Second WHO Meeting on Global Collaboration in Chemical Risk Assessment
- Strengthening Capacity Building and Networking -

Pre-Meeting Workshop on Risk Assessment Methodologies

28 March 2012
European Centre for Environment and Health, Bonn, Germany

Workshop Record

Opening and Welcome Address

1. The Workshop on Risk Assessment Methodologies associated with the Second WHO Meeting on Global Collaboration in Chemical Risk Assessment – Strengthening Capacity Building and Networking was held at the WHO European Centre for Environment and Health in Bonn, Germany on 28 March 2012. The workshop was officially opened by Dr Michal Krzyzanowski, WHO European Centre for Environment and Health, Bonn. Dr Krzyzanowski welcomed participants to the WHO Bonn facility.

2. Ms Carolyn Vickers of WHO thanked Dr Krzyzanowski for hosting the workshop and thanked the Planning Group for their efforts in organizing the event. Ms Vickers outlined the purpose and format of the workshop, followed by introduction of the participants. The list of participants appears in Annex 1. The adopted agenda for the workshop appears in Annex 2.

Workshop Presentations

3. The workshop consisted of presentations on WHO risk assessment training materials and recent WHO activities in methodology development.

4. Dr Salmaan Inayat-Hussain and Dr Kersten Gutschmidt delivered a series of presentations on the "WHO Human Health Risk Assessment Toolkit", followed by a panel discussion. Dr Inayat-Hussain provided background information on the history of the development of the Toolkit. Dr Gutschmidt introduced the Toolkit, describing its purpose and content, and gave a brief demonstration of its application, using cadmium as an example. Dr Inayat-Hussain

then provided a more detailed case study of the application of the Toolkit in the situation of mercury in oil and gas in Malaysia. Dr Gutschmidt then presented on how the Toolkit has been used in training to date, feedback received and next steps. A panel discussion followed, involving overviews of the importance of training and the WHO Toolkit in various regions by Dr Amir Johri, Dr Sam Adu-Kumi and Dr Raquel Duarte-Davidson and a presentation on the complementary OECD Environmental Risk Assessment Toolkit by Dr Hirofumi Aizawa. A general discussion followed in which options to further disseminate the WHO Toolkit were suggested, including introducing it at regional meetings (e.g., at African centres), at additional SAICM meetings or in university curricula. It was also noted that some countries and universities might be willing to fund training with the Toolkit.

5. Dr Elaine Cohen Hubal and Dr Thea de Wet presented on the draft WHO document "Setting Early Life Age Groups for Chemical Risk Assessment: Geographical and cultural factors". The objective of the project is to consider differences in exposure and risk across life stages as well as the genetic, geographic, and cultural factors that may account for such differences in order to facilitate risk prevention and mitigation for improved children's health. The draft document has undergone public consultation and feedback received is currently being considered. The topic stimulated extensive discussion and a number of suggestions were put forward, which will be considered in finalizing the document.

6. Dr Bette Meek presented the WHO framework for "Risk Assessment of Combined Exposures to Multiple Chemicals", describing the process involved in its preparation and the fit-for-purpose nature of the framework and provided some examples. In the following discussion, the importance of clearly laying out the rationale for grouping was emphasized, as was the linkage to problem formulation.

7. Dr Hirofumi Aizawa outlined a number of recent and planned OECD activities relevant to assessment of combined exposures, such as development of case studies, investigation of how the QSAR Toolbox can assist in hazard assessment of groups of chemicals, development of exposure models for co-occurrence of chemicals, development of a questionnaire for estimating aggregate exposure/health risk of biocides and conducting a scoping study on risk assessment of children's health to identify needs for further activities (including combined exposure).

8. The group discussed issues for further consideration in the area of risk assessment for combined exposures, such as methodologies for assessing exposures/risks from consumer products, the potential use of high throughput screening and biomonitoring data, and the Exposome project before adjourning for the day.

Second WHO Meeting on Global Collaboration in Chemical Risk Assessment
- Strengthening Capacity Building and Networking -

29-30 March 2012
WHO European Centre for Environment and Health, Bonn, Germany

Meeting Record

Opening and Welcome Address

9. Dr Michal Krzyzanowski, WHO European Centre for Environment and Health, Bonn welcomed participants to the Second WHO Meeting on Global Collaboration in Chemical Risk Assessment – Strengthening Capacity Building and Networking. Dr Krzyzanowski emphasized the importance of collaboration in the area of chemical risk assessment. He noted that the WHO European Centre for Environment and Health in Bonn is actively engaged in chemical safety projects. Dr Krzyzanowski announced that the Centre intended to be a strong supporter of the proposed WHO chemical risk assessment network to be further explored at this meeting.

10. Ms Carolyn Vickers of WHO thanked Dr Krzyzanowski for hosting the meeting and the Planning Group[1] for their efforts in organizing the workshop . She thanked Health Canada for providing staffing and financial resources in support of the meeting. Ms Vickers reminded participants about the WHO/IPCS Meeting on Strengthening Global Collaboration in Chemical Risk Assessment, held at WHO Headquarters in Geneva in March 2010, and recalled the four priority areas identified at that meeting (i.e. capacity building/training, chemical risk assessments/sharing knowledge, risk assessment methodology and research, as well as the recommendation that WHO establish an international chemical risk assessment network). It was noted that the March 2012 meeting is intended to follow up in particular on capacity building/training and the proposal to establish a network. It was indicated that, since the 2010 Meeting, WHO has engaged in numerous projects related to the priorities

[1] The Planning Group consisted of T. Vermeire (RIVM) (chair), M. Gulumian (University of Witwatersrand), A. Kadry (US EPA), B. Meek (University of Ottawa), S. Munn (EC JRC), M. Ruchirawat (Chulabhorn Research Institute), ECETOC (N. Carmichael), ILSI/HESI (S. Pettit/M Embry), Secretariat (C. Vickers and K. Hughes).

identified in that meeting, as outlined in Meeting Document 4, circulated to participants prior to the meeting.

Meeting Officers

11. After introduction of participants (Annex 1), the meeting elected Dr Theo Vermeire and Dr Mary Gulumian as co-chairs and agreed to the proposed arrangements for the breakout discussion group chairs and rapporteurs and the rapporteur for the session on proposed next steps (Dr Bette Meek).

