Decision-Recommendation of the Council on the Systematic Investigation of Existing Chemicals

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Background Information

The Decision-Recommendation on the Systematic Investigation of Existing Chemicals was adopted by the OECD Council on 26 June 1987 on the proposal of the Third High-Level Meeting of the Chemicals Group (today under the responsibility of the Chemicals Committee), as approved by the Environment Committee. This instrument aims to address the need for shared and co-ordinated efforts among Adherents in order to efficiently and effectively protect man and the environment from the potential hazards of existing chemicals. Hence, this instrument requires that Adherents establish or strengthen national programmes to systematically investigate existing chemicals in order to identify those which need to be managed.

THE COUNCIL,

HAVING REGARD to Articles 5 a) and 5 b) of the Convention on the Organisation for Economic Co-operation and Development of 14 December 1960;

HAVING REGARD to the Recommendation of the Council of 7 July 1977, establishing Guidelines in respect of Procedure and Requirements for Anticipating the Effects of Chemicals on Man and in the Environment [C(77)97(Final)];

HAVING REGARD to the conclusions concerning the control of existing chemicals reached at the First and Second High-Level Meetings of the Chemicals Group of 12 May 1980 and 15 November 1982;

HAVING REGARD to the Recommendation of the Council of 26 July 1983, concerning the Exchange of Confidential Data on Chemicals [C(83)97(Final)];

HAVING REGARD to the Recommendation of the Council of 26 July 1983 concerning the OECD List of Non-Confidential Data on Chemicals [C(83)98(Final)];

HAVING REGARD to point 6 of the Declaration on Environment: Resource for the Future, of 20 June 1985 adopted by the governments of OECD Member countries and of Yugoslavia that more effective control of both new and existing chemicals from their manufacture to ultimate disposal will be achieved through shared and co-ordinated efforts;

CONSIDERING that, although different kinds of work on existing chemicals are undertaken in Member countries, most existing chemicals have not been subjected to a systematic investigation of their potential hazards to man and the environment and that, for a large number of these chemicals, the available information is not adequate to undertake such an investigation;

CONSIDERING the need to establish the management and control of existing chemicals on a more anticipatory and systematic basis, whereby those existing chemicals which may pose an as yet unrecognised threat to man and the environment can be identified, assessed and, if necessary, controlled;

CONSIDERING the large scale and complexity of efforts required to ensure adequate control of existing chemicals and the limited resources available in Member countries for this purpose;

CONSIDERING, therefore, the need for shared and co-ordinated efforts among Member countries in order to efficiently and effectively protect man and the environment from the potential hazards of existing chemicals;

On the proposal of the Third High-Level Meeting of the Chemicals Group, as approved by the Environment Committee:

I. **DECIDES** that Member countries shall establish or strengthen national programmes to systematically investigate existing chemicals[1], in order to identify those which need to be managed and/or controlled.

II. **RECOMMENDS** that Member countries:

1. When investigating existing chemicals systematically, take into account the principles and technical guidance summarised in Annex I entitled Chemicals on which Data are Currently Inadequate: Selection Criteria for Health and Environment Purposes, which is an integral part of this Act;

2. When reviewing the information on an existing chemical for any of the various purposes associated with its systematic investigation, take into account Annex II entitled, Guidelines for Preparing Chemicals Reviews, which is an integral part of this Act;

3. Establish the means to collect, estimate or generate the information needed for a systematic investigation of existing chemicals;

4. Provide, to the extent possible and in accordance with existing OECD Council Acts on chemicals, the available information on an existing chemical when requested by another Member country for the purpose of investigating that chemical and that they establish mechanisms for such information exchange.

III. INSTRUCTS the Environment Committee and the Management Committee of the Special Programme on the Control of Chemicals to review actions taken by Member countries in implementing this Decision-Recommendation and to pursue a programme of work designed: a) to facilitate such implementation; and b) to assist Member countries to co-operate in systematically investigating existing chemicals.

