



INTERNATIONAL PROGRAMME ON CHEMICAL SAFETY

**Project on the Harmonization of Approaches to the Assessment of Risk
from Exposure to Chemicals**

**Report¹ of the 1st Meeting of the
IPCS Working Group on Uncertainty in Exposure Assessment
in conjunction with a Scoping Discussion on Exposure Data Quality**

19-20 August 2004, WHO Headquarters, Geneva

¹ This report contains the collective views of an international group of experts, and does not necessarily represent the decisions or the stated policy of the World Health Organization.

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Scoping Discussion on Exposure Data Quality**

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PLENARY REPORT (PART I)

WELCOME AND OPENING OF THE MEETING

1. The first meeting of the IPCS Harmonization Project Working Group on Uncertainty in Exposure Assessment was convened in conjunction with a Scoping Discussion on Exposure Data Quality on 19-20 August 2004, at WHO Headquarters, Geneva, Switzerland.
2. The meeting was opened on behalf of IPCS/WHO by Ms Carolyn Vickers, IPCS Secretariat for the Harmonization Project. Ms Vickers welcomed participants to the meeting and to Geneva. She explained the main tasks of the meeting were to: 1) commence work to develop internationally harmonized guidance on the treatment of uncertainty in exposure assessment; and 2) develop a proposal for possible future work to develop harmonized guidance on exposure data quality, including whether or not this could be combined with the work on uncertainty. The proposal on data quality is to be considered by the Harmonization Steering Committee for inclusion in its future workplan, at its meeting on 25-26 October 2004.
3. The meeting noted that the IPCS Harmonization Project aims to harmonize approaches to the assessment of risk from exposure to chemicals, and hence the documents produced are generally in the form of guidance that can be adopted for use by regulatory schemes. The work should not be specific to a particular category of chemicals, and hence should be applicable in the assessment of industrial chemicals, pesticides, food additives and contaminants, industrial byproducts, etc.. Ms Vickers requested the meeting to take into account the needs of potential users in designing what the outcome/s of their work would be, and also to consider and suggest how the finished products could be promoted for use.

4. After a round of introductions, the meeting recorded apologies from Drs Andy Hart, Haluk Ozkaynak and Chris Frey, however noting their willingness to participate in the Working Group in future. The invited participants list is at Attachment 1.

MEETING CHAIR, OFFICERS AND ARRANGEMENTS FOR MEETING REPORT

5. Dr Steve Olin, as Harmonization Steering Committee Liaison for exposure activities, kindly agreed to take the Chair of this combined meeting. The meeting noted that the Harmonization Committee Core Group had previously accepted the offer of Dr Gerhard Heinemeyer to Chair the Working Group on Uncertainty in Exposure Assessment, and accepted the IPCS proposal that Dr Bill Griffith lead the Scoping Discussion on Data Quality. Rapporteurs for the parallel sessions were assigned (Dr Roshini Jayewardene for Uncertainty, and Dr Chris Money for Data Quality), with the IPCS Secretariat responsible for preparation of the full meeting record.
6. On assuming the Chair, Dr Olin extended a warm welcome to participants, in particular those new to the Harmonization Project. He mentioned the products of the exposure work to date, namely Harmonized Exposure Assessment Terminology and a document on Principles of Characterizing and Applying Human Exposure Models, and he then outlined the importance of the work to be commenced at this meeting. Ms Valerie Rolland, representing EFSA, was welcomed, noting that EFSA is preparing guidance on uncertainty in dietary exposure assessment and the value of ensuring harmonization between sectors.

ADOPTION OF THE AGENDA

7. The meeting adopted the agenda as proposed (Attachment 2).

INTRODUCTION TO THE HARMONIZATION PROJECT

8. The Secretariat gave a brief presentation introducing the Harmonization Project. The meeting noted the Project Strategic Plan, the Terms of Reference of the Steering Committee and the Roles and Responsibilities document which outlined the functions of Working Groups.

