



Recommendations on Regulatory Cooperation and Standardization Policies

Revised Edition

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Managing Risk in Regulatory Frameworks¹

The Working Party on Regulatory Cooperation and Standardization policies,

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

Underlining that risk management is an important tool for promoting regulatory convergence at international and regional levels,

Emphasizing the role of risk management in achieving sustainable development goals, 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 the management of risk, such as ISO 31000:2009, ISO 9001:2008, ISO/IEC 17000:2004, and other standards, including sector-specific standards, such as ISO/IEC 27001:2005,

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

Stressing that risk management in regulatory frameworks:

- (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;

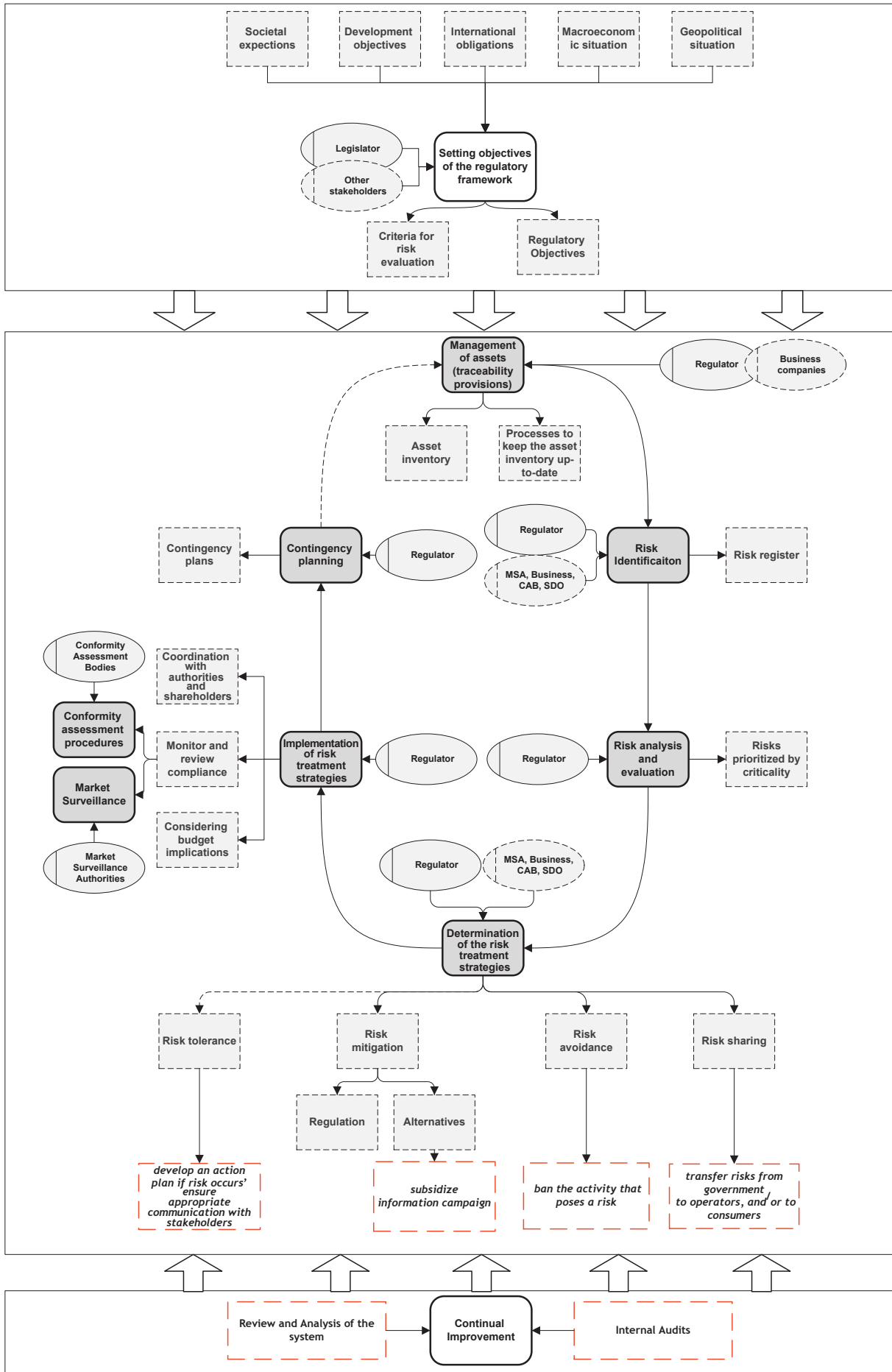
¹ Recommendation adopted in 2011

Recommends that:

- R.1** Regulatory authorities and other regulatory stakeholders should use the concept of “risk” to evaluate how balanced regulations are 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 to threats.
- 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 framework 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 stakeholders, regulatory authorities should establish, implement and maintain, a process for determining, analysing, reviewing and monitoring an acceptable level of risk within a regulatory framework.
- 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 including rare risk events and emerging risks and takes into account their relationships;
 - (b) Taking into account the different risk perceptions of the involved stakeholders, 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 frameworks described in the explanatory remarks below:
- (a) Setting the regulatory objectives;
 - (b) Management of assets (traceability provisions): 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.

R.5.1 Setting objectives of the regulatory framework

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 Management of assets (traceability provisions) within regulatory frameworks

A process of communication and consultation of regulators with stakeholders sets out to identify the relevant assets or objects, which the framework sets out to protect. One of the ways in which the communication process can be structured is by introducing traceability requirements, so that where appropriate products on the market can be traced back. It allows regulatory stakeholders to get information on processes, original materials and components used in the production.

R.5.3 Risk identification

Risks are identified starting with the most crucial ones. Regulators cooperate effectively with other stakeholders in identifying risks, as it increases the resilience of the framework 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. National 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.

If the regulator is not willing or is unable to take measures to reduce the probability of the expected impact of a risk, it should consider if and how this information should be communicated to relevant parties. It should also become an input into the contingency planning function;

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) Avoiding the risk by banning activities or processes where it has occurred;
- (b) Sharing the responsibility for managing the risk, including bearing responsibility if it occurs, to economic or social actors (families, firms);
- (c) 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 strategy

Implementing risk-management treatment within a regulatory framework, 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 ones;
- (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 to manage disruption related risk is widely recognized; however, these will be only be efficient if they are prepared within a framework where contingency planning is an integral part of 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 risk management processes implemented within a regulatory framework. 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 stakeholders.

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 frameworks. 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 frameworks.
- 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 framework.
- R.8** The implementation of this recommendation by Member States will be an important step in promoting regulatory convergence. For example, the recommendation can be used to structure the international regulatory cooperation, across the board as well as in specific sectors. Consistent application of risk management tools in regulatory frameworks will allow regulators to use the target level of risk as one of the tools for proving equivalency of technical regulations.
- R.9** Regulatory authorities participate in regional and international cooperation efforts and implement international best practice in the field of risk management in regulatory frameworks.
- R.10** Donors give priority consideration to capacity-building activities related to the management of risks within regulatory frameworks, especially to train officers responsible for technical regulation, conformity assessment and market surveillance activities.