

**2ND INTERNATIONAL RISK ASSESSMENT CONFERENCE  
A GLOBAL RISK ASSESSMENT DIALOGUE  
26-28 January 2011, Brussels**



**SUMMARY REPORT**

The conference was organized by the European Commission (EC), DG Health and Consumers (DG SANCO) and took place on 26, 27 and 28 January 2011 at Crowne Plaza Brussels City Centre Hotel, Brussels, Belgium. It was the second bi-annual International Conference on Risk Assessment (RA) following the 1<sup>st</sup> such Conference (13-14 November 2008, Brussels). Close consultations took place during the organisation of the Conference between DG SANCO, other Commission departments, the European Union (EU) Agencies and bodies involved in scientific advice and risk assessment, the US Office of Management and Budget (OMB) and the Treasury Board of Canada Secretariat, within the framework of the Transatlantic Risk Assessment Dialogue.

About 200 experts in risk assessment including scientists, practitioners, stakeholders, and representatives from various European institutions as well as international risk assessment bodies attended the Conference.

Speakers included experts and representatives from academia, industry as well as various authorities, departments and bodies involved in Risk Assessment and Risk Management (RM) from the US, Canada, Australia and the EU (in particular the EC, the EU Agencies involved in risk assessment and their Scientific Committees and Panels) as well as international expert groups.

The meeting was opened with a welcome address by Paola Testori Coggi, Director General of DG SANCO, who described the future challenges for the EU in particular the changing society, globalisation, governance, confidence, the needs for scientific advice, the challenges in the area of risk analysis and the need for global risk governance co-operation. Ms. Testori Coggi highlighted the importance of a framework for RA at international level which will increase its utility for all involved (assessors, managers and society), identified the need for clarity and consistency in RA, including the need for transparent terminology and description of uncertainties in the RA process. Finally she noted the

sustained interest by partners and stakeholders for the continuation of the dialogue and confirmed DG SANCO's commitment to explore appropriate avenues and modalities for the continuation of the dialogue in a value added, resource conscious manner.

Following Ms. Testori Goggi's intervention, Mr. Michael Fitzpatrick, the Associate administrator of the Office of Information and Regulatory Affairs (OIRA) of the OMB provided an overview of the US approach to regulatory review and risk analysis which focuses on four pillars: establishing a scientific integrity in government, public communications policies based on openness and transparency, rules governing the use of Federal Advisory Committees (FACs), and bolstering the professional development of government scientists and engineers. Dr. Charles Kleibert, Chairman of the board of the International Risk Governance Council (IRGC) provided an overview of the role of risk governance in Europe and the role science, technology and civil society are to play in the process.

The first plenary session of the Conference set the scene of the conference by providing a broad perspective of current risk governance problems (changing and evolving technologies and societal values, public perceptions and demands for greater transparency, complex, globalised interactions between science, technology, economy, etc) and by identifying some of the needs and directions that are necessary to be fulfilled to respond to current challenges to risk analysis in general and risk assessment in particular. Hans Yu of Health Canada stressed the need for global approaches to global risks, identified issues and challenges in science-based policy making, and highlighted the new technologies as drivers for changing our RA paradigms. Prof. Ortwin Renn from the University of Stuttgart, provided an overview of the IRGC report on risk governance, stressing the need for an integrated approach incorporating and establishing links between risk assessment and social, economic and societal needs, values and expectations, whereas Prof. George Gray from Georgetown University focused on the key elements necessary for improvement of the utility of the risk assessment process (e.g. framing of questions, trade-off analysis, tools to use identical metrics, ranges versus single point RA outputs, etc.).

In the second part of this first session, Dr. Dirk Hudig from the European Risk Forum provided some elements and challenges for the future focusing on the need for a proper analysis of risk-risk trade offs, on the need for evaluation and on the need to carefully monitor scientific developments so as to ensure that policy making is always in tune with scientific developments. Prof. Geoffrey Smith from Imperial College of London provided a biological risks angle to risk assessment citing some biological risk assessments and approaches to managing those risks.

Plenary session 2 presented progress on the collaborative projects on Risk Assessment terminology, Characterisation and description of Uncertainty in Risk Assessment and Exposure Assessment and set the scene for the work of three Workshops which were scheduled for day 2 of the Conference. The Chair of the session, Prof. T. Burke, Chair of the US National Academy of Sciences Committee on improving risk assessment, opened the session by providing a

brief overview of the work of the NAS group. Design of risk assessment, uncertainty and variability, selection and use of defaults, a unified approach to dose-response assessment, cumulative risk assessment, improving the utility of risk assessment, stakeholder involvement, capacity-building, and greater consistency throughout the process were the key elements in this work.

Dr. Margaret Hartley, CEO of the Australian Academy of Technological Sciences provided an overview of the WHO/IPCS 'Harmonisation project' stressing the added value of harmonisation in risk assessment terminology in terms of transparency and communication between Risk Assessors and Risk Managers. Prof. A. Hardy, Chair of the European Food Safety Authority (EFSA) Plant Protection Panel (PPP) provided an overview of the collaborative project analysing the terminology used in the risk assessment opinions of the EC Scientific Committees and EFSA panels.

