

Harmonization of Criteria Documents for Standard Setting in Occupational Health: A Report of a Workshop

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The paper presents the most important points of the discussion, recommendations, and conclusions of a workshop on harmonization of criteria documents (CDs) for standard setting in occupational health, with emphasis on standard setting in the European Community (EC). The objectives were to achieve harmonized CDs and to develop a mechanism for international co-operation. The discussion focused on three broad topics: contents of CDs; collection, assessment, and evaluation of data; and procedures for the preparation and exchange of CDs on specific chemicals. Annex A on the various procedures for standard setting by EC Member States, countries outside the EC, and international organizations and Annex B on the proposed contents of the CDs are also included. © 1991 Academic Press, Inc.

1. THE WORKSHOP

A workshop on Harmonization of Criteria Documents used for the establishment of Health-Based Occupational Exposure Limits was organized by the Dutch Directorate General of Labour and the Commission of the European Communities, and held in the Hague, The Netherlands, May 10-12, 1989. Participants were experts from the EC Member States, the Nordic countries, the United States (ACGIH and NIOSH), Canada, Australia, Switzerland and representatives of ILO, IPCS, the European Chemical Industry, and the Trade Unions.

The primary aim was to exchange information and experience regarding current procedures for standard setting and, where possible, to coordinate scientific activities in this area.

Three themes had been scheduled for discussion: each theme was discussed first in two parallel working group sessions and thereafter in a plenary session. Before the workshop convened a starting document was submitted to the attendees.

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This paper reviews the main points of discussion, the current procedures for setting occupational exposure limits by EC and non-EC countries and international organizations, and the conclusions and recommendations agreed upon by the participants. The discussion during the workshop was limited to the scientific health-based aspects of standard setting; technological and socioeconomic constraints were not discussed.

2. BACKGROUND

2.1. *Definition of the OEL*

In 1977 the International Labour Organisation (ILO) adopted the generic term occupational exposure limit (OEL) for the various operational chemical quality limits for workplace air, for instance, TLV, MAC, and MAK. This term has also been adopted by the World Health Organization (WHO, 1981).

The definition for the MAK applied by the German Scientific Society Senate Commission for the evaluation of health hazardous substances in the Federal Republic of Germany may serve as representative for the definition of the OEL. The OEL is defined as "the maximum permissible concentration of a chemical compound as gas, vapour, particulate matter present in the air within a working area which, according to current knowledge, generally does not impair the health of the employee nor causes undue annoyance, under the conditions that exposure can be repeated and in long-term duration over a daily period of 8 hours constituting an average work week of 40 hours. As a rule the MAK is integrated as an average concentration over periods of up to one workday or one shift. . . . Scientifically based criteria for health protection rather than their technical or economic feasibility are applied."

However, the operational definitions for the OELs as applied in the EC Member States may differ. The Dutch authorities for example added to the protection of workers' health also: "protection of worker's offspring." This may be done implicitly in other countries.

2.2. *Short History of the OELs*

Since 1887, when the first OELs were published in Germany, lists of OELs, covering up to about 1000 chemicals have been issued in both Western and Eastern European industrialized countries. The first ACGIH-TLV list was published in 1947. The German Commission was set up in 1955, the Dutch Expert Group in 1976, the Swedish Expert Group in 1978, and the Nordic group in 1977.

The first symposium on maximal allowable concentrations was held in 1959 in Prague, followed by a second symposium in Paris in 1963, which proposed a list of agents for which the ACGIH-TLVs and USSR-MPC's were considered more or less similar. In the same year the Permanent Commission on Occupational Health organized its conference in Madrid; one of the main topics was occupational exposure limits.

In 1968 the International Labour Organization and the WHO convened a meeting on the subject Permissible Levels of Toxic Substances in the Working Environment. In 1978, WHO announced a program for setting health-based recommended OELs along a two-step procedure and issued the first publication on heavy metals in 1980.

In a large number of countries, national policies were developed for setting OELs and several criteria documents (CDs) were prepared as an underpinning of their national OELs.

Because of different criteria, major discrepancies occurred, notably between ACGIH-TLVs and USSR-PMCs. These discrepancies gradually decreased during the eighties, partly as a result of a drawing together of expert opinion promoted by the ACGIH, who organized their annual meeting for 1985 in Copenhagen.

2.3. Occupational Exposure Limits in the EC and Procedures for Setting OELs

The *Annex* summarizes information on the EC approach and the standard-setting procedures in 11 of the 12 EC Member States and in countries outside the EC, and by other international bodies. From the material in Annex A, it can be concluded that (i) some EC Member States derive their own OELs, whereas others rely on ACGIH-TLVs; (ii) for those EC countries which set their own OELs, the definitions of and procedures for setting OELs differ considerably; and (iii) the CDs on which OELs are based differ in content and format. Additionally, it is known that the majority of OELs rely on limited information on toxic effects.

Clearly, the preparation of separate CDs by each country (organization) involves needless duplication of manpower and money, and cooperation, both within the EC and with outside groups, in preparing CDs is essential. This Workshop was set up as a means of examining such harmonization.

2.4. Workshop Objectives

To arrive at an agreement on a framework and format of harmonized criteria documents as a basis for setting health-based recommended (HBR) OELs, also called scientific (Sc)-OELs.

To develop a mechanism for international cooperation in the preparation and exchange of harmonized CDs on specific chemicals of interest by Member States and/or the EC.

To achieve the objectives the attendees had:

- to be informed on the procedures of standard setting in other countries;
- to exchange views on basic scientific principles of occupational standard setting;
- to exchange ideas and views about what is already mutual today and what could become common in the future in preparing documents;
- to arrive at an agreement on the contents of the CDs and on the ways by which data can be collected;
- to arrive at a mechanism for the exchange and the mutual use of CDs;
- and, finally, to arrive at an operational plan for this.

Close cooperation between expert committees of various countries should improve the usefulness of CDs and, by avoiding duplication, should increase the number of substances for which such documents are available.

3. THEME I: CONTENTS OF CRITERIA DOCUMENTS

3.1. *Table of Contents*

The format of available criteria documents appears to be highly variable in the different countries. The documents of the German Scientific Community (DFG), the Dutch Expert Committee for Occupational Standards, the British Health and Safety Executive, and the Swedish and Nordic Expert Groups are in general rather extensive, whereas the ACGIH presents a short summary of the database.

It was generally agreed that all essential information relating to health effects should be in a set format, with headings and subheadings. Gaps in the information available should be characterized in the CDs, in such a manner that further examination of original reports would not be necessary. A shortened procedure may be needed when, for example, new information indicates that reevaluation of data is urgently needed, for example, because of newly available relevant information or when OELs for some listed chemicals have recently been changed elsewhere, usually set at lower limits.

