United Nations ECE/CTCS/WP.6/2015/7

Economic and Social Council

Distr.: General
21 September 2015

Original: English

Economic Commission for Europe

Steering Committee on Trade Capacity and Standards

Working Party on Regulatory Cooperation and Standardization Policies

Twenty-fifth session
Geneva, 2 (pm) - 3 December 2015
Item 6(a) of the provisional agenda
International regulatory cooperation

Regulatory Cooperation: A Wikihow

Submitted by the secretariat

Summary

This document has been made co-authored by the Senior Advisor to the WP.6 Bureau (Mr Christer Arvius) and the UNECE Secretariat. It presents a roadmap for countries to enhance regulatory coherence across jurisdictions by engaging in regulatory cooperation.

The document was initially prepared as an input to the work of the "E15 Initiative" of the World Economic Forum (WEF) and the International Centre for Trade and Sustainable Development (ICTSD) on "Regulatory Coherence" (see: http://e15initiative.org/themes/regulatory-coherence)

It is submitted to the delegations for information as background for the discussion on the revision of the Recommendation L on the "International Model for Technical Harmonization".

I. Introduction

1. This Thinkpiece presents a roadmap for countries to enhance regulatory coherence across jurisdictions by engaging in regulatory cooperation. The scope of the paper is limited to the "non-food and feed" products and to "technical regulations" - regulations on product and production processes, at both sectoral and cross-sectoral levels – thus excluding more general and fundamental laws and bylaws.

2. Enhanced regulatory coherence is an area of increased priority for trade and regulatory authorities alike. As is well documented, regulatory fragmentation results in

unnecessary barriers to international trade as exporters need not only customize their products so that they comply with different and sometimes conflicting regulations, and also often have to test and certify their products multiple times over to ensure that compliance is proved to the satisfaction of the local authorities, according to the legislation in place in the each national market.

3. Multiple tests and multiple certification requirements do little to enhance safety for consumers and end users. On the other hand, in some sectors, they make a product or equipment so expensive that it may not be in the interest of a global firm to market the product to a specific country, especially if its market is small and heavily regulated. The overall impact on GDP from the deep regulatory reform that is necessary to ground a truly harmonized market is hard to estimate, and available estimates suggest that gains may be small1. At the same time, gains from regulatory harmonization can be very significant for particular segments and markets – leading to substantial gains in a country's overall economic performance.

4. The paper is organized as follows. Section 2 reviews the different options for increased regulatory coherence and cooperation among countries that wish to increase the coherence between their respective regulatory systems. Section 3 looks at the national discipline that grounds bilateral, regional or international regulatory cooperation, while Section 4 presents practical tools that are available to regulators to enhance regulatory coherence. Section 5 presents the UNECE International Model for Regulatory Cooperation" a simple tool that allows for the full coherence not just of regulations, but of regulatory frameworks in their entirety. The following section presents the example of one initiative that was developed on the basis of this model. Section 7 concludes with practical recommendations for the way forward.

II. The current menu

5. "Regulatory Systems Coherence" composes both national regulatory practices and trans-national regulatory cooperation for establishing various types of arrangements.

6. In more detail, we can think of regulatory cooperation as a "ladder of ambition". Depending on their reciprocal trade and investment interests, a pair or a group of countries will choose different "steps" on the ladder as their preferred form of regulatory cooperation.

7. The different steps can be represented as follows, in order of increasing complexity and level of engagement.

8. The first two steps relate to national practices:

(a) Observance of good (national) regulatory practice (WTO/TBT Agreement, APEC, OECD etc.)

(b) Transparency measures (WTO/TBT Agreement, regulatory dialogues, etc.)

9. The last four relate to (not necessarily successive) steps needed to establish operational mechanisms for engaging a partner country or countries. These are:

(c) Recognition by government bodies of tests and conformity assessment *procedures* conducted by the trading partner as well as recognition of accreditation systems

[1] See, for example, Francois et al, Reducing Trans-Atlantic Barriers to Trade and Investment, Centre for Economic and Policy Research (CEPR), London 2013.