ORIGINAL PROPOSALS ON UNCERTAINTY AND DATA QUALITY

9. Dr Olin explained the history behind the work to commence at this meeting. In 1999 an IPCS Harmonization Steering Committee meeting considered a number of proposals for work in exposure assessment. Two projects were agreed to commence (namely the terminology and modelling projects mentioned earlier) while the others were put on hold, including proposals on uncertainty and data quality. The original

proposals were provided in the papers for this meeting, however participants were advised that they need not be bound by these in their work.

10. Participants were then invited to address the meeting about the significance and relevance of background "library" documents they had provided for meeting participants in advance of the meeting. In particular the meeting noted: the early draft of the EFSA guidance on uncertainty; the European Union template for documenting an exposure study; the US White House Circular on a tiered approach to data quality issues; and the US EPA exposure factors handbook.

DEVELOPMENT OF OUTLINE AND PROCESS FOR DOCUMENT ON UNCERTAINTY IN EXPOSURE ASSESSMENT AND THE EXPOSURE DATA QUALITY PROJECT PROPOSAL

11. Prior to commencement of the parallel sessions of the break-out groups on the above issues, the meeting discussed their assigned tasks, noting in particular the need to consider the issue of whether the work on data quality should, or should not, be done as part of the work on uncertainty (if it is agreed by the Steering Committee that the data quality work should proceed).

12. The reports of the parallel sessions are incorporated in this report as follows:

Part II: Uncertainty in Exposure Assessment Working Group Report, including detailed document outline and timetable.

Part III: Proposal for IPCS work on a Harmonized Approach to Data Quality Principles: Their Relevance for Exposure Assessment.

Part IV: Towards a Strategy for Improved Exposure Data Quality.

13. In relation to the question of whether or not the work on data quality should be combined with the work on uncertainty, the proposal developed is for concise IPCS guidance on data quality, which could be prepared over a relatively short period of time, and feed into the longer term uncertainty project. Hence the work would support, rather than be subsumed, by the other project.
14. The additional suggestions presented in Part IV: Towards a Strategy for Improved Exposure Data Quality were proposed to be included in papers for the Harmonization Steering Committee meeting for their consideration in the Stocktake and future workplanning exercise.

CLOSURE

15. With no other business being raised, IPCS thanked Dr Olin for his expert chairmanship of the combined sessions, and Drs Heinemeyer and Griffith for leading their sessions to produce very useful documents to assist the future work of IPCS. Dr Olin also thanked Drs Heinemeyer and Griffith, and participants for their hard work and successful achievement of the meeting goals. He then declared the meeting closed.

REPORT OF THE WORKING GROUP ON UNCERTAINTY IN EXPOSURE ASSESSMENT

1. The Working Group first had an introductory discussion about general aspects of exposure assessment and uncertainty analysis. It was agreed that uncertainty analysis should be seen broadly, including all relevant aspects of uncertainty, and not purely focused on statistical approaches.
2. The Group confirmed that development of guidance in this area would be useful, and proceeded to discuss the features of the document. In order to facilitate uptake and use, it was noted that the document should be as short as possible, but could be extended as necessary.
3. The audience for the document was agreed not to be experts in statistics and uncertainty analysis, but to be targetted towards exposure assessors working on a practical level and being relatively unaware or having no detailed experience in uncertainty analysis.
4. A list of important items that should be addressed in the document was discussed, with reference to a list of "building blocks" and headings included in the meeting papers, and a preliminary structure of the document was developed. The working title was agreed to be "Harmonized guidance on characterising and communicating uncertainty in exposure assessment".
5. Possible approaches to preparation of the document were discussed, and it was agreed that each member of the Working Group should be responsible for a certain chapter.
6. The preliminary chapters and the responsible authors are shown in the table below:

