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Item 3 of the provisional agenda

**Matters arising from previous sessions of the Working Party,
and meetings of its Bureau, the Committee on Trade and
its Bureau, and the Executive Committee**

Report of the meeting of the Bureau, the rapporteurs and coordinators, the Team of Specialists on Standardization and Regulatory Techniques¹ (“START” Team), and the Advisory Group on Market Surveillance (“MARS” Group), held in Stockholm, 9-11 June 2010

Submitted by the secretariat

Summary

The report of the meeting of the “START” Team, held in Stockholm from 9 to 11 June 2010, is submitted for information.

The most important decisions emanating from the meeting were as follows:

- The Bureau recommends that a Group of Experts be established on Risk Management in Regulatory Systems. The decision will be put before the plenary at its November session.

¹ The ad hoc Team of Specialists on Standardization and Regulatory Techniques (“START” Team) was established by the Working Party on Regulatory Cooperation and Standardization Policies at its ninth session. Its terms of reference (TRADE/WP.6/2001/8/Add.1, annex 2) were last revised in 2001 by the UNECE Executive Committee at its meeting on 4 May 2009 (see www.unece.org/trade/ct/ct_2009/ct_09_011E.pdf).

- The Bureau requested the secretariat to organize two panel sessions as part of the twentieth session of the Working Party, respectively on Risk Management in Regulatory Systems, and on the Experience of the Working Party in promoting Regulatory Cooperation in Conformity Assessment.

I. Adoption of the agenda

1. The agenda was adopted. The secretariat and the Chair briefly presented WP.6, its goals and main activities.

II. Follow-up to the WP.6 annual session in November 2009 and of the Conference on Risk Assessment and Management

2. After reviewing the report of the nineteenth session of the Working Party (WP.6) including the Conference, participants discussed the provisional agenda for the forthcoming annual session. Several changes to the draft agenda and table of priorities were approved. It was also decided that two panel sessions would be organized on:

- Risk management in regulatory systems
- Options for regulatory cooperation in conformity assessment

III. Proposed Group of Experts on Risk Management

3. The secretariat presented the activities undertaken as follow-up to the Conference. These were:

- Publishing the outcome of the Conference and its report.
- Uploading a new section of the WP.6 website.
- Developing reference models for use of risk management tools by regulatory authorities, standardization bodies, conformity assessment bodies and market surveillance authorities.
- Developing questionnaires for the same stakeholders, based on the reference models.
- Establishing links with other organizations, as well as national and regional authorities having established expertise in risk management (see list below).

4. Planned activities included:

- Finalizing the risk management reference models.
- Undertaking the survey based on the questionnaires to document actual use of risk management tools and areas of outstanding needs.
- Organizing a panel session on this topic as part of the twentieth annual session.
- Developing a proposal for the 2011 session of the Economic Commission for Europe, which would take place in the first quarter of 2011.

- Working on the issue of “systemic risks”, to better understand what their characteristics are, what options Governments have in managing them and how WP.6, and the United Nations Economic Commission for Europe (UNECE) could assist in these processes (see www.unece.org/trade/wp6/ExtendedBureauMeetings/2010_June/systemic_risks.pdf)

5. Risk management tools are used within a regulatory system to achieve a balance between the costs of regulations and the protection they afford against hazards. The reference models illustrate how different stakeholders may use such tools in fulfilling their roles and responsibilities. The tools also serve as a benchmark to evaluate the results of a survey.

6. The reference models for the different stakeholders were then presented in detail (see ECE/TRADE/C/WP.6/2010/3). In the discussion, one participant informed the meeting that the European Commission was following the principle of consultation with all stakeholders as part of the “better regulation agenda”. In particular, the Commission had opened a public consultation for the proposed revision of 10 “New Approach” EU directives². Another participant pointed out that models should highlight the role of Customs.

7. Another participant said that risk management tools were extensively used in all kinds of regulations: deterministic, goal-setting and risk-based. But they could also help Governments to develop not only better regulations but also better regulatory systems. The United Kingdom, for example, had identified nine core risks to critical national infrastructure, and this provides a framework for the allocation of resources.

8. A government official from New Zealand presented the Risk Engine, a quantitative model developed to monitor the stringency of regulations and controls against the “riskiness” of products. Riskiness was a function of likeliness of non-compliance and its possible impact.

9. Likelihood of non-compliance was related to three main factors:

- regional regulatory coverage
- simplicity of testing
- deviation from international standards.

