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Working Party on Regulatory Cooperation and Standardization Policies

Twentieth session

Geneva, 1-2 November 2010

Report of the Working Party on Regulatory Cooperation and Standardization Policies on its twentieth session

Note by the secretariat

Summary

At its twentieth session, the Working Party:

- Established a Group of Experts on Risk Management in Regulatory Systems. The Group will develop best practice and recommendations on how to use risk-management tools in planning, developing and implementing technical regulations, conformity-assessment procedures, market-surveillance activities and inspections, as well as in the maintenance of an efficient body of technical regulations.
- Reviewed needs of business and developing countries and countries with economies in transition in the area of conformity assessment. The results of this discussion will serve as input to the ongoing revision of Recommendation L.
- Recommended the further development of a guidance document for market surveillance authorities; and of a common terminology for market surveillance.
- Supported the establishment of an online database aimed at sharing information about the competencies (sectors for which they are responsible), the legislative mandate for their activity, and the contact details (website/emails) of market-surveillance authorities in the UNECE region and worldwide.

Introduction

1. The Working Party on Regulatory Cooperation and Standardization Policies (WP.6) held its twentieth session on 1 and 2 November 2010. The meeting included two panel sessions: the first, on risk management in regulatory systems (1 November), and the second, on promoting regulatory cooperation in conformity assessment (2 November).
2. The following countries were represented: Austria, Belarus, Bulgaria, Brazil, Czech Republic, Finland, Germany, Japan, Kyrgyzstan, Netherlands, Norway, Poland, Russian Federation, Serbia, Slovakia, South Africa¹, Spain, Sweden, Swaziland¹, Switzerland, Trinidad and Tobago¹, Turkey, Ukraine, United Kingdom of Great Britain and Northern Ireland, United States of America, and Zambia.
3. The meeting was also attended by a representative of the European Commission (EC).
4. The following United Nations body and specialized agency participated: the World Bank Group (WBG) and the United Nations Interim Administration Mission in Kosovo (UNMIK).
5. Three intergovernmental organizations attended: International Bureau of Weights and Measures (BIPM), European Free Trade Association (EFTA), International Organization of Legal Metrology (OIML),
6. The following non-governmental organizations participated: European Committee for Electrotechnical Standardization (CENELEC), International Electrotechnical Commission (IEC) and International Organization for Standardization (ISO).
7. Observers present at the invitation of the secretariat included representatives of private-sector companies, associations and civil-society organizations from various regions.
8. The Director of the Trade and Timber Division, the Chair and the current and previous secretaries of the Working Party recalled the achievements of the WP.6 over its 40 years of existence. They thanked the many institutions and individuals who had contributed to the success of its activities, and encouraged participants to renew efforts towards effective cooperation among all stakeholders for reinforced regulatory cooperation.

I. Adoption of the agenda

Documentation ECE/TRADE/C/WP.6/2010/1 – Annotated provisional agenda

9. The Working Party approved the provisional agenda.

II. Election of the officers

10. 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. Koreshkov (Belarus) and Mr. J. Mihok (Slovakia) as vice-chairs.

III. Matters arising from the previous sessions of the Working Party and meetings of its Bureau, the Committee on Trade and its Bureau, and the UNECE Executive Meeting

Documentation: ECE/TRADE/C/WP.6/2009/19 - Report of the Working Party on Regulatory Cooperation and Standardization Policies on its nineteenth session
ECE/TRADE/C/WP.6/2010/2 – Risk assessment and management in the activities of the Working Party
ECE/TRADE/C/WP.6/2010/9 - Report of the meeting of WP.6 Bureau, rapporteurs and Coordinators, “START” Team and “MARS” Group (Stockholm, 7-9 June 2010)

11. The Working Party adopted the reports of its previous session and of the Conference on Risk Assessment and Management. It endorsed the report of the meeting of its Bureau, the Rapporteurs and Coordinators, “START” Team and “MARS” Group.

12. The Committee on Trade was carrying out a project to evaluate the needs of countries with economies in transition for regulatory cooperation and trade facilitation. The preliminary results of a needs-assessment study of Belarus were briefly presented and discussed. The study would be presented to the Committee on Trade for endorsement. Specific recommendations referring to regulatory cooperation would then be referred for consideration to the WP. 6.

13. The delegation of the Russian Federation called attention to the creation of the Customs Union between Belarus, Kazakhstan and the Russian Federation. They urged the Working Party and the Committee--in future projects--to consider the countries of the Union as a single entity for the purposes of international trade. Belarus commented that issues related to the creation of the Customs Union were addressed in the study. The secretariat would ensure that these matters are properly addressed in the final report.

14. For the next meeting of the Committee, in June 2011, the Working Party asked the secretariat to prepare an information note on the implementation by the WP.6 of recommendations agreed during the last session of the Committee.