(d) Recognition by Government bodies of the *results* of conformity assessments procedures conducted by trading partners for accepting products certified elsewhere onto their respective markets

(e) Recognition by Government bodies of *functionally equivalent* technical regulations

(f) Establishment of *fully harmonized* technical regulations

Table 1

Nature of action	*Different degrees of regulatory co-operation*	*Example of agreement*
National practices ("good regulatory practice")	Observance of principal trade policy provisions non-discrimination, proportionality, use of international standards etc	- TBT Agreement - UNECE recommendations - OECD/APEC/ASEAN best practice
	Information exchange procedures/ transparency measures	- TBT Agreement
Trans-national arrangements ("Regulatory co-operation")	Recognition of conformity assessment procedures - common procedures (testing procedures, test report forms) - accreditation systems	- MLA[2] - IECEEE, IECEx etc.
	Recognition of results of conformity assessment procedures - certificates of conformity - inspections - test results	- MRA - OECD: GLP[3] - IECEEE, IECEx etc.
	Recognition of (functionally) equivalent technical regulations - product specifications (essential requirements and standards linked to those requirements) - marking specifications, marks etc.	- ACAA[4] - PECA[5] - UNECE "International Model" - EU-South Korea FTA Annex on Automotives - NAMA (NTB annexes) - EU-US MRA on marine equipment
	Drawing up fully harmonized technical regulations	EU – harmonized area Eurasian Economic Union

[2] Multilateral recognition agreements between accreditors.
[3] Good Laboratory Practice.
[4] Agreements on Conformity Assessment and Acceptance of Industrial Products.
[5] Protocol to the European Agreements on Conformity Assessment and Acceptance of Industrial Products.

Source: The table is adapted from the document "Methodological Arrangements to Avoid Technical Barriers to Trade", available at: http://www.unece.org/fileadmin/DAM/trade/wp6/documents/2014/WP6_2014_11E.pdf

III. Good regulatory practice

10. Regulatory cooperation starts at home, or put differently, simply cannot start unless partners agree on the basic fundamental principles on which their national regulatory practices are based.

11. Effectively, these principles are defined in the World Trade Organization (WTO) agreements, and more specifically in the Agreements on Technical Barriers to Trade (TBT Agreement) and on Sanitary and Phytosanitary measures (SPS Agreement). This paper focuses mainly on the TBT area of work. In this area, the relevant discipline has been developed in the WTO TBT Committtee, on the basis of the TBT Agreement and in particular the Article 2.2 provision to only regulate for legitimate objectives in a way that does not create unnecessary obstacles to international trade.

12. The Committee has undertaken successive six triennial reviews (with the seventh presently ongoing), and in this context, national regulatory practices have been the subject of intense debate and discussion, leading to a substantiation of the concept of "good regulatory practice" (GRP). GRP is a loosely defined as a wide-ranging concept that relates broadly to regulatory quality, with an emphasis on transparency and accountability in the development of regulations, and inclusiveness in consultation processes 6. In broad terms, GRP involves a regulatory process based on non-discrimination, proportionality, and the use of international standards.

13. The TBT Committee has further called on its members to (voluntarily) institutionalize the various mechanisms, processes and procedures of regulatory practice through laws and regulations, as well as through the creation and designation of institutions within Member governments to oversee regulatory processes. Effective internal policy coordination, including among regulators, with standardizing bodies and trade officials implementing the TBT Agreement, has been stressed as another important component of GRP, along with the use of Regulatory Impact Assessments (RIAs)7.

14. It should be noted that these basic principles of GRPs are very broadly applied, beyond the WTO membership. Building on the WTO discipline, other regional and international organizations – including ASEAN, APEC, the OECD and the World Bank – have also promoted the development of GRP within their respective mandates.

15. At the United Nations, the UN Economic Commission for Europe (UNECE) and specifically its Working Party on "Regulatory Cooperation and Standardization Policies" has made significant contributions over the years to different dimensions of GRP. The most important deliverables are practical tools and recommendations concerning:

- how to reference standards in technical regulations;
- how to achieve proportionality between risks and regulatory policies through the use of risk management tools.

[6] WTO, Complilation of sources on Good Regulatory Practices, G/TBT/W/341, 13 September 2011, and "Sixth Triennial Review"

[7] Good Regulatory Practice (GRP): Voluntary Mechanisms and related principles, JOB/TBT/119/Rev.1

16. As regards the first, the Working Party adopted a Recommendation8 for regulatory authorities to "make use of international, regional and national standards in regulatory work" and "endeavour to apply references to standards methods that respect their voluntary nature, such as the "indicative reference", which retains the voluntary application of the standard". The recommendation also provides when indicative reference is considered unsuitable, regulatory authorities should make use of exclusive reference, which renders the standard or parts of the standard mandatory.

17. Reference to standards is indeed widely applied because it allows regulators to:

- Take advantage of available expertise and best practice internationally. State authorities do not necessarily have the means to develop and entertain technical expertise in all the diverse fields for which they are responsible. By having the regulators participate in the work of technical committees within standardization bodies they can effectively influence the standards development process in a way that responds to their regulatory concerns and use the resulting standards for policy purposes.
- Facilitate participation industry's participation in international trade networks. When developing a regulation, regulators will want to align their requirements with those of their trading partners in order to avoid having different or contradictory requirements in different export markets.