It was concluded that the table of contents, listed in Annex B, is acceptable as a basis for examining the available scientific data. The following items should explicitly be discussed:

—*The identity and chemical and physical properties* of the chemical. Information on impurities and additives, often present in technical products, should be included.

—Description of currently available analytical *methods for environmental and biological monitoring* of exposure was considered important. Older methods should also be included, when they are considered to be relevant for the evaluation of exposure-response relationships from past exposures mentioned in epidemiological studies.

—Information on *sources and levels of exposure* at the workplace. This may inter alia determine the range of actual exposure levels at the workplace. Although not a primary objective, additional information on historic *production quantities* and workplace exposure levels may be helpful when examining data on long-term exposure.

—*Environmental levels* (e.g., outdoor air, indoor air, drinking water, food) may yield important information on background levels of the nonoccupationally exposed general population. In combination with the occupational exposure levels they may facilitate the estimation of the total load of workers. Workers often are exposed not only through the respiratory route, but also for the same chemical through the dermal and/or the oral route, both at and outside the workplace.

—Information on *toxicokinetics* was generally considered of vital importance. Human data should be gathered wherever possible, even though one has to admit that these data are often not or insufficiently available for most chemicals. Particular attention should be given to inter- and intraspecies variability in internal dose. The possibility of interaction with other workplace and nonworkplace chemicals should not be underestimated (see Section 3.4).

—Information on the *toxicodynamics* was considered of similar vital importance. It was noted that different terms are being used, for example, short-term/long-term versus (sub)acute/chronic. The term *acute/chronic* may refer to either exposure or to effects; this raises confusion. Agreement on the terminology, especially with respect to reproductive toxicity, is needed; the term teratogenicity is used both for malformation (terata) and for other reproductive risks. Teratogenicity and other reprotoxic risks

should be clearly elucidated. The importance of a careful description of sensitization and other immunologic effects, if present, was stressed.

—All participants agreed that, where possible, the influence on *hypersusceptible* groups (i.e., those at extra risk) for specific chemicals and its impact on the OEL should be explicitly discussed (see Section 4.4).

—It was considered a matter of choice whether the CDs should end with a health-based recommended OEL (HBR-OEL) or not. The Dutch, German, and NIOSH criteria documents include such a HBR-OEL, whereas the United Kingdom and the Scandinavian countries do not. The ACGIH documents recommend an operational OEL. Consensus was achieved that it was necessary to establish a no-observed-adverse-effect level (NOAEL), derived from the dose–effect–response–(percentage of subjects with a specified effect) relationship. Some workshop attendees considered the establishment of a NOAEL sufficient.

—With respect to *recommendations for research*, it was proposed that this should refer particularly to those areas of toxicity that may be critical for setting the HBR-OEL; otherwise too many proposals for research on noncritical (sub)topics may clutter up priorities.

3.2. General Comments (See Also Theme II)

All available data should be critically examined. Absence of data should always be stated. If there exists a reason not to use the data of an apparently relevant paper, this should be explained, perhaps in an appendix. However, the quality of a document does not automatically correlate with its length.

The key references should be identified and critically discussed in detail, with a less detailed description of the supporting data. High-quality reviews can be used as the basic source of supporting data.

Whether additional information on, for example work practices, engineering control, labeling, and technological feasibility, should be included in the criteria document was discussed. The workshop considered this information important, although not necessary in a CD.

The data presented in a CD should be used to underpin a HBR-OEL for the working environment. Nevertheless, the use of CDs for purposes other than this is unavoidable. One of the uses mentioned was the production of datasheets. The documents may also be used for the assessment of the consequences of accidental exposure. Moreover, they may provide toxicological information relevant to determining acceptable environmental exposure data, including data for setting maximum acceptable levels of toxicants in food and drinking water.

3.3. Updating of Criteria Documents

The workshop attendees recommended that a procedure for updating criteria documents should be developed. The frequency of updating CDs varies considerably between countries, which may depend on the priority assigned to a chemical. On the other hand the vicious circle of updating “old” criteria documents while leaving other chemicals without any standard is a dangerous pitfall. There should be a pragmatic

approach, for instance, updating triennially, but not at the expense of the production of documents for further chemicals.

3.4. Exposure to Mixtures

How to handle processes in which mixtures of chemicals are used and the causative chemicals are not known remains unresolved. Long-term documented experience of experts in occupational health and hygiene may shed some light.

3.5. Procedure for Setting OELs

A two-step procedure for setting OELs is highly recommended, also at the EC level (see Section 4.6 and Annex A). The first step is to define a HBR-OEL; the second to examine its practical feasibility and, if necessary, define an operational OEL.

4. THEME II: COLLECTION, ASSESSMENT, AND EVALUATION OF DATA

4.1. Identification and Use of Data Sources

One should try as much as possible to identify all relevant sources of information by conventional methods, such as electronic databases (it was recommended to prepare a list of suitable ones), references cited in papers and reviews, complete data files and documents produced by expert committees and other nonprofit and profit organizations. ECETOC Technical Report No. 30 (ECETOC, 1989), which is regularly updated, appears to be a valuable source for identifying available criteria documents. Whenever possible, data from less conventional sources, gleaned from informal contacts with experts, from comments by industry-based scientists, and from health, safety, and social security agencies, should be used. Although more detailed evaluation of the data may be needed, it should not be rejected solely because it is not presented in a traditional scientific format.

Several problems were mentioned with respect to electronic databases: there are frequent alterations in performance; there exist differences in key words, even within a database; earlier literature often is absent, even though it may be useful; databases only identify sources, and are not themselves primary information.

Establishment of a new EC database with respect to data relevant for occupational health was considered not to be justified now. Elaboration of a more uniform procedure for literature search was recommended.

Language was not considered to be an insuperable barrier for accessibility and making proper use of information. Short communications, abstracts, conference proceedings, etc., also may identify sources for more detailed information when the amount of fully validated data available is limited. However, they should not be the sole basis for decision, opinion, or estimation of any numerical value (see Section 4.3). It is always up to the experts who prepare and evaluate CDs to decide whether the information presented is important enough to include in the documents. It was recommended that literature considered not critical should not be included in the CD; it may be listed in a separate bibliography.

4.2. *Unpublished and Confidential Information*

Published information should always be preferred to unpublished information. Unpublished information may be not, partly, or completely confidential. Recent unpublished company-owned data are usually reports on studies conducted and audited in accordance with Good Laboratory Practice and thus already subject to internal peer review. Therefore, these reports usually have the same quality as publications in a scientific journal. This information may fill important gaps in the toxicology database relevant to setting new or adapting existing OELs.

