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Risk management in regulatory systems

Risk management in regulatory systems: a proposed reference model

Note by the secretariat¹

Summary

This document describes a reference model of how to use risk management tools in designing regulatory systems. The model can be applied for (a) enhancing the operational procedures of regulatory-system stakeholders, (b) efficiently modelling the interaction among them and (c) raising the overall efficiency of the regulatory system.

It can be also used as a basis for conducting a survey to:

- Document the level of application of risk management tools within the regulatory system and by its main stakeholders.
- Identify outstanding stakeholders' needs in the development and implementation of risk management tools.
- Create the basis for developing recommendations for increased efficiency of the system.

¹ 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 (RMS) (ECE/TRADE/C/WP.6/2009/19, para.10).

Sample questionnaires to conduct the survey are presented in document ECE/TRADE/WP.6/2010/4.

The document suggests further steps on how the model could be applied for developing a comprehensive methodology for managing risks in regulatory systems. In particular, the Working Party can consider how to use the reference model to prepare recommendations for a more efficient use of risk management techniques, to build a common understanding of risks and risk management objectives and tools; and as the basis for capacity-building activities.

This document is presented to the Working Party for discussion and decision.

I. Objectives and scope

1. Mitigating risks that may affect society and hamper economic development is an important goal for policy-making. Risk-management tools are therefore essential to enhancing the efficiency of regulatory action and of regulatory systems.
2. “Risk”, as a concept, can be used to evaluate how balanced the regulatory system is against two extremes: (a) excessive regulations, i.e. regulations that are too stringent with respect to the risk they set out to address and (b) insufficient regulations that fail to address risks and unnecessarily or inordinately expose citizens and economic operators.
3. What are the benefits of using risk management within regulatory systems?
 - It provides the basis for developing recommendations for a more efficient system.
 - It makes regulatory processes more transparent.
 - It represents a more proactive approach to regulation and to regulatory reform.
 - It involves the stakeholders more closely in the regulatory processes.
 - It makes the functions of the system easier to understand.
 - It improves regulatory cooperation at a regional and international level, and a common understanding of risks leads to a common basis for regulatory action.
4. The document on the outcome of the Conference on Risk Assessment and Management (ECE/TRADE/C/WP.6/2010/2) describes the various roles in the risk management process of the regulatory system: regulators, standardization bodies, conformity-assessment bodies, market-surveillance authorities and economic operators
5. The model proposed here can also be used for assessing the effectiveness of risk-management processes that:
 - Function within each of the regulatory system stakeholders’ systems for raising their operational efficiency.
 - Form the basis for the interaction among the stakeholders for increasing the efficiency and resilience of the regulatory system.

II. Risk management at the core of regulatory systems

6. A regulatory system can be defined as a set of interdependent processes and functions performed by technical regulators, conformity assessment bodies, market surveillance authorities, standards development organizations and business operators.

7. The model covers the following processes:

- Planning, developing and implementing technical regulations.
- Planning, developing and implementing voluntary standards.
- Designing and carrying out market-surveillance activities.
- Planning, developing and implementing conformity-assessment procedures.
- Cooperation among stakeholders.

8. The reference model is presented in the figure on page 6. It describes how you can use risk-management tools throughout the various phases of the regulatory process. An integral part of the model is the communication strategy, which allows other regulatory system stakeholders to participate actively in the functions within the system.

9. Each of the stakeholders may use the tool in designing, planning and undertaking their processes and functions, and also as the basis for interaction among the stakeholders. The risk-management process includes the following functions:

- Setting the objectives.
- Identifying and managing the assets being protected.
- Identifying the risks to these assets.
- Prioritizing the risks and understanding the most important risks.
- Choosing risk-management strategies, starting with the most important risks.
- Implementing risk-management strategies.
- Developing a “crisis management” plan.

10. Risk management within regulatory systems will be efficient only if risk management processes are performed appropriately. This means that:

- Risks are timely identified and identification covers as many risks as possible.
- Risks are properly assessed and most important risks are given the highest priority.
- Balanced risk management strategies are chosen.
- Risk management strategies are efficiently implemented.
- Contingency plans are developed, tested and remain available.

11. The remainder of this document presents a description of the key functions of a regulatory system based on this reference model.