IV. Risk management in regulatory systems

Documentation: ECE/TRADE/C/WP.6/2010/2 - Risk assessment and management in the activities of the Working Party
ECE/TRADE/C/WP.6/2010/3 - Risk management in regulatory systems: A proposed methodology
ECE/TRADE/C/WP.6/2010/4 – Risk management in regulatory systems: A proposed survey

15. The panel session on “Risk Management in Regulatory Systems” gathered speakers from intergovernmental organizations (the International Finance Corporation (IFC) and UNECE, from regulatory and advisory bodies (European Commission; the Brazilian Standardization Agency, INMETRO; the former United Kingdom Cabinet office; and the Dutch project “Risk and Responsibility”) and from a scheme for the assessment of conformity (IECEE).

16. The panel session started with the screening of the short movie “Killer Trees” produced by the Central Government Reform Programme of the Netherlands. The movie illustrated the rising trend towards disproportionate measures targeting safety in Europe and internationally. It had been produced as a background for the 2010 “Day of Risk” Conference held in the Hague in May 2010 (see:<http://www.vernieuwingrijksdienst.nl/onderwerpen/interdepartementale/overheid-voor-de/risico's-en/english-page>).

17. The Working Party has undertaken a number of activities to follow up on the mandate received at its previous session. These included:

- Publishing the outcome and report of the Conference on Risk Assessment and Management (http://www.unece.org/trade/wp6/documents/2010/wp6_10_02e.pdf).
- Establishing partnerships with: national governmental institutions (i.e. INMETRO, Brazil and the Central Government Reform Programme of the Netherlands) international and regional organizations (the OECD, the European Commission); non-governmental institutions (the EMARS Project) and research networks (European Academy for Standardization, the London School of Economics).
- Developing an original model of how risk-management tools can be used to enhance the quality of technical regulations and their implementation based on existing risk management standards and international best practice (http://www.unece.org/trade/wp6/documents/2010/wp6_10_03e.pdf).
- Conducting a preliminary survey to identify the needs of the regulatory system stakeholders (http://www.unece.org/trade/wp6/documents/2010/wp6_10_04e.pdf).

18. The panel session discussed how authorities, business and other stakeholders in the regulatory systems could better manage the risks that confront consumers, workers and communities.

19. One of the speakers observed that decision makers are usually under intense pressure immediately following a serious accident. The continuous coverage by the media and the involvement of national and international stakeholders adds further pressure. In several sectors, this has sometimes led to a disproportionate regulatory response. According to the speaker, experience shows that a contingency plan is critical to manage crises, and should include:

- Taking steps to act quickly to avoid the building up of expectations, while avoiding using up the resources of the (typically few) subject matter experts.
- Carefully choosing the spokesperson and formulating a common response that should be adhered to. For example, in the aftermath of

the terrorist attacks in London, the Government held firm to the line that “London must stay open”, which proved successful in making the public resilient and avoiding the spread of panic.

- Separating the function of investigation from that of deciding any further action and long-term response. The Government or business affected does not necessarily have to conduct the investigation but may leave this to the independent experts. A common mistake is to place blame too quickly, although after careful investigation attributing responsibility to one individual may be appropriate.
- Taking interest in and care for the victims and their families should always be a priority.

20. Other presentations focused on how regulatory systems can optimize the cost/effectiveness ratio and take a risk-focused approach with a graduated response. This means focusing resources on priorities and accepting that some hazards will occur. Several countries presented their experience.

21. When developing proposals for new regulations, the European Commission carries out an impact assessment, which includes a detailed risk assessment. The Commission also considers professional and independent scientific opinion before deciding if action is required and which form it should take.

22. Under the EU “New Legislative Framework” (Regulation 765/2008, Decision 768/2008) the task of managing risks is shared among the regulatory authority, manufacturers, market-surveillance authorities and standardization bodies, each of which has its respective competency, both before and after the product is placed on the market.

23. Risk management is also applied in the choice of the conformity assessment procedure, so as to (a) take into account the risks entailed by the products concerned; (b) avoid creating unnecessary burdens for economic operators, and (c) be effective, and proportionate to the economic infrastructure of the given sector, and to the type and importance of production and risks. Decision 768/2008 sets out the different conformity assessment modules. These closely mirror those under the ISO/CASCO toolbox.

24. In Brazil, a large and growing number of conformity-assessment programmes are established through regulatory documents. Most have been developed without assessing the potential impact on the industry and society at large. Until recently the different regulatory agencies did not have common guidelines for good regulatory practice. But these have now been developed and are available on the INMETRO website (<http://www.inmetro.gov.br/qualidade/guiaRegulamentacao.asp>).

25. In developing new regulations, all the agencies carefully weigh the estimated positive and negative impact against the “do nothing” option.

