



International Programme on Chemical Safety Harmonization Project

What is the Harmonization Project?

The World Health Organization (WHO)/IPCS *Project on the Harmonization of Approaches to the Assessment of Risk from Exposure to Chemicals* ("Harmonization Project"), aims to harmonize global approaches to risk assessment by:

- ◆ increasing understanding and agreement on basic risk assessment principles
- ◆ developing international guidance documents on specific issues.

The Project enables risk assessments to be performed using internationally accepted methods and these assessments can then be shared to avoid duplication of effort. It translates advances in scientific knowledge into new harmonized methods, promotes transparency in risk assessment, and reduces unnecessary testing of chemicals. The project benefits all those involved in chemical hazard/risk assessment (chemical assessment authorities and other risk assessment bodies, professionals, and researchers).

The Goal of the Harmonization Project

To improve chemical risk assessment globally, through the pursuit of common principles and approaches and hence, strengthen national and international management practices which deliver better protection of human health and the environment within the framework of sustainability.

Reference: Harmonization Project Strategic Plan

How is the Harmonization Project managed and organized?

The Project is coordinated by WHO. The Project workplan is updated, approximately every two to three years, based on input from national and regional risk assessment institutions and experts, and non-governmental organizations in official relations with WHO.

Workplan activities are usually carried out by expert working groups, under the management of WHO, and involve a process of public and peer review. The Chairs of the working groups form an advisory **Core Group** which meets regularly by teleconference to share information among the activities and to provide advice to WHO on the Project.

The broad directions for the work are set out in the Harmonization Project **Strategic Plan**, with **Workplans** providing more detail.

Main publications of the Project

- ◆ **IPCS Risk Assessment Terminology. Part 1: IPCS/OECD Key Generic Terms used in Chemical Hazard/Risk Assessment; Part 2: IPCS Glossary of Key Exposure Assessment Terminology** (*Harmonization Project Document No. 1, 2004*)
<http://www.who.int/ipcs/methods/harmonization/areas/ipcsterminologyparts1and2.pdf> [pdf 973kb]
- ◆ **Harmonized Nomenclature for Developmental Toxicology** (regularly updated database)
http://www.who.int/ipcs/methods/harmonization/areas/repro_dev/en/index.html
- ◆ **Chemical-Specific Adjustment Factors for Interspecies Differences and Human Variability: Guidance Document for Use of Data on Dose/Concentration-Response Assessment** (*Harmonization Project Document No. 2, 2005*)
http://whqlibdoc.who.int/publications/2005/9241546786_eng.pdf [pdf 732 kb]
- ◆ **IPCS Conceptual Framework for Evaluating a Mode of Action (MOA) for Chemical Carcinogenesis**, *Regulatory Toxicology and Pharmacology*, 34 (2001): 146-152
<http://www.who.int/ipcs/methods/harmonization/areas/cancer/en/index.html>
- ◆ **Principles of Characterizing and Applying Human Exposure Models** (*Harmonization Project Document No. 3, 2005*)
http://whqlibdoc.who.int/publications/2005/9241563117_eng.pdf [pdf 538 kb]
- ◆ **IPCS Frameworks for Analyzing the Human Relevance of a Cancer and Non-Cancer Mode of Action for Humans** (*Harmonization Project Document No. 4, 2007 Part 1: Cancer and Part 2: Non-cancer*). Also appeared in *Critical Reviews in Toxicology* 36 (2006); 781-835 and 38 (2008), No. 2, 87-96
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>
- ◆ **Report of a WHO/IPCS International Workshop on Skin Sensitization in Chemical Risk Assessment** (*Harmonization Project Document No. 5, 2008*)
<http://www.who.int/ipcs/methods/harmonization/areas/sensitization/en/index.html>
- ◆ **Guidance Document on Characterizing and Communicating Uncertainty in Exposure Assessment** (*Harmonization Project document No. 6, 2008: Part 1*).
http://www.who.int/entity/ipcs/publications/methods/harmonization/exposure_assessment.pdf
- ◆ **Hallmarks of Data Quality in Exposure Assessment** (*Harmonization Project document No. 6, 2008: Part 2*).
http://www.who.int/entity/ipcs/publications/methods/harmonization/exposure_assessment.pdf
- ◆ **Assessment Of Combined Exposures To Multiple Chemicals: Report of a WHO/IPCS International Workshop** (*Harmonization Project document No. 7, 2009*)
<http://www.who.int/entity/ipcs/methods/harmonization/areas/workshopreportdocument7.pdf>
- ◆ **Mutagenicity Testing for Chemical Risk Assessment: Update of the WHO/IPCS Harmonized Scheme**. Published in *Mutagenesis* vol. 24 no. 4 pp. 341–349, 2009 doi:10.1093/mutage/gep014
<http://mutage.oxfordjournals.org/cgi/content/full/gep014?ijkey=Tu0KSLJmMJoa9J&keytype=ref>

Activities on the Workplan for 2010-2011

- ◆ Finalization of a framework for risk assessment of **combined exposures** to multiple chemicals (along with case studies) and subsequent training activities.
- ◆ Finalization of guidance document on **PBPK (physiologically-based pharmacokinetic) modelling** (along with case studies) and subsequent training activities.
- ◆ Maintenance and promotion of various harmonized **terminology** collections, including the harmonized morphological terminology for developmental toxicity.
- ◆ Publication of a **Human Health Risk Assessment Toolkit**, development of additional case studies, and training activities focussing on developing countries.

- ◆ International coordination of activities on **Mode of Action** through a Steering Committee, and update of the WHO/IPCS guidance.
- ◆ Guidance on **Immunotoxicity risk assessment for chemicals**.
- ◆ Guidance on **characterizing and communicating uncertainty and variability** in hazard assessment
- ◆ Guidance on **Identifying early life stages for characterizing chemical exposures**
- ◆ Guidance on **interpreting effects in toxicity studies** that may be modest or adaptive
- ◆ Further development of an international **network of risk assessment bodies**.

SAICM and the Harmonization Project

The Project contributes to SAICM (Strategic Approach to International Chemicals Management) in particular by addressing the objective on Risk Reduction and the Global Plan of Action activity to "**Develop and use new and harmonized methods for risk assessment**". For more information visit http://www.who.int/ipcs/features/saicm_revised/en/index.html

More about the Harmonization Project

Please visit the website

- ◆ www.who.int/ipcs/methods/harmonization/en/

In addition to existing publications, a range of related documents, such as background documents and meeting reports, are also available on this website.

To obtain further information or send comments and suggestions on the Harmonization Project, please contact the Harmonization Secretariat:

- ◆ By e-mail to: **IPCSharmonize@who.int**
- ◆ By fax to: **+41 22 791 4848**