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Working Party on Regulatory Cooperation and Standardization Policies

Twenty-first session
Geneva, 31 October – 2 November 2011

Report of the Working Party on Regulatory Cooperation and Standardization Policies on its twenty-first session

Note by the secretariat

Summary

At its twenty-first session, the Working Party:

- Approved three new recommendations: on "Risk Management in Regulatory Frameworks", "Crisis Management within a Regulatory Framework" and "Good Practices in Market Surveillance Policies".
- Launched a worldwide database of contacts of market surveillance authorities.
- Launched the publication: A Glossary of Market Surveillance Terms.
- Shared best practice on how traceability provisions help companies and regulators manage risks and reach policy objectives and business goals.
- Discussed how standards are essential to progress towards more sustainable production and consumption patterns.

Introduction

1. The Working Party on Regulatory Cooperation and Standardization Policies (WP. 6) held its twenty-first session from 31 October to 2 November 2011. The meeting included a workshop on "Traceability: a tool for managing risks" on 31 October and 1 November and a Panel discussion on "Standards and regulations" on 2 November.

2. The following countries were represented: Austria, Belarus, Brazil, Bulgaria, China, Czech Republic, Germany, Israel, Japan, Kyrgyzstan, Netherlands, Poland, Republic of Moldova, Russian Federation, Serbia, Slovakia, Sweden, Switzerland, Turkey, Ukraine, United Kingdom of Great Britain and Northern Ireland and United States of America.

3. The meeting was also attended by a representative of the European Commission (EC).

4. The following United Nations bodies and specialized agencies participated: the International Trade Centre (ITC) and the United Nations Framework Convention on Climate Change (UNFCCC).

5. The following non-governmental organizations participated: Federation of European Risk Management Associations, GS1, Ingénieurs du Monde, International Electrotechnical Commission (IEC), International Organization for Standardization (ISO), ORGALIME - The European Engineering Industries Association representing the interests of the mechanical, electrical, electronic, metalworking and metal articles industries.

6. Observers present at the invitation of the secretariat included representatives of private-sector companies, associations and civil-society organizations from various regions.

7. The Director of the Trade and Sustainable Land Management Division and the Chair of the Working Party opened the meeting. They praised the work of the WP.6 as it directly contributed to advancing the goals of the United Nations, including the management of risks that confronted our communities, and sustainable development. In doing so, they said that cooperation with other institutions was of paramount importance. They also emphasized the recent achievements and challenges that the WP.6 faced, making special reference to its limited budgetary and extrabudgetary resources.

I. Adoption of the agenda

Documentation ECE/TRADE/C/WP.6/2011/1 – Annotated provisional agenda

8. The Working Party approved the provisional agenda.

II. Election of officers

9. In accordance with the Commission's rules of procedure and established practice, the Working Party elected Mr. C. Arvius (Sweden) as Chair, and Mr. V. Koreshkou (Belarus) Ms. L. Gocníková (Slovakia) and Mr. S. Oriekhov (Ukraine) as vice-chairs.

III. Matters arising and areas of priority action for the Working Party

Documentation: ECE/TRADE/C/WP.6/2010/20 - Report of the Working Party on Regulatory Cooperation and Standardization Policies on its twentieth session

ECE/TRADE/C/WP.6/2011/2 – Report of the annual planning meeting of UNECE WP.6

ECE/TRADE/C/WP.6/2011/13 - Programme of Work for 2012-2013, including the revised table of priorities

ECE/TRADE/C/WP.6/2011/13/Corr.1 - Programme of Work for 2012-2013, including the revised table of priorities

10. The secretariat introduced the report of the previous session and the detailed progress made under the various work items intersessionally.

11. The Working Party adopted the report of its previous session and of the annual planning meeting of the WP.6 activities. It approved the programme of work for the following biennium.

12. The Director of the Trade and Sustainable Land Management Division informed participants about matters arising from meetings of the UNECE and of the Committee on Trade of relevance to WP.6, as follows:

- The UNECE Executive Committee had approved the creation of the Group of Experts on Risk Management in Regulatory Systems.
- UNECE had been requested by Headquarters to reduce its resources by 3% beginning in 2012, and one of the professional posts servicing WP.6 had been cut, along with seven other UNECE posts[1].
- In 2011 a review of UNECE had started. Due to be completed in 2012, it aimed at identifying areas of continuing priority. To assist the review, delegations were encouraged to share any examples of use of the Recommendations or best practices developed by WP.6.

13. Delegations expressed concern over the continuing and critical issue of scarce secretariat resources. The delegations of Belarus, Ukraine and Slovakia pledged to place increased resources in kind at the disposal of the secretariat, including staff time and tools such as databases.

14. In concluding the discussion, the Director:

- assured delegations of her commitment to finding increased resources for the WP.6 but regretted that she could not transfer any staff from other work areas;
- encouraged the Bureau to explore concrete ways of making use of proposals for in-kind assistance offered by delegations;

[1] The proposed reduction in resources for the UNECE was rejected by the General Assembly. therefore, this post was not cut.

- encouraged delegations to explore possibilities of funding a post for an associate expert or junior professional officer to support the WP.6

15. The secretariat updated participants on the progress of the project on "Needs Assessments in Countries with Economies in Transition", undertaken by the parent body of the Working Party, the Committee on Trade. The first report, on Belarus, was being finalized, taking into account recent developments in the technical regulations of the Customs Union among Belarus, Kazakhstan and the Russian Federation. Work had also started on a second report, on Kazakhstan, in cooperation with the International Trade Centre.