18. The use of this method in national regulatory practice greatly facilitates - as will be discussed further – regulatory cooperation at a bilateral, regional and multilateral level.

19. A second dimension of GRP is the proportionality between regulations and the risk that they address. Since 2009, UNECE WP.6 has carried out a number of activities relating to the management of risks in regulatory frameworks, with the aim of giving practical guidance to countries in striking an optimal balance between exposing the public unnecessarily and the societal costs of developing and enforcing technical regulations9.

20. This work also aims at eliminating technical barriers and unnecessary obstacles to trade by establishing a common understanding on risk classes and grounding regulatory activity around a common risk-based approach. The work of UNECE WP.6 in this area is not limited to the development of best practice concerning regulatory texts, but also looks at their actual implementation through an application of risk management tools to:

- requirements for achieving regulatory objectives: including technical requirements with references to available international standards;
- pre-market control provisions: establishing conformity assessment requirements that are proportionate to the risks of the products and services at issue;
- post-market control provisions: enforcing market surveillance mechanisms to remove non-conforming products or services from the market.

[8] UNECE Recommendation D "Reference to Standards" www.unece.org/fileadmin/DAM/trade/wp6/Recommendations/Rec_D.pdf

[9] See UNECE: "Risk Management in Regulatory Frameworks: Towards a Better Management of Risks" "http://www.unece.org/index.php?id=31684&L=0

IV. Transnational arrangements

21. Partners that adhere to the same basic common principles will often find it in their interest to pursue their regulatory cooperation further. In doing so, they will engage in a variety of mechanisms aiming at

- the mutual recognition of conformity assessment provisions;
- the mutual recognition of the results of conformity assessment;
- the mutual recognition of technical regulations; and
- the drawing up of common technical regulations within a common regulatory approach.

22. These four categories are the last four “steps” of the “ladder of ambition” that was introduced above.

A. Mutual recognition of conformity assessment provisions and procedures

23. A key step in establishing closer regulatory cooperation between a country pair or within a regional group is the recognition by government bodies of tests and conformity assessment procedures conducted by trading partner(s).

24. Conformity assessment and its mutual recognition is an important dimension - it helps validate the expectations by businesses customers, consumers, users and public about products and services relating to features like quality, ecology, safety, economy, reliability, compatibility, interoperability, efficiency and effectiveness. Within the regulatory contexts, regulations typically require compliance with a national, regional or international standard, with a technical specification or a code of good practice. Regulations can include requirements for how compliance is to be demonstrated and communicated (for example, regulations may require testing of a product by a recognised testing laboratory and the subsequent marking of those products if they have fulfilled the requirements).

25. In order for conformity assessment procedures to be recognized by trading partners, the bodies undertaking them are – at a very minimum - expected to use the standards developed by the Committee on Conformity Assessment of the International Standards Organization (ISO/CASCO). These standards define the techniques and activities that must be carried out to ensure that a product, process, service, management system, person or organisation fulfils specified requirements. 10 By relying on conformity assessment in accordance with international standards regulators and the market can be assured that claims of conformance in relation to the products, processes, services, management systems, persons or organisations are well-founded and legitimate. Additionally, it helps cut the costs of trade by ensuring a common and internationally harmonized approach.

26. Partners extensively use these international standards in a large array of procedures aimed at the mutual recognition of conformity assessment procedures and of the bodies that carry out these procedures, called conformity assessment bodies or CAB. This mutual recognition can be carried out in several ways including: government recognition, accreditation, peer assessment.

[10] For more details, please refer to http://www.iso.org/sites/cascoregulators/01_4_conformity-assessment-recognition.html

27. Governments can recognise one another's CABs by simple administrative recognition, with no requirement for proof of technical competence, or technical recognition, where proofs are required, according to mechanisms specified in laws or treaties.

28. A second way how authorities recognize CABs from other jurisdictions is through accreditation. This reduces risk for business and its customers by assuring them that CABs are "accredited" are competent to carry out the work they undertake, within their scope of accreditation.

29. Authorities often will only recognize Accreditation Bodies (ABs) that are members of the International Accreditation Forum (IAF) which focuses on issues related to consistent accreditation of certification bodies; or the International Laboratory Accreditation Cooperation (ILAC), which focuses on issues related to consistent accreditation of laboratories and inspection bodies. Both ILAC and IAF require that their ABs and CABs comply with appropriate international standards and mandatory documents for the consistent application of those standards. AB members of the IAF Multilateral Recognition Arrangement (MLA) conduct regular evaluations of each other to assure the equivalence of their accreditation programs, and a similar process is conducted through ILAC's Mutual Recognition Arrangement (MLA).

