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European Commission
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The EU Risk Analysis Approach and the Perspectives for a Global Risk Assessment Dialogue

OECD- Group on Regulatory Policy, Paris 1-2 December 2008

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Objectives of this presentation

- To provide factual information on the principles and structure of risk analysis at EU level
- To report on recent initiatives aimed at promoting international dialogue and collaboration on risk analysis

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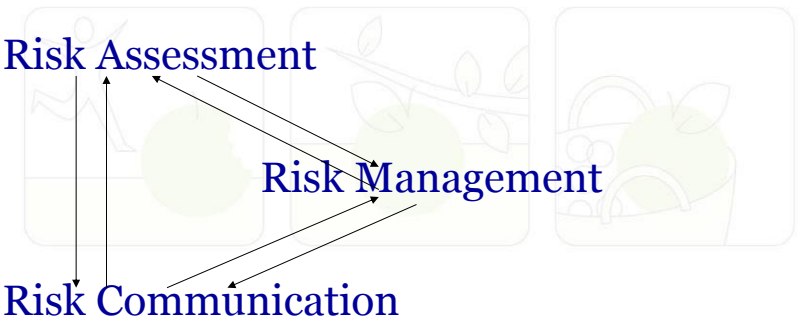
The Risk Analysis Concept:



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EU Principles of Risk Analysis: some references

- EU Treaty (references to scientific evidence/data as basis/justification for policy and measures)
- EU Commission: Communication on Consumer health and Food Safety (1997)
- EU Commission: Communication on Collection and Use of Expertise (2002)
- EU Food Law (2002)
- EU Commission Decision establishing Scientific Committees in the field of Consumer Safety, Public health and the Environment (2004, revised 2008)

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Communication on Consumer Health and Food Safety (1)

- Definition of Risk Analysis:
  - A systematic procedure comprising:
    - ✓ the scientific evaluation of hazards and the probability of their emergence in a given context (risk assessment)
    - ✓ The assessment of all measures making it possible to achieve an appropriate level of protection. It includes assessing the impact of policy alternatives in light of RA results and the desired level of protection (risk management)
    - ✓ The exchange of information with all the parties concerned (risk communication)

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Communication on Consumer Health and Food Safety (2)

- **Principles:**
  - Separation between scientific advice and regulatory responsibilities
  - Risk assessment advice to be provided by independent scientific committees
  - Scientific committees to be structured and to work in accordance with principles of excellence (highest possible quality), independence and transparency
  - Members, minutes, opinions, minority opinions to be published
  - Open calls for expression of interest for membership
  - System of indemnities

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Communication on Collection and Use of Expertise

- Scope: it applies to all external expertise to the Commission, on risks and beyond.
- Core principles established:
  - Quality: ***Excellence*** of scientists and availability of practical knowledge as appropriate, ***absence of interests*** that would prevent acting in an independent manner, practices promoting *integrity* by making dependency explicit, ***pluralism*** (of disciplines, cultural, gender, geographical diversity etc.)
  - Openness (transparency/accountability)): Pro-active ***public communication***, explain issues and results in *laymen language*, clarity on respective roles of scientists and policy makers, accountability of scientists for their opinions (accept to explain/justify)
  - Effectiveness: plan and organise taking into account the complexity, sensitivity and potential impact of the scientific advice requested

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Decision establishing Scientific Committees on Consumer Safety, Public Health and the Environment

Reflects the EU RA Principles:

- Independent experts (selection based on open expression of interest, public declarations of interest
- Pluralism ensured in the composition of SC
- Act collectively
- Transparency: composition, mandates, agendas, minutes, opinions, minority positions published
- Additional provisions taken for pro-active communication (newsletter, laymen versions) and stakeholder dialogue.

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EU Food Law

- Establishes the European Food Safety Authority (EFSA: non-regulatory Agency)
- EFSA provides scientific advice and scientific and technical support for the EU legislation and policies in all fields relevant for food/feed safety
- The same principles of independence and transparency of the Commission Scientific Committees apply, with similar provisions

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Conclusions

- To a great extent, similar principles and requirements are applied in relation to all EU Agencies
- No overarching set of rules and principles for risk analysis at EU level, but
- Several documents include horizontal risk analysis principles
- Such principles have been taken on board in specific instruments, overtime
- Rules of procedures, working practices and methodological guidelines reflect the same principles, with practical adaptations to specific needs

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The EU Scientific Advice Structure: Aims and Principles