12. Co-chair Dr Vermeire provided an overview of the goals of the meeting. These were to follow up on the recommendations of the 2010 Global Risk Assessment Meeting, by updating on progress to date and further exploring options for collaboration in the area of capacity building and training and to lay out next steps for the establishment of a WHO chemical risk assessment network. The agenda (Annex 2) was adopted.

Part A: Strengthening Capacity Building

13. The session on strengthening capacity building involved a series of invited presentations, followed by parallel breakout group discussions.

14. Ms Kathy Hughes presented an "Overview of capacity building needs from different countries/regions". This summary was based on the responses to the questionnaire circulated to various risk assessment institutions prior to the meeting, with analyses of commonalities and differences between low and middle income countries and developed countries in terms of current and potential future risk assessment activities and anticipated capacity and training needs to address emerging issues. The results of the survey suggested that low and middle income countries saw future challenges with assessment of more different types of chemicals, industrial processes and waste streams, while developed countries expected to face issues related to incorporation of advanced risk assessment methodologies and data from emerging testing technologies and other new sources. However, respondents saw a common need to increase capacity and training and enhance collaboration in order to face these challenges.

15. Dr Mathuros Ruchirawat outlined some needs of developing countries in terms of risk assessment training (highlighting the shortage of qualified personnel and a lack of understanding or basic knowledge of toxicology) and gave an overview of training activities at the Chulabhorn Research Institute, including the development of a Distance Learning Tool in collaboration with WHO/IPCS and the Universities of Ottawa and Utrecht. Dr Ruchirawat and Dr Kersten Gutschmidt then gave a live demonstration of the Distance Learning Tool,

noting its complementarity with the Human Health Risk Assessment Toolkit. Several of the modules of the Distance Learning Tool have been pilot tested in various fora. It is anticipated that the Distance Learning Tool will be made available to the public by February 2013.

16. Dr Elaine Faustman provided an overview of the size of the International Union of Toxicologists (IUTOX) and the wide geographical distribution of its members. Dr Faustman noted the range of venues at which training in the Risk Assessment Summer School had been offered and the large number of attendees at these courses. IUTOX has recently conducted a survey to identify training needs across member societies. As was seen in the WHO survey for this meeting, results indicated a need for training in both general risk assessment principles as well as complex methods. It was also noted that there was a need for students to apply their learning beyond case studies, perhaps through short stays at other institutions. It was also noted that students had set up a mechanism to maintain contact and share experiences after the formal training.

17. Dr Panagiotis Daskaleros recounted experiences with risk assessment training within the European Commission. It was noted that there is shortage of trained risk assessors to address increasing requirements, such as under REACH. Dr Daskaleros explained that the RISK ASSETS and TRISK projects were intended to be pilot activities to address these concerns. The approach to training under these projects has involved three pillars: development of guidelines, modular training courses and accreditation. Formal accreditation is seen to be key to levelling the playing field across the EU and ensure sustainability and global applicability.

18. Dr Becki Clark provided an overview of risk assessment products and activities of the United States Environmental Protection Agency (US EPA) and noted the need for training of risk assessors especially in an era of evolving scientific knowledge. Dr Clark outlined the EPA's Risk Assessment Training and Experience program, which consists of several modules and was developed in collaboration with other stakeholders. The program, which has been recently provided in a classroom setting, is planned to also be available on a web-based platform.

19. Dr Bette Meek provided an overview of experiences with uptake and implementation of WHO chemical risk assessment methodologies, such as physiologically based pharmacokinetic (PBPK) modelling, combined exposures and the Mode of Action/Human Relevance Framework. Dr Meek noted the need for risk assessment to be continually evolving and the requirement of the risk assessment community to adopt a broad approach, considering multiple information sources and mechanistic underpinning. Dr Meek described engagement mechanisms that have worked well, noting the importance of early, effective and continuous input from and collaboration with multidisciplinary and multistakeholder parties,

maximizing collective resources. Also important to effective engagement was having a flexible tiered approach to assessment, appropriate timing for the development and launch of new guidance, targeted training and simplification of concepts to increase understanding. Dr Meek also discussed some of the challenges including the continuing advancement of the science and constraints in regulatory mandates and resources.

20. Following the invited presentations, participants broke into four groups to discuss different related themes. These themes were: "Training and capacity building for risk assessment approaches in developed countries/regions; enhancing dissemination of training materials and support for implementation" (Chair Dr Raquel Duarte-Davidson, Rapporteur Dr Brian Priestly); "Training and capacity building for risk assessment approaches in low and middle income countries/regions; enhancing dissemination of training materials and support for implementation" (Chair Dr Abiola Olanipekun, Rapporteur Dr Jules de Kom); "Methodology development; enhancing uptake and implementation" (Chair Professor Alan Boobis, Rapporteur Dr Tiina Santonen) and "Information sharing; development of practical tools, methods to increase sharing" (Chair Dr Becki Clark, Rapporteur Dr Djien Liem). In the final session of the day, the groups presented the results of their discussions to plenary. The individual group reports are provided in Annex 3. Before closing, the meeting was informed that a consolidated summary of the session would be prepared by the Co-chairs and presented to plenary the next morning.

21. Co-chairs Dr Vermeire and Dr Gulumian summarized the key points emanating from the breakout group reports and subsequent plenary discussions. Several issues were identified:

    - The need for quality control for training courses/curricula as well as for training materials and tools. This could involve accreditation, establishment of rating systems, definition of core competencies for risk assessors, peer review by a network of experts and coordination by (for example) universities, research institutes, independent accreditation body, academic societies, or WHO Collaborating Centres.
    - The need to coordinate risk assessment activities and products; this would include mapping of a) training and other knowledge sharing activities, b) problem formulation, tools and methods for different tiers in the risk assessment process and c) peer reviewed assessments from internationally renowned sources and data sources. Coordination is also needed for quality control of training, methodology and assessments and for prioritization of capacity building needs and data.
    - The need for development of a strategy for training and knowledge sharing to enhance implementation of risk assessment approaches, which encompasses
        - choice of methods (e.g., case studies, e-learning, Distance Learning Tool, face-to-face, on-the-job, in-house, train-the-trainer, secondments, internships,