16. The representative of Belarus offered some complementary information to that contained in the needs-assessment report presented by the secretariat. He emphasized that the process of developing standards in Belarus was based on the World Trade Organization Agreement on Technical Barriers to Trade (WTO TBT Agreement), European Union (EU) legislation and international best practice, modern achievements in science and technology. Gosstandart participated in the work of ISO, IEC, the European Committee for Standardization (CEN) and the European Committee for Electrotechnical Standardization (CENELEC) among other organizations.

17. During the first half of 2011, more than 200 governmental standards had been approved in Belarus. Energy saving is an area of high priority, along with the chemical and construction industries.

18. Recent developments included:

- A revised law on conformity assessment (see: http://gosstandart.gov.by/en-US/Zakonodat-osnovu.php) that will be effective January 2016;
- A 30% reduction in the list of products subject to obligatory certification.;
- The Belarusian State Center for Accreditation had become an affiliate member of both the International Laboratory Accreditation Cooperation (ILAC) and the European Co-operation for Accreditation (EA).

19. The Director explained the role of UNECE Committee on Trade in promoting the Aid for Trade initiative in the UNECE region, in cooperation with donors and international organizations. Of interest to the Working Party was the establishment of the Implementation and Monitoring Council, tasked to ensure funding to support the priorities identified and agreed by the countries of the region.

IV. Workshop on "Traceability: a tool for managing risks"

Documentation: ECE/TRADE/C/WP.6/2011/5 - Concept note for the Workshop on traceability as a tool for managing risks

20. The Chair introduced the aims and structure of the workshop. He explained that, in preparing the workshop, the Working Party had built on its activities in the area of risk management in the past few years and had worked in synergy with governmental authorities and other stakeholders, as well as with the United Nations Centre for Trade Facilitation and E-business (UN/CEFACT). The secretariat had also established contacts with the Organisation for Economic Co-operation in Europe (OECD) Working Party on Consumer Product Safety, which had started to address the issue of traceability so as to ensure that the work would be complementary and mutually reinforcing.

21. He said that traceability was the ability to follow the movement of products through specified stage(s) of production, processing and distribution. The movement of products could relate to the origin of the materials used in the production process, processing history or distribution.

22. A traceability system was a useful tool to assist an organization operating within a supply chain to achieve a defined objective in a management system.

23. The choice and complexity of a traceability system was influenced by regulations, product characteristics and customer expectations on the features of the product and the objectives to be achieved.

24. Several speakers emphasized the benefits of traceability, which included:

- Better management of risks throughout the production and distribution processes
- Enhanced safety of consumers
- More effective enforcement of market surveillance actions
- Rapid and effective responses to crisis
- Protection against counterfeit goods
- Copyright and brand protection
- Reduced risk of legal action and readily available evidence in case of litigation
- Better inventory management
- Increased accountability at each level of the supply chain
- Collection of data that allows better planning, as well as metrics that can be used to monitor the use of resources and the sustainability of production and consumption processes, to minimize environmental impact during the product life cycle (production, use, and end-of-life cycle recycling).

25. Realizing these benefits required strengthened collaboration among all actors in the supply chain: including not only suppliers, producers, and distributors, but also regulatory bodies, enforcement authorities, conformity assessment bodies, trade agencies and logistics centres.

26. Conversely, insufficient traceability could lead to a loss of control of the production processes, smuggling, information tampering and unauthorized use, adulteration of products, and loss of cargo integrity. Traceability was especially important for sectors such as food, chemicals, pharmaceutical, and machinery.

27. Within a firm, the implementation of traceability solutions required, for instance:

- Identification of materials and components
- Tracking of materials and components during the manufacturing process
- Marking of finished products with unique mark (articles, packing, batches).

28. Traceability could be extended throughout the supply chain to include logistics providers, retailers, manufacturers, distributors, suppliers and consumers. Important tools for putting traceability solutions in place were: ISO 28000:2007 for security management systems for the supply chain; ISO 22000:2005 for food safety management systems; ISO 12875:2011 for traceability of finfish products and ISO 13485:2003 for medical devices.

29. In Belarus, a countrywide information and technology platform had been established to provide an “electronic passport for goods”. The system offered an electronic resource

allowing products to be identified and described in accordance with international standards, including the Harmonized System (HS) code, the Global Product Classification System.

30. For the smooth operation of this system, work was being done to identify all the participants and actors in the trade process, to create standard descriptions, using local and international classification systems, and to provide synchronization of data between participants of supply chains.

31. Belarus was also promoting the implementation of traceability tools at a regional and international level. A programme aimed at enhancing electronic data interchange for dangerous products had been launched at the level of the Customs Union with the Russian Federation and Kazakhstan, in close cooperation with UN/CEFACT, GS1 and the ISO/IEC JTC 1 Information Technology Committee.

32. To further develop the system, Belarus aimed at:

- Involving international experts to study similar approaches in other countries;
- Creating a group of experts to develop a regional project under the guidance of WP.6, UN/CEFACT, and GS1;
- Promoting the project at a regional level.

33. The National Institute for Metrology Quality and Technology of Brazil (Inmetro) had already developed about 180 programmes on conformity assessment, more than 80% of which were mandatory. A total of about 230,000 product types had already been certificated, and 88 more programmes were being developed. As part of the conformity assessment procedure (CAP), Inmetro required that the supplier guarantee that its product was traceable. The certification had to be done according to the quality management system audited by certification bodies, under ISO 9000 series criteria. Inmetro did not require any specific way to implement this traceability requirement as each industry and each company had their specific requirements and constraints. At the international level, Inmetro was part of the International Consumer Product Safety Caucus (ICPSC) Pilot Tracking and Traceability Project, which was currently initiating a pilot project on baby strollers.

34. In the EU, traceability systems were not a regulatory requirement but enabled economic operators to better comply with the obligations of the new EU legislative framework. In particular: that the manufacturer should design and manufacture a product in accordance with the requirements; that the importer should place only compliant products on the European market; that the distributor should act with due care in relation to the applicable requirements, and that the authorized representative should perform specific tasks on behalf of the manufacturer.

