1ST INTERNATIONAL RISK ASSESSMENT CONFERENCE
A GLOBAL RISK ASSESSMENT DIALOGUE
13-14 November, 2008, Brussels

SUMMARY REPORT

The conference was organized by the European Commission (EC), DG Health and Consumers (DG SANCO) and took place on 13 and 14 November 2008 at Crowne Plaza Brussels City Centre Hotel, Brussels, Belgium. It was the first of a series of regular, bi-annual International Conferences on Risk Assessment (RA). Close consultations took place during the organisation of the Conference between DG SANO, the US Office of Management of the Budget (OMB), the US Office of Science and Technology Policy OSTP) and the Treasury Board of Canada, within the framework of the Transatlantic Risk Assessment Dialogue.

Over 250 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, China, Japan, Russia, Australia and the EU (in particular the EC, the EU Agencies involved in risk assessment and their Scientific Committees and Panels and the European Parliament-STOA) as well as international expert groups.

The meeting was opened with a welcome address by Androulla Vassiliou, Commissioner for Health who described the future challenges for the EC and the (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. Commissioner Vassiliou mentioned examples of innovations associated

with potential health risks, referred to past crises and the role of science and RA as a basis for RM decisions at EU level. She highlighted the importance of a framework for RA at international level and confirmed her commitment to ensure continuity and support for the ongoing dialogue.

The first session of the meeting set the scene of the conference and focussed on the role of Risk Assessment, the interface between RA and RM and the current RA policies and key RA issues. It was opened by a speech of John Graham, Dean of the Indiana University, providing an overview of the role of RA for regulatory decision making, followed by speeches outlining the aim and suggested scope and contents for the international RA dialogue from the EU, US and Canadian perspective. This was followed by presentations on the Risk Analysis processes, approaches and structures in various regions and countries (EU, US, Canada, Japan, China, Australia, and Russia).

Several issues were highlighted and discussed during this session such as the need for transparency, the importance of stakeholder dialogue, responsiveness to the needs of risk managers, best practices for ensuring scientific excellence (rigorous expert peer reviews). In their introductory remarks, Bernardo Delogu, Nancy Beck, and Mohan Denetto emphasized the ideas underpinning the international RA dialogue –forward looking information sharing and collaboration; better understanding of the respectivet approaches to RA; finding ways for collaborative activities in the future. Takis Daskaleros. Nancy Beck, Bruce Rodan, Shane Morrise, and John Giraldez made a joint presentation on the regulatory analysis of RA in the EU, the US, and Canada. This was followed by presentations by Hidetaka Kobayashi, David Henrich, Junshi Chen, and Simon Avaliani who each presented the state of RA in their respective countries – Japan, Australia, China, and Russia. The invited comments by Erik Millstone further explored the issues of RA policy at the interface of RA and RM.

In the second part of this first session, Randall Lutter and James Hammitt provided further analysis of the RA process and its interface to RM, the role of science in the decision making process, other aspects considered in the decision making process (e.g. benefits, based on risk-benefit analysis, socio-economic aspects etc.), RA needs, methodological and other challenges for RA as well as for risk communication.

Jim Bridges discussed the current and future challenges in RA such as uncertainty due to lack of sufficient data, poor RA communication, lack of trained risk assessors, etc. Those presentations were followed by the invited comments of Gernot Klotz and a lively discussion of the issues with the participation of the audience. The consensus emerging pointed in particular to the importance of risk communication, of proper exposure measurements, of building stakeholder trust, the need for specific training

of scientists as risk assessors, the need to intergation between cost-benefit analysis and RA and the need to bring RM and RA closer to each other.

Session 2 of the first day of the meeting introduced and set the scene for the themes which would be covered in break out sessions on the second day of the meeting: Uncertainty analysis and terminology used in risk assessment, as well as Emerging Issues and Challenges. This was done by introductory speeches, presentations and invited comments by Ian Campbell, Anthony Hardy, Gerhard Heinemeyer, Zhi Su, George Gray, and Vittorio Silano.

The first day of the meeting closed with a keynote speech at the Conference Dinner on *Effective Risk Governance: the role of science and international cooperation*, provided by Paola Testori-Coggi, Deputy Director General, DG SANCO.