(a) Setting the regulatory objectives

12. The system is based on the regulatory objectives identified by the regulator. Regulatory objectives are used for setting the criteria against which the risks are evaluated. This approach implies that absolute safety is not considered as a regulatory goal. Appropriate criteria are selected to decide which risks are acceptable, and acceptance of risk is used as a method for achieving a regulatory balance.

13. The regulatory objectives are drawn up in consultation with the other stakeholders. For example, the system of railways regulatory objectives could include such objectives as safety, timeliness and cleanliness.

(b) Developing an asset inventory

14. Also in consultation with other stakeholders, the assets should be identified: objects or qualities that have value, and which the system sets out to protect. Again, in the system of railways, for example, assets would include tracks, staff and trains.

(c) Risk identification

15. Risks are then identified for each asset, starting with the most crucial ones. Using the reference model enables the regulators to cooperate effectively with other stakeholders in identifying risks, as it increases the resilience of the system by reducing the chances that certain risks might be overlooked. All stakeholders in the system can participate in identifying risks for the following reasons:

- Not only regulations but also voluntary standards help business and society deal with risks. Standards development organizations can provide important input for risk identification.
- For market-surveillance authorities, properly identifying the risks that products placed on the market may cause is a prerequisite for developing timely and appropriate measures and ensuring marketplace safety.
- Conformity-assessment procedures act as risk mitigation tools by reducing the risk of placing dangerous products on the market. Conformity-assessment bodies see the risks that the regulator may not be able to identify.
- Business operators may also inform the regulator about risks that in their view require regulatory intervention.

16. For example, the system of railways could be exposed to a risk of an increased number of passengers travelling without a ticket during the summer. The regulator could receive this information from the train inspectors that in this example perform the market surveillance function.

(d) Risk assessment

17. No matter from which source the regulator or other stakeholder learns about a risk, a risk assessment should follow, ranking the risk according to its seriousness. This step ensures that important risks are dealt with in a timely manner. In our example, the assessment of risks may show the probable losses caused by the non-paying travellers.

(e) Determining a risk management strategy

18. On the basis of the results of the risk assessment, and acting in consultation with the systems' stakeholders, the regulator chooses an appropriate risk management strategy. This can be:

- (i) Accepting a risk: deciding that the regulator is not willing or is unable to take measures to reduce the probability and the expected impact of a hazard. An important condition is that if a risk is accepted, it should be communicated to interested parties appropriately and become an input into the contingency planning function.
- (ii) Avoiding the risk by banning activities or processes where it has incurred.
- (iii) Transferring the responsibility for managing the risk, including bearing responsibility if it occurs, to economic or social actors (families, firms).

(iv) Mitigating the risk: developing a regulatory or non-regulatory response to reduce the probability and the expected impact of a hazard:

- A regulatory action implies not only developing a new or reforming an existing regulation, but also choosing appropriate conformity-assessment procedures and market-surveillance measures.
- Non-regulatory action, on the other hand, includes options such as educational or information campaigns, and subsidies or incentives to economic operators' activities.

19. In the railway example, if the regulators should decide that risk mitigation is necessary, they may choose to allocate additional resources and increase the number of inspectors.

(f) Implementing the risk management strategy

20. Implementing risk-management strategies within regulatory system, regardless of the strategy chosen, requires monitoring compliance, evaluating the effect of a risk management strategy on other regulatory processes, other stakeholders and areas of activities.

21. This involves:

- Integrating the regulatory and other measures with existing tools.
- Performing regulatory impact assessment.
- Establishing coordinating mechanisms among competent authorities and stakeholders.
- Giving guidance and establishing an appropriate budget for the institutions responsible for monitoring compliance (conformity assessment and/or market surveillance authorities).
- Deciding on penalties for non-compliance.

22. Continuing the example, the strategy chosen by the regulator – hiring new inspectors - requires hiring new staff, training them, etc. It also requires monitoring the effectiveness of the increased number of inspectors on passengers' compliance.