The impact of non-compliance was greater if the product was likely to be used by unsupervised children, for instance. The riskiness of a large range of products was then mapped out on a chart and compared against the current regulatory framework. Overall,

2 There are the Low Voltage Directive (2006/95/EEC); Simple Pressure Vessels Directive (2009/105/EC); Non-automatic Weighing Instruments Directive (2009/23/EC); Civil Explosives Directive (93/15/EEC); ATEX Directive (94/9/EC); Lifts Directive (95/16/EC); Pressure Equipment Directive (97/23/EC); Measuring Instruments Directive (2004/22/EC); Electromagnetic Compatibility Directive (2004/108/EC); Pyrotechnic Articles Directive (2007/23/EC). The Commission’s proposal intends to align these instruments with the provision of Decision 768/2008 as regards, in particular:

- Obligations applicable to manufacturers, importers and distributors.
- Market surveillance procedures.
- Notification of conformity assessment bodies.
- Harmonization of conformity assessment modules and definitions application to products falling under the scope of more than a harmonisation directive (see: http://ec.europa.eu/enterprise/newsroom/cf/itemlongdetail.cfm?item_id=4289&tpa_id=128&lang=en).

there was a good match between risks and regulatory response. The country's system was mainly based on pre-market controls. It had no controls for low-risk products, a declaration by the manufacturer for medium-risk products, and an ISO Guide 67 Type 1 Intervention for risky products.

10. Participants were interested in the system although it was difficult to see how it could be used in a system such as that of the EU, which is extensively based on post-market interventions. However, further collaboration with New Zealand could prove beneficial, in particular for sharing data on actual incidents.

11. In response to the request to provide references to work developed by other organizations, and national best practice as part of its report, the secretariat compiled the following list:

- EMARS: http://www.emars.eu/Risk_Assessment.html and Chapter 10 and Annexes B, C and D of the EMARS Book "Best practice techniques in Market Surveillance"
- EU: Risk Assessment Dialogue : http://ec.europa.eu/health/dialogue_collaboration/policy/index_en.htm
- European Risk Forum: <http://www.euportal2.be/index.php>
- IRGC: <http://www.irgc.org>
- Netherlands: Dutch project on risk and responsibility: <http://www.vernieuwingrijksdienst.nl/onderwerpen/interdepartementale/overheid-voor-de/risico's-en/english-page>
- OECD: www.oecd.org/document/23/0,3343,en_2649_34141_37551127_1_1_1_1,00.html
- United Kingdom: Assessing our Regulatory System – The Hampton Review: <http://www.berr.gov.uk/policies/better-regulation/improving-regulatory-delivery/assessing-our-regulatory-system>

12. Decision 1: The Bureau recommends the establishment of a Group of Experts on Risk Management in Regulatory Systems. The decision will be put before the plenary at its November session. In the meantime, Mr. Donald Macrae (United Kingdom) and Mr. Valentin Nikonov (Russian Federation) will take responsibility for the work moving forward.

13. Decision 2: The Bureau requests the secretariat to organize a panel session on Risk Management in Regulatory Systems as part of the November 2010 annual session.

14. Decision 3: The Bureau recommends that the secretariat organize a panel session on "regulatory cooperation in conformity assessment".

IV. Information on the needs assessment studies of regulatory and procedural barriers to trade

15. The secretariat informed the meeting of an ongoing project of the WP.6 parent body, the Committee on Trade, to assess the needs of the countries of the UNECE region in the areas of regulatory and procedural barriers to trade. The project was financed via extrabudgetary contributions. The objective of the project was to develop a methodology for needs assessment and conduct assessments in three countries. The Committee could then use the evidence from the studies to make recommendations and provide advice to governmental authorities. The subsidiary bodies of the Committee might also consider the studies in their areas of work. The first assessment was already being carried out in Belarus.

16. Decision 4: The Bureau asked the secretariat to include this item on the agenda of the twentieth session of the Working Party and provide an oral update on the project. The Bureau also recommended providing information to Eurasian Economic Community (EURASEC) and the Interstate Council for Standardization, Metrology and Certification of the Commonwealth of Independence States (EASC) about this activity, in cooperation with the Coordinator for Liaison with Market Surveillance Bodies of the Commonwealth of Independent States.