30. In other cases Governments will rely on "peer assessment". This means that to join the collective of bodies that are recognized, the applicant will be asked to satisfy an assessment carried out by other members of the collective, in other words the peers of the applicant. Peer assessment is at the heart of "international schemes for the assessment of conformity". These schemes offer authorities a large set of tools for the verification of both the provisions and the results of conformity assessment. The text box gives details.

Conformity assessment schemes

The International Electrotechnical Commission's (IEC) System of Conformity Assessment Schemes for Electrotechnical Equipment and Components (IECEE) is one example of a multilateral scheme for assessing conformity with standards. The scheme helps facilitate international trade in electrical and electrotechnical equipment, primarily intended for use in homes, offices, industrial plants and healthcare facilities by removing obstacles to international trade which arise from having to meet different national certification or approval criteria.

The Scheme is based on the principle of mutual recognition (reciprocal acceptance) by its members of test results for obtaining certification or approval at national level. In practice, when exporting a product covered by this scheme, a producer can choose to have his products tested and certified by the conformity assessment body of his choice. He can then use the test reports and certificates he obtains from this body to obtain national approvals in many other participating countries (see www.iec.ch and www.iecex.com). These will only carry out an administrative review of the documents, and will issue their national certification, without any re-testing of the product, because they recognize and have confidence in the testing and assessment that has already been done. Created in 1996, it has grown to a membership of 55 countries and delivered over 80 thousand certificates in 2013.

31. OECD (2006) already asked the legitimate question of why, despite an abundance of tools that are well recognised in the market, recognition of these schemes and tools by regulators is not common (although it is since then at least in part increasing). The OECD survey validates the hypothesis that regulators have a deeply engrained reluctance in trusting testing conducted in third countries. How that trust can be gained will be the subject of the last paragraph of this paper – that points to the need for improved dialogue

between standards bodies and regulators, and also among regulatory authorities, to win acceptance. We will return to this point further.

B. The mutual recognition of the results of conformity assessment

32. A further step in the "ladder of ambition" involves with the recognition by government bodies of results of conformity assessment procedures (i.a. test reports, certificates and inspection) conducted by relevant bodies in trading partner.

33. To ease the burden of proving compliance with technical regulations and to avoid duplication of testing, agreements have been formed with the purpose to enable firms to conduct conformity assessment in the home country with the regulations of the country where the products are to be sold. The parties in such an agreement are thus still free to formulate their own regulations, which is why MRAs of this type just partly remove TBTs.

34. In this form of MRAs the parties can designate Conformity Assessment Bodies (CABs) that have the right to assess conformity of technical rules and standards of the other part. In practice this implies that the authorities of one part reveal some of the enforcement of technical regulations to the other part. Such a system requires mutual confidence that the system of the other part is effective and can deliver reliable results. Examples of these MRAs are the bilateral MRAs between EU on the one hand and Australia, New Zealand, Canada, the US and Japan on the other. Other MRAs have been concluded between the countries within APEC. Overall, about 40 government-to-governments MRAs have been notified to the WTO.

35. MRAs of this type have shown to be complex both in negotiation and implementation. OECD (2009) has also extensively researched the effects on trade of MRAs, concluding that these effects tend to be lower than expected, due to a number of factors including: the lengthy negotiation time, the fact that they tend to pressure countries with less stringently regulated systems to introduce more regulation than they believe to be necessary, the need for constant regulatory dialogue to adjust the MRA to market developments, among others.

36. Evaluations[11] of the agreements led to the European Commission in 2001 concluding that MRAs are only worth negotiating if the certification systems are not too different, if the regulatory infrastructures are not too different, and if trade between the parties is sufficient to justify the cost.

37. The experience shows that, despite MRAs being in place, it has been hard to establish the necessary mutual trust so that in practice business hardly use this opportunity. Further, this has shown to be more difficult the larger the regulatory differences are between the parties.

C. Recognition of equivalent technical regulations (MRA+, ACAA and PECA)

38. Even in cases where technical regulations differ a possibility to create increased market access between parties exists if the parties recognize their respective regulations as equivalent. A prerequisite for recognition is that the regulations of the parties have the same regulative objectives, which also could be expressed as having the same effect. In such cases the parties can agree that products that fulfil the requirements of one member are

[11] E.g. Hogan & Hartson LLP (2003).

allowed to be placed on the market of the other member(s). This type of agreement is recommended in the WTO/TBT Agreement.