26. In the Netherlands, a new project on “Risk and Responsibility” will help the Government to deal with risks and incidents in a more balanced way. In the coming two years, the programme aims at: (a) promoting public debate on this topic, in particular as concerns physical safety (transport, labour safety, environment, health care, food safety etc); (b) putting together a national catalogue of risks, developing pointers for ministries and officials for dealing with the aftermath of an incident, as well as a set of principles for

a well-considered government risk policy; and (c) developing a Cabinet vision on government's responsibility role with regard to risks.

27. One speaker compared different regulatory systems, in particular prescriptive regulations versus performance-based approaches. In assessing their merits, he concluded that:

- The two different approaches may be better suited to addressing different risks. In particular, risks may affect different stakeholders. They may also have different roots such as hazards to life and health and to the environment; risks related to the incompatibility of goods/techniques; risks of fraud against consumers and finally risks of theft or tax evasion.
- The requirements of a prescriptive approach may be easier to understand, implement and monitor, but can have an adverse effect on innovation. Prescriptive regulations typically require frequent legislative updates and large resources to run market checks.
- A performance-based approach requires a more mature level of collaboration with industry, demanding consumers, a strong liability regime for producers and a good accreditation system.

28. If a decision is taken to change from one approach to another, it is essential to carefully regulate the process.

29. Major lessons can also be learnt from experience at the sectoral level. One example is medical electrical equipment, which has a direct effect on health and has major repercussions not only on risks incurred by patients, but also on the personnel using it, and on the surrounding environment.

30. This sector widely applies the IEC 60601-1 Edition 3: 2005 standard, which fully incorporates risk-management principles according to the ISO 14971 standard. This means implementing the highest standards of risk management, and it is very demanding for the industry and also for the conformity-assessment bodies. Specific guidelines have therefore been developed and training workshops will be carried out.

31. The risk-management process under this system mirrors closely UNECE's proposed reference model. For example, the manufacturer is required to have a policy for determining criteria for risk acceptability and record it in the risk-management file. Because the sector is covered by a voluntary certification scheme within the IECEE scheme (www.iecee.org) manufacturers who adhere to the scheme are required to provide the complete risk management file only to one certification body. This body reviews it and issues an IEC certificate. In a number of countries, this gives direct access to the national market. In others, national certification bodies are required to review the IEC certificate (but not the complete risk management file) and then issue the national mark required to access the market.

32. One delegate pointed out that presentations mostly addressed governmental organizations but that each of the stakeholders in the regulatory system had a significant role to play in managing risks effectively. The Group of Experts on Risk Management in Regulatory Systems should therefore include participants from different backgrounds, who would be defining best practice in different domains.

33. In summing up, the interim coordinator said that the most important task for the Group would be to develop recommendations on how to strike a balance between safety and costs. Risk management was already permeating regulatory systems as well as voluntary industry standards. But two elements needed to be further developed, especially risk judgment (determining the acceptable level of risk, prioritizing risks, choosing among risk management strategies, etc.) and risk-based processes. The Group would build upon the expertise and best practice of WP. 6. The session concluded by presenting a preliminary plan of action of the proposed Group of Experts (http://www.unece.org/trade/wp6/documents/2010/wp6_10_04e.pdf).

34. The Working Party adopted the terms of reference of the Group of Experts on Risk Management in Regulatory Systems (GRM) contained in the annex of document ECE/TRADE/C/WP.6/2010/2 and decided to establish this new Group of experts.

35. The Working Party elected Mr. D. Macrae and Mr. V. Nikonov as Convenors of the Group of Experts on Risk Management in Regulatory Systems.

36. The Working Party noted the proposed reference model for risk management in regulatory systems (ECE/TRADE/C/WP.6/2010/3), as well as the proposed survey based on this approach (ECE/TRADE/C/WP.6/2010/4). It asked the secretariat to pursue its efforts in order to map risk management needs of relevant stakeholders.

V. Standardization and regulatory practice

37. In this session, the representatives of the International Electrotechnical Commission, CEN/CENELEC, President of the Czech Office for Standards, Metrology and Testing, and other organizations professionally involved in risk-management development, training and implementation discussed the latest developments in standardization.

A. Review of developments

Documentation: ECE/TRADE/C/WP.6/2010/6 - Compilation of regulatory developments
ECE/TRADE/C/WP.6/2010/7 - Modalities for improving information sharing on technical regulations

1. Standardization

38. Under the standing item on standardization, delegations were briefed on some recent developments, including:, as follows:

- The World Standards Cooperation (WSC) had been working to increase the awareness of the contribution of standards to our daily life. Under the WSC, the three most important international standards-setting Organizations (IEC, ISO, ITU) work together to identify themes for the World Standardization Day and organize training sessions for the national members' staff. The possibility for

joint work with the Working Party on the topic of sustainable development in future was raised.

