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OCCUPATIONAL HEALTH POLICY

OCCUPATIONAL EXPOSURE STANDARDS. HISTORICAL OUTLINE AND PRESENT STATE

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Abstract. The paper presents the history of hygienic standards setting in various countries, as well as the current situation in this respect. Methodological approaches to hygienic standards setting in the USA and USSR have been analysed and compared. The paper shows also the contribution of international organizations to unification of both the definition and the approach to MAC setting. The authors present systems of MAC setting in such countries as USA (ACGIH, NIOSH, OSHA), former USSR, Germany, Scandinavian countries, Hungary and Poland.

The paper comprises also classification of substances and carcinogenic agents adopted by IARC as well as the classifications in those countries which publish lists of carcinogens.

It was recognised early on that it is the air concentration of a given chemical that best characterises the work environment under conditions of exposure to this chemical. This finding has given rise to prophylactic activities concerning the determination and enactment of such air concentrations of toxic chemical in the workplace that would be harmless to exposed workers. In 1886, K.B. Lehmann published a work on the principles of setting safe concentrations during a short- and long-term exposure to selected toxic substances in industry. In 1919 he began collaborating with F. Flury, a toxicologist, who was the first to discuss theoretical aspects of the dose-response relationship for some respiratory tract irritants (8, 9). The same researchers in 1938 presented a provisional list of hygienic standards for 100 chemicals, mostly irritants. It was the first list of MAC values published in Germany (8, 9, 18).

The first MAC value register ever was published in the USSR in 1920 and comprised 6 chemicals for which the 'safe' concentration had been determined. This list was extended to 14 substances in 1933 (18, 24). In the United States the first list of maximum allowable concentrations for several chemical compounds was developed and published by the authorities of Massachusetts in 1937 (18, 24).

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Continuous progress in the industrial toxicology after WW II has contributed to the increase of the scope of MAC value registers. The MAC values have become either recommended or enacted parameters which may diminish the risk arising from occupational exposure of workers. They have been regarded as one of the most essential criteria for the assessment and monitoring of occupational exposure.

This seems to be a particularly significant assumption. It should be emphasized that the applicability of MAC values to exposure assessment is limited to the chronic or long-term, exposure repeated daily and oraly to the instances when the potential toxicant enters the workplace atmosphere and then is being absorbed by the worker through his respiratory tract. The MAC values cannot be considered in the assessment of contact dermal exposure to liquid and solid substances.

Apart from the MAC values, the admissible concentrations in biological material are used for the assessment of exposure. These two notions are very closely related with both the theory and methodology. It should be stressed that many of admissible concentrations have been determined under experimental conditions of inhalation exposure to industrial toxicants.

There have been different international activities for unifying the criteria for setting hygienic standards. The first international conference on this subject was held in Prague in 1959 (16). The next one took place in Paris in 1963 but no Eastern European countries participated in it (18). In 1965 the countries of Eastern Europe organized a meeting on the unification of hygienic standards in Lodz, Poland (17).

The notion of the maximum allowable concentration was for the first time defined at the symposium on toxicology organized by the International Union of Pure and Applied Chemistry (IUPAC) in Prague (16). According to the definition, the maximum allowable concentration is the mean air concentration of the chemical which does not produce any symptoms of a disease or physical weakness detectable by most sensitive, internationally adopted tests in any worker except for highly susceptible individuals during the normal daily work.

The adoption of the definition by all the participating delegations did not mean that differences between the approaches of particular expert groups had been eliminated. The differences referred mainly to the approaches of the USSR and American groups of specialists in industrial toxicology. The tendency to adopt different approaches in those two countries lasted approximately till the beginning of the '80s. Simplifying the situation with respect to setting hygienic standards for industrial toxicants, one may say that, at present, there operate two main lists of MAC values: the American and the USRR one. The values determined for most of the substances included in the list differ from one another by about a few to a hundred times (Table 1). The former USSR name for the hygienic standards remained the same whereas the American have changed theirs to the name of threshold limit value in 1965 (18).

The inconsistencies between the two lists have resulted both from different approaches and viewpoints concerning the determination of safety levels while setting standards.

