# Update on the UNECE Activities in Regulatory Cooperation

# World Trade Organization – TBT Committee

## 20-22 March 2012

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## In a Nutshell

Regulatory cooperation to avoid unnecessary barriers to trade while promoting sustainable development, protecting consumers and workers' health and safety and preserving the natural environment

The Working Party on Regulatory Cooperation and Standardization Policies (WP.6) is an intergovernmental body, open to the participation of business, standards-making bodies, civil society and other international organizations as well as private individuals, from any of the United Nations Member States. It holds one plenary session every year, while working on a continuous basis through groups of experts.

It develops and shares best practices in the areas of: technical regulations and regulatory cooperation; standardization policies, conformity assessment; consumer protection; market surveillance; and related activities at national, regional and international level. A recent area of focus for the Working Party has been how regulatory activities within this mandate contribute to manage risks that confront citizens, businesses and communities.

#### Its main deliverables are:

- Recommendations aimed at facilitating international trade through the harmonization of national policies and the promotion of best practices based on good-governance principles in all the areas within its mandate;
- Common frameworks of technical regulations for key sectors of economic activity based on international standards. These frameworks can set the basis for national legislation or be used as a basis for regulatory convergence among countries;
- Advisory services and capacity-building projects for countries or regional groups aimed at implementing best practices in standardization, regulatory cooperation, conformity assessment and market surveillance.

This report will provide an update on the work of WP.6. For more detailed information, connections with our network of experts or any other queries do not hesitate to contact us at <a href="mailto:Regulatory.Cooperation@unece.org">Regulatory.Cooperation@unece.org</a>.

## I. INTRODUCTION: MAIN AREAS OF ACTIVITY

- 1. WP.6 works both at a vertical level by promoting convergence of regulations in specific sectors and at a horizontal level, by sharing best practices in regulatory activities related to the development and implementation of technical regulations.
- 2. In this report we will sketch out:
  - The principles on which regulatory cooperation is based (paras. 3-7);
  - The related initiatives for regulatory cooperation developed at a sector level (paras. 10-28);
  - The work related to risk management in regulatory frameworks, which aims at building regulatory systems that provide the desired level of safety without creating unnecessary barriers to trade (paras. 29-38);
  - The work related to market surveillance (paras. 39-43); and
  - On-going work in related areas (section IV).

#### II. THE DRIVING PRINCIPLES OF OUR WORK

- 3. Regulatory cooperation in the UNECE starts from the assessment of a need for regulatory convergence in a specific sector. This assessment may come from one or more UN Member States and is generally based on the excessive costs of trade, the safety concerns arising from the coexistence of different safety rules, and the wish to avoid the delays related to duplicate tests and certification. The activity starts with the definition of the objectives Governments are aiming at by regulating the sector of concern.
- 4. The "international model", as contained in WP.6 "<u>Recommendation L</u>", 1 sets out a clear roadmap for countries wishing to align their regulatory frameworks in a specific sector, or for free trade areas or customs unions that aim at approximating their technical regulations across the board.
- 5. This leads to the first core output: Common Regulatory Objectives (CROs) which address legitimate concerns that usually relate to public health, safety or environmental protection. They include:
  - International standards that contain product-related requirements;
  - How compliance with the CROs will be assured and demonstrated;
  - If third-party-assessment bodies are going to be involved, which conformity assessment bodies are recognized as competent and how they will be accredited or assessed;
  - How post-market surveillance will be performed.
- 6. By using CROs, whenever appropriate, the means of assuming compliance should be a Supplier's Declaration of Conformity (SDoC). However, in other cases, Countries participating in a sectoral initiative may decide to use more stringent conformity-assurance procedures.<sup>2</sup>
- 7. The "international model" refers extensively to the WTO Agreement on Technical Barriers to Trade (TBT Agreement). For example, it explicitly acknowledges the TBT provisions relating to the use

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<sup>&</sup>lt;sup>1</sup> See http://www.unece.org/fileadmin/DAM/trade/wp6/Recommendations/Rec L.pdf.