mentoring, partnerships/twinning between institutions, networking, workshops, conferences, or guidance/guidance documents),
    - tailoring of methods and content to the target audience (e.g., government, academia, industry, professional and community organizations, general public, etc.; different approaches may be required for developed versus low and middle income countries), and
    - structure of training (i.e., modular programs with geographical orientation).
- Consideration also needs to be given to how to ensure sustainability of training and how to ensure and maintain quality. This could involve engaging the research community to keep up to date with developing technologies; the IUTOX Risk Assessment Summer School was also used as an example of a training program that is regularly updated Sustainability will depend on commitment and network involvement.
- A strategy is also needed for raising awareness (in the short, medium and long term) through collaboration and networking options at local, national, regional and global levels.
- Need for funding and support (several suggestions were made, including partnerships with governments, industry, consultants, regional organizations, cost recovery approach, leveraging existing programs and groups, etc.). The World Health Organization was envisioned as playing a coordination/assistance role (WHO "stamp of approval" will help acquire funding) and the need for lead institutions to implement activities was noted.
- In terms of risk assessment methodology, issues affecting implementation include harmonization and varying regulatory mandates, limited resources, lack of scientific background, perceptions regarding uncertainty, and lack of communication. Suggested strategies for enhancing uptake and implementation were development of more case studies and a repository for these, mapping and coordination of products and activities, incorporation into continuing professional development, e-learning, etc., potentially with support from organizations such as WHO, the EU and others.
- New areas identified for development of methodology included: mapping of the various risk assessment tools and methods, use of high throughput data, exposure driven assessment, sensitivity analysis, value of information analysis, problem formulation, communication of uncertainties, and impact assessment/risk-risk comparison.
- With respect to information sharing, many different types of information were identified. Several needs and challenges were noted, including a mapping of data sources, prioritization of data sources, updating, translation and interpretation, training in data evaluation/selection/prioritization, etc., confidentiality and copyright issues, administration aspects (i.e., ownership, clearance to release) and access to underlying context/methods/tools. It was noted that many data needs are already

fulfilled or partly fulfilled; however, access to data on exposure scenarios, and overviews of research projects and work programmes were definitely considered to be currently inadequate.

- Several suggestions for enhancing information sharing were made, including establishment of a roster of experts for peer review (role for lead organizations), training on model and data selection (including developing guidance and extending existing training), creating "one stop shops" or sites to easily access up to date tools, developing harmonized formats for data submissions (involving an exchange of experiences), conducting research on local/regional exposure factors and creating partnerships.

Part B: Strengthening Networking

22. The session on strengthening networking involved a presentation to focus the day's deliberations, followed by parallel breakout group discussions in the morning and afternoon.

23. Carolyn Vickers gave a presentation summarizing the responses received on the questionnaire related to the proposed WHO chemical risk assessment network. Respondents had seen a network as providing value in the areas of knowledge and expertise sharing, methodology development and dissemination, training and collaboration and envisioned such a network playing a range of roles in these areas. Institutions saw themselves as being able to contribute primarily to training and provision of expertise, which track well with their expressed desired roles and functions. It was noted that the formation of a network will be determined by institution interest in participation, resources, priorities, and the added value that a network based at WHO can provide. Ms Vickers then outlined the various models of collaboration in which WHO has engaged to date, involving individual experts, bilateral and multilateral collaboration with institutions (including WHO Collaborating Centres and non-governmental organizations in official relations with WHO) and combinations of experts and institutions (such as the Harmonization Project). Ms Vickers closed her presentation with stating that the aim of the day's session was to discuss the design of the network, its goals, objectives, structure and function and options for implementation.

24. The theme for the morning breakout group discussions was the "Role/Function of a Risk Assessment Network". Chairs for the groups were Dr Christopher Weis (Rapporteur Dr Rohini Seneviratne), Dr Barry Kistnasamy (Rapporteur Dr Herman Autrup) and Ms Christine Norman (Rapporteur Dr Per Johansson).

25. In the afternoon session, the breakout group discussions focussed on "Practical Considerations for a Risk Assessment Network (funding needs, commitment requirements from members, membership)". Chairs for the groups included Dr Daniela Leonte

(Rapporteur Dr Koula Ziegler-Skylakakis), Dr Salmaan Inayat-Hussain (Rapporteur Dr Sam Adu-Kumi) and Dr Elaine Faustman (Rapporteur Dr Martin Wilks).

26. Session Rapporteur Dr Bette Meek opened the discussion on proposed next steps for the network by providing an overall summary of the recommendations from the morning and afternoon breakout group discussions (see Annexes 4 and 5 for individual group presentations). Based on this presentation and the ensuing discussion, the formation of a WHO chemical risk assessment network was strongly supported by meeting participants and the following proposed approach to the establishment of the network was outlined:

    - Next steps towards the establishment of the network were proposed to occur in a step-wise fashion over approximately the **next 12 months**.
    - This would involve the drafting of a **business plan** to acquire "seed money" and the creation of WHO convened **steering group** of activity leads and/or focal points. This would follow an **initial steering group** of interested parties to set up the network. The WHO would establish the governance structure of the steering group. The key task of the initial steering group would be to develop a **strategic plan** for the network which would take into consideration prioritization of needs and project areas/activities and include funding aspects; several potential sources of funding for the Network were suggested (e.g., national and supra-regional authorities, scientific societies, non-governmental organizations, development banks, cost recovery training, etc.).
    - **Contributors to the network** could include institutions (international, national and supranational), key individuals, professional and scientific bodies; WHO Collaborating Centres could also play an important role. A range of individual organizations had been mentioned over the course of the meeting as potential network contributors; however, the importance of involving OECD was noted in particular, given the work of the OECD on risk assessment methodology and chemical risk assessment information sharing at the international level. There should be **criteria for network contributors** (e.g., ability/willingness to actively commit time, financial or in-kind resources and disseminate information, involvement in risk assessment activities, not-for-profit institutions).
    - The network would be **project oriented**; projects could be international, regional, multilateral, or bilateral in scope. Activities or project areas would have **lead/champion institutions**. Development of WHO guidance and other materials bearing the WHO logo would be led by WHO, using the established processes.
    - It was envisaged that there would be need for periodic network meetings to share, evaluate and plan, using other means of communication between meetings (e.g. teleconferences).

- In order to maintain momentum and continue to move forward during the development of the strategic plan, **short term concurrent activities** to be carried out would include, in addition to continuing with on-going activities, the mapping and coordination of training/capacity building materials, activities and international and regional approaches, as well as implementing some training activities. Another short term concurrent activity would be the creation of a clearing house of information on activities, such as methodologies (including uptake), case studies and assessment work.
- Envisioned **longer term activities** of the network would relate to its function of providing a forum for identification of gaps, needs and emerging issues, scientific exchange and collaboration on risk assessment activities, identification of resources and mutual support.