It is difficult to find an explanation for the differences in the methodology of setting hygienic standards for airborne chemicals. One may at this point refer to the papers by I. Sanotsky and H. Stockinger Geneva (30), discussed at the VI Session of Joint ILO/WHO Committees for Occupational Health, which concerned the maximum allowable concentration of toxic chemicals in the workplace, Geneva,

Table 1. Comparison of hygienic standards determining admissible concentration of industrial toxic agents in the air, set in USSR and USA on a significantly different levels (18)

Group of substances	Substance	Admissible concentration in mg/m³		Differences (multiple)
		USSR	USA	
Irritants	acetic aldehyde	5	360	72
	formaldehyde	0.5	3	6
Metals	manganese	0.3	5	16.6
	nickel-soluble compounds	0.005	1	200
Chlorinated hydrocarbons	benzyl chloride	0.5	5	10
	ethyl chloride	50	2600	52
	methylene chloride	50	1740	35
	methyl chloride	5	210	42
	vinyl chloride	30	1300	43
	chloroprene	2	90	45
	tetrachloroethylene	10	670	67
	dichlorobenzene	10	200	20
	dichloroethylene	50	790	16
	trichloroethylene	10	535	53
Organic solvents	acetone	200	2400	12
	benzene	5	80	16
	cyclohexane	80	1050	13
	nitroethane	30	310	10
	toluene	50	750	15
From various groups	hydrogen cyanide	0.3	11	33
	chlordane	0.01	0.5	50
	dioxane	10	360	36
	ethylenimine	0.02	1	50
	α-methylstyrene	5	480	96
	styrene (monomer)	5	420	82
	ethylene oxide	1	90	90

1968, as well as to the publication by Timofyevska (32). They reflect significant methodological differences with respect to the problem although the presented approach is fairly similar. All the papers considered experimental animal studies as the first stage of the standard setting procedure with the determination of the lowest concentration of the chemical which produces adverse health effects and a slightly lower one which evokes no effects. The latter concentration is the basis for setting a provisional MAC value, also taking into account the safety factor depending on the type of effect of the chemical in question.

Without going into details, one may assume that the above mentioned differences refer mainly to the kind of testing of pathological changes within the system, scope of medical examinations and result interpretation. The discussion which has been going on among the researchers would indicate that the methodological differences have become less and less numerous and that a tendency for a more similar approach is prevailing. In 1968 the Joint ILO/WHO Committees partly reached an agreement with regard to the scope of examinations which would serve as

a basis for determining MAC values for toxic chemicals in the air. The same also holds true for the issue of setting minimum requirements for the documentation of experimental studies and medical obervations. These recommendations were published by ILO in 1970 (30). However, the matter of the safety factor in exposure assessment and in determining MAC values is still debatable (30).

One of the most essential assumptions with respect to setting hygienic standards is the one saying that the determination of MAC values is a result of a certain compromise between setting MAC at values close to null, which follows the principles of work safety and hygiene, and determining the technically feasible level of the chemical concentration.

The argument of technical feasibility has been put forward by the American party who has also claimed that there may be chemical concentrations which do not induce any adverse health effects in the workers. The USSR party has advocated the superiority of the principles of work hygiene over the technical capacity for observing the determined value. The different viewpoints have affected the process of setting hygienic sandards in both countries, which resulted in some inconsistencies between the American and USSR lists of MAC values.

Generally, the USSR MACs are lower than their American counterparts. Other differences refer mainly to the interpretation and observance of MAC values. The definition of MAC values as formulated in Prague has never been completely adopted in the former USSR. The USSR standards refer not to the mean concentrations but to single exposure to all the chemicals, regardless of their activity. Accordingly, even a momentary excess of the MAC value is considered a disobeyance of the hygienic standard. In the U.S. most of the TLVs concern the time weighted average concentration within an 8-hour daily exposure. Only for a few substances are the maximum concentrations denoted as C ("ceiling value") determined; these cannot be exceeded even within a very short period of time.

The concept of the regulation of occupational exposure as developed in the U.S. derives from an assumption that the aim of the regulation is to diminish the health effects rather than try to eliminate them completely. To some extent this concept has been in use up to the present, depending on the philosophical foundations of setting MAC values for toxic chemicals in the air and in biological material.

This can be reflected in an approach that treats the MAC values as the threshold limit values (American concept adopted by most of the countries) which ensures the safety of workers with the exception of some individuals with acquired or genetically determined susceptibility to the toxic effect of chemicals.

Referring to chemical hazards, it is possible to determine MAC values for the following safety levels for the exposed groups of workers:

– "safety level" which is to prevent the worker from any health effects resulting from occupational exposure;

– "threshold level" which provides safe conditions of work for the exposed, except for highly susceptible individuals;

– "compromise level" which reflects the compromise between the principles of work hygiene and the actual possibility of observing them.

The theoretical fundamentals for setting hygienic standards comprise:

– results of experimental animal studies;

– results of medical observations of workers exposed to given toxic agents under industrial conditions;

– results of epidemiological studies of a relationship between the magnitude and duration of exposure and the induced health effects.

It has to be stressed that the majority of the determined MAC values are based only on the results of experimental studies.

The procedure of applying hygienic standards for airborne industrial toxicants in the assessment of occupational exposure has recently become more and more complex. This has been reflected in respective legislation in many countries. The progress in the field of toxicology and the collected experimental data seem to indicate a necessity for adjusting the methods of exposure assessment to the kind of the toxic activity exerted by a given chemical.