Preliminary structure of the document and responsible authors

Introduction	G. Heinemeyer
Scope, Objectives and Outcomes of the Activity	R. Jayewardene
Historical context and background Definitions Separation of uncertainty and variability	C. Frey
Sources of uncertainty in exposure assessments models examples (e.g. to be put into a box)	D. Papamelitiou C. Delmaar T. McKone
Steps of exposure assessment (according to the model paper)	G. Heinemeyer
Principal methods of uncertainty analysis	H. Ozkaynak/C. Frey
Harmonization aspects of uncertainty analysis	G. Heinemeyer
Tiered approach for uncertainty analysis	B. Meek/H. Ozkaynak

Case studies	T. McKone
Presentation/communication of uncertainty analysis	To be assigned
Implications of uncertainty analysis - Model development - Data acquisition - Risk assessment - Risk management	M. Schümann C. Delmaar
Quality assurance of process (to be confirmed)	D. Papamelitiou

7. An important feature of the document will be a number of case studies/reports, which will be drawn on through the various sections to illustrate particular aspects of uncertainty analysis. This will be particularly relevant for the "sources of uncertainty" chapter. The cases will be provided in full (although concisely), in a dedicated chapter on case studies. Possible case studies discussed included: exposure with a heavy metal, e.g. lead; and a multipathway scenario with a hydrocarbon.
8. A schedule for the initial drafting was prepared. It was noted that more than one more meeting would be necessary to complete the work.

general discussion, project planning	Aug. 2004
Introduction, Scope, Objectives, etc	Oct. 2004
Extended Outline	Oct. 2004
Historical context and background	Dec. 2004
Case studies	Dec. 2004
Separation of uncertainty and variability	Dec. 2004
Sources of uncertainty	Dec. 2004
Next meeting	Early February 2005 (to be confirmed)
Definitions	December 2005? (To be decided)

Initial Document Outline

Working Title: Harmonized guidance on characterising and communicating uncertainty in exposure assessment.

Note: Items are not listed under all headings due to lack of time to discuss them in detail. The proposed contents are not complete, but provide an indication of content for the chapters, which can be further developed by the chapter authors.

Introduction (G. Heinemeyer)

- Clearly articulate the purpose of uncertainty analysis in exposure assessment.
- Describe the advantages of uncertainty analysis (ie convince audience).
- Overall, uncertainty analysis is dependent on experience in managing available data.
- Uncertainty analysis is not probabilistic methods only, discuss different approaches used in uncertainty analyses e.g. source to dose assessments vs biological monitoring.

- Explain the challenge of addressing different data sources used by different jurisdictions
- Exposure assessment requires the consideration of exposure information of the same chemical from various sources e.g. food, ambient air etc and regulatory regimes may be different for these various types of chemicals.
- Discuss the disconnect between (a) scientists and stakeholders (who demand linguistic interpretation of uncertainty analyses) and (b) exposure assessors and regulators (decision makers).
- Emphasis that uncertainty analysis must be fully integrated into an exposure assessment and be carried all through the assessment. It is not the last step in exposure assessments.

Scope (R. Jayewardene)

Target Audience

- Exposure analysts – both experienced and relatively inexperienced practitioners
- Policy makers (Regulators):
 - to inform risk management decisions;
 - to legitimise population based and distribution based assessments in jurisdictions;
 - to inform law/regulation.
- Industry - need to be convinced that uncertainty analysis is beneficial.
- This project will look at what types of uncertainty analyses have been done in past exposure assessments, evaluate their effectiveness at giving decision-makers the types of information they need for their decisions, and derive a series of principles - specifically for exposure assessment applications - that will form the basis for beginning harmonization in this area.
- Explain the complexities associated with exposure assessments, often they are interdisciplinary activities that will always include some level of uncertainty. Discuss boundary setting in an exposure assessment (ethnicity, environment, sources, pathways etc)
- Clearly describe qualitative and quantitative uncertainties in exposure assessments. Explain how exposure assessments are conducted with little data and with increasing data sets.

Objectives (R. Jayewardene)

Outcomes of the Activity (R. Jayewardene)

- The document is intended to be used as guidance for exposure assessors to give help for considering uncertainty aspects during the whole assessment.
- Discuss how a risk assessor can handle the results of an exposure assessment where uncertainty is identified as a major problem.