39. An example of an agreement of this type is the MRA between the US and EU on maritime equipment, which is based on regulations developed under the Conventions of the International Maritime Organization (IMO). The Agreement is based on international, within the IMO, agreed definitions of equipment, which is to be covered by mutual recognition. For each product, relevant equivalent regulations in the US and EU are identified. This agreement also opens up for negotiations with third countries. Thus, this bi lateral agreement between the EU and the US could be developed into a plurilateral agreement with other interested countries. The experience of this type of agreement is that it is considered to be well- functioning.

40. When it comes to agreements between EU and neighbouring countries alignment mechanisms are used in order to achieve functioning regulative cooperation. The alignment mechanism requires that accession or neighbour countries achieve full conformity with Community technical regulations and conformity assessment procedures. This can be done on full scale, like in the cases of the pre EU accession strategy (in the field of free movement of goods) of certain countries in forms of PECAs, or, where alignment is achieved in few specific sectors based on prioritized sectors in form of ACAAs. The different degrees of alignment processes aim to integrate third countries to the union in the area of free movement of goods, and expand trade, without putting certain EU interest, like public protection, on stake.

41. As the alignment mechanisms are relatively new the real effects of the mechanisms are hard to evaluate. A prerequisite for successful alignment in the area of free movement of goods is, however, that the legislative alignment is followed by practical implementation of organizational and methodical systems. There is evidence from trade related technical assistance that legislative implementation is not always followed by practical implementation of the system, but that principles of the European alignment of technical regulations and conformity assessment merely exist on paper in countries integrating with the EU.

42. In relation to ACAAs, problems occur when only certain product sectors have been subjected to alignment and others are left out, creating confusion of the underlying principles of technical harmonization. It must also be observed that in transition economies pre-accession process often start with building up the national conformity assessment infrastructure (based on the EU system with large freedom of the manufacturer) while the enforcement infrastructure, with market surveillance, gets less attention. This naturally creates problems in trade with countries with no, or very weak, consumer protection.

43. As a result the most important factor in achieving successful technical harmonization in transition economies and accession countries is not the technical assessment projects as such, but the quality of measures that are taken for infrastructure development as well as for the quality of conformity assessment, enforcement and consumer protection.

V. The UNECE International Model for Technical Harmonization

44. These elements are also a foundation of regulatory cooperation as developed within the framework of the United Nations, as based on the approach outlined in UNECE Recommendation “L” (UNECE, 2001). It enshrines the International Model – i.e. a set of principles and procedures that countries can implement to approximate technical regulations among themselves in one specific sector.

45. At the core of the model is the concept of common regulatory objectives (CROs) which are jointly drafted by regulators wishing to approximate their regulations in a specific sector, and should address legitimate concerns for the sector(s) in question with regard to public health, safety, environmental protection and other relevant national interests. These CROs are in practice defined with reference to applicable international standards, and also specify how to assess compliance with these standards. If relevant, CROs should include a list of conformity assessment bodies that are recognized as competent, e.g. through detail ways to be accredited. Additionally, and to recognize that increasingly conformity assessment is only one way of ensuring compliance, CROs should include market surveillance provisions.

46. The International Model promotes a "standards-receptive regulatory" approach, which is also one of the cornerstones of the European regulatory model, described in the box below. One difference between the two models is that the UNECE one is a bottom up approach – based on an initiative by the industry and the private sector - whereas the EU is essentially top down.

47. In the International Model, while standards are used as the basis for regulation, regulators are first to agree on if and why there is a need to regulate in that sector in the first place and what the purpose of regulation is. There is also a need for coherence of their regulation(s) in order to refer to/use the same international standard(s). This echoes the conclusions of a pilot study by OECD (July 2010):

"...there is no point in encouraging a country to use international standards as a basis of regulation of a given issue if that country does not regulate that issue in the first place...".

EU's "New Approach"

The EU's "New Approach" was introduced in a European Council resolution of May 1985. It is based on the principle that "the objectives being pursued by the Member States to protect the safety and health of their people as well as the consumer are equally valid in principle, even if different techniques are used to achieve them".

The resolution lists the main principles for the division of labour in technical regulation among the parties involved and calls for a "a clear separation of responsibilities between the EU legislator and the European standards bodies CEN, CENELEC and ETSI in the legal framework allowing for the free movement of goods".

The main concept behind this European regulatory model and of the corresponding regulatory process is the following:

(a) European Commission directives define the "essential requirements" for goods, which primarily cover health and safety issues.

