ANNEX 1.A2

Risk Policy in Practice

Selected examples from country practices

The OECD has recognised that applied risk assessment is an important factor in the governance arrangements for regulatory quality systems. In its 2002 report[1] the OECD remarked that:

> Quantitative risk assessment improves the capacity of a government to focus on the most important risks and reduce them at lowest cost while identifying those risks that fall below a threshold justifying government action.

A robust system of risk and regulatory governance needs not only the tools of risk assessment and management, but also an institutional structure to guide and oversee these analyses. In OECD countries this function is largely decentralised. In 2007 a survey of OECD country practices was undertaken to identify the extent to which countries had developed and promoted a policy driven approach to identifying and managing risk. The questions were structured first to identify the extent to which policies and institutional approaches had been formulated and secondly to elicit information about these formalised approaches. Nineteen of the thirty OECD countries responded to the survey, and of these only four countries completed the entire survey. The results indicated that most OECD countries have limited integrated policies for the treatment of risk in regulation. In some countries risk assessment is applied in the formulation of RIA. The United Kingdom has also developed a formal policy on risk-based compliance and enforcement. However, these risk-based approaches are not routinely adopted among OECD countries. For the most part risk assessment is not routinely required in the development of RIA, nor is it applied systematically to the reduction of compliance burdens. Except in limited instances it appears that guidance material on the application of risk assessment is not usually prepared by the centres of government and provided to regulators.

For an example of some existing policies on risk-based approaches, a brief overview of some of the guidance provided to regulators in the United States and in the United Kingdom is summarised below.

The United States – applying risk principles to the development of regulation

The joint OMB OSTP Memorandum M-07-24 for The Heads of Executive Departments and Agencies issued on 19 September 2007 outlines clear principles for risk assessment, risk management, risk communication, and priority setting. The memorandum advises agencies to review their risk analysis practices and guidelines and incorporate these principles as they develop, update, and issue risk analyses and guidelines. The following text reproduces the main headings from the memorandum. Further guidance not reproduced here can be found in the original document.[2]

Principles for risk assessment

- Agencies should employ the best reasonably obtainable scientific information to assess risks to health, safety, and the environment.
- Characterisations of risks and of changes in the nature or magnitude of risks should be both qualitative and quantitative, consistent with available data. The characterisations should be broad enough to inform the range of policies to reduce risks.
- Judgments used in developing a risk assessment, such as assumptions, defaults, and uncertainties, should be stated explicitly. The rationale for these judgments and their influence on the risk assessment should be articulated.
- Risk assessments should encompass all appropriate hazards (*e.g.* acute and chronic risks, including cancer and non-cancer risks, to human health and the environment). In addition to considering the full population at risk, attention should be directed to subpopulations that may be particularly susceptible to such risks and/or may be more highly exposed.
- Peer review of risk assessments can ensure that the highest professional standards are maintained. Therefore, agencies should develop policies to maximise its use.
- Agencies should strive to adopt consistent approaches to evaluating the risks posed by hazardous agents or events.

Principles for risk management

- In making significant risk management decisions, agencies should analyse the distribution of the risks and the benefits and costs (both direct and indirect, both quantifiable and non-quantifiable) associated with the selection or implementation of risk management strategies. Reasonably feasible risk management strategies, including regulation, positive and negative economic incentives, and other ways to encourage behavioural changes to reduce risks (*e.g.* information dissemination), should be evaluated. Agencies should employ the best available scientific, economic and policy analysis, and such analyses should include explanations of significant assumptions, uncertainties, and methods of data development.
- In choosing among alternative approaches to reducing risk, agencies should seek to offer the greatest net improvement in total societal welfare, accounting for a broad range of relevant social and economic considerations such as equity, quality of life, individual preferences, and the magnitude and distribution of benefits and costs (both direct and indirect, both quantifiable and non-quantifiable).

Principles for risk communication

- Risk communication should involve the open, two-way exchange of information between professionals, including both policy makers and "experts" in relevant disciplines, and the public.
- Risk management goals should be stated clearly, and risk assessments and risk management decisions should be communicated accurately and objectively in a meaningful manner.

