

# National and International Approaches to Occupational Standard Setting Within Europe

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## Introduction

Occupational exposure limits (OELs) for chemicals in workroom air have been published in more than 70 countries. However, few countries generate or update their national lists of OELs independently. The acronym "OEL" is used here as a general term independent of what it is called in an individual country. OELs may be recommendations or they may have a legal status. They may be based on economic impact and technological feasibility. This makes a simple comparison of OELs from different countries partly misleading. OELs should not be compared without an opportunity to review the methods in each case.

The development of OELs in Europe has been described previously.<sup>(1)</sup> Briefly, the first recommendations for use of OELs were established in Germany as early as 1886. After the Second World War, the list of threshold limit values (TLVs) from the American Conference of Governmental Industrial Hygienists (ACGIH) was used in some European countries with a more or less mandatory function. In 1958, West Germany developed its own list and some countries (Austria, Switzerland) adopted the German list. In the 1970s, The Netherlands and Sweden introduced their own systems for establishing and validating OELs. Several other European countries followed later on.

## Risk Management and OELs

Standards setting, including OELs, is part of risk management. Risk management could be divided into four steps.<sup>(2)</sup> 1) risk identification; 2) risk estimation; 3) risk evaluation; 4) risk acceptance.

Risk identification (i.e., demonstrating an increased risk in experimental animals caused by a toxic substance in the work environment) is considered to be a scientific issue. Risk estimation, including establishment of dose-effect and/or dose-response relationships, may also be considered to be a scientific issue. Risk evaluation includes deciding which adverse effect should be the critical one for an OEL, and then a no-observed-effect level/lowest-observed-effect level (NOEL/LOEL) for this effect is established. This third step in risk management is both a scientific and a

transscientific issue. Transscientific issues are areas where laypersons may contribute as well as specialists in the decisions.<sup>(3)</sup> The final step, risk acceptance, involves setting a numerical value (i.e., setting an OEL), taking economic issues and technological feasibility into account. This step is also a transscientific one.

The scientific parts of risk management have been dealt with nationally by standing committees. In some cases, the committees have been set up by governmental bodies such as the Directorate-General of Labour in the Netherlands and the National Institute of Occupational Health in Sweden. In other cases, the committees are formed within the science society as in Germany. The committees generally consists of scientists from academia, government, and industry. The scientists from industry are said to be committee members because of their personal expertise and not as representatives of the industry. More rarely, scientific representatives from employees are members of the committees.

The common task for all national committees is to produce scientific background for an OEL. This means that the relevant scientific literature is carefully scrutinized and, if possible, a dose-response/dose-effect relationship is presented. Based on epidemiological and experimental data, a critical effect is identified and a NOEL/LOEL for the effect is defined. In some cases, the scientific committee also addresses a transscientific issue by proposing a safety factor and a numerical value of an OEL. Documentation is prepared that is usually published in the form of a criteria document or a consensus report.<sup>(4-6)</sup>

## International Projects

The scientific part of risk management should preferably be performed on an international basis. The scientific data as presented in the literature are available internationally. The data—and the effects—that serve as the basis of the OELs in different countries are often the same. Joint international ventures are therefore advantageous to the involved parties since writing criteria documents is both a time and cost consuming process. Cooperation offers a clear benefit, especially for smaller countries with a limited

number of experts. This was the idea when the Nordic Council of Ministers in 1977 decided to establish the Nordic Expert Group (NEG). The task of the NEG was to develop scientifically based criteria documents to be used as a common scientific basis of OELs by the regulatory authorities in the five Nordic countries: Denmark, Finland, Iceland, Norway, and Sweden.

Management of the NEG has been described previously.<sup>(7)</sup> In short, the criteria documents from the NEG (Table I) lead to the definition of a critical effect and dose-response/dose-effect relationships. The critical effect is a standard setting effect defined as the adverse effect that occurs at the lowest exposure.<sup>(8)</sup> There is no discussion of safety factors and a numerical OEL is not proposed. Since 1987, the criteria documents are published concurrently in English on a yearly basis.<sup>(9)</sup> The transscientific part of risk management, including economic and technological considerations, will then be dealt with by each individual country.

During the last 5 years, the NEG has extended its international contacts. Agreements have been set up between the NEG and the Dutch Expert Committee on Occupational Standards as well as between the NEG and the National Institute for Occupational Safety and Health, Division of Standards Development and Technology Transfer, in the United States. The purpose is to write joint criteria documents that will be discussed scientifically by both parties.<sup>(10,11)</sup> Based on the resultant document, the transscientific part will be the responsibility of the individual country. Other bilateral, cooperative arrangements exist or are planned including one between the Netherlands and England.

