

The International Programme
on Chemical Safety (IPCS)



WHO



UNEP

**Steering Committee on the
Harmonization of Approaches to the Assessment of Risk
from Exposure to Chemicals**

Report of the 8th Meeting

10-11 May 2007, Berlin, Germany

INTERNATIONAL PROGRAMME ON CHEMICAL SAFETY**Report¹ of the 8th Meeting of the Steering Committee
on the Harmonization of Approaches to the Assessment of Risk
from Exposure to Chemicals****ITEM 1: WELCOME AND OPENING OF MEETING**

1. The 8th meeting of the IPCS Harmonization Steering Committee convened on 10-11 May 2007, at the Federal Institute for Risk Assessment (BfR), Berlin, Germany. The meeting was opened by the Chair of the Steering Committee Dr Margaret Hartley, Director, Office of Chemical Safety, Commonwealth Department of Health, Australia, who invited Prof. Dr. Dr. Andreas Hensel, President, Federal Institute for Risk Assessment to deliver the official welcome address.
2. Prof Hensel welcomed participants to the Institute and to Berlin. His address highlighted the importance of the IPCS Harmonization Project to risk assessment, including the work performed by the BfR and other European institutions in implementing REACH. In closing he wished the Committee well in its task of developing the new strategic work directions for the Project. The Chair thanked Prof Hensel for his remarks and support for the Harmonization Project, and for hosting the meeting.
3. Ms Carolyn Vickers delivered opening remarks on behalf of WHO/IPCS. She thanked Prof Ursula Gundert-Remy and her staff at the BfR for the excellent preparations made for the meeting. The tasks for the meeting were highlighted, in particular; to recommend the new workplan for the Harmonization Project; to advise on communication and promotion of uptake and use of the products of the Project, and to review administrative arrangements, such as the Committee's terms of reference. She thanked participants in advance for their input, either as WHO Temporary Advisers, or as representatives of organizations that work in partnership with WHO on the Harmonization Project activities.
4. After a round of introductions, the Chair welcomed in particular the new members of the Committee and also Dr Chris Portier, on temporary assignment to WHO to develop a new WHO Public Health and Environment Department Risk Assessment Strategy (refer to Agenda Item 3). A list of participants appears at Annex 1.

ITEM 2: APPROVAL OF THE AGENDA

5. The Chair outlined how the Committee's terms of reference had been addressed by the provisional agenda, which the meeting was then invited to consider. The

¹ This report contains the collective views of an international group of experts, and does not necessarily represent the decisions or the stated policy of the World Health Organization.

adopted agenda is at Annex 2. In accordance with Steering Committee procedures the Secretariat was the meeting Rapporteur.

ITEM 3: WHO UPDATE ON CHEMICAL RISK ASSESSMENT AND RELATED ACTIVITIES

ITEM 3.1: WHO REPORT

6. The Secretariat introduced the document for this item, which provided background information on WHO/IPCS activities on risk assessment and methodology issues other than the Harmonization Project activities. The Committee noted the importance of reflecting the Harmonization Project products in other risk assessment products where relevant. In addition to the recently published "yellow cover" Environmental Health Criteria (EHC) documents covering a range of risk assessment methodology issues, the Committee noted with interest the development of an EHC titled "Principles for Modelling Dose-Response for the Risk Assessment of Chemicals" (draft).

ITEM 3.2: DEVELOPMENT OF WHO PUBLIC HEALTH AND ENVIRONMENT DEPARTMENT RISK ASSESSMENT STRATEGY

7. Dr Portier delivered a presentation on the Development of a WHO Public Health and Environment Department Risk Assessment Strategy. The Committee then discussed the presentation, focusing on the risk assessment methodology aspects, the importance of risk assessment in "decision-support" and its interaction with other aspects of the risk analysis framework. There was a firm view that the IPCS/OECD "Key Generic Terms used in Chemical Hazard/Risk Assessment" should be reflected in the document. Also, that a WHO Strategy on risk assessment should address the needs of developing countries for information and practical tools. Dr Portier thanked participants for their valuable input, which would contribute to the further development and finalization of the strategy.