- A representative from the CEN-CENELEC Management Centre presented the organizations' current priorities. Standards-setting organizations could play an important role in fostering recovery from the crisis in Europe by improving energy efficiency, promoting the take-up of "green products", developing clean technologies, and removing barriers to trade. To fulfil this role, the two organizations needed to work together effectively, and for this purpose had established a novel management structure. They also needed to strengthen ties with research institutions and reach out to SMEs and societal stakeholders. He pointed out the importance of the European single market, highlighting three strategic aims: innovation, competitiveness and internationalization/globalization of the European community.
- The Chair of the External Relations Committee of CEN/CENELEC/ETSI further explained that the three organizations were also strengthening their cooperation with countries outside Europe. For instance, they were granting affiliate status to the standardization organizations of countries listed in the European Neighbourhood Policy, and developing partnerships and memoranda of understanding with several other national and regional standards-setting institutions. Notably, they were strengthening cooperation with China, India, the countries of the Southern African Development Cooperation (SADC) in the framework of "joint activities", under the condition that those countries complied with EU standards. Cooperation with countries of EASC and particularly with the Russian Federation was another important priority. With their activity, they would contribute to the objectives of the present-day strategy of the EU's "Europa 2020" aimed at the revival of the European economy.
- The representative of EC, DG ENTR gave information on the latest progress in the field of the "EU New legislative framework" launched in 2008 (its three main objectives: (a) Market Surveillance, (b) accreditation including cross-border accreditation and (c) launching of CE campaign on EU level) and about the "Standardization Package", adopted by the EU. A document summarised initiatives referred for standardization, primarily from the legal point of view. Due to the complexity of this issue and the current economic and financial situation in Europe, we could expect the first concrete results by April 2011. This agenda was also a part of strategy "Europe 2020" (research, development, standardization, etc., the list is still open).
- The Chair of the Czech Bureau of Standards reported on the use of World Trade Organization principles in European standardization. The legal foundation for European standardization had been laid down in Directive 98/34/EC, which recognized the three European standardization organizations CEN, CENELEC and ETSI and enabled the Commission to ask them to undertake standardization work in specific areas. Standardization in the ICT sector had been framed by Council Decision 87/95/EEC. He then made a detailed review of the

key principles applied in the development process of standards at the international level, including transparency, openness, impartiality, consensus, efficiency, relevance and consistency.

39. The Chair recalled that Annex 3 of the TBT Agreement contained provisions principles for national and regional standardization bodies, but not for international bodies. This was why the EU proposed to develop a code for international standardization bodies during the Second Triennial Review of the TBT Agreement. For the development of international standards, guides and recommendations certain principles had been agreed by the WTO TBT Committee, as mentioned in the presentation by the Czech Bureau.

40. The Russian Federation presented a proposed Model for the Assessment of Technical Regulations and Standards (MASTERS: see ECE/TRADE/C/WP.6/2010/7). The model would allow countries to systematically organize and compare requirements contained in technical regulations in different countries and regions. Requirements and specifications could be organized into an online database, according to sectors or products, according to the type of danger they sought to address (mechanical, electrical, chemical, etc.) and also the type of regulatory measure (voluntary national standard vs. regional compulsory regulation). This would provide the basis for regional or international regulatory convergence, with the goal of developing common standards and technical regulations or working towards regulatory equivalence (i.e. common safety requirements).

41. The Working Party considered the proposal by the Russian Federation to find modalities for improving information-sharing on technical regulations and standards (ECE/TRADE/C/WP.6/2010/7) and asked the Bureau and the rapporteurs to prepare appropriate proposals on the matter.

42. The Working Party took note of the proposal made by the Russian Federation to start an exchange of information on ways to assess the impact of new regulations on trade in UNECE member States, and considered the possibility of developing guidelines with a view to preventing technical barriers to trade.

1. Customs Union among the Russian Federation, Belarus and Kazakhstan

43. The representative of Belarus presented the progress made in developing a customs union between member States of the Eurasian Economic Community. Belarus, Kazakhstan and Russia are so far part of the union created in 2010. Its objective was to pursue further economic integration among its members through free movement of goods, services, capital and persons.

44. Harmonization of technical regulations was a prerequisite for the free movement of goods. Members were drafting common technical requirements, and a common regulatory framework with mutually recognized conformity-assessment and certification bodies, as well as procedures to avoid repeated testing and common accreditation rules. Common rules for market surveillance and the control of products from third countries were also being set. Thirty-four working groups had already started

examining ways to harmonize technical regulations in specific production sectors.

45. This harmonization process was inspired by the EU model, and the working groups had been formed according to the model contained in the New Approach EU Directives. It also included food products and related phyto-sanitary requirements.

2. *EU REACH (Registration, Evaluation, Authorization and Restriction of Chemicals) Regulation*

46. The Rapporteur on regulatory developments in the chemical industry introduced document ECE/TRADE/C/WP.6/2010/8. She emphasized the importance of striking a balance between safety and measures that had the potential to restrict trade, in particular as regards the chemicals industry, which was characterized by high research and development costs and rapid innovation.

