

The IPCS Harmonization Project

September 2008 Newsletter

What is happening in the IPCS Harmonization Project?

This Newsletter provides an update on the various events and activities that have taken place under the WHO/IPCS Harmonization Project since the December 2007 Newsletter. These activities cover a number of areas, as described below, which are included in the current 2007-2009 Project Workplan.

Risk Assessment Toolkit for country use

A draft risk assessment toolkit has been prepared following an expert meeting in March 2008 in Montreux, Switzerland. This activity marks a new emphasis of the Harmonization Project to make the international tools and guidance available on chemical risk assessment more readily-accessible in the form of a "toolkit" and to provide related training materials including case study examples of use of the tools. Key target groups and audience for the toolkit are developing countries and countries with economies in transition. The toolkit will deliver practical tools for risk assessment in a user-friendly format.

The draft will be considered and refined by the expert group over September-November 2008. The next phase of the project will involve pilot testing in countries, to inform further development of the toolkit.

 http://www.who.int/ipcs/methods/harmonization/areas/ra_toolkit/en/index.html

Aggregate/cumulative risk assessment (combined exposures to multiple chemicals)

A draft Framework to Consider Combined Exposures in risk assessment is nearing completion for release for public and peer review from September 2008. An illustrative case study will accompany the draft. During 2009 further case studies will be developed to assist the further refinement of the framework. An international workshop to finalize the framework is planned for late 2009.

 <http://www.who.int/ipcs/methods/harmonization/areas/aggregate/en/index.html>

Immunotoxicity

Harmonized guidance on Immunotoxicity Risk Assessment is being developed. A meeting to discuss the draft document will take place at RIVM, Bilthoven, The Netherlands, on 4-7 February 2009. This new activity will build on the WHO/IPCS Environmental Health Criteria documents on immunotoxicology.

 <http://www.who.int/ipcs/methods/harmonization/areas/immunotoxicity/en/index.html>

Mutagenicity

An expert meeting to finalize guidance on Mutagenicity Testing for Chemical Risk Assessment took place on 30 June-1 July 2008, at the University of Bradford, United Kingdom. The final text is being edited.

 <http://www.who.int/ipcs/methods/harmonization/areas/mutagenicity/en/index.html>

Skin Sensitization

The report of the 2006 Berlin Sensitization workshop has been published in Regulatory Toxicology and Pharmacology (see <http://dx.doi.org/10.1016/j.yrtph.2007.11.008>) The Harmonization Project publication version of the document is now available on the IPCS web site.

 <http://www.who.int/ipcs/methods/harmonization/areas/sensitization/en/index.html>

PBPK modelling

The draft PBPK (physiologically-based pharmacokinetic) guidance on "Principles of Characterizing and Applying PBPK Models" (along with illustrative case studies) has been completed for release for public and peer review from September 2008. An international workshop will take place in 2009 to finalize the guidance.

 <http://www.who.int/ipcs/methods/harmonization/areas/pbpbk/en/index.html>

Harmonization Project Training Group

This is a new group collaborating on the training aspects of the Harmonization Project. Membership of the Group comprises: interested members of the Harmonization Steering Group or experts from their organizations; and a number of NGOs in official relations with WHO (ECETOC; ILSI Research Foundation; IUPAC and IUTOX).

The Training Group had its first teleconference in July 2008 and discussed ways to gather experience to date in training under the Harmonization Project and to implement this in new activities. As well as facilitating uptake and use of the products of the Harmonization Project through communication, outreach and training activities, the Group will: collaborate in and lead the development and maintenance of training materials, including distance learning tools; and form partnerships with others (e.g. professional societies, organizations conducting training) to support the above and to facilitate integration of the products into general training on risk assessment.

Exposure Assessment

The guidance document on **Data Quality** in Chemical Exposure Assessment is in the final stages of editing. It will be soon co-published with the guidance on "**Characterizing and Communicating Uncertainty** in Exposure Assessment" (Harmonization Project Document No. 6 already available as a PDF file on the website). A Continuing Education Course on Characterizing and Communicating Uncertainty in Exposure Assessment will be delivered at EUTOTOX 2008, 5 October 2008, in Rhodes, Greece.

 <http://www.who.int/ipcs/methods/harmonization/areas/exposure/en/index.html>

Non-Cancer Mode of Action (and Cancer MOA)

The article on the IPCS non-cancer human relevance framework has been published in Critical Reviews in Toxicology (see <http://dx.doi.org/10.1080/10408440701749421>). The two-part Harmonization Project publication (Part 1: Cancer; Part 2: Non-cancer) is also available on the IPCS webpages.

 http://www.who.int/ipcs/methods/harmonization/areas/non_cancer/en/index.html

 <http://www.who.int/ipcs/methods/harmonization/areas/cancer/en/index.html>

More about the IPCS Harmonization Project

The next meeting of the **Harmonization Steering Committee** will take place in late 2009.

Please also visit the WHO/IPCS website at:

 <http://www.who.int/ipcs/methods/harmonization/en/>

This site provides more information about the Project, how the work is organized, meetings of the Project Steering Committee, Brochure, details of activities, regular updates and the list of publications. Please send your comments and suggestions on the Harmonization Project to Carolyn Vickers at the Harmonization Secretariat:

 By e-mail to: **IPCSharmonize@who.int**

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