



## Economic and Social Council

Distr.: General  
19 August 2011

Original: English

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### Economic Commission for Europe

Committee on Trade

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

Twenty-first session

Geneva, 31 October – 2 November 2011

Item 5 of the provisional agenda

### Draft of the general recommendation “Risk Management in Regulatory Systems”

Note by the secretariat<sup>1</sup>

#### *Summary*

This document presents the draft of a recommendation on the use of risk management tools in regulatory systems.

The recommendation calls for a more consistent and systemic application of risk management tools in regulatory work and describes the role of each of the regulatory stakeholders - including regulatory authorities, standardization bodies, economic operators, conformity-assessment bodies and market-surveillance authorities - in managing risks that affect communities and organizations of different kinds.

The draft recommendation is submitted for further discussion and approval by the Working Party.

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<sup>1</sup> The group is mandated to “developing and sharing best practice, including if relevant in the form of recommendations” (see the Group’s Terms of reference, adopted at the twentieth session of the Working Party in document ECE/TRADE/C/WP.6/2010/2, Annex).

## I. Introduction

1. One of the objectives of the Group of Experts on Risk Management in Regulatory Systems is to develop best practice and recommendations on the use of risk management tools in regulatory systems. According to its mandate, the GRM prepared a draft of the general recommendation “Risk Management in Regulatory Systems”.
2. This recommendation:
  - (a) Presents an overall picture of how risk management can be applied within a regulatory system to help achieving regulatory objectives;
  - (b) Describes the role of each of the regulatory stakeholders - including regulatory authorities, standardization bodies, economic operators, conformity-assessment bodies and market-surveillance authorities - in managing risks that affect communities and organizations of different kinds. It specifies how and by which regulatory system stakeholder each of the functions of the risk management process is performed within a regulatory system;
  - (c) Shows how risk management functions can be integrated into main regulatory processes.
3. Based on the draft of the general recommendation, the GRM has also developed a specific recommendation “Crisis management in regulatory systems” (ECE/TRADE/C/WP.6/2011/14), which provides guidance on performing the crisis management function of the risk management process. The Group will continue developing specific recommendations covering all of the risk management functions as they are described in the general recommendation.

## II. Purpose of the Recommendation

4. The recommendation calls for a more consistent and systemic application of risk management tools in regulatory work. The expected benefits are manifold. At a whole-country level, this recommendation promotes the understanding that absolute safety is unattainable and that regulation – along with other means – necessarily strike a balance between safety and measures that have costs both for consumers and citizens and for business operators.
5. At a national, regional and international levels, a common understanding and assessment of risks will contribute to a more coherent and cohesive response, and to increase regulatory convergence.
6. Finally, implementing this recommendation will structure and reinforce cooperation among the regulatory stakeholders within a given regulatory system. More specifically this will enable:
  - (a) Regulatory authorities to establish a common risk language among regulatory system stakeholders, and a common risk management process within a regulatory system;
  - (b) Economic operators to more actively participate in regulatory processes and to call the attention of the regulatory stakeholders on risks that economic operators cannot manage on their own;
  - (c) Standardization bodies to ensure that their activities address the most critical risks across regulatory systems;

(d) Conformity assessment bodies and market surveillance authorities to optimize their operations and enhance coordination of their activities with other regulatory stakeholders.

### III. Text of the draft recommendation

The Working Party on Regulatory Cooperation and Standardization policies:

*Recognizing* that mitigating risks that may affect society and hamper economic development is an important goal for policy-making,

*Stressing* that risk-management tools are essential to enhancing the efficiency of regulatory action and of regulatory systems,

*Recognizing* the need of regulatory authorities, standardization, conformity assessment and accreditation bodies, as well as market surveillance authorities, economic operators, consumers, as well as other regulatory stakeholders, in promoting coherent, consistent, efficient, effective and systemic application of risk management in regulatory systems,

*Taking into account* international standards related to risk management, such as ISO 31000:2009, ISO 9001:2008, ISO 27001:2005, and other standards, including sector-specific standards,

*Underlining* that regulation in many cases may not be the best response to risks, and that absolute safety cannot be a regulatory goal, as it is impossible to make the world risk-free,

*Stressing* that risk management in regulatory systems:

- (a) Makes regulatory processes more transparent;
- (b) Represents a more proactive approach to regulation and to regulatory reform;
- (c) Forms the basis for the interaction among the stakeholders and is a tool to involving the stakeholders more closely in the regulatory processes;
- (d) Makes the functions of the system easier to understand;
- (e) Improves regulatory cooperation and harmonization at a regional and international level;
- (f) Is indispensable for increasing the efficiency and resilience of the regulatory system;

Recommends that:

**R.1.** Regulatory authorities and other regulatory system stakeholders should use the concept of “risk” to evaluate how balanced the regulatory system is against two extremes:

- (a) Excessive or over regulation, i.e. regulations that are too stringent with respect to the risk they set out to address;
- (b) Insufficient regulations that fail to address risk and unnecessarily or inordinately expose citizens and economic operators.