Historical context and background (C. Frey)

In this chapter a short overview about uncertainty analysis should be given. What are the "classical views", concepts and approaches.

Definitions

The terminology paper lists lots of items used in exposure assessments, However, they need to be considered in the context of the uncertainty questions. The question is, what is missing in the terminology paper? [DRAFTING NOTE: Gerhard, Roshini please clarify what terminology paper this is]

Remarks: there are lots of aspects that must be clarified for understanding. Some definitions from the terminology paper need some interpretation remarks in relation with the uncertainty discussion, other points items such as scenario, model and input should be defined on the harmonization background.

- Define “uncertainty” and “variability”.
- Use definitions from Glossary of Key Exposure Terms – where applicable.
- Identify other terms and agree definitions as required.

Separation of uncertainty and variability

(Please note that this list is not complete due to lack of time for discussion)

- Explain the challenge of addressing different data sources used by different jurisdictions.

Sources of uncertainty of exposure assessments (D. Papameletiou)

(Model aspects will be covered by C. Delmaar)

(Please note that this list is not complete due to lack of time for discussion)

- Discuss the use of default parameters and the uncertainty associated with the use of defaults.
- Emphasise that uncertainty analysis must be fully integrated into an exposure assessment and be carried all through the assessment. It is not the last step in exposure assessments.
- Extrapolation of data from studies having other objectives than exposure assessments.

Measurements

- Sample collection.
- Analytics.
- Statistics.
- Impact of biomonitoring studies.
- Discuss the pros and cons of using higher bound data on the distribution curve (eg 99th percentile), discuss the management of variability using higher bounds not applicable to uncertainty.
- Discuss the level of certainty on exposure and effect – and their effect on the level of confidence.
- Discuss the possibility of using product information (eg from poisons information centres or product databases) to advise exposure assessments.

Examples of uncertainties as shown by case studies. These examples will be highlighted in the text (e.g. to be put into a box) (T. McKone)

- Use a few case studies to illustrate concepts, carry case studies all through the document where relevant.

- Progress case studies using increasing data sets, where possible.
- Proposed case studies:
 - Multimedia - multipathway exposure to high volatile VOC
 - Lead exposure
 - Persistent bioactive Substance (e.g. dioxin)

Presentation of case studies:

- Short, simple and transparent examples of relevant sections to explain the uncertainties (to be identified as such by writing it into boxes etc.) not using the proper chemical name.
- High quality data shall be used that are highly representative.
- Biomarkers may be considered.
- Special focus on exposure assessments for children.

Steps of exposure assessment (according to the model paper, G. Heinemeyer)

Categories of uncertainty:

- Uncertainty in the scenario includes descriptive errors (e.g., wrong or incomplete information), aggregation errors (e.g., approximations for volume and time), errors of assessment (e.g., choice of the wrong model), and errors of incomplete analysis (e.g., overlooking an important pathway of exposure).
- Uncertainty of parameters includes errors of measurement (e.g., inaccurate or distorted measurements), sampling errors (e.g., too small or non-representative samples), errors concerning variability (e.g., volume, time, or activity variations), and errors in using surrogate data (e.g., comparisons using structure relationships).
- Model uncertainty includes relationship errors (e.g., wrong conclusions from correlations), and errors in modeling (e.g., non-consideration of relevant parameters).
- Variability and uncertainty can overlap and have to be separated. A way to solve this problem may include the use of probabilistic approaches that have been introduced during the past few years.

Uncertainty of scenarios

- Identify scenario components.
- Characterise whether or not all relevant scenarios are included.
- Non-harmonization of scenarios (scenarios are not agreed).
- Interpretation and understanding.
- Multichemical exposures (covered in the model document).
- Population of exposure.
- Representativeness of scenarios.
- Establish criteria for scenario descriptions - these should be as descriptive as possible.
- Include a listing and description of standard scenarios.
- Scenarios should be established so they can be coded and captured in a database at a national level.

