



# Economic and Social Council

Distr.: General  
11 August 2011

Original: English

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## Economic Commission for Europe

### Committee on Trade

### Working Party on Regulatory Cooperation and and Standardization Policies

#### Twenty-first session

Geneva, 31 October – 2 November 2011

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 annual planning meeting of WP. 6 activities

### Submitted by the secretariat

#### *Summary*

The report of the annual planning meeting of the “START” Team, held in Stockholm from 4 to 6 May 2011, is submitted for information.

The most important decisions taken at the meeting were as follows.

The Bureau recommends that the secretariat organize a Workshop on “Traceability as a tool for managing risks”, as part of the 2011 WP.6 annual session.

The Bureau also recommends that WP.6 consider establishing a new Sectoral Initiative on “Medical Equipment”, based on Recommendation L and under the WP.6 Start Team.

The Bureau further recommends that new Recommendations on: Enhanced Effectiveness of Market Surveillance Policies be submitted to the WP.6 for consideration at its twenty-first session.

## I. Adoption of the agenda

1. Following attendees’ introduction of themselves and the organizations they represented, the agenda was adopted.

## II. Follow-up to the WP.6 annual session in October 2010 and preparation of the 2011 session

2. The secretariat presented the most important developments under relevant agenda items of the report of the twentieth session of the Working Party. The following were the most important items of information (I) and decision (D):

(a) The report assessing the needs of Belarus in the field of regulatory barriers to trade and trade facilitation was being finalized by the secretariat and would be presented to the Committee on Trade at its annual session in June 2011 (I);

(b) The Group of Experts on Risk Management in Regulatory Systems had established its membership, which was quite broad and diverse and included standardization bodies, regulatory authorities, conformity assessment experts, international organizations, business companies and business associations, NGOs and academic institutions. It had started its activities, and now had a fully functional wiki website (accessible to members of the group, but with some public pages: [http://www1.unece.org/reg\\_coop/platform/display/News/News+GRM](http://www1.unece.org/reg_coop/platform/display/News/News+GRM)) and held regular monthly webinars. The Group was preparing two recommendations for consideration at the twenty-first session of WP.6 and was also considering participation in an ISO 31000 project group (I);

(c) The Bureau recommended that the secretariat should seek advice from the Russian Federation in following up on the proposal made at the 2010 session on starting an exchange of information on ways to assess the impact of new technical regulations on trade (D);

(d) The Bureau recommended that the secretariat should seek advice from the delegations of the European Union and of the Russian Federation on how to continue work on regulatory developments in the chemical industry (D);

(e) The Bureau recommended that the discussion on the revision of the Recommendation D on “Reference to standards” should be postponed (D);

(f) The Bureau recommended that the Working Party should consider developing a new Recommendation on Conformity Assessment, using as its basis WP.6 Recommendations F and G, as well as the report of the panel session on Conformity Assessment contained in ECE/TRADE/C/WP.6/2010/20 paras 56-61 (D).

3. Participants discussed the provisional agenda for the forthcoming annual session. Several changes to the provisional draft agenda and timetable were approved. It was also decided that a Workshop on “Traceability as a tool for managing risks” would be organized as part of the 2011 WP.6 annual session and that the theme for the presentations by representatives of standardization bodies would be “Sustainable development and social responsibility”.

## III. START Team: Sectoral initiatives: updates & work plans

4. The Convenor of the Sectoral Initiative on Telecom presented the current status of the Initiative. He recalled that the Working Party had approved the Common Regulatory Objectives (CROs) in 2004. He said that the CROs – which had not been transposed into national regulations – could nevertheless be used in the context of the WTO Non-Agricultural Market Access (WTO NAMA) negotiations and of the WTO Information Technology Agreement (ITA). Several countries proposed a reopening of the ITA negotiations to expand the product and country coverage of the agreement and to include

not only tariffs but also non-tariff barriers. UNECE could offer the negotiators a platform that included all relevant items including market surveillance.

5. The Convenor said that the international standards referenced in the CROs are broadly applied by all countries, but different countries apply different options for conformity assessment. An additional barrier to trade are labelling requirements. The delegate from the International Electrotechnical Commission (IEC) agreed that Special International Committee on Radio Interference (CISPR) standards and IEC standards broadly cover regulatory requirements.

6. The Chair of the MARS Group encouraged the Convenor to examine how the EU Standardization Package, especially as regards the ICT field, could be used to promote the Sectoral Initiative.

7. The Convenor of the Earth Moving Machinery Initiative (EMM Initiative) updated participants about the status of the initiative. He recalled that revised CROs had been approved in 2009 to take into account concerns by countries that could not readily adopt the Supplier Declaration of Conformity (SDOC) for regulatory enforcement in this sector.

8. Over the years, the task force that works to promote the EMM initiative had organized training courses in China, India, the Russian Federation and the Republic of Korea. These training courses involve all stakeholders, including business associations and regulatory authorities.