47. She welcomed the forthcoming launch of a REACH implementation assessment announced by the EU and hoped that third countries would be consulted in the exercise. She expressed concern over perceived differences in interpretation of the REACH regulation by the European Chemical Agency (ECHA) and by national agencies. A representative of the Russian steel industry then presented a case in which products could be registered both as semi-finished products and as mixes. A set of documents was provided as back-up.

48. Following the session, the EC delegate regretted that the item had been scheduled for discussion at a time when he was unable to be present. The EC suggested that the specific issues raised by the Russian Federation with respect to REACH would be followed up in the framework of the EU-Russian Federation dialogue on chemicals, and that the WP.6 should rather be used as a general forum for identifying and exchanging good regulatory practices.

49. The Working Party took note of the proposal of the Russian Federation to continue the work on regulatory developments in the chemical industry and their impact on trade.

3. *Quarterly reports*

50. The EC representative provided an update on recent developments. He reported in particular that a proposal for the Review of the European Standardization System was in preparation, as well as a proposal to align 10 product harmonization directives to Decision 768/2008. He also informed delegations about important developments related to the implementation of Regulation 765/2008 in the field of accreditation (creation of a common framework for accreditation in the EU) and market surveillance. The WP.6 secretariat referred to the last WP. 6 newsletter (posted on the WP. 6 website) and document (ECE/TRADE/C/WP.6/2010/6) for an overview of recent legislative developments in the EU.

51. In the absence of the rapporteur for African countries, the representative of South Africa informed the Working Party that SADC member States had decided to establish a Technical Regulation Liaison Committee, and that they would report to it at its March 2011 meeting about developments occurring in the UNECE region. The Chair noted that no

rapporteur had yet been designated by CIS countries, but that the presentation made by the representative about the customs union was partly addressing this issue. The secretariat furthermore noted that it was now more intensively collaborating with countries of South-Eastern Europe, notably through the participation in the CEFTA Week event that would provide an opportunity to create new contacts.

52. The representative of ITU updated the Working Party on developments of interest to the Working Party. At the recent ITU Plenipotentiary Conference, a resolution on the ITU mark was adopted, which aimed at ensuring the compatibility and interoperability of ITU recommendations. Member States had also asked ITU to further work on four action lines, including the development of a conformity database to ITU standards and recommendations, interoperability events based on ITU recommendations, capacity-building as well as the establishment of test laboratories in developing countries.

B. Development and update of recommendations on regulatory cooperation and standardization policies

Documentation: ECE/TRADE/378 – UNECE Recommendations on Standardization Policies
Proposed revision of Recommendation D, “Reference to Standards” (ECE/TRADE/WP.6/2009/8/Rev.1)

53. The Working Party considered the set of recommendations and supported the proposal made by the Chair to establish a subgroup for revising Recommendation D “Reference to Standards” as well as the proposal of the MARS Group to amend or supplement Recommendation M “Use of Market Surveillance Infrastructure as a Complementary Means to Protect Consumers and Users against Counterfeit Good”.

54. Following its discussion on further work on revising Recommendation “D”, the Working Party noted the importance of considering the ISO/IEC guide to “Using and Referencing ISO and IEC Standards for Technical Regulations”.

55. In its work on revising Recommendation “M”, the Working Party noted the demand to create a system for the identifying and tracing counterfeit products within the supply chain.

Panel session on Conformity Assessment

56. Countries with economies in transition face particular challenges regarding both conformity assessment and the whole system of technical regulations. The following were issues of concern to Belarus:

- Developing and implementing horizontal legislation – such as the law on general product safety and on liability for defective products – in particular as regards general safety requirements, the obligations of manufacturers and distributors, the rights of surveillance authorities, etc.
- Assessing and managing the risks related to specific products, so as to improve the quality of product-specific regulations.

- Establishing a system to exchange information about dangerous products and a database of accidents related to product use.
- Avoiding duplication of tests, which often results from responsibility for different aspects being entrusted to different authorities and ministries.
- Need to translate standards and other technical documents into Russian.
- Need for a better understanding of how to establish presumption of conformity, specifically as regards matching the regulatory objectives to the standards' provisions, as well as when no standards are available to suit the regulator's needs.
- Better matching the choice of conformity-assessment options to the product risks.
- Completing the transition from a system based on pre-market certification to one based on post-market surveillance, which requires additional resources.

57. In many developing countries, authorities did not have sufficient trust in their manufacturers to generalize the use of the Supplier's Declarations of Conformity (SDoC). They also lacked resources to conduct post-market surveillance and therefore rely on third-party conformity assessment and certification. These systems, although they might be appropriate for products with significant risks, presented high costs. In developed economies as well, after many years of cooperation in this area, the system of designation (usually based on accreditation) of conformity-assessment bodies was criticized because it was not homogeneous in its evaluations, as a result of a perceived lack of detailed operational documents and procedures.