Uncertainty of models (i.e. algorithms, without data)

- Use of "commercially" available tools.

- Several models for one scenario.
- Evaluation of models.
- Interpreting and understanding models and model results.
- Aggregation level of each model ie aggregation of time.
- Prerequisites to the use of a particular model: transparency , familiarity and confidence of the practitioner in the model, public availability of the model.
- Discuss the importance of model evaluation – the possible use of several independent models to evaluate reliability of a particular model.
- Discuss the circumstances under which simple models are useful despite the introduction of greater uncertainty.
- Computerised models that use data should be described separate from algorithms as they provide a higher level of certainty.
- Model developers must identify drivers for a particular model– however an experienced modeller can identify main drivers in a model.
- Explain the desirable level of detail that will need to be determined case-by-case based on the requirements of each model.
- Discuss the principle of “Good Modelling Practice” in the development and use of models and interpretation of model results.
- Establish criteria for evaluation of models.
- Explain how models can be used to back up biomonitoring results or trends.

Uncertainty of exposure variables(ie input into models, exposure factors))
(Please note that this list is not complete due to lack of time for discussion)

- Unreliable input data (defaults, expert judgement values, single point estimates).
- Data bases and data collections.
- Data categories eg food codes, product codes vary significantly between countries.

Principal methods of uncertainty analysis (H. Ozkaynak/C. Frey)

- Develop criteria to establish boundaries in an exposure assessment. These will in turn determine data requirements.
- Discuss access to available data and the implications of using proprietary data.
- Discuss the use of limited data sets to set bounds on exposure levels, eg the law of chemical thermodynamics in determining the upper bounds of exposure.
- Identify work required to reduce uncertainty in risk assessment e.g. WHO Project on childrens´ health.
- Discuss the pros and cons of using higher bound data on the distribution curve (eg 99th percentile), discuss the management of variability using higher bounds not applicable to uncertainty.
- Discuss the level of certainty on exposure and effect – and their effect on the level of confidence.
- Uncertainty analysis is not probabilistic methods only, discuss different approaches used in uncertainty analyses e.g. source to dose assessments vs biological monitoring.

Harmonization aspects of uncertainty analysis (G. Heinemeyer)

Sources of exposure was discussed according to a separation into scenario, model and data, which lead to some different understandings, which however should be described under the aspect of harmonization.

- *There might be a separation into formalistic views of exposure assessments, for example. due to EU regulations compilations of exposure scenarios have to be worked, which should be explained.*
- *A more common view was also presented which does not separate scenario, model and variable but emphasises the relations.*

Tiered approach for uncertainty analysis (B. Meek/H. Ozkaynak)

- When using tiered uncertainty analysis, the degree of quantitative analysis should increase as progress is made through each tier.

Case studies (T. McKone)

In this part examples of complete exposure assessments shall be presented to show a complete exposure assessment including the uncertainty at different levels.

Presentation / communication of uncertain analysis (To be assigned)

- Discuss the disconnect between (a) scientists and stakeholders (who demand linguistic interpretation of uncertainty analyses) and (b) exposure assessors and regulators (decision makers).

Implications of uncertainty Analysis (M. Schümann)

- Importance of Project: Uncertainty analysis has critical consequences for interpretation of an assessment and any management decisions made based on the assessment. Uncertainty analysis in exposure assessments is not being looked at in a systematic way, to our knowledge.
- Discuss how a risk assessor can handle the results of an exposure assessment where uncertainty is identified as a major problem.

Model development (C. Delmaar)

Data acquisition

Risk Assessment

Risk Management

Risk Communication

- Briefly discuss the importance of risk communication and building trust in the exposure analyst.
- Discuss the disconnect between: (a) scientists and stakeholders (who demand linguistic interpretation of uncertainty analyses); and (b) exposure assessors and regulators (decision makers).