35. The EU Rapid Alert System for non-food dangerous goods (RAPEX) had contributed to cutting the number of untraceable products to 10% of the total number of dangerous products in 2010.

36. DG Health and Consumers had set up an Informal Expert Group on Product Traceability in September 2011, to examine state-of-the-art and voluntary/best practices in the field of traceability, observe how economic operators were coping with their obligations and to produce a final report with recommendations to stakeholders.

37. In the view of GS1 (which develops the most widely used system of international standards for supply chains, with more than 1 million users around the world) an effective traceability system should have the following characteristics:

- Be comprehensive, to address all traceability principles and include regulations, standards, guidelines and implementation;

- Be industry-wide, and maximize interoperability between companies, between sectors and between countries;
- Be built in a way that would encourage and facilitate self and third-party assessments of the traceability system;
- Clearly distinguish between expectations — defined by the regulations and company specifications and technical solutions — which depend on technical standards, industry guidelines and good practices.
- Build upon and contribute to collective knowledge.

38. The recently launched GS1 Global Traceability Program (GTP), included a methodology for on-site assessments, and a programme for training and certifying accredited auditors.

39. One private company gave a demonstration of an IT platform that was used in the food sector in North America. The platform allowed tracking every movement of the products from the field to the final point of sale. This allowed monitoring the use of resources and the collection of metrics that could be used to determine the goods' carbon footprint.

40. In the United States, the Agricultural Marketing Service of the Department of Agriculture (USDA) audited, verified and approved companies' production practices for all food products. It both developed specific standards for quality and for traceability and served as an independent third-party verifier of industry-developed standards. Two important programmes maintained by the Department are: (a) "Process Verified", i.e. oriented towards export markets and (b) "Quality System Assessment", i.e. oriented towards domestic markets. Both were voluntary, and cost-recovery and market-focused. USDA did not require a complete supply chain traceability system, and only about 3% of cattle carry radio-frequency identification (RFID) tags.

41. In the agricultural sector, in particular, the United Nations Centre for Trade Facilitation and Electronic Business (UN/CEFACT) acted as a standards-development body, developing messages that allowed for standardized information-exchange on sanitary and phytosanitary certificates, animal identification and e-animal passports, etc. UN/CEFACT planned to work on integrating different parties of the "production-trade-transport" chain (including customs).

42. Traceability also helped increase the effectiveness of market surveillance activities. A high percentage of dangerous products from third countries were still unidentified, causing a need for repeated testing by authorities, and complicating the task of removing the product from the supply chain. To meet that challenge, it was important to strengthen cooperation regionally (through the EU rapid alert system (RAPEX), the internet-supported information and communication system for the pan-European market surveillance (ICSMS), the EU's Communication and Information Resource Centre Administrator (CIRCA), and the Group of Administrative Co-operation under the R&TTE Directive 99/5/EC (R&TTE-ADCO) as well as internationally not just among market surveillance authorities but also with customs, and with economic operators. Databases were important tools: for example, the Slovak ECHO database, which gathers information from consumers on accidents caused by non-food products.

43. From the point of view of industry, represented at the workshop by Orgalime, EU compliant producers were overwhelmed by legislative requirements, but weak market surveillance and lack of enforcement across the EU allowed rogue producers to take advantage and left consumers exposed to risks.

44. To address that challenge, different traceability requirements had been introduced in different sectors, including:

- In the sector of electric and electronics, through the Waste Electrical and Electronic Equipment Directive (WEEE Directive) national registries had been created in all 27 EU member countries. This had led to legal uncertainty due to the different requirements in each country, additional administrative burdens and costs for companies, and difficulties in consulting the different registries for enforcement authorities
- In the chemical sectors, the REACH (Regulation on Registration, Evaluation, Authorization and Restriction of Chemicals) Regulation had created a centralized, EU registry. The Commission was considering a similar solution for the sector of Radio and Telecommunications Terminal Equipment (R&TTE).

45. Both national and EU-wide registries had:

- Failed to address the critical problem of rogue producers, who simply did not register or forged the registration number;
- Added a burden on lawful companies (encoding, additional IT…)
- Removed resources from focused surveillance actions in order to "administer" the register.

46. Using traceability requirements in regulations could still be an effective solution, provided that the tools were:

- Cost effective and flexible, including through the use of modern means;
- Technology neutral, affordable to economic operators and Small and Medium Enterprises (SMEs) and interoperable;
- Proportionate to the added-value of the product and the potential level of risk / severity of harm;
- Combined, most importantly, with effective controls.

47. Another business representative, from a private company, reported on the challenges of tracing substances that were contained in product components, which made it difficult to ensure compliance with the product safety rules for final product manufacturers. This was a particular challenge for ICT products, which typically consist of thousands of parts and components, making final product testing economically unrealistic.

48. Therefore, supply-chain management was important to ensure that all components complied with the safety requirements, so as to guarantee compliance of the final product with the Restrictions of Hazardous Substances (RoHS) and other directives. A number of tools could be used, including:

- Company online guiding documents, agreements and tools for suppliers;
- Maintaining a list of banned and restricted substances online;
- Gathering materials data from suppliers;
- Industry guides and/or standards, such as the draft IEC standard for materials declaration - in approvals phase (to become IEC 62474), which would include data format and data-exchange requirements.

49. Experience showed that it was critical to involve suppliers when compiling material declarations and appropriately inform partners who either recycled the products or were responsible for compensation about possible dangerous substances.

50. In global industry, like the ICT industry, if one country introduced a new substance ban, companies based in other countries would have to comply with this requirement. Technical regulations, therefore, had a global and sizable economic impact.