27. In summing up, Co-chairs Dr Vermeire and Dr Gulumian thanked participants and asked that, when they return to their institutions, they give thought to the suggestions for next steps put forward at the meeting and how they as individuals and as institutions could potentially contribute to the network as a means to strengthen global collaboration in chemical risk assessment.

28. After the customary exchange of courtesies, the meeting was closed at 16:00.

ANNEX 1

Second WHO Meeting on Global Collaboration in Chemical Risk Assessment: Strengthening Capacity Building and Networking, with associated Workshop
Bonn, Germany

28-30 March 2012

List of participants

Sam ADU-KUMI, Environmental Protection Agency, Ghana

Alan BOOBIS, Imperial College London, United Kingdom

Becki CLARK , US Environmental Protection Agency, USA

Elaine COHEN HUBAL, US Environmental Protection Agency, USA

Sunitha Rohini DE ALWIS SENEVIRATNE, University of Colombo, Sri Lanka

Jules de KOM, Ministry of Health, Suriname

Thea de WET, University of Johannesburg, South Africa

Raquel DUARTE-DAVIDSON, Health Protection Agency, United Kingdom

Mary GULUMIAN, University of Witwatersrand, South Africa

Salmaan INAYAT-HUSSAIN, Universiti Kebangsaan, Malaysia

Per JOHANSSON, Swedish Chemicals Agency (KemI), Sweden

Barry KISTNASAMY, National Institute for Occupational Health, South Africa

Daniela LEONTE, National Industrial Chemicals Notification and Assessment Scheme (NICNAS), Australia

Oliver LICHT, Fraunhofer Institute, Germany

Mieke LUMENS, Utrecht University, Netherlands

Bette MEEK, University of Ottawa, Canada

Sharon MUNN, European Commission's Joint Research Centre, Italy

Christine NORMAN, Health Canada, Canada

Mattias OBERG, Karolinska Institute, Sweden

Abiola OLANIPEKUN, Federal Ministry of Environment, Nigeria

Jean-Nicolas ORMSBY, Agence nationale de securité sanitaire de l'alimentation, de l'environnement et du travail (ANSES), France

Brian PRIESTLY, Australian Centre for Human Health Risk Assessment (ACHHRA), Australia

Mathuros RUCHIRAWAT, Chulabhorn Research Institute (CRI), Thailand

Tiina SANTONEN, Finnish Institute of Occupational Health (FIOH), Finland

Theo VERMEIRE, National Institute for Public Health and the Environment (RIVM), Netherlands

Christopher WEIS, National Institute of Environmental Health Sciences, USA

Martin WILKS, Swiss Centre for Applied Human Toxicology, Switzerland

Kyriakoula ZIEGLER-SKYLAKAKIS, Secretariat of the Commission for the Investigation Of Health Hazards of Chemical Compounds in the Workplace Area (MAK Commission), Germany

SUPRANATIONAL ORGANIZATION REPRESENTATIVES

Herman AUTRUP, Public Health, Denmark/International Union Of Toxicology (IUTOX)

Hirofumi AIZAWA, Organisation for Economic Co-Operation and Development (OECD), France

Panagiotis DASKALEROS, European Commission, Belgium

Elaine FAUSTMAN, University of Washington, USA/International Union Of Toxicology (IUTOX)

Djien LIEM, European Food Safety Authority (EFSA), Italy

Syril PETTIT, International Life Sciences Institute (ILSI), USA

Kurt STRAIF, WHO International Agency For Research On Cancer (IARC), France

Henk VRIJHOF, European Centre For Ecotoxicology And Toxicology Of Chemicals (ECETOC), Belgium

WHO Regional Offices

Amir JOHRI, Centre for Environmental Health Activities, WHO Regional Office For Eastern Mediterranean (EMRO), Jordan

Michal KRZYZANOWSKI, WHO European Centre for Environment and Health, WHO Regional Office For Europe (EURO), Germany

Elizabet PAUNOVIC, WHO European Centre for Environment and Health, WHO Regional Office For Europe (EURO), Germany

Irina ZASTENSKAYA, WHO European Centre for Environment and Health, WHO Regional Office For Europe (EURO), Germany

Secretariat

Richard BROWN, World Health Organization, Switzerland

Kersten GUTSCHMIDT, World Health Organization, Switzerland

Kathy HUGHES, Health Canada, Canada

Carolyn VICKERS, World Health Organization, Switzerland

ANNEX 2

Second WHO Meeting on Global Collaboration in Chemical Risk Assessment
– Strengthening Capacity Building and Networking –

March 29-30, 2012 and Workshop March 28, 2012

Background:

At the March 2010 WHO Meeting on Strengthening Global Collaboration in Chemical Risk Assessment, participants identified a number of key issues and priority actions to address needs of the institutions engaged in chemical risk assessment and guide future activities of the risk assessment community internationally. Needs identified by institutions included those related to capacity building/training, chemical risk assessments/sharing knowledge, risk assessment methodology and research. Meeting participants also discussed means of strengthening collaboration globally to support chemical risk assessment, including the recommended option of establishing a WHO international risk assessment network.

A second WHO meeting is being convened to further facilitate and follow up on actions aimed at strengthening global collaboration that were recommended by the first meeting. A workshop on WHO Risk Assessment Methodologies is also being held in conjunction with the meeting.

Meeting Goals:

- To provide an update on tools developed to increase capacity globally in chemical risk assessment and propose strategies to enhance uptake of risk assessment methodologies.
- To further explore interest in participating in a WHO risk assessment network, to discuss the proposed network design in terms of vision, goals and objectives, structure and function, as well as to propose options for its implementation

A report of the meeting, summarizing recommendations for strengthening capacity building and networking, will be published by WHO on the internet.

Meeting venue:
WHO European Centre for Environment and Health
"Langer Eugen" Building (UN premises), Hermann-Ehlers-Strasse 10
53113 Bonn, Germany, Tel: +49 228 815 0415; Fax: +49 228 815 0440

Workshop on Risk Assessment Methodologies

28 March 2012

09:00 Registration

09:30 Workshop Opening.

- The workshop will be officially opened by WHO.
- Participants will be invited to introduce themselves.
- Practical announcements.