Most workshop attendees emphasized that confidential information should also be available to the expert committees. The chemical industry was urged to make all data available, if possible, in a form comparable to that for publication in scientific journals. Expert groups might even offer to prepare such papers, which should be authorized by the relevant company prior to publication. Three possibilities have been discussed:

1. Restrict the scope of the CDs to include only published data (e.g., Nordic countries).
2. Use evaluations by the expert committee (and authors of the CD) of nonconfidential test reports not formally published in the scientific press, yet available from the owners of the data, and of confidential data; all data in full detail should be accessible on request (e.g., Federal Republic of Germany).
3. Obtain limited access to confidential data by some members of the expert group with the option that these data will be accessible after a specified period of time for everyone who wants to consult them (e.g., The Netherlands).

Representatives of most EC Member States preferred the second option. When confidential data have been made accessible, the expert committees should discuss if the data should be included in the criteria document.

4.3. *Assessment and Evaluation of Validity and Relevance*

Validation of data. For a criteria document it is essential to examine all data, including chemical and physical properties and biological and toxicological effects. It was agreed that only validated data should be used. It was not considered practicable to define general criteria, because validation takes place at various levels before publication. The institute that prepares a draft CD also will validate the data. The same will finally be done by the expert committee members, and maybe outside experts. If data are rejected, then the reasons should be presented. All "critical" effects should be discussed explicitly in relation to exposure profiles, because they may vary with concentration and time.

Relevance of data. It is not possible to develop a general criterion for what should be considered relevant or not. The effects should be related to occupational exposure and to a defined occupationally exposed subpopulation. The relevance (significance) to health has to be discussed explicitly in a case-by-case manner, taking into account the variability in health and disease status of the workers. Evaluation with respect to carcinogenicity, mutagenicity, and reproductive risks should be included. Moreover, gaps in knowledge and information on research projects to fill these gaps, should also be identified.

4.4. *Evaluation of Data*

Health. This criterion was not explicitly discussed during the workshop, although an initial definition was provided by the Dutch Expert Committee. Health was defined

as "a nonstable condition of the human organism, of which the functional capacities leave nothing to be desired in the worker's own opinion and/or according to health experts; pre-existing physical and mental capacities, depending on, e.g., age and sex, have to be taken into account; the functional condition should be comparable to that in non-exposed otherwise similar groups of workers in the same society; allowance should be made for the present state of the art, presentday objectives of health care, social acceptability and social habits." This description is essentially an epidemiological construct: it compares exposed workers with nonexposed workers. OELs are meant to preserve health, not only to prevent disease.

It was emphasized that the actual state of health of workers and reference groups may differ considerably between countries, which may lead to different HBR-OELs.

Nuisance. Development of this criterion was considered difficult because of the large subjective element and the wide individual variation in the perception of "nuisance," and also because of the possibility of habituation or adaptation. Although not all workshop attendees considered it proper to describe "nuisance" as "adverse," it was nevertheless acknowledged that "nuisance" may lead to discomfort and may adversely affect performance and safety. Unpleasant odors and exposure-related symptoms, e.g., headache and nasopharyngeal discomfort, may be a common "nuisance." The place of "nuisance" in occupational exposure should be reexamined. Despite the problem of subjectivity, data should be collected and assessed in a comprehensive review. "Nuisance" should be considered a "health effect" as such and should be taken into account in setting OELs.

No-Observed-Effect Level [N(O)EL], No-Observed-Adverse-Effect Level (NOAEL), Minimal-Observed-Adverse-Effect Level (MOAEL), Lowest-Observed-Adverse-Effect Level (LOAEL). Some workshop attendees considered the difference between "adverse" and "nonadverse" highly philosophical. Some would refer the decision on such a distinction to the decision makers. Other members expressed the view that the expert committees should determine what should be considered "adverse" or "nonadverse"; socioeconomic and/or technological constraints should not determine the adverse character of an effect. Biological response may also depend on lifestyle and personal factors. Special care should be taken when interpreting epidemiological studies. Unusual working conditions, such as abnormal shift patterns, exposure to hyperbaric atmospheres, or exposure to mixtures, need to be taken into account. Selective dropout (self-selection out of study) may cause elevated NELs, NOAELs, MOAELs, or LOAELs. Self-selection into a study may also occur. Careful vetting of study and control group composition is essential.

It was also considered important to distinguish between NOAELs and MOAELs/LOAELs. Dose(exposure)-effect-response or dose(exposure)-response relationships and data on reversibility or irreversibility of effect were thought to be essential complementary information. It is necessary to state exactly what is being reported when using these terms. The basis for these levels and the relationships, and also their use in the extrapolation for setting HBR-OELs, should always be explicitly described in the CDs. It is of paramount importance that all the steps taken in the evaluation process be explicitly described and discussed.

Groups/subjects at extra risk. Among the working population there exists a variability in health and disease status, due, for instance, to inborn errors of metabolism, intercurrent diseases, sexual dimorphism, pregnancy, lifestyle factors (consumption of tobacco, alcohol, addictive drugs, pharmaceutical medicines). Subgroups or individual

workers may be hypersusceptible (orthoergy) to local or systemic chemicals or may become sensitized (allergy) to some agents. The HBR-OELs and consequently also the OELs have to take this into account.

Extrapolation from animal to human. When possible, well-designed and well-performed epidemiological studies should be used to establish a HBR-OEL. However, such studies are not always available. In many cases one has to rely largely on animal data. In extrapolating from animal to human one has to adjust the most relevant lowest NOAEL for (1) differences in body size between laboratory animals and human beings and (2) differences in toxicokinetics and in toxicodynamics between the specific animal species and human beings (species specificity). Moreover there exists a variability within the species, more so in humans than in experimental animals with more or less homogeneous genetics and exposed under controlled experimental conditions. This requires a decision on safety (uncertainty) factors. Extrapolation procedures have been discussed in a Report on a Workshop on New Approaches in Extrapolation Procedures and Standard Setting for Noncarcinogenic Substances in Human Exposure (Arlman-Hoeke and van Genderen, 1988).

4.5. *Relative Importance of Studies*

The importance of a study depends on several factors, for example, route and kind of exposure, test species, degree of absorption of the test substance, its physicochemical properties, and their relevance to workplace factors. Any hierarchy defining the relative importance of studies depends on the chemical being evaluated. The expert review and evaluation could give an indication of the relative importance to be attached to the study cited by identifying *key studies*.

