Risk Management in Regulatory Systems. A proposed Methodology

Note by the secretariat

I. Mandate

1. At its nineteenth session, the Working Party agreed to “encourage further cooperation to achieve a shared regulatory framework that meets societal demand without stifling innovation or creating technical barriers to trade” (ECE/TRADE/C/WP.6/2010/19, para. 10). This document contains a proposed methodology for assessing the use of risk management tools in regulatory systems. The methodology is accompanied by a proposed survey to document actual use and outstanding needs in all the areas of activity of the Working Party: technical regulations, standardization conformity assessment, market surveillance and business operations. The proposed survey is issued separately under document ECE/TRADE/C/WP.6/2010/4.

2. This document is presented to the Working Party for information.

II. Objectives and scope

A. Risk management in the regulatory system

3. Application of sound risk management tools is essential for creating an efficient regulatory system.

4. Risk has always been one of the rationales for imposing a regulation. Errors in risk assessment and management could lead, on one hand, to excessive regulation: when regulation inadequately addresses the risk thus leading to additional costs and hampering economic development. On the other hand, if there is a risk which is not addressed by a regulation, this situation could be described as insufficient regulation, and could lead to severe societal, environmental and economic impacts. Professionalism in risk management
within the regulatory system in general and regulatory authorities in particular is a necessary condition for creating a balanced regulatory framework: when risks are adequately addressed and no risks are missed.

5. Moreover, imposing a regulation is of itself a risky project: new regulations may, for example, change the market structure and lead to undesirable results. To avoid it, timely identification and management of risks is crucial.

6. Not only regulations, but voluntary standards are important tools that help business and society deal with risks. Therefore risks should be considered while planning the standards development process, when drafting and publishing a standard. Special techniques for risk identification, quantification and for determination of risk management strategies etc. should be therefore embedded in the processes run by standardization bodies.

7. Conformity assessment procedures could be considered as risk mitigation tools that help to reduce the risk of placing dangerous products on the market. More importantly - in the context risk management helps Conformity Assessment Bodies to increase the efficiency of conformity assessment processes and to choose appropriate conformity assessment procedures. Again, mistakes in assessing risks may lead to failures in the whole regulatory system.

8. For market surveillance authorities, proper management of risks that products placed on the market may cause (these risks may influence health and safety of people and have other undesirable impacts) results in development of timely and appropriate measures that are essential to providing safety on the marketplace. Therefore risk management is one of the major tasks performed within the market surveillance system on a regular basis. Besides providing safety on the market place, sound risk management helps minimizing the costs of compliance with regulations- necessary conditions for strengthening economic competitiveness.

9. In general, the objective of risk management, no matter at what level it is applied, is to provide the necessary and sufficient level of safety - one which is not hampering economic development. It implies that safety costs for all stakeholders are not more and not less than needed; and that additional and opportunity costs that arise due to risk realization are minimized.

10. Application of this approach implies that absolute safety is not considered as a regulatory objective: absolute safety can not be achieved. Implementation of safety measures for business companies adds costs, and imposing new costs should be a justified decision.

11. To achieve a regulatory balance, all interested parties (technical regulation authorities, standardization bodies, conformity assessment bodies, market surveillance authorities) should:

   • Know what are the risks as broadly as possible – this is the identification stage;
   • Understand the risks that are the most important, and for these purposes their quantification and evaluation is required;
   • Starting with the most important of them, choose the risk management strategy (we can accept the risk, avoid it, mitigate or transfer);
   • Implement the decision that was taken – that is the practical and palpable result of the risk management process.
   • Develop a “crisis management” plan for the risks that we accepted and for those that were mitigated (quite seldom risk mitigation can provide absolute safety). This results in an action plan in case the risk occurs.

12. Recent changes in regulations and regulatory approaches require wide application of risk management tools. At the same time, this is still a rather new concept – though many organizations have
already started applying it, there are areas that need to be further developed. This needs assessment and gap analysis methodology should provide interested parties with information on how risk management tools are applied within the regulatory system, and help identify bottlenecks and current needs of stakeholders. More specifically, this methodology aims at:

(a) Gathering information on the current level of risk management application in regulatory system of the country;

(b) Developing “reference models” on risk management in different processes within the regulatory system;

(c) Comparing existing risk management systems in regulatory frameworks with existing reference models (based on various standards, roadmaps and regulations) and analyzing the gaps;

(d) Understanding and gathering objective evidence on the needs of organizations involved in the regulatory system in further development of risk management tools.

13. The Survey address all the stakeholders within the regulatory system and in particular:

- Technical Regulation Authorities
- Standardization Bodies
- Business Companies
- Conformity Assessment Bodies
- Market Surveillance Authorities

14. This document has five chapters addressing the concerns of the stakeholders mentioned above. Each chapter contains:

- Basic principles of risk management application within its scope of activities;
- A reference model, against which the questionnaires were developed, and, where necessary, its brief description;
- Questionnaires for performing a survey.

Each questionnaire aims at information on:

- The level of implementation of general “sound risk management practices” (see above);
- Implementation of risk management functions specific to the processes of the stakeholder;
- Transparency of risk management cooperation within a regulatory system;
- Risk management tools that are perceived as the most important and of interest to the stakeholder;
- “Risk management needs” of a stakeholder based on the identified obstacles in performing risk management tasks.

16. Guidance on data analysis and methodology for performing a survey is presented in the last chapter. The stakeholders are presented in the following way:
(a) Technical Regulation authorities;

(b) Standards Development Organizations;

(c) Conformity Assessment Bodies;

(d) Market Surveillance Authorities;

(d) Business Organization.

**B. Risk management in technical regulations**

1. **Basic Principles**

   A. When risk is a rationale for imposing a regulation, regulation should be adequate to the risk being mitigated and this fact should have objective evidence.