(g) Contingency planning

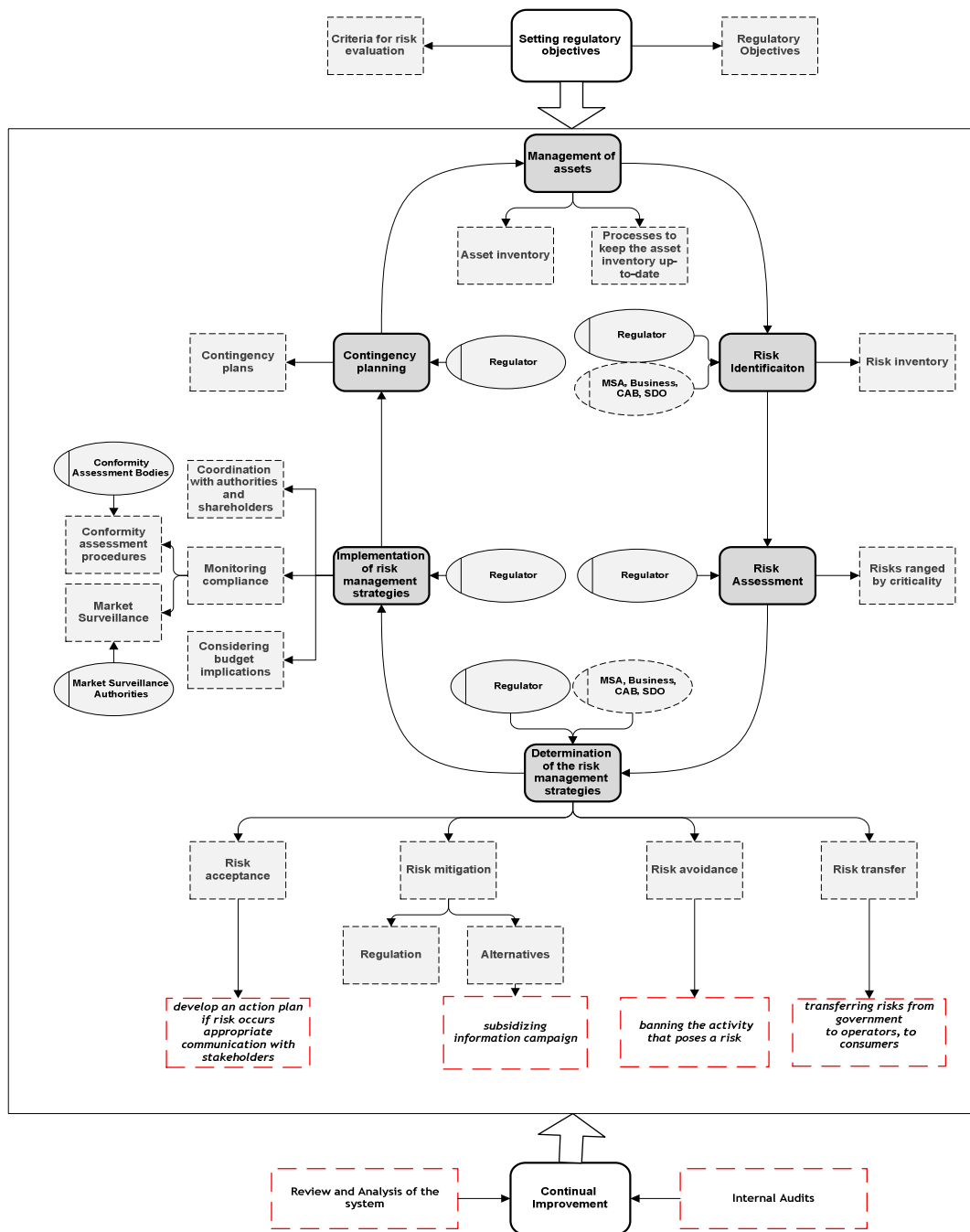
23. This is the last step in this process. Since there are risks that are unavoidable and some are almost impossible to forecast, the regulator must prepare a plan: if the risk occurs, what is to be done, who should do it and how. The need for developing contingency plans is widely recognized; however, these will be only be efficient if they are prepared within a system, where contingency planning is a step in the risk management process.

24. In the example above, even if the number of inspectors were increased but the problem remained, the regulator would have to consider other options.

(h) Review and analysis of the system

25. Regulators or other interested parties also run processes necessary for continual improvement of the whole regulatory system. These may include performing regular internal audits, analysis and review of processes and methodologies that function within the whole system. The purpose of these activities is to raise the efficiency of process interfaces and to provide common understanding of the regulatory system policy among all regulatory system stakeholders.

