CHAPTER 6: POST-SIDS WORK

6.4 Provisional Guidance for the Initial Assessment of Occupational and Consumer Exposure

NOTE: This section was prepared by the OECD Secretariat in 1992 based on the results of the OECD/US EPA Workshop held in Orlando, Florida, in February 1992. It has been updated to reflect comments by Member countries and agreements reached in the context of the OECD Existing Chemicals Programme up to mid-1994. It has not yet been revised in the context of the refocused HPV Chemicals Programme. The guidance provided in this section can nevertheless be used as such for an initial assessment of occupational and consumer exposure as a post-SIDS activity.

6.4.1 Introduction

1. This document provides guidance for the initial assessment of the occupational and consumer exposure of High Production Volume (HPV) chemicals for which a full SIDS is available, based mainly on the results of the OECD/US EPA Workshop held in Orlando, Florida in February 1992. The results of the Workshop are published by the OECD as OECD Environment Monograph No. 70, *Occupational and Consumer Exposure Assessments* (from now on referred to as "Monograph No. 70").

2. The objective of any occupational and consumer exposure assessment is to calculate a **"realistic"** Estimated Human Exposure (**EHE**) level, expressed in terms of dose per unit weight, e.g. mg/kg, based on data contained within the full SIDS Dossier for the "sponsored" chemical. This level can then be compared with the results obtained from conducting the Initial Assessment of Health Effects and a judgement made as to whether the chemical presents a cause for concern and the possibility of further action. For consistency within assessments, when calculating the human exposure level, in the absence of evidence to the contrary, there may be a need to standardise some of the appropriate physiological parameters. In this respect it is suggested to assume that:

(a) an adult weighs 70 kg;
(b) the respiratory volume is 10 m^3 (i.e. 10,000 litres) per working day (8 hours);
(c) the consumer respiratory volume is 15 litres per minute.

3. Other factors, which should be obtained before assessing exposure, relate to the physical state of the chemical and its weight fraction in any product or formulation that is professionally used. If the chemical is also present in consumer products, an appropriate adjustment should be made to the EHE.

6.4.2 Occupational Exposure

4. For exposure via the inhalation route, some chemicals may have been assigned a national or company-based occupational exposure limit (e.g. TLV, MAK, MAC, OES, etc.), perhaps even further refined to encompass short-term limits or ceiling values. Whenever possible these levels, preferably expressed as **mg/m^3** rather than **p.p.m.**, should be used as the basis for calculating the EHE. It is important to compare these occupational exposure limits as the values may differ between Member countries. The toxicity and exposure data used and the date the limits were set should also be considered in the comparison.

5. In other cases actual monitoring data, both personal and background, may be available and can, after suitable statistical treatment (e.g. geometric mean and standard deviation), be used in a similar manner. The overall procedure should be repeated for all the various production processes and uses made of the chosen chemical and, from a knowledge of frequency and duration of exposure, the results of the "worst

case" highlighted. Again knowledge that technical or personal protective equipment is required may assist in formulating views.

6. However, for the majority of SIDS chemicals it is anticipated that **"real"** data will **not** be available and hence "estimation" methods will need to be used. Three such methods, as proposed by Germany, the UK and the USA, with varying levels of detail and from which the National SIDS Contact Points are free to choose, have been identified. These are attached to Monograph No. 70 as Annexes I-III. They rely on a knowledge of similar production processes and use patterns and/or on the physical-chemical properties of the "sponsored" or surrogate chemical. Thus where "real" data are missing for the chosen chemical it may be possible to substitute data from another chemical meeting the criteria mentioned above. In all these methods the amount of detail and level of sophistication required for a "quantitative" estimation depends to some extent on the toxicity of the chemical. Therefore, the occupational exposure (and consumer exposure) assessment should not be conducted in isolation. For example, a chemical showing low toxicity may require only qualitative, or at most semi-quantitative, exposure estimation. In those cases where a chemical is also incorporated into a consumer product, the occupational or professional exposure should be supplemented by the appropriate component of the consumer exposure assessment in calculating the overall EHE. The situation is not so clear-cut regarding dermal exposure and only the model used by the US EPA addresses this point. Indeed one of the conclusions of the Orlando workshop was that more work was needed in this area and that Member countries should share their experiences. Such information will be invaluable in updating this provisional guidance, for both occupational and consumer exposure.

Overview of Models for Estimating Occupational Exposure

7. The US EPA submission provides a number of model approaches whose applicability relies on some knowledge of production and use scenarios in the US (e.g. the NIOSH National Occupational Exposure Survey). The identification of critical unit operations during manufacture and use leading to significant exposure scenarios allows a degree of specificity in the assessment. However, some reservations as to the applicability of the models, in circumstances of more modest resources or expertise, could restrict their use. (See Annex I to Monograph No. 70.)

