http://regulationforum.org/agenda/

The Annual Regulatory Affairs International Symposium 2010

14th - 15th July 2010, The Commonwealth Club, London -

Center for Parliamentary Studies - http://parlicentre.org/

15th July 2010

11:15	**International Agreements and Regulations** • Regional Regulation and Expertise • Capability and Structures for incorporating Regulation in the Developing World • Capacity and Logistics in implementing Regulation **Eric Philippart, Principal Administrator with the European Union and Deputy Head of Unit, Impact Assessment Team, European Commission Directorate General for Enterprise and Industry (confirmed)** **Professor Malgosia Fitzmaurice**, Professor of Public International Law, Queen Mary University London (confirmed)

http://electoralforum.org/brussels/docs/03%20Eric%20Philippart.pdf

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

Regulatory Failure and Risk Assessment
Risk assessment and regulation
14 July 14:15

Eric Philippart
European Commission
Directorate General for Enterprise and Industry

European Commission

Impact Assessment – Managing their production and dissemination 1

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

Impact Assessment – Managing their production and dissemination 2

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)

Impact Assessment – Managing their production and dissemination 3

- 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 …

Impact Assessment – Managing their production and dissemination 5

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

Impact Assessment – Managing their production and dissemination 6

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)

Impact Assessment – Managing their production and dissemination 9

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).

Impact Assessment – Managing their production and dissemination 10

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.

Impact Assessment – Managing their production and dissemination 11

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.

Impact Assessment – Managing their production and dissemination 12

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

Impact Assessment – Managing their production and dissemination 13

Thank you

eric.philippart@ec.europa.eu

Impact Assessment – Managing their production and dissemination 14

---

http://regulationforum.org/speakers/eric-philippart.php

Eric Philippart

Impact Assessment Team, European Commission Directorate General for Enterprise and Industry

Eric Philippart is currently working with the European Commission, Directorate General for Enterprise and Industry (DG ENTR), responsible for the Impact Assessment team. He was till March 2010 the manager of the "Action Programme for reducing administrative burdens in the EU". He previously worked with the Secretariat General of the Commission, where he was leading on a number of better regulation issues (EU database on self and coregulation, subsidiarity, Impact Assessment Guidelines of 2005-6, etc). A former post doctoral fellow at Cambridge University and Michigan University, he teaches still seminars at the University of Brussels and the College of Europe on ex ante and ex post evaluation of EU policies and programmes.