Special Report

No 2

Existing Chemicals
Recommendations for Priority Setting

June 1991

ISSN-0773-8072-2

SPECIAL REPORT

No. 2

EXISTING CHEMICALS

Recommendations for Priority Setting

Brussels, June 1991

Contents

ECETOC Special Report

Existing Chemicals: Recommendations for Priority Setting Report

A. Introduction

The chemical industry and national and international organisations have undertaken evaluation of environmental and toxicological risk on many of the chemical products produced and marketed over past years. It is recognised however, that there is need to undertake a systematic examination of all existing chemicals to identify those with the greatest hazard potential and to undertake risk assessments when necessary. Recently, international and national authorities have been devoting effort to identify such "priority chemicals".

The magnitude of the task is great since large numbers of chemicals are involved. There are over 60,000 on the US-TSCA list and more than 100,000 on the EEC inventory (although fewer are of commercial importance). Moreover, the information needed to set priorities for many of these chemicals is either not available or difficult to obtain. Therefore the chemical industry and the EEC require a system which is economical in the use of time and resources and yet identifies those chemicals with the greatest potential risk to man or the environment for more detailed assessments.

Initial attempts at priority setting are based upon arbitrary selection of certain groups of chemicals rather than upon a systematic evaluation of all existing chemicals. To improve upon this the OECD (1986) reviewed possible approaches to priority setting and developed guidelines.

More recently the EEC Commission has made a proposal for an EEC Council Regulation on the evaluation and control of environmental risks of existing chemicals. However, although this proposal describes how data will be collected, it does not specify how the data will be used to select the priority chemicals for further risk evaluation.

In order to clarify how priority chemicals can be identified ECETOC has reviewed the principles involved and put forward ideas and proposals for a systematic step by step process.

This report

- discusses the principles underlying priority setting
- describes the EEC Commission Proposal
- makes recommendations for a priority setting process for existing chemicals.

B. General Principles

The ultimate aim of priority setting for existing chemicals is the identification of chemicals which have a potential for significant risk to man or environment and which require further evaluation.

Because of the large number of existing chemicals any procedure will necessarily consist of a number of steps, as described in the following sections.

B.1 Initial Selection : Starting List

The first step is to select from the chemicals on the inventory lists a starting list of chemicals of particular interest. Selection should be based on data which are easily obtainable.

Those selected would be :

- chemicals for which a significant exposure potential can be assumed from the quantities produced and/or their use pattern;

- chemicals for which a health and/or environmental hazard potential can be assumed from their chemical structure;

- chemicals identified by analysis in the work place and/or in the environment.

The aim of this initial step is to produce a manageable list of chemicals on which, given available resources, more extensive data can be collected for priority setting. The particular basis of initial selection will depend on the objective of the priority setting process. Thus if chemicals are to be identified which might be hazardous to the environment it will be advisable to start with a list of chemicals likely to produce high environmental exposure. On the other hand, chemicals expected to have a high toxic potential should be listed if the aim is to identify chemicals likely to be hazardous in the workplace.

B.2 Identification Step

In the identification step, chemicals on the starting list are screened to identify those which have priority for further consideration because there is evidence of hazard or, alternatively, because there is insufficient evidence to assess hazard. For the majority of chemicals only a limited amount of data is expected to be available within a reasonable time period and a compromise has to be found between the need to collect the maximum possible data relevant to hazard assessment and the availability of resources necessary for the collection of all information on a chemical.

After collation, the data are evaluated to identify those chemicals which may merit risk assessment either because available information suggests a high hazard potential or because data inadequacies suggest an urgent need for hazard assessment.