51. Lessons could also be learnt from experience in the health and safety domain. Blood banks, for instance, were using electronic information systems that allowed for data about transfusions to be collected from emergency departments and remote hospitals. That ensured total traceability of a blood unit, from the time it got extracted from a donor's arm to the time it was transfused to a patient.

52. In concluding, the Chair requested that the Bureau and the secretariat further discuss the follow-up to the workshop.

53. One of the vice-chairs suggested considering how traceability was applied in different sectors, and on that basis developing guidelines and common principles for traceability to facilitate the establishment of national and international registries that would then be compatible with one another. Traceability was important both in regulatory work and in meeting consumer requirements. The legislative and regulatory work should be given priority in the follow-up. One interesting sector for starting work was the RoHS directive.

V. Risk management in regulatory systems

Documentation: ECE/TRADE/C/WP.6/2011/3 - Report on the activities of the Group of Experts on Risk Management
ECE/TRADE/C/WP.6/2011/4 - Draft of the general recommendation "Risk Management in Regulatory Systems"
ECE/TRADE/C/WP.6/2011/14 - Draft Recommendation on Crisis Management in Regulatory Systems

54. The coordinator of the Group of Experts on Risk Management in Regulatory Systems (GRM) presented a report ECE/TRADE/C/WP.6/2011/3 on the completion of the Group's project plan. The group had a broad and diversified membership, from different geographical regions, areas of competence and interests. Its main accomplishments included:

- An agreement on and implementation of methods of work based on webinars and an interactive wiki website;
- A liaison membership with the ISO TC 262 Project committee "Risk management";
- Participation in work on the draft recommendation of the Organization for Economic Cooperation and Development (OECD) on Regulatory Policy and Governance;
- Development of two draft recommendations: ECE/TRADE/C/WP.6/2011/4 and ECE/TRADE/C/WP.6/2011/14.

55. The draft general recommendation "Risk Management in Regulatory Systems" aimed at a consistent and systematic treatment of risk at both national and international level by increasing cooperation among stakeholders. It laid out a common risk management process for: choosing areas to regulate, analysing the existing stock of regulations concerning risks that they had been set out to address, and removing unnecessary regulations. It was based on the ISO 31000:2009 international standard.

56. Delegations agreed to change the title of the recommendation to read, “Risk Management in Regulatory Frameworks”, to clearly restrict its scope to areas within the mandate of the Working Party. In the view of several delegations, including the Russian Federation and Slovakia, the recommendation and more generally the work of WP. 6 in risk management should:

- Aim at developing and implementing good regulatory practice based on risk management, and be a practical link between regulatory practices and regulations and risk management.
- Develop provisions on how to use risk-management tools for the purpose of harmonizing technical regulations across countries, through harmonization of requirements and through functional equivalency (i.e. promoting the understanding that requirements for products, even if established by different means, could lead to the same results in terms of safety).
- Focus on practical and tangible results to assist countries in managing risks, e.g. encourage countries to develop information systems to facilitate information exchange which would help to better manage risks.
- Clearly describe the roles of regulatory stakeholders with regard to performing the functions of the risk management process, in particular the “management of assets”.

57. The draft recommendation “Crisis Management in Regulatory Systems” defined crises as “unexpected events that threaten strategic objectives”. Because crises often affect the functioning of regulatory systems, they raise issues covered by the mandate of the WP.6 mandate. In particular, unpreparedness for crises often leads to inadequate regulatory responses, disproportionate to the risks they set out to address.

58. The recommendation aimed at guiding regulatory stakeholders in developing a comprehensive approach to managing a crisis (i.e. focusing on affected individuals, collecting relevant data, activating the crisis management teams, developing specific and generic contingency plans, etc). The implementation of the recommendation requires only modest resources, primarily training of personnel, planning, and getting people ready to handle a crisis.

59. Several delegations expressed support for the recommendation, and proposed textual changes to improve its readability. Belarus also suggested removing the word “normative” from the title (as it appears in the Russian translation of the document).

60. Discussion on the two recommendations continued informally through a drafting group, which suggested the following:

- Changing the titles of the two recommendations to read: “Crisis Management within a Regulatory Framework” and "Risk Management in Regulatory Frameworks";
- Amending the text of the Recommendation on “Crisis Management within a Regulatory Framework” as requested by the delegations.

61. The delegation of Belarus proposed that two recommendations be adopted, on the condition that any changes made during the drafting session, other comments expressed by the delegates, and changes that had been discussed but remained to be implemented, would be taken into account[2].

[2] The final texts of the two recommendations on “Risk Management in Regulatory Frameworks”, as approved intersessionally, are now available on the website.

62. The Working Party amended the text of the proposed recommendation, as contained in document ECE/TRADE/C/WP.6/2011/14. It changed its title to read Recommendation on “Crisis Management within a Regulatory Framework”, and amended the text now available on the UNECE website. It then approved the revised recommendation. It asked the secretariat to publish the text as recommendation P and as part of the volume “Recommendations of the Working Party”.

63. The Working Party changed the title of the recommendation “Risk Management in Regulatory Systems” to read "Risk Management in Regulatory Frameworks". It approved the recommendation with the proviso that comments expressed by the delegates be taken into account. The Working Party proposed that the work in the area of risk management should continue in specific areas, e.g. focusing on sectors with high-risk products.

64. The delegation of Belarus expressed its support for the continuation of the work in risk management within the Working Party and suggested that that work should focus more on specific areas, and, in particular, on economic sectors with a high level of risk. Belarus emphasized the importance of the work in risk management, noting that it should result in consistent application of risk-management tools by trading countries. The Russian Federation supported the proposal by Belarus.

