

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 R Management and the current Risk Assessment policies and key risk assessme 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 Systems - 1	Presentations of the Regulatory Risk Assessment process in the EU, US and Canada	Joint presentation by: Takis Daskaleros, Health			



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			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
10: 30- 10: 50	Questions & discussion		Board of Canada
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 communicationetc. 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 Chemical Industry Council (CEFIC)	and Innovation, European
14:50- 15:10	Questions & Discussion		
15:10- 15:30	Coffee Break		

15:30-

Session 2: Key Note Thematic Presentations Invited presentations introducing the themes intended for discussion in the 18:00 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 GeneralInvited 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

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9:00-	ion 2, Part 2 (continued): Key Note Thematic Presentations
10:45	ir: Zhi Su, Deputy Director General, Bureau of Health Inspection, Ministry of Health,
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10:45- 11:00	Coffee Break		
10: 30- 10: 45	Questions & Discussion		
10: 10- 10: 30	Invited comments	William Ross, Director, Health Canada, Bur	eau of Biostatistics
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
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
9:00-9:25	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)

11:00 3: Parallel Break Out Sessions 13:00

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 b	reak out sessions and High Level Panel discussion

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15:05		_		
14:00- 14:05	Introduction by the Chair	Robert Madelin, Dire General, European Cor	ctor General Health and Consumer Directora mmission	te
14:05-	Reports (15mn each) of	parallel break out ses	sions	
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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	Robert Madelin Director General, Health and Consumers Directorate General, European Commission
		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		hnology Policy
	Zhi Su , Deputy Director General, Bureau of Health Inspection, Ministry of Health, China		
17:00- 17:15	Final conclusions by the Chair		
17:15	END		