The second day of the meeting, started with two presentations and two invited comments by Helmut Greim, Vicki Dellarco, Antonia Calafat, and William Ross on non-threshold carcinogens and exposure assessment. Session 3 consisted of four break-out sessions held in parallel, covering 4 topics (terminology, non-threshold carcinogens, emerging issues, and exposure assessment). The break out sessions allowed for a more in depth discussions and the identification of areas where international dialogue and collaborations can be pursued. Each group was supported by a chair, rapporteur and a steering group. Each break out group prepared a presentation capturing the key elements of the discussion and the main conclusions/recommendations in the group. These were reported by the respective rapporteurs in the subsequent plenary (Session 4) chaired by Robert Madelin, Director General, DG SANCO.

The main conclusions resulting from the plenary and breakout sessions were discussed briefly in the concluding High Level Panel discussion. The panel discussion was aimed at summing up the discussions and the results of the break out session, and presenting proposals for conclusions and recommendations on the conference themes and the future of the international RA dialogue. Heinz Zourek emphasized the need of harmonization of RA given the free flow of goods and services on a global scale. Masao Hirose mentioned the need to improve the RA efficiency and its communication to all consumers based on international cooperation and science-based discussions with practical outcomes for the next conference. Mohan Denetto proposed the establishment of a network working group looking at case studies especially on emerging risks. Simon Avaliani proposed the establishment in Moscow of a training centre for risk assessors aimed at alleviating the lack of such professionals in the countries of the former Soviet Union. Jim Jones

spoke of the need to promote the best practices within a broad community of different practices, "broadness" being the keyword. Bruce Rodan emphasized the need to increase the independence and transparency of the science-based RA. Zhu Su indicated that given the global nature of RA, there should be more cooperation between the developed and the developing world, i.e. the next conference ought to involve more countries.

The final conclusions were drawn by the Chair:

- The role of science to address high-level needs for a safe and competitive world was highlighted. A stronger input from science and RA in particular is important but there is a need to focus on what RM wants from RA.
- Three relevant areas were identified:
  1) The benefits from knowledge sharing and a common knowledge of the state of the art were recognized.
  2) Consensus building within community of practice on what is known / not known – to decrease the levels of uncertainty (as persons who are non-scientists tend to portray findings as inconclusive)
  3) Assertiveness – The separation between RM and RA is important but there is a need for discussion and interaction between assessors and policy makers (which should involve the scientists).

Process outcomes of the meeting:

- It is planned to continue the work of the 4 subgroups and produce 4 processes of work as suggested by the four breakout sessions with mutual interaction ("cross-fertilization"). These should produce an outcome by summer 2010. For common approaches, the following aspects should be included:
  - Provide usable, practical approaches.
  - Produce constructive output usable in different cultures
  - How to do it? The establishment of a common platform will be pursued (including the possibility of electronic working groups which might meet separately before the next conference in 2010.

- While doing so initiatives will be taken to reach out to other communities, international organizations and other countries.

- A 2nd International Risk Assessment Conference will be convened in the fall of 2010.

Next steps

– DG SANCO will maintain the Conference website and upload in it all the documents of the Conference

– DG SANCO, in consultation with the four thematic steering groups and all the major players, will prepare an operational follow up action programme covering the proposed activities for the years 2009-2010. It will disseminate the programme to the participants for comments and expressions of interest in the various activities.

General outcome:

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.

Annex I

Conference Programme

Programme

TIME	SUBJECT	DESCRIPTION	SPEAKER
DAY 1 13 November 2008			
8:15-9:00	REGISTRATION AND COFFEE		
9:00-9:10	Welcome Address	**Androulla Vassiliou**, Commissioner for Health, European Commission	
9:10-15:10	**Session 1: Setting the Scene The role of Risk Assessment, the interface between Risk Assessment and Risk Management and the current Risk Assessment policies and key risk assessment issues**		
9:10-9:35	Part 1: Introductory speech by the Chair	Overview of the role of RA in decision making. Outline of Risk Analysis process. Highlight of interfaces between the various Risk Analysis components	**John Graham**, Dean, Indiana University, School of Public and Environmental Affairs
9:35- 9.55	Presentation of the International Risk Assessment Dialogue: Aims, Structure, Contents and Progress	Proposed aims and suggested scope and Contents for the RA dialogue	**Nancy Beck**, US Office of Management of the Budget **Bernardo Delogu**, Head of Unit Risk Assessment, Health and Consumers Directorate General, European Commission **Mohan Denetto**, Director of Regulatory Policy, Regulatory Affairs Division, Treasury Board of Canada
9:55-10:30	Role of Risk Assessment in some Regulatory and Policy	Presentations of the Regulatory Risk Assessment process in the EU, US and	Joint presentation by:

	Systems - 1	Canada	**Takis Daskaleros**, Health and Consumers Directorate General, European Commission **Nancy Beck**, US Office of Management of the Budget **Bruce Rodan**, US Office of Science and Technology Policy **Shane Morris**, Regulatory Affairs Division, Treasury Board of Canada **John Giraldez**, Regulatory Affairs Division, Treasury Board of Canada
10:30-10:50	Questions & discussion		
10:50-11:10	Coffee Break		
11:10-12:00	Role of Risk Assessment in some Regulatory and Policy Systems - 2	Presentations of the Regulatory Risk Assessment process in Japan, China, Australia and Russia	**Hidetaka Kobayashi**, Associate Director, Food Safety and Consumer Policy Division, Food Safety and Consumer Affairs Bureau, Japan Ministry of Agriculture, Forestry and Fisheries **David Heinrich**, Manager, America, New Zealand, Europe and Africa Team, Plant Biosecurity, Australia **Junshi Chen**, Senior Research Professor Institute of Nutrition and Food Safety, Chinese Centre for Diseases Control and Prevention **Simon Avaliani**, Head, Department of the Communal Hygiene, Centre for the Risk Assessment, Russian Academy of the Advanced Medical Studies
12:00-12:15	Invited Comments	Risk Assessment Policy: an interface between risk assessment and risk management	**Erik Millstone**, SPRU - Science and Technology Policy Research Freeman Centre, University of Sussex
12:15-12:30	Questions & Discussion		

12:30-13:30	Lunch		
13:30-13:40	Part 2: Introduction by the Chair	The role of science in the decision making process. Integration between natural and socio-economic sciences in the risk analysis process. A science-based risk governance approach: benefits, perspectives, conditions for its success	**Randall Lutter**, Deputy Commissioner for Policy, US Food and Drug Administration
13:40-14:05	An Overview of Risk Assessment Policy Issues: Experience and Current Problems	Presentation on the policy issues of risk assessment focusing on the separation between RA and RM, risk benefit analysis, the impact assessment that should or should not accompany risk assessment, comments on whether the risk assessment process should provide policy options to decision makers, risk governance, the role of risk communication...etc. Possible directions for dealing with the main risk assessment policy issues	**James K. Hammit**, Professor of Economics and Decision Sciences, Department of Health and Policy Management, Harvard University School of Public Health, Boston, Massachusetts, USA
14:05-14:30	An Overview of Risk Assessment Scientific Issues: Experience and Current Problems	Overview presentation on RA policy that should cover items like lack of hazard and exposure data, uncertainty, weight of evidence, non threshold chemicals, separation of RA and RM, poor risk communication, lack of trained risk assessors, independence, transparency, alternative methods to animal testing, etc…	**Jim Bridges**, Chair of the European Commission Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR)
14:30-14:50	Invited Comments	**Gernot Klotz**, Executive Director, Research and Innovation, European Chemical Industry Council (CEFIC)	
14:50-15:10	Questions & Discussion		
15:10-15:30	Coffee Break		

15:30-18:00 Session 2: Key Note Thematic Presentations
Invited presentations introducing the themes intended for discussion in the parallel breakout sessions

15:30-15:40	Part 1: Introduction by the Chair	Dealing with and communicating uncertainties in risk assessment. Weight of evidence and causality criteria in science and policy analysis	**Ian Campbell**, Director, Plant Health Science Canadian Food Inspection Agency (CFIA)
15:40-16:05	Risk Assessment Terminology, Expression of Nature and Level of Risk and of Uncertainties	Presentation of a report on the terminology used by the European Commission Scientific Committees. Highlights on key issues emerging from the report and discussion of areas and initiatives for work at international level	**Anthony Hardy**, Chair of the European Food Safety Authority (EFSA) Plant Protection Panel
16:05-16:20	Invited comments	Considerations in light of the WHO/IPCS guidelines on expression of uncertainties	**Gerhard Heinemeyer**, Chair of WHO/IPCS Working Group on Uncertainty in Exposure Assessment, Federal Institute for Risk