ANNEX I

CHEMICALS ON WHICH DATA ARE CURRENTLY INADEQUATE: SELECTION CRITERIA FOR HEALTH AND ENVIRONMENTAL PURPOSES

I. Introduction

1. Since the resources needed to satisfactorily and expediently identify all of the existing chemicals which may pose as yet unrecognised threats to human health or the environment are limited, it is necessary to develop mechanisms for selecting existing chemicals and establishing priorities among them for further study. In response to this need, the Management Committee of the Special Programme on the Control of Chemicals established two Expert Groups in 1982 to develop Selection Criteria for Health and Environmental Purposes to assist Member countries in identifying these existing chemicals.

2. The Expert Groups identified and analysed:

a) **Selection Elements** which could be used individually or in combination to select chemicals in need of further information development for health or environmental purposes;

b) **Priority Setting Processes** to weigh, combine and assemble Selection Elements in order to produce management tools for the systematic selection of chemicals;

c) **Data sources**, including major inventories and compilations, where information might be found which could be of use in that context.

3. This Annex summarises the sections of the Final Reports of the Expert Groups relating to Selection Elements and Priority Setting Processes which provide technical guidance in the development and use of the Priority Setting Processes to select chemicals for further study of their potential effects on human health and the environment. Those sections, and a compilation of data sources for existing chemicals, will be found in the complete Expert Groups Report, *Existing Chemicals: Systematic Investigation - Priority Setting and Chemicals Reviews* (OECD, 1986).

II. Selection Elements

4. Selection Elements include both the parameters and characteristics of a chemical; its use (from manufacture to disposal) and occurrence; and the characteristics of exposed human populations or ecosystems.

5. A number of exposure- and effects-related Selection Elements are identified, including both primary exposure and effects parameters and surrogates which can be used to estimate these parameters when such substitute information is more readily available. An example of a surrogate Selection Element would be production volume, which can be used to estimate potential exposure.

6. Although they are presently limited in scope, qualitative or quantitative structure-activity relationships (SAR) or techniques and other techniques, such as property-property correlations, for estimating some of the following exposure- and effects-related Selection Elements can play an important role in the processing of large numbers of chemicals for which little if any data are available.

The approach most commonly used at present is qualitative. It involves the examination of a chemical's structure and the use of expert knowledge and suitable compilations of data. Since a quantitative approach involves analysis of relatively large numerical data bases for chemicals and specific effects, its applicability is presently limited to a few types of health and environmental effects and, even for these, is still undergoing development. Expert judgement is necessary in applying these techniques since a full understanding of their assumptions and limitations as well as their implications for the selection of chemicals is required.

Exposure-related Selection Elements

7. The exposure-related Selection Elements are divided into three groups. Those especially relevant for each group are the following:

a) Workplace Exposure:[2]

- Production and import volume/industrial use volume;
- Industrial use patterns;
- Physical-chemical characteristics;
- In-plant operating conditions and activities;
- Route of exposure;
- Extent of exposure;
- Characteristics of the exposed worker population.

b) General Population Exposure:[3]

- Production and import volume/volume in commerce;
- Use patterns;
- Release to the environment;
- Physical-chemical characteristics (including physical form and matrix);
- Environmental fate;
- Characteristics of the exposed population;
- Monitoring information.

c) Environmental Exposure:

- Detection in the environment;
- Release potential to the environment, including:

  i) Production and import volume/consumption volume;

  ii) Environmental release during manufacture and processing;

  iii) Use patterns;

  iv) Mode of waste disposal.

- Environmental fate, including:

  i) Environmental distribution;

  ii) Transformation/degradation;

iii) Bioaccumulation.

Effects-related Selection Elements

8. The effects-related Selection Elements are divided into two groups. Those especially relevant for each group are the following:

a) Health Effects:

- Mutagenic effects;
- Carcinogenic effects;
- Embryotoxic and teratogenic effects;
- Effects on reproduction;
- General toxicity and specific organ effects, including:

  i) Effects on the immune system;

  ii) Neurotoxic effects;

  iii) Irritation of eye, skin and mucous membranes.

b) Environmental Effects:

- Effects on aquatic ecosystems;
- Effects on terrestrial ecosystems;
- Effects on other target systems, including:

  i) Function of biological sewage treatment systems;

  ii) Atmospheric changes.