Quality assurance of process (To be confirmed) (D. Papamelitiou)

**A HARMONIZED APPROACH TO DATA QUALITY PRINCIPLES: THEIR
RELEVANCE FOR EXPOSURE ASSESSMENT**

Proposed Project Title

A harmonized approach to data quality principles for exposure assessment

Background

No globally harmonized guidance is available that describes quality considerations for exposure data (whether relating to occupational, consumer or indirect exposures to chemicals). Risk assessors and managers who use exposure data need to better understand the key elements that describe data quality, and the implications of poor data quality. Data quality principles provide criteria by which to evaluate the usefulness of exposure data for risk assessments and risk management decisions. The primary means a user has for evaluating data quality is the description of an exposure data set so that a judgement can be made about the strengths and weaknesses of the data, and a determination made about the degree to which a data set may resolve or introduce uncertainties and variability into the risk assessment process. Use of these principles can improve the quality of risk assessments and decisions by providing a more realistic description of its accuracy and limitations. In order to address this need, it is recommended that IPCS develop a concise document that describes the quality considerations for exposure data with examples of their use.

Scope

A short stand-alone document should be developed that aims at informing those responsible for collecting and using exposure data why quality considerations are important. The document would describe the principles of data quality and include brief illustrative examples that highlight the importance of the key principles. In order to increase the usefulness of the document, it is envisaged that it would be about 10 pages in length so that it could be readily translated into the 6 UN languages and distributed widely to maximize its usefulness and impact.

The evaluation of quality goes beyond the use of statistical criteria to describe the variability in a particular data set. Although statistical measures of variability are important tools in making judgements about quality they often cannot capture major aspects of uncertainty about the potential uses and limitations of a data set. These uncertainties usually transcend in many aspects the conditions under which a particular exposure data set was collected, whereas statistical measures only capture the variability within the data set under the collection conditions. Assessment of the quality of a data set is largely dependent on having a complete description of the conditions under which a data set was collected. A more complete description of the conditions of data collection provides the user of an exposure data set a means to judge the quality of the data in terms of the types of uncertainties it may or may not introduce into a risk assessment.

It is suggested that the document could be organized around three aspects of quality—appropriateness, accuracy, and integrity.

- **Appropriateness:** For a particular application the usefulness of a data set depends upon the relevance of the exposure data set to the purpose of a risk assessment or risk management question. For example, the characteristics of a population for which a risk assessment is being made may differ from the population for which exposure data was collected. The degree of similarity between the populations is important in evaluating the quality of the assessment
- **Accuracy:** Accuracy of a data set relates to many issues including factors such as sampling design, types of standards used in laboratory analyses, calibration procedures for instruments, completeness of the description of a data set, and whether the measurements can be replicated.
- **Integrity:** The integrity of exposure data includes factors such as quality assurance procedures used during the collection of data, assuring that the data has not been compromised or corrupted, and that appropriate privacy safeguards have been followed.

Importance

The three characteristics of data quality outlined above - appropriateness, accuracy, and integrity - are closely related and in many ways overlap. For an exposure data set to have these three characteristics of quality requires making the circumstances and process of collection of a data set transparent to the potential users of the data set. A complete and transparent description of the data allows others to evaluate for their uses whether the data set is appropriate, accurate, and has integrity. The production of a concise document that describes quality, including considerations relating to transparency, is important for evaluating exposure data and its uncertainty and for improving harmonization of exposure assessments.

Related Initiatives

Several national initiatives have described data quality considerations for specific types of exposure data, e.g. workplace monitoring. Several other initiatives (including at the IPCS and WHO levels) have described how human exposure assessments should be undertaken in general terms, but data quality principles are not discussed.

Two workshops held in early February 2004 assigned high importance to the need to improve the collection and use of exposure-related information to improve the use of existing observational data in risk assessment. The first of these held by the European Centre for Ecotoxicology and Toxicology of Chemicals (ECTOC) in collaboration with IPCS identified that existing human data was not addressed consistently in chemical risk assessment and questions of quality, most commonly relating to exposure data inhibited their use.

