Environmental Health Criteria 170

ASSESSING HUMAN HEALTH RISKS OF CHEMICALS: DERIVATION OF GUIDANCE VALUES FOR HEALTH-BASED EXPOSURE LIMITS

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INTERNATIONAL PROGRAMME ON CHEMICAL SAFETY

ENVIRONMENTAL HEALTH CRITERIA 170

ASSESSING HUMAN HEALTH RISKS OF CHEMICALS: DERIVATION OF GUIDANCE VALUES FOR HEALTH-BASED EXPOSURE LIMITS

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 United Nations Environment Programme, the International Labour Organisation, or the World Health Organization.

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The International Programme on Chemical Safety (IPCS) is a joint venture of the United Nations Environment Programme, the International Labour Organisation, and the World Health Organization. The main objective of the IPCS is to carry out and disseminate evaluations of the effects of chemicals on human health and the quality of the environment. Supporting activities include the development of epidemiological, experimental laboratory, and risk-assessment methods that could produce internationally comparable results, and the development of manpower in the field of toxicology. Other activities carried out by the IPCS include the development of know-how for coping with chemical accidents, coordination of laboratory testing and epidemiological studies, and promotion of research on the mechanisms of the biological action of chemicals. WHO Library Cataloguing in Publication Data

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NOTE TO READERS OF THE CRITERIA MONOGRAPHS

Every effort has been made to present information in the criteria monographs as accurately as possible without unduly delaying their publication. In the interest of all users of the Environmental Health Criteria monographs, readers are kindly requested to communicate any errors that may have occurred to the Director of the International Programme on Chemical Safety, World Health Organization, Geneva, Switzerland, in order that they may be included in corrigenda.

* * *

A detailed data profile and a legal file can be obtained from the International Register of Potentially Toxic Chemicals, Case postale 356, 1219 Châtelaine, Geneva, Switzerland (Telephone No. 9799111).

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ENVIRONMENTAL HEALTH CRITERIA FOR GUIDANCE VALUES FOR HUMAN EXPOSURE LIMITS

This Environmental Health Criteria monograph was developed in the course of three meetings, i) a Discussion Group, World Health Organization, Geneva, Switzerland, 14-17 January 1992, opened by Dr E. Smith, IPCS, ii) a Consultation, Langen, Germany, 19-22 January 1993, opened by Dr D. Kello, World Health Organization, Regional

Office for Europe, and iii) the final Task Group, World Health Organization, Geneva, 14-18 June 1993, opened by Dr E. Smith, IPCS.

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The WHO Regional Office for Europe collaborated with the International Programme on Chemical Safety in the development of the Guidance Value concept.

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ABBREVIATIONS

ADI	acceptable daily intake
AUC	area under the curve
EPI	exposure/potency index
LO(A)EL	lowest-observed-(adverse)-effect level
NO(A)EL	no-observed-(adverse)-effect level
SAR	structure-activity relationship
TI	tolerable intake
UF	uncertainty factor

SUMMARY

Guidance values for exposure to chemicals in environmental media should be developed in IPCS Environmental Health Criteria (EHC) monographs and can be modified by national and local authorities in their development of limits and standards for environmental media. For any chemical, the steps involved are:

1. Evaluate and summarize the information on toxicity in animals and humans and exposure in humans which is most relevant to derivation of guidance values. The most appropriate format for presentation of the data relevant to derivation of guidance values is a written narrative summarizing the critical data complemented by graphical presentation.

2. Such data can be used to derive a Tolerable Intake (TI) for various routes of exposure for effects considered to have a threshold. This will involve application of uncertainty factors, generally to the no-observed-adverse-effect level (NOAEL) for critical effects in the

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