For each Selection Element, the following aspects are presented:

- A short description;
- Relevant primary and surrogate information and/or data related to the Selection Element;
- Applicability and use of the Selection Element in the priority setting process;
- Scope, strengths and weaknesses, as well as assumptions and limitations associated with its use;
- Data availability.

III. Priority Setting for Health or Environmental Purposes

9. The two priority setting processes, one for health and the other for environmental purposes, describe how the relevant Selection Elements can be applied individually or in combination to select those chemicals that most urgently need further information development. They have similar overall structures characterised by flexibility sufficient to assist in the design and conduct of various selection exercises, taking into account differing specific purposes, national needs and priorities and varying availability of information and resources. Under certain circumstances, they may be combined in the same process.

Aspects Common to Both Processes

10. Identifying the purpose and scope of a priority setting exercise is of paramount importance since they may influence the approaches to inclusion or exclusion of chemicals in or from the exercise, the choice of Selection Elements, and other practical considerations. Clarification of scope and purpose may entail the defining of practical constraints under which the process is undertaken, legislative/administrative considerations, and scientific/technical considerations. Such definition would involve the determination of factors such as the time in which the results are required; availability of resources; national priorities, regulatory requirements and policies; effect(s) of interest (e.g. carcinogenicity, toxicity for aquatic organisms); and specific broad category(ies) of chemicals of interest (e.g. chemicals in food, chemicals found at a waste disposal site).

11. To reduce to a manageable number the chemicals under consideration about which further information may be sought, a four-stage process (**Compilation, Screening, Refinement** and **Review**) is recommended.

12. The quantity and complexity of the information needed, as well as the resources used to process each chemical, increase from the Compilation Stage to the Review Stage, so that the optimum use of resources for retrieving and evaluating the information is ensured. The information most readily available (e.g. least expensive or time-consuming to obtain) is used in the early stages, when the largest number of chemicals is being dealt with. In the later stages, when the number of chemicals involved is considerably smaller, data acquisition can be more comprehensive (and expensive) based on, e.g., in-depth literature searches. Information used at the Screening Stage could, for instance, be obtained primarily from the tertiary literature, machine-readable data bases and SAR, whereas that used at the Refinement Stage could come largely from medium-depth information searches. In the initial stages, care must be taken not to miss chemicals of concern (i.e. to limit the number of false negatives). In the Review Stage, on the other hand, the selection of chemicals should be much more specific, i.e. only chemicals which are of high concern should be selected (thus limiting the number of false positives). It is important at this stage that the quality of the data used throughout the process be evaluated and the "concern" for a chemical be adjusted as appropriate.

13. Although the two processes allow flexibility in the choice and application of Selection Elements at the different stages, in both it is recommended that data on exposure- and effects-related Selection Elements be used in combination. It is also recognised that information on only one type of Selection Element may be sufficient to move a chemical to the next stage. In neither process is the combining of priorities, or degrees of concern for different types of toxic responses, recommended. Instead, an output matrix is proposed which sets out priorities by types of specific toxic responses, specific target organisms, specific exposure situations or media, and/or information needs. By treating concerns and priorities in this way, those areas in which efforts would be best concentrated for further information gathering can be identified.

14. When a selection exercise has been completed, the main output is the group of "selected priority chemicals" from the Review Stage (Figure 1). But at both the Screening and Refinement Stages another group of so-called "incompletely processed/standby chemicals" is identified about which information sufficient for processing is lacking at that selection stage (Figure 1). These chemicals, too, are associated with some degree of concern, depending on the amount of information characteristic of the selection stage at which they were produced. This category of chemicals for which data appear to be insufficient, and for which there is no method of estimating data so that they can be considered appropriately in the process, is an important one. Possible approaches are suggested for further processing of these chemicals through more extensive data gathering.

15. By-products of the selection exercise are groups of "non-selected/lower priority chemicals" and of "non-relevant chemicals" from the Screening, Refinement and Review Stages (Figure 1). These non-relevant chemicals are either outside the scope of the selection exercise, or they are chemicals for which data are adequate.