B.3 Hazard Assessment Step

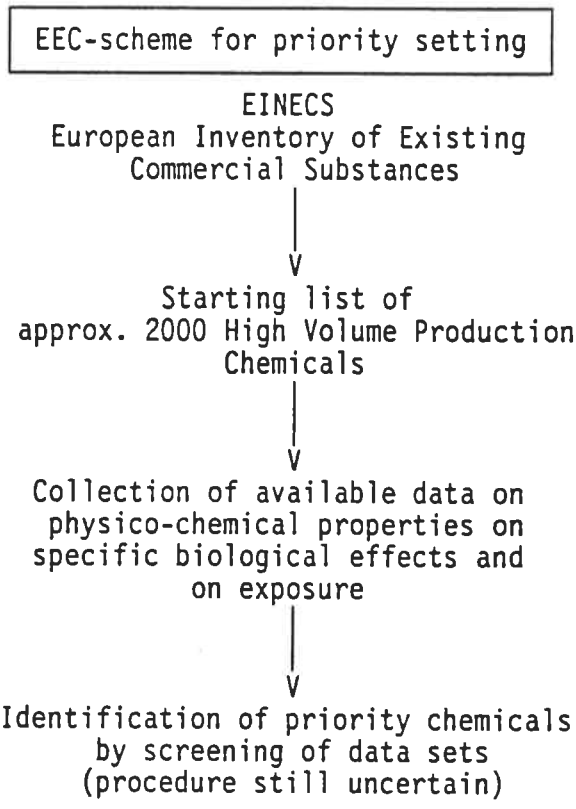
In the hazard assessment step the available data are reviewed in order to determine the nature and extent of any risks to man or environment and measures necessary for the control of risks associated with production and use of the chemicals.

For those chemicals for which available data are insufficient even for a preliminary assessment of hazard potential, the additional data required for risk assessment to man or the environment will need to be defined.

C. <u>Proposal for a Council Regulation (EEC) on the Evaluation and the Control of Environmental Risks of Existing Substances</u> **(see Official Journal of the European Communities C 276 from 5.11.90 ISSN - 0378-6986)**

The general concept of this proposed regulation requires that certain information concerning chemicals produced or imported in quantities of more than 1,000 tonnes per year will have to be reported. The primary information requirements are: chemical identity, quantities produced or imported, use-pattern, specific physico-chemical data, chemical fate, ecotoxicological and toxicological data. On the basis of this information and national lists of priority chemicals, the Commission in consultation with Member States, will regularly draw up lists of priority chemicals or groups of chemicals requiring special attention because of the possible effects they may pose to man or the environment. Therefore, a systematic stepwise approach is to be adopted as shown below.

The proposed Regulation does not describe how these priority chemicals will be selected.



D. Approaches to the Identification of Priority Chemicals

D.1 General

One of the most difficult aspects in all priority setting systems is how to assess the data collected in the screening phase (use pattern, toxicology ecotoxicology, etc) and present it in a clear and comparative format.

This will require methods that are a balance between scientific accuracy and regulatory requirements. An apparently easy method would be to allocate numerical scores to the chemicals on the basis of their respective hazard potential and to sort them according to the magnitude of a combination of scores.

There are occasions when it is useful to assign a numerical value to a combination of biological effects produced by a chemical and then use the value obtained as a standard against which to measure the effectiveness of control procedures. Hygiene standards (TLV'S, MAKs, etc) are the best example of this concept and the process of their derivation has acceptance throughout the world. Even so, the assigned numbers should not be used without expert knowledge on the significance of the biological test results on which they are based. The numbers themselves merely represent a value in specific units that provide adequate levels of protection. It is inappropriate to rank chemicals in terms of their hygiene standards because they are set to control different types of adverse effects. One chemical is not necessarily considered a higher priority (or greater risk) than another with a standard twice as high. For example phosgene has an MAK value of 0.4 mg/m^3, whereas hydrogen cyanide has a value of 11.0 mg/m^3. The numbers do not simply mean that hydrogen cyanide is 27.5 times less hazardous than phosgene - rather that knowledge is necessary to recognise the very different toxicological hazards that each represents.

Nevertheless numerical scoring systems have been proposed for priority setting purposes.

D.2 Scoring Systems

These systems rely on condensing, the information (sometimes complex) gained from physico-chemical properties, toxicological and ecotoxicological effects into simple numerical scores for each chemical and for each property.