58. The different systems used in different countries ultimately result in (a) business having to obtain certificates of conformity in each of the countries to which they exported and (b) being audited several times by different authorities, with a significant waste of resources.

59. What answers can be found to address these concerns? Which stakeholders can be involved? What role can WP. 6 play? The experience with mutual recognition agreements (MRAs) shows that, while they are an important tool, they require burdensome designation procedures and generally heavy maintenance costs, against low perceived benefits. MRAs - according to one of the speakers can really only deliver in situations where there is an approximation in the underlying system of technical regulations.

60. The following elements might be considered as part of the solution.

- Reducing the cost of third-party conformity assessment by strengthening the cooperation between manufacturers and third-party conformity assessment bodies, in particular by encouraging the latter to avoid repeating tests already performed, under certain conditions.
- Increasing interlaboratory cooperation – and in particular proficiency testing - as a basic condition for achieving the homogeneity of testing, measurement and conformity assessment procedures.
- Building on the positive experience of the multilateral schemes of assessing conformity to standards, such as the IECEE and the IECEX.

Under these schemes, testing and certification is carried out by bodies that are accepted into the systems through agreed procedures and by peer assessment. These systems are transparent, fully democratic and self-financing.

- Working within the WTO TBT Committee to develop guidelines on how to develop tools to facilitate the acceptance of CA results.
- Promoting use of international standards as the basis for regulations as this creates a common language that greatly facilitates cooperation in CA.
- Encouraging cooperation between accreditors and CA bodies.
- Engaging in regulatory cooperation both in a voluntary setting and in the context of bilateral binding agreements, which leads to a better understanding of, and more convergence among, regulatory choices;
- Furthering agreements on good laboratory practice.
- Encouraging use of the ISO/CASCO toolbox consisting of guidance documents covering: vocabulary, principles and common elements of conformity assessment (such as codes of good practice, product, system, and persons certification, testing, calibration, inspection, marks of conformity, supplier's declaration of conformity, accreditation, peer assessment, and mutual recognition arrangements).

61. WP.6 through Recommendation L can promote a trade-friendly regulatory regime, based on the full responsibility of all stakeholders in the system, in particular the manufacturers and distributors.

VI. Regulatory Cooperation

Documentation: ECE/TRADE/C/WP.6/2010/9 - Report of the meeting of WP.6 Bureau, rapporteurs and Coordinators, "START" Team and "MARS" Group (Stockholm, 7-11 June 2010)

62. The Working Party noted 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), who had met in Stockholm in June 2010.

A. Regional projects

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

B. Sectoral projects

Documentation: ECE/TRADE/C/WP.6/2010/10 - Progress report on

the sectoral initiative on Telecom
ECE/TRADE/C/WP.6/2010/11 - Progress report on
the sectoral initiative on Earth-Moving Machinery
ECE/TRADE/C/WP.6/2010/12 - Progress report on
the sectoral initiative on Explosive Environments
Equipment
ECE/TRADE/C/WP.6/2010/13 - Progress report on
the sectoral initiative on Pipeline Safety

64. The Working Party discussed the continued relevance of Recommendation L. It was observed that countries could use the UNECE model and the Common Regulatory Objectives (CROs) that had already been developed in different sectors, not only with the aim of entering into binding agreements but also as the basis for good legislation and good regulatory practices.

65. It was also considered useful to extend Recommendation L to explicitly refer to current work items in the Working Party's programme, specifically those relating to market surveillance.

1. Telecom Initiative

66. The Convenor of the Telecom Initiative noted the limited interest from member countries in applying the CROs adopted in 2003. The current CROs address the main areas of concern for trade in telecom equipment, i.e. safety and electromagnetic compatibility, but they could be extended to also address emerging concerns on energy efficiency. However, in the context of the ongoing negotiations on Market Access for Non-Agricultural Products (NAMA), it remains to be seen to what extent member States of the WTO are willing to use this model to reduce non-tariff barriers (NTB) to trade in telecom equipment.

67. The Working Party took note of the progress made by the Task Force (ECE/TRADE/C/WP.6/2010/10). It also invited the secretariat, the Rapporteur and the Task Force to continue to promote the CROs and encouraged countries to further implement them.

2. Earth-Moving Machinery Initiative

68. The Convenor of the Task Force on Earth-Moving Machinery (EMM) and ISO TC-127 Chair presented the Initiative, which aims at minimizing the risks during the lifetime of the machine and at facilitating international trade. EMM is a global industry with a limited number of manufacturers, but with complex and costly conformity assessment procedures. Many manufacturers therefore support the long-term objective of the SIEMM of establishing supplier's declaration of conformity (SDoC) as the preferred mode of conformity assessment. As trust in manufacturers is not sufficiently established in some countries, the current CROs provide, as a transitional measure, the possibility for the manufacturer to work with a third party for assessment of conformity.

