systems were an important complement to standards and were an equally important tool for regulators.

## Countries’ experiences related to reference to standards in regulations

Mr. Piet-Hein Daverveldt, the Managing Director of the Dutch Standardization Institute emphasized that reference to standards in regulations had many advantages, but should respect the voluntary nature of standards and protect the intellectual property contained in standards. Within the EU New Approach, when an organization decided to fulfill a regulation’s requirements by making use of the referenced standard it also benefitted from the knowledge contained in the standard, hence the reason to pay for it. In cases in which a regulator could find no alternative to mandatory reference to a standard, then there was a case for free access to mandatory standards referred to in the legislation, provided that copyrights held by standardization organizations are respected and they are compensated. Free access should be limited to “read only”, and to registered users, so as to avoid the proliferation of pirated copies. He then commented on the respective benefits of dated and dynamic reference to standards, and referred to the recent experience of the Netherlands, where the Dutch Government intended to compensate the Dutch Standardization Institute for making mandatory standards referred to in legislation, available.

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Mr. Alexander Zazhigalkin, Deputy Head, Federal Agency on Technical Regulation and Metrology (GOST R) offered an overview of the evolution of the Russian standardization system over the last twenty years. After a period of transition, starting from 2007, standards in Russia had had an exclusively voluntary nature. However, under the current system, the text of several technical regulations had basically been copied from the content of standards. This practice had resulted in a number of shortcomings and could not be further continued, so Russia had for several years already started to work on the basis of the EU new approach of reference to standards. The creation of the Customs Union had contributed to and strengthened this trend. The proposed draft law on standardization – that could be finalized as early as the end of 2013 - had reference to standards as its cornerstone, and would explicitly refer to the UNECE Recommendation D. The law would also contain a number of additional elements, including the priority use of standards in public procurement, and would contribute to strengthen the role of standardization in Russian society. As the reference to standards became more prevalent, the issue of access to referenced standards had become an issue of debate. The Russian Government was willing at a minimum to pay compensation to the national standardization bodies for free access.

Mr. Arman Shakkaliyev, Director General of the Kazakhstan Institute of Standardization and Certification, of the Ministry of Industry and New Technologies, explained that in his country the “Law on Technical Regulations” established the legal framework of both mandatory and voluntary standards. One of the principles of the technical regulations system was voluntary reference to standards, but there were exceptions, in cases in which the laws or technical regulations made national standards compulsory, for example, in the fields of health and safety, energy efficiency and gas supply. In these cases, because standards were mandatory, free access was provided. In the case of Customs Union regulations, reference to standards was not mandatory, so in this case not abiding by the standard referenced in the regulation was not an infringement of the law.

Mr. Miroslav Chloupek, Director of the Department of Foreign Relations in the Czech Office for Standards, Metrology and Testing, explained that in his country, reference to standards in regulations was either to “Harmonized Standards”, transposing requirements specified in a European standards or to “Specified Standards”, which were Czech, foreign or international standards or specifications and contained requirements for fulfilling Government orders and other technical regulations. Until recently, the principles of using and referencing standards had not been applied cohesively, resulting in some standards becoming de facto mandatory. This had led to controversies, resulting in a revision of the Czech “Legislative Rules”. Under the new provisions, reference to standards was in most cases indicative – in which case the presumption of conformity mechanism would be used. If this was not possible, regulators could use “exclusive reference”, but would have to: include a justification in the preamble to the regulation; make a clear and specific reference to the standard and make it publicly available. For this purpose, reading rooms were provided at relevant ministries and at the Office for Standards, Metrology and Testing. Additionally, the Office also offered a very reasonably priced access on the basis of an annual subscription.

Ms. Sara Gobbi, Director of EU Affairs of ASTM International recalled that ASTM International was a leader in the development and delivery of international voluntary consensus standards, driven by the contributions of its members. More than 30,000 world’s top technical experts collaborated in its committees representing producers, users, government, universities, laboratories and professionals from 135 countries. ASTM did not have official national delegations but a direct membership and voting process. Being based on good standardization practice, its voluntary consensus standards could be used by regulators with confidence. There were over 7,000 references to

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ASTM standards in regulations and national standards of 120 countries worldwide. ASTM standards were also used in international regulations, for example, in UNECE World Forum, a regulation on tire safety and performance references four different ASTM standards. ASTM was also engaging in international cooperation with developing countries through the so called Memorandum of Understanding Program. ASTM had currently signed 82 MOUs with developing countries worldwide thus further ensuring the global relevance of its standards.

Mr. Francisco Verdera, Director, International Relations & Co-operation of AENOR explained that its organization was mainly financed by the provision of services, with very small contributions from the national government. In addition to its EU and international obligations, AENOR was an adherent member of COPANT, deployed important technical assistance activities and was one of the main translators of international standards into Spanish. Mr. Verdera made reference to the sector of low voltage electrical installations as an example of good practice. In this sector, the regulation relied explicitly on the principle of presumption of conformity and clearly specified that if another equivalent means of proving conformity to the requirements could be found, it would be accepted, so the regulation did not hinder innovation. Additionally, in this sector, in cases in which the regulation contained a dated reference, a special clause provided that the last version of the standards was applicable unless otherwise specified, signaling a high level of confidence in the SDO.

A question from Brazil related to how other countries solved the problem of making standards accessible to SMEs which had a limited budget. The panelists provided examples from their respective national experience: in the Czech Republic, the cost of a read-only subscription with no printing allowed was lower than 50 euros; in Spain, AENOR was a membership organization which maintained special agreements with its members – which were mainly associations of SMEs – on the basis of which specially priced packages could be made available for the specific sector of interest. Similarly, in the United States, SMEs could buy binders of specially priced standards. In the Customs Union of Belarus, the Russian Federation and Kazakhstan, there is also a database of 3034 technical regulations referring to more than 7000 standards. For a reasonable fee, users were given full access to this database which also included international document such as for example UNECE documents. Another speaker recalled, however, that the main cost of standards for SMEs was implementation, rather than purchase.

