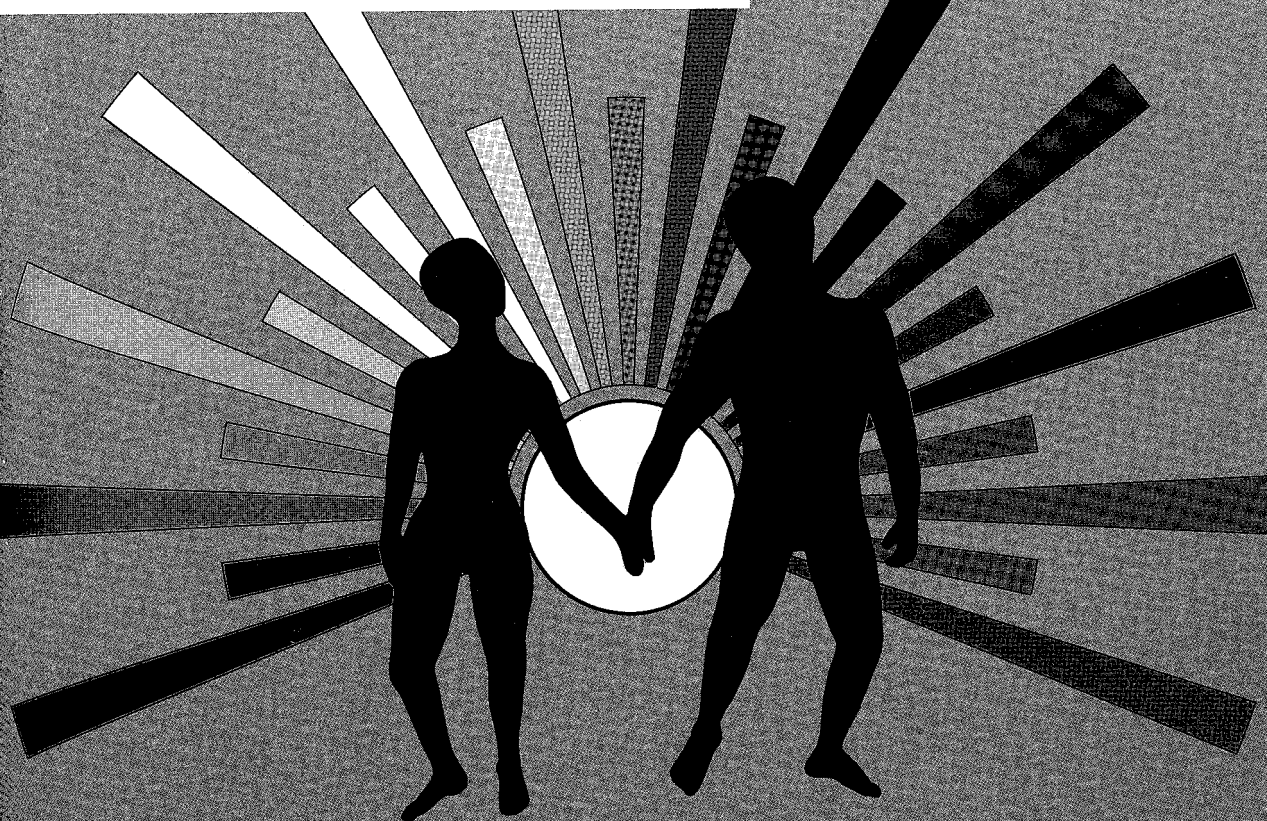


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SPECIAL ISSUE:
EXPOSURE LIMITS FOR OCCUPATIONAL AND
ENVIRONMENTAL CHEMICAL POLLUTANTS

INTERNATIONAL APPROACH TO THE ASSESSMENT OF CHEMICAL RISKS

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ABSTRACT

One of the main objectives of the International Programme on Chemical Safety, a joint venture of the World Health Organization, the United Nations Environment Programme and the International Labour Organization, is to carry out and disseminate evaluations of the risk to human health and the environment from exposure to chemicals, mixtures of chemicals, or combinations of chemicals and physical and biological agents.

These evaluations, performed by groups of internationally reputed and independent experts, provide a scientific and objective basis that national authorities may be able to use for planning and for the development of control measures, such as the establishment of exposure limits for chemical pollutants.

