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Regulatory Cooperation: A Wikihow

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EXECUTIVE SUMMARY

This think-piece presents a roadmap for countries to enhance regulatory coherence across jurisdictions by engaging in regulatory cooperation, 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 to not only customise their products so that they comply with different and sometimes conflicting regulations, but also often test and certify them multiple times over to ensure that compliance is proved to the satisfaction of the local authorities. 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 gross domestic product (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 small. 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. Following a review of the different options for increased regulatory coherence and cooperation among countries that wish to increase coherence between their respective regulatory systems, the paper looks at the national discipline that grounds bilateral, regional, or international regulatory cooperation. It then presents practical tools that are available to regulators to enhance regulatory coherence, including the United Nations Economic Commission for Europe's (UNECE) "International Model for Regulatory Cooperation," and presents the example of an initiative that was based on it.

The results on the ground of the current menu of options is deepening regulatory fragmentation in key economic sectors, and high rates of non-conformity of products on the market, while the basic problem of establishing mutual trust among regulators has still not been resolved. Additionally, the regulatory community at the global level is not now capable of the coherent regulatory framework that we need internationally to respond to new UN mandates. Most regulatory co-operation arrangements other than full harmonization have only resulted in a partial elimination of Technical Barriers to Trade (TBTs) covering specific aspects. On the other hand, full market access (free circulation) through full harmonization has normally to be carried out at huge costs.

What alternative approaches are possible? What contribution can come from the private sector and the financial community? As the paper exemplifies, there are a multitude of instruments to use in the complex work to eliminate or reduce the effect of TBTs. Which instrument to use depends on the situation at hand, for example, 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. 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. A fundament in the effort to avoid TBTs is to also apply good regulatory practice (GRP) from a trade perspective in the preparation, adoption, and implementation of technical regulations and standards. This is also important in the field of services. Active participation on information exchange and further developments of GRP within the TBT Committee, in combination with technical assistance in this area to developing countries, should continue to be a priority. International cooperation in the field of GRP between the OECD and other organizations such as the APEC should also be supported. One important aspect of regulatory cooperation is trade policy dialogue between countries (including all relevant stakeholders) and the UNECE WP on Regulatory Cooperation and Standardization Policies provides an ideal forum for this.

Solving existing TBTs is also important. A strategy should include a long-term plan of action to avoid TBTs in new legislation based on GRP and regulatory cooperation. Therefore, efforts to reduce TBTs in existing fora for regulatory trade dialogue, in the TBT Committee and through Mutual Recognition Arrangement- (MRA) based solutions, are needed.

MRAs on results of conformity assessment procedures have, however, shown disappointing results. Complex and costly negotiations have been followed by practical problems and slow implementation. The focus should instead be on an MRA of equivalent technical regulations (MRA+). Such agreements are possible only when such equality is codified, for example, in a specific agreement. Therefore, it should be worth aiming at effective participation in the work of the UNECE and other relevant international organizations to increase equivalence of technical regulations at the international level. In the area of standardization, the work should focus on promoting increased identity between regional and international standards. Emphasis should be made to use standards-receptive regulatory models such as the International Model in regulatory traderelated cooperation. When it comes to developing countries, technical assistance is needed both to governments developing and implementing quality infrastructures and to firms to ease the burden of complying to mandatory requirements and product specifications demanded by business partners.