   B. Regulation should not be excessive.

   C. Regulation should not be insufficient.

2. **Description of the reference model**

   17. Identification of risks that should be addressed by regulations is implemented as a systemic process, which implies communication with all stakeholders and results in a document where all risks are listed, ranked by their level of criticality. For this purpose, risk identification and assessment tools are systematically applied. Starting with the most important risks, and depending on the risk acceptance criteria, technical regulation authority determines whether regulation is required in order to mitigate risks; if that is the case, it is developed. Risks that may occur when implementing a regulation are also identified and assessed, risk mitigation strategies are developed. New technical regulations are imposed along with strategies that help to mitigate “implementation risks.”
Risk management in technical regulations development and implementation
C. Risk management in standardization

1. Basic Principles

1. Risks should be considered as an important input into standards development planning process;

2. Comments on the standards should include risk identification, requests for comments should contain a clear methodology on how to identify the risks;

3. Risk management records should prove that risks were addressed when revising a standard.

2. Description of the reference model

18. When making a decision on market relevance of the standard, Standards Development Organizations consider risks that implementation of this standard would help to manage. Proper risk identification and assessment is performed before making a decision on the relevance of the standard. When the standard draft is ready, the map of how risks would be mitigated by the standard and what residual risks will remain is performed. When the standard is sent out for comments, the request for comments sent to stakeholders contains a brief guidance for identification of risks that the implementation of the standard may cause. Similar requests are sent out for the public; with the idea of getting evidence that the risks the standard is due to mitigate would indeed be mitigated, as well as identification of risks that the implementation of this standard may cause. Risk management records are maintained during standard development process and considered when revising the standard in five years.
Risk management in technical regulations development and implementation for standardization bodies
D. Risk management in conformity assessment

1. Basic Principles

1. Conformity Assessment procedures are chosen on the basis of risks related to the products and services.

2. Risk assessment is performed during certification procedures: risk associated with a possible failure of a product is taken into account when devising a sample plan to optimize the conformity assessment costs; in management system certification, non-conformities to the standard are issued on the basis of a proven risk, showing why the nonconformity is important to the business.

3. Assessment of risks related to products is submitted along with technical documentation to conformity assessment bodies.

2. Description of the reference model: Write a brief description – comment on pictures.

Risk Management in Product/System certification

Risk Management in technical Documentation Assessment

Risk Management in CE Marking
E. Risk management in market surveillance

1. Basic Principles

1. Intensity of Market Surveillance for various products depends on the level of risks that these products present. Risk assessment is an important input for planning of market surveillance processes;

2. Market Surveillance Authorities cooperate with Economic Operators to determine appropriate measures for risk mitigation; manufacturers (importers, distributors) inform Market Surveillance Authorities about the risks and vice versa.

2. Description of the reference model

Determination of a product that presents a risk, cooperation with economic operators
F. Risk management in business operations of interest to the Working Party

1. Basic Principles

   1. Adequate (balanced) regulatory framework could be achieved when business companies actively participate in risk management processes of the regulators. Risk management processes serve as a basis for efficient cooperation between regulators and business companies aiming at implementation of appropriate risk mitigation measures and a balanced level of safety.

   2. Application of risk management tools within business companies is essential for successful implementation of risk-based regulation.

   3. Risks should be considered in a consistent and systemic way by business companies when making strategic and operational decisions.

2. Description of the reference model

   20. Write a brief description

   Adequacy of risks and regulations

   Cooperation between business companies and regulators
Risk management as a regulatory requirement

Risk management system within a business company

Risk management in operational decision
Risk management in developing of technical documentation and declaration of conformity

Cooperation in risk mitigation (manufacturer, importer, distributor, market surveillance Authorities)

II. Performing the survey

21. To conduct this survey, the following preparatory steps are essential:

- Know what are the risks as broadly as possible – this is the identification stage;
- Assigning the roles within the regulatory system – determining organizations that should be contacted;
- Contacting the organization and setting the date of the introductory webinar;
- Conducting an introductory webinar – presenting
  - The basic concepts of risk management
  - Reference model relevant to the organization
  - Making a brief overview of questions
  - Going through the first five questions of the questionnaire
  - Setting a date for filling out the Internet form.

22. This methodology and questionnaires will be used for building Internet Survey. The respondents should be left alone facing the screen, the interviewer should be either present in person (ideally) or guiding the respondent by phone or Skype. The work of the interviewer holds for 50% of the success of the survey; the interview should check that he or she understands the questions that she will ask. If the respondent doesn’t understand the question, it is necessary to provide a short explanation. If the question still remains unclear, it must be skipped.

23. Since the scope of the survey is broad and one of its goals is to develop reference models, there are a lot open questions, requests to provide examples and opinions. That is why there is no need to assign any ratings to answers; results of the survey should be analyzed manually.
IV. Conclusion

24. This methodology could be used as a first step in assessing the level of risk management implementation within the regulatory system of any country. It is important to always keep in mind that risk management is only a tool; in this context – for creating a balanced regulatory system, which would benefit all stakeholders involved. If the results of the survey show that the regulatory system is balanced without deliberate risk management application, further analysis should be made on whether systemic application of risk management would increase the level of dependability of the system. If the results of the survey show that the risk management application improvement, a plan for capacity building could be easily designed: the survey combines gathering objective evidence on the realization of specific risk management functions in the processes and subjective needs assessment of the stakeholders.

26. Conducting the survey would help to plan the work for further increasing the level of professionalism of stakeholders in risk management tools. This, in turn, would lead to a balanced regulation system which would provide necessary and sufficient level of safety and would stimulate innovation, development and economic growth.