V. Exchange of experience implementing the EU Regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) in non-EU countries

17. The delegate of the Russian Federation explained that the purpose of the proposed initiative was not to express criticism regarding the REACH Directive. The Russian Federation wanted to make the national authorities in the European Union better aware of the difficulties encountered by third countries in complying with the Directive. In particular, differences in the implementation of the Directive in the EU Member States made compliance more difficult. For this reason, the Russian Federation would make a written report available for the twentieth session to highlight areas where it would welcome further regulatory cooperation among UNECE Member States.

18. The Russian Federation informed participants about a forthcoming international conference on this subject, which would take place in Irkutsk.

VI. “START” Team and revision of WP.6 Recommendations

19. The Convener of the Sectoral Initiative on Telecom called the attention of delegations to two negotiating proposals under the World Trade Organization (WTO) non-agricultural market access (NAMA) negotiations (TN/MA/W/129 and TN/MA/W/125), which were complementary to the UNECE Telecom Initiative. The possible synergies between the WP.6 “International Model” and the Doha negotiations had been the subject of an exchange of correspondence between the WP.6 Chair and the Chair of the WTO NAMA negotiating group. The Chair would follow up on the correspondence with the assistance of the secretariat. When contact information for market surveillance authorities in UNECE member States became available, it would also be possible to follow up on the initiative through contact with them.

20. In the absence of the Convenor of the Sectoral Initiative on Earthmoving Machinery (SIEMM), the secretariat reported on progress under the Initiative. The revised common regulatory objectives (CROs), adopted at the previous annual session, had been widely promoted by the Convenor, especially in China. The Convenor was currently developing a model conformity assessment certificate based on best practice in the Earthmoving and other industrial sectors.

21. The current priorities of the Sectoral initiative on Equipment for Explosive Environments were:

- To revise the CROs according to comments received – including from the delegation of the Russian Federation.
- To promote awareness and adoption of the CROs.
- To further develop the CROs as relates to market surveillance (MS) activities.

The main references were: the of the German government guidelines for MS (in general and specifically for the sector, and the EU Guidelines on the ATEX directive).

22. The Chair of the ATEX Administrative Cooperation Committee (ATEX ADCO) expressed support for the UNECE initiative and interest in being informed of activities going forward. ATEX ADCP was a body set up by EU national authorities to discuss matters relating to market surveillance and other issues of mutual interest.

23. The delegation of the Russian Federation recommended that UNECE organize a session at the next meeting of the IECEEx scheme in Berlin to formally present the CROs as they were adopted and to nominate the national focal points of the Initiative so as to have a group of experts moving the work forward.

24. The secretariat reported on the lack of progress in the Initiative on Pipeline Safety. The initiative had been started following interest expressed by the private sector, and had successfully collected information about regulatory frameworks in six countries. Since the 2009 session, no nominations had been received for the position of Coordinator of the Initiative. Nor had any progress had been made in drafting the proposed CROs. The secretariat awaited further instructions on how to proceed.

25. Participants agreed on the need to revise Recommendation “D” on Reference to standards to take into account a number of new developments. These included the debate on private standards in WTO, and the work of the panel on the future of standardization in the EU.

VII. Market surveillance group: update and future activities

26. The meeting discussed the priorities of the “MARS” Group and the dates of its next meeting. It was agreed that it would be held in Bratislava on 6 and 7 October 2010. As part of the preparations for the “MARS” meeting, delegations from non-EU Member States were encouraged to send the secretariat the contact information for their market surveillance authorities, as agreed at the annual session (see: ECE/TRADE/C/WP.6/2009/19, para. 52).

27. The Coordinator of the Initiative on the General Market Surveillance Procedure (GMSP) reported on the progress made in developing a sub-procedure of GMSP. When finalized, it would allow market surveillance authorities to optimize sampling procedures. Based on a classification of the essential requirements within a particular directive, the subprocedure could be used to determine a level of confidence and the number of lots to be inspected.

28. The sampling procedure had also been presented to the European Commission and to the Product Safety Enforcement Forum of Europe (PROSAFE) and its Enhancing Market Surveillance through Best Practice (EMARS) project representatives. . Participants said that the sub-procedure required homogeneous lots, and when this was not the case, authorities could not be sure that the sample they chose was representative. The Coordinator replied that the sub-procedure could be adapted to non-homogeneous lots if it had been calibrated using a large sample of data.