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LIST OF ABBREVIATIONS

ABs	Accreditation Bodies
ACAA	Agreements on Conformity Assessment and Acceptance of Industrial Products
APEC	Asia-Pacific Economic Cooperation
ASEAN	Association of Southeast Asian Nations
CABs	conformity assessment bodies
CASCO	Committee on Conformity Assessment
CROs	common regulatory objectives
EU	European Union
FTA	free trade agreement
GDP	gross domestic product
GLP	good laboratory practice
GRP	good regulatory practice
IAF	International Accreditation Forum
IEC	International Electrotechnical Commission
IECEE	System of Conformity Assessment Schemes for Electrotechnical Equipment and Components
IECEx	IEC System for Certification to Standards relating to Equipment for Use in Explosive Atmospheres
ILAC	International Laboratory Accreditation Cooperation
IMO	International Maritime Organization
ISO	International Standards Organization
MLA	Multilateral Recognition Arrangement
MRA	Mutual Recognition Arrangement
OECD	Organisation for Economic Co-operation and Development
PECA	Protocol to the European Agreements on Conformity Assessment and Acceptance of Industrial Products
RIAs	regulatory impact assessments
SDGs	sustainable development goals
SIEEE	Sectoral Initiative on Equipment for Explosive Environments
SMEs	small and medium-sized enterprises
SPS	Sanitary and Phytosanitary
TBT	Technical Barriers to Trade
UN	United Nations
UNECE	United Nations Economic Commission for Europe
US	United States
WTO	World Trade Organization

LIST OF ABBREVIATIONS USED IN THE 'INTERNATIONAL MODEL'

CAB	Conformity Assessment Body
CRO	Common Regulatory Objective
ISB	International Standardizing Body
PC	Protection Clause
RCAB	Recognized Conformity Assessment Body
SDoC	Supplier's Declaration of Conformity
TR	Technical Regulation
UNECE	United Nations Economic Commission for Europe

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INTRODUCTION

This think-piece 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 the sectoral and cross-sectoral levels—thus excluding more general and fundamental laws and by-laws.

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 to not only customise their products so that they comply with different and sometimes conflicting regulations, but also often test and certify them multiple times over to ensure that compliance is proved to the satisfaction of the local authorities, according to the legislation in place in each national market.

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 gross domestic product (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 small.[1] 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.

The paper is organized as follows. The next section reviews the different options for increased regulatory coherence and cooperation among countries that wish to increase coherence between their respective regulatory systems. The following looks at the national discipline that grounds bilateral, regional, or international regulatory cooperation, while the fourth section presents practical tools that are available to regulators to enhance regulatory coherence. The fifth section presents the United Nations Economic Commission for Europe's (UNECE) "International Model for Regulatory Cooperation," a simple tool that allows for full coherence not just of regulatory objectives, but of regulatory frameworks as well. The sixth section presents the example of an initiative that was developed on the basis of this model. The seventh section puts forth practical recommendations for the way forward, while the eigth concludes.

THE CURRENT MENU

"Regulatory systems coherence," as defined by the E15 Taskforce, could—with regard to international trade policy cooperation—be looked at as being made up of two "segments."

– The disciplines on national regulatory practices; and

– different levels of trans-national regulatory cooperation for establishing various types of arrangements.

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.

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

The first two steps relate to national practices.

a) Observance of good (national) regulatory practice (the World Trade Organization's [WTO] Technical Barriers to Trade [TBT] Agreement, the Asia-Pacific Economic Cooperation [APEC], the Organisation for Economic Co-operation and Development [OECD], and so on).

b) Transparency measures (TBT Agreement, regulatory dialogues, and so on).

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

c) Recognition by government bodies of tests and conformity assessment procedures conducted by trading partners as well as recognition of accreditation systems.

d) Recognition by government bodies of the results of conformity assessments procedures conducted by trading partners for accepting products certified elsewhere into their respective markets.

e) Recognition by government bodies of functionally equivalent technical regulations.

f) Establishment of fully harmonized technical regulations.

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

GOOD REGULATORY PRACTICE

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.

Effectively, these principles are defined in World Trade Organization (WTO) agreements—more specifically in the Agreements on Technical Barriers to Trade (TBT) and on Sanitary and Phytosanitary (SPS) measures. This paper focuses mainly on the TBT area of work. In this area, the relevant discipline has been developed in the TBT Committee, 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.

