Ref. Ares(2010)896804 - 02/12/2010

Global Risk Assessment Dialogue

Draft Programme

2ND INTERNATIONAL CONFERENCE ON RISK ASSESSMENT

Brussels, 25 – 28 January, 2011

Presentation of the Conference

This is the second edition of the regular (bi-annual) International Conferences on Risk Assessment hosted by the European Commission in Brussels (the first edition took place on 13-14 November 2008).
The Conference aims at providing a Forum for global dialogue on risk assessment principles, methods, criteria, practices and arrangements in the various jurisdictions around the world. It builds upon the Transatlantic Risk Assessment Dialogue launched in 2008 between the US, Canada and the EU. It is intended to complement the relevant activities in the area of risk assessment of international bodies and specialised organisations by providing a discussion and collaboration platform to the main actors from the most relevant institutions, agencies, organisations and professional networks. The focus of the Conference is on scientific risk assessment as a central element of the risk analysis paradigm. The overall objectives of these Conferences are to facilitate the exchanges on practices and methods, to identify areas of mutual interest, promote collaborative projects and formulate, where possible, consensus-based conclusions and recommendations, with a view to improve mutual understanding and enhance consistency. The Conferences aim at promoting robust, effective and recognised risk assessment approaches and, by that, at facilitating effective and efficient governance of international and global risks.

The programme for this edition of the International Risk Assessment Conference includes discussion on the needs and directions for enhancing the role of risk assessment in risk governance, reinforcing the utility of risk assessment and integrating risk assessment practice with new scientific and policy developments. Moreover, the discussion on issues of common interest identified at the 1st Conference in 2008 will be further discussed in light of results of collaborative activities conducted since then.

Day 0 (25.01.11)

17:00 – 18:30 Coordination meeting of all chairs, invited speakers, rapporteurs and panellists for the final arrangements and exchanges on the themes and intended results of the Conference, to ensure that all documentation/presentations in place, and to review the final questions for breakout sessions and discussion panel

19:30 -21:30 Dinner

Day 1 (26.01.11)

ED_002435_00000183-00001

08:15-09:00 Registration and Coffee

Introductory Session

09:00-09:15 Welcome and key-note speech by *Paola TESTORI COGGI, Director General for Health and Consumers, European Commission*

09:15-09:45 Current US Approach to Regulatory Review and Risk Analysis, *Dr. **Michael FITZPATRICK, Associate Administrator**, Office of Information and Regulatory Affairs, US Office of Management and Budget*

09:45-10:15 Risk Governance in the European Union: The role of Science, technology and civil society, Prof. José Mariano GAGO, Minister of Science, technology and Higher Education, Portugal

10:15-10:30 Background and objectives of the Conference, *Co-Chairs of the Conference Steering Committee (EC, USA OMB and CANADA TBS)*

Plenary Session I: The future of risk analysis: meeting the challenges *Chairperson: Dr.Hans H. YU, Health Canada, Director Science and Policy Directorate,*

Background, Objectives:

The role of science in the decision making processes of the main jurisdictions as well as internationally has become more important, more visible but also more controversial. Globalisation of technology, production and trade has increased the need for consistent, shared and recognised risk analysis approaches across the main jurisdictions. Public opinions have become more sceptical on the neutrality and effectiveness of science in ensuring health and environmental protection. The request for transparency has increased. At the same time, practical experience has shown the complex interaction in risk governance between science, communication, public perceptions, values and societal preferences and the need to better integrate all such elements into a more structured and reliable approach. New challenges have appeared for risk assessors. Technological development in new areas like nanotechnology has quickly surpassed the ability of research bodies to timely generate safety data and of risk assessors to adapt and apply appropriate tools to evaluate new risks.
The objective of this session is to set the scene by providing a broad perspective of current risk governance problems and the need and directions for responding to the current challenges to risk analysis and , more specifically, in the risk assessment area.

10:30-10:45: Introduction by the Chair on Globally relevant Risks and the Role of Science

10:45-11:15: Risk Governance: Towards an Integrative Approach
Prof. Ortwin RENN, Professor of Environmental Sociology and Technology Assessment at the University of Stuttgart, International Risk Governance Council

ED_002435_00000183-00002

11:15-11:30: Coffee Break

11:30-12:00: Improving the Utility of Risk Assessment

Prof. George GRAY, George Washington University School of Public Health and Health Services, Department of Environmental and Occupational Health and Director of the Centre for Risk Science and Public Health.

