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The International Programme on Chemical Safety

The IPCS Harmonization Project

2004 Stocktake Analysis Summary

Objectives of the Stocktake

In the second half of 2004, IPCS conducted a Stocktake of the Harmonization Project with the objectives of:

- evaluating the outcomes of the Project since its inception in 1993-1994
- collecting feedback on the use and usefulness of the Products of the Project
- identifying any gaps or issues to be addressed
- gathering proposals for future work.

The Stocktake outcomes were discussed by the Harmonization Steering Committee at its 7th meeting in October 2004. The results helped both shape the future of the Project and prepare the new Project Strategic Plan for 2005-2008.

Approach for undertaking the Stocktake - Three survey questionnaires

The Stocktake involved a series of three questionnaires, relating to the experience of the following groups:

- chemical assessment authorities - Survey No. 1 (S1)
- experts who have been involved in the work of the Harmonization Project - Survey No. 2 (S2)
- experts who have not been involved in the work of the Project - Survey No. 3 (S3).

The three surveys were organized in a similar way, although the specific questions differed slightly, depending on the past/current involvement of the respondents in the Harmonization Project.

Distribution and timing

Approximately 265 requests to complete a survey (either Survey 1, 2 or 3) were sent out in mid-July 2004 (e-mail and website). The majority of survey recipients had no previous involvement in the project. The following groups were included in the survey distribution:

- Harmonization Steering Committee members
- IPCS expert committee members (past and present)
- Standard IPCS lists of experts who are invited to peer review documents
- Recent JMPR (FAO/WHO Meeting on Pesticide Residues) and JECFA (Joint FAO/WHO Expert Committee on Food Additives) meeting participants
- IPCS Programme Advisory Committee (Standing Committee) members
- OECD cancer and reproductive toxicity working group members
- National authority contacts in the European Union (EU)
- Miscellaneous contacts provided by Harmonization Steering Committee members.

Responses

A total of **67 responses** were received by mid-September 2004, resulting in a response rate of about 25%. Twelve responses came from national assessment authorities, 35 from experts with previous involvement in the project and 20 from experts with no previous involvement.

All of the **12 chemical assessment national authorities** that responded to Survey 1 originated from industrialized countries, with nine from the European Union (Czech Republic, Denmark, Germany (2), Hungary, Lithuania, Latvia, Slovakia, United Kingdom) and the three others from Australia, Japan and the US. Most of the authorities indicated that their responses covered situations related to industrial chemicals assessment (five mentioned biocides and three mentioned pesticides assessment). Five countries also added that they dealt with occupational health and safety.

Fifty-four individual experts filled in a questionnaire (either S2 or S3), representing **17 countries and the European Commission**. Among these countries, eleven were in the EU and five others (i.e. Australia, Canada, Japan, Switzerland and the US) were also in the industrialized world. Only two responses came from developing countries (i.e. Ghana and Uruguay), a proportion that does not reflect the geographic composition of participants in the harmonization project (the various working groups are constituted with representatives from a broader range of countries).