The experts taking part in the conferences in Paris in 1963 and in Geneva in 1968 discussed the need for classifying toxic chemicals into three groups according to the nature of their activity, namely:

1. fast or threshold activity chemicals
2. cumulative activity chemicals
3. carcinogens.

As for the group no. 1 including mainly irritants, it is said that the risk of the toxic effect depends mostly on exceeding the threshold values, even when very shortly, and not the mean values of the concentration during a working shift. For the second group the risk is related both to the concentration level and exposure time, hence the mean time weighted values for the 8-hour daily exposure may be of use. With respect to the carcinogens it has been decided that due to the lack of experimental data on the safe levels of exposure any contact with those substances poses a risk of the neoplastic development.

Curiously enough, up to now there has been no common name for the hygienic standard, no matter how far the international activities in this respect would go. In 1971 ILO proposed a name of the Occupational Exposure Limit (OEL) which was accepted by WHO in 1981. The name has been adopted by the EEC countries and Sweden. However, in other countries the OELs are known also as Threshold Limit Value (TLV) – ACGIH – USA, Recommendation Exposure Limit (REL) – NIOSH – USA, Permissible Exposure Limit (PEL) – OSHA – USA, Maximal Concentration (MK) – Hungary, Concentration known to be hazardous – (HTP) – Finland, Maximum Allowable Concentration (MAC) – Poland. USSR and Czechoslovakia, Maximum Concentration Values (MAK) – Germany.

After WWII a number of institutions in many countries of the world have begun systematic activities for developing and setting hygienic standards for toxic chemicals in the industry. Below is a description of the procedures used for setting hygienic standards and their definitions as adopted in different countries. In many of the countries the values of the standards are recommended only and they have no legal status. They are often based on the health criteria. These standards can be made use of in the interpretation of the results of exposure assessment and monitoring. Another group are the legally binding hygienic standards. In their determination not only the health criteria are taken into account but also the opinion and expertise of the representatives of employers and employees. The feasibility of abiding by the standards is then considered, including the technological capacity of the industry.

So far, the hygienic standards have been determined and published in 17 countries, where the relevant legal acts are in force, and altogether they comprise 2128 chemical compounds (27).

The United States

Since 1947 the American Conference of Governmental Industrial Hygienists (ACGIH) has been publishing annually the registers of hygienic standards for chemical hazards in the working environment (10). The registers are not official documents but owing to the high prestige of ACGIH they become guidelines for the decision-makers in the U.S. and elsewhere. The standards referred to as the Threshold Limit Values (TLV) have no legal status and are treated as recommendations for providing appropriate working conditions. Three categories of TLVs can be distinguished (31):

– TLV-TWA (Time Weighted Average) – mean weighted average for the 8-hour working shift and 40-hour working week, denotes the level of concentration to which the workers can be exposed day after day and which does not induce any adverse health effects;

– TLV-STEL (Short-Term Exposure Limit) – mean weighted concentration that the workers can be exposed to for a period of about 15 min; this level should not be exceeded during a working shift. The concentration at the level of STEL should not occur more often than 4 times during a working shift;

– TLV-C (Ceiling) – the concentration level which should not at any time be exceeded during a working shift.

Abridged documentations are published in ACGIH TLV's Documentation (7).

Recommended hygienic standards are developed and presented by the National Institute for Occupational Safety and Health (NIOSH) as REL (Recommended Exposure Levels) on the basis of relevant criteria for setting hygienic standards (6, 25). REL is the mean weighted concentration for the working shift of up to 10 hours and the working week of 40 hours.

NIOSH uses also the terms of STEL and REL but their definitions differ slightly from those of ACGIH. According to NIOSH, STEL is the mean weighted concentration for 15 min which should not be exceeded at any time during a working shift. REL (Ceiling) is regarded as the concentration which should not at any time be exceeded during a working shift. The documents are published under the title of NIOSH Criteria for a Recommended Standard (25).

The federal lists of hygienic standards are developed and published by the Occupational Safety and Health Administration (33). The Administration was established by the Congress of the United States in 1970. Till that time there was no legally binding system of the occupational health care for workers potentially exposed to different hazards. OSHA was established on the strength of the Occupational Safety and Health Act of 1970 and is directly subordinate to the Department of Labour. OSHA is responsible for setting legal regulations related to occupational health care. It also deals with the development and publication of federal hygienic standards which along with the justification for the determined values and respective legislation are published in the Federal Register. Apart from that, OSHA handles the proposals of corrections to hygienic standards as well as it notifies about the MAC values for new toxic chemicals by publishing them as the "Notice of Proposal Rulemaking" in the Federal Register.