- Several scientific bodies assist EU institutions on a variety of risk related issues
- The general aim is to provide the EU with independent scientific risk assessment advice
- The underlying principle is that EU policy are to be based on best available and independent scientific knowledge

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The EU Risk Analysis Structure

Risk Management:

Parliament- Council- Commission

Risk Assessment:

EFSA- EMEA-EEA-ECDC-ECHA-SCENIHR/SCCP/SCHER and SCOEL

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Areas of Competence of EU RA Bodies

RA Body	Area of Competence
EFSA	Food and feed safety, Animal health and welfare, Plant health
EMEA	Safety/effectiveness medicines human use; Safety/effectiveness medicinal products for veterinary use, Pharmaco-vigilance
ECHA	Registration, evaluation of chemicals (REACH)
ECDC	Communicable disease, surveillance, preparedness and response
EEA	Air, water, soils pollution, climate change, natural resources and bio-diversity
SCENIHR	Emerging or newly identified health risks
SCHER	Risks related to toxicity and eco-toxicity of chemical, bio-chemical and biological compounds
SCCP	Health risks of non-food consumer products
SCOEL	Occupational exposure to chemicals

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The Transatlantic Risk Assessment Dialogue

- A triangular Risk Assessment dialogue EU-US-Canada was launched at a meeting in Washington (10-11 July 2008):

- Aims at promoting mutual understanding of risk analysis systems and approaches
- Is a framework for collaboration and convergence on risk assessment methodology and on substantive risk issues
- Will run in parallel and will be co-ordinated as appropriate with the Global Dialogue
- Will help creating and sustaining momentum for the Global Dialogue

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A Global Dialogue on Risk Assessment

- Aimed at promoting collaboration for effective and efficient risk governance
- A science-based approach for ensuring the effectiveness, efficiency, sustainability, acceptability and compatibility of risk governance
- A central role of scientific Risk Assessment in the risk analysis paradigm
- Local needs, desired levels of protection, perceptions and priorities may differ, but
- Risk Assessment is most suitable for a common framework

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The need for an international dialogue on Risk Assessment

A potential for divergent approaches and conclusions:

- Risk Assessment is science based, but is not "pure science"
- RA covers a wide range of application fields and of disciplines, involving specific and different issues and matters and a variety of bodies
- Risk Assessment, Management and Communication are closely interconnected. RA policy frameworks may be different.

...with possible, significant negative effects on risk governance, trade and innovation

- Divergent approaches may adversely affect both
  - ✓ The effectiveness and recognition of Risk Assessment, and
  - ✓ Trade and innovation

...but also great potential for developing and sharing best practices

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The proposed objectives of a Global Risk Assessment Dialogue are:

Overall:

- To work more closely in pursuit of a common Risk Assessment Framework

Specifically:

- To improve mutual understanding of respective risk analysis systems and approaches
- To develop and/or share best practices on key aspects of risk assessment approaches and methods, and on the organisation of the interface with risk management and communication
- To promote collaboration on substantive risk issues, notably on emerging risks

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The proposed approach

- *Responding to shared interests*: to identify areas and issues of common interest
- *Learning by doing*: to start with a few, concrete priorities, where a higher added value is recognised
- *Allowing for flexibility and pragmatism*: a variable configuration and participation for the various collaboration activities identified
- *Taking benefit from activities in other international fora*: co-ordination, synergism and no duplication with relevant international activities

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Instruments and Steps under the label of the "Global Risk Assessment Dialogue"

Instruments

- Bi-annual International Risk Assessment Conferences
- Exchange of information, documents and consultations on planned and on-going, relevant activities
- Establishment of ad hoc working groups
- Thematic workshops
- Deliverables: consensus based reports and documents

Steps

- Consensus on aims and approach
- Definition of areas of interest for the dialogue and themes for pilot activities (2009-2010)
- Pilot activities during 2009-2010
- 2nd International Risk Assessment Conference (November 2010)

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Results of the 1st International RA Conference :

- An initial review of risk assessment systems and approaches
- Identification of some key issues and challenges for risk assessment
- Identification of areas and themes of common interest for dialogue and collaboration
- Launching the discussion on a few selected topics
- Discussing the approach and priorities for the continuation of the dialogue and the follow initiatives for 2009-2010

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Next steps and Perspectives

- Definition of specific collaboration projects is in progress
- Pilot stage during 2009-2010
- Reports and further direction at the 2nd International RA Conference (Fall 2010)
- Good perspectives for concrete results in areas where positions are not yet fixed (notably emerging issues and challenges)

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THANKS