4.6. *The Kind of Conclusions*

It was agreed that the CDs should at least attempt to assess a NOAEL. The experts may or may not conclude on a HBR-OEL. Particularly when the ultimate operational OEL also uses criteria based on socioeconomic and/or technological constraints, it has to be made clear that the OEL might not prevent health effects. Setting a HBR-OEL is a scientific process and is only one part of the subsequent policy discussions which result in the operational OEL (see Section 3.5 and Annex A). However, it was considered important that the experts, who set HBR-OELs, be aware of the practical implications.

4.7. *Qualifications for Preparing and Evaluating Criteria Documents*

Defining individual or institutional qualifications for preparing CDs was not considered necessary. An institute undertaking the preparation of a CD will qualify or disqualify itself on the basis of the scientific quality of its products.

For an expert or peer review committee a wide range of disciplines [toxicologists, occupational physicians, occupational hygienists, (bio)chemists, biostatisticians] is needed to function effectively, although not all disciplines are needed all the time. The core committee could also be supplemented by invited outside consultants on a case-by-case basis.

The name of the institution charged with the preparation of CDs and its responsibility should clearly be stated. All experts should be regarded responsible for the contents of the document.

THEME III: PROCEDURES FOR THE PREPARATION AND EXCHANGE OF CRITERIA DOCUMENTS ON SPECIFIC CHEMICALS

5.1. Selection of Chemicals

The following criteria were considered of importance in setting priorities:

- signals from occupational health and industrial hygiene practice;
- public pressure, information from “social partners”;
- extent of production/application, populations at extra risks, exposure levels;
- changes in technology and related hazards;
- new use of existing chemicals, ranking of toxic effects (severity);
- EEC notifications (new chemicals).

Also of importance are available expertise and availability of existing documents (already 400–500 documents have been prepared according to ECETOC No. 30).

An absolute ranking of chemicals was not considered useful. Priority setting appears to be important; a group of compounds can be selected for which criteria documents should be prepared within a specified period.

A comparable system for setting priorities in different countries is recommended. The workshop attendees recommended that a governmental body should prepare and update a national priority list; expert groups should be consulted. At EC level for instance the EC could be involved in the preparation and updating of priority lists. EC priority lists would have to reconcile differing national priorities.

5.2. Exchange of Priority Lists

The exchange of priority lists between countries was fully agreed. Such an exchange could be arranged either via an international organization such as the WHO or the OECD or by a newly set up international “clearinghouse” with the following tasks:

- to create an inventory of priorities existing in different countries/bodies;
- to create an inventory of ongoing and planned activities regarding the preparation of criteria documents;
- to coordinate future activities (new documents, research);
- to develop “contact points” in different regions (worldwide) (the EC, the Nordic countries (Secretariat Nordic Expert Group), Canada, and Australia are willing to act as such).

It was recommended that information on completed documents be placed in a databank.

5.3. Cooperation

The workshop attendees fully endorsed cooperation. Bilateral cooperation already exists and should be stimulated further. A network of cooperating committees was

considered desirable. The EC could have a valuable position in such a network of cooperating national committees by acting as a body for exchanging and transferring information to and from the national expert committees or institutions in the EC.

It was concluded that there should be agreement on format, content, and time schedule of the preparation and assessment of criteria documents when being produced in partnership. Only literature that is relevant for setting health-based limits should be included. Exposure data should be included in the document (see Section 3.1). Peer review by the cooperating parties before final publication was considered necessary by some attendees, whereas others considered this for practical reasons to be too difficult or impossible.

There were different opinions regarding the inclusion of health-based OELs. Moreover, it was suggested that new data regarding potential health risks be distributed via "alerts" from the (inter)national bodies through their governments to the contact points. Also, a Good Documentary Practice (quality control criteria) for production of CDs was considered necessary.

5.4. *Language of the Criteria Documents*

Although there may be reasons to write in the national language, most attendees recommended that the document be written in English, with a summary or a full paper in the national language. In special cases the document could be written in another language to facilitate international peer review. Publication and distribution of the documents might be done either by the producing body or by an international body such as the EC.

The observer from ECETOC made the following personal suggestions for further progress (these should not be seen as a commitment by ECETOC):

- There might be a role for ECETOC in publishing a technical report on Good Documentary Practice.
- There is a need for a "Journal of Virtual Publications" publishing the abstracts of negative studies which have been written up in a classical publication format and peer reviewed; readers who wish to receive the full report could request a copy from the authors; this might contribute to solving the problem of "published data only" in this and other contexts (see Section 4.2).
- There is a need to consider a model as follows:

Comprehensive Health and Environmental Hazard Review

Criteria for OEL	Criteria for ADI (Acceptable Daily Intake)	Criteria for EEL (Emergency Exposure Limit)	Criteria for Other
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5.5. *New Chemicals*

New chemicals are those defined as being placed on the EC market after 1 January 1982. The Community requirement is a minimum data package to be submitted with several notifications, including limited toxicity data. In dealing with new chemicals problems might arise such as confidentiality (see Section 4.2) and lack of data (especially

for the so-called “base set notifications” for “basic level zero announcements”). Even setting a tentative value might be difficult due to a limited amount of toxicity data (see Section 4.7). Perhaps only in exceptional cases, for instance, compounds of high toxicity, tentative OELs might be set. Setting of OELs for new level “basic level” compounds may not be very important because of limited production or marketing quantities.

6. CONCLUSIONS AND RECOMMENDATIONS

One major conclusion of the Workshop was that it would certainly be possible to prepare criteria documents suitable for use in setting OELs on a cooperative or supranational basis. Criteria documents would need to contain all available information relevant to identifying health risks for exposed workers, critically examined to assess its validity (see Annex B). A HBR-OEL might be appended, but was not essential and, if present, it should take into account so-called “nuisance” effects. Operational OELs would then be developed taking into account information on practicability.

The use of comparable priority-setting procedures in different countries was recommended, and it was suggested that cooperation in sharing the work of preparing CDs should be stimulated through international organizations and perhaps Regional Contact Points. The CDs would need to be written in English (as a *lingua franca*), with a summary in the appropriate national language. Development of a code of Good Documentary Practice (paralleling Good Laboratory Practice) was considered a potentially effective way of ensuring that CDs were drawn up using adequately documented and acceptable procedures and that each document could be considered valid by all the authorities interested in it.

It was recommended that OELs should be set by a two-step procedure (see Annex A): (1) define a health-based recommended OEL; (2) examine its practical feasibility and, if necessary, define an operational OEL, which might be higher than the HBR-OEL.

A final conclusion was that, by bringing together many of those involved in preparing and using criteria documents for OELs, the Workshop had contributed to an understanding of the different ways in which this work is conducted and to ways in which these documents could be improved.