			Assessment, Germany
16:20-16:40	Questions & Discussion		
16:40-16:50	Part 2: Introduction by the Chair	The need for international collaboration to ensure identification, assessment and governance of emerging risks	**Zhi Su**, Deputy Director General, Bureau of Health Inspection, Ministry of Health, China
16:50-17:15	Emerging Issues and Challenges	Overview of activities to identify and assess new and emerging issues and challenges related to chemical, physical, and biological agents. Aspects on which international collaboration would be beneficial	**George Gray**, Assistant Administrator for the Office of Research and Development, US Environmental Protection Agency
17:15-17:40	Invited comments	State of the art in the European Union on monitoring and assessing emerging risks. Considerations on possible directions for greater international collaboration in this area	**Vittorio Silano**, Chair of the Scientific Committee of the European Food Safety Authority (EFSA)
17:40-18:00	Questions & Discussion		
18:00-18:10	Organization of Day 2: Communication on the organisation of parallel break out sessions. Introduction of key issues and questions for the sessions. European Commission, Health and Consumers Directorate General		
END DAY 1			
19:45-21:30	Dinner	Key-note speech on "Effective Risk Governance: the role of science and international co-operation"	**Paola Testori-Coggi**, Deputy Director General, European Commission Health and Consumers Directorate General Invited Guest Speaker: **Joel Hasse Ferreira**, Member of the European Parliament Internal Market and Consumer protection Committee (IMCO) and the European Parliament Science and Technology Policy Option Assessment (STOA) Panel

DAY 2 14 November 2008			
TIME	**SUBJECT**	**DESCRIPTION**	**SPEAKER**

9:00-10:45 **Session 2, Part 2 (continued): Key Note Thematic Presentations**
(Chair: Zhi Su, Deputy Director General, Bureau of Health Inspection, Ministry of Health, China)

9:00-9:25	Assessing the Risk of Non-Threshold Carcinogens	Presentation of the Commission Scientific Committees draft opinion on the approach to the assessment of carcinogens and mutagens (both threshold and non threshold) that will include comments on the hazard/toxicity data, exposure data, risk assessment methodology (uncertainty factors, linear versus non linear approach), etc…	**Helmut Greim**, Chair of the Scientific Committee on Health and Environmental Risks (SCHER)
9:25-9:45	Invited comments	Presentation of EPA's Weight of evidence approach	**Vicki Dellarco**, Health Effects Division, Office of Pesticide Programmes, US Environmental Protection Agency
9:45-10:10	Exposure assessment: role, challenges and needs. Presentation of an invited paper	Presentation of the key aspects of exposure assessment in RA: needs and challenges	**Antonia M. Calafat**, Division of Laboratory Sciences, National Center for Environmental Health, US Centers of Disease Control and Prevention
10:10-10:30	Invited comments	**William Ross,** Director, Health Canada, Bureau of Biostatistics	
10:30-10:45	Questions & Discussion		
10:45-11:00	Coffee Break		

11:00-13:00 **Session 3: Parallel Break Out Sessions**
In depth discussion of issues, based on key questions. Short summary of plenary presentations and 1-2 additional 10 minute presentations from other scientists/bodies.
Reports, conclusions and recommendations from each parallel session

11:00-13:00	**1) Terminology**	Session 1 Chaired by: **John Monninger**, US Nuclear Regulatory Agency Rapporteur: **David Gee**, European Environmental Agency **Steering Group:** **George Gray**, US Environmental Protection Agency **Anthony Hardy**, European Food Safety Authority Plant Protection Panel **Andy Hart**, European Food Safety Authority Plant Protection Panel