10:00 WHO Human Health Risk Assessment Toolkit *(S Inayat-Hussain & K Gutschmidt)*

11:10 Coffee

11:30 WHO Human Health Risk Assessment Toolkit *(continued)*

12:15 Lunch

13:30 Setting Early Life Age Groups for Chemical Risk Assessment: Geographical and cultural factors *(E Cohen Hubal & T De Wet)*

15:00 Coffee

15:20 Risk Assessment of Combined Exposures to Multiple Chemicals *(B Meek)*

16:40 Closing remarks

17:00 Welcome Reception

18:00 (approx): Meeting of the Planning Group

Second WHO Meeting on Global Collaboration in Chemical Risk Assessment – Strengthening Capacity Building and Networking
29-30 March 2012

Meeting Schedule

29 March

09:00 Registration

09:30 Meeting Opening.

- The meeting will be officially opened and participants welcomed.
- Approval of the Meeting Co-Chairs.
- Practical announcements.

10:00 Overview of Meeting Goals and Expected Outputs.

10:15 Plenary Presentations

- Overview of capacity building needs from different countries/regions *(based on responses from questionnaire) (K Hughes)*
- Experiences with recent international training materials *(Distance Learning Tools, WHO Human Health Risk Assessment Toolkit) (M Ruchirawat & K Gutschmidt)*

11:00 Coffee

11:20 Plenary Presentations (cont.)

- EU experiences regarding capacity building *(P Daskaleros)*
- US EPA experiences with risk assessment training activities *(B Clark)*
- Uptake and implementation of international risk assessment methodologies *(experience with strategies of engagement to promote understanding and uptake of guidance on evolving methodologies) (B Meek)*
- General Discussion

12.30-13.30 Lunch

13:30 Parallel Breakout Groups

Group A: Training and capacity building for risk assessment approaches in developed countries/regions; enhancing dissemination of training materials and support for implementation

- *Who are the targeted audiences for training and capacity building in developed countries?*
- *What type of training is most likely to be needed (i.e., general risk assessment approaches and/or newer methodologies)?*
- *What are the best mechanisms for training?*

- *How can the burden of training and developing training expertise be shared?*
- *Who should be responsible for maintaining consistency and quality in training materials?*
- *What are potential sources of funding for training in developed countries?*
- *What mechanisms could be developed to enhance the probability that risk assessment approaches are implemented in the targeted audience institutions?*
- *How can we ensure that of training materials are kept up to date, especially for advanced methodologies?*

Group B: Training and capacity building for risk assessment approaches in low and middle income countries/regions; enhancing dissemination of training materials and support for implementation

- *Who are the targeted audiences for training and capacity building in low and middle income countries?*
- *What type of training is most likely to be needed (i.e., general risk assessment approaches and/or newer methodologies)?*
- *What are the best mechanisms for training?*
- *How can the burden of training and developing training expertise be shared?*
- *Who should be responsible for maintaining consistency and quality in training materials?*
- *What are potential sources of funding for training in low and middle income countries?*
- *What mechanisms could be developed to enhance the probability that risk assessment approaches are implemented in the targeted audience institutions?*
- *Should follow-up be integrated into training/ capacity building initiatives? If so, how?*

Group C: Methodology development; enhancing uptake and implementation

- *Is it felt that risk assessment methodologies are being implemented in institutions conducting risk assessment to the extent that they could be?*
- *If not, what are some possible reasons that are impeding implementation?*
- *What strategies could be developed to enhance uptake and implementation?*
- *Are recent developments in methodology considered helpful by risk assessment programmes? Are they targeting appropriate areas?*
- *In what (additional) areas of risk assessment are new/updated methodologies needed?*

Group D: Information sharing; development of practical tools, methods to increase sharing

- *What types information relevant to chemical risk assessment would be of value to share?*
- *What are some current barriers to open sharing of this information?*
- *What strategies could be employed or tools developed (and by whom) to overcome these barriers?*
- *Which of these data needs are already being met and which are not currently being met?*
- *How would development and maintenance of these tools be funded/supported?*

15:45 *Coffee*

16:00 Breakout Group Reports and Discussion on Proposed Actions

17.30 *End of Day1.*

30 March

09:00 Announcements on practical matters.

09:05 Summary of Proposed Actions from the previous day.

09:30 Establishment of a WHO Chemical Risk Assessment Network *(Thoughtstarter based on questionnaire responses)* (*C Vickers*)

10:15 Coffee

10:35 Parallel Breakout Groups (n=3)

Role/function of Risk Assessment Network

- *What do you see as being specific objectives of the Network?*
- *What activities could be coordinated to achieve these objectives?*
- *What would be the key roles of the Network?*
- *How do you see the Network functioning?*
- *How do you see the Network interacting with other international risk assessment organizations on risk assessment projects? With national risk assessment programmes?*

11:40 Report to plenary from breakout groups

12:30 -13:30 Lunch

13:30 Parallel Breakout Groups (n=3)

Practical considerations for Risk Assessment Network (funding needs, commitment requirements from members, membership)

- *What are potential sources of funding for the Network?*
- *What activities should this funding support?*
- *Do you think that there should be criteria for membership in the Network?*
- *What should be obligations of Network members?*
- *What is the optimal structure of the Network?*

14:30 Report to plenary from breakout groups

15:20 Coffee

15:40 Plenary Discussion: Proposed Next Steps

16:30 Closing remarks

ANNEX 3

Breakout Group Presentations on Capacity Building/Training

Breakout Group A Report

Training and capacity building for risk assessment approaches in developed countries/regions; enhancing dissemination of training materials and support for implementation

Chair: Raquel Duarte-Davidson

Rapporteur: Brian Priestly

Who are the targeted audiences for training and capacity building in developed countries?

- Depends on whether audiences are early-career or experienced risk assessors, or whether the primary needs are for enhancement of skills in toxicology or related health/biological science disciplines, or for development of broader health risk assessment (HRA) skills
- The various sectors (government, academia, consultants, professional organizations; community NGOs or the general public) likely to encompass both categories
- Basic training and continuing education are both important
- Risk managers need general understanding but not necessarily a high level of technical expertise

What type of training is most likely to be needed (i.e., general risk assessment approaches and/or newer methodologies)?

- Needs to be tailored to the audience; therefore all tiers may be required
- New technologies need to be introduced at an appropriate time

What are the best mechanisms for training?

