

The Annual Regulatory Affairs International Symposium (14-15 July 2010)

Regulatory Failure and Risk Assessment

Risk assessment and regulation

14 July 14:15

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Conceptual background - Regulation

Fluctuating notion, but often defined as:

- having people doing what they would normally not do
 - Self-interest
 - Self-control
 - Limited rationality ...
- in order to generate individual and collective benefits (servicing society needs)
- without assuming unaffordable risks

Conceptual background - Risk

- Risk = undesired event / development that may happen
 - Situation of risk = where probabilities can be assigned to various outcomes
 - Situation of uncertainty = where no probabilities can be assigned
- In most cases risk cannot be eliminated, but only mitigated (prevention / substitution / compensation)

Conceptual background - Risk

- Risk tolerance is a relative and evolutive notion, depending on
 - core values and
 - circumstances
- For some, risk should not be eliminated
 - Risk is part of life
 - Risk bring opportunities
 - Risk suppression is unaffordable and dangerous
 - Substitute risks (GMOs, drug lag, ...)

Risk assessment and regulation: evolution in the debate

- on principles
 - precautionary principle
- on structures
 - functional vs institutional separation of risk identification / assessment
- on processes / methodologies
 - 3+ pillars approach
- on (regulatory) tools
 - banning / restricting substances, products, activities
 - market authorisation subjected to specific proofs ...

Risk assessment and regulation: the Precautionary Principle (1)

- Precaution (in cost-benefit analysis):
 - incurring costs now
 - to reduce the chance of
 - incurring greater costs in the future
- Precautionary principle (continuum of understandings)
 - Radical: When “potential adverse effects are *not fully understood*, the activities *should not proceed*” – UN World Charter for Nature 1982
 - Moderate: “Where there are threats of serious or irreversible damage, *lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation*” – UN Rio declaration on environment and development 1992

Risk assessment and regulation: the Precautionary Principle (2)

- Passionate debate
 - Only a reckless mind could believe in safety first? Jamie Whyte
- EU sometimes targeted
 - Communication from the Commission of 2 February 2000 on the precautionary principle (COM(2000)1)
 - “Exporting precaution – How Europe’s risk-free regulatory agenda threatens American free enterprise” Lawrence A. Kogan (altruistic agenda hiding the protectionist agenda of a power wishing to slow down faster innovators)
- Progressive convergence at bilateral and multilateral levels
 - OIRA – from ‘deregulation is not the only option’ (John Graham) to ‘regulation is not the only option’ (Cass Sunstein)
 - EU case law
 - OIRA – European Commission ... (US-EC high level regulatory cooperation forum) and other regulatory fora (2008 and 2010 OECD reports on risk governance)

Risk assessment and regulation: processes

- Step-wise Process
 - 1a. Risk tolerance identification (what is an unacceptable risk?)
 - 1b. Risk identification (which substances, products, activities are potentially risky?)
 - 1c. Risk assessment (what is the value of the risk at stake?)
 - = magnitude of the hazard (danger)
x
probability that hazard will
 2. Risk management
 3. Risk communication

Risk assessment and regulation: structures

- Functional separation of risk assessment and risk management within a single institution (Food and Drug Administration)
- Institutional separation (European Chemical Agency ECHA and the Commission)

Thank you

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Risk assessment and the European Commission

- The European Commission is submitting all its major legislative and policy initiatives to an “impact assessment” (on average 130 IAs per year).

Risk assessment and the European Commission

“Impact Assessment Guidelines” 2009

http://ec.europa.eu/governance/impact/commission_guidelines/commission_guidelines_en.htm

Key analytical steps in an IA:

- 1. Identify the problem.
- 2. Define the objectives.
- 3. Develop main policy options.
- 4. Analyse their impacts.
- 5. Compare the options.
- 6. Outline policy monitoring and evaluation.

Risk assessment and the European Commission

4. Analyse the impacts of the main options

- Identify (direct and indirect) environmental, economic and social impacts and how they occur.
- Identify who is affected (including those outside the EU) and in what way.
- Assess the impacts in qualitative, quantitative and monetary terms where possible and appropriate.
- Consider the risks and uncertainties in the policy choices, including obstacles to compliance.

Risk assessment – basic concepts

- A risk assessment is necessary mainly when
 - there is a non-zero probability that a certain adverse event or development will occur AND
 - the negative consequences for certain parties (individuals, businesses, regions, sectors) will be very serious (fatalities, invalidity, ...) and irreversible.
- Value of a risk = magnitude of the hazard (*danger*) x probability that hazard will occur