The second IPCS Workshop on the collection, reporting and use of human data held to address the recommendation of the Intergovernmental Forum on Chemical Safety that IPCS take the international lead in the development of guidance on, and mechanisms for

collecting, disseminating and utilizing clinical and exposure data from human observations, discussed the related activities of poisons centres and chemical incident alert and response activities. This Workshop also found that the quality of exposure data needed to be tackled as a priority (<http://www.who.int/ipcs/events/2004/en/cardiffReportIPCS04.2.pdf>) .

An Action Plan from these two workshops is currently being developed collaboratively under the Chairmanship of Professor Jim Bridges. Development of the proposed document would need to be linked to this work to complement and build on the existing IPCS work on improving the use of human data.

Proposed Process

A document as described above would be developed by:

- Establishing a small working group of experts, perhaps building from the Ad Hoc group, the Human Data Steering Group, and linked to the Uncertainty Working Group.
- Appointing one member of the group to develop a first draft of the narrative of the guidance. Other working group members would be responsible for editing the draft and providing illustrative examples. This is thought not to be a major task.
- Assuming IPCS approval of this proposal in October 2004, a first draft could be made available for electronic discussion and development within the working group by early January 2005 prior to wider discussion at the next meeting of the Uncertainty Working Group in early February 2005. The Uncertainty Working Group would provide a broader geographic representation and broader experience to provide a wider range of examples.

Developing a document such as described is considered to be a task that is likely to require minimal effort and bring tangible rewards over the short term

Timetable

Provided support is obtained from the Steering Group, it is envisaged that a draft document could be available for extended comment by late spring 2005. Subsequent to finalisation, the document would be presented at relevant international meetings e.g. ISEA 2005; ISEE 2005; SRA 2005, EU TCNES meeting in 2005; Medichem/ICOH 2006; EPA SAB annual meeting 2005; NAS exposure modelling group; etc..

In addition, and recognising the geographical limitations of established scientific meetings, IPCS may want to develop other materials in support of the document that would raise awareness and understanding in a wider audience (e.g., through the IPCS website).

TOWARDS A STRATEGY FOR IMPROVED EXPOSURE DATA QUALITY

**SUGGESTIONS OF AN INVITED EXPERT GROUP DISCUSSION,
IPCS OFFICES, GENEVA, 19-20TH AUGUST 2004**

Background

No globally harmonised principles are available that describe the quality considerations necessary to support exposure data (whether relating to occupational, consumer or indirect exposures to chemicals). However, several initiatives have addressed elements considered necessary when exposure data are collected and archived, notably with respect to workplace exposure monitoring. In contrast, few co-ordinated activities have addressed how available data might be subsequently interpreted and used within risk assessment processes, accounting for the variable quality that is associated with available data.

If the exposures are to be consistently and reliably evaluated, then there is a need for a strategy to be established that seeks to ensure exposure data quality considerations are integrated into the processes for exposure data collection and use. In developing such a strategy, it has to be recognised that this is a significant task that will challenge pre-conceptions and prejudices. Specifically, those involved in collecting data need to be persuaded to improve their customs and practices. And those that use the data need to be convinced to build upon its benefits and strengths. Such broader considerations point to such a strategy being best developed and facilitated through an appropriate global NGO(s).

Elements for Consideration

The Expert Group discussed a range of activities that any such strategy might extend to and which IPCS (ideally in partnership) might consider sponsoring:

- Development of a short stand-alone orientation document aimed at improving/informing those responsible for collecting/using exposure data why quality considerations are important.
- Development of a supporting IPCS monograph that describes a framework in which exposure data of varying quality can be reliably used within risk assessments. This would tie in with use of tiered approaches to improving data quality, based upon data availability and use and would make poor data sets more useful as it would enable their limitations to be more readily recognised.
- Use the documents to serve as a focus for a network of activities that would detail how different exposure data elements relate to various types of Risk Assessment e.g. types of workplace RAs, consumer RAs (c.f. the EFSA work on different types of consumer RAs).
- To extend the quality principles into related templates and processes for the collection of human data e.g. INTOX, role of IRB, company data recording, OECD voluntary reporting.