The Committee has undertaken six successive triennial reviews (with the seventh going on), and, in this context,

TABLE 1:

Degrees of Regulatory Co-operation

Nature of action	Nature of action	Example of agreement
National practices (good regulatory practice)	Observance of principal trade policy provisions, non-discrimination, proportionality, use of international standards, and so on	- 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 - IECEEE, IECEx, and so on.
	Recognition of results of conformity assessment procedures - certificates of conformity - inspections - test results	- MRA - OECD's GLP - IEC System of Conformity IECEE, IECEx, and so on.
	Recognition of (functionally) equivalent technical regulations - product specifications (essential requirements and standards linked to those requirements) - marking specifications, marks etc.	- ACAA - PECA - UNECE "International Model" - European Union (EU)-South Korea free trade agreement (FTA) Annex on Automotives - NAMA (NTB annexes) - EU-United States (US) MRA on marine equipment
	Drawing up fully harmonized technical regulations	EU – harmonized area Eurasian Economic Union

Notes: OECD: Organisation for Economic Co-operation and Development; APEC: Asia-Pacific Economic Cooperation; ASEAN: Association of Southeast Asian Nations.

MLA: multilateral recognition agreements between accreditors; GLP: good laboratory practice; IECEE: IEC System of Conformity Assessment Schemes for Electrotechnical Equipment and Components; IECEx: Scheme for Certification to Standards for Explosive Atmospheres; ACAA: Agreements on Conformity Assessment and Acceptance of Industrial Products; PECA: Protocol to the European Agreements on Conformity Assessment and Acceptance of Industrial Products; NAMA: non-agricultural market access; NTB: non-tariff barriers; MRA: mutual recognition agreement.

Source: Adapted from "Methodological Arrangements to Avoid Technical Barriers to Trade," http://www.unece.org/fileadmin/DAM/trade/wp6/documents/2014/WP6_2014_11E.pdf.

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.[2] In broad terms, GRP involves a regulatory process based on non-discrimination, proportionality, and the use of international standards.

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).[3]

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 the Association of Southeast Asian Nations (ASEAN), APEC, the OECD, and the World Bank—have also promoted the development of GRP within their respective mandates.

At the United Nations (UN), 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; and
- how to achieve proportionality between risks and regulatory policies through the use of risk management tools.

As regards the first, the Working Party adopted a Recommendation 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."[4] The recommendation also provides that when indicative reference is considered unsuitable, regulatory authorities should make use of exclusive reference, which renders the standard or parts of the standard mandatory.

Reference to standards is indeed widely applied because it allows regulators to do the following.

- 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 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 industry's participation in international trade networks. When developing a regulation, regulators will want to align their requirements with those of their trading partners to avoid having different or contradictory requirements in different export markets.

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.

A second dimension of GRP is the proportionality between regulations and the risk that they address. Since 2009, the 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 unnecessarily exposing the public and the societal costs of developing and enforcing technical regulations. [5]

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 the 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 the following.

- 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.

2 WTO, Complilation of Sources on Good Regulatory Practices, G/TBT/W/341, 13 Sept. 2011, and Sixth Triennial Review.

3 Good Regulatory Practice (GRP): Voluntary Mechanisms and Related Principles, JOB/TBT/119/Rev.1

4 UNECE Recommendation D, "Reference to Standards," www.unece.org/fileadmin/DAM/trade/wp6/Recommendations/Rec_D.pdf.

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

TRANSNATIONAL ARRANGEMENTS

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.

These four categories are the last four "steps" of the "ladder of ambition" that was introduced above.

MUTUAL RECOGNITION OF CONFORMITY ASSESSMENT PROVISIONS AND PROCEDURES

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).

Conformity assessment and its mutual recognition is an important dimension—it helps validate the expectations of businesses customers, consumers, users, and the public about products and services relating to features such as quality, ecology, safety, economy, reliability, compatibility, interoperability, efficiency, and effectiveness. Within 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).

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.[6] By relying on conformity assessment in accordance with international standards, regulators and economic operators and other relevant stakeholderscan 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.

