2ND INTERNATIONAL CONFERENCE ON RISK ASSESSMENT

THE GLOBAL RISK ASSESSMENT DIALOGUE

BRUSSELS, 26-28 JANUARY 2011

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1. Welcome and Introduction

Ladies and gentlemen,

It is my pleasure to open this second international conference on risk assessment, organised by the European Commission's Directorate General for Health and Consumers (DG SANCO).

I would like to welcome you all and thank all those involved in the organisation of this event – particularly our partners in the transatlantic risk assessment dialogue who have contributed to setting up the programme and preparing the background for the forthcoming discussions.

It is most encouraging to see such a highly qualified, high level and indeed very large audience here today – a clear sign that there is a sustained interest in the development of a global risk assessment dialogue.

This is the second time that DG SANCO has taken the lead in promoting a broad and truly international conversation on risk assessment.

As many of you will remember, we organised a first conference in 2008 with the aim of establishing a global forum for exchanging experiences and promoting collaboration on risk assessment.

DG SANCO is responsible within the European Commission for food safety, public health and the safety of consumer products and therefore has a special interest in risk assessment.

Let me say a few words on the background and objectives for this event.

2. Background to this Conference

All jurisdictions are nowadays increasingly confronted with challenging risk governance issues, notably those related to new technologies.

Policy makers and risk managers are faced with all sorts of actual, potential or perceived risks – the known ones but also new, emerging or re-emerging risks.

Health threats in the area of communicable diseases, food safety as well as risks associated with climate change and the potential risks of the newest technologies are high on the agenda of policy makers.

Consumers and the public expect a high level of assured, demonstrable safety. At the same time, public opinions are nowadays less inclined to trust the conclusions of "official" science.

For a long time now, risk governance has no longer been a purely internal matter. Many of the risks in the areas I have mentioned are global and therefore require a global approach.

And policy and regulatory decisions on certain risks have the potential to significantly impinge on exchanges, on trade and on global technology development.

Moreover, scientific and technological development poses new and very complex risk problems that often require major research efforts and a very high level of scientific expertise, which is not easily available.

Also in this respect, international collaboration and co-ordination of research and risk assessment efforts are vital.

Specific needs, circumstances and requirements vary across jurisdictions. Nevertheless, there is a clear interest in pooling expertise, exchanging practices and collaborating towards more effective and recognised risk governance approaches in areas of common interest, where collaboration may bring a clear added value.

Science-based risk assessment plays an increasingly important role in the decision making processes.

Technical risk assessment does not exhaust the complex, multi-dimensional analysis that leads to risk management decisions.

Such decisions must also take account of the specific legal frameworks and other relevant factors such as, for example, socio-economic aspects, values and social preferences.

Nevertheless, robust and recognised risk assessment approaches can greatly contribute towards supporting effective and consistent risk management globally.

With these considerations in mind, a Transatlantic Dialogue on risk analysis was launched in 2008 between the European Commission (DG SANCO), the Office of Management and Budget together with the Office for Science and Technology Policy in the US, and the Canadian Treasury Board.

The dialogue started in July 2008 with a meeting in Washington, followed by the 1st International Conference on Risk Assessment in November 2008 in Brussels. That first Conference enabled more jurisdictions to become associated with the dialogue.

The objectives were to exchange approaches, experiences and expertise on risk assessment and to identify areas for collaboration on both methodological and specific risk issues. The Conference offered an opportunity for direct contacts and discussion between risk assessors and other players in the risk analysis process, across jurisdictions.

Since 2008, sustained contacts have been maintained within a core group of officials and scientists on both sides of the Atlantic in order to ensure progress on certain priority themes identified in 2008 – exposure assessment, uncertainty in risk assessment and risk assessment terminology.

A mid-term meeting took place in June 2010 in Ottawa, in the context of a Conference organised by our Canadian Treasury Board Secretariat colleagues. Results of such contacts will be reported here as a basis for further discussion, in this broader configuration.

3. An EU perspective on innovation and risk governance

I would like now to briefly give an up-to-date EU perspective on the importance of effective risk governance in responding to the current and forthcoming major challenges.

The EU is currently embarking on a major programme for growth, the EU 2020 strategy. The aim of the strategy is to strive for smart, sustainable and inclusive growth, by addressing economic, environmental, demographic and social problems through structural change and innovation.

Innovation lies at the very core of the strategy. Indeed one of the flagship initiatives of EU 2020 is entitled "Innovation Europe".

The goal is to bring to the market new ideas and technologies and to respond to the major challenges – such as the ageing of the EU population – through innovative solutions mobilising research, science and technology.

In order to deliver on its promises, innovation must bring a genuine, visible added value. It must be safe, sustainable, and, last but not least, be accepted by consumers and the public.