16. At no stage should the selection exercise be solely mechanical. There is a need throughout for expert judgement involving the use of techniques such as SAR and other methods to provide estimates of missing information when appropriate. Each of the two processes allows for the fact that information available on a chemical could be sufficient either to move it directly to the subsequent stages or to drop it from the ongoing selection exercise altogether (i.e. into the group of non-relevant chemicals). Moreover, initial stages of the process may be bypassed if the number of chemicals

involved is small enough to be handled with the resources available at a higher stage. The selection process should be repeated at intervals to reconsider chemicals not selected in previous exercises (including those previously designated as "non-relevant"), rectify possible errors, take into account new data and improve the selection methods. This is particularly important in that existing chemicals must be selected for further review on the basis of limited information. Consequently, some harmless chemicals are likely to be selected and some hazardous ones missed.

Aspects Specific to Each Process

17. The two priority setting processes differ primarily in the Selection Elements chosen for use, and in the ways they are used and/or combined with other Selection Elements at each stage.

Priority Setting for Health Purposes

18. The process of selecting chemicals on the basis of their potential to cause adverse health effects begins at the **Compilation Stage** designed to compile the list of chemicals to be subjected to the selection process. Various approaches to the inclusion of chemicals on the candidate list (or their exclusion therefrom) are described which may require the use of expert judgement. These approaches are based on production/import volume data, chemical analogy, selected physical chemical properties, monitoring data, spill statistics, effects-monitoring data and case-by-case nominations. The information needed for these approaches can be obtained from national inventories, industry and trade data, lists of chemicals for toxic effects, and lists of chemicals found in the workplace, environment, etc.

19. At the **Screening Stage**, chemicals from the candidate list are selected for further processing. Chemicals are identified about which information is insufficient for an evaluation to be made. Readily available information is used for Selection Elements related to workplace or general population exposure (e.g. production and import volume; volume in commerce; use patterns) and/or to relevant health effects (e.g. lethal acute dose; mutagenicity). The Selection Elements for which data are best estimated by SAR are most useful at this stage. Combining information on exposure and effects is recommended when establishing broad categories of concern. Thus, health effects could be described as "likely" or "unlikely" without specifying the type of effect. Volume and use-pattern information could be broadly categorised ("high" or "low") in relation to the level, frequency and duration of exposure, and the size of the exposed population.

20. At the **Refinement Stage**, the Selection Elements already applied at the Screening Stage are used more critically and in greater detail, possibly together with some additional ones, to further define the potential concern for chemicals selected at the Screening Stage. Data on exposure-related Selection Elements are used to give a more precise estimate of the level, frequency and duration of exposure and to identify relevant target population groups (size and composition). There are cases in which total exposure to a chemical is significantly greater than exposure derived from either general population or workplace considerations alone, or in which the priority setting exercise includes considerations of total exposure. In such cases it may be necessary to evaluate human exposure in an integrated way by the combined use of all the relevant exposure-related Selection Elements. Data on health effects-related Selection Elements are used to evaluate concern for specific types of effect(s). Estimates concerning exposures and specific types of effect(s) can then be integrated. Scoring approaches may be used at this stage. The chemicals selected for the Review Stage are listed in an "output matrix" which sets out priorities concerning the potential for specific toxic responses determined in combination with more detailed exposure considerations and/or priorities for further information needs.

21. At the **Review Stage** the quality or adequacy of the data used to select a chemical is evaluated and an attempt is made to specifically identify health effects or exposure data which are needed to establish priorities. Specific methods are not described; rather, data acquisition and evaluation on a case-by-case basis is recommended.

Priority Setting for Environmental Purposes

22. The process of selecting chemicals on the basis of their potential for adverse environmental effects begins with the identification of "chemicals of interest" from the universe of chemicals. Those chemicals which are non-relevant for administrative/legal or technical/scientific reasons are excluded.

When the number of chemicals is larger than can be handled at the Screening Stage, they are reviewed at the **Compilation Stage** using three broad groups of Selection Elements related to potential exposure of the environment, detection in the environment and potential effects on the environment. Selection is based on expert judgement and on information contained in existing lists of chemicals related to one or more of these three groups of Selection Elements. Thus, only minimal data collection takes place at this stage.