<sup>&</sup>lt;sup>2</sup> Ibid., para. 26.

of international standards in technical regulations and conformity-assessment procedures, as well as the TBT exhortatory language aimed at fostering the creation of mutual recognition mechanisms whenever and wherever feasible. "The model adds to this framework by suggesting solutions for the practical implementation of technical harmonization and draws from existing schemes for good regulatory practice to be used in the process of international technical harmonization."

- 8. In Part A, this report will offer an overview of the specific areas in which the international model has been or is being applied. These areas include four sectoral initiatives:
  - Equipment for Explosive Environments;
  - Pipeline Safety;
  - Earth-moving Machinery;
  - Telecommunications Terminal Equipment.
- 9. In Part B, this report will present the on-going WP.6 work in risk management, crisis management and market surveillance. It will conclude by providing examples of WP.6 acvtivities in capacity-building and awareness-raising.

#### III. KEY AREAS OF WORK AND RELATED DEVELOPMENTS

A. REGULATORY COOPERATION THROUGH SECTORAL INITIATIVES

## 1. Equipment for Explosive Environments

- 10. Explosions in offshore facilities, on vessels or in mines, refineries, chemical plants or mills entail high risks for individuals and the natural environment. Equipment used in explosive environments must therefore have a high level of safety.
- 11. The initiative to develop common regulations in this specific sector was based on the international model of Recommendation L. It was launched in 2006 with a view to developing CROs covering the definition of area classification, verification of the equipment and its production, installation, inspection, maintenance, repair and the related conformity-assessment procedures for products, services and competency of personnel. The general goal of this sectoral initiative is to promote and enhance safety, while eliminating barriers against the free trade and use of equipment for explosive environments.
- 12. The Working Party finally approved the <u>CROs</u> in 2010. <sup>4</sup> A questionnaire was distributed to participating member States to share information about the national norms regulating this industrial sector.<sup>5</sup>
- 13. 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 harmonisation 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

 $\underline{http://www.unece.org/fileadmin/DAM/trade/wp6/SectoralInitiatives/EquipmentForExplosiveEnvironment/SIEEE\_C \\ \underline{RO.pdf}$ 

 $\underline{http://www.unece.org/fileadmin/DAM/trade/wp6/SectoralInitiatives/EquipmentForExplosiveEnvironment/SIEEE\_updatedreplies.pdf}$ 

<sup>&</sup>lt;sup>3</sup> Ibid., para. 6.

<sup>&</sup>lt;sup>4</sup> See:

<sup>&</sup>lt;sup>5</sup> Available at:

resources to field work" and it is "fully consistent with international obligations under the WTO agreement".

- 14. The latest development relating to this sectoral initiative will be the 2012 gathering of business and governmental representatives with a stake in the International Electrotechnical Commission System for Certification to Standards Relating to Equipment for Use in Explosive Atmosphere (IECEx). This international conference takes place in Dubai and is organized jointly by the International Electrotechnical Commission (IEC), the Emirates Authority for Standardization and Metrology (ESMA) and UNECE.
- 15. The UNECE could not have drawn up CROs in this sector without the partnership with IECEx and the support from the Government of Germany and the *Physikalisch-Technische Bundesanstalt* (PTB).

## 2. Pipeline Safety

- 16. Accidents on international pipelines endanger human lives and the environment, cause serious revenue losses and generate a climate of public hostility towards pipelines. Meanwhile, if designed, constructed and maintained according to the proper norms and standards, pipelines can be one of the most efficient and environmentally friendly means of energy transportation and distribution.<sup>7</sup>
- 17. A sectoral initiative aimed at developing a common regulatory basis in this sector was formally proposed in 2007. If officially launched, the initiative will be based on Recommendation L and will identify best regulatory practices in technical regulations concerning project design, construction, testing, use of materials, operation, maintenance, conservation and utilization of pipelines for oil and gas industry products. The initiative could capitalize on: (a) an advanced set of 177 international standards already developed by the Technical Committee 67 (TC67) of the International Organization for Standardization (ISO) to address specific technical issues related to pipeline safety; and (b) the UNECE expertise in administering the 1992 Convention on the Transboundary Effects of Industrial Accidents, which resulted inter alia in the formulation of Safety Guidelines and Good Practices for Pipelines for the Prevention of Accidental Water Pollution.
- 18. The key points of this initiative, highlighted in particular by the Russian Federation's Service on Ecological, Technological and Nuclear Supervision, are the need to coordinate mandatory requirements for industrial and ecological safety, and to harmonize national approaches to safety regulations.
- 19. All interested parties are encouraged to contact Working Party 6 at Regulatory.Cooperation@unece.org if they wish to join the preparatory work for this initiative or receive further information or updates on its progress.