**R.2.** All functions of the risk management process, as they are presented in the text of this recommendation, should be consistently described in legislation that lays out the regulatory system at a general level or for a specific sector. Legislation should specify

allocation of responsibilities for performing the risk management functions outlined in the model.

**R.3.** Taking into account the level of risk tolerance of various regulatory system stakeholders, regulatory authorities should establish, implement and maintain, a process for:

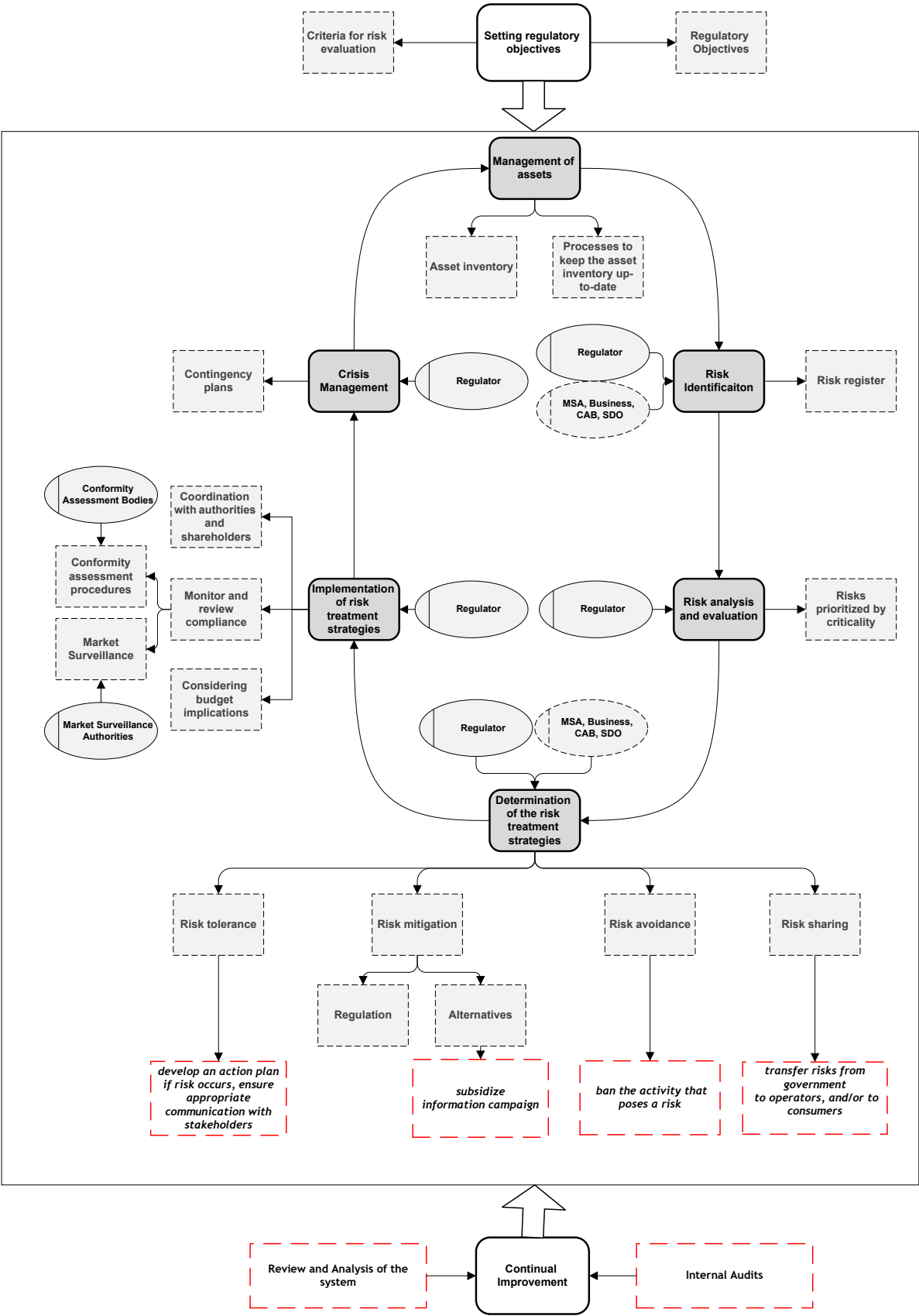
- (a) Determining;
- (b) Analysing;
- (c) Reviewing and monitoring an acceptable level of risk within a regulatory system.