65. The secretariat informed the Working Party about the draft publication “Risk Management in Regulatory Systems”, which aimed at providing a broader explanation of the ideas expressed in the two recommendations. The secretariat invited the delegations to comment on the publication within the following two months so that the publication could be finalized and printed in early 2012.

66. The Working Party took note of the report on the Group of Experts on Risk Management in Regulatory Systems and approved its programme of work.

67. The Working Party elected Mr. K. Knight as Chair, and nominated Mr. D. Macrae and Mr. V. Nikonov as coordinators of the Group of Experts on Risk Management in Regulatory Systems.

VI. Regulatory cooperation

Documentation: ECE/TRADE/C/WP.6/2011/7 - Progress report on Sectoral initiative on Telecom
ECE/TRADE/C/WP.6/2011/8 - Progress report on the on the sectoral initiative on Earth-Moving Machinery
ECE/TRADE/C/WP.6/2011/9 - Progress report on the sectoral initiative on Explosive Environments

68. The Working Party adopted the report of activities of its ad hoc Team of Specialists on Standardization and Regulatory Techniques (“START” Team) and its Advisory Group on Market Surveillance (“MARS” Group).

A. Regional projects

69. Regional organizations were invited to provide updated information on their regulatory cooperation activities and projects. The Working Party requested the secretariat to include these reports in the documentation for the next plenary session.

B. Sectoral projects

1. Earth-Moving Machinery Initiative

70. The Convenor of the Task Force on Earth-Moving Machinery (EMM) and ISO TC-127 Chair reported on the progress made by the initiative since the previous session. The common regulatory objectives, which had been developed in 2003 and revised in 2008, had been presented and discussed in Argentina, Australia, Brazil, Chile, China, the Republic of Korea and South Africa.

71. These consultations had revealed a need to expand the reach of the initiative beyond that of facilitating trade in safe machinery to the broader goal of contributing to worksite safety with the long-term goal of "zero injury". This could be achieved by: developing guidelines for safe use of machines on the worksite, adapted to local conditions and to the people present on the worksite; providing training for operators; ensuring appropriate maintenance for machinery; and implementing a general worksite risk management plan.

72. The Task Force is also working on a template Model Declaration of Conformity certificate that aims at further harmonizing ways of reporting conformity to standards and industry requirements.

73. The Working Party took note of the progress made by the Sectoral Initiative, and adopted its progress report (ECE/TRADE/C/WP.6/2011/8). It also invited the secretariat, the Rapporteur and the Task Force to continue to promote the Common Regulatory Objectives (CROs), develop a readily acceptable common certificate of conformity, and encourage countries to further implement them.

2. Telecom Initiative

74. The Convenor of the Telecom Initiative noted the limited interest from member countries in applying the CROs adopted in 2003 as originally foreseen at the time of their development.

75. The CROs are also an example of good regulatory practice, suitable for wider use. In particular, they may be valuable as a possible means of addressing non-tariff barriers (NTBs) to trade in the Information and Communication Technology (ITC) sector within the Non-Agricultural Market Access (NAMA) negotiations of the World Trade Organization (WTO).

76. As negotiations in the WTO Doha round are currently stalled, an alternative being explored is the expansion of the WTO Information Technology Agreement (ITA), which currently removes tariffs from a number of ICT goods and could be in the future extended to include NTBs.

77. The Working Party took note of the progress made by the Task Force (ECE/TRADE/C/WP.6/2010/10) and adopted the report of the Telecom Initiative, as contained in document ECE/TRADE/C/WP.6/2011/7. It also invited the secretariat, the Rapporteur and the Task Force to continue to promote the CROs and encouraged countries to further implement them.

3. Equipment for explosive environments

78. The Convenor of the Sectoral Initiative on Equipment for Explosive Environments (SIEEE), from the German Physikalisch-Technische Bundesanstalt, presented achievements of the initiative during 2011:

- The publication of the CROs as a bound document, which is also available for download on the ECE website: http://www.unece.org/fileadmin/DAM/trade/wp6/SectoralInitiatives/EquipmentForExplosiveEnvironment/SIEEE_CRO.pdf;
- A document comparing the UNECE CROs, the IECEx system, the ATEX directive and Russian regulatory requirements had been presented and discussed (the document is available at: http://www.unece.org/fileadmin/DAM/trade/wp6/SectoralInitiatives/EquipmentForExplosiveEnvironment/Ex-CROs-Analysis.pdf);
- Regulators of products used in mines, oil platforms and chemical plants from Australia, Brazil, the European Union, the Russian Federation, and the United States at a workshop, held back to back to the meeting of the IECEx scheme in Split in September, agreed that products used in dangerous facilities needed a common regulatory framework. They also agreed that countries could reach that objective in the medium term (see press release: http://www.unece.org/index.php?id=26114);
- A presentation of the project's activity, as an example of best practice in regulatory cooperation, at the Second Seminar of the International Organization for Legal Metrology (OIML) on Conformity to Type, held in Prague, in October 2011.

79. The initiative had also been active in preparing a first draft of the Guidelines for Market Surveillance of Equipment for Explosive Environments (Hazardous Locations). These guidelines need to be further elaborated so that they could be included as an integral part of a future, revised edition of the CROs.

80. The Convenor also presented a project for organizing regional workshops in partnership with the industry to promote the initiative among regulators. This project would entail the development of guidelines, awareness-raising and training materials for regulators to familiarize them with technical terms and the duties of stakeholders in the Explosive Environments sector. A prerequisite for undertaking this project would be to raise sufficient funds.

81. Activities planned for 2012 include:

- A pilot regional workshop for the countries of the Gulf Region to be held in the United Arab Emirates in March 2012;
- Participation in the activities of a Task Force aiming at the Approximation of the Technical Regulations, Standardization and Certification Systems of the European Union and the Russian Federation.