(b) Once the essential requirements have been defined, the European standards bodies are tasked with developing the corresponding technical specifications whose application would enable the essential requirements of the directives to be met. Compliance with these standards will provide a presumption of conformity with the essential requirements. The specifications are referred to as "harmonized standards". Such standards must offer a guarantee of quality with regard to the essential requirements of the directives.

(c) A producer thus has several options for showing proof of conformity with the essential requirements, as follows:

(i) Products manufactured in conformity with harmonized standards are presumed to be in conformity with the essential requirements.

(ii) Standards are not mandatory, and a producer may choose other ways to show

proof of compliance.

The flexibility of the New Approach is linked to the following features:

(a) It indicates what has to be achieved, but not the details of the corresponding technical solutions.

(b) It presents different options for conformity assessment.

(c) It does not necessitate regular adaptation to technical progress.

48. Within the cooperation in the UNECE - there are currently three initiatives of cooperation with the aim to obtain converging rules in the areas of Earth- moving machinery, Telecommunication Equipment, and Equipment for explosive environments. In the next paragraph, the last of these initiatives is presented in more detail.

VI. The UNECE initiative on equipment used in environments with explosive atmosphere: a case study

49. Mines, offshore platforms, chemical and energy plants are amongst the world's most risky environments. Unsurprisingly, each of these environments is associated in our minds with several tragic accidents, which have resulted in casualties, environmental degradation and widespread human suffering and economic losses.

50. This does not need to be so. Safety in these and other high risks sectors, characterized by a high likelihood of explosions, is an attainable goal, if it becomes a shared priority for all stakeholders involved, and if sufficient resources are allocated to it by policymakers acting cohesively and decisively, at local, regional and global levels.

51. Explosion protection is an essential part of the overall risk management to be conducted for mines and industrial plants, to ensure safety in industrial processes using or producing hazardous materials like – for example – flammable liquids, combustible gas, or vapors. It is also used widely in environments where combustible dusts are likely to occur in quantities sufficient to cause a fire or explosion; for instance, in the chemical and oil industry, gas stations, facilities for handling and storage of grains, woodworking areas and sugar refineries.

52. The equipment used in plants where these processes are carried out and the overall design of the plants where explosions may occur is increasingly based on a single engineering approach and on the fundamental principles of explosion protection, which have been applied for over 100 years. These principles are codified in international standards which are also at the basis of a product certification systems scheme: the IEC System for Certification to Standards relating to Equipment for Use in Explosive Atmospheres (IECEx)12.The significance of the international standards upon which the industry relies can be seen by the increased participation in IEC Technical Committee, TC 31: Equipment for explosive atmospheres, which reached 44 countries as of April 2009, either participating or observing.

53. Many national and regional regulations already use the technical requirements contained in the international standards drawn up by IEC TC 31, which, in cooperation with ISO, also develops standards covering non-electrical equipment (mechanical). The ISO and IEC International Standards are increasingly adopted by participating countries either in

[12] www.icex.com

full, without any variation, or in part, with supplementary requirements contained in national standards.

54. Countries use these standards in their regulations in different ways, including: a) by making standards mandatory through a legislative act; b) by making compliance with the standards a means of proving compliance with the essential health and safety requirements laid out in the legislation: under this approach, equipment that complies with the provisions of the standards is "deemed to comply" with the requirements specified in the regulations.

55. There can be no doubt that international standards are in this sector a shared and common basis for all stakeholders, including the industry, the regulators, as well as conformity assessment and accreditation bodies. However, national laws and regulations are still diverging, and at times indeed conflicting in their requirements. In addition, many regulatory environments emphasize the mandatory approval by domestically recognized notified bodies of all imported equipment. 13

56. This makes it difficult to open markets for explosion-protected equipment and services and is against the interest of both industry and consumers. Indeed, repeated testing does not lead to additional safety, but only to additional costs. It means - indeed paradoxically - that safe and reliable equipment becomes so costly that it is unaffordable precisely for those countries that need it the most.

57. Mandatory national certification also results in very high costs for international trade. One private company, active in the sector of instruments for level measurement, flow measurement and pressure measurement reported product type certification costs of more than 100,000 euros per year and delays of 1.2 years in reaching global markets.[14] These costs are likely an even larger share of turnover and profits for SMEs.

58. It should also be noted that certification costs, unlike import tariffs, are sunk costs. In other words, if a producer sends equipment for testing abroad, so as to be able to place it on international markets, and the equipment is rejected, the company does not simply lose a fraction of its gains. It indeed stands to lose the whole of the costs incurred in producing and shipping the equipment, and conducting all the necessary preparatory processes.