In particular, actual, potential or perceived risks of innovative technologies, like, for example, nanotech and synthetic biology, must be addressed up front, at an early stage.

Experience has shown that effective risk governance is vital for the success of innovative technologies. Risk governance is a complex process and its success depends on several factors. I will focus on risk assessment which is at the core of our Conference.

4. How can the use of Risk Assessment be increased?

Risk assessment underpins the consumer safety and public health approach of the European Commission.

Decisions on food safety, pharmaceutical products, non-food consumer products and the safety of medical devices, for instance, are taken in light of independent risk assessment advice.

A comprehensive structure is in place to provide such independent advice. In particular, DG SANCO works in close contact with the European Food Safety Authority (EFSA), the European Medicine Agency (EMA), the European Centre for Disease Prevention and Control (ECDC) and three independent Scientific Committees (SCHER, SCCS and SCENIHR) providing advice on a wide range of health and environmental risks.

Let me briefly summarise the EU risk analysis approach in the policy areas under the responsibility of DG SANCO.

Under the EU approach, risk management and risk assessment are clearly separated functions.

Sound and timely scientific advice is an essential requirement for Commission proposals, decisions and policies relating to consumer safety, public health and the environment.

Risk assessment is therefore undertaken by independent bodies. The mission of risk assessors is to assist the Commission and the other European Institutions, with scientific advice, in compliance with the principles of excellence, independence and transparency.

The scientific advice delivered must represent the best information and guidance on the assessment of the risks in question that science can provide at the time of adoption of the opinion under the conditions and deadlines imposed. It shall be based on the best data, scientific knowledge and state-of-the-art methodologies available.

The principle of excellence refers to the performance and outcome of the entire process.

It refers in particular to the intrinsic scientific quality of the opinion, its adequacy in relation to the aims of the consultation, its clarity, completeness and transparency.

It also refers to the effective communication of the contents and conclusions of the opinions and the actual and perceived credibility of the process.

The scientific advice delivered by the Agencies and the Committees must not be influenced by any consideration other than the scientific assessment of the risks in question.

This principle implies, in particular, independence from any external economic or political interests, and also from influence and bias related to political, economic, social, philosophical, and ethical or any other non-scientific considerations.

The principle of independence refers to the organisation and results of the process, including, in particular, the independence criteria and conditions and arrangements for the participation of members, advisors and experts.

The meaning of the scientific advice, the way conclusions were drawn up, the limits of their validity and the relevant uncertainties must be clear and understandable for users, relevant stakeholders and the public.

Equally, the organisation and process leading to the scientific advice, as well as their rationale, must be presented in a clear and understandable manner. Openness, dialogue and collaboration with other bodies and third parties should also contribute to transparency.

Although in the EU, as well as in other jurisdictions, the role, principles and methods of risk assessment are well established, risk assessors are faced with significant challenges in practice, and it is appropriate to consider how the utility and recognition of risk assessment can be increased.

In that respect, I would like to mention some issues and problem areas which, in our experience, are most relevant. No doubt this conference will help to identify possible directions for improvement.

On Transparency and Recognition

More and more often, public opinion reacts sceptically to the conclusions of risk assessors.

Several factors may contribute to such scepticism:

- Lack of clarity and consistency of the scientific advice is one such factor.

  An assessment made for DG SANCO of a sample of scientific opinions highlighted the great variability, within and across the opinions considered of the terminology used to express the risk and the different ways to address and communicate uncertainties.

  When scientific opinions are not clear and consistent, risk communication is obviously unlikely to be effective.

- Transparency of both the risk assessment process and the resulting advice is also vital for the recognition of scientific advice.

In particular, risk assessors may need to devote more attention to explaining the criteria for selecting the data, test results and studies on which they base their conclusions; the way they weigh scientific evidence and draw conclusions on causal links; as well as the assumptions or extrapolations made and the "defaults" used.

Limitations of the validity of risk assessment conclusions should sometimes be more clearly expressed.

- Assessment of exposure to risk factors is the aspect of risk assessment where most often divergences between risk assessment bodies appear.

  These divergences may in turn be the source of diverging risk management approaches across jurisdictions and cause uncertainty and confusion among the public.

Since currently there are no generally accepted approaches and standards on such important aspects of risk assessment, practices may continue to differ.

It is important that the risk assessment community identifies and promotes best practices in this area. I am glad that our Conference will address these issues.

Uncertainty

Risk Managers are most often faced with the difficult task of taking decisions on complex issues in the presence of a significant level of uncertainty. This is particularly relevant in the case of emerging risks or new technologies.

Managers need to understand the sources of uncertainties as well as their nature and size, how they influence the conclusions on the existence and level of risks and whether, how and how quickly they could be reduced by research, data generation or studies.

Risk assessors may assist in addressing uncertainties in a rational and transparent manner. Effective communication on uncertainties between risk assessors and risk managers is therefore vital in that respect.