Reference model for regulatory systems



III. Proposed next steps

(a) Specific models for regulatory system stakeholders

26. As the description above shows, all regulatory stakeholders have their own role in the overall risk management process, which is at the basis of a regulatory system. At the same time, regulatory system stakeholders have their own internal risk management processes that function within their organizations to increase operational efficiency. The

Working Party could develop specific models adapted to the specific functions of the stakeholders.

27. The Working Party may decide to continue using the reference model detailed above to develop specific models for each of the stakeholders in the regulatory system and in particular for:

- technical regulators
- standardization bodies
- conformity assessment bodies
- market surveillance authorities
- business operators.

28. Developing these models would allow the Working Party:

- To perform a representative risk management needs assessment survey.
- Taking into consideration the results of the survey, to build a comprehensive methodology for managing risks within regulatory systems.

(b) Risk-management needs assessment survey

29. The secretariat has already used this reference model to develop a set of questionnaires tailored to the specific functions of the different stakeholders in the regulatory system. These questionnaires are set out in document ECE/TRADE/C/WP.6/2010/4. The secretariat has used them as the basis of a preliminary survey of risk-management needs for the different stakeholders of regulatory systems.

30. The reference model could be further applied to develop a methodology for a risk management needs assessment survey for the purposes of:

- Obtaining objective evidence on the level of application of risk management tools by regulatory system stakeholders; evaluating their satisfaction with application of risk management tools and with that of their partners.
- Gathering international best practice on the risk-management application. In particular, developing a repository with examples of how different functions have been carried out successfully in different countries or regions (asset and risk identification, risk assessment, development and implementation of a risk management strategy, contingency planning) and by different stakeholders in the regulatory system.
- Identifying bottlenecks in the use of risk-management tools and stakeholders' needs related to developing and implementing these tools.
- Creating a basis for developing a methodology for managing risks in regulatory systems and recommendations on how to apply risk-management tools.

31. The findings of the survey could be the basis for technical assistance projects, which would consist of an in-depth analysis of how risk-management functions are performed in the regulatory system as a whole and in each of the stakeholders' internal processes. The analysis would be based on the model contained in this document and the questionnaires set out in document ECE/TRADE/C/WP.6/2010/4.

(c) Comprehensive methodology for managing risks within regulatory systems

32. On the basis of the models and the results of the survey, the Working Party could develop a methodology for management of risks within regulatory system. This methodology could be used to:

- Prepare recommendations for improving the stakeholders' own internal processes by the means of more efficient use of risk management techniques.
- Prepare recommendations for enhanced cooperation among stakeholders at national, regional and international levels.
- Build a common understanding of risks and risk management objectives and tools.

33. The Working Party may also wish to promote the use of the proposed methodology as the basis for capacity building and technical assistance activities with the aim of increasing the efficiency of regulatory systems at the national or regional levels.

IV. Conclusions

34. Risk-management processes lie at the core of any regulatory system. Stakeholders' professionalism in managing risks and their common understanding of risk-management methodologies have a strong impact on the efficiency and resilience of a regulatory system.

35. The reference model set out here provides an overview of how risk-management tools could be used in designing regulatory systems. It could serve as a concept model for initiating a set of projects with an overall objective of increasing the maturity of risk management application throughout regulatory systems.

36. The document describes the model and shows how it could be applied in three interdependent set of activities: (a) developing specific models of risk-management application by regulatory stakeholders (b) performing a risk-management needs assessment survey and (c) developing a comprehensive methodology for managing risks within regulatory systems.

37. The development of specific models of risk-management application in various processes of various regulatory stakeholders would create a basis for increasing their operational efficiency and for enhancing cooperation among them. Also, the models can be used for designing the risk-management needs assessment survey methodology.

38. Conducting a survey should provide objective information on how risk management is currently applied within regulatory systems in general and within a given regulatory system, identify best practice as well as bottlenecks in the processes. Therefore, it will create a basis for developing immediate recommendations and a methodology for improving risk-management application. It may also lead to technical assistance and capacity-building projects in the field.

39. Development of a comprehensive methodology for management of risks in regulatory systems will provide guidance on effective and efficient risk-management utilization throughout regulatory systems. This, in turn, would lead to a more balanced regulatory system, to one that provides necessary and sufficient level of safety and stimulates innovation, development and economic growth.
