This Newsletter provides an update on WHO/IPCS Harmonization Project activities in 2010.

**Risk Assessment Toolkit**

The WHO Human Health Risk Assessment Toolkit delivers practical tools for risk assessment in a user-friendly format, in particular for developing countries and countries with economies in transition. The Toolkit provides “road maps” for addressing common risk assessment problems, along with illustrative case examples. In 2010 the Toolkit was finalized following pilot testing in a number of developing countries. The Toolkit is available from:


WHO is participating in a project led by the WHO Collaborating Centre at the Chulabhorn Research Centre, Thailand, to develop distance learning materials in risk assessment. The distance learning materials will draw upon and complement the WHO Human Health Risk Assessment Toolkit.

**PBPK Modelling**

Following public and peer review, final guidance has been published on “Characterizing and Applying Physiologically based Pharmacokinetic Models in Risk Assessment”. The primary goal of the guidance is to document the key principles and best practices for characterizing and applying PBPK models in chemical risk assessment. These principles are presented both for risk assessors who need to evaluate PBPK models for use in risk assessment as well as for PBPK modellers who are interested in developing models capable of risk assessment applications. The guidance is available at:

http://www.who.int/entity/ipcs/methods/harmonization/areas/pbpk_models.pdf

**Immunotoxicity**

Harmonized guidance on Immunotoxicity Risk Assessment is being developed. Draft guidance, along with a series of illustrative case studies, was released for public and peer review in November 2010. Comments are due by 31 January 2011.


**Combined Exposures to Multiple Chemicals**

A Framework for Risk Assessment of Combined Exposures to Multiple Chemicals has been further developed following public and peer review, and three case studies finalized. As at January 2011 the framework was in press. The public review draft is available at:


A WHO OECD ILSI/HESI International Workshop on Combined Exposures is scheduled for 15-16 February 2011. The workshop aims to inform participants about the WHO framework, share information about current issues in combined exposure assessment and identify needs for further work on combined...
exposures. The outcomes of the workshop will be considered by WHO, OECD and other interested stakeholders.

**Mode of Action**

A meeting held 14-15 October 2010, at Imperial College, London, agreed an Umbrella Plan for future international work on "Mode of Action", including activities in the following areas: A. Update of the WHO Mode of Action Framework Guidance; B. Development of Case Studies to illustrate the updated guidance; C. Implementation of MOA in category approaches to the assessment of chemicals; D. Education; and E. Development of an MOA Database. A international Steering Committee was established to oversee implementation of the Umbrella Plan. Activities will be implemented in collaboration with risk assessment institutions. For further information, contact the WHO Harmonization Secretariat.

**Identifying Early Life Stages for Characterizing Chemical Exposures**

This project aims to develop a practical tool for countries to explicitly consider early life stages in chemical risk assessment. Age and life-stage related differences in behaviour and physiology determine critical windows of susceptibility as well as the appropriate distribution of exposure factors required to address specific exposure scenarios. In addition, age and life-stage (as well as geographical and cultural) differences in nutrition, disease, and how people interact with the environment may be major determinants for identifying the individual or population most vulnerable to risks from particular exposures to environmental contaminants. In 2010 the basis for guidance was developed. Planning for an international meeting is underway.

**Guidance on Uncertainty and Variability in Hazard Assessment**

This project will develop WHO guidance on characterizing and communicating uncertainty in chemical hazard assessment and guidance in relation to the uncertainty and variability underlying the various default assessment factors and dose-response methods used in human threshold effects assessment. The guidance will form a companion document to the WHO/IPCS document on characterizing and communicating uncertainty and variability in exposure assessment (IPCS/WHO, 2006). In 2010, draft documentation was prepared and discussed at an expert meeting held on 16-17 September at RIVM, Bilthoven, The Netherlands. The document will be further developed and released for public comment.

**Interpreting effects that may be modest or adaptive**

An initial draft document has been developed addressing the interpretation of effects in toxicity studies that may be modest or adaptive. Following further development the draft will be released for comment.

**Strengthening Global Collaboration in Chemical Risk Assessment: A WHO Risk Assessment Network**

In March 2010, WHO convened a meeting on Strengthening Global Collaboration in Chemical Risk Assessment. This meeting discussed current needs in chemical risk assessment and priority areas for development of methodologies, and cooperation on training. The meeting supported the establishment of a WHO chemical risk assessment network. Recommendations of the meeting are being implemented through the WHO chemical safety risk assessment programmes. Activities on risk assessment of chemicals, including CICADs, and activities on Harmonization of methodologies have been brought together under the umbrella of the network. Risk Assessment institutions interested in joining the network are invited to contact the WHO Secretariat.

**More about the IPCS Harmonization Project**

Visit the WHO/IPCS website at:


Contact the WHO Harmonization Secretariat:

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