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Item 4 of the provisional agenda

Risk management in regulatory systems

Proposed Group of Experts on Risk Management in Regulatory Systems

Note by the secretariat* **

Summary

This document complements the draft mandate of the proposed Group of Experts on Risk Management in Regulatory Systems (Annex to ECE/TRADE/C/WP.6/2010/2).

It contains a proposal for the organization of the work of the Group and a high-level project plan. It also summarizes the results of a survey conducted by the Secretariat, to assess existing needs related to Risk Management in Regulatory Systems.

The document is submitted to the Working Party for discussion and decision.

I. Introduction

1. At its nineteenth session, the Working Party discussed a draft of the Terms of Reference of the proposed Group of Experts on Risk Management in Regulatory Systems,

* At its nineteenth session, the Working Party agreed to consider establishing a Group of Experts on Risk Assessment and Management and requested the secretariat to report on activities on risk management systems (ECE/TRADE/C/WP.6/2009/19, para.10).

** The present document was submitted late due to resources constraints.

which are set out as an annex to the document “Risk Management in the Activities of the Working Party” (ECE/TRADE/C/WP.6/2010/2).

2. This document complements the Draft Terms of Reference by proposing how the work of the Group could be organized and structured, and what its initial activities could be.

II. Organization of work

3. The Chairperson of the Group should be a government representative with the following functions:

- Giving final approval to the work plans of the Group
- Undertaking resource planning
- Contacting governmental bodies, as necessary, for achieving the Group’s goals
- Representing the group in meetings of other international organizations
- Reporting to the Working Party on the Group’s progress
- Organizing the meetings of the Group: deciding on relevant topics, audience and speakers
- Fundraising.

4. The Coordinator of the Group is responsible for:

- Preparing and keeping up-to-date project plans
- Identifying the project’s risks
- Project communication, including maintaining the web-site
- Consolidating information required for developing the recommendations
- Internal reporting, including reporting to the secretariat
- Other functions as required.

5. Decisions within the group will be made by simple majority rule. Proposals for decision will be communicated to members by e-mail; a deadline for decisions will be one week.

6. The Group will consist of a maximum of twenty members. Required areas of competence include:

- Planning, developing and implementing technical regulations
- Choosing and implementing conformity-assessment procedures
- Promoting cooperation among business companies and regulators
- Risk-management methodologies
- Project management.

7. The Group membership will be published on the Group’s website.

8. All members are expected to contribute to monthly webinars organized by the coordinator.

9. The Group will report to the plenary session of the Working Party, As well as to the meeting of the WP.6 Bureau, Rapporteurs and Coordinators.

10. Should it become clear that the project's objectives are unlikely to be achieved, the Chairman and Coordinator may request the Working Party to disband the Group.

11. Main risks:

- Insufficient funding for the organization of the work and for the field work
- Lack of competence
- Poor management of the project
- Lack of cooperation from UNECE member States
- Lack of governments' representation.

III. High-level project plan

<i>Task</i>	<i>Deadline</i>
Stage 1: Initiation	
Prioritizing areas of work	November 2010
Searching for members	January 2011
Designing the group's website	January 2011
Developing reference model for the areas approved as of the highest priorities	February 2011
Approving reference models within the group	March 2011
Fundraising	March 2011
Stage 2: Gathering information (first iteration)	
Performing a desk research on risk management best practice by: <ul style="list-style-type: none"> • Research on risk management in legislation and procedures (members of the group would research different regulations and compare results) • Conducting a survey and checking the results against the reference models • Actual model and needs. 	July 2011
Analysis of the international legislation: <ul style="list-style-type: none"> • Building a reference model for a risk-based legislation • Analysing consistency of risk management processes in the fields to be selected by the Group • Preparing a report on use of risk management in 	August 2011

<i>Task</i>	<i>Deadline</i>
international legislation, areas for improvement and recommendations on the use of best practice in developing risk-based legislation.	
Consolidating information	August 2011
Stage 3: Drawing up recommendations	
Drafting recommendations	September 2011
Developing training material for authorities	October 2011
Intergroup approval	October 2011
Presenting the draft	November 2011
Performing the field work (data gathering – second iteration): <ul style="list-style-type: none"> • Presenting the reference models and analyzing the changes (to the model or to the process) with stakeholders • Consolidating information • Preparing reports on best practice and problems to be solved. 	June 2012
Developing databases on risks and software tools	October 2012
Running pilot implementation projects	September 2012
Updating the draft recommendation and intergroup approval	October 2012
Approving recommendations	November 2012
Stage 4: Promotion and implementation	November 2013
Promoting the recommendations	November 2013
Presenting the feedback	November 2013

Annex

Summary of the results of the test survey

1. The secretariat sent an invitation to participate in the web survey to 80 regulatory stakeholders, who had expressed interest in the ongoing work on Risk Management in Regulatory Systems. The respondents were asked to complete an online questionnaire with the assistance of the secretariat. A quarter of the questionnaires were returned by the end of August, 2010.
2. The questionnaires have been published in document ECE/TRADE/C/WP.6/2010/4 "Risk management in regulatory systems: A proposed survey". They were based on the reference model contained in document ECE/TRADE/C/WP.6/2010/3.
3. Five different online surveys were conducted, tailored to the specific functions of the different stakeholders in the regulatory system:
 - Technical regulators
 - Standardization bodies
 - Conformity-assessment bodies,
 - Market-surveillance authorities
 - Economic operators.
4. We present below the findings from the surveys of the first four groups of respondents. No answers were received from business operators.
5. These findings are to be considered preliminary, due to the small sample size. The survey was intended as a test of the validity of the model. Should the Working Party approve of the work in this area to go forward, a larger survey may be conducted.