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 CABs. This mutual recognition can be carried out in several ways, including

- government recognition,
- accreditation, and
- peer assessment.

Governments can recognize 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.

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 that are "accredited" are competent to carry out the work they undertake within their scope of accreditation.

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 the ILAC and the IAF require that their ABs and CABs comply with appropriate international standards and mandatory documents for their consistent application. 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 the ILAC's Mutual Recognition Arrangement (MRA).

In other cases, governments will rely on "peer assessment." This means that to join the collective of bodies that is recognized, the applicant will be asked to satisfy an

6 For more details, see http://www.iso.org/sites/cascoregulators/01_4_conformity-assessment-recognition.html.

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 (Box 1 gives details).

The OECD (2006) has already asked the legitimate question of why, despite an abundance of tools that are well recognized 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 later.

MUTUAL RECOGNITION OF THE RESULTS OF CONFORMITY ASSESSMENT

A further step in the "ladder of ambition" involves the recognition by government bodies of the results of conformity assessment procedures (that is, test reports, certificates, and inspections) conducted by relevant bodies in trading partners.

To ease the burden of proving compliance with technical regulations and to avoid duplication of testing, agreements have been formed 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.

In this form of MRAs, the parties can designate 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 such MRAs are those between the 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 in the APEC. Overall, about 40 government-to-government MRAs have been notified to the WTO.

MRAs of this type have proved to be complex both in negotiation and implementation. The 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, that they tend to pressure countries with less stringently regulated systems to introduce more regulation than they believe to be necessary, and the need for constant regulatory dialogue to adjust the MRA to market developments, among others.

Evaluations 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,[7] if the regulatory infrastructures are not too different, and if trade between the parties is sufficient to justify the cost.

7 Hogan and Hartson LLP, May 2003, "The Economic Impact of Mutual Recognition Agreements on Conformity Assessment – A Review of the Costs, Benefits, and Trade Effects Resulting from the European Community MRAs Negotiated with Australia and New Zealand".

BOX 1:
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 that 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 the 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 more than 80,000 certificates in 2013.

The experience shows that despite MRAs being in place it has been hard to establish the necessary mutual trust, which, in practice, means business hardly uses this opportunity. Further, it shows that it is more difficult if the regulatory differences between the parties are larger.

RECOGNITION OF EQUIVALENT TECHNICAL REGULATIONS (MRA+, ACAA, AND PECA)

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 country are allowed to be placed on the market of the other country (ies). This type of agreement is recommended in the TBT Agreement.

An example of an agreement of this type is the MRA between the US and the EU on maritime equipment, which is based on regulations developed under the Conventions of the International Maritime Organization (IMO). The agreement is based on internationally agreed definitions of equipment (within the IMO), which is to be covered by mutual recognition. For each product, relevant equivalent regulations in the US and the EU are identified. This agreement also opens up for negotiations with third countries. Thus, this bilateral 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.

When it comes to agreements between the EU and neighbouring countries, alignment mechanisms are used to achieve functioning regulative cooperation. The alignment mechanism requires that accession or neighbouring countries achieve full conformity with the Community's technical regulations and conformity assessment procedures. This can be done on a 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 the Protocol to the European Agreements on Conformity Assessment and Acceptance of Industrial Products (PECA), or where alignment is achieved in a few specific sectors based on prioritized sectors in the form of Agreements on Conformity Assessment and Acceptance of Industrial Products (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 interests, like public protection, at stake.

As the alignment mechanisms are relatively new, their real effects 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, and that the principles of the European alignment of technical regulations and conformity assessments merely exist on paper in countries integrating with the EU.

In relation to ACAAs, problems occur when only certain product sectors have been subjected to alignment and others left out, creating confusion of the underlying principles of technical harmonization. It must also be observed that in transition economies the pre-accession process often starts with building up a 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.