<sup>&</sup>lt;sup>6</sup> See: http://www.unece.org/index.php?id=26114.

<sup>&</sup>lt;sup>7</sup> See e.g. Goodland, R. (Ed.), *Oil and Gas Pipelines: Social and Environmental Impact Assessment – State of the Art*, International Association for Impact Assessment, 2005, available at

<sup>&</sup>lt;a href="http://www.unece.org/index.php?id=26114">http://www.unece.org/index.php?id=26114</a>>, visited 8 March 2012.

<sup>&</sup>lt;sup>8</sup> See UNECE Document ECE/TRADE/C/WP.6/2007/6, available at http://www.unece.org/fileadmin/DAM/trade/wp6/documents/2007/WP6 07 006e.pdf.

<sup>&</sup>lt;sup>9</sup> See UNECE Documents ECE/CP.TEIA/2006/11 and ECE/MP.WAT/2006/8.

## 3. Telecommunications Terminal Equipment

- 20. Compatibility of products of the telecom industry often causes problems to end-users, who can find themselves unable to use imported material or equipment they have bought in another country. Most incompatibility issues could be solved through harmonizing the standards in this sector.
- 21. In April 2002, an informal meeting was held in Geneva to discuss the need for improved market access on the telecom market. It was attended by representatives of the European Commission (EC) and the International Telecommunication Union (ITU), telecom companies from the UNECE region and business associations from Australia and Japan, and by members of the Ad Hoc Team of Specialists on Standardization and Regulatory Techniques (START Team). Participants suggested initiating a dialogue following the model of Recommendation L to explore the possibilities of regulatory convergence.
- 22. CROs in this sector, covering for instance personal computers (PCs), PC peripherals, legacy Public Switched Telephone Network (PSTN) terminals, Bluetooth, Wireless Local Area Network (WLAN), Global Standard for Mobile Telecommunication (GSM) and International Mobile Telecommunications (IMT-2000), were drawn up in 2004. However, they have not yet been applied in national legislations or in the context of mutual recognition arrangements. They remain relevant nevertheless in other key negotiating arenas: the WTO non-agricultural market access (NAMA) negotiations, and the consultations at ITU on "conformance assessment and interoperability".
- 23. In the context of the NAMA talks, several proposals have addressed the possibility of simplifying conformity assessment procedures as they apply to trade in electronic products. <sup>10</sup> The proposed CROs could be applied to the results of this chapter of the NAMA negotiations in a way that would further the latter's objectives while assuring compliance with the overall WTO legal framework. In the context of the ITU consultations, on the other hand, the proposed CROs could represent a complement and a tool for implementing the relevant standards once agreed.

## 4. Earth-moving Machinery

- 24. Cranes, bulldozers and other Earth-moving Machinery (EMM) have been part of a global industry for years. ISO standards (ISO/TC127) have been used as a common denominator to minimize safety risks. However, the market remains segmented owing to the rarity of mutual recognition agreements in this sector, and, as a consequence, repeated testing and certification—which are particularly costly and lengthy in this sector—unnecessarily elevate prices and distort competition.
- 25. In 2003, Working Party 6 set up this sectoral initiative on EMM to increase the scope of application of the existing ISO standards while fostering the mutual recognition of conformity-assessment procedures on the basis of Recommendation L. The initiative's underlying rationale being to enhance safety while reducing barriers to international trade.
- 26. In 2004, a first model regulatory framework via draft-CROs was adopted. It was revised in 2009. The draft CROs are primarily based on the ISO/TC127 standards. In 2010, the EMM project initiated a model certificate of conformity that, if broadly adopted, would simplify the exchange of data between the producers, machine users, third-party certifiers and the authorities of exporting and importing countries.
- 27. In 2011, the project formally embraced "risk management" and "market surveillance" (in this case "worksite surveillance") as key tools for achieving the "zero injuries" long-term goal for machine