29. The meeting decided to continue developing the sub-procedure and to explore the possibility of accessing large databases and other supporting tools for MS methodology and networking, including those of PROSAFE, that of New Zealand and Australia, and the Internet-based Information and Communication System for Market Surveillance (ICSMS). It requested the secretariat to explore the possibility of collaboration with these organizations and organize a teleconference or a “webinar” to follow up.

30. Participants discussed how to progress the work of the Initiative on Market Surveillance definitions. Some participants were of the opinion that the document might need to be adapted to recent legislative changes in the EU, while the Coordinator believed that it needed to be complemented by definitions from other legislative frameworks.

31. The secretariat was asked to re-circulate the document ECE/TRADE/C/WP.6/2009/13/Corr.1 among delegations, inviting them to send their own national definitions to complement the document.

32. In the absence of the Coordinator of Liaison with the CIS Working Group on Market Surveillance, the secretariat gave an update on her behalf. The CIS Working Group had held a meeting in Kharkov in May 2010. In anticipation of the meeting, the secretariat had transmitted to the Coordinator a template for collecting the contact information of the national market surveillance authorities. The Working Group had discussed the Initiative, circulated the document, and encouraged its members to send the requested information to the UNECE.

33. The Working Group had discussed other aspects of the work at UNECE, and reiterated its support of the activities of UNECE WP.6 and the “MARS” Group. Its current priorities were: (a) to ensure that a training document, based on an improved version of the GMSP is developed; and (b) to further develop the document on Common Terminology so that it would be a truly comparative document, containing a collection of terms and their sources. Concerning the work under way in risk assessment and management, the Working Group was interested in receiving guidance in how to plan controls, carry them out and generalize their results.

34. Finally, the UNECE secretariat reported that it was cooperating with the secretariat of the Central European Free Trade Area (CEFTA), a project implemented under the Instrument for Pre-Accession Assistance (IPA) of the European Union, and the Deutsche Gesellschaft für Technische Zusammenarbeit (GTZ) in the organization of a panel session on market surveillance as part of the CEFTA week, in Belgrade, on 11 November 2010.

VIII. Outreach activities: Web2 and WP.6 newsletter

35. A first electronic newsletter had been sent out in March, as had been agreed by the Working Party at its nineteenth session. The Bureau thanked the Rapporteur for developments in EU countries for his contribution. A second e-newsletter would be sent out in June, and that the second newsletter would be the basis for the consolidated yearly report.

36. The secretariat had continued updating the website, including by adding a new section on “Risk Management in Regulatory Systems”. A preliminary presence had been established on “Linkedin” and could be strengthened if delegations express interest.

37. WP.6 could also now use the new software tool “Confluence” to improve interaction among small teams of experts working on a project or a document. The secretariat would make a first trial of the new tool and report to the Bureau at the “MARS” meeting.

IX. Structure and role of the bureau and rapporteurs

38. The participants discussed the structure of the WP.6 Bureau and the role of its rapporteurs, based on a document prepared by the secretariat. Some changes were proposed and the amended version is reproduced in document on the Working Party’s Programme of Work (ECE/TRADE/C/WP.6/2010/19). Discussions on the Bureau’s structure would also continue informally.

X. Cooperation with other organizations

39. UNECE has joined the DCMAS network. The DCMAS (Network on Metrology, Accreditation and Standardization for Developing Countries). The Network comprises representatives of specialized international organizations promoting and implementing metrology, standardization and conformity assessment activities in developing countries.

40. The other members are: BIPM (International Bureau of Weights and Measures); IAF (International Accreditation Forum); IEC (International Electrotechnical Commission); ILAC (International Laboratory Accreditation Cooperation); ISO (International Organization for Standardization); ITC (International Trade Centre); ITU-T (Telecommunication standardization sector of the International Telecommunication Union); OIML (International Organization of Legal Metrology) and UNIDO (United Nations Industrial Development Organization).

41. The secretary of the Working Party reported on her participation in the meetings of the ISO/CASCO Strategic Alliance and Regulatory group “STAR” Group of ISO/CASCO. The ISO/CASCO Committee was collecting good practice in market surveillance, and would publish this information later on. ISO/CASCO would also organize a workshop on 17 November 2010 in Paris on “Risk-based conformity assessment”. UNECE had been invited to make a presentation.

42. The secretary of the Working Party had initiated an exchange of information with the OECD secretariat on risk-management activities

43. She had also established a preliminary contact with the European Risk Forum, an expert-led and not-for-profit think tank. She had discussed possible participation of UNECE at their event on “Regulatory Spillovers and Non-EU Countries - The EU and the Global Management of Risk”, to be held on 7 December 2010 in Brussels.