### **Practical ways of enhancing cooperation between standards-making bodies and regulators**

Mr. Lotsmanov briefly introduced RSPP – the Russian Union of Industrialists and Entrepreneurs – whose members included not only large companies but also many SMEs, altogether accounting for over 60% of Russia’s GDP. The RSPP’s Committee on Technical Regulations, representing Russian industry, had been working closely with Rosstandart, with the Ministry of Trade and Industry and its regional bodies, and with the regulators both in the reform of the Russian technical regulations system and in the creation of the Common Regulatory System of the Customs Union, and in the reform of the law on standardization currently in progress. All these efforts were proving fruitful: the total budget devoted to standardization in Russia had increased by a multiple of 30 over the last 5 years, to 1566 million rubles, with industry currently contributing over half of that amount, resulting in a marked increase in the volume of adopted standards.

Another important area of activity for RSPP was international cooperation: RSPP had worked with experts from the EU in the elaboration of recommendations for approximation of the technical

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regulation system of the EU and Russia, and had also contributed to the Cooperation agreement between CEN/CENELEC and Rosstandart ([http://en.rgtr.ru/international\\_cooperation](http://en.rgtr.ru/international_cooperation)). This agreement would pave the way for increased use of international standards and best practice in Russia.

RSPP hoped to strengthen its international activities in cooperation with Orgalime, by jointly creating a Council on Standardization that would bring together representatives of industry from Russia, Belarus and Kazakhstan, as well as from the European Union, to support the harmonization of standards and conformity assessment procedures, to ensure the participation of industry in the implementation of the CEN/CENELEC-Rosstandard agreement, and to synchronize and simplify the procedures for exports and imports of goods between the two economic unions.

Mr. Daniel Mansfield, Head of Policy Engagement, BSI, commenting on the subject of reading rooms, said that BSI standards were available at a number of locations in the UK, and in particular libraries. He reiterated that while regulations set a minimum baseline, standards are “a ladder of opportunity”, for better performance. Standards are a means of sharing the knowledge that the industry has developed, and are much more than an instrument to implement regulations. In the EU system, only 20% of European Standards (ENs) are cited in the European Journal of the EU, and only one third of new standards in development respond to ‘mandates’. In the UK, an example of how BSI has contributed to UK better regulation is in the field of environmental management. For example: for firms that were subject to the Environment Agency’s controls and inspections, the Agency could decide to reduce fees for its services if the firm used ISO 14001. Authorities could also use standards as a way to influence new developments, for example, to build confidence in new technologies, when a field is not mature enough for regulatory intervention.

Mr. Mansfield recalled that BSI had organized an event on the subject of Standards and Regulations earlier in 2013, and that a panel session had also been held on this topic at the ISO General Assembly. In response to the need by both regulators and standards bodies for further guidance in this area, BSI together with the UK Accreditation Service had recently published a handbook on “Standards and Accreditation as tools for Better Regulations” (see: [www.ukas.com/Library/Media-Centre/Promotional-Materials/Brochures/Ministers%20Handbook.pdf](http://www.ukas.com/Library/Media-Centre/Promotional-Materials/Brochures/Ministers%20Handbook.pdf)). The booklet had been sent out by the Prime Minister’s Office to all Ministers in the UK.

Ms. Emmeline Skelton and Mr. James Crask, Senior Manager Business Resilience, PricewaterhouseCoopers gave the perspective of the industry on how implementing standards helps both business efficiency and resilience. As a case study in this issue, they made an example of how firms with a positive approach to crisis management and recovery emerged well ahead of their competitors in the aftermath of a crisis. Successful firms were doing a lot more than their statutory requirements and also a lot more than what was required in standards they were certified to, creating their own business best practice. This best practice informed the development of standards, which had a cross-fertilization effect on the development of regulations. For example, the Security Policy Framework and the Civil Contingencies Act were guidance documents for government agencies, managed by the UK Cabinet Office, which were developed in parallel with BS 25999. This collaboration allowed for new areas of work where best practice, or standards, or regulations were needed to be identified quickly and responded to adequately and at the desired level.

Participants discussed another important function of conformity assessment in facilitating international trade and avoiding duplication of testing, especially as regards electrical products.

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Mr. Inklaar, a private consultant, presented the reasons that had guided the revision of Recommendation D. He explained that a number of changes had occurred since the last revision of UNECE Recommendation D, almost 20 years previously. Over this period, the EU New Approach had consolidated its success, the US administration had issued and implemented Circular A-119, and all over the world legislators and authorities had acknowledged that co-regulation – making use of standardization by independent bodies – was often a more cost efficient and expedient method for addressing certain policy objectives than the classical legislative tools. As standards were currently widely used in support of legislation, the outstanding question that remained to be addressed was, “how are standards used”? Frequently, reference to standards had been by means of incorporation or exclusive reference, which had generated a debate on: whether the referenced standards maintained their voluntary nature; to what degree and how access to these standards needed to be afforded to the general public; and what impact this would have on the SDOs’ intellectual property and business model, relying on the sales of standards. There was a need to: give priority to development of models allowing for flexible use of standards in support of legislation in the context of Good Regulatory Practice, and ensure stable, favorable conditions for inclusive, consensus-based development of high quality voluntary standards facilitated by independent SDOs.

This intervention opened a lively discussion on the revision of Recommendation D, which was finally adopted unanimously after all the comments by delegates present in the room had been incorporated in a revised version, which is available as part of the Report on the 23rd session of the Working Party.

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