11:00-13:00	**2) Non-Threshold Carcinogens**	Session 2 Chaired by: **Hans-Georg Eichler**, European Medicines Agency Rapporteur: **Hermann M. Bolt**, Vice-Chair of the Scientific Committee on Occupational Exposure Limits **Steering Group:** **Helmut Greim**, Chair of the Scientific Committee on Health and Environmental Risks (SCHER) **Vicki Dellarco**, Health Effects Division, Office of Pesticide Programmes, US Environmental Protection Agency **John Christian Larsen**, Chair of Panel on additives, flavourings, processing aids and materials in contact with food, European Food Safety Authority
11:00-13:00	**3) Emerging Issues and Challenges**	Session 3 Chaired by: **Piotr Kramarz**, European Centre for Disease Control and Prevention Rapporteur: **Shane Morris**, Regulatory Affairs Division, Treasury Board of Canada **Steering Group:** **Jim Jones**, Principal Deputy Assistant Administrator, Office of Pesticides, US Environmental Protection Agency **Jim Bridges**, Chair of the European Commission Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) **Hubert Deluyker**, European Food Safety Authority **Ralf Reintjes**, European Food Safety Authority
11:00-13:00	**4) Exposure Assessment**	Session 4 Chaired by: **Derek J. Knight**, Senior Scientific Advisor to Executive Director, European Chemicals Agency (ECHA) Rapporteur: **Valerie Zartarian**, Office of Research & Development, National Exposure Laboratory, US Environmental Protection Agency **Steering Group:** **Valerie Zartarian**, Office of Research and Development, National Exposure Laboratory, US Environmental Protection Agency **Bo Oscar Jansson**, Vice-Chair of the European Commission Scientific Committee on Health and Environment Risks **Stefan Fabiansson**, European Food Safety Authority
13:00-14:00	Lunch	

14:05-15:05 **Session 4 – Reports of break out sessions and High Level Panel discussion**

14:00-14:05	Introduction by the Chair	**Robert Madelin**, Director General Health and Consumer Directorate General, European Commission
14:05-	**Reports (15mn each) of parallel break out sessions**	

15:05			
14:05-14:20	**1) Terminology**	**David Gee**, European Environmental Agency	
14:20-14:35	**2) Non-Threshold Carcinogens**	**Hermann M. Bolt**, Vice-Chair of the Scientific Committee on Occupational Exposure Limits	
14:35-14:50	**3) Emerging Issues and Challenges**	**Shane Morris**, Regulatory Affairs Division, Treasury Board of Canada	
14:50-15:05	**4) Exposure Assessment**	**Valerie Zartarian**, Office of Research and Development, National Exposure Laboratory, US Environmental Protection Agency	
15:05-16:00	Discussion		
16:00-16:15	Coffee Break		
16:15-17:00	Final High Level Panel Discussion: Summing up and proposals for conclusions and recommendations on the conference themes and the future of the international RA dialogue	Panel discussion, with interventions from the audience, on the issues and proposals emerging from the first day, the parallel break out sessions and the plenary discussion. Consensus building on the follow up priorities and initiatives **Panel members:** **Heinz Zourek**, Director General, Enterprise and Industry Directorate General, European Commission **Masao Hirose**, Commissioner, Japanese Food Safety Commission **Mohan Denetto**, Director of Regulatory Policy, Regulatory Affairs Division, Treasury Board of Canada **Simon Avaliani**, Head, Department of the Communal Hygiene, Center for the Risk Assessment, Russian Academy of the Advanced Medical Studies **Jim Jones**, Principal Deputy Assistant Administrator, Office of Pesticides, US Environmental Protection Agency **Bruce Rodan**, US Office of Science and Technology Policy **Zhi Su**, Deputy Director General, Bureau of Health Inspection, Ministry of Health, China	**Robert Madelin** Director General, Health and Consumers Directorate General, European Commission
17:00-17:15	Final conclusions by the Chair		
17:15	END		

Annex II

Conclusions of the Parallel Sessions held on Day 2:

- **Parallel Session 1: Terminology and expression of risk, evidence and uncertainty**

- **Parallel Session 2: Non-Threshold Carcinogens**

- **Parallel Session 3: Emerging Issues and Challenges**

- **Parallel Session 4: Exposure Assessment**

- **Parallel Session 1: Terminology and expression of risk, evidence and uncertainty**

Session 1 - Terminology and Expression of Risk, Evidence, and Uncertainty

Report of Session 1

Question 1

- Is it useful to develop a set of harmonized terms for strength of evidence and other dimensions of risk?
  - Yes, if we can get it to work
  - Need separate terms for different dimensions of risk and uncertainty
  - Start by trying to get agreement on terms between scientists; subsequently consider how these can help communicate to risk managers and others