The Notice includes complete argumentation for the corrections or proposals of new MAC values as well as the name of the institution which postulates the alterations. Within 60 days after the publication appears, the interested institutions

such as representatives of industry, employers, employees, research centres and federal agencies may submit in writing their comments to the proposed alterations.

After receiving the comments, OSHA organizes public hearings of the authors of the project of the MAC value for a given chemical by the representatives of the interested institutions. During the hearing, questions and remarks on the project are presented. After the hearing, representatives of the participating institutions present, in writing, their arguments for, or against a given project. OSHA analyzes all the data, determines the MAC value for the toxic chemical and publishes a full final version justifying the changes made to the existing standard or the introduction of a new hygienic standard in the Federal Register.

OSHA presents the MAC as PELs (Permissible Exposure Limits), STELs (Short-Term Exposure Limits), and Ceiling Values. The PEL (Permissible Exposure Limit) is the average weighted concentration not to be exceeded during an 8-hour shift, 40-hour working week. The STEL (Short-Term Exposure Limit) is the average weighted 15-min concentration never to be exceeded during 8-hour working shift. The Ceiling Value is the concentration not to be exceeded during a working shift (1).

Germany

Systematic work on the preparation of hygienic standards started in Germany in the '50s. The Commission for Evaluation of Dangerous Industrial Substances (MAK Kommission) is the body responsible in Germany for preparing the proposals for admissible concentrations of chemical substances at workplaces. The MAK--Kommission compiles and publishes lists of admissible concentrations, based on the Kommission's own works and experience. The levels established are not obligatory but recommended (23).

According to the definition presently in force in Germany, the maximum concentration in the workplace (MAK — Maksimale Arbeitsplatzkonzentration) is the maximum allowable concentration of a chemical (gas, vapour or aerosol) in the ambient air at workplaces which, according to the present state of knowledge, does not cause any change in the health condition of workers nor excessive work arduousness. The MAK value is the weighted average for one working day. Under these conditions, the exposure may be repeated 8 hours a day 40-hour working-week system.

The German MAC list also includes short-term MACs (peak limitations). The value of a short-term MAC (peak limitation) depends on the toxic effect. According to their toxic effect, the chemicals are divided into 5 categories. The philosophy concerning MAC short-term level is associated with the multiple occurrence of MAC, duration of the short-term concentration, and time intervals at which this concentration may occur during the shift.

When determining the hygienic standard values, health criteria are the priority, although some practical criteria associated with technological processes or with worker exposure are sometimes taken into account.

Besides, for many carcinogenic substances for which safe concentrations cannot be determined, so-called technical values (Technische Richtkonzentrationen — TRK) are used. Keeping the concentrations of the chemical substances in the ambient air below the technical values is expected to substantially reduce the risk of health loss in employees, although it does not eliminate it completely. For the substances with

recommended technical values, it is advisable to keep their concentrations as low as possible. By definition, TRK values are mean 12-month values at 8-hour daily exposure, 40-hour working week. During 1 hour the concentration should not exceed three times the TRK value.

MAC documentation is published in Toxikologischarbeitsmedizinische Begrundung von MAK-Werten.

Former USSR

In January 1991 the Ministry of Health of the former USSR published a list of MAC values for toxic substances in the working environment (22). The list had been prepared by PROMEDAC, the Association for Preventive Medicine and Environmental Protection in collaboration with experts from medical research institutes, Russian Academy of Medical Sciences, and Institute of Organic Chemistry and Chemical Engineering.

The work on the preparation of hygienic standards was carried out as follows: stage I involved research on the toxicity evaluation of chemicals before they would be released to the market: during stage II, medical and biological data were considered to establish hygienic standards and to compare them with the technical and economic capabilities of the industry; stage III was associated with the concept of the threshold dose (concentration).

The hygienic standards for new substances are developed in a three-stage process:

1. Establishing temporary safe exposure level (TSEL). This value was used for the period of laboratory testing of new substances.
2. Establishing MAC values for substances which are being introduced into the industry in pilot tests.
3. Establishing official MAC-values. After considering the working conditions and health condition of workers, the MAC values could be corrected, but this should be done not later than 3–5 years from the date of their incorporation in the list of hygienic standards.

In the former Soviet Union, the hygienic standards were called maximum concentrations, defined as the concentration which should never be exceeded during 8-hour working day, 41-hour working week, and which should not produce any health effects in the workers or their descendants. The MAC value documentation has never been published, and it is not clear, therefore, what is the basis for the MAC values.

Today's Russia has the same system of establishing hygienic standards as the former USSR.