I. Risk Management in Technical Regulations

6. Most of the respondents (80%) use risk management tools in the development and implementation of technical regulations. All of the respondents encounter obstacles in using these tools.
7. Respondents identified the following problems:
 - Lack of information for risk identification
 - Lack of methodologies for risk prioritization
 - Lack of commonly agreed criteria for choosing risk management strategies, and for assigning a level of risk to areas that require regulatory intervention
 - Determination of the acceptable level of risk
 - Inclusion of contingency planning into regulatory processes.
8. Risk-management processes are applied in the work of the regulatory authorities. However, there are indications that these processes could be enhanced and made more systemic and consistent.
9. Two thirds of the respondents said they had an approved methodology for managing risks; but none of the respondents use special software tools for processing risks. In some

cases the methodology does not cover risk quantification and management of the risks that may occur during the implementation of a specific regulation.

10. Regulatory authorities have no special person responsible for risk management methodologies and risk management tools. It is likely that risk-management functions are performed inconsistently (in most cases addressing risks is one of the functions performed by people responsible for other areas).

11. Regulatory authorities do not perform systemic risk identification in deciding in which areas regulatory action is a priority. Most authorities conduct risk identification when designing during the design of a specific regulation. This may lead to a mismatch between regulatory action and risks.

12. Two thirds of respondents refer to a risk acceptance strategy in deciding which risks are not considered worthy of regulatory intervention. However, most respondents said that risk acceptance criteria were determined by experts case by case.

13. Conformity-assessment bodies, market-surveillance authorities and other regulatory stakeholders participate in risk identification performed by the regulatory authorities. However, there is no information system in place that can be used for efficient processing of the information. Some of the respondents indicated that they face obstacles in choosing risk management strategies.

14. Possible responses to the problems outlined above include:

- Developing common databases on risks and hazards
- Developing tools for assigning a level of risk to areas that require regulatory intervention
- Developing methodologies for risk prioritization and for choosing risk management strategies and providing assistance and their implementation.

II. Risk management in conformity assessment

15. All conformity-assessment bodies that completed the questionnaires use risk-management tools. They all encounter obstacles in applying them.

16. The main obstacles include the following:

- Lack of a global common understanding of risk management among the manufacturers, conformity-assessment bodies and regulators. Risk management is part of the requirements of (some) standards and risk management requires a uniform understanding of the requirements by all parties, which is currently lacking;
- Identification of risks for ecology management systems (ISO 14001), for medical manufacturers (ISO 13485 and 14971) and in energy management (ISO 50001);
- Lack of data on relevant risk factors.

17. All of the respondents have an approved methodology for managing risks. They estimated the percentage of timely identified risks at 50 per cent. Some of the conformity-assessment bodies have agreed on criteria for risk acceptance described in methodologies, some use experts' judgement. Methodologies used include "IEC 60601-1 3rd Edition - ISO 14971-IECEE "Guidance for the Evaluation of Risk Management in Medical Electrical Equipment", internal procedures, "Norwegian offshore practices".

18. In most cases, conformity assessment bodies do not have a special person responsible for risk-management tools and methodologies. The survey provides examples

of disputes that conformity assessment bodies had with business companies related to the assessment of risks, most of them were related to risk quantification.

19. Respondents marked the following areas as ones in which they would like to receive assistance:

- Devising a sample plan for product certification
- Carrying out risk identification when issuing a non-conformity in management system certification
- Identifying special risks during CE marking process
- Checking the correctness of risk identification in conformity-assessment procedures (in technical documentation).

III. Market Surveillance

20. Only 60 per cent of the market-surveillance authorities who replied to the survey apply risk-management tools in their work. Nonetheless, within the EU, applying risk-management tools in market-surveillance procedures is a legislative requirement. The level of application of risk-management tools varies considerably among the authorities that participated in the survey.

21. Examples of methodologies used in conducting risk assessment are the: “Nordic Failure Code” and the “Rapex Guidelines”. Some market-surveillance authorities have no approved risk-management methodology.

22. Most of the respondents have no approved methodology for ranking products on the basis of the level of risks. They use no software tools for performing risk assessment. Respondents reported that risks were timely identified in 50 per cent of cases or less. Some respondents said that they have ‘a risk library’; some said that they do not have any risk database.

23. Risk-management activities are performed by inspectors and there are no staff members responsible for the methodologies. In most cases, market-surveillance authorities have no approved methodology for quantifying the risks, for any approved risk-acceptance criteria. Two thirds of the authorities collaborate with conformity-assessment bodies and regulators in performing risk identification.

24. Market-surveillance authorities say that they seldom have disputes with economic operators on the correctness of the results of the risk assessment. When the authorities request economic operators to provide information on risks they do not refer to any recognized methodology.

25. A number of authorities would like to receive training in risk identification.

26. Authorities expressed interest in:

- Identification of products’ risks
- Quantitative analysis of risks
- Communication with business companies on risks
- Verification of risk assessments made by business companies
- Software tools for risk management.

IV. Standardization bodies

27. Most of the standardization bodies that participated in the survey do not apply risk-management tools in developing standards. Those who use risk management tools do not face any obstacles in the process.

28. However, the standardization bodies said they would need information on the following subjects:

- Risk identification (mapping out the risk, development of risk profiles), considering risks during standard development process planning;
- Risk quantification and prioritization for planning the standards development process;
- Management of standards-implementation risk;
- Determination of risk-management strategies.

V. Standardization bodies

29. Business operators did not respond to the test survey.
