# Draft of the General Recommendation Risk Management in Regulatory System

**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,

• Taking into account international standards related to risk management, such as ISO 31000:2009, ISO 9001:2008, ISO 27001:2005, and other standards,

• Underlining 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

• makes regulatory processes more transparent,

• represents a more proactive approach to regulation and to regulatory reform,

• forms the basis for the interaction among the stakeholders and is a tool to involving the stakeholders more closely in the regulatory processes,

• makes the functions of the system easier to understand,

• improves regulatory cooperation and harmonization at a regional and international level,

• is indispensible for increasing the efficiency and resilience of the regulatory system,

recommends that:

**R1**. Regulatory authorities and other regulatory system stakeholders 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 and

(b) Insufficient regulations that fail to address risk and unnecessarily or inordinately expose citizens and economic operators.

**R2.** Regulatory authorities establish, implement and maintain, taking into account the level of risk tolerance of various regulatory system stakeholders, a process for:

(a) Determining,

(b) Analyzing,

(c) Reviewing and monitoring, and

(d) Adjusting

an acceptable level of risk within a regulatory system.

**R3**. Regulatory stakeholders, as well as international organizations and other interested parties, use the following criteria when evaluating regulatory systems:

(a) Risks are timely identified and identification covers as many risks as possible.

(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) Contingency plans are developed, tested and remain relevant; resources are available to implement them.

**R4.** Where appropriate, regulatory authorities implement the following functions within regulatory systems, in the logical sequence as presented in the picture 1 and described in clauses R4.1-R4.8:

(a) Setting the regulatory objectives.

(b) Developing asset inventory: identifying and managing the assets being protected.

(c) Risk identification: identifying the risks to these assets.

(d) Risk analysis and evaluation: understanding the most important risks).

(e) Choosing risk treatment strategies.

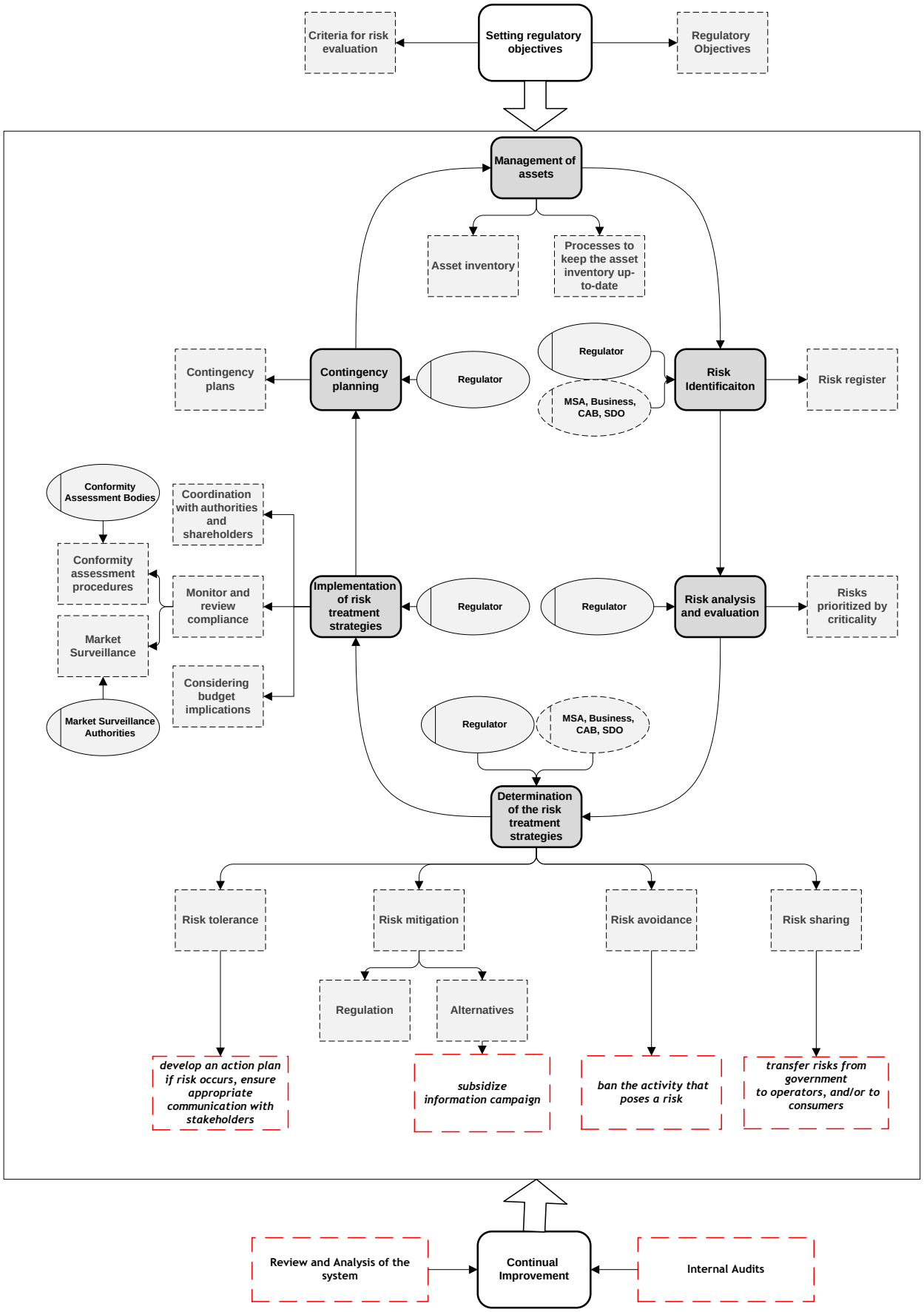
(f) Implementing risk treatment strategies.

(g) Developing a plan to deal with disruption related risk.

(h) Monitoring, reviewing and improving the risk management process.

### R4.1 Setting the regulatory objectives

The system is based on the regulatory objectives identified by the regulator. Regulatory objectives are used for setting the criteria against which the risk is evaluated. Absolute safety is not considered 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.




### R4.2 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.

### R4.3 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:

- Not only regulations but also voluntary standards help business and society deal with risk. 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.

### R4.4 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.

### R4.5 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:

(i) 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.

(ii) Avoiding the risk by banning activities or processes where it has incurred.

(iii) Sharing 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 risk:

- 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.

### R4.6 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:

- Integrating the regulatory and other measures with existing processes.
- 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.

**R4.7 Contingency planning**

Since there are risks that are unavoidable and some are almost impossible to forecast, the regulator prepares 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 an integral part of the risk management treatment.

**R4.8 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.

The Working Party trusts that:

**R5.** 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.

**R6.** 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 risk within regulatory systems.

**R7**. 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 and harmonization among them. Also, the models can be used for designing the risk-management needs assessment survey methodology.

**R8**. Development of a comprehensive methodology for management of risk 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.