Poland

The first list of hygienic standards in Poland was published in 1956. It was prepared as a provisional document by a group of experts: included 14 substances and was brought into practical use. The specified standard values did not differ from the MAC values which were at that time in force in the USSR (12). The first list of maximum allowable concentrations for 127 substances was published in 1959. Since 1982, the MAC values in Poland have been determineed as follows: the Group of

Experts for Chemical Agents within the Inter-Sectoral Committee for MAC and MAI (Maximum Allowable Intensities of Physical Factors) Value Updating performs a critical evaluation of the documentation for the MACs prepared by individual members of the team and estblishes MAC values based solely on health criteria and most recent research data. Those proposals, together with the documentation, are presented during a session of the Inter-Sectoral Committee for MAC and MAI Value Updating, (the Committee including representatives of the ministries of health and labour, and representatives of industry and of scientific insitutions), and are then submitted to the Minister of Labour and Social Policy. After being accepted by the Minister of Labour and Social Policy, the MAC value is published in the Law Gazette as an Act of the Minister of Labour and Social Policy regulating maximum allowable concentrations and intensities of harmful agents in the working environment (14).

This is a hygienic standard valid over the whole territory of Poland. The specified MAC values constitute the guidelines for the designers of new and updated technologies and products, the criteria for evaluation of working conditions, and a basis for planned preventive activities in industrial plants. Industrial plants are obliged to estimate concentrations of the toxic substances specified in the list of MAC values at a frequency and in the scope required to determine the degree of workers' exposure, and to keep records of those estimations. The aim of these activities is an improvement of working conditions.

The Polish list of hygienic standards includes three MAC categories (29):

– Maximum Allowable Concentration – weighted average during the whole of the employment period in an 8-hour shift system, which should not cause any adverse health effects in the worker or their descendants.

– Maximum Allowable Short-Term Concentration – mean values of the concentration which should not cause any adverse effects in the health status of workers or their descendants if they persist in the working environment no longer than for 30 minutes during the working shift.

– Maximum Allowable Threshold Concentration, which should never be exceeded in the working environment.

The Polish register of MAC values includes presently 249 toxic substances. Documentation for further 120 toxic compounds is under preparation. The documentation is published successively in the Bulletin of the Inter-Sectoral Committee for MAC and MAI Value Updating.

The Ministries of Health of the Scandinavian countries (Sweden, Denmark, Finland, Norway and Iceland) have formed an international association for collaboration, coordination and exchange in various fields. The association has established a committee for specifying scientific health criteria to develop hygienic standards (10, 11).

The prepared documentation is shared by five Scandinavian countries and forms a basis for developing national hygienic standards. The criteria are prepared by scientists from all the Scandinavian countries. The scientists represent the following fields: toxicology, occupational medicine, epidemiology, pharmacology,

and veterinary medicine. The criteria are published under the heading of "Arbete och Halsa" in the scientific journal of the National Institute of Occupational Health (NIOH) in Sweden. Between 1978 and 1988, 78 documents were published. They appear in the Scandinavian languages and since 1987 also in English.

Representatives of the individual countries submit the list of priorities to the Nordic Group of Experts, which selects the chemicals for which the documentation is to be prepared. The selection criteria are as follows: application of the substance, number of workers exposed and substance toxicity.

After the documentation has been compiled, its first version is discussed by the Group of Experts and published, subject to ammendments. The documentation comprises data on dose-effect, dose-response relationships and data analysis. No hygienic standard value is suggested in the documentation. The documentation is forwarded to the representatives of individual Scandinavian countries, where it may be used to determine MAC values.

The determination of the hygienic standards in the particular countries is carried out as follows:

Denmark

The Danish MAC value register has a legal status and is established by the National Labour Inspection. The register is corrected and supplemented every two years. The scientific principles for the hygienic standard values are discussed by a special working group including scientific workers, employers, employees, and people representing the technical and economic points of view. The working group discusses the documentation prepared by the Nordic Group of Experts, and the ACGIH documentation. While determining the MAC values, other publications containing data pertinent to the hygienic standards are also taken into consideration.

Finland

In 1981, the Finnish National Board of Labour Protection published a list of MAC values. This list included substances of adverse toxic effect which may be present in the working environment. The list had no legal status and served only as a recommendation. In 1987, a new MAC value list was published. To that purpose, an Expert Group was established which comprised reprentatives of the Finnish National Board of Labour Protection and of the Institute of Occupational Health. To determine a hygienic standard values, the Group uses the documentation of the Nordic Group of Experts as well as reports prepared by the Swedish Criteria Group (15).

Iceland

In 1978, the Icelandic Administration of Occupational Safety and Health published recommended MAC lists. Those lists were translations of the Danish list. At present, the Danish list is published every year, and the documentation of the Nordic Group of Experts and the available Swedish and U.S. documentation is also taken ino account during determination of MAC values.