9. The Task Force is now planning to update the CROs to include:

(a) Market surveillance: because the safe use of machinery was of paramount importance in the Earth-Moving sector, market surveillance needed to include work-site surveillance to be effective in preventing accidents;

(b) Risk management: the ISO/TC 127 was developing standards to address specific safety risks for all EMM, currently with the objective of having zero injuries in the workplace. These could be included in a revised version of the CROs;

(c) A global certificate of conformity.

10. The Convenor observed that work-site surveillance was more appropriate for that sector than market surveillance, to verify that machines met the safety standards and were used safely and that the work-site had a sufficient work-site safety process. Work-site risk management was also needed to address additional risks to the machine and workers, such as underground gas or power lines and other machines and workers on the site.

11. The delegate from International Organization of Legal Metrology (OIML) expressed interest in using the International Model in the field of legal metrology, and said that one difficulty in that field was the number of national deviations from the OIML standards.

12. Delegations discussed whether the International Model should refer to international standards, or simply to standards that were chosen by regulators in the context of the CROs agreement. A fundamental issue was that there was no common understanding of what international standards are, and which organizations could be referred to as “international standardization organizations”.

13. In the absence of the Convenor of the Sectoral Initiative on Equipment for Environments with an Explosive Atmosphere (SIEEE), the secretariat presented the most recent developments, as follows:

(a) UNECE had worked together with IEC to publish a booklet that presents the CROs approved by the Working Party at its last session. The booklet was available online at [http://www.unece.org/trade/wp6/SectoralInitiatives/EquipmentForExplosiveEnvironment/SIEEE\\_CRO.pdf](http://www.unece.org/trade/wp6/SectoralInitiatives/EquipmentForExplosiveEnvironment/SIEEE_CRO.pdf) and [http://www.iecex.com/docs/UNECE\\_CRO\\_en.pdf](http://www.iecex.com/docs/UNECE_CRO_en.pdf) ;

(b) IEC and UNECE were working together to promote the CROs: both organizations have issued a press release: [http://www.iecex.com/docs/110324\\_IECEX\\_UNECE.pdf](http://www.iecex.com/docs/110324_IECEX_UNECE.pdf) and [http://www.unece.org/press/pr2011/11trade\\_p03e.htm](http://www.unece.org/press/pr2011/11trade_p03e.htm).

(c) The UNECE secretariat was organizing an event back to back to the Annual Meeting of the IECEX System in Split, Croatia. Policy officers from different countries would present their regulatory systems and discuss a way forward towards an internationally shared framework. See: [http://www.unece.org/trade/wp6/SectoralInitiatives/EquipmentForExplosiveEnvironment/Split\\_Sept11/Split\\_Sept11.html](http://www.unece.org/trade/wp6/SectoralInitiatives/EquipmentForExplosiveEnvironment/Split_Sept11/Split_Sept11.html).

14. A representative of the Russian Federation expressed some reservations about the current version of the CROs and shared his views on how it should be revised. In particular, he wished to see a stable Working Group formed to move the work forward.

15. The Chair of the ATEX Administrative Cooperation Committee (ATEX ADCO) expressed his continued support for the UNECE initiative. ATEX ADCO was a body set up by EU national authorities to discuss matters relating to market surveillance and other issues of mutual interest.

16. He presented the preliminary results from a voluntary joint action on market surveillance launched by ATEX/ADCO to check documentary requirements of Ex-Equipment in the countries of the European Union. The results had shown worrying rates of non-compliance. The research had also revealed a lack of common understanding among EU Member States on how different non-conformities should be followed up to (i.e. which kinds of non conformities warrant an immediate market recall). The delegations discussed how to promote a better understanding of the UNECE initiative by EU Member States, and how it could be used to increase the safety of the equipment in the workplace.

17. A proposal was made for establishing a new Sectoral Initiative on Medical Equipment. Cooperation among regulatory authorities in this sector was already quite active, as authorities from many countries were aware of and make active use of the Worldwide System for Conformity Testing and Certification of Electrotechnical Equipment and Components (IECEE). The Bureau agreed that a task force to support the initiative should be established, and would prepare a proposal to be presented at the twenty-first session of the Working Party.

#### **IV. Third webinar of the Group of Experts on Risk Management in Regulatory Systems**

18. The third extended webinar of the UNECE Group of Experts on Risk Management in Regulatory System (GRM) was broadcasted live to the annual planning meeting, allowing members of the WP.6 Bureau and other Working Party stakeholders to participate in the event.

19. The goals of the webinar were to:

(a) Initiate a discussion and make a decision on going forward with developing a specific recommendation on contingency planning (“crisis management in regulatory systems”);

(b) Discuss how ISO 31000 could be used in regulatory work and align the reference model developed by the Group with the main concepts of ISO 31000;

(c) Analyse the progress made so far and make decisions related to:

(i) Developing a general recommendation (how the comments of the Group were taken into account);

(ii) Fundraising (present project proposals based on the concepts approved at the previous webinar);

(iii) Planning the next steps.