With the formation of the European Communities (EC), international cooperation between member states became a necessity. The question of joint criteria documents was obvious. In 1989, a workshop was organized on the "Harmonization of Criteria Documents for the Establishment of Health-based OELs." Representatives from the EC member states as well as from the United States, Australia, and Sweden were invited. The group concluded that a harmonized format for the presentation of criteria documents would be an important step in developing international cooperation. It was also recommended that an international inventory of

ongoing and planned activities relative to the preparation of criteria documents should be created. A network of cooperative committees was considered desirable.<sup>(12)</sup>

The goal for the EC is to agree upon a list of OELs that is equally valid in all member states. If one then also involves the transscientific parts of risk management (i.e., has an equal risk acceptance in all member states), then all the states "must be" equal when it comes to technical development and economic capacity.

In this context it should be noted that there was a trial in 1953 to promulgate a unified European list of OELs, but at that time it failed.<sup>(6)</sup>

## The "Ideal" Future

Based on the results from the EC workshop<sup>(12)</sup> as well as on personal experiences from bilateral cooperation between the NEG and others, certain points can be made on how to have a "standardized" criteria document accepted everywhere as the scientific basis for an OEL.

- A standardized criteria document should reflect the up-to-date knowledge as presented in the scientific literature.
- The literature used should preferentially be peer-reviewed scientific papers but at least be available publicly. Personal communications should be avoided. An openness toward the general public—particularly workers—decreases the suspiciousness of a kind that recently has been addressed toward documentation from the ACGIH.<sup>(13)</sup>
- The scientific committee should consist of independent scientists from academia and government. If the committee should include scientific representatives from the labor market, both employers and employees should be represented.
- All relevant epidemiological and experimental studies should be thoroughly scrutinized by the scientific committee, especially "key studies" that present data on the critical effect. All observed effects should be described.
- Environmental and biological monitoring possibilities should be pointed out. It is also necessary to thoroughly scrutinize these data, including toxicokinetic data.
- Data permitting, the establishment of dose-response and dose-effect relationships should be stated. A NOEL/LOEL for each observed effect should be given.
- The critical effect (i.e., the effect that occurs at the lowest exposure level)<sup>(8)</sup> should be stated in the conclusions. If necessary, reasons should be given as to why a certain effect is the critical one. The toxicological significance of an effect is thereby considered.
- Specifically, mutagenic, carcinogenic, and teratogenic properties should be pointed out as well as allergic/immunological effects.
- A reference list for all studies described should be given. If it is stated in the document that only relevant studies

TABLE I. The Format of Criteria Documents From the NEG

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| 1. Physical and chemical data                              |
| 2. Occurrences and uses (including hygienic measurements)  |
| 3. Kinetics (including biological exposure indicators)     |
| 4. General toxicology                                      |
| 5. Effects on organs (presented organ by organ)            |
| 6. Immunotoxicity and genotoxicity                         |
| 8. Carcinogenicity   |
| 9. Reproduction toxicology                                 |
| 10. Dose-response and dose-effect relationship             |
| 11. Research needs   |
| 12. Discussion and evaluation (giving the critical effect) |
| 13. Summary (and key words)                                |
| 14. References   |

have been used, there is no need to give a list of references not used or why. On the other hand, it could be of interest to list those databases that have been used in the literature search.

There are, in fact, only minor differences between existing scientific documentations for OELs in Europe today. It would, thus, be relatively easy to agree upon the format of a standardized criteria document containing the scientific parts of risk management.

As mentioned above, risk acceptance is a transscientific issue. To set a numerical value by using safety factors or other criteria implies an agreement upon what frequency of injury, disease, or discomfort can be acceptable.

In this context, it should be stressed that an important criterion for setting low OELs may be technological feasibility including judgment on the best available technology. Should technological changes, which are not too expensive to implement, result in a lower exposure level than the level deduced from the biological data alone, the technological feasibility criterion may have the final weight in deciding on an OEL. Technological criteria may also involve decisions leading to improvement of existing technology.<sup>(4,5)</sup>

## Conclusion

Whatever criteria are used, the ultimate goal must be to have an OEL as low as reasonably achievable in order to establish a safe working environment. The risk acceptance process should involve the participation of representatives from the employer's and employee's organizations. It should be, as in Sweden according to the Work Environment Act, the responsibility of the employers to control the risk and to inform the workers about the risks. The employees are those who actually are taking the risks.

Finally, setting OELs is a scientific challenge and an important issue in the management of occupational hazards. The challenge includes the development of more refined methods for risk identification and risk evaluation, particularly for the analysis of long-term effects. Although the scientific basis is invaluable in setting an OEL, a transscientific basis sometimes adds an important contribution to the decision process. This makes an OEL more of a norm than a limit between hazardous and nonhazardous concentra-

tions; a norm that is part of a greater system such as codes of practices. In the context of mixed exposures, codes of practices are even more effective than the numerical OELs for the individual components of the mixture, as regulatory instruments for improving the work environment.

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