Currently, practices for dealing with uncertainties in risk assessment range from purely qualitative approaches to sophisticated statistical methods.

I would like to invite the representatives of the risk assessment community here to continue the reflection on this subject that was launched at the 1st Conference and provide guidance towards a common framework on uncertainties in risk assessment.

The need for a more holistic approach to risk assessment

Normally, risk assessors focus on single risk factors and individual sources of exposure (for instance the health risks from exposure to a given substance from a certain type of products).

This targeted approach is the consequence of both the regulatory requirements in most sectors and the limitations due to the current state of development of risk assessment methods.

Nevertheless, man and the environment are exposed in a cumulative manner to an increasing variety of risk factors from a multitude of sources.

There is considerable interest for developing a more comprehensive approach, closer to real exposure conditions. In the EU in particular, work is in progress following an invitation by Environment Ministers to improve consideration of chemical mixtures in risk assessment.

This Conference will discuss how to treat cumulative effects and the possible interactions between various substances and other risk factors.

The emerging challenges for risk assessment

Nowadays, science and technology develop at an unprecedented pace. Rapid developing knowledge in areas such as genomics, proteomics and metabolomics opens new perspectives for the identification and assessment of health risks.

Nevertheless, these new perspectives also bring new challenges. They involve, in particular, a need to develop a consensus among scientists on what they mean for risk assessment and how they should be used, notably in association with, or as replacement for, traditional methods.

Moreover, the rapid development of technologies like nanotech and synthetic biology challenge the ability of risk assessors to provide risk managers with early assessment of potential risks since adequate data and appropriate methods may not be readily available.

I expect this Conference to help us to form a better view of the current and foreseeable challenges for risk assessment, the priorities for research in this area and the opportunities for collaboration to effectively respond to such challenges.

5. The future of this Global Risk Assessment Dialogue

I would like now to expand on the aims of this global risk assessment dialogue.

As I have already said, in collaboration with our partners in the Transatlantic Dialogue, in 2008 DG SANCO took the initiative to launch this forum in order to facilitate international exchanges between bodies, practitioners and scientists involved in risk assessment.

The aim was to improve mutual understanding of the respective risk analysis approaches and to promote consistency between risk assessors in practice.

In light of the experience since the 1st Conference in 2008, I would like to suggest the following four, interlinked, broad areas for the future of this international dialogue:

- First, the exchange of experiences and practices on selected methodological aspects of risk assessment and, where possible, the identification of best practices;

- Second, a common reflection on needs and directions for improving risk assessment utility;

- Third, the monitoring and discussion of emerging challenges for risk assessment and the exchange of views on the way to respond to them; and

- Fourth, the exchange of information on risk assessment developments related to new or emerging risks of common interest.

This dialogue should not duplicate other relevant bilateral or multilateral collaboration processes, but contribute to mutual understanding, promote convergence of approaches and practices in an informal and pragmatic way and facilitate the establishment of contacts between the relevant bodies and practitioners on issues of common interest.

6. Proposed objectives for this conference

This Conference provides an excellent opportunity for progress in pursuit of the aims I have mentioned.

We have the pleasure to host here an impressive group of high level players from some of the most relevant bodies involved in risk analysis in major jurisdictions across the world.

Collectively, they bring a critical mass of expertise and experience and the weight of some of the most authoritative advice available on the subjects to be considered.

Since the first Conference, fruitful contacts between interested experts have been maintained on several of the relevant issues, such as uncertainty in risk assessment, assessment of exposure and risk assessment terminology. Results will be reported here and will provide a good basis for discussion in the breakout groups.

The programme allows for a comprehensive review and discussion of several of the issues that I have mentioned, notably improving risk assessment utility, the need for new risk assessment approaches, how to address combined exposure and synergistic effects.

I would therefore like to propose two main objectives for this Conference, on which I would like to discuss and propose conclusions at the final session:

- First, this Conference should provide concrete guidance on directions and steps for developing or validating common frameworks on the subjects discussed in the breakout sessions (Risk assessment terminology; Uncertainty in Risk Assessment; Exposure Assessment; Evaluating Scientific Evidence; Combined Exposure and Synergistic Effects).

– Second, I expect the Conference to help us to identify the specific themes of common interest for the continuation of this global risk assessment dialogue as well as pragmatic, sustainable arrangements for the future.

Let me conclude by saying that we strongly believe in the value of improved mutual understanding of the respective risk analysis approaches, the exchange of best practices and a sustained dialogue between risk assessors, on both methodological aspects of risk assessment and the major substantive risk issues of common interest, notably in relation to new technologies.

We look forward to stimulating presentations and discussions during the three days of the Conference leading to positive outcomes to guide us in future.

Thank you.

End

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