INTRODUCTION

The primary purpose of chemical safety is to learn how to live with chemicals in our daily life, to ensure that exposure to chemicals, natural as well as synthetic, does not harm humans nor the environment. This is not only to avoid the dramatic effects of acute poisoning but also to prevent the possible insidious effects of long-term low level exposures of large populations.

Regulatory agencies with the responsibility of controlling hazardous chemicals need a number to give reality to a regulation, standard, guideline, or even a recommendation. Whatever the regulatory action, a number provides the reference point for enforcement, surveillance, and subsequent monitoring. The number enables one to make a judgment as to what is safe — or, more correctly, what is judged as an acceptable risk — as opposed to what is negligent or criminal.

There may not be a significant increase in risk between driving a motor car at 58 and 62 kilometres per hour (KMH), but 60 KMH can provide a suitable reference point for public safety.

The number chosen should, of course, be both enforceable and amenable to change as the scientific knowledge on which it is based evolves. At best, the number will be an approximation for health protection. In no sense can it be considered to give an absolute guarantee of freedom from risk.

Whether a government chooses to enforce compliance with health and safety requirements through the forces of law and prosecution, or through gentler routes of suasion and recommendations, there is always the essential flow-path for health protection:

Research — Criteria — Standards — Regulations — Enforcement and Compliance.

That is to say, investigation and research lead to an evaluation of the health hazards, formulated as criteria. From these criteria, health standards are derived, which are in turn converted to a legislative reality when promulgated as regulations.

The final stage is enforcement of these regulations. The control loop is completed by monitoring the effectiveness of regulations, so that if they are not achieving the original intention, the cycle of investigation and regulation must be repeated once more. Ideally, such measures relate achievements to needs.

It is at the *criteria* stage that the role of international evaluation is so critical. Few countries have the resources or expertise to carry out the assessment of health risk on the multitude of chemicals to which we are exposed. The cost of testing and evaluating chemicals is so high, and skilled personnel so scarce, that it is incumbent on all of us to share limited resources and avoid overlap and duplication. Even for those that have the ability, the necessary objectivity and consistency can best be obtained in the international forum. Consistency of testing and evaluation lead to comparability and acceptability of data obtained in different countries and — in the final analysis — facilitates both international trade in chemicals, and the harmonization of control measures.

THE INTERNATIONAL PROGRAMME ON CHEMICAL SAFETY (IPCS)

In 1977 the World Health Assembly, the governing body of the World Health Organization (WHO), requested the Director-General to study the problem of long-term strategies to control and limit the impact of chemicals on human health and the environment. As a response to this request, the International Programme on Chemical Safety (IPCS) was developed and structured by WHO. The interest of other international organizations in chemical safety was clearly demonstrated when the International Labour Organization (ILO) and United Nations Environment Programme (UNEP) joined with WHO in the IPCS which was formally launched in 1980.

The IPCS is conceived as a confederation of these three Cooperating Organizations contracting to collaborate in those activities related to chemical safety which correspond to the objectives of the Programme.

The IPCS is therefore a truly international and intersectorial cooperative programme of the ILO, UNEP, and WHO; with WHO being the executing agency for the Programme.

The overall objectives of the IPCS are to catalyze and coordinate activities in relation to chemical safety, and in particular to:

- (1) carry out and disseminate evaluations of the risk to human health and the environment from exposure to chemicals, mixtures of chemicals, or combinations of chemicals and physical and biological agents;
- (2) promote the development, improvement, validation, and use of methods for laboratory testing and ecological and epidemiological studies and other methods suitable for the evaluation of health and environmental risks and hazards from chemicals;

- (3) promote technical cooperation with Member States, in particular developing countries to:
 - (a) facilitate the use of available evaluations of health and environmental risks and hazards from chemicals;
 - (b) improve the capabilities of national authorities in conducting their own evaluations of health and environmental risks and hazards from chemicals;
 - (c) strengthen infrastructures for safety aspects relating to chemicals — their production, importation, transportation, storage, use, and disposal.
- (4) promote effective international cooperation with respect to emergencies and accidents involving chemicals;
- (5) support national programmes for prevention and treatment of poisoning involving chemicals;
- (6) promote training of the required manpower.