69. The Task Force is developing a template Model Global Certificate that aims at further harmonizing ways of reporting conformity to standards and industry requirements.

70. The Working Party took note of the progress made by the Sectoral Initiative, and adopted the revised CROs as proposed, as well as the terms of

reference of the Initiative (ECE/TRADE/C/WP.6/2010/11). 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

71. The Convenor of the Sectoral Initiative on Equipment for Explosive Environments (SIEEE), from the Physikalisch-Technische Bundesanstalt, recalled that the SIEEE has a very broad range and covers technical and conformity assessment requirements, as well as requirements pertaining to installation, repair, overhaul and the training of personnel handling Ex-equipment.

72. The CROs developed under the initiative had been adopted in 2009. Since then, they had been presented, to the industry and the regulatory stakeholders, at two meetings. The first had been held back to back to that of the WP.6 Bureau, and the second as part of the Annual Meeting of the International Electrotechnical Commission (IEC) System for Certification to Standards relating to Equipment for Use in Explosive Atmospheres (IECEX System).

73. To reflect the inputs received at the meetings, the Convenor had revised the CROs in consultation with all stakeholders and presented them to the WP6 for approval. He recalled that the CROs make reference to international standards and conformity-assessment procedures developed by IEC and ISO and internationally recognized certification schemes, such as IECEX, are recognized in the CROs as an acceptable system for proving compliance to the proposed CROs.

74. The Convenor also presented the project of 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, aimed at regulators, to familiarize them with technical terms and the duties of Explosive Environments sector stakeholders. Specifically the material would provide advice on optimal ways to react when defaults and/or issues are encountered, or on how to conduct market surveillance. A prerequisite for undertaking this project is the successful raising of funds in order to prepare the necessary training documents and guidelines.

75. The Working Party took note of the progress made by the Sectoral Initiative and adopted the proposed revised CROs (ECE/TRADE/C/WP.6/2010/12). It also invited the secretariat, the Rapporteur and the Task Force to promote the CROs and encouraged countries to implement them.

4. Safety of pipelines

76. The representative of the Russian Union of Industrialists and Entrepreneurs presented the Sectoral Initiative on Pipeline Safety. She confirmed that a candidate for the position of Coordinator would be presented at the next Bureau meeting in June 2011.

77. She said that the initiative under WP.6 aims at defining a set of safety requirements flanked by standards to be used to provide a presumption of conformity with these requirements. Requirements would need to be

specified with reference to different geographical, climatic and morphologic conditions to provide optimal protection from risk without excessive costs.

78. The Working Party requested the secretariat to continue providing annual updates on the work of all the sectoral initiatives.

VII. Review of recent developments in conformity assessment and accreditation

79. Following the discussions that took place during the panel session on Conformity Assessment, the Working Party invited delegations and regional and international organizations to continue to exchange information and experiences on conformity assessment and accreditation for facilitating international trade, especially with regard to the proposed revision of Recommendation L.

80. The representative of IEC provided an update on conformity-assessment activities over the last year. He stressed that IEC respects the neutrality principle and does not promote any kind of conformity assessment methods over others. He also pointed out that an important challenge for the conformity-assessment community is the need to support energy efficiency standards.

81. Developing countries face even larger challenges in implementing conformity assessment as they often lack adapted infrastructure. In 2010, the IEC had contributed to the setting up of electrical testing laboratories in two developing countries.

VIII. Market surveillance

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

Documentation: ECE/TRADE/C/WP.6/2010/14 - Report of the Advisory Group on Market Surveillance, its activities and its meeting in Bratislava (27-29 September 2010)
ECE/TRADE/C/WP.6/2010/16 - List of market surveillance authorities in UNECE member States with their respective competences

82. The representatives of IECEE, the Chair of the MARS group, and some professionals and experts on market surveillance discussed the technical and policy aspects of developing a market-surveillance database.

83. The Working Party adopted the report of the meeting of the MARS Group, which was held in Bratislava from 6 to 8 October 2010 (ECE/TRADE/C/WP.6/2010/14), and presented by the Chair of the MARS Group.

84. The Working Party asked the MARS Group to prepare proposals for revising Recommendation M, as well as to propose ideas for a new recommendation on the cooperation among market surveillance authorities to improve the traceability of counterfeit products.

85. The Working Party considered the list of market surveillance authorities in UNECE member States with their respective competences (ECE/TRADE/C/WP.6/2010/16), as well as the prototype database on market surveillance authorities. It encouraged the MARS Group to define proper typologies for the database, and invited member States to send the secretariat updated information on their market surveillance authorities.