- Plenary sessions outlined US EPA, EU, IUTOX and WHO initiatives in HRA training
- Targeted in-house training and external degree-based courses
- Distance Learning has its place, but needs to be taken in context
- Short or modular courses and specialised workshops

- Facilitating attendance at relevant scientific congresses
- Published guidance documents
- On-the-job training, secondments, internships
- Importance of case-studies
- Importance of having mixed groups within training programs to share experiences
- The 'best' model depends on the circumstances of the relevant sector or agency and will use a combination of the above

How can the burden of training and developing training expertise be shared?

- Developing modular programs that are geographically distributed, using relevant expertise at different institutions
- Need to train the trainers?
- Sharing of knowledge gained - Can training of individuals translate to home institutions? (agencies unlikely to send large numbers of staff to training)
- May need to build a business model to justify the expenditures on any sharing model
- Sharing of knowledge, curricula and course elements, e.g. by creating modules that can be shared across different programs and universities, with trainees selecting modules that fit their development needs (provided that individual modules achieve an agreed quality standard)
- Need for an international coordinating body to oversee this?

Who should be responsible for maintaining consistency and quality in training materials?

- Need for quality assurance and course accreditation a common theme in many of the plenary presentations
- ….but who can/should provide this QA/accreditation?
- University course/curriculum managers with regular accreditation/oversight of course content and delivery
- How to ensure consistency across universities or other training institutions?
    - – an independent external authority or a national accreditation body or professional society?
- Will a research component strengthen the thinking process for trainees and move the field forward with developing technologies?
- Greater clarity around the core competencies required of a risk assessor and matching with training programs

What are potential sources of funding for training in developed countries?

- Funding for training should have a higher priority than funding for certification
- Training grants (only from governments?)
- Stakeholders (industry, consultants, government agencies) should be prepared to meet costs for their staff to attend training programs (but is this sufficient incentive for the courses to be offered)
- Some small amounts of funding in developing countries for women

What mechanisms could be developed to enhance the probability that risk assessment approaches are implemented in the targeted audience institutions?

- Apply the principles of 'implementation science'
- Conduct surveys of the application of knowledge gained
- Use of internships to transfer knowledge
- Proper evaluation versus testimonials to gauge course uptake
- Encourage trainees to bring relevant case studies to a course
- Repository of evaluated case studies
- Guidance on developing appropriate case study material
- Apply knowledge gained to retention and advancement of employees
- Application of knowledge gained to guidance manuals

How can we ensure that training materials are kept up to date, especially for advanced methodologies?

- Regularity of specified training programs (e.g. RASS) with regular updates of course material
- Other points already covered in previous discussion

Breakout Group B Report

Training & Capacity Building In Low & Middle Income Countries

Chair: Abiola Olanipekun

Rapporteur: Jules de Kom

Who are the target audiences for training & capacity building in low and middle income countries?

- Need critical mass of trainers; through academic institutions, train the trainer program
- Regulators of different ministries
- Technical assessors of different ministries
- Academia undergraduate and graduate programmes
- Industry
- Trade unions (risk communications)
- Community based organisations (idem)
- Senior management

What type of training is most likely to be needed (i.e., general risk assessment approaches and/or newer methodologies)?

- Strategy of training that is needed
- Credit points for training
- For each category of target audience we need same course, to have a basic knowledge at the same level, followed by different tiers and modules; selective and electives
- Risk assessors and regulators general training, in face to face setting
- Executive management, half-one day course
- Civil servants, in house service course

What are the best mechanisms for training?

- Primary mechanism for this group of countries face to face, (hand out documents, CDs), followed by distance learning training modules
- Introduce a graduate system with credit points and ratings
- There needs to be a coordination mechanism in place to deliver the training courses to avoid duplication from different sectors
- Exact mechanism for the coordination needs to be defined
    - Need to be flexible
    - Commitment issues
    - Etc.

How can the burden of training and developing training expertise be shared?

- Partnerships
- Networking; awareness raising
- Need to define a lead agency in the country

- Be aware of champions role of health sector
- Grouping and work on regional and sub-regional levels
- Develop expertise or critical mass, train the trainer on sub and regional levels and then go to country level
- Sustainability, short, long term
- Awareness, risk assessment is a tool that is available, promote it

Who should be responsible for maintaining consistency and quality in training materials?

- Different players, WHO facilitating the review
- WHO collaborating centres role
- Academic societies
- The institutions involved, guidance for new comers

What are potential sources of funding for training in low and middle income countries?

- Funding from government and industry, private partnership program models, pool versus discrete funding; middle income
- Funding for low income, strategies to access funding, e.g., through regional organisations, awareness how to approach funding
- Role for WHO to convince, bring them in as appropriate partner, to assess regional funding possibilities, countries need to take the lead

What mechanisms could be developed to enhance the probability that risk assessment approaches are implemented in the targeted audience institutions?

- Sensitisation and awareness, creating the demand at government level
- Information to the governments of activities that took place
- Establish collaboration centres
- Network

Should follow-up be integrated into training/capacity building initiatives? If so, how?

- Short, medium, and long term strategy, work plan, awareness raising
- Academy should play a role in the long term
- Sustainability depends on network involvement, commitment
- Gaps; transversal activities need to be supported

Breakout Group C Report

Methodology Development

Chair: Alan Boobis

Rapporteur: Tiina Santonen

Is it felt that risk assessment methodologies are being implemented in institutions conducting risk assessment to the extent that they could be?

- general consensus: no

Why?

- tight link between data requirements and risk assessment, may make risk assessment a box ticking exercise
- limited resources in risk assessment, lack of familiarity, lack of training or possibility to follow the science
- when we reduce uncertainty by using more accurate methods=>we end up less conservative risk assessment => perception is more risk
- lack of communication between risk assessors and risk managers => risk managers should be involved in the process
- lack of communication between risk assessors and research, e.g. modellers

What strategies could be developed to enhance uptake and implementation?

- development of real life case studies using different RA methodologies
    - how to constitute a good case study, who to involve, guidance needed?
- mapping of products/tools for RA, tools for different tiers
- mapping of tiers to the problem formulation (when to use tier 1 methods etc.)
- repository of e.g. case studies
- coordination of activities
- continuing professional development, maintenance of capacity through the University Centres, meeting of representatives of Universities
- elearning, EU/WHO support?