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

THE UNECE INTERNATIONAL MODEL FOR TECHNICAL HARMONIZATION

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

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 the legitimate concerns

of 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 CABs that are recognized as competent, for example, through detailing ways to be accredited. In addition, to recognize that conformity assessment is increasingly only one way of ensuring compliance, CROs should also include post-market surveillance provisions.

The International Model promotes a "standards-receptive regulatory" approach, which is also one of the cornerstones of the European regulatory model, described in Box 2. One difference between the two models is that the UNECE one is a bottom-up approach—based on an initiative by industry and the private sector—whereas the EU is essentially top-down.

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) to refer to/use the same international standard(s). This echoes the conclusions of a pilot study by the OECD (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."

In the UNECE, there are currently three initiatives of cooperation with the aim of obtaining converging rules in the areas of earthmoving machinery, telecommunication equipment, and equipment for explosive environments. In the next part, the last of these initiatives is presented in more detail.

BOX 2:
The 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.

- European Commission directives define the "essential requirements" for goods, which primarily cover health and safety issues.
- 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.
- A producer thus has several options for showing proof of conformity with the essential requirements, as follows.
    - Products manufactured in conformity with harmonized standards are presumed to be in conformity with the essential requirements.
    - 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.

- It indicates what has to be achieved, but not the details of the corresponding technical solutions.
- It presents different options for conformity assessment.
- It does not necessitate regular adaptation to technical progress.

UNECE INITIATIVE ON EQUIPMENT USED IN ENVIRONMENTS WITH EXPLOSIVE ATMOSPHERE: A CASE STUDY

Mines, offshore platforms, and chemical and energy plants are among 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.

This does not need to be so. Safety in these and other high-risk 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 the local, regional, and global levels.

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 such as, for example, flammable liquids, combustible gas, or vapours. 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 storing grains, wood-working areas, and sugar refineries.

The equipment used in plants where these processes are carried out and the overall design of 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 more than 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). The significance of the international standards on which the industry relies can be seen by the increased participation in the IEC Technical Committee, TC 31: Equipment for Explosive Atmospheres, which had 44 countries as of April 2009, either participating or observing.

Many national and regional regulations already use the technical requirements contained in the international standards drawn up by the IEC TC 31, which, in cooperation with the ISO, also develops standards covering non-electrical equipment (mechanical). The ISO and IEC international standards are increasingly adopted by participating countries either in full, without any variation, or in part, with supplementary requirements contained in national standards.

Countries use these standards in their regulations in different ways, including a) by making standards mandatory through a legislative act; or 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 the latter approach, equipment that complies with the provisions of the standards is "deemed to comply" with the requirements specified in the regulations.

There can be no doubt that international standards in this sector are a shared and common basis for all stakeholders, including industry, regulators, and conformity assessment and accreditation bodies. However, national laws and regulations are still diverging, and at times even conflicting in their requirements. In addition, many regulatory environments emphasize the mandatory approval by domestically recognized notified bodies of all imported equipment.[8]

This makes it difficult to open markets for explosion-protected equipment and services and is against the interests 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 for those countries that need it the most.

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. These costs are likely an even larger share of turnover and profits for small and medium-sized enterprises (SMEs).

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 stands to lose the whole cost incurred in producing and shipping the equipment, and conducting all the necessary preparatory processes.

8 For an extensive analysis of regulations applied in this sector in major markets, see http://www.unece.org/trade/wp6/sectoralinitiatives/equipmentforexplosiveenvironment/sieee.html.

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 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 the global level in this sector would allow the following.

- 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.

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 UN involvement in the sector was to act as a catalyst for a 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 life from hazards. Additionally, it would promote development that is in keeping with the needs of present and future generations.

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

The SIEEE went on to develop a first draft of the CROs that were discussed at two successive meetings held back-to-back with IECEx meetings to ensure the 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 is to be translated into many languages. [9]

The CROs contain the following.

- 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.
- A precise reference to the international standards where these requirements are laid out.
- How compliance with these standards should be assessed if relevant prior to the placement of the equipment on the market.
- How a continued surveillance of the equipment, as well as of the plants and facilities where they are used, should be ensured.