23. At the **Screening Stage**, the potential of each chemical for environmental exposure and effects is assessed. Exposure potential is estimated on the basis of the release potential of the chemical to the environment, its detection in the environment, or its persistence and/or bioaccumulation. Effects potential is the potential for any adverse effect on any aquatic or terrestrial species. Without recommending a standard procedure for estimating these potential effects, the relevant Selection Elements and considerations related to their use are described. Exposure and effects potentials can be categorised into broad classes of concern (e.g. "high/low" or "high/medium/low"). Chemicals can be selected by choosing cut-off values for certain Selection Elements and considering exposure and general effects potentials in an integrated way.

24. At the **Refinement Stage**, the number of chemicals is further reduced through more sophisticated consideration of exposure to, and effects on, target organisms in the environment. Information on all relevant Selection Elements is used to characterise the exposure pattern of a chemical in various media (air, water and soil) and to estimate its effect on specific target organisms. Each Selection Element for environmental effects should be considered separately at this stage and then combined with exposure estimates for relevant environmental media (target/media combinations). Scoring approaches may be used at this stage. For those chemicals selected for the Review Stage, the concern areas (e.g. aquatic organisms, terrestrial ecosystems, etc.) and important data gaps may be identified. A matrix is useful in relating chemicals with concern area(s) and corresponding data gaps.

25. The purpose of the **Review Stage**, which is similar to the priority setting process for health purposes, is to evaluate the quality of the data used to select a chemical so that it does not become a priority chemical on the basis of incorrect or incomplete information. The main difference between the Refinement Stage and the Review Stage is that data on a chemical are scrutinised more intensively, and on a case-by-case basis, in the latter.

IV. Data Sources

26. In order to provide some guidance in finding the information and/or data necessary to carry out the selection of priority existing chemicals for further development of information, the Report of the Expert Groups contains a Data Sources Section that includes:

i) A compilation of 195 handbooks and tables, 335 monographs, reports and other printed documents, and 54 computerised data bases;

ii) A compilation of many existing public sources of information on the use of industrial chemicals;

iii) A review of the principles used to compile the major available chemical inventories.

Figure 1 **FRAMEWORK FOR HEALTH AND ENVIRONMENTAL SELECTION PROCESSES**

(not available electronically)

ANNEX II

GUIDELINES FOR PREPARING CHEMICALS REVIEWS[4]

I. Introduction

1. Review documents and reports on chemicals differ widely in their purpose, format and content. The various reasons for preparing chemicals reviews include:

a) Identifying chemicals for further data development;

b) Reviewing a specific property of a chemical;

c) Supporting decisions to regulate or not to regulate chemicals.

Whatever the ultimate reason for preparing a chemicals review may be, it will generally involve some assessment of the potential hazard of the chemical concerned.

2. These Guidelines are intended to promote the consistent presentation of information in chemicals reviews, which will:

a) Facilitate international use and exchange of chemicals review documents;

b) Provide the reader with an indication of the amount of available information or the lack thereof;

c) Allow the reader to locate information of interest.

The exchange of reviews would avoid duplication of efforts, thereby conserving scarce resources.

3. While these Guidelines are aimed at achieving consistency, flexibility in their application is essential. Since chemicals reviews may be developed for a wide variety of purposes and reflect a broad range of information needs and availability, all reviews will not contain the same data elements. Whether certain data elements are included will also depend on the type of chemical under review.

4. A list of data elements for possible inclusion in chemicals reviews is found in paragraphs 9 through 21.

5. The Guidelines address the following points:

a) Elements to be considered in a chemicals review;

b) Quality of data;

c) Format of review documents.

II. Elements to Consider

6. Prior to the preparation of any review document, it is important to consider the potential hazard of the chemical in order to determine the amount of scrutiny which may be necessary. The selection of data elements to be included in a chemicals review depends upon this preliminary hazard assessment and the importance of the data elements relative to the specific purpose of the review. The depth at which properties of a chemical are reviewed also depends upon the degree of concern derived from the preliminary hazard assessment. Technical knowledge and sound scientific judgement are of importance both in selecting data elements and in determining the depth of the review.