This paper will limit itself to the first objective:

As the first of its objectives, the IPCS has been required to prepare evaluations of the risk to human health and the environment from exposure to chemicals. In response, its wide range of publications including: Environmental Health Criteria documents (EHC), Health and Safety Guides (HSGs), International Chemical Safety Cards (ICSCs), toxicological monographs on food additives and contaminants and residues of veterinary drugs and pesticides in food. The preparation and review of these documents represent a large coordinated effort by the IPCS staff, consultants and scientists from all over the world; this joint effort culminates in the publication of peer-reviewed documents containing an evaluation based on a consensus from a Task Group of internationally reputed and independent experts convened by the IPCS. These documents are translated into several languages and between 5,000 and 10,000 copies distributed to all Member States in order to provide a scientific and objective basis that national health or other relevant authorities may be able to use for planning and for the development of regulatory actions and control measures. I must stress here that evaluations provided by international groups of reputed and independent experts, under the aegis of WHO, are much more readily acceptable, especially by countries which do not have the capacity to perform their own assessments, than an evaluation provided by any one national authority.

During the last two decades, evaluation of the health hazards from chemical and other environmental agents has received considerable attention in several WHO programmes. High priority was given to drinking water quality (1), food additives (2), and pesticide residues (3), to occupational exposure (4), air quality in urban areas (5), and, more recently, to the carcinogenic risk of chemicals to man (6).

In most instances, man's total exposure to a given agent, from different media or conditions (air, water, food, work, home), was not considered. The inadequacy of this ap-

proach is obvious for pollutants that may reach man by several pathways, as is the case with lead, cadmium, and some other metals, and certain persistent organic compounds. This concern has led to the creation of the Environmental Health Criteria Programme, which has the following objectives:

- (I) to assess existing information on the relationship between exposure to environmental pollutants (or other physical and chemical factors) and man's health, and to provide guidelines for setting exposure limits consistent with health protection, i.e., to compile environmental health criteria documents;
- (II) to identify new or potential pollutants by preparing preliminary reviews on the health effects of agents likely to be increasingly used in industry, agriculture, in the home or elsewhere.
- (III) to identify gaps in knowledge concerning the health effects of recognized or potential pollutants or other environmental factors, to stimulate and promote research in areas where information is inadequate; and,
- (IV) to promote the harmonization of toxicological and epidemiological methods in order to obtain research results that are internationally comparable.

Considering the large number of environmental agents and factors that may adversely influence human health, a practical programme for the preparation of criteria documents must be based on clearly defined priorities. The list of priorities is based on the following considerations:

- *Severity and frequency of observed or suspected adverse effects on human health.* Of importance are irreversible or chronic effects, such as genetic, neurotoxic, carcinogenic, and embryotoxic effects including teratogenicity. Continuous or repeated exposures generally merit a higher priority than isolated or accidental exposures.
- *Ubiquity and abundance of the agent in man's environment.* Of special concern are inadvertently produced agents, the levels of which may be expected to increase rapidly, and agents that add to a natural hazard.
- *Persistence in the environment.* Pollutants that resist environmental degradation and accumulate, in man, in the environment, or in food chains, deserve attention.
- *Environmental transformations or metabolic alterations.* Since these alterations may lead to the production of chemicals that have greater toxic potential, it may be more important to ascertain the distribution of the derivatives than that of the original pollutant.
- *Population exposed.* Attention should be paid to exposures involving a large portion of the general population, or occupational groups, and to selective exposures of highly vulnerable groups represented by pregnant women, the newborn, children, the infirm or the aged.

The full list is periodically reviewed.

SCOPE

The purpose of the criteria documents is to compile, review, and evaluate available information on the biological effects of pollutants and other environmental factors that may influence man's health, and to provide a scientific basis for decisions aimed at protecting man from the adverse consequences of exposure to such environmental factors, both in the occupational and general environment. Although attainment of this objective entails consideration of a wide range of data, no attempt is made to include in the documents an exhaustive review of all published information on the environmental and health aspects of specific agents. In the progress of collecting the required information, the available literature has been carefully evaluated and selected as to its validity and its relevance to the assessment of human exposure, to the understanding of the mechanism of biological effects, and to the establishment of dose-effect and dose-response relationships.