20. The secretariat opened the meeting by recalling the objectives and achievements of the GRM. This was followed by a presentation on contingency planning as one of the essential functions of the risk management process (as presented in the reference model used by the group). Handling incidents well was important both for governments and for companies. It could help avoid regulations that were disproportionate to the risks they set out to address. Contingency plans – both subject specific and generic - should therefore be developed by governments and other governmental agencies.

21. The Group agreed that a specific recommendation should be developed on crisis management. This recommendation would be complementary to the general recommendation on “Risk Management in Regulatory Systems” based on the reference model - as it would provide details on how to implement one of the essential functions of the risk management process. In developing this specific recommendation, the GRM would take into account existing legislation and best practice in the field of crisis management.

22. This was followed by a presentation by the Chair of the ISO Technical Committee that had developed the ISO 31000 standard, on why and how it could be applied to regulatory work. Systematic management of risk in both public and private organizations benefitted all organizations by inducing forward thinking, responsible thinking, balanced thinking, maximizing opportunity and minimizing threats, and facilitating more effective decision making. The presentation then addressed:

(a) The ISO 31000 framework, based on the Plan-Do-Check-Act cycle that helped to feed the principles into the organization’s management systems to ensure that the latter address the risks systematically;

(b) The risk management process;

(c) The ISO/IEC 31010 standard, which contained a lot of risk assessment techniques; which brought its users to consider the context and objectives of organization, available resources, how risk assessments would be reviewed, etc.

23. How could the key principles of risk management be fed into in the work of regulatory stakeholders? Risk management should create value, and help create a culture that maximizes opportunities. It should be the part of the management system, and should not be considered only as a part of compliance management. It was very much about decision making, it helped to prioritize actions, which was very important in governmental work since regulatory actions should in the first place address the areas of higher risks. Participants discussed examples of use of risk management in regulatory work.

24. The Group decided to extensively apply the presentation on the use of ISO 31000 in regulatory work in developing the general recommendation on risk management in regulatory systems.

25. The Group then requested the secretariat to:

(a) Prepare a draft (written text) of the general recommendation based on the UNECE background document “Risk Management in Regulatory Systems: A Proposed Reference Model”;

(b) To align the model with ISO 31000 (done by Mr. Kevin Knight);

(c) To stress test the reference model (by, for example, applying it to tobacco regulation in Europe);

- (d) To include into the model a function related to identifying if there was a need for a regulation;
- (e) To prepare project proposals;
- (f) To plan presentations on how risk management concepts and standards were applied in different sectors.

## V. Outreach

26. The secretariat presented its outreach efforts: i.e. the newsletter, website, publications, the new Wiki website of the GRM Group, and participation in events by partner organizations. There was a discussion about the newsletter, as contributions from regional partners on which it should have been based, had not been received by the secretariat. The WP. 6 Bureau advised to:

- (a) Keep the newsletter brief;
- (b) Focus on sharing news about ongoing UNECE WP.6 initiatives;
- (c) Ask partner organizations to put the newsletter on their website, and send it to their own contacts.

27. It was agreed that a possible UNECE – OIML Memorandum of Understanding was not yet mature for discussion at the annual session.

28. The secretariat also informed delegations about a planned event to be organized in cooperation with major international and regional standards-setting bodies, aimed at drawing the attention of the Geneva-based diplomatic community to the importance of standards for trade and for development.

## VI. MARS group: updates and work plans

29. The MARS Group aims at supporting all UN Member States in setting up and conducting market surveillance activities and, more broadly, enforcement. While the European Union has a large body of expertise in this area, it is not immediately applicable in all UN Member States. The Work of the MARS Group currently focuses on the following priorities:

- (a) Finalizing and publishing the “A glossary of Market Surveillance Terms”;
- (b) Finding resources to use best practice developed by the Group, and in particular the General Market Surveillance Procedure, for the purpose of training and field work;
- (c) Preparing a new Recommendation on Market Surveillance and revising Recommendation M;
- (d) Developing a repository of information and a database on market surveillance authorities worldwide.

30. The delegation of Sweden had prepared a draft Recommendation on “Enforcement Policies”. The aim of the Recommendation was to give general political guidance that all countries could apply, both as regards general product safety and specific sectoral legislation. Participants suggested several points for revision, including: taking into account the definitions contained in the Glossary; more explicitly addressing the link between product risk and market surveillance; putting more emphasis on communication; etc.. **Delegates agreed that the document should be revised and submitted to the WP.6**

**annual session for discussion.** It was also agreed that the secretariat should circulate the document to other stakeholders in the MARS Group and advance the work on the draft recommendation through one or more webinars.

31. For the further development of the database, delegations recommended that the secretariat try to increase the visibility of the project by printing a small brochure, mentioning it more prominently on the newsletter and website, and seeking a partnership with other organizations.

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