ANNEX A: OCCUPATIONAL EXPOSURE LIMITS AND THE EC AND PROCEDURES FOR SETTING OCCUPATIONAL EXPOSURE LIMITS

1. *The EC Approach*

1.1. *Increasing Demands for Improving Working Conditions*

The governments of the EC Member States and countries outside the EC show an ever-increasing desire to improve working conditions in the workplace. Cooperation between authorities, employers, and employees has become more efficiently organized as evidenced by an improved working environment in many areas of activity.

If one examines the two earlier Commission programs on health and safety at work one can note that some 11 directives were proposed, 8 of which are now adopted, on

the protection of workers exposed to physical and chemical agents and the prevention of major hazards related to chemicals. Thus, efforts at the European level have mirrored the kind of increased awareness taking place in individual Member States of the EC and overseas.

1.2. The Single European Act

The Single European Act amended the treaties binding the governments together; it reinforced the cohesion between them and with the express intention of relaunching a somewhat moribund Community.

Crucial to the development is the creation of the Internal Market by 1992: "the heart of the strategy to relaunch the construction of Europe." However, the program must encompass a significant element of social policy within which the physical and mental well-being of workers stands high on the list of priorities. The new treaty is specific in its inclusion of provisions in this respect.

The new Article 118A provides three main instruments:

1. Harmonization of conditions of protection while maintaining existing improvements. On this basis Directives should provide minimum provisions for gradual implementation.
2. The possibility for Member States to introduce more stringent requirements.
3. The need to avoid unnecessary financial or administrative burdens on small or medium-sized enterprises.

The Commission has already sent to the Council a number of measures, of which a new more generally applicable framework directive on health and safety in the workplace has a predominant role. This proposal provides an overall legal "framework" for a series of measures which will be introduced to encourage improvements in the workplace. At the same time it gives a context in which the existing rules developed as a result of the previous programs may be consolidated through the earlier framework directive on chemical, physical, and biological agents in the workplace, so that in the years to come these measures, developed through various legal initiatives, may find a comprehensive legal context more transparent than the situation appears today. The proposal for this new framework directive was adopted in 1989. Of specific relevance are two proposals on carcinogens and biological agents in the workplace. These texts are based on the earlier framework directive. Nevertheless it is essential that the terminology in the various texts be harmonized. The Commission expects that these two texts will be quickly adopted following the new orientations agreed in the new framework directive.

The legal situation to be clarified is one in which a directive providing a framework for action on dangerous agents in the workplace, and its attendant specified directives from earlier programs, have to be consolidated, anomalies rectified, and coherence ensured on the basis of new measures made possible by a new Treaty. As the political objectives have been clearly stated, it should be left to the experts to execute these objectives in the most practical way.

The texts which finally describe the new legal structure in the EC will reaffirm the absolute need to produce criteria documents (CDs) to assist experts to establish occupational exposure limits (OELs). The new texts will encourage cooperation at the

international level not only to conserve scientific resources but also to demonstrate to employee and employer alike that figures proposed by whatever competent administrative unit have as a first step a scientific appreciation of the latest scientific information on the safety of the agent concerned. The origin of the proposed limit value must be clear, and the figure must enjoy the confidence of those who need to apply its warnings.

1.3. *Limit Values*

The earlier "framework" directive (Directive 80/1107/EC) on chemical, physical, and biological agents provided an overall strategy for the control of dangerous substances in the workplace. It was recognized, perhaps belatedly, that the rate of progress using this system was too slow, particularly if the legal texts were to be kept up to date in a way that enables worker exposures to be kept as low as is opportune given the technological possibilities and safety data of the day.

In 1988 the Community—through a Council modification to this framework text (Directive 88/642/EC)—adopted a more flexible approach to setting limit values. Where the limit values are to be binding on Member States, the existing procedure is to be applied. However, in the situation in which Member States are required only to use these values as an indication of what is reasonably tolerable, a more flexible legal procedure is foreseen which will enable more rapid progress to be achieved.

The OELs to be proposed by the commission will, as agreed with the Council, take into account expert evaluations based on scientific data. The proposals will also be forwarded to the tripartite Advisory Committee on Safety, Hygiene, and Health Protection at Work so that social opinions can also be taken into account in the final official text (*second step*). The Commission has decided that to ensure that data are properly presented and up to date, it will fund the preparation of criteria documents prepared in a standard form acceptable throughout the EC and possibly to other nations.

A committee of scientific experts from the various Member States is to be convened by the Commission to provide an independent scientific evaluation of data serving as a basis for any eventual Commission proposal (*first step*). It is expected that the group will contain a representation of disciplines, for example, toxicology, industrial hygiene, industrial medicine, and epidemiology. However, the scientific contribution of technologists and other disciplines such as chemists or analysts will not be overlooked.

1.4. *EC Criteria Documents*

In July 1989 the Commission invited institutes with a particular knowledge of this subject to indicate their willingness to collaborate in the preparation of basic scientific documents. In drawing together the expertise of the Member States, the Commission believes that this Community approach to EC-OELs will not only give confidence to the economic interests in the Community, but also lead to international confidence that the Community can act as a partner in cooperative ventures.

The 1992 Internal Market will impose on the Community a new situation in which the Commission will play a leading role coordinating the praiseworthy initiatives of Member States and complementing their efforts by its own contributions.

2. Procedures for Setting Occupational Exposure Limits

During the workshop representatives of 11 of the 12 EC Member States and of countries outside the EC presented information on the present procedures for setting OELs. A condensed review of the information is presented.

2.1. EC Member States

Belgium. The general rule has been set in The Anti-nuisances Law—1972, which reads that “the concentration of air pollution at the work places has to be kept as low as possible and must never exceed the tolerated limit values fixed for certain dangerous substances.” The limit values used in the legislation are the ACGIH-TLV values, with two exceptions: OELs set in EC Directives, and some carcinogens (“the workers shall not be exposed to products containing substances with potential carcinogenic effects, be it via the respiratory tract, the mouth or the skin”). Belgium is considering formation of a Scientific Expert Committee.

*Denmark.*² The basis of assessment of OELs is the scientific documentation on health aspects and control techniques from some other countries, including the Nordic countries and experiences from Danish workplaces, prepared by the Labour Inspection. OELs are assessed after notice has been given and any objections have been received. The documentation of health aspects is discussed in the Limit Value Committee of the tripartite Working Environment Council (WEC). The WEC Committee on Substances and Material then performs the technological/economic evaluation which is submitted to the National Labour Inspection. In the event of this agreement within the WEC the Labour Inspection acts according to the following guidelines:

—A specific OEL should not be any stricter than in those countries Denmark can normally be compared with.

—Any information involving considerable extra costs as a consequence of changes in the OELs must be compared with documentation obtained from medical literature.