 $<sup>^{10}</sup>$  See e.g. WTO Documents TN/MA/W/105/Rev.3 of 26 November 2010; TN/MA/W/125 of 4 December 2009; and TN/MA/W/119 of 9 September 2009.

operators and the people on the worksite. This goal was originally set by Working Party 6 members. More specifically, it has been recognized that in the EMM sector the sole SDoC would not be acceptable for certain countries, and that third-party assessments of conformity would still be needed. Moreover, the safety of EMM is dependent upon the safety of the workplace where the machines are used. These considerations increase the number of variables to be taken into account for achieving the "zero injuries" goal and beg a holistic approach to the management of risks connected to the use of EMM.

- The revised CROs, therefore, reflect these considerations by proposing a risk-based "Safety Process for EMM" and by reporting a "model global certificate of conformity". In 2012, Working Party 6 is expected to adopt a consolidated version of the CROs for the EMM sector. 1
- В. REGULATORY COOPERATION ON RISK AND CRISIS MANAGEMENT
- In 2011, the Working Party approved the recommendations on "Risk Management in Regulatory 29. Frameworks" and "Crisis Management within a Regulatory Framework". 12

#### 1. Recommendation "R" — Risk Management in Regulatory Frameworks

- The Recommendation on Risk Management in Regulatory Frameworks (hereinafter 30. "Recommendation R") sets out a checklist of best practices for preparing, adopting and implementing risk-based regulation. It aims at a consistent and systematic treatment of risk at a whole Country as well as at an international level by increasing cooperation among stakeholders. It lays out a common risk management process for: choosing areas to regulate, analyzing the existing stock of regulations with regard to risks that they had been set out to address, and removing unnecessary regulations. It draws on the principles set out in the general standard ISO 31000:2009 on risk management, but adapts that conceptual model to regulatory practice.
- 31. The concept of "risk" applied to regulatory frameworks refers to the effects of uncertainty on the achievement of one or more of the objectives of a regulatory intervention. The opportunity cost connected to the choice of regulating a specific sector in a certain way or another is also a key variable to be taken into account. For instance, suppose the core objective of a regulatory intervention is preserving the quality and safety of fresh waters by avoiding the risk of contamination from potentially carcinogenic agents in imported auto parts.
- 32. Once the existence itself of a risk has been identified and assessed, the regulator has to set a risk treatment strategy where several options can be contemplated. These could include, for example, avoiding the risk by banning the products at issue, sharing the responsibility or mitigating the risk by reducing the probability of its occurrence (e.g. by establishing chain-of-custody standards for the traceability of the targeted group of products). In other cases, the regulator may choose to tolerate the risk, or to choose nonregulatory action, such as information campaigns.
- 33. In any event, according to the scheme proposed in the Recommendation, the choice to regulate and the extent of the intervention will depend on a wide range of variables, and will include a regulatory

http://www.unece.org/fileadmin/DAM/trade/wp6/documents/2011/WP6\_2011\_8e.pdf.

12 See UNECE Document ECE/TRADE/C/WP.6/2011/21.

<sup>&</sup>lt;sup>11</sup> See the "Progress report on the sectoral initiative on earth-moving machinery", UNECE Document ECE/TRADE/C/WP.6/2011/8, available at

impact analysis (RIA). <sup>13</sup> In trade-related terms, all things being equal, this approach will ensure the most efficient and effective level of protection with the least restrictive effects on trade flows.

# 2. Recommendation "P"—Crisis Management within a Regulatory Framework

- 34. The <u>Recommendation on Crisis Management in Regulatory Frameworks</u> (hereinafter "Recommendation P") sets out a series of basic principles and best practices to be followed by regulatory authorities both to prevent and to deal with unexpected events. It applies the general risk management model developed under Recommendation R to situations where unexpected events need immediate responses. The concept of "crisis", however, is not defined in Recommendation P, but is understood as an unexpected event that threatens strategic objectives.
- 35. Recommendation P builds upon two main concepts: the social and economic desirability of acting within a pre-decided and well-structured set of actions when responding to crises, and the need for harmonizing those responses internationally. It also acknowledges that a good level of preparedness for facing unexpected crises can be achieved using relatively modest resources such as training of personnel and good planning practices.