B. Update on the Market Surveillance Model Initiative

Documentation: ECE/TRADE/C/WP.6/2009/11 – Market surveillance: general concept and how it relates to the activities of the Working Party
ECE/TRADE/C/WP.6/2009/12 - Draft guide to the use of the General Market Surveillance Model

86. The Convenor of the General Market Surveillance Model Initiative presented his ongoing research on sampling techniques for market surveillance. Such research is required because it could further improve the impact of market surveillance authorities' activities on health, safety and fair competition. The Convenor noted that available sampling techniques are not adapted to market surveillance, including those defined in ISO standards. And although general guidance is necessary, sampling techniques need to be tailored to the level of risk presented by the examined goods/sector being inspected. The “market surveillance effectiveness model” put forward by the Convenor is based on a recurrent approach enabling results from previously conducted inspection to feedback into the model. To develop and improve sampling models for specific sectors, data on results of market surveillance actions should be recorded and made available. The representative from the Netherlands suggested to consider data from a 2009/10 project on measuring instruments in the UK (National Measurement Office, Market Surveillance: MID and NAWI Directive - Trim Reference: E1103/0007/0001)

87. The Working Party encouraged member States to find donors to support the development of the draft guide for the General Market Surveillance Model as a training document and invited the MARS Group to continue its improvement and promotion.

C. Common definitions and terminology in market surveillance

Documentation: ECE/TRADE/C/WP.6/2011/17 - Second draft of the common definitions and terminology in market surveillance

88. The Convenor of the Initiative on Common Definitions and Terminology in Market Surveillance presented document ECE/TRADE/C/WP.6/2011/17. He acknowledged that only a few comments had been received so far, but that some terms had been clarified in the process. Firstly, the term “manufacturer” should be used as designating the entity responsible for the design and production of a product. Since it did not need to produce the product, the term “manufacturer” should be preferred to the term “producer”, which is sometimes used as well. Secondly, it had been pointed out that “authorized representatives” were not always taken as

responsible when market surveillance authorities noticed an irregularity. And there were sectoral differences in the extent of responsibility attributable to “authorized representatives”. The Convenor suggested to clarify this issue in a note. Thirdly, the term “safe product” could mean two different things (a) compliance with requirements and (b) absence of risks. The Convenor proposed to use the term with the second meaning only. In the discussion it was suggested to add to the list 2 new terms: “adulterated product” and “counterfeit product”.

89. The Working Party encouraged delegations to send the secretariat any definitions contained in their national regulations, which differed from those in the current document. It asked the secretariat to incorporate contributions from member States and regional organizations, and to circulate a revised draft of the document for the meeting of the Bureau and “START” Team scheduled for early June 2011. The document is expected to be approved as an information document at the next annual session of the Working Party. The new draft of the document should be submitted to the Working Party at its session in October 2011.

IX. Metrology

Documentation: ECE/TRADE/C/WP.6/2010/18 – Proposed memorandum of understanding between UNECE and the International Organization of Legal Metrology

90. The representative of OIML provided an update on activities of that Organization. He stressed the need for further cooperation and coordination with other stakeholders. OIML had revised its MoUs with ILAC and IEC, and hoped to find ways to collaborate with WP.6 and possibly also with other UNECE working groups.

91. Currently, OIML pursues its efforts to create a better legal framework for metrology and is in the process of revising its publication OIML D 1:2004 (Elements for a law on metrology). A draft for this revision entitled “Considerations for a law on metrology” has recently been circulated for comment. OIML also decided to revise its Guide for the application of ISO/IEC Guide 65 to assessment of measuring instrument certification bodies in legal metrology. This work will be undertaken by OIML TC 3/SC 5 following the publication of ISO 17065, superseding ISO/IEC Guide 65.

X. Programme of work and priorities of the Working Party

Documentation: ECE/TRADE/C/WP.6/2010/19 - Programme of work
ECE/TRADE/C/WP.6/2010/20 - Revised table of priorities
ECE/TRADE/C/WP.6/2010/21 - Evaluation of the Working Party

92. The Russian Federation welcomed the new programme of work and table of priorities, but asked the secretariat to more actively involve Member

States in future revisions of these documents. For this purpose, a draft will be circulated in advance of the next Bureau meeting.

93. The Working Party took note of the self-evaluation document.

XI. Capacity-building

94. The secretariat informed delegations that it had made efforts to raise funds to finance the General Market Surveillance Procedure (GMSP) as a training document, but that it had not been successful. However, the United Nations Industrial Development Organization was considering financing a national pilot project in Azerbaijan that would be based on the GMSP model. Fundraising efforts would be stepped up in 2011.

XII. Other business

95. The Working Party will hold its twenty-first session from 25 to 27 October 2011.

XIII. Adoption of the Report

96. According to established procedure, the Working Party approved a list of decisions taken at its session. The list of decisions is available at: http://www.unece.org/trade/wp6/documents/2010/decisions_final.pdf It 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.