For the purpose of ranking, other scores are necessary e.g. estimates of concentrations in the environment, during domestic use or in the work place.

Finally all the scores are combined by arbitrary mathematical equations which differ according to the system used to produce one or more final score(s) for priority setting for each chemical.

D.3 Comments on Scoring Systems

Many scoring systems for priority setting have been developed e.g. Sampaolo and Binetti (1985, 1989); Weiss et al (1988), Koenemann and Visser (1988) and more recently by the UK-Department of Environment (DoE 1991). (A detailed description and critique of these systems are given in the Appendix I of this report).

Although these four scoring systems differ from one another, all are based on the principles described above. They have the advantage of being clear because decisions can be reached easily and they can be adapted to computerised systems.

Usually the available toxicological and ecotoxicological data are incomplete and thus no direct comparison between the chemicals is possible. For unavailable data estimated scores are used based either on related properties from which data are available or on structure activity relationships or simply by inserting "default" scores which assume certain properties for the chemical for the purpose of priority setting.

The systems combine in various ways the scores for different properties by mathematical treatment, e.g. for estimating the possible concentration of a

chemical in the environment, scores for release rates are integrated with those for biodegradation, atmospheric half life etc. The main drawback with this method is that if scores allocated to biological end points are combined with each other or with surrogate scores on exposure, this leads to scientifically meaningless figures with an unjustifiable degree of accuracy.

For example the scoring system of Sampaolo and Binetti (1985, 1989) collates scores for biological effects with exposure surrogate data in mathematical equations even though these scores have different meanings and therefore are not equivalent.

The UK "DoE (1991) Priority Setting Scheme" is quick and simple, but it is based on only few data and ignores more complex aspects such as chronic toxicity for which data may be available. It uses "worst-case" default values if information is unavailable. The mathematical calculations combining the scores to produce priority figures are entirely arbitrary.

The system of Weiss et al (1988) also combines all data on biological effects into a single score, although it discriminates between the three compartments air, soil and water. It is based on standardised data suitable for computer evaluation thus rendering it difficult to include any non-standardised additional information which may be of great value in priority setting. Additionally it does not take into account the important field of human exposure via consumer products.

The scoring method used in the system of Koenemann and Visser (1988) is also based on rough assumptions and arbitrary score ratios but discriminates between different exposure/effect combinations. Scoring requires expert judgement. The "scoring profile", consisting of 10 different end scores, could be used to score a number of chemicals in different ways according to anticipated hazards, but it does not allow allocation of an overall priority ranking.

D.4 Conclusion

Ranking chemicals according to a numerical value which is solely and directly related to one property only, can be an acceptable procedure. Such a procedure could lead to a valid list of chemicals ranked for example, according to their eye irritancy. It is wholly inappropriate to compare a dose (or concentration level) with another, obtained in a different laboratory with a different chemical and end-point in order to claim that one chemical has a higher priority for hazard assessment than another. For example, the sub-acute toxicity of chemicals may be ranked by comparing the highest dosage levels which produce no adverse biological responses in animal studies (i.e. by comparing the no-effect levels). Nevertheless expert judgement is needed to assess the relative significance of the effects produced by each chemical on man or the environment when deciding which of the chemical constitutes the greatest potential human health or environmental hazard.

The principle of assigning scores to each and every physical property and biological test result and totalling the scores to set relative priorities is scientifically unsound. It is impossible to reduce the multivariate human and environmental responses to one or even a single numerical values. A further criticism of all systems discussed is the use of surrogates for exposure in calculating numerical values for priority setting.

As a result of these deficiencies it is recommended that scoring systems should not be used for priority setting.

E. ECETOC Recommendation for Priority Setting

Bearing in mind the considerations and principles formulated in chapters B and D, a proposal is made for a priority setting system which is more sound from scientific basis and is manageable for screening a significant number of chemicals.

By analysing the data given in the EEC data sets [Annex II of the EEC Proposal of a Council Regulation (EEC) in Off. J. C276, vol 33, 5.11.1990]*, chemicals can be screened according to exposure and possible hazard potential to man and environment in order to assign them to different priority groups.