Question 2

- What approaches could be considered for evaluating and expressing uncertainties, in addition to those mentioned above (EFSA, REACH, GRADE, IPCS)?
  - Too early to choose between methods
    - Need to try them out
  - Can already agree on some principles;
    - Need to be transparent
    - Need to be systematic
    - Need a tiered approach
    - Need a way to communicate the results

Question 3

- Is there a need to review the types of participation, the types of evidence admitted and the approaches to the weighing of evidence by scientific committees?
  - Safety is a social construct – implies a need to engage with the public
  - Important to involve stakeholders in framing of issue
    - Including what uncertainties will be addressed and which excluded
    - Helps risk assessors to address stakeholder concerns
    - Helps with subsequent communication
  - Define criteria for weighing evidence in advance (as far as possible)
  - Be transparent afterwards about the choices you make

Question 4

- What types of activity are required for progress on these issues in the short and medium term?
  - Try out alternative approaches for questions 1-3 on examples, i.e. gather evidence
    - How doable is it?
    - How useful is it?
  - Ask Sci Panel A to express consequences of a risk assessment, then ask Sci Panel B how they interpret that expression of consequences
  - Some EU research funding available for projects on communication of food risks and benefits

Question 5

- Would it help to develop case studies based on practical examples of risk problems?
  - Yes: see question 4
  - But bear in mind that new issues may require new approaches in future risk assessments
    - Include some emerging issues in case studies
  - Bear in mind assessments of the same problems in different countries etc. may need to take account of different factors

Recommendation

- Establish a Working Group to develop a reference document reviewing available approaches to uncertainty, weighing of evidence and terminology
- Get various committees/authorities to try out the approaches
  - How doable are they?
  - How useful are they?
- Workshop to review outcome and draw conclusions

▪ Parallel Session 2: Non-Threshold Carcinogens

1. Identification of methodologies and approaches

Valid documentations are available:

- Risk assessment methodologies & approaches by SCHER, SCCP, SCENIHR (prelim. Report of 24. Oct. 2008)
- IPCS Mode-of Action Framework
  (different publications)

2. Particular relevant problems

- The threshold concept is generally accepted for nongenotoxic carcinogens and is plausible for certain genotoxic carcinogens
- Carcinogenicity, especially quantitative, generally cannot be predicted based on in vivo data only. They may point to hazard only. Importance of toxicokinetics.
- Dose selection problems important!
- The WoE (weight of evidence) -> MoE approach appears appropriate. But how large should the MoE be?
- BMD / T-25 calculations again depend on the quality of data; they can be used if quanti tative data are needed.
- The current classification system is only hazard-based. This is not the scientific state of the art.

3. Identify best practices

- There are guidance procedures from EFSA, JECFA, IPCS, EPA that can be used.
- Exposure assessment is frequently the weak point (-> other workgroup).
- Case study developments should be enforced.

4. Recommendations to improve practices

- We need an inventory/repository of existing case studies (include- MoA and regulatory status).
- Research in the MoA area should be internationally supported as to contribute to the development of case studies
- The translation of scientific findings into regulation is inadequate and thus necessary

5. Recommendations to be followed up

- The present hazard-based classification system should be re-evaluated to incorporate elements of risk, to the extent possible.
  - Integrate existing elements (such as of EPA, national bodies, SCOEL).
  - A task group should be committed with developing a white paper.
  - Continue a global dialogue, as also GHS is to be addressed.

Emerging Issues and Challenges

Breakout Session 3

Key Questions:

1. **"New, emerging, re-emerging risk/risk areas which may pose specific challenges to risk assessors "**
2. **"Methodological challenges"**
3. **"Uncertainty, providing info in a manner which enables effective decision making"**

Q1: How to define "emerging risk"?