82. The Working Party took note of the progress made by the Sectoral Initiative (ECE/TRADE/C/WP.6/2011/9). It also invited the secretariat, the Rapporteur and the Task Force to promote the CROs and encouraged countries to implement them.

4. Proposed initiative on medical equipment

83. A representative of the International Accreditation Forum (IAF) presented the major issues confronting the certification of quality management systems of organizations providing medical devices and related services. In this sector, regulations on major markets were harmonized with, or relied on, ISO 13485, which set out requirements that allowed an organization to demonstrate its ability to provide medical devices and related services that consistently met both customer and regulatory requirements.

84. However, in the absence of an internationally recognized system for assessing conformity, national regulatory bodies allowed third-party auditors/inspectors to carry out audits and accredit auditors/inspectors independently. Many countries were contemplating

developing ISO 13485-based national quality management systems for regulatory purposes. If countries drew up their own mandatory programmes for assessing conformity, the result would be duplication of testing and increased costs for international trade in medical devices. That would have consequences not only for SMEs and for producers from developing countries, but also for the international healthcare system.

85. IAF had developed the ISO 13485 Medical Device programme to provide medical device providers with one ISO 13485 audit that could be "accepted everywhere", based on audits conducted by native-speaking auditors

(www.compad.com.au/cms/iafnu/workstation/upFiles/IAF__ISO_13485_0112.pdf). The programme would become active in July 2012 when IAF adopted mandatory documents.

86. IAF hoped that UNECE might assist in bringing this programme to the attention of regulators internationally including, if appropriate and resources permitting, by means of a sectoral initiative. Further consultations would be pursued by the Bureau and the secretariat on this proposal.

87. IEC observed that challenges similar to those described by IAF existed in the sector of electrical equipment used in medical practice, addressed by several IEC standards.

88. The Working Party took note of developments regarding accreditation in the medical-devices sector.

5. Proposed Initiative on Safety of Pipelines

89. A representative of the private sector and the Deputy Head of the Russian Federation Federal Service of Ecological, Technical and Nuclear Surveillance (Rostechnadzor), responsible for market surveillance related to pipeline safety, presented recent regulatory development in this sector in the Russian Federation. They emphasized that the Russian Federation supported the harmonization of regulatory requirements in this sector to gain access to best practice, especially in laboratories and testing. The Russian delegation invited other delegations to share information about regulations in this sector in their countries. That could be done through a questionnaire, which would be prepared in due time.

90. The Working Party took note of the information on the pipeline safety project from the coordinator of the project and on the development of a technical regulation on pipeline safety in the Customs Union.

91. It invited interested stakeholders to participate in the discussions on this technical regulation and requested the secretariat to inform the UNECE Working Party on Gas about the ongoing work. The Working Party invited the Russian Federation to nominate a coordinator for the project.

VII. Standardization and regulatory practice

Documentation: ECE/TRADE/C/WP.6/2011/6 - Compilation of regulatory developments

A. Review of relevant developments in standardization

92. In the EU, standardization was an important priority, and one of the 12 key actions of the 2011 Single Market Act.

93. The most important related development was the adoption of the "Standardisation Package" in June 2011 (available at: http://ec.europa.eu/enterprise/policies/european-standards/standardisation-policy/index_en.htm). It included a political communication with a strategic vision on standardization, a proposal for a regulation, and the results of the accompanying impact-assessment study.

94. The political communication contains 29 legislative and non-legislative actions in five major fields: industrial policy and innovation, key societal challenges, inclusive standard-setting process, standards for services, and ICT standards and interoperability.

95. If adopted by the European Parliament and Council, the proposed regulation would, for instance, consolidate the legal basis for European standardization, extend definitions and scope of standards to services, enhance the participation of stakeholders' in standardization, revamp the process of standardization planning and financing to ensure that it was accelerated, simplified and more inclusive, and promote the recognition of ICT standards in public procurement.

96. A discussion ensued regarding the importance of NGO participation in standardization work and how it could be enhanced, and on how cooperation with standards bodies of major trading partners could be promoted.

97. In concluding the discussion, the Chair pointed out that it was in the best interest of governments to ensure that the public sector took part in standard making, and that they made use of standards in enforcement activities.

B. Review of relevant developments in regulatory practice

98. The delegation of Belarus updated participants about progress in developing the technical regulations of the Customs Union since the previous session.

99. The Customs Union had developed its technical regulations based on the EU directives and international best practice, including the principle of presumption of conformity. It had adopted the following fundamental documents: a set of common principles, a systematic policy agreement, a common list of products subject to mandatory conformity assessment (the "unified list"), and an agreement on the mutual recognition of accreditation of certification bodies and testing laboratories.

100. The process of development of technical regulations included: a period of public consultation, of at least 60 days; followed by the approval of the final draft and the development of supporting documents. These included: the list of standards for presumption of conformity, the list of standards for tests, the relevant forms to be used for certification and declaration, and the rules applicable for the transition period. The final step of the process was adoption by the Customs Union Commission. After this, the technical regulation became compulsory for all the participants in the market. Sectors of current priority were: safety, energy efficiency, environmental protection, and the prevention of fraud and deceptive practices. A total of 61 technical regulations were foreseen, 47 were identified as priority and 14 had already been adopted. The development of a regulation similar to the EU General Product Safety directive was also foreseen.

101. The "unified list" was available online in Russian (http://www.etalon-test.ru/uploads/engg/singlelistofproductsinregardtothatobligatoryrequirementsaresetwithintheframeworkofthecustomsunion.pdf). Products on the list were those for which a common Customs Union technical regulation was being developed. All products not included in the list could circulate freely in the Customs Union if they complied with the regulations of the CU country where the good was either produced or imported. For products on the list, instead, circulation on the markets of partner countries in the Customs Union required

certification in accordance with the requirements of the Customs Union. Once common technical regulations were in place, the list would be phased out.