**R.4.** Regulatory stakeholders, as well as international organizations and other interested parties, should apply the following criteria when evaluating regulatory systems:

- (a) Risks are timely identified, and identification covers as many risks as possible and takes into account their relationships;
- (b) Risks are properly analysed and evaluated and the most critical risks are given the highest priority;
- (c) Balanced risk treatment is chosen;
- (d) Risk treatment is efficiently implemented;
- (e) Ongoing monitoring of risk treatment strategies through regulatory activities is carried out and is effective;
- (f) Contingency plans are developed, tested and remain relevant; resources are available to implement them.

**R.5.** Where appropriate, regulatory authorities implement the following functions within regulatory systems, in the logical sequence as presented in picture 1 and described in the explanatory remarks below:

- (a) Setting the regulatory objectives;
- (b) Developing an asset inventory: identifying and managing the assets being protected;
- (c) Identifying the risks to these assets;
- (d) Analysing and evaluation the most important risks;
- (e) Choosing risk treatment strategies;
- (f) Implementing risk treatment strategies;
- (g) Crisis management (including developing a plan to deal with disruption related risk);
- (h) Monitoring, reviewing and improving the risk management process.



## IV. Explanatory remarks

### R.5.1. Setting the regulatory objectives

The system is based on the regulatory objectives identified by the regulator. Regulatory and societal objectives are used for setting the criteria against which the risk is evaluated. Absolute safety is not regarded as a regulatory goal. Appropriate criteria are selected to decide which risks are tolerable, and risk tolerance is used as a method for achieving a regulatory balance. The regulatory objectives are drawn up in consultation with all relevant stakeholders.

### R.5.2. Developing an asset inventory

A process of communication and consultation with stakeholders sets out to identify the relevant assets: objects or qualities that have value, and which the system sets out to protect.

### R.5.3. Risk identification

Risks are identified for each asset, starting with the most crucial ones. Regulators 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 are allowed to participate in identifying risks for the following reasons:

(a) Not only regulations but also voluntary standards help business and society deal with risk. Standards development organizations can provide important input for risk identification;

(b) 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;

(c) 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;

(d) Business operators may also inform the regulator about risks that in their view require regulatory intervention.

### R.5.4. Risk analyses and risk evaluation

No matter from which source the regulator or other stakeholder learns about a risk, a risk analyses and evaluation must follow, ranking the risk according to its seriousness. This step ensures that critical risks are dealt with in a timely manner.

### R.5.5. Determining a risk treatment strategy

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 treatment. This can be:

(a) Tolerating 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 risk. An important condition is that if a risk is tolerated, it should be communicated to interested parties appropriately and become an input into the contingency planning function;

(b) Avoiding the risk by banning activities or processes where it has incurred;

(c) Sharing the responsibility for managing the risk, including bearing responsibility if it occurs, to economic or social actors (families, firms);

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

- (i) 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;
- (ii) Non-regulatory action, on the other hand, includes options such as educational or information campaigns, and subsidies or incentives to economic operators' activities.

#### **R.5.6. Implementing the risk treatment**

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

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

#### **R.5.7. Crisis Management**

Since there are risks that are unavoidable and some are almost impossible to forecast, the regulator prepares a plan setting out: if the harm associated with 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 an integral part of the risk management treatment.

#### **R.5.8. Monitoring and review of the system**

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.

## **V. General implementation principles**

The Working Party trusts that:

**R.6.** The reference model set out here provides an overview of how the risk management process can 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.

**R.7.** The recommendation describes the model which can be applied in three interdependent set of activities:

(a) Developing recommendations on implementing risk-management tools in the activities of each of the regulatory stakeholders;

(b) Developing specific recommendations on each of the functions of the risk-management process;

(c) Developing a comprehensive methodology for managing risks within a regulatory system.

**R.8.** Regulatory authorities participate in regional and international cooperation efforts and implement international best practice in the field of crisis management.

**R.9.** Donors give priority consideration to capacity-building activities for crisis management and contingency planning, especially to train officers responsible for technical regulation, conformity assessment and market surveillance activities.

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