The ECETOC recommendation for priority setting does not use numerical scores but relies upon case by case evaluation using expert judgement. This expert judgement should be supported by a short written explanation.

E.1 The Identification of Priority Chemicals at the Screening-Stage

To screen chemicals according to exposure and possible hazard potential the following sequence of steps for priority setting are proposed:

First step: Exposure potential
should be expressed in practical terms relevant to a few use pattern categories rather than on the basis of scores allocated to estimates of emission quantities and physico-chemical data.

Chemicals should first be prioritised according to their use patterns* and hence exposure as follows:

- High exposure corresponds to wide-dispersive use,
- Medium exposure corresponds to non-dispersive use,
- Low exposure corresponds to uses in closed systems and/or inclusion on or into matrices.

* See ECETOC (1991) "Guidance for Completion of the EEC Data Set" Special Report N°. 1.

Information on environmental compartments to which a chemical is discharged and in which it will accumulate is also of use in priority setting. This can be derived from knowledge of physico-chemical properties (ECETOC, 1988). This information is included in the process, as given in the Examples 1 and Example 2.

Chemicals which have low exposure are set aside. Chemicals for which available information on exposure is insufficient for a decision to be made are considered to have high exposure potential.

Second Step: Toxicological or ecotoxicological data
should be used to evaluate the potential hazard to man or the environment. Since multiple biological observations should not be expressed as a simple numerical score, toxicological or ecotoxicological data should be summarised by short descriptions suitable for subsequent expert evaluation. It is recommended, for comparability and clarity, that the effects are grouped as follows:

- acute effects,
- subacute/subchronic and chronic effects (including effects on reproductive organs),
- genotoxic/carcinogenic effects,
- teratogenic effects,
- ecotoxic effects.

Such data should be evaluated and the chemical placed into one of the 3 following hazard categories using the guidance given in Section E.2.

- confirmed hazard,
- no clear decision possible,
- low hazard.

Third Step: Gaps in information
should be clearly identified. If, on the basis of scientific judgement certain types of data seems unnecessary, this should be stated and justified briefly.

Fourth Step: The selection of priority chemicals
should proceed by correlating the exposure assessment (first step) with the biological data (second and third step) and allocating them to one of the following 3 Main Priority Groups by using the matrix described on page 15.

Group I

Chemicals for which, on the basis of their exposure potential and biological properties, a confirmed hazard potential exists for man and/or the environment. These are candidates for hazard assessment.

Group II

Chemicals for which available data do not allow a clear decision to be made about their hazard potential. In these cases either additional tests will have to be conducted or additional information on use patterns will have to be collected.

It should be possible to re-assign these chemicals to Groups I or III, when the additional data have been collected or developed.

Group III

Chemicals with a low exposure potential, low biological hazard or both are considered to have low priority for risk assessment. This group of chemicals is set aside.

Chemicals placed in Group I or Group II may be further subdivided into different Priority Ranges by ranking exposure and/or toxic potential as described in Section E.4 and summarised in the flow chart of the ECETOC screening process (Fig 1).

E.2 Guidance for Assigning Chemicals to Hazard Categories

When assigning chemicals to one of the 3 hazard categories (see under E.1, second step) the following criteria should be used:

Toxicological Effects

Confirmed Hazard

Include all chemicals for which data demonstrate one or more of the following effects:

Acute mammalian effects:
Chemicals which are very toxic, toxic, corrosive or sensitising as defined by the EEC 7th amendment.

Subacute, subchronic, chronic mammalian effects:
Substances labelled with R48 as defined by criteria in the EEC 6th amendment.

Genotoxic / Carcinogenic effects:
Substances which show positive results in relevant mutagenicity screening tests or in relevant long term studies.

Teratogenic effects:
Substances which show teratogenic effects if administered in dosages not producing maternal toxic effects (ECETOC 1986a).

No Clear Decision Possible

Include all chemicals for which there is insufficient data for one or more parameters listed above to allow evaluation of toxicological effects.