The National Labour Inspection also may set an OEL without regard to the general procedure, whenever information is available to substantiate a particular risk involved in using the substance. Documentary evidence of the harmful effects of substances is available from the Labour Inspection.

In addition to these procedures it is a rule in Denmark that

—unnecessary exposure to substances and materials shall be avoided (exposure during work shall therefore be reduced to a level reasonably matched with the technological development, and fixed limits shall be observed);

—compliance to an OEL cannot be used as the only basis for the assessment of safety and health conditions;

—a concrete assessment of working conditions and possible health hazards in using substances and materials shall always be made with a view to the necessary measures to be taken.

Federal Republic of Germany. Germany was the first country to introduce OELs more than a century ago, and the first to introduce biological tolerance levels and an integrated system of peak exposure limitations.

² See also Nordic countries.

The system of setting OELs and classifying carcinogens and embryotoxic and mutagenic compounds may be described as a two-step procedure. In the first step, a scientific committee of the German Science Society recruited from independent scientists evaluates all literature data and produces a scientific document which ends with a proposal for a standard (air or biological material, or classification as carcinogenic, embryotoxic, mutagenic). These proposals are published in an annually revised list as recommendations. In the second step, another committee recruited from representatives of all interested society groups (industry, consumer organizations, trade unions, trade organizations) decides on the proposals which then are published as an official "technical rule."

All proposals by the scientific committee are entirely health based; economical, technological, or analytical feasibility is not taken into consideration. If a company is not in a position to comply with a newly introduced or reduced standard, then it has to make an application for an interim solution, based on an argumentation of the constraints. The second committee will then deal with the matter and decide whether or not an exemption will be permitted.

The criteria documents are published in a loose leaflet collection at annual intervals. Up to now, 309 compounds or mixtures for occupational exposures have been dealt with in the case of workplace air limits, 35 for biological tolerance limits.

France. A scientific committee comprises experts appointed by the French Ministry of Labour and administration representatives. This committee critically reviews published data, discusses possibilities, and selects a level for proposal to the Conseil Supérieur de la Prévention des Risques Professionnels. Two kinds of limits have been defined: a short-term OEL (VLE, Valeur Limite d'Exposition) to protect against immediate or short-term effects (expressed as a TWA—15 min) and an OEL TWA—8 hr (VME, Valeur Moyenne d'Exposition).

The OELs are generally considered indicative. Except for official texts issued by the French Standardization Organization, no information on exposure assessment is presented. Official texts permit the Labour Inspectorate to conclude that health and safety conditions are not acceptable, when the OELs are "obviously" exceeded. If no corrective measures are applied to obtain an acceptable situation, the inspectors are entitled to propose that the administration imposes control of the quality of the air at the workplace. For some chemicals regulatory limits have been established by the French Council of State, some according to the EC Directives. The texts define places to be controlled, methods to be applied, and frequency of sampling. Limits recommended by the national health insurance body are adopted by technical bodies at a national level.

Greece. The Frame Law 1568/85 Health and Safety at Work contains a chapter on the protection of workers against physical, chemical, and biological agents; article 26 refers to OELs. The presidential Decree 307/1986 set binding OELs for a number of chemicals as advised by the Health and Safety Council (representatives of governmental agencies, trade unions, organizations of employers, and scientists). The Council evaluated lists of OELs proposed by for instance the ACGIH, EC Member States, and the United States. Moreover, the Council, taking into account the socioeconomic conditions in Greece, proposed a list of OELs, which was adopted by the government.

Ireland. The safety, health, and welfare of workers in factories is covered by the Safety in Industry Act 1955 and 1980. No OELs have been set, except for some agents. Instead, a twofold approach to protecting workers from exposure to chemical substances

is applied. In every factory in which there is exposure to any dust, fume, or other impurity—likely to be injurious to the workers—all practicable measures must be taken to protect the workers exposed, including the provision of exhaust ventilation as near as possible to the source. In the absence of a domestic limit value, the OELs of the ACGIH-TLV list or the UK Health and Safety Executive list, whichever gives the greater degree of protection, are accepted.

Italy. To date there exists neither an official list of OELs nor an official document on how to set OELs, with a few exceptions. The Labour Law of 1956 presented general rules for the prevention of health risks in the production and usage of chemicals; articles 20 and 21 consider it to be the duty of employers to “adopt any measure in order to avoid or reduce, as much as possible (recently interpreted as: “as much as feasible”), emission and diffusion of chemicals in workplaces.” A nonofficial activity to establish a first list of about 100 OELs was undertaken by the Clinica del Lavoro in 1968. The Association of Occupational Medicine and the Association of Industrial Hygienists compiled a new list of about 200 OELs in 1975. In 1976 the Minister of Labour instituted a committee to establish an extensive official list, which was published in 1977, and based mainly on the ACGIH-TLV list. However, the Minister did not adopt this list as law or a recommendation. To date the organizations of employers and employees rely mainly on the ACGIH list. The government awaits the action to be taken by the EC.

The Netherlands. Until 1978 the ACGIH-TLV list was used. In 1978 the Directorate-General of Labour (DGL) published the first official list of OELs (MAC list), to a large extent similar to the ACGIH-TLV list. Since 1978 new MACs and changes in existing MACs are established in a *three step-procedure*, which started in 1976/1977. In the *first* purely scientific step the Dutch Expert Committee for Occupational Standards (DECOS, experts appointed à titre personnel, an advisory group of the DGL) prepares a CD and establishes a HBR-OEL. Draft CDs are prepared by four research institutes and critically evaluated by the DECOS. The final draft document is submitted for comments to experts assigned by various industry and trade unions. Since 1979 about 60 documents have been prepared, since 1987 in the English language, with an executive summary in Dutch.

Parallel to the activity of the DECOS the DGL prepares a “workplace document” (exposure levels, technological and/or socioeconomic constraints). On the basis of the DECOS criteria document and the DGL workplace document, the DGL sets a proposed OEL (MAC).

In the *second* policy-making step the proposed MAC is submitted to the Commission on Standards for Hazardous Substances (CSHS) of the Labour Conditions Council, an advisory body to the Ministry of Social Affairs and Employment. The CSHS consists of representatives of organizations of employers, trade unions, and governmental departments; it evaluates the technical and/or socioeconomic feasibility of the proposed MAC and recommends an operational MAC; only for a few chemicals was the recommended MAC set higher than the HBR-OEL.

In the final *third* administrative step the DGL sets the administrative MAC. When the MAC exceeds the HBR-OEL then a period may be set in which this OEL has to be reduced down to the HBR-OEL. All documents produced in the three steps are open to the public.

