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SUMMARY

The main objective of the work described in this report was the development of a process for the Environmental Hazard Assessment of Substances, including principles and practical approaches. The concept is applicable to all substances, whether "new" or "existing" and to all environmental compartments.

The assessment of whether a substance presents a hazard to organisms in the environment is based on a comparison of the predicted environmental concentration (PEC) with the predicted no effect concentration (PNEC) to organisms in ecosystems.

The extent and nature of the information available to make such a comparison varies for different substances and environments. A practical hazard assessment scheme must allow for this. The process described in this report comprises a universal approach in which the estimation of PEC values is based on exposure model calculations and PNEC values on toxicological data. It should be recognized that where more precise information is available, for example direct observations linking measured concentrations in the environmental compartments of concern with effects, or abscence of effects, on organisms in the corresponding ecosystem, this should take precedence.

The proposed scheme involves a stepwise or sequential process in which increasingly refined estimates of PEC and PNEC can be introduced if necessary and as data become available. Less refined estimates represent more conservative values. Comparison between PEC and PNEC can be made at different stages in the sequence. This makes it possible to reach a conclusion and terminate the assessment at the earliest possible point in the sequence, thus optimising effort and resources. Where PEC exceeds PNEC at an early point in the sequence, it is necessary to proceed further until a later comparison using more refined information proves satisfactory or risk management must be considered. It is not necessary that PEC and PNEC values are at the same level of refinement for PEC:PNEC comparisons.

In the sequential process, PEC values are estimated using predictive mathematical models for two geographical scales: regional and local. For diffuse sources, regional models based on representative environments estimate average environmental concentrations and provide information for the particular substance on environmental compartments of concern (air, water, sediment, soil or biota). Local models are used to estimate concentrations near the point of entry into the environment. The sequence comprises three levels of refinement: a preliminary or "Screening" phase, a "Confirmatory" phase and a final or "Investigative" phase. Different release

patterns are considered (dispersive, diffuse and localised) and the losses of the substance to the environment during the full life cycle (manufacture, formulation, use and disposal) are addressed.

PNEC values can be estimated from toxicological data for the substance concerned. Such data may comprise acute or chronic toxicity measurements for various species in laboratory tests or (less frequently) toxicity measurements made in the field. PNECs may be derived from these data by extrapolation using appropriate "application factors" to allow for differences between the conditions under which the measurements were made and those applying in practice. In the present scheme, these application factors were determined empirically by comparing reliable, validated acute, chronic and field toxicity data for sub-sets from a data base relating to 360 industrial and agricultural chemicals. This comparison indicated that for the majority of the substances listed, to estimate a PNEC from acute toxicity studies (which should involve at least three species from at least two taxa), the lowest of the median effect concentrations (EC_{50}s) should be divided by an application factor of 200. Where chronic toxicity data are available, the PNEC may be derived by dividing the lowest no-observed-effect concentration (NOEC) by 5, whereas the NOEC from a multi-species ecosystem study can be taken directly as the PNEC. Certain categories of substances, for example metals and metal-containing compounds do not appear to fit the general relationships and have been excluded. Other product groups such as petroleum products may also require further consideration.

The Environmental Hazard Assessment follows a pragmatic approach in evaluating PEC/PNEC ratios. Where PNEC exceeds PEC in the evaluation for the regional case, the next step in the assessment is to determine a PEC for the local situation. If PNEC exceeds PEC at the local level, because of the conservative approach it can be concluded that the substance does not constitute an environmental hazard and hence the assessment can be finalised.

Environmental Hazard Assessment of substances is a demanding task. The central challenge is to develop practicable and valid means of reflecting behaviour in highly complex real environments on the basis of inevitably limited test data and models. It is believed that the approach proposed here represents the current state of the art (particularly with respect to application factors and regional models). However, although the basic concepts should be universally applicable, it is not yet possible to work out detailed applications of the scheme for all situations. Environmental Hazard Assessment is evolving rapidly and significant further advances in models or in availability of ecotoxicological data can be expected.

Thus, to date most Environmental Hazard Assessment schemes have concentrated on freshwater systems and much less attention has been paid to sediments, soil or the marine environment. As a reflection of this, for this report it proved possible only to undertake the ecotoxicological evaluation and derivation of PNECs for aquatic organisms.

Furthermore, the concepts presented in the report are at present only worked out for steady-state environmental concentrations resulting from continuous emissions and should not be used for non steady-state situations resulting from intermittent releases such as batch processes.