7. A review process usually begins with the gathering of available information. In some cases, sufficient information is available for the preparation of a chemicals review. In other situations, gaps in information elements may be identified.

8. Since the broad dissemination of chemicals reviews is desirable, non-confidential data should be used to the greatest extent possible. Nonetheless, in certain situations the use of confidential data may be unavoidable. This will not necessarily preclude the exchange of review documents. The problems associated with the exchange of confidential information have been addressed by the OECD. Its work resulted in three Recommendations, adopted by the OECD Council in 1983, concerning:

- The Protection of Proprietary Rights to Data Submitted in Notifications of New Chemicals [C(83)96(Final)];
- The Exchange of Confidential Data on Chemicals [C(83)97(Final)];
- The OECD List of Non-Confidential Data on Chemicals [C(83)98 (Final)].

These Recommendations should be taken into account when preparing and exchanging chemicals reviews.

III. Elements for Possible Inclusion in Chemicals Reviews

9. Data elements for possible inclusion in a chemicals review may be categorised in the following way:

Executive Summary

10. Under this heading would be included: the purpose of the review, a description of substance(s) reviewed, major findings and deficiencies, a general statement describing whether quality considerations were included, major conclusions, and recommendations (in the national language and a translation into English or French, as appropriate).

Chemical Identity

11. Under this heading would be found the constituent(s) of product(s) under review including:

a) Primary constituent:

- IUPAC-name (with indication of system used);
- Other names - common, (registered) trade, CAS-name;
- Empirical formula;
- Structural formula (where relevant, isomeric composition);
- CAS-number;
- Molecular weight;
- Spectral data.

b) Impurities (identity, range of percentage composition);

c) Additives (identity, range of percentage composition).

Physical and Chemical Properties

12. The data included here are those relevant for assessing exposure and effects, such as: physical state (including colour, smell, taste); melting and boiling points; vapour pressure; density; solubility in water and organic solvents; partition co-efficient (specifying solvents pairs used, e.g., n-octanol/water, oil/water, etc.); surface tension; reactivity (e.g. oxidising properties, flammability, explosive properties); soil absorption constant; dissociation constant; Henry's constant; volatility; particle size.

Analytical Methodology

13. Methods used,[5] including media and sampling procedures and preparations, would be given under this heading.

Exposure Data

14. The data to be included here are:

a) Those relevant for assessing exposure via the workplace, consumer products or the environment, such as:

- Natural occurence;
- Production volume and trends;
- Consumption, import, export;
- Production process types;
- Handling (including transportation) and distribution aspects;
- Plant releases during manufacture and processing;
- Waste disposal (including incineration);
- Use pattern (types of use, dispersiveness of use, exposed populations and special sub-populations, routes, frequency and duration of exposure).

b) Those relevant for assessing transport, distribution and transformation/degradation in the environment, such as:

- Transport and distribution between different media;
- Biotic and abiotic degradation;
- Bioaccumulation;
- Soil absorption constants;
- Interaction with other physical factors;
- Ultimate fate following use.

c) Those relevant for monitoring data, such as level in air, water, soil/sediments, plants, food, feed, working environment, domestic environment, biological samples and consumer products.

Effects on Experimental Animals and In Vitro Test Systems

15. Data to be included here are those relevant to assessing the metabolism and effects of the chemical, or the lack thereof, on animal and in vitro systems used to model human health, such as:

- Metabolism (absorption, distribution, metabolic transformation, elimination, and retention);
- Acute toxicity, short-term repeated dose toxicity, subchronic toxicity, chronic toxicity, allergenicity, embryotoxicity and teratogenicity, mutagenicity, carcinogenicity; effects on the reproductive system, immune system, nervous system, behaviour, cardiovascular system, hemapoietic system; effects on skin, eye and mucous membranes; organ-specific effects on gastrointestinal tract, kidney, liver, etc.; effect on cellular, sub-cellular and biochemical structures or processes (e.g. DNA damage, cell transformation, clastogenic alterations, enzyme inhibition, etc.); data related to synergistic phenomena or antagonistic effects; and other phenomena which modify the toxicity profile of the chemical (e.g. age, sex, nutritional status).