ITEM 4: HARMONIZATION PROJECT OCTOBER 2004-APRIL 2007 REPORT

8. The Secretariat introduced the Harmonization Project Report for the period October 2004 to April 2007, noting that almost all of the activities had been completed or would be completed in the near future. The Chair then invited each of the activity Liaisons (or in the absence of a Liaison, the Secretariat) to highlight lessons learned from implementation. Key points noted in the discussions are summarized under the relevant topics:
 - Human Relevance Framework for Cancer (Liaison: Dr Farland). This is now well addressed by the published materials, including the November-December 2006 Special Issue of Critical Reviews in Toxicology containing the WHO/IPCS Cancer Mode of Action Framework and three case studies. The case study approach was particularly useful and has been successfully used in

other activities. Future efforts need to focus on: training in use of the framework, including in developing countries; gaining experience in use; collecting case studies of use; and evaluating its impact on risk assessment at international and national levels. The assistance of ILSI, Health Canada and the US EPA in the development of training materials and organization of a number of workshops/events at major scientific conferences on both the cancer and non-cancer frameworks was recognized. A paper being prepared by the US EPA on their experience in use of the framework, was offered as a contribution to be taken into account in further work.

- Non-cancer Human Relevance Framework: The Committee recognized the important contribution ILSI had made to the overall international effort by developing and publishing a number of case studies on a non-cancer framework.
- Exposure Assessment, including 1) guidance for characterizing and applying human exposure assessment models; 2) guidance on characterizing and communicating uncertainty in exposure assessment; and 3) data quality in chemical exposure assessment (Liaison, Dr Olin). 1) Uptake of the concept that models need to be characterized was reported to be good, and presentation at professional society meetings helpful in this regard. It has been used as a basis for REACH guidance under development. 2) The development of the uncertainty guidance was mentioned to be a good example of complementary work between EFSA and IPCS. The document is almost complete and the Working Group is focussing on outreach and promotion. 3) The Secretariat invited any additional comments on the data quality draft, to be submitted in writing. The document may have a specific audience, and could be useful to editors of some journals. The terminology used needs to be considered in relation to terms defined by OECD.
- Terminology, including developmental effects. Efforts should continue on translation of the risk assessment and exposure assessment terminology into other languages, and to promote uptake and use by other bodies (a number of which were mentioned for specific follow-up). The continuing development of internationally harmonized morphological terms by the WHO Collaborating Centre for Developmental Toxicology also contributes to the terminology project. The Committee noted that the Centre was currently being considered for redesignation as a WHO Collaborating Centre, that this process would result in a new workplan being agreed, and that the outcome would be reported back to the Committee.
- Chemical-Specific Adjustment Factors (CSAF): The final document has been in use for some time. Sharing of training materials and case study examples would be useful. The guidance to be developed on PBPK modelling will be a useful companion document.
- Skin sensitization (potency) (Liaison: Prof Gundert-Remy). This was an example of a "short-sharp activity" intended to address a specific issue, rather than a broad field. A one-off workshop had been convened to consider the

issue of potency/dose-response in skin sensitization chemical risk assessment. The small planning meeting had proved to be a very efficient mechanism for organizing the workshop in a short period of time. The workshop outcome had been used to restart discussions on this issue in the OECD group working on guidance for the Globally Harmonized System for Classification and Labelling (GHS). However there was also a view that a report with recommendations was not as useful in carrying forward risk assessment practice in this field as the type of harmonized guidance produced by longer/broader activities.

- Aggregate/cumulative risk assessment (Liaison: Bette Meek) The planning group meeting approach had also worked well in preparing for this international workshop. This activity was designed as a "one-off" workshop, aiming to discuss the state-of-the-science, risk assessment practice, gaps and research needs. The workshop identified some threshold issues to address (e.g. terminology), outlined the conceptual basis for development of a framework for aggregate/cumulative risk assessment, and provided valuable advice for a longer term activity by WHO/IPCS on this issue. The Committee supported the next phase of the work to develop the framework itself and release it for public and peer review. ECETOC and ILSI offered to assist by the developing case studies.
- Update of the IPCS Qualitative Scheme for Mutagenicity A small drafting group process to develop a proposal for broader public and peer review had been effective. The outcome will be of interest to the OECD Test Guidelines Programme. Thought should be given to how to maintain the currency of the scheme, given the rapidly moving field.
- PBPK modelling (Liaison: Bette Meek). The umbrella project planning approach, although extending the duration of this activity, allowed for two international workshops hosted by others (the United States, and the United Kingdom) to work through some of the detailed technical issues first. A workshop planning group process will now be initiated, and was envisaged would follow the Harmonization Project model, involving development of case studies and a strawman guidance, followed by a workshop.