The proposed approach was evaluated for several representative chemicals with differing properties and for which sufficient data were available. PECs and PNECs were derived from all available data so that for evaluation purposes PEC/PNEC comparisons could be made at as many stages in the sequential process as possible, including greater levels of refinement than needed to indicate absence of hazard according to the step-wise scheme.

This evaluation demonstrated that, for the limited number of substances tested, the proposed approach represents a workable system for the aquatic environment. Based on PEC:PNEC comparisons, further refinement did not alter the final judgement once the criteria for absence of hazard had been satisfied.

For both the exposure estimation and the assessment of effects, further work is required to demonstrate and verify the applicability of the scheme and to develop it further. This would include evaluating the scheme with additional chemicals, extending to other environmental compartments and taking into account non steady-state conditions. The present document should therefore be seen as an initial report.

SECTION 1. INTRODUCTION

The production, distribution, use and disposal of substances lead almost inevitably to their presence in the environment on a localised basis and, in some cases their more widespread occurrence. The way in which substances enter the environment depends on their physico-chemical properties, the production process, including extraction of natural resources and manufacturing, as well as on the pattern of use and the means of disposal.

The environment has a capacity to assimilate substances (to render them harmless by breakdown or dilution) but if this is exceeded damage may ensue. To evaluate the impact on the environment of substances which may be introduced into it, it is necessary to have a hazard assessment process. The hazard posed by a substance is a function of its inherent toxicity to organisms in the environment and the concentration attained.

To develop a process for hazard assessment it is necessary to define the principles, and establish practical approaches for:-

- predicting environmental concentrations (i.e. exposure assessment) and
- estimating maximum safe levels in the environment (i.e. effects assessment).

In the 'Exposure assessment' the concentration a substance will reach in the environment is calculated. The 'Predicted Environmental Concentration' (PEC) can be estimated if it is known how and in what quantity a substance enters the environment and how it is subsequently distributed and transformed. Alternatively, the environmental concentration can be measured.

'Effects assessment' establishes a maximum concentration of a substance not causing adverse effects: the 'Predicted No Effect Concentration' or PNEC. The PNEC is derived from whatever ecotoxicological data are available, using, where appropriate, an application factor to compensate for any restrictions in the data.

There has been considerable recent interest in the development of processes for hazard assessment, focused to an extent by impending changes in legislation at the European Community (EC) level.

The principal purpose of this report is to propose a sound, practical and pragmatic approach for the hazard assessment of substances in the environment, outlining procedures for exposure assessments to obtain PECs and effects assessments to derive PNECs. The schemes developed are mainly based on empirical data and give guidance on the application of the hazard assessment process for most substances. The approach should be considered as the default and can be superseded by improved knowledge, taking into account that it represents "state of the art".

This report is dealing with continuous emissions leading to steady-state environmental concentrations in the relevant compartments. Intermittent releases resulting from batch processes have not yet been covered.

Only hazards related to organisms in the environment are considered in this report. Indirect effects on man (e.g. via taint) will be covered separately. Effects on the physical environment e.g. those causing climate change or ozone depletion are not considered. The report also does not address risk assessment i.e. the probability that a hazard will occur.

In principle, the hazard assessment scheme developed should be applicable to all environmental compartments. Because the aquatic environment is generally regarded as one of the main compartments at risk, emphasis has been placed on the latter in the development and evaluation of the proposed scheme.

It is recognised that hazard assessment is an evolving technique and the method presented here is just one stage in a process which will be subject to refinement. Therefore this is an initial report, in which recommendations to enhance the development of the hazard assessment process are included (Section 7).

SECTION 2. BACKGROUND

2.1 LEGISLATION

On 30th April 1992 the European Council adopted the "7th Amendment" of Directive 67/548/EEC (EEC, 1992a). This will come into force on 30th October 1993. Article 3.2 of this Council Directive requires that risk assessment be carried out according to principles to be laid down in a Commission Directive. This Directive, which requires an evaluation of the potential hazards and risks of notified substances to man as well as the environment, is to be adopted 12 months following the adoption of the 7th Amendment i.e. by 30th April 1993.

The EC proposal for a Council Regulation on the evaluation and control of the environmental risks of existing substances (EEC, 1992b) requires competent authorities to evaluate the real or potential risks of an existing substance to man or the environment. Implementation of the regulation on existing substances is expected by May/June 1993.

Apart from development in the EC legislation, some national authorities have developed similar principles dealing with the evaluation of existing and new chemicals (e.g. UBA, 1990; UBA 1992).