Effects on Man

16. Data included here are those obtained in observations from exposed persons which are relevant in a hazard evaluation:

a) Studies and observations of:

- Acute toxicity;
- Poisoning incidents;

- Subacute effects;
- Effects of longterm exposure.

b) Epidemiological studies of:

- General populations;
- Sub-populations (samples with reference to age, sex, occupational exposure).

Effects on the Environment

17. Data to be included here are those relevant for estimating the impact on the ecosystem and the bioaccumulation potential, such as toxicity to aquatic organisms, toxicity to terrestrial organisms, toxicity to micro-organisms, effects on ecological processes and biotransformation, population and ecosystem effects, and effects on the abiotic environment.

Other Pertinent Data

18. Data to be included here are those which are not relevant to any other heading but which may be of importance in a hazard evaluation, such as combustion products and transformation products from use or disposal techniques.

Current Regulations, Guidelines and Standards

19. Under this heading would be found: regulations, guidelines, and advice issued by relevant international or national bodies or by the manufacturers.

Hazard Assessment

20. Included here would be:

a) Assessment of exposure;

b) Assessment of health effects;

c) Assessment of environmental effects;

d) Overall assessment of hazards - human health and the environment, general population or ecosystem, special sub-populations or ecosystems (workers, etc., aquatic, terrestrial, etc.) or a more specific part of them (fish, birds, etc.);

e) Gaps in knowledge.

References

21. A list of sources of data consulted should also be included. Citations should give all information needed to identify and locate each reference.

IV. Quality of Data

22. Confidence in the quality of information used in preparing the review is fundamental to confidence in the conclusions of the review itself. Deficiencies in a certain investigation of a chemical do not preclude the use of that information, but they may reduce confidence in the use of such data for hazard assessment. Nonetheless, the reviewer is often faced with the task of making use of data partly derived from deficient studies.

23. Chemicals reviews are produced for different purposes, and consequently data quality requirements will vary depending on the user's needs. Data which are acceptable to one user under a specific set of conditions may not be acceptable under other circumstances.

24. It is important to inform the reader of the type of criteria and the purpose of the review when selecting, assessing, using and presenting the data. This can be accomplished in two ways: first, by a general statement describing whether quality considerations were included and, if so, the specific methods used to do so; second, by indicating in the report, as far as is practicable, the reasons for selecting key references and excluding others.

25. Assessment of data quality is a process which involves:

a) A review of individual data elements with respect to how the study was conducted and how the results were interpreted;

b) A critical selection (and rejection) of data in its proper context and in accordance with the purpose of the review.

26. Since any information related to toxicological effect or to exposure is potentially useful, general principles for quality assessment should be applied in the review process. Rather than telling the user how "good" or "bad" the data are, such principles should be used to assess the limitations of the data within the context of the user's specific needs.

27. In some cases certain studies (when compared with currently accepted, standardized guidelines) may be regarded as unacceptable. Nevertheless, it should be emphasized that in a specific context such studies contain information which, when viewed together with results from other studies, may be useful. This is particularly important with regard to highly specialised studies intended to resolve specific issues. In such situations, quality standards will be difficult to apply. Such information can be reviewed only on a case-by-case basis and in its proper context.

28. Sound scientific judgement acquired through experience cannot be superseded by any set of general rules for quality evaluation.

29. Current references should be used to assist the reviewer in determining standards for evaluating the quality of individual data elements. Such standards ought to be developed by experts in each individual discipline. In this regard, it should be noted that a great deal of progress has been made and that a number of references are available to guide the reviewer.

30. In evaluating the quality of data in a particular study, the reviewer should take into account other contemporary studies of similar design to that of the study under review. It is obvious that the reviewer cannot control the conduct of reported studies. Moreover, the information available to the reviewer is rarely sufficient to assess how well a study was conducted. On the other hand, serious deficiencies in description of design, procedures used for generating the data, and reporting of results may suggest that important aspects of the conduct of the study have been neglected. It is in this context that the reviewing of other contemporary studies of similar design is desirable.