Meeting in Split, Croatia, in September 2011, policymakers from Australia, Brazil, the EU, the Russian Federation, and the US 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."[10]

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.

A PRACTICAL RECOMMENDATION FOR THE WAY FORWARD: BASIC STEPS TO ESTABLISH A COMMON REGULATORY FRAMEWORK

In practice, as the case study shows, applying the UNECE "Recommendation L" to other sectors, or as the basis for coherent regulations internationally, is relatively

9 For details, see http://www.unece.org/trade/wp6/SectoralInitiatives/EquipmentForExplosiveEnvironment/SIEEE.html.

10 See press release, http://www.unece.org/index.php?id=26114.

straightforward and builds on a succession of well-defined steps. These include the following.

1. Initiative by the private sector documenting excessive costs of trade in a specific sector and backed by
    - studies by international experts documenting the costs of trade;
    - existing bilateral/regional initiatives by one or more countries to harmonize their technical regulations in the sector; and
    - feasibility of cooperation documented by a strong body of global standards.
2. Setting up an open-ended task force. Based on an initial assessment by the Working Party, an open-ended task force comprising interested country-representatives and representatives of standards bodies and the business community can be set up jointly to discuss what the CROs are 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.
3. Drafting an arrangement, 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.

The process could well stop here, with the outcome being 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," a ready-to-use framework for countries that do not already have regulations in that sector, or as the basis for approximating regulations in a sector.

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 Annex B of Recommendation L, which is reproduced in the Appendix. That would entail practical changes to participating countries' trade procedures. In the end, countries that agree 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).

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

CONCLUSIONS

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

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 be carried out at huge costs.

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 instruments to use in the complex work to eliminate or reduce the effect of TBTs.

Which instrument to use depends on the situation at hand, for example, 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 a long-term character and it easily falls into complex negotiations, it is important to be careful that the choice of level of ambition is based on the expected result and economic potential of a measure.

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.

A fundament in the effort to avoid TBTs is to also apply GRP from a trade perspective in the preparation, adoption, and implementation of technical regulations and standards. If countries follow the principles of the TBT Agreement, on, for example, transparency and non-discrimination, it would be a substantial achievement in efforts to avoid TBTs. This is also important in the field of services.

Efforts to develop and implement GRP domestically should continue. Active participation on information exchange and further developments of GRP within the 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 to further develop the concept, identify best practice, and to increase the efficiency in implementation. International cooperation in the field of GRP between the OECD and other organizations such as the APEC should also be supported.

One important aspect of regulatory cooperation is trade policy dialogue between countries (including all relevant stakeholders) and the UNECE WP on Regulatory Cooperation and Standardization Policies provides an ideal forum for this.
Solving existing TBTs is also important. A strategy should include a long-term plan of action to avoid TBTs in new legislation based on GRP and regulatory cooperation. Therefore, efforts to reduce TBTs in existing fora for regulatory trade dialogue, in the TBT Committee and through MRA-based solutions, are needed.

MRAs 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 an MRA of equivalent technical regulations (MRA+). Such agreements are possible only when such equality is codified, for example, in a specific agreement. Therefore, it should be worth aiming at effective participation in the work of the UNECE and other relevant international organizations to increase equivalence of technical regulations at the international level. In the area of standardization, the work should focus on promoting increased identity between regional and international standards.

Further emphasis should be made to use standards-receptive regulatory models such as the International Model developed by the UNECE in regulatory traderelated cooperation. When it comes to developing countries, technical assistance is needed both to governments developing and implementing quality infrastructures and to firms to ease the burden of complying to mandatory requirements and product specifications demanded by business partners.