To date about 100 of the almost 700 chemicals in the national MAC list have been established according to the three step-procedure; the other MACs still originate from

the ACGIH-TLV list; changes in the annual TLV, German MAK, Swedish, and UK lists are adopted in the MAC lists after assessment of possible technological and/or socioeconomic constraints. The administrative MACs have no legal status, except when they are based on EC Directives. In the near future the Ministry will have the authority to set legal standards.

Portugal. The ACGIH-TLV list is used as reference for the OELs. The Labour Inspectorate can enforce the application of OELs if a significant health risk exists; this is prepared by a technical committee of the Portuguese Institute for Quality, together with representatives of government departments, industry, and labour unions. To date, no procedure exists for the development of OELs.

For chemicals for which there exists an EC Directive the OELs are mandatory. The National Institute of Health is considered to be the reference body for quality control of exposure assessment.

Spain. To date the legislation for about 160 chemicals is based on the TLV list of 1961. In recent years some new OELs have been adopted. The National Institute of Occupational Safety and Hygiene presently provides information on health hazards, based mainly upon the latest ACGIH-TLV lists. The Labour Inspectorate applies the appropriate regulations. Since Spain joined the EC in 1986 the legislation is in the process of a major revision.

United Kingdom. OELs are an important element in determining adequate control of exposure to hazardous substances under the new Control of Substances Hazardous to Health (COSHH) Regulations, which came into effect in 1989. The Regulations specify two different types of exposure limits:

1. The maximum exposure limit (MEL) should not be exceeded and exposure should also be reduced as far as is reasonably practicable below it.
2. The occupational exposure standard (OES) is a level at which there is no evidence that exposure to the substance at this concentration is likely to be injurious to employees. Control will be considered as adequate if this level is met or if exposure exceeds the OES provided the cause is identified and action is taken to reduce exposure to the OES as soon as is reasonably practicable.

MELs are set in Regulations placed before Parliament. These Regulations are proposed to Ministers by the Health and Safety Commission (H&S), a tripartite body involving representatives of employers' and employees' organizations and local authority associations. H&S is advised by the tripartite Advisory Committee on Toxic Substances (ACTS), following extensive reviews of the toxicity data, information on manufacture and use, exposure levels and control measures, and methods of measurement. Before final agreement, the recommendations are subject to a period of public consultation.

OELs are agreed to by H&S, which acts on the basis of recommendations from ACTS. ACTS, in turn, is advised by its specialist subcommittee, the Working Group on the Assessment of Toxic Chemicals (WATCH). WATCH is concerned primarily with the scientific assessment of these substances. Before being finally incorporated into the H&S's list of approved OESs, these recommendations are also subject to public consultation.

2.2. Non-EC Countries and International Organizations

Australia. The federal government established the National Occupational Health and Safety Commission (NOHSC) in 1985 to act as a forum for the development of

uniform approaches to occupational health and safety (OHS) throughout Australia. The NOHSC can recommend national standards and codes of practice; however, these must be adopted by the individual states and territories to be given legal force. The NOHSC is a tripartite organization composed of representatives from employers' and employees' organizations as well as each state/territory and the federal ministers for industrial relations and health. Specialist committees and working groups are used to develop OHS policies, strategies, codes of practice, and standards for consideration by the NOHSC. Draft proposals for OELs are developed by the Exposure Standards Working Group (ESWG), which is composed of experts in the field. Background papers for individual substances are prepared by the NOHSC Staff in the Standards and Chemicals Branch. Recommendations made by the ESWG are forwarded to the tripartite Standards Development Standing Committee (SDSC) where scientific, social, economic, and other considerations are addressed before the recommendations are passed to the NOHSC to be released for public comment. After the public comment phase a final recommended standard is declared.

The Working Group prepared a draft document for public comment entitled *Exposure Standards for Atmospheric Contaminants in the Occupational Environment*; the public comment is currently being considered by the Working Group in preparation for submission to the SDSC. The final document was published. Of the 654 substances for which draft exposure standards have been published for public comment some 91 have been identified as requiring further review.

Canada. The responsibility for regulating occupational safety and health is divided between the ten provinces, two territories, and the federal government. Generally, the federal government has jurisdiction over interprovincial and international undertakings, and certain other activities which cover about 10% of the workers. The remaining 90% are subject to provincial or territorial jurisdiction. However, between the various jurisdictions, there is considerable uniformity in the prescribed requirements. Nationally developed standards are usually references in regulations. The federal instrument of regulating occupational safety and health is Part II of the Canada Labour Code, administered by Labour Canada. The 18 regulations issued pursuant to the Code prescribe various minimum standards, including OELs. The limits prescribed for hazardous substances are the ACGIH-TLVs with one exception (grain dust). The other regulators in Canada also reference the ACGIH-TLVs.

The federal regulations on hazardous substances are being reviewed by a Working Group made up of representatives of organized labour and employer associations, with Labour Canada providing facilitators and technical and legal advisers. Those items on which consensus is reached are incorporated into the regulations, subject to certain legal limitations. Those items on which an impasse is reached are referred to Labour Canada for resolution. Progress is being hampered by the variety and inconsistency.

*Nordic Countries.*³ The "Nordic Council of Ministers" is an inter-Nordic (Sweden, Finland, Norway, Denmark, Iceland) body. It has established inter alia the Nordic Senior Executive Committee for Occupational Environmental Matters. In 1977 this Committee started a project to produce scientific criteria documents for occupational standard setting, to be used by the national regulatory authorities as a common scientific basis for setting national OELs. The project is managed by a group of scientists: the Nordic Expert Group for Documentation of Occupational Exposure Limits. To date

³ See also Sweden and Denmark.

more than 80 criteria documents have been published. The possible dose-effect and dose-response relationships are presented and a critical effect is defined. An OEL is not proposed. This is the responsibility of the national regulatory authorities in each country, which may have to take into account economical and technological aspects. Agreements have been set up between the Expert Groups and the Dutch Expert Committee (DECOS) as well as with the U.S. NIOSH, for the purpose of preparing joint criteria documents.

*Sweden.*⁴ The Swedish Criteria Group for scientific risk evaluation for occupational standards was established in 1979. It consists of scientists and experts from the National Institute of Occupational Health, from universities, and from employees' and employers' central organizations. The group evaluates the dose-effect-response and dose-response relationships and assesses the critical effect for chemicals on a priority list delivered by the National Board of Occupational Safety and Health (NBOSH). The scientific evaluation is made in consensus and the reports are published. As of 1988, about 160 reports had been published. No OEL is proposed.

Technological feasibility criteria determine the exposure level for most carcinogens; no extrapolation is made for this class of substances. The Regulation Group of the NBOSH establishes a priority list for the Scientific Criteria Groups and analyzes possible technological and/or socioeconomic constraints. A standard is proposed taking the constraints into account. In the last step the NBOSH report is submitted to a Layman Board of the NBOSH, which promulgates the standard.