Are recent developments in methodology considered helpful by risk assessment programmes? Are they targeting appropriate areas?

- yes, but there is still lack of harmonization. However, main problem is implementation!

In what (additional) areas of risk assessment are new/updated methodologies needed?

- mapping of tiers, mapping of different tier RA tools
- how to handle high through-put data
- exposure-driven assessment
- sensitivity analysis, value of information analysis
- problem formulation
- how to communicate uncertainties, graphical presentation of uncertainties

Breakout Group D Report

Information sharing, development of practical tools, methods to increase sharing

Chair: Becki Clark

Rapporteur: Djien Liem

Type of information to be shared

- Completed assessments
- Methods and tools
- Chemical specific information, production & use levels, occurrence data (e.g. warehouse, repository, database, regulatory health based guidance values)
- Exposure factors: local, regional & national
- Different exposure scenarios

Type of information to be shared

- Burden of disease data
- Occupational exposure data (global project)
- Network of experts for peer review
- Supporting documentation/publications/guidelines
- Information on research projects, work programmes related to chemical risk assessments
- Chemical incidents/information on lessons learnt

Challenges

- Where to find what data?
- Standardised/harmonised formats for data submission
- Too much, how to order/prioritise?
- How to keep the information updated
- Confidential data
- Tools for prioritisation (e.g. reliability, …)
- Language problems

Challenges

- Disagreements due to differences in interpretation, different datasets, …
- Training of users of information
- Handling of personal data/data confidentiality
- Sharing attribution, copyright issues including costs
- Bureaucratic procedures (ownership & clearance)
- Access to underlying context, methods and tools of the assessments (overview is missing)
- Guidance and training on the methods and tools to be used (both a technical and perception issue)

Which of these data needs are already being met?

- Completed assessments: yes, probably not the whole universe and some only parts of the risk assessment (e.g. hazard assessments)
- There are many methods and tools already available e.g. OECD, QSAR toolbox, probabilistic modelling tools, CHESAR, ECETOC TRA, CONSEXPO, but one size does not fit all
- Chemical specific information, production & use levels, occurrence data , regulatory health based guidance values: situation is quite satisfactory for high production chemicals
- Exposure factors: data is available but not covering all continents; good food consumption data in EU
- Different exposure scenarios: access to data expected to improve (REACH) but still limited
- Burden of disease data : YES (WHO)
- Occupational exposure data: YES (e.g. ILO, IARC)
- Network of experts for peer review: limited
- Supporting documentation/publications/guidelines: some are available

- Information on research projects, work programmes related to chemical risk assessments: available, improves, but an overview is difficult to get
- Chemical incidents/information on lessons learnt: some national and WHO reports available, but not comprehensively captured

Strategies to overcome these barriers

- Establish a roster of experts for peer review and provide incentives for these experts
- Develop training on selecting which models to be used
- Encourage “one stop shops” for maintained tools
- Encourage the use of harmonised formats for data submission
- Research to establish local and regional exposure factors and leverage existing infrastructure

How to fund/support these tools

- Few organisations can take the lead to establish a network of peer reviewers
- Leverage existing training programmes to add guidance on selection and use of models
- Enhance exchanging experience in the use of harmonised data submission formats
- Strengthening partnerships with existing groups (e.g. OECD exposure task force)

ANNEX 4

Breakout Group Presentations on Role/function of Risk Assessment Network

Breakout Group A Report

Chair: Christopher Weis

Rapporteur: Rohini Seneviratne

What do you see as being specific objectives of the Network?

- To enhance the dissemination and uptake of new concepts and methodologies related to risk assessment in different countries, e.g. Provide particular resources. Contacts informal? To start addressing the issue i.e. Peer consultation
- Identify interest groups through dialogues, blogs, formal?
- Consensus building, as a focus group, identify key issues/priorities for research
- Capacity building /training in core concepts
- Support implementation in countries which have not taken up risk assessment
- Disseminate information on best practices
- To create opportunities for collaboration
- Share work programmes, cooperate and harmonise methodologies for risk assessment
- Set up databases for sharing and to contribute new information
- Identify emerging issues, discrepancies/agreements
- Stimulate collection of data and information including nomenclature, search terms etc.

What activities could be coordinated to achieve these objectives?

- Creation of a framework for identification of champions, an institution, organization, region?
- Identify a mechanism for posing problems
- Identify members of the network, (individuals and centres) able to contribute in terms of the resources, subject matter/experts, and specific areas of support
- Identify key areas for collaboration and funds

What would be the key roles of the Network?

- Raise the visibility of the role of risk assessment (before risk management) for early intervention
- Dissemination to a wider audience, assessors, managers, authorities including
- Capacity building in core competencies
- Identification and promotion of research
- Collaboration in above areas

How do you see the Network functioning?

- Consensus building among members on guidelines, methodologies
- Identify a steering group
- Communication network, web
- Follow up activities
- Exchange of personnel, secondment

How do you see the Network interacting with other international risk assessment organizations on risk assessment projects? With national risk assessment programmes?

- Through interactions, posting notices
- Provide support , identify experts, opportunities, workshops, through professional societies, national risk assessment programmes
- Calendars of events and activities

Breakout Group B Report

Chair: Barry Kistnasamy

Rapporteur: Herman Autrup

What do you see as being specific objectives of the network?

- Establishment of network –individual and institution and professional bodies
- Coordination of capacity building in risk assessment
- Development of new methodologies and integrating into training courses

- Clearing house function platform
    - Updated material
    - Case studies repository
    - Learning opportunities
- Coordination of training

What activities could be coordinated to achieve these objectives?

- Development of a strategic plans – mission, vision, objectives
    - roadmap (dynamic)
- Identify other partners -
- Coordination
    - Capacity building
        - Curriculum and material
        - Review and update of existing training material
    - Information sharing regional and global level Collaborating centers
        - Capacity and involvement in training center
        - Resources individuals and economy

What would be the key roles of the Network?

- Clearing house and identification of new partners
- Identification of possibilities
- Complementarity and mutual support

How do you see the network functioning?

- Core – involvement of WHO Headquarters
- regional, country, collaboration between these network partners – multilateral and bilateral

With national risk assessment programmes?

- Training workshop should not be duplicated
    - UN and national agencies, special interest group
- Information sharing – access to data bases

- Learning opportunities
- Policy and advocacy – funding opportunities

Breakout Group C Report

Chair: Christine Norman

Rapporteur: Per Johansson

What do you see as being specific objectives of the Network?