APPENDIX

RECOMMENDATION L REVISION: INTERNATIONAL MODEL FOR TRANSNATIONAL REGULATORY COOPERATION BASED ON GOOD REGULATORY PRACTICE FOR THE PREPARATION, ADOPTION AND APPLICATION OF TECHNICAL REGULATIONS VIA THE USE OF INTERNATIONAL STANDARDS

The Working Party, noting that

a) there is a clear market need from trade and industry and a positive interest from Governments in further reducing trade barriers and facilitating market access and

b) that the "International Model" developed by the United Nations Economic Commission for Europe provides a voluntary framework for regulatory cooperation that facilitates market access through the use of good regulatory practice and options for establishment of sectoral agreements between interested UN member countries

c) that the "International Model" provides good regulatory practices that facilitates global harmonization of national or regional regulation

d) that the experience gained so far with the "International Model" and developments in international and regional fora shows the importance of a flexible voluntary mechanism for market access of products following relevant international standards and related practices.

Recommends:

- that regulators use the process outlined in Annex A to develop cooperation based on good regulatory practice in regulatory fields and accompanying trade and industry sectors.

- that countries wishing to go further and establish special operational transnational sectoral arrangements to use the process outlined in Annex B.

(Recommendation was adopted in 2001)

ANNEX A

PRINCIPAL ELEMENTS FOR REGULATORY COOPERATION BASED ON GOOD REGULATORY PRACTICE IN REGULATORY FIELDS AND ACCOMPANYING TRADE AND INDUSTRY SECTORS

The principal issues to be addressed by interested regulators in a Common Regulatory Objective (CRO) document, would include:

- Legitimate regulatory objectives that usually relate to public health, safety or environmental protection, etc.;

- Applicable international standards that contain requirements for systems, processes, products and services;

- Ways of assuring and demonstrating compliance with the CROs;

- Provisions on third-party-assessment bodies, when recourse to third party assessment is needed;

- Provisions for post-market surveillance.

The CRO would specify the following principal elements:

Scope statement

A statement of the products or product areas that are covered by the CRO.

Regulators should agree on the products for which legitimate regulatory objectives are required. For this purpose regulators may use international classification schemes such as the harmonized commodity description and coding system.

Product requirements

Legitimate regulatory objectives reflect the requirements to protect public interest in areas such as human health or safety, animal or plant life or health or the environment. The requirements needed for protection of legitimate objectives should lay down the principal issues of concern and be specified in terms of performance requirements rather than design or descriptive characteristics. Requirements should be limited to relevant aspects and be proportionate to the hazard inherent in a given product or product area.

The detailed provisions on how to meet the requirements of the CRO should preferably be specified in applicable

international standards. Such standards will be referenced in the CRO.

Reference to standards clause

The CRO should contain a list of applicable international standards that correspond as a whole or partially to the requirements.

The CRO may contain a provision that products complying with the referenced international standards are presumed to comply with the requirements.

Compliance clause

The CRO should contain a provision on how compliance is demonstrated.

Regulators should agree on the range and contents of possible conformity assessment procedures that are considered to give the necessary level of protection under the CRO. The CRO should also specify the conditions under which suppliers can make a choice if more than one option is provided for. Such options are, for instance, supplier's declaration of conformity, third party certification or inspection.

In considering such options regulators should aim to avoid duplicative conformity assessment testing and certification for products (and replacement parts that are included in the product certification) that add unnecessary costs and time delays.

When applicable, the CRO should also contain provisions on the conformity assessment bodies that are recognized to assess and attest compliance as well as the competence criteria to be fulfilled by such bodies.

Market surveillance clause

Regulators having agreed on CROs are responsible for market surveillance on their territory and have the right to withdraw products from their markets if these are not in compliance with the CRO.

The CRO should contain a provision (protection clause) that if products claiming conformity with a CRO that do not conform to its requirements, the regulator may, with the intention to preserve legitimate objectives, withdraw such a product from its market. Furthermore, the CRO should contain a provision that the regulator using the Protection Clause should state specifically what products have been removed from the market and what requirements of the CRO have been claimed to be met but have not been met.