Norway

Since 1974, the Norwegian Institute of Occupational Health has been preparing the list of MAC values which is basically translated from the list of MAC values prepared by American hygienists (ACGIH). Since 1978, The National Board of Occupational Safety and Health has published a list of MAC values which is, to some extent, based on the Danish MAC list. The values in these lists are regarded as recommended only and have no legal status.

While developing the MAC values health criteria have been considered. Besides, an analysis is made of the Nordic Group of Experts documentation, the U.S. (ACGIH and NIOSH) documentation, as well as the documentation by the Swedish Expert Group.

Sweden

The first recommended list of hygienic standards was published by the Institute of Occupational Medicine in 1967. Since 1974, the National Board of Occupational Safety and Health (NBOSH) has been establishing MAC value lists, which since 1981 have had a legal status. NBOSH has been publishing the updated MAC lists every three years. The most recent list was published in 1990. During the '70s, there was no formal procedure for determining the scientific principles of setting MAC values. Since 1978, MAC value determination has been structured as a multi-stage process (2).

The first stage includes a critical evaluation of the toxicological and medical literature data as well as a discussion of their significance in setting MAC values for specific chemical compounds. This task has been performed by the Criteria Group. The Group includes experts in toxicology, chemistry, hygiene and occupational health from the National Institute of Occupational Health and from the medical universities, as well as expert representatives of employers and employees. The expert group prepares a report discussing the dose-effect and dose-response relationships as well as the fatal effect. The group does not specify the value of the standard. Those reports are published (in Swedish and English) under the heading of "Arbete och Halsa" in the NBOSH scientific magazine. Until 1988, the Expert Group published 140 reports on various chemicals (20).

The next stage involves transferring the report to the Working Group dealing with legal regulations. The Group includes representatives of NBOSH, as well as of employers and employees. When determining the MAC values, the Working Group takes into account also the costs, advantages, technological feasibility and performs an analysis of the consequences of modifying the MAC value, or of introducing a new MAC. These data are not published, although they are officially available.

The presented MAC proposal is then discussed by various interested institutions and organizations. After the discussions, the value of the standard is determined by the Laymen Board of NBOSH. The MAC value register is legally binding in Sweden, and presently comprises 252 toxic substances (26).

Hungary

The first MAC list was issued in 1954 and it included MAC values for 64 chemical compounds.

In 1955 the Minister of Health issued a regulation (General Measures for Prevention of Accidents and Health Protection). This document comprised information on MAC values for gases, vapours and dusts in the working environment air. In 1965 the Hungarian register included 104 substances. Since 1973 the Hungarian MAC lists have been regularly published.

The hygienic standards in Hungary are being worked out by a group of experts from the National Institute of Occupational Health (NIOH). During the years 1950–1960 the Hungarian MAC values were adopted from the Soviet and the American lists, whereas since 1973 the experts' group has started to prepare MAC documentations based on literature data. In addition, the MAC values adopted in some other countries and results of experiments of the Hungarian researchers have also been taken into account. The MAC list is updated every five to ten years, according to the needs.

The Hungarian list of hygienic standards covers two MAC categories:

MC – maximum concentration i.e. a concentration of air pollutants which during an 8-hour work-day and 40-hour work-week exposure do not produce any adverse health effects in workers' health status as well as in their progeny.

CC – ceiling concentration (maximum concentration admissible for a short time only) i.e. maximum concentration of the air pollutants (usually higher than MC) the exposure to which should not last longer than 30 min. per one shift (24).

EEC

In 1980 the EEC Directive No 80/1107/EEC on the protection of workers from the risks related to exposure to chemical, physical and biological agents at work, was issued. In 1984 the EEC developed a programme of safety and health in the working environment, to harmonize all respective legal acts of particular member states.

The amendment No 88/642/EEC to the Directive 80/1107/EEC issued in 1988 comprises all definitions pertaining to the protection of workers from adverse effect of chemical, physical and biological agents, also in this, is the MAC definition.

According to this definition MAC (OEL) is a mean weighted concentration during eight hour shift, at workposts where exposure to gases, vapours or suspended forms occurs. OEL is defined as a "limit value", whereas exposure is understood as presence of chemical agents in the workers' breathing zone.

In 1991 a new Directive No 91/322/EEC was issued (as a supplement to Directive No 80/1107/EEC) to establish indicative limit values. In this directive, the EEC OELs for chemical substances whose values are close to those in MAC lists of particular member countries, are presented. The list includes such substances for which there are sufficient scientific data on the health changes induced by occupational exposure to these substances.

The MAC list of the EEC comprises 27 substances. It is not legally binding but a recommendation only. Currently, MAC documentations for those substances are being prepared. These documentations will be prepared on the basis of the world literature data and published successively during the next three years (2, 4).