To maximise public understanding and participation in risk-related decisions, agencies should:

- explain the basis for significant assumptions, data, models, and inferences used or relied upon in the assessment or decision;
- describe the sources, extent and magnitude of significant uncertainties associated with the assessment or decision;
- make appropriate risk comparisons, taking into account, for example, public attitudes with respect to voluntary *versus* involuntary risk; and
- provide timely, public access to relevant supporting documents and a reasonable opportunity for public comment.

Principles for priority setting using risk analysis

- To inform priority setting, agencies should seek to compare risks, grouping them in broad categories of concern (*e.g.* high, moderate, and low).
- Agencies should set priorities for managing risks so that those actions resulting in the greatest net improvement in societal welfare are taken first, accounting for relevant management and social considerations such as different types of health or environmental impacts; individual preferences; the feasibility of reducing or avoiding risks; quality of life; environmental justice; and the magnitude and distribution of both short- and long-term benefits and costs.
- The setting of priorities should be informed by internal agency experts and a broad range of individuals in state and local government, industry, academia, and nongovernmental organisations, as well as the public at large. Where possible, consensus views should be reflected in the setting of priorities.
- Agencies should attempt to co-ordinate risk reduction efforts wherever feasible and appropriate.

The United Kingdom – applying the principles of risk in compliance and enforcement

The United Kingdom Hampton review on reducing administrative burdens through better compliance and enforcement practices[3] was published in March 2005. In April 2008, the United Kingdom issued *The Regulators Compliance Code*;[4] a statutory code of practice intended to ensure that inspection and enforcement is efficient, both for the regulators and those they regulate and based upon risk principles. The Code gives the seven Hampton principles relating to regulatory inspection and enforcement a statutory basis and is binding on UK regulators. It requires the following of regulators:

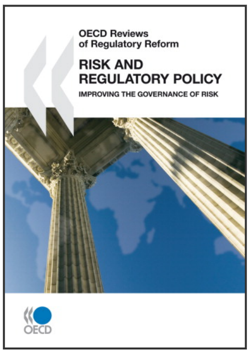
- Regulators should recognise that a key element of their activity will be to allow, or even encourage, economic progress and only to intervene when there is a clear case for protection.
- Regulators, and the regulatory system as a whole, should use comprehensive risk assessment to concentrate resources in the areas that need them most.
- Regulators should provide authoritative, accessible advice easily and cheaply.
- No inspection should take place without reason.

- Businesses should not have to give unnecessary information or give the same piece of information twice.
- The few businesses that persistently break regulations should be identified quickly and face proportionate and meaningful sanctions.
- Regulators should be accountable for the efficiency and effectiveness of their activities, while remaining independent in the decisions they take.

It is important to review the success of these measures in practice and in July 2008, the United Kingdom National Audit Office reported on reviews of the performance of the five largest regulators in implementing the Hampton principles.[5] The regulators were the Environment Agency, Health and Safety Executive, Financial Services Authority, Food Standards Agency and the Office of Fair Trading. The general conclusion was that regulators had accepted the need for risk-based regulation and in most cases had established mechanisms to assess risk and direct resources accordingly. There were however a number of common challenges faced by regulators. Among these was the development of a comprehensive risk assessment system to deal with a wider range of risks including those applying to the regulated sector generally and at the level of the firm so that resources could be applied effectively. The review concluded that there was considerable value in regulators sharing their knowledge and experience.

Notes

1. OECD (2002), *Regulatory Policies in OECD Countries – From Interventionism to Regulatory Governance*, p. 130.
2. United States Government (2007), Memorandum of the Executive Office of the President, Office of Management and Budget, USA concerning the "Updated Principles for Risk Analysis", 19 September 2007, *www.whitehouse.gov/omb/memoranda/fy2007/m07%1e24.pdf*.
3. United Kingdom Government, The Hampton Review – Reducing Administrative Burdens Effective Inspection and Enforcement, March 2005, available online at *www.hm-treasury.gov.uk/media/7/F/bud05hamptonv1.pdf*.
4. United Kingdom, *Regulators Compliance Code – Statutory Code of Practice for Regulators*, Department of Business Enterprise and Regulatory Reform, 17 December 2007, available online at *www.berr.gov.uk/files/file45019.pdf*.
5. United Kingdom Government (2008), National Audit Office, *Regulatory Quality: How Regulators are Implementing the Hampton Vision*, *www.nao.org.uk*.



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Improving the Governance of Risk

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