

## The IPCS Harmonization Project

### December 2007 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 August 2007 Newsletter. These activities cover a number of areas, as described below, which are included in the current Project Workplan for 2007-2009.

The report of the May 2007 meeting of the Harmonization Project Steering Committee, the revised strategic plan and the 2007 brochure containing the new workplan are now available on the Project website.

#### Aggregate/cumulative risk assessment

Following the March 2007 International Workshop on this topic and a recommendation of the May 2007 Harmonization Steering Committee meeting, a Planning Group is developing a draft framework for aggregate/cumulative risk assessment (along with case studies). The draft will be released for public and peer review comment (scheduled for 2008).

#### PBPK modelling

The Harmonization Project activity on PBPK (physiologically-based pharmacokinetic) modelling aims to promote best practice in PBPK modelling, including transparency, and will result in a high-level guidance document on "Principles of Characterizing and Applying PBPK Models". The PBPK planning group met in Buxton, UK, on 5-6 November 2007 to further develop the document, which will be released for public and peer review comment (scheduled for 2008). Following this, an international workshop will take place, either in late 2008 or early 2009.

#### Exposure Assessment

The Guidance on "**Characterizing and Communicating Uncertainty** in Exposure Assessment" is in press. A symposium on this topic was presented at the ISEA annual Conference in October 2007.

Experts are considering the comments received on the draft guidance document on **Data Quality** in Chemical Exposure Assessment. The guidance will be co-published with the above document on Uncertainty in Exposure Assessment.

For information about additional exposure assessment activities, please visit <http://www.who.int/ipcs/methods/harmonization/areas/exposure/en/index.html>

#### Mutagenicity

The public comment period on the Mutagenicity Testing document (i.e. revision of the 1996 IPCS Qualitative Scheme) closed at the end of November 2007. The expert meeting to finalize the document is planned for mid 2008.

For more information, visit <http://www.who.int/ipcs/methods/harmonization/areas/mutagenicity/en/index.html>

## Guidance for immunotoxicity risk assessment

**New!**

An expert scoping meeting to plan the development of guidance on immunotoxicity risk assessment is scheduled for 28-29 February 2008 at the WHO Collaborating Centre for Immunotoxicity and Hypersensitivity at RIVM, Bilthoven, The Netherlands. This new activity will build on the WHO/IPCS Environmental Health Criteria documents on immunotoxicology.

## Risk Assessment Toolkit for country use and Guidance on problem formulation

**New!**

A meeting on the development of a chemical risk assessment toolkit for country use, immediately followed by a meeting to develop tools for problem formulation have been scheduled for 5-7 March 2008, in Montreux, Switzerland.

## Skin Sensitization

The report of the 2006 Berlin Sensitization workshop has been accepted for publication in Regulatory Toxicology and Pharmacology. The workshop summary can also be downloaded from:

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

## Non-Cancer Mode of Action

The Critical Reviews in Toxicology article on the IPCS **Non-cancer** human relevance framework (published in 2006 along with three case studies) is expected in early 2008. For information on the **Cancer** Mode of Action activity visit: <http://www.who.int/ipcs/methods/harmonization/areas/cancer/en/index.html>

## Guidance on interpreting effects that may be modest or adaptive

**New!**

Consultation is underway to elicit further views on issues to be addressed in this activity.

## Harmonization Project Training Group

**New!**

This is a new group of members interested in collaborating on development of the training aspects of the Harmonization Project. Its functions will include:

- Facilitate uptake and use of the products of the Harmonization Project through communication, outreach (e.g. the website) and training activities, as well as promotion of products at international conference symposia, continuing education sessions, etc.
- Collaborate in and lead the development and maintenance of training materials, including distance learning tools.
- 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.

## More about the IPCS Harmonization Project

**The 2007 Brochure is available!** Please download it from 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, 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**

 By fax to: **+41 22 791 4848**