31. If a study fails to meet modern requirements, it may still satisfy some less rigorous minimum requirements and be judged of sufficient quality to be useful in a review. For certain specific review purposes, it may therefore be useful to develop such minimum standards.

V. Format of Review Documents

32. The review document should begin with a brief executive summary highlighting the purpose of the review, a description of substances reviewed, major findings and deficiencies, a general statement describing whether quality considerations were included, and major conclusions and recommendations. At the end of the document there should be a list of sources of data consulted in the preparation of the review.

33. Closely related types of data can be grouped together in various ways to form separate data categories or information clusters. The data elements in the review should be presented in the sequence set out in paragraphs 9 through 21 above.

34. The review document should give information about the purpose for which it was prepared. Such information allows the reader to evaluate the relevance of the review to his particular needs.

35. The title, tables and diagrams contained in the review, as well as the executive summary, should be presented in one of the OECD languages, that is, in English or French.

36. It should be assumed that if a data element has not been included in the review, it has not been searched for. If a data element has been searched for and not found, this should be indicated. When data are searched for and found, but not included (e.g. for reasons of data quality, confidentiality or irrelevance), this should also be indicated.

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1 For purposes of the Decision-Recommendation, systematic investigation of existing chemicals may include the following steps: identification of relevant chemicals; priority-setting, including collection or estimation of information needed for the setting of priorities; generation of necessary further information, including testing; performance of hazard assessments.

2 Monitoring information is discussed under General Population Exposure.

3 Pathways of general population exposure may not only involve contact with a substance during its use, but may also arise from contact with contaminated environmental or natural sources within the environment. Guidance in estimating the route and extent of general population exposure is included (as appropriate) in the Selection Elements listed. Route and extent of exposure have not, therefore, been developed as specific Selection Elements.

4 These Guidelines have been harmonised with the recommended format for environmental Health Criteria Documents of the International Programme for Chemical Safety.

5 It will sometimes be preferable to indicate the source where a full description will be found.

About the OECD

The OECD is a unique forum where governments work together to address the economic, social and environmental challenges of globalisation. The OECD is also at the forefront of efforts to understand and to help governments respond to new developments and concerns, such as corporate governance, the information economy and the challenges of an ageing population. The Organisation provides a setting where governments can compare policy experiences, seek answers to common problems, identify good practice and work to co-ordinate domestic and international policies.

The OECD Member countries are: Australia, Austria, Belgium, Canada, Chile, Colombia, Costa Rica, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Israel, Italy, Japan, Korea, Latvia, Lithuania, Luxembourg, Mexico, the Netherlands, New Zealand, Norway, Poland, Portugal, the Slovak Republic, Slovenia, Spain, Sweden, Switzerland, Türkiye, the United Kingdom and the United States. The European Union takes part in the work of the OECD.

OECD Legal Instruments

Since the creation of the OECD in 1961, around 460 substantive legal instruments have been developed within its framework. These include OECD Acts (i.e. the Decisions and Recommendations adopted by the OECD Council in accordance with the OECD Convention) and other legal instruments developed within the OECD framework (e.g. Declarations, international agreements).

All substantive OECD legal instruments, whether in force or abrogated, are listed in the online Compendium of OECD Legal Instruments. They are presented in five categories:

- **Decisions** are adopted by Council and are legally binding on all Members except those which abstain at the time of adoption. They set out specific rights and obligations and may contain monitoring mechanisms.

- **Recommendations** are adopted by Council and are not legally binding. They represent a political commitment to the principles they contain and entail an expectation that Adherents will do their best to implement them.

- **Substantive Outcome Documents** are adopted by the individual listed Adherents rather than by an OECD body, as the outcome of a ministerial, high-level or other meeting within the framework of the Organisation. They usually set general principles or long-term goals and have a solemn character.

- **International Agreements** are negotiated and concluded within the framework of the Organisation. They are legally binding on the Parties.

- **Arrangement, Understanding and Others**: several other types of substantive legal instruments have been developed within the OECD framework over time, such as the Arrangement on Officially Supported Export Credits, the International Understanding on Maritime Transport Principles and the Development Assistance Committee (DAC) Recommendations.