Collaborative agreements have been signed between the Criteria Groups and the Division of Standards Development and Technology Transfer, U.S. NIOSH, and with the Dutch Expert Committee (DECOS) for the preparation of joint scientific documents.

Switzerland. The Swiss National Accident Insurance Fund (SUVA) published a mandatory list of 48 gases and vapors in 1948 which has been updated at irregular intervals. The 1988 list identified each substance by its CAS number and STEL, and presented information on reprotoxic fetal risks and appropriate methods for exposure assessment. The OELs correspond largely to the ACGIH-TLVs and/or the German DFG-MAK list; some OELs have been set higher because of experiences at the national level. Since 1974 the SUVA has been assisted by a Committee of Experts.

United States of America. The Occupational Safety and Health Administration (OSHA) regulatory scheme is based on the OSHA and MSH (Mining Safety and Health) act. The OSHA Act of 1970 (Public Law 91-596) reads: Sec 20(a)(3) "The Secretary of Health, Education and Welfare . . . shall develop criteria dealing with toxic materials and harmful physical agents and substances which will describe exposure levels that are safe for various periods of employment, including but not limited to the exposure levels at which no employee will suffer impaired health or functional capacities or diminished life expectancy as a result of his work experience."

The MSH act regulates the surveillance of miners, mine health research and testing, and certification of respiration and hazard measuring devices.

NIOSH prepares recommendations (REL) and criteria documents in cooperation with the Swedish and Nordic groups; moreover, the WHO/IPCS criteria are reviewed.

The ACGIH-TLV Committee consists of 16 regular voting members (governmental employers or university staff members), and also nonvoting members (from profit-making corporations or labor unions). Work on a new TLV begins when new toxi-

⁴ See also Nordic Countries.

ecological or epidemiological findings come to the attention of the TLV Committee. Professionals throughout the world bring to attention preliminary findings, draft reports, published papers, and material that is not normally available through regular publication channels. Manufacturers may provide internal research reports which suggest that a TLV should be lowered. Moreover, the ACGIH staff continually scans the professional literature and forwards abstracts and complete papers to committee members.

The information is forwarded to the chair of one of the three (substance oriented) subcommittees. If the information seems significant, then one of the members becomes responsible for preparing a complete documentation and for recommending a new or revised TLV. The basis for discussion in the subcommittee is the original data rather than the summary presented in a documentation. After approval of a new TLV, the proposal with its supporting documentation is transmitted to the full TLV Committee which meets twice a year. All proposals, regardless of the seniority of the person introducing it, are subject to the same searching review and correction. If a value is approved, it is presented to the ACGIH membership at the annual American Industrial Hygiene Conference and, if approved, it is placed on the Notice of Intended Changes (NIC). Entries on the NIC remain there for at least 2 years to permit interested parties to submit data and views. After final approval has been obtained the Notice of Intended Changes is published in the annual TLV booklet and new documentations are printed in a supplement to the documentation volume.

A proposed TLV does not become a final adopted value until the Committee has voted its approval. Where there has been an existing TLV, the old value remains in effect until superseded by the new one. During this period interested persons, usually industry groups, submit data and opinions.

The ACGIH Committee was originally established to provide assistance and guidance in the evaluation of airborne exposures in the workplace. Over the years as the needs and concerns of industrial hygienists have grown, the Committee has tried to assist them by providing guidance on the evaluation of brief excursions above the TLVs and of exposures to mixtures. Recently it has provided a summary table of the carcinogen determinations of several U.S. and foreign organizations and has identified those TLVs where OSHA or NIOSH recommendations are lower. It is currently working on guidance statements in the areas of reproductive hazards, altered work shifts, and skin absorption. Through all of its activities, the TLV Committee remains cognizant of its primary goal of providing practical guidance to industrial hygienists as they measure, evaluate, and control health hazards in the workplace.

The International Labour Organization (ILO). The ILO instruments with respect to OELs follow:

- Recommendation 97 on the protection of workers' health, 1953;
- Convention 148 and Recommendations 156 on the work environment, 1977;
- Convention 139 and Recommendation 147 on prevention and control of risks for workers caused by carcinogenic substances and agents, 1974;
- Convention 162 and Recommendation 172 on the safety usage of asbestos.

The 1989 ILO Conference examined the feasibility of adoption of an international instrument on the safe use of chemicals at the workplace. The following information has been distributed:

—*Occupational Exposure Limits for Airborne Toxic Chemicals*, Series Safety, Hygiene and Occupational Medicine 37, containing OEL lists of 20 countries for about 1000 chemicals;

—*Encyclopedia Occupational Health and Safety*, with data on about 5000 chemicals;

—International Alert System on Safety and Health;

—The “CIS” analyzes annually 500 to 600 documents on chemicals;

—in cooperation with WHO and UNEP the IPCS publishes “Health Criteria” on pollutants in the ambient and occupational environment.

Moreover, there exists a Joint Committee ILO/WHO on Occupational Health inter alia to establish HBR-OELs; in 1977 this Committee published *Methods Used in Establishing Permissible Levels in Occupational Exposure to Harmful Agents* (WHO TRS 601).

ANNEX B: CONTENTS OF CRITERIA DOCUMENTS

Criteria documents should contain all available information relevant to identification of health risks for exposed workers, critically examined to assess their validity. The following items are to be explicitly discussed in the criteria documents:

identity, physical and chemical properties, monitoring (environmental and biological);

sources of exposure;

environmental levels and human exposure;

toxicokinetics;

toxicodynamics;

evaluation of human health risks—(a) guidelines and standards from national and international bodies, (b) previous evaluation by international bodies, (c) assessment of human health risks [dose–response relationships (NO(A)EL)], (d) groups at risk⁵;

recommendations for research;

references.

It is a matter of choice whether a criteria document should end with a health-based recommended occupational exposure limit or not.

REFERENCES

ARLMAN-HOEKE, M., AND VAN GENDEREN, H. (1988). Workshop on new approaches in extrapolation procedures and standard setting for non-carcinogenic substances in human exposure. *Regul. Toxicol. Pharmacol.* **8**, 381–437.

Ecology and Toxicology Centre (ECETOC) (1989). *Existing Chemicals: Literature Reviews and Evaluations*, Technical Report No. 30(2). European Chemical Industry, Brussels.

World Health Organisation (WHO). *Recommended Healthbased Limits in Occupational Exposure to Selected Solvents*, Tech. Rep. Series 664. WHO, Geneva, 1981.

⁵ Most workshop attendees preferred a merge of (sub)topics a, b, and c into the topic evaluation of human health risks.