- **A definition is needed to ensure common understanding and to aid inter-jurisdiction cooperation**
- **Would recommend working on definition:**
- **Sub-definition considerations….e.g. urgent v. long term**
- ***Proposed start:***
- ***"An emerging risk is understood as a risk resulting from a newly identified hazard to which an exposure may occur or from a new or increased exposure and/or susceptibility to a known hazard"***

Q1: How to approach urgent emerging issues vs. long-term (mega) trends

- **Time frames need to assessed during the risk characterisation/risk forecasting activity**
- **Data collection: consideration of type and detail**

Q1: How to identify emerging/re-emerging risks in different sectors

- **Concept of indicators leading to signals**
- **Identification of change in hazard and exposure**
- **Concept of reporting and communication**

Q2: Key Points for "methodologies"

1. **<u>Urgent</u> risk assessment should be explored more widely and issue for next conference**
2. **Risk identification (early warning: for chemical and environmental risks; projections: biohazards) needs further development and <u>learning for other sectors.</u>**
3. **<u>Transparancy</u> about the values and processes used in grading of risks are essential.**
4. **<u>General common approachs</u> for food transmission might be possible for events with short time to outcome. For other areas seperated approaches are needed.**
5. **<u>Network are needed</u> for: Sharing risk assessment and identification methodolgies, epidemiological principles for assesssing the risk, how we approach the different typs of evidense**

Q 2: Fora for discussion

- **Existing fora:**
  - **Meetings of Chairs of Commission's and Agencies' Scientific Committees/Panels**
  - **Transatlantic Risk Assessment Dialogue – Global?**
  - **International Food Chemical Safety Liaison Group**

- **Need for a new forum (fora)?:**
  Conference 2010
  Common research programmes for the output

Q3: How the emerging methodologies impact the risk assessment?

- ***Through use of 'smarter' approaches allows for***
  - *better prioritization (and later as an integral part of the RA once we know how to interpret these results).*
  - *could help deal with the area of chemical mixtures and new hypotheses on mechanisms of action*
- ***Areas for collaboration in the high throughput:***
  - *what hazards need to be studied*
  - *what targets need to be studied,*
  - *the interpretation of the results: at the moment not clear what the results mean*
  - *proper communication on evolving science*

Q3: New strategies can be designed for data-poor situations?

- **This depends on the context: is it an urgent, big problem e.g. melamine versus nanotechnology**

- **For urgent issues:**
  - **Sharing best practices for rapid response among authorities but also involve stakeholders when there is a specific issue**
  - **Learning from experience in other domains with well-established procedures e.g. transportation: learning to collaborate in peace time with all involved**

- **However, what about tools for looking ahead to the unknown unknowns?**

Q3: Interaction between RA and RM

- We need rethink the interface: need a **more dynamic** interactive cooperation between RA and RM

- **Clear communication:**
  - all along rather than only at the beginning and the end
  - role for risk assessors

Q3: Discussion Fora

Need for a new forum (for a):

- Alternative methods for understanding hazards being developed:
- EPA on pesticides – interpretation is the next challenge and impact on hazard assessment, start the discussion early enough
- Toxico-genomics, toxidynamics, toxicokinetics

Conclusions and Recommendations

- Internationally agreed definition needed on “emerging risks”
- Need to develop and enhance “community practice”/fora to learn from different sectors (e.g. best practices in com. diseases/transport)
- Needed a meeting/workshop/working group on Rapid/urgent risk assessment and identification to develop a session in next conference 2010.
- Incorporation and sharing of new methodologies for risk identification and forecasting
- Need to enhance risk communication between jurisdictions and stakeholders. Recommend session in 2010 conference.

Exposure Assessment session: Goals

To exchange information & enhance understanding of different methodologies, tools, uncertainties & needs; make progress towards improving current science & use of exposure assessment to inform risk assessments & regulatory decision making

Participant Key Issues

- Pull together review of models
- Dealing with detection limits
- Cosmetics/toiletries: use patterns & concentration/exposure data
- Aggregate & cumulative approaches
- Indoor environment issues, e.g. air concentrations in the EU
- Credibility of models/uncertainity

Participant Key Issues

- Systemic way to develop exposure scenarios including mixtures
- Need for more exposure assessor professionals
- Forum for exposure models (at global level)
- Education of exposure assessor in Europe
- Follow-up for previous policy decisions
- Surveillance monitoring

Participant Key Issues

- Shared experiences for biomonitoring
- Focus on REACH Emission Scenarios: guidance on exposure models

Recommendations

- Develop Ad Hoc Exposure Working Group to Explore the following
  - Review existing approaches in exposure assessment (models, measurements & questionnaires, exposure scenarios)
  - Methods to Make Data More Available
  - Collaborative exposure case studies
  - Education and hands –on training (e.g. exposure models)
  - Shared information on biomonitoring study designs and application of data globally