ITEM 5: REPORTS FROM INTERNATIONAL/SUPRANATIONAL PARTNERS ON ACTIVITIES RELEVANT TO THE HARMONIZATION PROJECT

9. OECD, EU (ECB and EFSA), ECETOC and ILSI were invited to provide information on their recent and future work plans on risk assessment methodology, for the purpose of coordination and identification of issues relevant for the future Harmonization Project workplan.
10. Dr Visser's presentation included OECD activities on: the eChemPortal which will be an important contribution to the Strategic Approach to International Chemicals Management (SAICM) and which will also provide access to WHO/IPCS

chemical risk assessments; an integrated approach to testing and assessment (i.e. integrating the different approaches in vitro, in vivo, QSARs and toxicogenomics); and manufactured nanomaterials. In the discussion, it was noted that efforts on nanomaterials should not be duplicative, and that perhaps IPCS could assist with the development of human health QSARs.

11. Ms Munn presented four "actions" (areas of work) being addressed by the EU/ECB, i.e. CompuTERM - Computational Toxicology and Environmental Risk Modelling; SUPCHEM - Support to Chemicals Legislation; RefineRISK - Integrated Risk Assessment of Chemicals; and Glob-Chem - Global Chemical Data Management and Harmonization. RefineRISK includes harmonization of risk assessment methodologies and addresses guidance for the authorities conducting the risk assessments, test strategies, assessment factors, and other activities of relevance to the Harmonization Project.
12. Dr Kleiner's presentation of EFSA activities highlighted: ongoing work to improve and harmonize risk assessment methodologies and to promote transparency in risk assessment; development of risk-benefit assessment guidance (health effects) which includes guidance on problem formulation; development of an opinion on the usefulness of the benchmark dose method versus use of the NOEL; and the colloquium on cumulative risk assessment.
13. Dr Doe outlined the activities of ECETOC, which is a Non-Governmental Organization in official relations with WHO, and as such has an agreed workplan including activities in support of IPCS and the Harmonization Project. Topics being addressed include: use of human data in risk assessment; chemical mixtures risk assessment (in collaboration with ILSI/HESI); the threshold of toxicological concern concept; assessment and management of dermal risks; guidance on classification under the GHS; and refinement of mutagenicity/genotoxicity risk assessment. ECETOC confirmed that they could assist with the development of case studies for Harmonization Project activities.
14. Dr Olin outlined the activities of ILSI, which is also an NGO in official relations with WHO and working in support of IPCS and the Harmonization Project. Topics being addressed include: chemical mixtures risk assessment, which presented an opportunity for IPCS/ECETOC/ILSI cooperation; application of the human relevance framework; use of "omics" in risk assessment; integration of biomonitoring exposure data into the risk assessment process; mutagenicity/genotoxicity testing; and advancing use and availability of developmental toxicity data for SAR.

ITEM 6: DEVELOPMENT OF NEW WORKPLAN

ITEM 6.1: REVIEW OF AIDE FOR CONSIDERATION OF ACTIVITIES DEVELOPED BY HSC7

15. The Committee noted the "Aide for Consideration of Activities" that was developed by the 7th Meeting of the Harmonization Project Steering Committee,

as a useful list of factors to take into account when considering the new activity proposals.