- Capacity building – training needs different between organisations
- Information sharing
    - info on ongoing activities
    - between different areas of RA (e.g. pesticides – occupational health)
    - harmonisation of methodology (sharing, not development), feedback to methodology development projects
- Coordination, including regional cooperation
- What is out of scope?

What activities/roles could be coordinated to achieve these objectives?

- Short term
    - Mapping common background, identify needs, barriers, organizational and individual expertise
    - Identify elements of training objectives
        - Core competencies
        - Links to existing material
        - Exchange opportunities (e.g. mentorships, exchange of personnel)
- Medium term
    - Priority setting based on identified needs
    - Facilitating training efforts (e.g. identify potential training individuals/organisations in specific regions/countries)
    - Training modules
    - Exchange training material, repository. Case studies. Needs coordination
    - Evaluate training

- Long term
    - Improving risk assessment through research

How do you see the Network functioning?

- Coordinating group / steering group
    - Milestones, common work plans, project oriented
    - Periodic review
- Tools/mechanisms for sharing information online
    - Dedicated website
    - Periodic meetings
- Adaptability for changing functions over time
- Focal points for specific activities (champions)
- Focal points for each network member

How do you see the Network interacting with other international risk assessment organizations on risk assessment projects? With national risk assessment programmes?

- International/national/supranational organisations (e.g. OECD, USEPA, EC) as part of network
- Membership would include professional and scientific bodies
- Individual organisations (champions) for specific activities

ANNEX 5

Breakout Group Presentations on Practical Considerations for Network

Breakout Group A Report

Chair: Daniela Leonte

Rapporteur: Koula Ziegler-Skylakakis

What are potential sources of funding for the network?

Stepwise approach:

- Stage 1: Funding to kick off, seed money (SAICM could be a potential donor)
  - Core group to act as catalyst
- Stage 2: Funding to maintain the network by searching for target specific donors (Potential sources for funding: national and supra-regional authorities, scientific societies, NGOs, commercial organizations, development banks)
  - Broaden the term "funding"

What activities should this funding support?

- Initially:
  - IT – teleconferences
  - Communication
  - Compilation of training material
- Support for the network and steering committee
  - Secretariat

Do you think that there should be criteria for membership in the Network?

- (Time) commitment of man power
- Risk assessment activity of the members
- Different tiers in the Network
- Screening criteria for the steering committee

- Network with defined membership and then dissemination of information
- Minimum number of organisation members and of organisations?
- Relevant job responsibilities
- Active contributors / people accessing information

What should be obligations of Network members?

- Why do contributors have obligations?
- Share experience, materials and resources (free and open to everybody)
- Host meeting if possible
- Attend meetings
- Communication
- Contribute to the development/growth of the Network
- Identify a lead person acting as contact
- Coordinate within your own organization but also use internet contacts
- Conduit for information on risk assessment activities coming out WHO and other organization bodies.
- Provide regular updates

What is the optimal structure of the Network?

- Steering committee
- Two tiers approach of the steering committee:
    - nucleus to drive the policies
    - setting up a representative group of people for the network
- Full time secretary (one of the network partners)
- Serving term on rotational principle
- Regional versus global network

Next step: Develop a strategic plan coordinated by WHO with the help of the workshop participants

Breakout Group B Report

Chair: Salmaan Inayat-Hussain

Rapporteur: Sam Adu-Kumi

What are potential sources of funding for the Network?

- Activities identified :
    - Setting up IT system
        - WHO IT platform available
        - Salary
        - Administrative unit
        - Steering group
        - Dissemination of information
- Capacity training
    - Fellowship for participants
    - Organisational expenses
- Steering group
    - Have a plan of action
    - Initiate activities
    - Organise group meeting in group
    - Time commitments on the part of members/in kind contribution

What are potential sources of funding for the Network?

- Grants and contributions
- US National Institute of Environmental Health Sciences (U13 or R13)
- ADB
- WB
- Inter-American Development Bank
- SAICM (QSP?)
- WHO Regional Offices (have potential to facilitate in the raising of funds)
- Professional societies
- PPP
- Country driven projects (within MDAs)
    - organise executive meetings/sensitisation
- Matching funds (WHO and countries)

- Professional societies
- Cost recovery (organisations pay course fees)

Do you think that there should be criteria for membership in the Network?

- Yes, flexible
- Open network (non-exclusiveness)
- Organisational participation
- Possibility for individuals/experts with credentials
    - Academicians
    - Organisations

What should be obligations of Network members?

- Contributions (Organisations or individuals)
    - Active participations required

What is the optimal structure of the Network?

- Steering committee
- Regional/sub-regional in scope
- Short-term and long term
- Over-arching areas for global and regional issues on risk assessment
- Initial meetings by WHO to produce plan of action
- Expression of interest to be sought by end of today's meeting
- Phased implementation

Breakout Group C Report

Chair: Elaine Faustman

Rapporteur: Martin Wilks

What activities should be funded?

- Sources of funding should be activity based
- Can be in kind or actual
- Different activities require different sources of funding
    - Management focus: governance, administration, coordination
        - International organizations?
    - Science focus: capacity building, databases, research, new methods, translation
        - Direct through projects

Potential sources of funding for the Network?

- Industry / public sector partnership: guidelines need to be set up
- Good examples exist
    - Health Effects Institute (USA)
    - Mine safety (levies for specific legacy problems (can be used for capacity building))
    - Product specific; breast implants
    - Non-competitive research, e.g. Innovative Medicines Initiative
- Regional sources
    - Development Banks (Asia, Africa)
    - Government programmes (Australia)
- Private foundations
- Partner schemes (e.g. EU & other countries), science-based
- Professional societies

Do you think that there should be criteria for membership in the Network?

- Need to define what functions are specific to the network
- Criteria for membership
    - Not-for-profit
    - Is there room for ‘passive‘ membership?
    - Users of products vs. members
- Collaborating centres are one part of the network (nucleus, sustaining), there are others
- What’s special about networking activities as opposed to others, e.g. in professional societies?
    - Not mutually exclusive

What should be obligations of Network members?

- Strategic plan should define obligations
- Needs basic rules
    - Ethics, quality standards, governance, intellectual property, etc.
- Contractual arrangement with coordinating centre?
    - How formal can / should this be?
- Stepwise process