## 3. Group of Experts on Risk Management in Regulatory Systems

- 36. The texts of Recommendations R and P were prepared by the <u>Group of Experts on Risk</u> <u>Management in Regulatory Systems</u> (UNECE GRM). The GRM gathers experts in specific risk-related areas from the private and public sectors, as well as academics and independent consultants.<sup>14</sup>
- 37. In 2011, besides having carried out the technical work necessary for the preparation of Recommendations R and P, the GRM has, *inter alia*:
  - Participated in the preparation of the draft-OECD Recommendation on Regulatory policy and Governance:
  - Participated in the preparation of a "Regulatory Annex" to a new ISO standard aimed at setting forth guidelines for the implementation of ISO 31000:2009;
  - Prepared a book on behalf of the UNECE (forthcoming) on "Risk Management in Regulatory Frameworks: towards a Better Management of Risk". 15
- 38. In its latest webinar in February 2012, the GRM decided to include in its work programme for the current year the preparation of a case study where the principles and guidelines of Recommendation R will be applied, as a starting point, to the sector of electrical and electronic appliances as currently regulated under EU and Australian law.<sup>16</sup>

http://www.unece.org/fileadmin/DAM/trade/wp6/AreasOfWork/RiskManagement/ListOfMembers Dec2011.pdf

<sup>&</sup>lt;sup>13</sup> On RIA see e.g. Organisation for Economic Co-operation and Development (OECD), *Regulatory Impact Analysis: A Tool for Policy Coherence*, OECD Publishing: Paris, 2009.

<sup>&</sup>lt;sup>14</sup> The members of the GRM are listed here:

<sup>&</sup>lt;sup>15</sup> More detailed information on the work of the GRM can be found in UNECE Document ECE/TRADE/C/WP.6/2011/3 of 18 August 2011.

<sup>&</sup>lt;sup>16</sup> The report of the latest GRM webinar is available here: <a href="http://www.unece.org/fileadmin/DAM/trade/wp6/AreasOfWork/RiskManagement/Report-Webinar">http://www.unece.org/fileadmin/DAM/trade/wp6/AreasOfWork/RiskManagement/Report-Webinar</a> February2012.pdf

## C. REGULATORY COOPERATION ON MARKET SURVEILLANCE

39. In 2011, Working Party 6 approved a recommendation on "Good Market Surveillance Policies and Practices".

## 1. Recommendation "N" — Good Market Surveillance Policies and Practices

- 40. The <u>Recommendation on Good Market Surveillance Policies and Practices</u> (Recommendation N) is a complementary tool to Recommendations R and P, and an essential element in a risk-management strategy. Responding to the call of the United Nations General Assembly decision 54/449 of 22 December 1999 on United Nations Guidelines for Consumer Protection, Recommendation N aims at facilitating the establishment and enforcement of national legislation protecting final users of potentially dangerous or counterfeit goods and services.
- 41. Market surveillance and the fight against counterfeit and potentially dangerous goods had already been addressed by Working Party 6 in 2007 with the approval of Recommendation M on the "<u>Use of Market Surveillance Infrastructure as a Complementary Means to Protect Consumers and Users against Counterfeit Goods</u>" (Recommendation M). That Recommendation intended to capitalize on the synergies between actions aimed at enforcing intellectual property rights, and related actions of a more general nature aimed at consumer protection. Recommendation N, however, expands the scope of application of by proposing a basic model for national regulators to set up and enforce market surveillance-related actions.
- 42. Recommendation N, in fact, provides for a checklist of actions to be undertaken in order to ensure that national authorities have the right tools to enforce market surveillance measures. These tools comprise the establishment of solid legal bases for enforcing market surveillance actions; a strong political commitment to the overall objective of consumers and final users' protection; and the reliance on best practices in the field of market surveillance, such as those proposed by the UNECE Model for Market Surveillance Procedures.<sup>17</sup>
- (a) The Advisory Group on Market Surveillance
- 43. The <u>Advisory Group on Market Surveillance</u> (MARS Group) carries out the technical functions connected to the UNECE work on Market Surveillance. It was up in 2003 and has produced several deliverables in its years of existence. Besides Recommendations M, N, and the above-mentioned UNECE Model for Market Surveillance Procedures, the MARS Group has prepared or is in the process of preparing:
  - A system of information on market surveillance authorities <sup>18</sup> and a related database; <sup>19</sup>
  - The UNECE publication Market Surveillance in the UNECE Region; <sup>20</sup>
  - The UNECE publication Glossary of Market Surveillance Terms.<sup>21</sup>

http://www.unece.org/fileadmin/DAM/trade/wp6/SectoralInitiatives/MARS/Slovakia Oct09/GMSP3.pdf.