ITEM 6.2: ACTIVITIES TO BE CARRIED FORWARD FROM THE PREVIOUS WORKPLAN

In final publication preparation/in press

16. The Committee noted the following documents were in final preparation for publication, or in press.
- IPCS Framework for Analyzing the Relevance of a Non-cancer Mode of Action for Humans (in press).
 - Guidance on Characterizing and Communicating Uncertainty in Exposure Assessment (final preparation for publication).
 - Skin Sensitization in Chemical Risk Assessment: Report of a WHO/IPCS International Workshop Focusing on Dose-Response Assessment (full report in final preparation for publication; summary already published). This activity helped build consensus about the consideration of potency in advance of an OECD workshop in early 2007 on the GHS classification criteria.

Activities already commenced, or ongoing.

17. The Committee agreed that the following Harmonization Project activities which have already commenced, were recommended for additional work, or are ongoing activities, should be continued:
- Update of the 1996 IPCS Qualitative Scheme for Mutagenicity Testing (to be released for public and peer review in 2007).
 - Guidance on Data Quality in Exposure Assessment (currently in public and peer review).
 - Framework for aggregate/cumulative risk assessment. This is the second phase of work on this issue, which follows on from the WHO/IPCS International Workshop on Aggregate/Cumulative Risk Assessment, 19-21 March 2007, Washington, United States. The second phase involves further development of a framework and associated case studies.
 - Guidance on good practice in PBPK modelling. An international Planning Group is coordinating the IPCS activity, which will build on the outcomes of recent international workshops organized by the US EPA and the UK Health and Safety Laboratory.
 - Maintenance, translation into languages and promotion of various harmonized terminology collections, (ongoing). This includes further development of harmonized morphological terminology for developmental toxicity (pending

review of work when WHO considers redesignation of the Collaborating Centre leading this activity).

ITEM 6.3: NEW ACTIVITIES

18. The Committee considered proposals for new Harmonization Project activities received from: members of the Committee; WHO expert meetings/groups; and a WHO Collaborating Centre. In addition the meeting was invited to consider whether there were any other emerging issues in risk assessment that should be addressed in the workplan.

Recommended new activities

19. The Committee recommended the development of the following new guidance/tools, on which work will commence in phased approach reflecting available resources:
- Guidance on characterizing and communicating uncertainty and variability in hazard assessment. This will complement the Harmonization Project Guidance on Characterizing and Communicating Uncertainty in Exposure Assessment.
 - Approach for identifying important life stages for monitoring and assessing risks from human exposures to environmental contaminants, that takes into account a range of factors that may vary (e.g. nutritional status, breastfeeding period, cultural practices, etc) so that guidance developed is relevant for use in different parts of the world. This will build on the WHO/IPCS Environmental Health Criteria document 237 "Principles for Evaluating Health Risks in Children Associated with Exposure to Chemicals".
 - Risk Assessment Toolkit for country/local use. An important user group will be developing countries. However, the Toolkit should be useful to risk assessors globally. The Committee agreed that the related activity addressing problem formulation (refer below) will be important for this toolkit, as the problem formulation step would be a logical entry point for users. This activity would necessarily include training elements and would complement the proposed development of a network of risk assessment bodies (Item 7).
 - Guidance for documentation and process for efficient and iterative priority setting and assessment including use profiling, issue identification (problem formulation) and peer engagement (i.e., peer input, consultation and review).
 - Expansion of the WHO/IPCS cancer and non-cancer frameworks on human relevance of mode of action to incorporate the WHO/IPCS guidance on chemical-specific adjustment factors. Lessons learned/experience gained in use of the IPCS frameworks will be considered. Associated training materials will be developed.

- Guidance on interpreting effects in toxicity studies that may be modest or adaptive. Noting similar work planned by the OECD Pesticides Working Group (but restricted to pesticides), the Committee decided the work should be coordinated with that of OECD to ensure there is no duplication of effort. Also, it was stressed that the guidance developed should recognize that effects occur as a continuum rather than there being a "bright line" delineating adverse from non-adverse effects.
 - Guidance for immunotoxicity risk assessment. This will build on the WHO/IPCS Environmental Health Criteria documents 180 "Principles and Methods for Assessing Direct Immunotoxicity Associated with Exposure to Chemicals", 212 "Principles and Methods for Assessing Allergic Hypersensitization Associated with Exposure to Chemicals" and the recently published 236 "Principles and Methods for Assessing Autoimmunity Associated with Exposure to Chemicals".
20. The Secretariat was tasked with ensuring that the written proposals considered are revised to reflect recommended amendments, so that they may form a starting point for the experts/working groups when work commences.