Key findings of the 2004 Stocktake

- **The Harmonization Project is known by 3/4 of the respondents.** The IPCS website and communication with colleagues were the main channels for obtaining information on the Project.
 - **The main Products (publications or databases) were known by the majority of the respondents.** However, the level of awareness varied according to the Products. The “MOA framework (P1)”, the “guidance on CSAFs (P2)” and the “OECD/IPCS descriptions of key generic assessment terms (P5)” were the most well-known publications.
 - Below is a summary of information **on the adoption and use of each Product** under consideration in the survey.
 - **P1 (Cancer Mode of Action Framework, 2001).** This document appears to be among the most used harmonization Products. It is being used, considered by, and sometimes included in, guidance in many international organizations (e.g. IPCS, ILSI, JEFCA, JMPR, OECD, EU, DG SANCO CSTE) representing many countries worldwide. Many countries (e.g. Australia, Canada, Germany, Japan, UK and US) have also reported the use (or reference) of the Framework at national levels.
 - **P2 (Guidance for the use of Chemical-Specific Adjustment Factors (CSAF), draft 2001).** Although quite well known, at the time of the stocktake the document was in peer review and so not yet available as a “final”. However it had already been used in some countries/organizations (Canada, US, JEFCA, JMPR) and identified for use in others (Australia, Japan, UK, the EU and ILSI). This guidance is applicable mainly to “data-rich” chemicals.
 - **P3 (IPCS Qualitative Scheme for Mutagenicity, 1996).** The Scheme was reported to be specifically used in the UK and by the EU). However the Scheme is compatible with many guidance documents on mutagenicity developed since it was published in 1996.
 - **P4 (IPCS Glossary of Key Exposure Assessment Terms, December 2002).** The Glossary had only been finalized relatively recently. However it was shortly after adopted by the International Society for Exposure Analysis (ISEA) as the Society’s official glossary. ISEA members and authors of articles for the International Journal of Exposure Analysis are being encouraged to use the Glossary. This is expected to greatly foster use of the Glossary by experts/researchers worldwide. In addition, IPCS is translating it into other languages, which should increase availability.
 - **P5 (Descriptions of Selected Key Generic Terms Used in Chemical/Hazard Risk Assessment, 2003).** Although this document had only been recently finalized, its adoption/use was been reported by Australia, Germany, Japan and ECETOC. It is currently being translated into other languages, which should increase availability.
 - **P6 (Harmonized Nomenclature for Developmental Toxicology, 1997).** The Nomenclature is reported to be helpful as a reference document. It is mainly used by specialists analysing raw data and study reports for developmental toxicity studies.
 - **P7 (Database on Hazard/Risk Assessment Methodologies, 1999).** This database has been used as a reference tool, for example for indicating areas for possible Harmonization Project work.
- Finally with respect to the use of these seven Products by the various sectors, the responses show that **the publications have been taken up by most of the assessment sectors**, i.e. industrial chemicals, biocides, pesticides, veterinary products, pharmaceuticals, occupational and public health.
- The survey respondents proposed many topics for new work, and made a range of suggestions of a more general and managerial nature, e.g.:
 - Promotion, marketing of the Project and distribution of Products (to enhance the visibility, acceptance and use of the Products)
 - Focusing on some shorter projects and on key projects, with visible outcomes
 - Developing training on risk assessment
 - Translation of key IPCS documents
 - Communicating information on both new and in-progress publications (so that new products are anticipated)
 - Encouraging more regular contacts among experts.

- Finally, the proportion of experts interested in participating in future activities was very encouraging, with **89% of experts willing to participate**.

Follow-up to the Stocktake analysis

Based on feedback received in the Stocktake, the Harmonization Steering Committee agreed to continue the following activities:

- **Cancer:** completion of the guidance extending the IPCS Cancer MOA Framework (P1) to include consideration of human relevance of animal tumours
- **Exposure assessment:** development of harmonized guidance on characterizing and communicating uncertainty in exposure assessment
- **Terminology:** maintenance, translation into other languages and promotion of the key generic hazard/risk assessment terms (P5) and glossary of exposure assessment terms (P4).
- **Mutagenicity:** updating the IPCS Qualitative Scheme for Mutagenicity
- **Reproductive and developmental toxicity:** development of harmonized morphological terms (by the WHO Collaborating Centre on Developmental Toxicology in Berlin).
- **Extension of the IPCS Cancer MOA Framework to other end-points.**

Following the recommendations made by Stocktake respondents, the Steering Committee also proposed to initiate work on the four areas listed below:

- **Aggregate/cumulative risk assessment**
- **Data quality in exposure assessment**
- **Immunotoxicity (skin sensitization)**
- **Problem formulation in risk assessment process**

The three latter areas will be addressed using a “sharp-focus” approach in order to produce shorter, targeted guidance.

Finally, the Committee agreed to address the following suggestions for improvement:

- The need for balance between **expert activities to develop the products and implementation activities** (such as development of training modules for products). However, the need for general training in risk assessment in developing countries was also noted.
- Improvement of **promotional/contact mailing lists** to enable regular newsletter-type communications to engage and inform more experts during the process.
- Further **development of links** with regulatory authorities, professional associations, universities or other institutions.

More about the IPCS Harmonization Project

Don't forget to visit the website regularly for updates on new projects.

🌐 www.who.int/ipcs/methods/harmonization/en/

Please send your comments and suggestions on the Harmonization Project to the Harmonization Secretariat:

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