- Compile a package of training materials to address the issue of capacity building an effective knowledge transfer across the global Risk Assessment community. Part of this package could include a library of case studies, plus illustrative examples, that demonstrate importance of the key principles.
- Constitute a suitably diverse (balance of science and regulatory communities and geographical interests) group to oversee and champion the activity. Recognise the value of incorporating the target audience into the peer/stakeholder consultation process from the very beginning.
- Promote documents via appropriate (inter)national meetings and other suitable forms of communications.

**IPCS Uncertainty in Exposure Assessment Working Group plus
Scoping Discussion on Data Quality**

19-20 August 2004, Geneva

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WORLD HEALTH ORGANIZATION
INTERNATIONAL LABOUR ORGANIZATION
UNITED NATIONS ENVIRONMENT PROGRAMME

IPCS/EWG/04.01
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**INTERNATIONAL PROGRAMME ON CHEMICAL SAFETY
Project on the Harmonization of Approaches to the Assessment of Risk
from Exposure to Chemicals**

**IPCS Uncertainty in Exposure Assessment Working Group and
Scoping Discussion on Exposure Data Quality**

**19-20 August 2004, WHO Headquarters, Geneva
Commencing at 9.30 am on 19 August in Room C.202**

Adopted Annotated Agenda

1. Welcome and Opening of Meeting. (see Invited Participants List)

The meeting will be opened by Ms Carolyn Vickers on behalf of WHO/IPCS. Participants will be invited to introduce themselves. The Secretariat will make housekeeping announcements.

2. Meeting Chair, Officers and arrangements for meeting report.

The Secretariat will propose that plenary section of this meeting be Chaired by the Harmonization Project Steering Committee Liaison for Exposure Assessment Activities, Dr Steve Olin. By previous decision, the Chair of the Working Group on Uncertainty in Exposure Assessment is Dr Gerhard Heinemeyer, Germany. A discussion leader for the Data Quality session will be confirmed at the meeting.

In accordance with IPCS practice, the Secretariat will prepare the draft meeting report, which is circulated after the meeting for comment by participants and finalized in consultation with the Chairs. The Uncertainty Working Group and the breakout discussion group on data quality are asked to each identify a rapporteur at the start of their sessions to compile the product/s of the two parallel sessions, which are to be agreed before the close of the meeting for attachment to the full meeting report.

3. Adoption of the Agenda (IPCS/EWG/04.01)

The Chair will invite participants to adopt the agenda, amended as necessary.

4. Introduction to the IPCS Harmonization Project.

(IPCS/EWG/04.02: Strategic Plan; Roles and responsibilities document, November 2002; Steering Committee Terms of Reference, November 2002)

The Secretariat will make a brief presentation on the Harmonization Project goals and activities. This will include information on the terms of reference of the Steering Committee, and the roles and responsibilities of Working Groups.

5. Background: Original proposals on Uncertainty and Data Quality (IPCS/EWG/04.03)

In 1999 an IPCS meeting considered a number of proposals for work in exposure assessment. Some projects were agreed to commence, and others were put on hold. Two projects put on hold related to Uncertainty and to Data Quality. The original proposals are provided as a background resource, however the meeting should not be bound by their content. There will be an opportunity for questions, however the detailed discussion of content will take place in the later parallel sessions.

6. Development of Outline and Process for Document on Uncertainty in Exposure Assessment, and the Exposure Data Quality Project Proposal

i. Charge to the Uncertainty Working Group and breakout Scoping Discussion on Data Quality. (IPCS/EWG/04.04; IPCS/EWG/04.05)

The charge to the parallel sessions will be presented and there will be an opportunity for discussion. Details are provided in the above-listed agenda papers.

ii. Parallel sessions.

This will include a progress report to plenary to identify and discuss overlapping issues, including whether work on data quality should be merged with the work on uncertainty.

7. Any other Business.

Participants will be invited to raise any other business.

8. Closure.

Participants are asked to be available until 4pm on 20 August.