102. For the majority of products, a declaration by the manufacturer was sufficient; but certification was required for products of high risk. The Customs Union is also working on electronic declarations. Enforcement relies on risk assessment and priorities for subjects and sectors of special concern.

103. It was also important to develop common standards to support the technical regulations. During the transition period, national standards could be used to prove compliance. Once the intergovernmental standards were adopted, all conflicting national standards were cancelled.

104. The delegation of the Netherlands informed delegations about its regulatory reform programme, based on the "Standard Cost Model", which allowed unnecessary regulatory costs to be made visible to policymakers. Compliance costs had been reduced; starting from those that were clearly disproportionate to the risks addressed. Concrete examples of the outputs of the reform effort included:

- Reductions in the costs of inspection (by focussing on sectors of high risk and allowing business that was consistently compliant a lighter inspection regime);
- The "right to challenge": allowing business to propose changes in regulations if they could propose more effective alternatives;
- The "common commencement date": a fixed period of each year when regulatory reforms are implemented.

105. Some lessons learned:

- Successful reform required political commitment, sufficient resources, a proper infrastructure and strong incentives (clear targets, sense of ownership, stakeholders' involvement);
- Timing was crucial and a stepwise approach worked best, with an appropriate mix between easy victories (the low-hanging fruit) and successfully addressing complex issues;
- Management of expectations was key, because in the short term, a successful reform might even increase the regulatory burden before the benefits fully kicked in.

106. In conclusion, successful regulatory reform did more than just reduce red tape. It increased compliance, in turn allowing—in different sectors—for a safer workplace, a well-functioning health sector, and reliable statistics.

VIII. Standards and regulations as a tool for promoting sustainable development: preparing for Rio +20

107. The panel opened with a presentation on the forthcoming United Nations Conference on Sustainable Development, to be held in June 2012 in Rio de Janeiro, Brazil, and the related preparatory processes. The two main topics of the conference would be: (a) a green economy in the context of sustainable development and poverty eradication; and (b) the institutional framework for sustainable development.

108. The Conference aimed at involving all major groups, including business and NGOs, who would be contributing to a "zero-draft document" that would serve as the basis for negotiations.

109. The Conference outcome document would target the integration of economic, social and environmental goals through consistent and committed action at all levels.

110. Another important ongoing negotiation, within the United Nations system, is progressing within the United Nations Framework Convention on Climate Change (UNFCCC). Within UNFCCC, standards play a very important role, especially in connection with the three market-based mechanisms under the Kyoto Protocol, namely:

(a) International emissions trading: until now 3,536 registered projects in 72 countries, with over 750 million certified emission reductions (CERs) issued to date and more than 2.7 billion expected by the end of 2012;

(b) Clean Development Mechanism (CDM): Projects in developing countries;

(c) Joint Implementation: Projects in any country with a commitment under the Kyoto Protocol.

111. Speakers from standards-development organizations and private-sector conformity-assessment bodies then shared their vision of how standards and certification could be instrumental to these two major processes and more generally to sustainable development.

112. ISO reported how its activities supported progress towards a green economy by delivering different types of international standards: specifications for products and materials or for processes, standards for measurement and conformity assessment, and management standards.

113. These were complemented by the ISO 26000 standard, which provides guidance on social responsibility. Published in November 2010, with contributions from more than 400 experts, from 99 countries, it received more than 26,000 international comments during development. Taken together, these tools responded to the demand of business companies for which sustainability was no longer an extra but rather a core issue, and also contributed to a better use of the earth's scarce resources.

114. The representative of IEC stated that meeting the challenge of a growing demand due to growing world population and growing energy use would require an improvement in utilization of resources by a factor of four: using half as much, twice as efficiently.

115. The main priorities were to:

- Make energy use more efficient
- Electrify and "de-carbonize" transport and heating
- Invest in renewables.

116. That could be realized by agreeing on the "what" —precise technical specifications based on consensus, and the how—conformity-assessment modules to check that requirements are met and to compare efficiency.

117. Regulations could refer to, or be based on, standards, which then became the basis for policy-making and investment. Additionally, the IEC provids global schemes for assessment with reliable and predictable results, as well as obligatory mutual acceptance of test results. That gave policymakers the advantages of Mutual Recognition Agreements without the overheads and difficulties.

118. The European Standardization System contributed effectively to shaping the EU single market with significant industry involvement, representing a unique model of co-regulation.

119. In that context, current priorities in the development of standards focused on the three components of sustainable development:

(a) Economic growth (promoting competitiveness and innovation, realizing economies of scale, and facilitating trade);

(b) Environmental integrity (in particular efficiency, environmental management and ecological safety);

(c) Societal progress (consumer protection, worker protection, health services, accessibility).

120. Within CEN/CENELEC, a number of specific standards in each of those areas had been recently adopted or were in progress.

121. Another important dimension of the sustainability debate was the availability of data to measure progress towards sustainability, both for a single company and at an aggregated level. Standards also played a key role in supporting the global deployment of new metrics particularly in the consumer goods sector, and for the automated exchange of this information between trading partners.

122. A pilot project had been undertaken to measure the sustainability of packaging, with input from the Consumer Goods Forum. Sustainability was a multi-dimensional concept, which included the sustainability of inputs used in the production of packaging, and the packaging biodegradability, recyclability, compostability, and contribution to responsible land use through lowering the contribution to landfills.

123. The reduction of energy and water use in the production of packaging was also important. To measure all these different dimensions effectively required a common language, effective information sharing between trading partners, a common interpretation by all, and reliable and up-to-date data.