59. While costs of repeated testing and certification are large for all producers, they have a disproportionate impact on producers from developing and transition economies. These countries in fact lack adequate testing facilities and internationally accredited certifying bodies. For this reason, the costs for the local industry in accessing international markets are especially high. The adoption of a shared regulatory framework at a global level in this sector would allow:

- Increased safety for workers, communities living in the vicinity of plants, and the natural environment;
- Lower costs for international trade;
- More opportunities for producers from countries with economies in transition and developing countries.

60. Against these findings and expectations, a sectoral initiative was launched by the UNECE Working Party on Regulatory Cooperation and Standardization Policies in 2006. The aim of the United Nations involvement in the sector was to act as the catalyst for a

[13] For an extensive analysis of regulations applied in this sector in major markets, please see: http://www.unece.org/trade/wp6/sectoralinitiatives/equipmentforexplosiveenvironment/sieee.html
[14] http://www.unece.org/fileadmin/DAM/trade/wp6/documents/2010/Presentations/Klotz-Engmann.pdf

broad and global coalition of forces aiming at ensuring the safety of high-risks facilities. Members agreed that this action would contribute to the organization's most important goals: protecting workers, consumers, and more broadly, all citizens and human beings, and all forms of lives, from hazards. And additionally, promoting development that is in keeping with the needs of present and future generations.

61. The Sectoral Initiative on Equipment for Explosive Environments (SIEEE) informally started its work in 2007 by gathering details of the regulatory systems applied in different countries through a questionnaire. The answers received documented the fact that – noted above – notwithstanding the wide application of standards by all stakeholders – costs of trade in the sector remained wide and regulatory regimes were still widely divergent.

62. The SIEEE went on to develop a first draft of the CROs that were discussed at two successive meetings held back to back to the meetings of the IECEx to ensure a maximum involvement of relevant stakeholders. The CROs developed by the Sectoral Initiative were then approved by the Working Party at its 2010 Annual Session and later published as a bound volume, which would be translated in many languages.15

The CROs contain:

(a) A detailed description of essential requirements for producers of equipment used in environments with an explosive atmosphere, as well as for owners and operators of plants in which these are used;

(b) A precise reference to the international standards where these requirements are laid out;

(c) How compliance with these standards should be assessed if relevant prior to the placement of the equipment on the market;

(d) How a continued surveillance of the equipment, as well as of the plants and facilities where they are used should be ensured.

63. Meeting in Split, Croatia, on 7 and 8 September 2011, policymakers from Australia, Brazil, the European Union (EU), the Russian Federation and the United States declared that "global harmonization promoted and adopted at UNECE is beneficial", in particular because it "allows for reduced government liability without increasing risk to workers, and consequently enables authorities to allocate more resources to field work" and it is "fully consistent with international obligations under the WTO agreement"16.

64. Since their adoption, a dedicated taskforce has been conducting awareness-raising activities for the benefit of regulators. The initiative appears to have been broadly successful in establishing and detailing a "turn-key" model for regulatory action, but would need to be further supported by dedicated means for further adoption by regulatory authorities, especially in developing countries.

[15] See: http://www.unece.org/trade/wp6/SectoralInitiatives/EquipmentForExplosiveEnvironment/SIEEE.html for details.

[16] See press release : http://www.unece.org/index.php?id=26114

VII. A practical recommendation for the way forward: basic steps to establish a common regulatory framework

65. In practice, as the Case Study reviewed above shows, applying the UNECE Recommendation "L" to other sectors, or as the basis for coherent regulations internationally is relatively straightforward and builds on a succession of well-defined steps. These include:

(a) Initiative by the private sector documenting excessive costs of trade in specific sector and backed up by:

(i) Studies by international experts documenting the costs of trade;

(ii) Existing bilateral/regional initiatives by one or more countries to harmonize their technical regulations in the same sector;

(iii) Feasibility of cooperation documented by a strong body of global standards

(b) Setting up of an open-ended task force. Based on an initial assessment by the Working Party, an open-ended task force composed of interested country-representatives and representatives of standards bodies and the business community can be set up jointly to discuss what are the common regulatory objectives that countries would agree to pursue, in terms of safety, health, environmental protection and other legitimate Government concerns about the products or group of products in question.

(c) Drafting an arrangement – a common regulatory objective or CRO - that will cover the following elements:

- A statement of the scope of the proposed initiative
- Product requirements
- Reference-to-standards
- Compliance and conformity assessment
- Market surveillance

66. The process could perfectly well stop here, with the outcome being that of an openly agreed framework that comprises all the elements that are necessary for regulating in a specific sector. The framework could then be used as a "turn-key", ready to use framework for countries that do not already have regulations in that sector, or as the basis for approximating regulations in a given sector.