2.2 EXISTING HAZARD ASSESSMENT SCHEMES

The Commission of the European Communities, Directorate General XI, organised a workshop on "Environmental Hazard and Risk Assessment in the Context of Directive 79/831/EEC" (EEC, 1990) in collaboration with the Environmental Institute of the Joint Research Centre Ispra. This workshop discussed and identified common principles for the environmental hazard assessment of substances to achieve a harmonised and transparent procedure for evaluation of new substances within the Community.

At the request of the Commission the conclusions of the 'Ispra workshop' were discussed by various interested organisations. ECETOC (1991) concluded that the outcome of the Ispra workshop formed a good basis for further discussions. The main points of agreement were that the hazard assessment process should be iterative, that exposure scenarios should be developed for 'use-families' (e.g. surfactants and solvents) and that there was a need for differentiation in the assessment process of the exposure from limited point sources (e.g. manufacturing sites) and exposure from diffuse release (e.g. via widespread use of substances).

Several national authorities and international organisations are developing hazard and risk assessment concepts for new and/or existing substances (e.g. Germany, The Netherlands, UK, Switzerland, USA and the OECD).

The Dutch authorities with support from the National Institute of Public Health and Environmental Hygiene (RIVM) have developed hazard and risk assessment schemes (VROM, 1988/89, 1992). Partly as a result of these developments, the Dutch authorities were requested by DG XI to assist with the development of a system for ranking existing substances on the basis of their environmental hazard. They also developed similar schemes for estimating the environmental hazard of new substances and pesticides for the Dutch authorities. The application of an early version of the Dutch hazard/risk assessment scheme for existing substances indicated that a significant number would have restrictions or would have to be abandoned. This may be due to the conservative approach of applying high safety factors, sometimes unsatisfactory input data and stringent default values where data were missing.

At the request of DG XI, the UK authorities have developed a hazard and risk assessment scheme for new substances for incorporation in the '7th Amendment'.

Existing schemes for hazard assessment generally follow a stepwise approach in which, if necessary, increasingly refined estimates of the PEC(s) and PNEC(s) can be compared in a series of stages. Table 1 outlines some existing/proposed environmental hazard assessment schemes together with brief comments on each. Some approaches are restricted to certain categories of substances such as household substances (e.g. AIS, UBA) whereas others are generally applicable to industrial and consumer products/substances. The approaches tend to be conservative in their estimation of environmental concentrations due to a number of assumptions.

TABLE 1 - (Part 1)

COMPARISON OF EXISTING/PROPOSED HAZARD ASSESSMENT SCHEMES

Name	General outline of the procedure	Use pattern	Release estimation	Exposure assessment (Target compartment)	Proposed models for calculation of environmental concentration
CH-Switzerland (Ordinance on substances)[1]	Stepwise procedure: estimation of emissions/ effect data/hazard assessm. /env. risk ass.	- Uses with direct or high emissions - Incorporated into a matrix - Closed systems - Destructive uses	Based on type of use and amount as well as on mode of disposal (see use categories)	Based on assumed distribution into the different env. compartments	No specific models
UBA (Germany)[2]	Definition of degradation and ecotoxicity criteria for ecolabelling of detergents (German "blue angel")	Detergent ingredients (i.e. wide dispersive use) which enter quantitatively sewage and subsequently receiving waters without/after passing sewage treatment	Rough calculation taking into account the total detergent consumption (of the country concerned) and the proportion of each individual ingredient formulation	Calculation of the substance concentration in raw sewage, in sewage plant effluents and receiving waters taking into account substance consumption figures, the proportion of the substance which is eliminated / biodegraded in sewage treatment plants, the per capita sewage output and the dilution factor of the sewage effluent by the receiving water volume.	Emission algorithm. Standard dilution factor (SDF) = 10 is normally used.
VROM (NL)[3]	Stepwise procedure with increasing level of complexity of data (effects and exposure)	Several use categories such as textile dyes, paper chemicals, etc.	Release estimation according to use categories	All environmental compartments: Air, water, soil, sediment.	DRANC; Local models PRISEC: Mackay + local models USES: Mackay + local models
ISPRA (EC)[4]	Stepwise approach (Screening stage, etc.)	Different use categories	- continuous - intermittent - dispersive - non-dispersive	Based on realistic worst case assumptions	No specific models
OECD[5]	Tiered approach: - initial - intermediate - comprehensive	Grouping of substances according to type of use: industrial, public, ... use categories: dye stuff, intermediates, ...	Covering whole life cycle:- - production - processing - use - recycling - disposal and waste treatment	Focused on:- - air - water - soil	3 local models concerned with a single compartment (SAMS) 1 regional/global model (Mackay Level III)

TABLE 1 - (Part 1 cntd.)