International Agency for research on Cancer

Among occupational health hazards, exposure to carcinogens is one of the crucial problems. Since 1971 the International Agency for Research on Cancer (IARC) has initiated a project aimed at developing monographs on the risk created by contact with carcinogens (12). Hitherto, 53 monographs for various compounds and agents causing neoplastic diseases have appeared.

The Agency is also involved in developing criteria for evaluating carcinogenic effects and classification of carcinogens.

The Working Group of IARC has adopted the following criteria for the evaluations of the strength of the evidence for carcinogenicity to humans and experimental animals (13):

Sufficient evidence of carcinogenicity. There is a causal relationship between exposure to the agent and human cancer that has been found in studies in which – at a determined confidence level – chance, bias and confounding factors could be excluded.

Limited evidence of carcinogenicity. The causal relationship between exposure to the agent and human cancer is credible, however, chance, bias or confounding factors could not be excluded at a determined confidence level.

Inadequate evidence of carcinogenicity. The quality, consistency and power of statistical evidence in the available studies are insufficient to conclude that there is or is not a causal relationship between exposure to the agent and human cancer.

Evidence suggesting lack of carcinogenicity. There are available some appropriate studies covering the full range of doses to which, as it is known, humans may be exposed. The results of these studies show that no case of cancer has been observed at any exposure level.

Evidence For Carcinogenicity To Animals

Sufficient evidence of carcinogenicity. A causal relationship has been found between exposure to the agent and increased incidence of malignant neoplasms or of benign and malignant neoplasms together; (a) in two or more animal species (b) in two or more independent studies carried out at different times, or in different laboratories, or using different methods.

"Exceptionally, a single study in one species may be considered to provide sufficient evidence of carcinogenicity if malignant neoplasms occur to an unusual degree with regard to incidence, site type and age at onset" (13).

In the case of a lack of relevant data on humans, it is a biologically justified precaution to consider the agents, for which there is a sufficient evidence of carcinogenicity in experimental animals, as ones creating similar carcinogenic risk in humans.

Limited evidence of carcinogenicity. The data suggest a carcinogenic effect but their strength as evidence for evaluation is limited because: (a) they are based on the results of a single experiment; (b) there are some hitherto unsolved questions of the appropriate design, conducting and interpretation of the study; (c) the factor increases the incidence of benign neoplasms only which may occur spontaneously, at a high incidence rate, in some strains prone to developing them.

Inadequate evidence of carcinogenicity. The studies cannot be interpreted as showing the presence or the absence of carcinogenic effects due to essential qualitative and quantitative limitations.

Evidence suggesting lack of carcinogenicity. There are available results of studies, carried out at least in two animal species, showing (within the range of the tests applied) that the agent is not carcinogenic. The evidence suggesting lack of carcinogenicity refers to the determined animal species, neoplasm sites and dose studied only.

Overall Evaluation of Carcinogenic Effect in humans

Based on the criteria of evaluation of evidence of carcinogenicity, the Working Group of the International Agency for Research on Cancer has adopted the following categories of human carcinogens (13):

Group 1 – The agent is carcinogenic to humans.

This group includes only those factors for which sufficient evidence of carcinogenic effect in humans exists.

Group 2A – The agent is probably carcinogenic.

The group covers the factors for which limited evidence of carcinogenicity in humans and sufficient evidence of carcinogenicity in experimental animals exist. Exceptionally, some other agents have also been included solely on the basis of limited evidence of carcinogenicity in humans or of sufficient evidence of carcinogenicity in experimental animals if some other data supporting the evidence were available.

Group 2B – The agent is possibly carcinogenic to humans.

This group includes the agents for which there is limited evidence of carcinogenic effect in humans although there is no sufficient evidence of carcinogenicity in experimental animals. Some other agents for which there is inadequate evidence of carcinogenic effect in humans or there are no human data available but there is sufficient evidence of carcinogenicity in experimental animals, are also included into this group. Exceptionally, there are also the agents for which there is inadequate evidence or no human data, however, there is limited evidence of carcinogenicity in experimental animals supported by some other relevant data.

Group 3 – The agents is not classifiable as to carcinogenicity to humans.

This group includes the agents that cannot be classified into any other group.

Group 4 – The agent is probably not carcinogenic to humans.

This group comprises the agents for which there is evidence suggesting lack of carcinogenicity in humans, together with the evidence suggesting lack of carcinogenicity in experimental animals. In some exceptional cases, the agents for which there is inadequate evidence of carcinogenic effect in humans or no human data available but there is evidence suggesting lack of carcinogenicity in experimental animals strongly supported by some other relevant data, may also be classified into this group.

So far, the lists of carcinogens published by IARC have comprised 709 factors divided into the four groups discussed earlier.

Some countries developing MAC lists attach to them the lists of carcinogens. Below, the system of establishing and classification of harmful agents in various countries, is presented.