67. Should countries wish to go beyond this base arrangement, they can decide to incorporate the CROs into their respective national legislation, and start a formal process of agreement as that described in the Annex B of the Recommendation L, which is reproduced at the end of this paper. That would entail practical changes to the participating countries' trade procedures. In the end, countries that agreed on CROs must ensure that products which comply with them can be placed on their market for free circulation without being subject to any additional product or conformity assessment requirements (such as testing or certification).

68. Concretely we propose that this menu is discussed as a common basis and ground for regulatory cooperation internationally (trans-nationally), and that the Recommendation L on which this menu is based be officially endorsed by the WTO as a recommended way to establish regulatory cooperation mechanisms. The Recommendation L is currently under revision, and the current revised draft is made available as an Annex to this paper.

VIII. Conclusions

69. The results on the ground of the “current menu” of options is deepening regulatory fragmentation in key economic sectors, high rates of non-conformity of products on the market, while the basic problem of establishing mutual trust among regulators is still not resolved. Additionally, the regulatory community at a global level is not presently capable of the coherent regulatory framework that we need internationally to respond to the new UN mandates (from the Sendai Conference on Disaster Risk Reduction, to the SDGs, to the hoped for Paris climate change agreement).

70. Most regulatory co-operation arrangements other than full harmonization have only resulted in a partial elimination of TBTs covering specific aspects. On the other hand, full market access ("free circulation") through full harmonization has normally to carried huge costs.

71. What alternative approaches are possible? What contribution can come from the private sector and the financial community? As the paper has exemplified, there are a multitude of instrument to use in the complex work to eliminate or reduce the effect of TBTs.

72. Which instrument to use depends on the situation at hand, e.g. on the degree of regulatory difference between the parties or on whether appropriate international standards exist in a particular sector and the amount of trade. Since the work of avoiding TBTs is of long term character, and it easily falls into complex negotiations it is important to be careful in the choice of level of ambition based on the expected result and the economic potential of a measure.

73. Different types of arrangements and measures are thus required. With regard to the general relationship between trade in goods and services, the methods at hand to avoid obstacles to trade from technical regulations or standards do not differ in substance. Thus, a strategy to avoid TBTs may well be applied to trade in services as well as in goods.

74. A fundament in the effort to avoid TBTs is to apply good regulatory practice (GRP) also from a trade perspective in the preparation, adoption and implementation of technical regulations and standards. If countries follow such principles of the WTO/TBT Agreement, on e.g. transparency and non-discrimination, it would be a substantial achievement in the efforts to avoid TBTs. This is not the least important in the field of services.

75. The efforts to develop and implement GRP domestically should continue. Active participation on information exchange and further developments of good regulatory practice within the WTO/TBT Committee in combination with technical assistance in this area to developing countries should continue to be a priority. Further, the OECD conducts important work in this area in the form of studies and country peer reviews, which needs to be continued in order to further develop the concept and identify best practice as well as to increase the efficiency in implementation. International cooperation in the field of GRP between the OECD and other organizations such as APEC should also be supported.

76. One important aspect of regulatory cooperation is trade policy dialogue between countries (including all relevant stakeholders) and the UNECE WPon Regulatory cooperation and Standardization policies provides an ideal forum for this.

77. Solving existing TBTs is also important. A TBT strategy should include a long-term strategy to avoid TBTs in new legislation based on GRP and regulatory cooperation. Therefore, the efforts to reduce TBTs in existing fora for regulatory trade dialogue, in the WTO/TBT Committee and through MRA-based solutions are needed.

78. MRA on results of conformity assessment procedures have however shown disappointing results. Complex and costly negotiations have been followed by practical problems and slow implementation. Previous conclusions by the EU on MRAs with trading partners imply that such agreements should only be negotiated when the regulatory differences between the parties are not too large and when trade is sufficient to justify the cost of such an investment. The focus should instead be on MRA of equivalent technical regulations (MRA+). Such agreements are possible only when such equality is codified e.g. in a specific agreement. Therefore, it should be worth aiming at effective participation in the work and support to the efforts within UNECE and other relevant international organizations to increase equivalence of technical regulations on international level. Within the area of standardization, the work should focus on promoting increased identity between regional and international standards.

79. Emphasis should be made to use standards receptive regulatory models such as the "International Model" developed by the UNECE in regulatory trade-related cooperation. When it comes to developing countries technical assistance is needed both as regards to governments developing and implementing quality infrastructures and to firms to ease the burden of complying to mandatory requirements as well as to product specification demanded by business partners.