COMPARISON OF EXISTING/PROPOSED HAZARD ASSESSMENT SCHEMES

Name	General outline of the procedure	Use pattern	Release estimation	Exposure assessment (Target compartment)	Proposed models for calculation of environmental concentration
AIS[6]	Stepwise procedure: Screening, confirmatory, investigative phase	Related to detergent substances only	Emission algorithms	Focus on surface water, soil (modification by waste water treatment)	Biodegradation model for screening phase
UK DoE/CIA Model[7]	Iterative: assessment refined as more data on substance becomes available	Point source: direct discharge or via sewage treatment plant. Diffuse: from several sites to whole country	Based on production, use and disposal	Aquatic environment only; removal in STW considered and dilution in river	No specific models

1 BUWAL, 1989
2 UBA, 1991a; 1991b
3 Van de Meent and Toet, 1992
4 EEC, 1990
5 OECD, 1989; 1991
6 AIS, 1989
7 DoE/CIA, 1992

TABLE 1 - (Part 2)

COMPARISON OF EXISTING/PROPOSED HAZARD ASSESSMENT SCHEMES

Name	Proposed (eco-) toxicity tests	PEC / PNEC comparison	Safety factors / Uncertainty factors	Status	General Remarks
CH -Switzerland (Ordinance on substances)	Acute tests (point emissions) Chronic tests (dispersive use)	To be taken into consideration for risk assessment only (2nd stage)	Not explicitly given	Legally required - responsibility of manufacturer / importer	Guidelines provide a useful general instrument for a rough environmental hazard assessment. No strict scheme to be followed. Guidelines give useful specific figures for CH (waste water pro capita, etc.)
UBA	Tolerable effect concentrations are deduced from acute/chronic test data applying assessment factors. Approach is consistent with the ISPRA document.	yes (Ratio of PEC surface water / Tolerable effect concentration)	Depending on the ecotoxicological test data base, assessment factors of 1000 (few acute data), 100 (several acute data) and 10 (chronic data for 3 species) are applied.	Approach forms the basis of the criteria setting for the German ecolabel established for "detergents as a component system". The UBA approach has also been applied for hazard assessment of detergent ingredients by the UBA (cf. DTDMAC discussion).	UBA approach is principally based on the hazard assessment scheme of the ISPRA document. Exposure assessment is expected to yield overestimated PEC values particularly in those cases where the major part of domestic sewage is treated in biological sewage treatment plants.
VROM (NL)	Acute, chronic, more comprehensive tests according to step of the procedure	yes	10 - 1000 (according to test level, using modified EPA approach)	Discussion documents	Env. PEC's are expected to be sometimes overestimated.
ISPRA (EC)	Acute tests Chronic tests Biodegradation tests	yes	Assessment factors 10-times more conservative as comp. to EPA/AIS approach	Summary of a workshop (Oct. 1990)	Confusing description of receiving environment Simple initial env. conc. calculation including corresp. dilution factors.
OECD	Acute/chronic tests; human exposure via food to be considered	yes	10-1000 according to type and number of tests	Effect/hazard assessment: - OECD report no. 26 (1989) Exposure assessment: - Draft report Jan. 1992 (Berlin workshop 1991)	Exposure assessment process in evaluation (different approaches by different member countries) Local models (SAMS) and global model available for testing in May 1992

TABLE 1 - (Part 2) cntd.

COMPARISON OF EXISTING/PROPOSED HAZARD ASSESSMENT SCHEMES

Name	Proposed (eco-) toxicity tests	PEC / PNEC comparison	Safety factors / Uncertainty factors	Status	General Remarks
AIS	- Acute tests (screening) - Simulation tests (conf. level) - Field trials (invest. stage)	yes	No fixed safety factors. Increasing certainty with increasing level of assessment	Surfactant industry proposal	
UK DoE/CIA Model	Acute and chronic tests	yes PNEC replaced by Env. Conc'n of Concern = Effect Conc'n/Assessment Factor	Assessment factors: 1-1,000 depending on available toxicity data (after US-EPA) Factors may be reduced if data available to suggest this is appropriate.	Official UK proposal to the Commission	A simple approach to the estimation of PEC is adopted and this concentrates primarily on the aqueous phase. Since losses to other environments are ignored probably a "worst case" PEC is obtained