12:00-12:30: The Need for New Risk Assessment Approaches: the Case of Biological Risks

Prof. Geoffrey SMITH, Chair of the Royal Society Advisory Committee on the Scientific Aspects of International Security

12:30-13:00: Discussion

13:00-14:30: Lunch

Plenary Session 2: Working Towards Consistency in Risk Assessment
Chairperson: Prof. Thomas BURKE, John Hopkins Bloomberg School of Public Health. Chair of the US National Academy of Sciences Committee on Improving Risk Analysis

Background, Objectives:

Discussions in international bodies as well as between EU scientific bodies involved in risk assessment have highlighted, among the areas where collaboration would be beneficial in order to improve the quality, consistency and recognition of risk assessment across various sectors, the approaches to evaluate/express uncertainties and more in general the terminology to express risks, with a particular focus on transparency, as well as exposure assessment. These issues were in particular discussed at the 1st International Conference on Risk Assessment organised by the European Commission (DG SANCO) in Brussels on 13-14 November 2008 and found to be suitable for collaborative projects. A group of experts helped the discussion at the international conference and informal contacts were continued after the conference.

The issues of risk assessment terminology and the approach to deal with and express uncertainties cover in particular the concepts, words and expressions which are used to communicate the contents and results of a risk assessment to policy makers, stakeholders and the public as well as the relationship between the data, models, assumptions, methods, procedures used by risk assessors and the way in which these are reflected and explained in a risk assessment report.

They should be considered in light of the needs of the users of risk assessment reports, in particular risk managers. As such, risk assessment terminology is a major element of the interface between risk assessment and risk management responsibilities. Of particular importance are:
- The concepts of "risk" and "hazard", their definitions and presentation,
-Probability and severity as components of risk

ED_002435_00000183-00003

-How risks are communicated (contents, expressions)
-Qualitative and quantitative expression of risks
-Distribution of risk and risk for different population groups
-Framing and comparing risks
- Uncertainty analysis and its communication
-Distinction between variability and uncertainty
-Distinction between uncertainty for lack of data (uncertainty of assumptions, defaults) and uncertainty related to the underlining processes (physical, chemical, biological...)
-Influence of uncertainties on conclusions (sensitivity analysis)
-Direction and balance of uncertainties
-The communication of methodological aspects which are relevant for the understanding of the risk assessment results

Practical experience in the U.S., Canada, and E.U. has shown that differences in human exposure assessment, due to different approaches, models, data sets, and assumptions, are a key source of uncertainty and divergences in the assessment of risk. There is an added value in exchanging information on different methodologies, tools, and uncertainty analysis techniques for exposure assessment in order to enhance the international understanding and dialogue in the context of environmental and health risk assessment. The anticipated outcome of a collaborative effort is a set of specific recommendations (e.g., data sharing, bio-monitoring considerations, hands-on modelling training, collaborative case studies, international working groups to address specific approaches and needs in more detail) that may guide and advance the use of reliable and appropriate exposure assessment information internationally, in support of research and regulatory decision-making.

The objective of the session is to introduce the issues in question and to present the progress on the collaboration projects launched after the 1st International Risk Assessment Conference of 2008.

14:30-14:45: Introduction by the Chair on Improving Risk Assessment Approaches and Ensuring Consistency in Risk Assessment

14:45-15:45: Risk Assessment to Risk Management - Terminology of Risk Assessment

- Introduction to the issue
  Dr. Margaret HARTLEY, CEO Australian Academy of Technological Sciences and Engineering and Chair of the Steering Group "Harmonisation Project" International Programme of Chemical Safety (WHO)
- Improving the Risk Assessment process – Meeting the needs of Risk managers
  Prof. Peter CALOW, Vice Chair of the European Commission Scientific Committee on Health and Environmental Risks (SCHER)
- Presentation of the collaborative project
  Prof. Tony HARDY, Chair of the Plant Protection Panel, European Food Safety Authority

15:45-16:00: Coffee Break

16:00-16:45: Presentations on Treatment and Expression of Uncertainty in Risk Assessment

- Introduction to the issue
  Prof. Gérard LASFARGUES, Directeur général adjoint scientifique, ANSES, ***Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail, France***
- Presentation of the collaborative project
  Dr. Andy HART, Plant Protection Panel, European Food Safety Authority, The Food and Environment Research Agency, FERA United Kingdom