http://www.unece.org/trade/wp6/AreasOfWork/MarketSurveillance/Contacts.html.

<sup>&</sup>lt;sup>17</sup> Available at:

<sup>&</sup>lt;sup>18</sup> For the system of information see:

<sup>&</sup>lt;sup>19</sup> For the database see: http://apps.unece.org/WP6/.

<sup>&</sup>lt;sup>20</sup> Available at: http://www.unece.org/fileadmin/DAM/trade/wp6/SectoralInitiatives/MARS/ECE\_TRADE\_301.pdf.

<sup>&</sup>lt;sup>21</sup> Available at: http://www.unece.org/fileadmin/DAM/trade/wp6/documents/2009/WP6 2009 13e final.pdf.

# IV. EXAMPLES OF CAPACITY-BUILDING AND AWARENESS-RAISING ACTIVITIES

Activity	Description
Model Programme on Standardization	As part of WP.6 and UNECE Secretariat's standards-related awareness activities, a number of educational institutions in the Commonwealth of Independent States (CIS) were approached to analyse how standardization and regulatory matters are reflected in their curricula. It turned out that such programmes exist only in specialized institutions (usually, under the umbrella of governmental standards-related bodies) offering high-school diplomas in the areas of standards, certification, etc.
	The analysis of the existing courses highlighted differences in basic approaches and coverage of the existing programmes. Against this backdrop, the UNECE secretariat initiated work on drawing up a "Model Programme on Standardization". The basic idea is to provide future graduates with an introductory understanding of standards. The Programme will be based on a product life-cycle approach ("from cradle to grave"). It will include standards, technical regulations, accreditation, conformity assessment, metrology, market surveillance and other functions.
	The first draft of the Programme was prepared in February 2012 by a group of experts representing educational institutions from Europe and the CIS region. It was sent for comments to international standard-setting organizations, and consultations are expected to be finalized by mid-April. In addition, Recommendation I of 1970 on "Methodological Studies and Education" will be reviewed at the next Working Party 6 plenary session (October 2012) by using the "Standardization Programme" as a background for discussion.
Needs Assessments in Economies in Transition	The UNECE is currently undertaking a series of needs assessments related to regulatory and procedural barriers to trade in transition economies. The first Needs Assessment was carried out in Belarus and the final report is expected in the third quarter of 2012. The second Assessment will address Kazakhstan and is expected in late 2012. The section on standardization and technical regulations covers a wide range of issues falling under the mandate of WP.6, such as regulatory impact assessments, risk management tools, metrology and market surveillance.
Workshop on Traceability: A Tool for Managing Risk & Panel discussion on "Standards and Sustainable Development"	On 31 October and 1 November 2011, a workshop on "Traceability: a tool for managing risk" was held in parallel with the annual session of WP.6. Following the event, on 2 November WP.6 organized a panel discussion on "Standards and sustainable development". Both events were aimed at raising awareness on: (a) how the concept of traceability is currently defined and interpreted in legislation, and how it can serve as a tool for managing risk; and (b) how international standards can serve as tools for achieving sustainable development goals, considering, for example, that common standards and rules and procedures for measurement, reporting and verification are key to the success of the market-based mechanisms set up under the UNFCCC.

# V. FORTHCOMING MEETINGS

Date and venue	Meeting
17 April 2012	DCMAS - Network on Metrology, Accreditation and Standardization for
Geneva	Developing Countries.
(Palais des Nations)	
[4-6] May 2012,	Bureau Meeting - Annual planning meeting for UNECE Working Party 6
Stockholm	activities
22-24 October 2012	Annual session of Working Party 6
Geneva,	
(Palais des Nations)	