New Activities Conditionally Supported

21. The Committee also conditionally supported the development of the following new guidance/tools, subject to the stated prerequisites and qualifications:
- Guidance on interpretation of in vitro skin absorption data, to build on the recently published Environmental Health Criteria Document 235 "Dermal Absorption". The Committee requested WHO to review the output of an OECD activity on interpretation of dermal absorption data for pesticides (expected to be available at the end of 2007) and to consider undertaking a WHO activity to extend the work beyond pesticides.
 - Guidance on read across/chemical category development. Noting activity by other bodies on this issue, the Committee agreed that further discussion between OECD, EU, US EPA and the United Kingdom (proponents for this activity) would be needed to clarify any work proposal and which body would be best placed to do the work.
 - Case studies demonstrating application of the WHO/IPCS Guidance on Characterizing and Communicating Uncertainty in Exposure Assessment, particularly qualitative assessment case studies. It was decided to collect cases as they (and resources) become available, with a view to possible review of experience gained in application of the guidance.
 - Incorporate a case study on use of toxicogenomics data in risk assessment into the recommended activity on mode of action frameworks, at a later date.

Information exchange and "watching briefs"

22. The Committee recommended the following information exchange activities, and "watching briefs":
- The Committee requested WHO to share information with OECD on the WHO/IPCS Concise International Chemical Assessment Document programme work on International Comparison of Methodologies for Environmental Hazard Assessment. Proposed next steps should include sharing the results and consultation with OECD to avoid duplication with OECD work on risk assessment methodologies.
 - Participants agreed to share information on activities/guidance development on risk assessment for short term exposures, e.g. in case of spills/emergency response, batch processing, etc.. This may in time lead to a proposal for new activity.
 - Noting the numerous activities underway in WHO and other bodies on the use of biomonitoring data in risk assessment, the Committee agreed to maintain a watching brief on the issue.
 - The Committee also agreed to keep a "watching brief" on the following areas: neurotoxicity risk assessment; risk benefit analysis; and risk assessment of manufactured nanomaterials.
23. In concluding the item on new activities to be included in the workplan, the Committee reflected on priorities. It was agreed that there were no low priority activities, however it was recognized that activities would have their own timelines influenced by their stage of development (e.g. brand new activities, extension of existing activities, activities requiring consultation) and other factors including the process utilized (e.g. workshop, working group, or Collaborating Centre).

ITEM 7: PROJECT COMMUNICATIONS AND PROMOTION OF UPTAKE AND USE OF PROJECT OUTPUTS IN COUNTRIES

24. The discussion of this item focussed on reviewing communication and promotion activities in general, in order to identify any other approaches that should be undertaken (many individual activities had been discussed under the previous agenda items). It was noted that the Committee members are ambassadors for the project and chosen for their ability to promote the project in their own countries.
25. The Committee recommended that WHO/IPCS investigate development of a network of risk assessment bodies. Functions of such a network, could include: to facilitate uptake and use of the Harmonization Project products; for mutual support; and to facilitate training in risk assessment. This would complement the activity on the risk assessment toolkit. In addition, a group of Committee

members interested in collaborating on development of the training aspects of the Project should be convened.

26. Additional approaches that could be employed included: more use of local professional societies; exploiting electronic means of delivering training and presentations; publication/open use of training materials. Specific opportunities identified included the IUTOX 7th Congress of Toxicology in Developing Countries (CTDC) in 2009, South Africa; and the 12th IUTOX International Congress of Toxicology (ICT) in 2010, Barcelona.
27. Finally, the Chair requested that participants keep the Secretariat informed about possible opportunities to promote uptake and use of the Harmonization Project products.