16:45-17:30: Presentations on Exposure Assessment

- Introduction to the issue
  Prof. Helmut GREIM, Chair European Commission Scientific Committee on Health and Environmental Risks
- Presentation of the collaborative project
  Dr. Haluk OZKAYNAK, Senior Scientist, Office of Research and Development, National Exposure Research Laboratory, U.S. Environmental Protection Agency

17:30-18:00: Discussion and announcements for Day 2

19:30-22:00: Dinner

Day 2 (27.01.11)

Objectives of the Workshops
These workshops are devoted to in-depth, interactive discussion on the three subjects identified for collaborative projects (terminology, uncertainty and exposure assessment) and for a preliminary exchange on two additional subjects: the approaches to weigh scientific evidence in risk assessment and for risk assessment of combined exposure and synergistic effects. The expected outcome in each case is a report to the Plenary on the issues, state of the art, possible recommendations and proposals for further collaborative work.

9:30-13:00: Parallel Workshops

- Workshop 1: Risk Assessment Terminology
  Chairperson: Dr. Peter CHAN, Director General, Health Evaluation Directorate Pesticides and Pest Management (PMRA), Health Canada
  Rapporteur: Dr. Theo VERMEIRE, Deputy head of the RIVM Expert Centre for Substances, European Environmental Agency Scientific Committee, Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR)

- Workshop 2: Uncertainty in Risk Assessment

Chairperson: Prof. Michel PETIT, Chair of the Environment Committee, French Academy of Science, and co-author of the IPCC Guidance Notes on Addressing Uncertainties
Rapporteur: Dr. Gerhard HEINEMEYER, Chair of WHO/IPCS Working Group on Uncertainty in Exposure Assessment, Federal Institute for Risk Assessment, Germany

- Workshop 3: Exposure Assessment
  Chairperson: Dr. Jose TARAZONA, Chair of the Risk Assessment Committee, European Chemical Agency
  Rapporteur: Dr. Valerie ZARTARIAN, Office of Research and Development, US EPA

13:00-14:30: Lunch

14:00-17:30: Parallel Workshops

- Workshop 4: Evaluating Scientific Evidence in Risk Assessment
  Chairperson: Prof. Jim BRIDGES, Chair EC Scientific Committee on Emerging and Newly Identified Health Risks
  Rapporteur: Dr. Vicki L. DELLARCO, Office of Pesticide Programs, U.S. Environmental Protection Agency

- Workshop 5: Risk assessment of Combined Exposure and Synergistic Effects
  Chairperson: Prof. Andreas KORTENKAMP, Head of Centre for Toxicology, University of London,
  Rapporteur: Dr. Bette MEEK, Associate Director, Chemical Risk Assessment, McLaughlin Centre for Population Health Risk Assessment, University of Ottawa.

Day 3 (28.01.11)

Plenary Session 3: First Results of the Dialogue
Chairperson: Dr. Benoit D. TURCOTTE, Director, Regulatory Policy Regulatory Affairs Sector, Treasury Board of Canada Secretariat, Director of Regulatory Policy, Treasury Board of Canada

Objectives:

The objectives for the Session are to discuss the reports from the parallel workshops 1, 2 and 3, endorse the conclusions and recommendations proposed and reaching consensus on the proposals for further activities.

9:30- 10:00: Report Workshop 1 and Discussion

10:00-10:30: Report Workshop 2 and Discussion

10:30-11:00: Report Workshop 3 and Discussion

11:00- 11:30: Coffee Break Report Workshop 3 and Discussion

11:30- 12:00: Report Workshop 4 and Discussion

12:00-12:30: Report Workshop 5 and Discussion

12:30- 13:00: Conclusions by the Chair

13:00 – 14:30: Lunch

Plenary Session 5: The Future of the Global Risk Assessment Dialogue
Chairperson: Ms Paola TESTORI COGGI, Director General for Health and Consumers, European Commission

Objectives:
This final session will be devoted to a broad discussion on the experience, priorities, challenges and perspectives on risk analysis in the various jurisdictions and internationally and the priorities for the continuation and further development of the international dialogue and collaboration in this area. Panellists are also expected to comment on how best the dialogue platform offered by these International Conferences on risk assessment can provide risk-governance added value. Finally, this session will allow for the final conclusions, recommendations and decisions for future collaboration.

14:30- 15:45: Final Panel Discussion Chaired by Paola Testori Coggi, Director General of the Health and Consumers Directorate General, European Commission with a high level panel

15:45- 16:00: Conference Conclusions

ED_002435_00000183-00007