124. A representative of the European Academy for Standardization (EURAS) shared the view that to promote further use of standards, including in the context of sustainable development, training and education was an essential priority—at all levels of the educational curriculum but especially in vocational training and in universities.

125. The Working Party welcomed the exchange of experience regarding the role of standards in the three dimensions of sustainable development. It requested the secretariat, the Bureau and delegations to find appropriate ways of channelling the Working Party expertise into work related to the preparations for the Rio+20 Conference.

IX. Review of recent developments in conformity assessment and accreditation

126. It was agreed to continue, intersessionally, discussions on how to follow up on the panel session on Conformity Assessment held at the previous annual session, including with a view to revising Recommendations F, G and L.

X. Market surveillance

A. Updates from regional groupings and the Advisory Group on Market Surveillance ("MARS" Group)

Documentation: ECE/TRADE/C/WP.6/2011/11 - Report on MARS Group activities and and its meetings
ECE/TRADE/C/WP.6/2011/12 - Draft Recommendation on Market Surveillance

127. The Chair of the MARS Group informed the Working Party about the recent activities and reported on the meetings held in June in Sweden and in October in Bratislava (ECE/TRADE/C/WP.6/2011/11).

128. She reported, in particular, about the exchange of information and strengthened cooperation among market surveillance authorities, proposals for revising Recommendation M, taking into account the new rules concerning author piracy and protection of intellectual property rights, and the proposed Recommendation N.

129. The Working Party encouraged delegations, the Bureau and the secretariat to continue working on revising Recommendation M, taking into account the output of the workshop on traceability.

130. Concerning the General Product Safety Model Initiative, the Chair of the MARS Group concluded that assistance was needed especially as regards statistical tools (maximum number of instances of tolerated non-conformity needed to be identified).

131. The delegation of Sweden introduced the draft recommendation on good market surveillance policies and practices. It had been prepared in consultation with a number of experts. It aimed at drawing the attention of United Nations Member State Governments to the need for effective market surveillance. It tried to define the basic key elements required for effective Market Surveillance. The MARS group hoped that countries could benefit from more systematic guidance in relation to the enforcement of legal requirements (ECE/TRADE/C/WP.6/2011/12/Rev.1).

132. The representative of Belarus thanked the Chair of the MARS Group and the Swedish Institute for the work on Recommendation N and proposed that it be approved.

133. He also proposed a strengthened exchange of information between the RAPEX system and that of the CIS. He also reported that a new agreement on market surveillance being drafted within the Customs Union was based on Recommendation M. He underlined that Recommendation M should be updated, based also on a proposal for revision presented by Belarus in 2010.

134. The Chair of the MARS Group confirmed that the work on Recommendation M would continue, taking into account the outcomes of the workshop on traceability.

135. The Working Party adopted Recommendation N and the report of the MARS Group, as contained in document ECE/TRADE/C/WP.6/2011/11. It also requested the secretariat to publish the text of Recommendation N as part of the volume "Recommendations of the Working Party".

136. The representative of the European Union reported on the New Legislative Framework (NLF). He stressed that the implementation of this regulatory legislation required coordination between Market Surveillance Authorities (MSA) and customs

authorities of the Member States at different levels, to ensure border controls on an adequate scale before the release of products for free circulation.

137. Another obligation was to publish information (according to the EU template) on the National market surveillance programme of each Member State. This would allow fulfilling the objective of the NLF to get a peer review of these programmes and identify best practices.

138. In 2010/2011, notifications in RAPEX had been extended to professional (i.e. non-consumer) goods and to risks other than those of health and safety. The EU planned to set up a general information support system with: (a) information on general issues relating to market surveillance activities; (b) information on products presenting a risk, identification of risks, test results, provisional measures, and contacts with economic operators. The prototype would be the Internet-supported information and communication system (ICSMS) currently used by Austria, Belgium, Cyprus, Estonia, Germany, Luxemburg, Malta, Slovenia, Sweden, Switzerland, the Netherlands and the United Kingdom.

139. The EU representative also gave an overview of the following: the future legislation within the "Product Safety Package"; the CE marking information campaign launched in April 2010 and still ongoing; and the Alignment of existing New Approach Directives to the requirements laid down in Decision 768/2008.

B. Common definitions and terminology in market surveillance

Documentation: ECE/TRADE/389
Publication "A Glossary of Market Surveillance Terms"

140. The Working Party welcomed the publication of the first edition of the *Glossary of Terms on Market Surveillance* and encouraged delegations to provide comments for further development of the glossary.

141. The representative of the Russian Federation acknowledged the *Glossary*'s relevance; however, he mentioned some divergence of the terms from Russian legislation and encouraged a further discussion and exchange of ideas in order to arrive at more exact definitions.

C. Update on the development of the Global Market Surveillance database

142. The secretariat presented the functional database on market surveillance, explained the different possibilities for searches and encouraged member States to further provide the secretariat updates for their countries. The secretariat also addressed the member States with regard to the questionnaires for the database on data compatibility.

143. A company also shared information about a proprietary database, comprising about 60 countries, which mapped products to legislation and countries.

XI. Metrology

144. Owing to the absence of the representative of OIML, discussions on metrology had to be postponed until the next session.

XII. Capacity-building

145. The secretariat informed delegations that it had tried unsuccessfully to raise funds to finance a project in Azerbaijan and had prepared a number of project proposals for other countries and regions.

XIII. Other business

146. The secretariat proposed the tentative dates for the twenty-second annual session from 22 to 24 October 2012.

XIV. Adoption of the report

147. The Working Party approved a list of decisions taken at its session. The list is available at: http://www.unece.org/trade/wp6/documents/2011/decisions_final.pdf The Working Party requested the secretariat, in consultation with the office bearers, to complete the descriptive part of the report taking into account the contributions made and the discussions held during the session.