LAYOUT OF AN ENVIRONMENTAL HEALTH CRITERIA DOCUMENT FOR A CHEMICAL OR GROUP OF CHEMICALS

1. *Summary, Conclusions, and Recommendations for further research.*
2. Identity, physical and chemical properties, analytical methods.
3. Sources of human and environmental exposure.
4. Environmental transport, distribution and transformation.
5. Environmental levels and human exposure.
6. Effects on organisms in the environment (e.g., microbes, plants, insects, fishes, birds, mammals).
7. Kinetics and metabolism.
8. Effects on experimental animal and *in vitro* test systems.
9. Effects on humans.
10. *Evaluation of human health risks and effects on the environment.*
11. Recommendations.
12. Previous evaluations by international bodies.
13. References.

The EHC documents are written preliminary for the specialist and some basic knowledge is required to make full use of them. However, the summary, conclusions, and evaluations sections would be clear even to non-specialists. The main recommendation for practical use is to use them not just as sources of information but as examples of the ways in which toxicological data are interpreted and used for predicting effects on humans and ecosystems and deriving exposure levels designed to prevent these effects.

The EHC documents provide the evaluation of the risk of adverse health and environmental effects of chemicals as a background for decisions of the appropriate regulatory bodies in the Member States. These decisions and their implementations are determined, of course, by the socioeconomic conditions and other factors specific for a given Member State or a given situation. The criteria documents may be used for different purposes in different parts of the world while the contents of the documents must have

global validity and must reflect, in an objective way, the results from all parts of the world. For this reason, the documents are not only published for all the Member States, but are also prepared with the participation of all the Member States willing to contribute.

EHC's provide the scientific basis and serve as guidelines for health assessments and regulatory decisions in the same manner as other WHO activities such as: Drinking Water Quality Guidelines; Air Quality Guidelines, and health based Occupational Exposure Limit Guidelines.

Also, in collaboration with FAO, the IPCS operates the Joint FAO/WHO Expert Committee on Food Additives (JECFA: food additives, food contaminants, and residues of veterinary drugs) and the Joint FAO/WHO Meeting on Pesticide Residues (JMPR); these Committees establish safe levels of food chemicals for the human body (ADI's and other endpoints). These levels are used by the Member States and the Codex Committee to establish *Maximum Residue Limits* in food.

GLOBAL HARMONIZATION

Safety considerations related to human health and the environment (including risk assessment) may affect in various degrees the production, availability, and international trade of many chemicals. It is therefore paramount that the conclusion reached in this field be based on sound data, good science, and credible risk and safety evaluations.

The proliferation of groups undertaking toxicological evaluations and safety assessments of chemicals is today a fact that is looked upon with concern by national regulatory authorities, as well as industry, since the end-points of these evaluations often diverge from one another. Such discrepancies could be due to different interpretation of data, but generally they arise because of a difference in the sets of data available for risk evaluation. International expert groups have issued recommendations repeatedly asking for the establishment of mechanisms to effect a better liaison between the various evaluative groups in order to assure a greater degree of uniformity of their conclusions.

I believe that the IPCS, by promoting a global approach in safety assessment of chemicals, represents the mechanism whereby a higher degree of uniformity and harmonization may be achieved among the various national and international assessment groups.

Understanding what is meant today by harmonization is a difficult task. The difficulty arises in part from the complexity of interests affected by regulatory decisions when acceptable or tolerable levels of chemicals are proposed or established.

Regardless of possible divergent views on the significance, need, and type of harmonization in the fields of risk evaluation of chemicals, it may be of some use to attempt to identify certain elements which may contribute to the clarification of the issue. This may help lead the way to the building of a rational basis for harmonization. The following elements are proposed: firstly, a potentially harmonizing group may wish to acquire a working knowledge of what other assessment groups are doing, or propose doing. Secondly, a potentially harmonizing group may wish to achieve a deep percep-

tion of all the reasons underlining the conclusions reached by other groups. Thirdly, a potentially harmonizing group may wish to exercise critical judgment as to whether what has been decided by another group represents the best decision.

Finally, harmonizing groups seeking a global approach in solving problems related to risk and safety assessments of chemicals may find it convenient and profitable to join forces with the IPCS.