44. A Memorandum of Understanding with the Organization of Legal Metrology was being discussed and would be presented to the Working Party at its twentieth session.

45. The Executive Secretary of IECEE presented the purpose and activities of the Worldwide System for Conformity Testing and Certification of Electrotechnical Equipment and Components. IECEE operates third-party conformity assessment schemes. In this sector, for a number of products, third-party certification was needed due to the inherent dangers of electrical appliances, and the proliferation of counterfeit items. The system aimed at guaranteeing safety, and at the same time facilitating trade of compliant products. Its goal was to have one test, one international certificate, and one or more certification marks as needed or direct acceptance in the market place by regulators, customs, retailers, buyers, vendors, etc.

46. IECEE, itself a quasi-intergovernmental organization, actively collaborates with governmental bodies. Market surveillance authorities, customs, and INTERPOL were given access to privileged information in the system. Participants discussed how closer collaboration with IECEE could assist the WP.6 in furthering its goals and agreed that:

- IECEE would be invited to contribute to the panel session discussion on “Options for regulatory cooperation in conformity assessment” at the twentieth annual session.
- The experience of IECEE should be considered when Recommendation “M” was being revised. In particular, text could be added to encourage market surveillance authorities to use data from third-party certification schemes, which may assist in countering proliferation of counterfeit products

- The Working Party might wish to consider new sectoral initiatives in the fields covered by the IECEE scheme, should a request be made by Member States. Subsectors of particular interest were: medical appliances, and content of hazardous substances. In case such an initiative were developed, the IECEE scheme could be considered as an acceptable means of establishing conformity to commonly agreed standards.
- A Memorandum of Understanding with IEC might also be envisaged by the parties.

XI. Fundraising

47. The secretariat presented a proposal for a technical assistance project which it had prepared and submitted to several donors. The project would, for instance, allow for the development of training courses on the basis of the GMSP. UNIDO had expressed interest in financing a part of the project. This would be implemented in a pilot country of the region of SPECA (UN Special Programme for the Economies of Central Asia) – most likely Azerbaijan. The project would be flagged at the forthcoming Ministerial Meeting on Aid for Trade for countries of SPECA, which was going to be held in Baku in December 2010. Discussions with UNIDO on the project were at an advanced stage and a reply was expected in the near future.

48. The secretariat had also prepared a project proposal for supporting activities to promote the Initiative on Equipment for Environments with an Explosive Atmosphere. Consultations with PTB, the German National Metrology Institute, were at an initial stage to identify possible donors.

Annex

Agenda

1. Adoption of the agenda
 2. Follow-up to the WP.6 annual session in November 2009:
 - Report of the 2009 session and Conference
 - Agenda of the 2010 session and priorities of WP.6 in 2010-2011
 3. Proposed Group of Experts on Risk Management
 - Risks and regulatory systems
 - Systemic risks
 - Needs and priorities of stakeholders (e-survey)
 - Presentation via web-link of the New Zealand Risk Engine
 - Mapping of other organization's activities and role of UNECE
 - Plan of work of WP.6 in this area and discussion on the establishment of the Group
 4. Information on the needs assessment studies of regulatory and procedural barriers to trade in the UNECE region conducted by the Committee on Trade
 5. Exchange of experience implementing REACH in non-EU countries
 6. “START” Team
 - Sectoral Initiative on Safety of pipelines
 - Sectoral Initiative on Explosive Environments Equipment
 - Sectoral projects: Telecom & Earthmoving equipment
 - Recommendation “L” and the NAMA negotiations
 - Revision of WP.6 Recommendations
 7. Market surveillance (“MARS”) group: update and future work
 - General Market Surveillance Procedure: update
 - Ongoing work on common definitions
 - Report of meeting of CIS working group on Market Surveillance
 - UNIDO-UNECE project on Market Surveillance in SPECA countries
 8. Outreach activities: Web2 activities and WP.6 Newsletter
 9. Structure and role of the WP.6 bureau and rapporteurs
 10. Cooperation with other organizations (DCMAS, UNIDO, OIML, IEC, ISO, OECD, CEFTA, EMARS, the European Risk Forum...)
 - Presentation on IECEE scheme and possible areas of cooperation
 11. Fundraising
 12. Other business
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