The United States

The American Conference of Governmental Industrial Hygienists (ACGIH) in the yearly publication Threshold Limit Values and Biological Exposure Indices, includes also the classification of carcinogenic agents. ACGIH divides the carcinogens into five categories: A1 – confirmed human carcinogen, A2 – suspected human carcinogen, A3 – animal carcinogen, A4 – not classifiable as a human carcinogen, A5 – not suspected as a human carcinogen (31).

The ACGIH experts consider that exposure to carcinogenic agents should be as low as possible. The workers exposed to the agents from the A1 group, for which there is no TLV determined, should perform the work only after elimination of the possibility of exposure to those agents.

Work associated with exposure to agents from groups A1, A2 and A3 for which there are TLVs may be performed under a strictly controlled working environment.

NIOSH in its publication "Pocket Guide to Chemical Hazards" marks on the MAC lists all substances considered by NIOSH to be potentially Carcinogenic in humans with the symbol "Ca". NIOSH has not determined exposure limits for carcinogenic compounds, which could ensure safety for the population exposed but it recommends using the best available protective respirators to ensure maximum protection from the exposure to these substances (25).

In 1974 the Occupational Safety and Health Administration (OSHA) published, without determining MAC values, a list comprising 13 chemical compounds identified as occupational carcinogens. Exposure of workers to these compounds should be systematically controlled and the workers should be equipped with personal respirators (after 29 CFR 1910. 1003–1910. 1016) (25).

Germany

The Commission for the Investigation of Health Hazards of Chemical Compounds in the Work Area of the German Scientific Society (DFG, 1990) distinguished two categories of agents of different strength of evidence for carcinogencity (23).

Group A – substances, which have been unequivocally proved to be carcinogenic.

Group A1 – substances which may contribute to the development of malignant tumours as shown by observations in human populations.

Group A2 – substances for which there is evidence obtained in experiments on animals that they are undoubtfully carcinogenic under conditions comparable to the exposure of humans on the workposts.

Group B – substances, which for some plausible reasons may be considered as suspected of carcinogenic effect.

For the substances numbered among group A there are no admissible concentration values determined chiefly because it is not possible to determine safe concentraton. However, if their usage cannot be avoided, special control and measurements are required. The protective measures include: (1) routine measurements of the concentration of the substances in the workroom air by means of the relevantly sensitive analytical methods; (2) specialist medical examinations of

persons exposed with the use of tests allowing to detect the substance or its metabolites in the human body. There are also recommended some other protective measures such as personal protectors of respiratory tract and the body surface, shortening the time of work in the dangerous zone etc. to limit the exposures to the minimum attainable level.

The substances included in group B do not require such strict observation of protective and preventive procedures in the working environment, as those from group A. However, in the case of occupational exposure to the substances from group B it is recommended to carry on systematic control of health status of persons exposed and to maintain the possibly lowest exposure level. The substances from this group should be subject to repeated evaluation of their strongest biomedical evidence for carcinogenicity and according to the study results, they may be reassigned to group A or excluded from the list of carcinogens.

In the Scandinavian countries, the first classification of occupational carcinogens was established in 1974. In particular Scandinavian countries, the lists of carcinogenic compounds are an annex to the national MAC lists (11).

Denmark

The list of carcinogenic compounds in this country includes 180 substances and is established by the National Board of Environment and by the National Labour Inspection Services. The criteria for listing are based on IARC criteria. The carcinogens have been divided into two groups A1 and A2, i.e. those for which there is sufficient evidence of carcinogenicity in humans and sufficient evidence of carcinogenicity in animals, respectively.

Finland

The Finnish list of carcinogenic compounds consists of 172 substances divided into three groups. Group 1 includes substances used in scientific research after obtaining permission from the Labour Inspectorate. This group comprises 15 substances. Group 2 covers substances of limited use and their handling is determined by the Labour Inspectorate and it consists of seven substances. The third group comprises 150 substances for which there are special regulations concerning their handling.

Sweden

The Swedish list of carcinogens covers 85 substances. The list is based on biomedical criteria such as epidemiological studies and long-term animal experiments (OEL-s, Sweden 1990).

The carcinogenic compounds in the Swedish list are divided into three groups: A – prohibited compunds; B – chemical compounds that can be used after obtaining a permission of the Labour Inspectorate; C – chemical compounds for which there are the same legal regulations as those for MACs in the case of some other toxic substances.

Poland

Polish list of carcinogenic agents specific jobs prohibited for adolescents. It consists of 59 substances, preparations and industrial processes. The carcinogens are divided into two groups: group 1 – chemical carcinogens (29 agents), group 2 – substances, preparations and industrial processes of probable potential carcinogenic effect (30 agents). The list is based on IARC classification criteria (28).

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