In a case where products are in conformity with the CRO or the applicable international standard but are still found to endanger legitimate objectives, the regulator having agreed on a CRO could withdraw such products from the market or restrict free circulation. In this case, the use of the Protection Clause should also be subject to the condition that the regulator using it should indicate the reasons for this decision.

ANNEX B

ADMINISTRATIVE PROCEDURES AND INSTITUTIONAL PROVISIONS (INCLUDING THE CALL FOR PARTICIPATION IN FORMULATING 'COMMON REGULATORY OBJECTIVES' AND THE PREPARATION OF THESE OBJECTIVES)

Article 1

General Institutional Framework

1.1 The process of registering Common Regulatory Objectives (CROs) and interpreting the provisions of the "International Model" shall be the task of the UNECE Working Party on Regulatory Cooperation n and Standardization Policies (Working Party 6 – WP.6) which shall ensure coordination of the work on requests for technical harmonization received by the UNECE secretariat. If deemed appropriate, Working Party 6 could set up groups of experts to monitor and implement such work in practice.

Article 2

Call for Participation

2.1 Country/Countries shall make a "Call for Participation" through the UNECE secretariat to all United Nations Member States. The Call should contain the necessary information for formulating a CRO. Countries wishing to join the work under such a Call should respond to the secretariat, stating their interest to participate in the work.

2.2 Based on responses to the Call, an open-ended task force composed of interested countries shall be set up with the purpose to jointly develop CROs regarding the safety, health, environmental protection, and other legitimate concerns of governments regarding the products or group of products in question.

2.3 These open-ended task forces should work in a transparent way and participation in them shall be open at any moment to any other United Nations Member State that expresses the wish to join the work. The task forces will agree on their own working procedures. The task forces should inform the UNECE secretariat about their work which will be made publicly available by appropriate means (for example, via the Internet).

Article 3

UNECE Registry of Common Regulatory Objectives

3.1 A registry shall be created and maintained by the UNECE secretariat for the CROs developed under the "International Model". The registry shall be known as the "UNECE Registry for CROs".

3.2 The countries that agreed on a CRO shall submit it to Working Party 6 through the UNECE secretariat.

3.3 The agreed CRO specified in the paragraph above shall contain the principal elements as set out in annex B to the "International Model". The CRO shall not be prepared, adopted or applied with a view to or with the effect of creating unnecessary obstacles to international trade.

3.4 If formal elements in the agreed CRO (as specified in the Model) are met, the CRO shall be considered to be established in the UNECE Registry on the date of its submission to the UNECE secretariat.

3.5 The secretariat shall, when registering the CRO, append copies of all relevant documentation to that CRO. All documentation received by the UNECE secretariat under the provisions of this Article shall be made publicly available by appropriate means (for example, via the Internet).

3.4 The process of the further revision of the already agreed CROs should follow procedures as specified under Article 2 above.

Article 4

National Adoption and Notification of application of Registered Common Regulatory Objectives

4.1 A country that has agreed on a CRO shall submit the CRO to the process used by it to adopt technical requirements specified in the CRO into its own legislation. Any other country at any time may inform the UNECE secretariat about its intention to implement and use the CRO (and, thus, it will follow the procedures as specified under this Article).

4.2 A country that adopts a CRO into its own legislation shall notify the UNECE secretariat in writing of the date on which it will begin to apply that CRO. The notification shall be provided by the country within 60 days after adoption of the CRO.

4.3 A country that is specified in paragraph 1 of this Article and that has not, by the end of the one-year period after the date of the registration of the CRO in the UNECE Registry, adopted the CRO into its legislation, shall

report on the status of the CRO in its domestic process. A status report shall be submitted for each subsequent one-year period if no such action has been taken by the end of that period.

4.4. A country that is specified in paragraph 1 of this Article and that accepts products that comply with the technical requirements of a registered CRO without adopting the CRO into its own legislation shall notify the UNECE secretariat in writing of the date on which it began to or will begin to accept such products.

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