ITEM 8: MID-TERM REVIEW OF THE STRATEGIC PLAN

28. The 7th Meeting agreed the Strategic Plan would cover 2005-08, with possible review at the half-way mark. The Committee reviewed the Plan, and noted that some aspects of the text need to be updated, e.g. to reflect the new work priorities, the Strategic Approach to International Chemicals Management (SAICM), and the harmonized terminology for the risk assessment process. Also, the statement that the project is about "increasing understanding and acceptance of methods and practices used by various countries" should be amended as the project aims and achievements had now developed beyond this original aim.
29. The Chair and Secretariat were charged with preparing a draft revised Strategic Plan, for consideration out of session by the Committee.

ITEM 9: REVIEW OF THE COMMITTEE'S TERMS OF REFERENCE AND ROLES AND RESPONSIBILITIES

30. The Committee reviewed its Terms of Reference and the Roles and Responsibilities document. The Secretariat noted that some minor amendments were needed to reflect changes in administration in WHO. It was also noted that Terms of Reference of the Risk Assessment Steering Group may be amended and that this may indicate consequential amendments to the HSC documents. The Committee noted that the Secretariat would circulate revised Terms of Reference and Roles and Responsibilities for review, at an appropriate time.
31. The Secretariat provided an update on WHO procedures relevant to implementation of the Harmonization Project, i.e. a new, more detailed, form for declaration of interests; requirement for Director General's Office clearance for development and publication of health information products (which includes Harmonization Project documents, abstracts/presentations at conferences, etc.); attribution of authorship and placement of acknowledgements in documents (Harmonization Project products reflect the views of individuals/groups); and copyright (WHO is to retain copyright on all printed, electronic and audiovisual

materials). In relation to copyright, the Secretariat has made arrangements for publication of Harmonization Project articles in scientific journals, while retaining copyright.

ITEM 10: PROJECT LIAISONS AND MEMBERSHIP OF THE CORE GROUP

32. The Committee reviewed the arrangements for constituting the Core Group and agreed that it should continue to include the "liaisons" for Project activities, plus the international bodies (to facilitate continued coordination), plus the NGOs in official relations with WHO (reflecting their joint workplans with WHO). In the past not all the international bodies and NGOs had participated. They will now be invited to do so. The Chair and Vice Chair of the Committee are the Chair and Vice-Chair of the Core Group.
33. Volunteers were sought to undertake the role of activity liaison for the new activities. The Secretariat will follow up the expressions of interest received with the individuals involved.

ITEM 11: ELECTION OF CHAIR AND VICE-CHAIR

34. The Secretariat assumed the Chair for this item, during which Dr Hartley was re-elected as Committee Chair, and Prof Gundert-Remy as Committee Vice-Chair.

ITEM 12: ANY OTHER BUSINESS

35. In response to a question about the budget situation for the Project, the Secretariat informed the Committee that, as with many WHO activities, the Project was funded by extra-budgetary (voluntary donor) resources for both salaries and activities, and therefore donor support was a prerequisite for continuation of the Project. The Committee expressed its support for the Project in fulfilling an important international role in the global improvement and harmonization of risk assessment methodologies, and requested the Chair to formally convey these views to WHO.

ITEM 13: NEXT MEETING AND CLOSURE

36. The Committee proposed to meet again in approximately 18 months to two years. Noting that this meeting had recommended a substantial plan of work, at the next meeting the Committee should focus in depth on its other terms of reference, in particular on the training, promotion and uptake aspects. In closing the meeting, thanks were extended to participants for their contribution to the development of the new workplan and their continued efforts in support of the Harmonization Project; to Dr Hartley for her expert Chairing of the meeting; and to Prof Gundert-Remy, Vice-Chair, and her staff for their generous hospitality and efficient organization of the local arrangements for the meeting.

**List of Invited Participants
8th Meeting, 10-11 May 2007, Berlin, Germany**

AFRO

Dr Edith Clarke, Occupational Health Unit, Ministry of Health, Accra, Ghana.

AMRO

* Dr Cristina Alonzo, Coordinator, Chemical Safety and Environmental Health Department, Ministry of Public Health, Montevideo, Uruguay.

* Dr P. Michael Bolger, Chief, Risk Assessment Staff, Center for Food Safety and Applied Nutrition, US Food and Drug Administration, College Park, United States of America.

Dr William H. Farland, Vice President for Research, Professor, Environmental and Radiological Health Sciences, Colorado State University, Fort Collins, United States of America.