8. The UK HSE submission illustrates a possible approach based on a structured logic tree using analogous exposure data. Its recent development into a simple, validated "expert system" for screening purposes is attractive, particularly as the ultimate choice of exposure databases could be adapted to national needs. In the first instance the use of the UK National Exposure Database (NEDB) could be a relevant tool in the development of this approach. The classifications based on physical and (apparent) toxicological properties and containment levels will need careful definition for more general future use. (See Annex II to Monograph No. 70.)

9. The German BAU submission offers a generally qualitative screening approach based on common knowledge of the exposure situations in different areas of use and on an example of "mass balance" calculations. This could be a particularly relevant screening tool when there was an early indication that a high degree of sophistication was unlikely to be warranted. (See Annex III to Monograph No. 70.)

6.4.3 Consumer Exposure

10. Much of the foregoing can also be applied to the assessment of consumer exposure in that the objective, when combined with any possible occupational exposure, is to calculate an EHE, that "real" data is to be preferred, and that the toxicity of the chemical should be brought to bear on the level of detail required. Again for most SIDS chemicals, it is expected that "estimation" methods will be required and two have been identified. One of these, as used by the US EPA, is available on computer diskette. Although a synopsis is attached to Monograph No. 70 as Annex IV, further details of its use are best obtained from the incorporated files, most of which are "menu-driven". The other one, a discussion paper from the Netherlands, is also

attached to Monograph No. 70 as Annex V. Unlike the occupational setting where, to a greater or lesser extent, some exposure is bound to occur, there will of course be no requirement to undertake an exposure assessment if the chemical is not present in a consumer product. Product registers and inventories, etc. will need to be consulted, perhaps with assistance from other Member countries, to check if this is indeed the case. There may, however, be the need to incorporate other factors, such as presence in drinking water, in obtaining an overall EHE.

Overview Models for Estimating Consumer Exposure

11. Details of the method proposed by the US EPA are obtained from the diskette which contains the SCIES, AMEM, FLUSH and DERMAL procedures and explanatory documents. Both have been distributed to the SIDS Contact Points (see the list in Reference as well as details in Annex IV to Monograph No. 70.)

- SCIES is a Screening-level Consumer Inhalation Exposure Software program for the passive and active annual average inhalation exposure to components of consumer products.

- AMEM is an estimation model for assessing migration of a chemical from a polymer and the inhalation exposure.

- FLUSH is a program for estimating concentrations of chemicals in surface waters that may result from disposal of consumer products containing these chemicals into household wastewater and also provides estimates of human exposure from ingestion of drinking water and fish that may become contaminated by these household wastewater releases.

- DERMAL is a program which allows estimation of dermal exposure, in terms of potential dose rate, for contact with (1) a film of liquid deposited on the skin, (2) dusts and powders, and (3) chemicals contained in or adhering to solid matrices.

A computer expert may need to be consulted on the AMEM program as a "maths co-processor" is required.

12. The proposed model from the Netherlands in Annex V to Monograph No.70 is self-explanatory and allows one to input selected values or, in certain circumstances, to choose the "default" value.

6.4.4 Reporting

13. General guidance for preparing the report is given in the document entitled "Provisional Guidance for the Outline of the SIDS Initial Assessment Report" (see Section 4.2), but it is worth re-emphasizing that the approach used in obtaining any estimation of the EHE, including the underlying assumptions and uncertainties, should be sufficiently well explained to enable other interested parties to confirm the conclusions and respond effectively. Also as a reminder, it is requested that the use, or otherwise, made of this "provisional" guidance be highlighted so that future versions can be modified. Views of the users on the suitability of various "default" or other "standardised" values will also be welcome.

Reference

List of Diskettes and Documents for Consumer Exposure Assessment
Distributed to the SIDS Contact Points
(ENV/EHS/AS/fcl/92.4, 11th August 1992)

- A diskette of "Models for Consumer Exposure Assessment"
- An explanatory note for the diskette
- Screening-level Consumer Inhalation Exposure Software (SCIES): Description and User's Manual, Version 3.0 (Draft), USEPA
- FLUSH User's Manual (Final Draft Report), USEPA
- Dermal Exposure Model Description and User's Manual (Draft), USEPA
- Methods for Assessing Exposure to Chemical Substances Volume 11, Methodology for Estimating the Migration of Additives and Impurities from Polymeric Materials, USEPA

Annexes

(not reprinted here: to be found in OECD Environment Monograph No. 70, Occupational and Consumer Exposure Assessments, OECD, 1993)

Annex I Approaches for Developing Screening Quality Estimates of Occupational Exposure used by the US EPA's Office of Toxic Substances and their Applicability to the OECD SIDS Programme, US EPA, December 1992

Annex II The estimation of Occupational Exposure to Chemicals, HSE, UK

Annex III Occupational Exposure Assessment for Selected SIDS Chemicals, BAU, Germany

Annex IV Screening Level Consumer Exposure Assessment, US EPA

Annex V Estimation of Consumer Exposures to Chemicals: Application of Simple Models, RIVM, the Netherlands