In the second part of this session, Prof. G. Lasfargues from the Agence Nationale de Sécurité Sanitaire de l'Alimentation, de l'Environnement et du Travail (ANSES, France) introduced the issue of uncertainty in risk assessment and highlighted some of the causes of uncertainty in risk assessment, how uncertainty is dealt with, some key issues and challenges and stressed the need for better characterisation and communication of uncertainties. Dr. A. Hart of the EFSA PPP provided an overview of the transatlantic collaborative project on characterising and describing uncertainty using the template the experts have developed to provide detailed but succinct semi-quantitative descriptions of uncertainty.

In the third part of the session, Prof. H. Greim, Chair of the EC Scientific Committee on Health and Environmental Risks (SCHER) introduced the subject of exposure assessment. Dr. H. Ozkaynak, from the USA Environmental Protection Agency (US EPA), presented a progress report on the transatlantic collaborative project on exposure assessment and specifically on Product 1 which is a compilation and evaluation of exposure assessment practices in the EU, USA and Canada and Product 2 which is a guidance document on the use of biomonitoring data in exposure assessment.

The last presentation of the session, by Prof. P. Calow, Vice Chair of SCHER, provided a brief overview of the work SCHER was undertaking to improve the risk assessment process in order to meet the need of risk managers. Although this is work in progress, Prof. Calow identified relevance (for managers, for society) as a key ingredient of an improved risk assessment process.

Day 2 of the Conference was devoted to breakout Workshops. There were three morning workshops devoted to in-depth, interactive discussion on the three subjects identified for collaborative projects on: (i) Risk Assessment Terminology; (ii) Characterisation and Description of Uncertainty; and (iii) Exposure Assessment. In the afternoon, there were two workshops devoted to a preliminary exchange on two additional subjects: the approaches to weigh scientific evidence in risk assessment and for risk assessment of mixtures of chemicals.

Each Workshop was supported by a chair, rapporteur and a steering group. A presentation was prepared for each of the workshops capturing the key elements of the discussion and the main conclusions/recommendations in the group. These were reported by the respective rapporteurs in Plenary on Day 3 (Session 3) of the Conference chaired by Mr. B. D. Turcotte, Director Regulatory Policy/Regulatory Affairs, Treasury Board Secretariat, Canada, identifying the issues, state of the art, possible recommendations and proposals for further collaborative work.

The main conclusions resulting from the plenary and breakout sessions were discussed briefly in the concluding High Level Panel discussion aimed at summing up the discussions and the results of the breakout sessions, and presenting proposals for conclusions and recommendations on the conference themes and the future of the international RA dialogue. The Panel was chaired by Mr. Benoit Turcotte and was composed of John Giraldez, Vicki Dellarco, Jim Bridges, Nancy Beck, Margaret Hartley, Vittorio Silano, Michel Petit and Peter Calow.

Some directions to be considered for future collaborative activities emerged from the Panel. An overarching, common important priority was the reinforcement of the dialogue and interaction between risk assessors and risk managers. There is a need to explore how the utility of risk assessment for informing the risk management and policy making processes can be increased. Risk assessment should be better connected with cost/benefit assessment and the assessment of socio-economic factors. A shift of the traditional risk assessment framework towards a more comprehensive assessment based on consideration of policy options was suggested. The risk-risk balance should be more systematically considered. In general, risk assessment should evolve towards a more holistic approach. Current challenges need collaboration in order to develop a consistent approach, notably on how to integrate into the assessment practice the increasing amount of data coming from new scientific knowledge (e.g.: produced by the various "-omics"). For the continuation of the dialogue, it was suggested to integrate the groups dealing with related subjects like for example uncertainty and terminology, to conduct stock taking exercises of existing harmonisation activities and to consider, in addition to cross-sector subjects, some possible vertical issues (like for example, in the area of food, harmonised criteria for additives).

The final conclusions were drawn by Bernardo Delogu, Head of the Risk Assessment Unit of DG SANCO. The wide and qualified attendance of this second edition of the Conference, the quality of debates as well as the results achieved are a clear encouragement to pursue the objectives of the global risk assessment dialogue. Both the objectives to improve mutual understanding across jurisdictions and to promote consistency on specific methodological and substantive issues should be pursued further. The best option for the sustainability of the process seems to be to continue and further develop collaborative projects through dedicated international working groups. On the EU side, DG SANCO will consider how to reinforce the involvement of and co-ordination with the relevant Agencies involved in risk assessment. There is a need to define very concrete objectives and deliverables for the continuation of

the dialogue on the identified issues of common interest. To that aim, DG SANCO would discuss with its partners in order to define road maps for completing or developing the relevant projects. It has clearly appeared that some groups should be integrated. A review of the conclusions and recommendations from the breakout workshop and the panel will be made in order to set up priorities for the further development of the dialogue, while carefully considering the sustainability of the process. On the practical side, the Conference web site will be used to provide access to all documents presented at the conference and to share information on the follow up. Finally, DG SANCO will consider and discuss with its partners the possibilities for a 3<sup>rd</sup> Conference.

The Conference was considered by all who attended a very successful event that showed the high potential for a sustainable international dialogue on risk analysis.