Ms Bette Meek, Health Canada, Ottawa, Canada.

Dr Peter W. Preuss, US Environmental Protection Agency, National Center for Environmental Assessment, Washington, DC, United States of America.

EMRO

Prof Wagida A. Anwar, Department of Community, Environmental and Occupational Medicine, Faculty of Medicine, Ain Shams University, Cairo, Egypt.

EURO

Prof Erik Dybing, Norwegian Institute of Public Health, Division of Environmental Medicine, Oslo, Norway.

* Dr Steven Fairhurst, Health and Safety Executive, Bootle, United Kingdom.

Mr Peter Ridgway, Health and Safety Executive, Bootle, United Kingdom.

Prof Ursula Gundert-Remy, Bundesinstitut für Risikobewertung (BfR), Federal Institute for Health Protection of Consumers and Veterinary Medicine, Berlin, Germany.

* *Unable to participate*

Ms Helena Knez, Ministry of Health, National Chemicals Bureau, Slovenia.

Dr Theo Vermeire, Deputy Head Expertise Centre for Substances, National Institute for Public Health and the Environment (RIVM), Bilthoven, The Netherlands.

SEARO

Dr Mathuros Ruchirawat, Vice President for Research, Office of Academic Affairs, Chulabhorn Research Institute (CRI), Bangkok, Thailand.

WPRO

Dr Margaret Hartley, Director, Office of Chemical Safety, Australian Government Department of Health and Ageing, Canberra, Australia.

* Dr Tohru Inoue, Director, Center for Biological Safety and Research, National Institute of Health Sciences, Tokyo, Japan

Prof Bingheng Chen, Professor, School of Public Health, Fudan University, Shanghai, People's Republic of China.

REPRESENTATIVES OF ORGANIZATIONS

European Centre for Ecotoxicology and Toxicology of Chemicals (ECETOC), Dr John Doe, Syngenta.

European Chemicals Bureau, Joint Research Centre - Institute of Health and Consumer Protection, Ms Sharon J. Munn.

OECD Environment Directorate, Dr Robert Visser.

International Life Sciences Institute (ILSI), Dr Stephen Olin, ILSI/RSI.

European Food Safety Authority (EFSA), Dr Juliane Kleiner.

INVITED GUEST

Dr Christopher J. Portier, Associate Director, NIEHS, National Institute of Environmental Health Sciences, Research Triangle Park, United States of America

SECRETARIAT

Ms Carolyn Vickers (Harmonization Project Coordinator), International Programme on Chemical Safety, World Health Organization, Geneva, Switzerland

* Dr Vincent Coglianò, Chief, Unit of Carcinogen Identification and Evaluation International Agency for Research on Cancer, Lyon, France.

**INTERNATIONAL PROGRAMME ON CHEMICAL SAFETY
Project on the Harmonization of Approaches to the Assessment of Risk
from Exposure to Chemicals**

8th Meeting of the Harmonization Steering Committee

Adopted Agenda

1. Welcome and Opening of Meeting.
2. Approval of the Agenda
3. WHO Update on Chemical Risk Assessment and Related Activities.
 - 3.1 WHO Report.
 - 3.2 Development of WHO Public Health and Environment Department Risk Assessment Strategy
4. Harmonization Project October 2004-April 2007 Report.
5. Reports from International/Supranational Partners on Activities Relevant to the Harmonization Project.
6. Development of New Workplan.
 - 6.1 Review of aide for consideration of activities developed by HSC7.
 - 6.2 Activities to be carried forward from the previous workplan.
 - 6.3 New activities (including: consideration of proposals received; and discussion of emerging issues in risk assessment and any other proposals from the floor).
7. Project Communications and Promotion of Uptake and Use of Project Outputs in Countries.
8. Mid-term Review of the Strategic Plan.
9. Review of the Committee's Terms of Reference and Roles and Responsibilities.
10. Project Liaisons and Membership of the Core Group.
11. Election of Chair and Vice-Chair.
12. Any Other Business.
13. Next Meeting and Closure (Scheduled meeting closure time is 16.00).