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The Development of Occupational Exposure Limits for Chemical Substances in China

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This paper presents a comprehensive review of the occupational exposure limits (OELs) of chemical substances in China. It provides historical background on the development of OELs in this country, with a complete list of traditionally adopted and newly developed OELs for chemicals in workplaces. The philosophical thoughts, the administrative system, the scientific protocols for setting and amending health standards, with emphasis on making health a basic criterion for setting health standards, strengthening epidemiological studies of the human population, integrating epidemiological and toxicological studies, considering technological and economical feasibilities, and making full use of literature information sources are discussed. Further perspectives with respect to practical issues of maximum allowable concentration and time-weighted average, selection of safety factors, and establishment of biological exposure limits are also considered, with the authors' contributions to a discussion on these topics. © 1995 Academic Press, Inc.

INTRODUCTION

In China, the central government began to promulgate documents concerning the adoption and implementation of occupational exposure limits (OELs) for chemical substances, dusts, and physical agents in the workplace in the mid-1950s. Among the series of relevant documents issued since then, the documentation *Health Standards for the Design of Industrial Premises (Standard TJ 36-79)* is regarded as the backbone for setting occupational health standards. It was jointly promulgated by the Ministry of Health, the State Capital Construction Commission, the State Planning Commission, the State Economic Commission, and the Ministry of Labour, the People's Republic of China in 1979 (Ministry of Health, 1979). The document contains a list of maximum allowable concentrations (MACs) for 120 toxic chemical agents and dusts in the air at workplaces (Table 1). In addition, the *Health Standard of Noise for Industrial Premises* (interim) (1980) was announced by the Ministry of Health and the Ministry of Labour; the official documents concerning OELs for other physical agents were issued by relevant industries as well (Division of Health Standards Setting, Chinese Academy of Preventive Medicine, 1992).

In 1981, the Ministry of Health set up a National Technological Committee of Health Standards Setting (NTC-HSS). Under this, the Subcommittee of Occupational Health Standards is responsible for seeking the advice of experts in setting or amending occupational health standards. As a result, a more sophisticated system of scientific research on setting health standards was developed. The new system emphasizes the principles of making health a basic criterion, strengthening epidemiological studies on human populations, making full use of information sources and integrating them with the data studied, investigating economical and technological feasibilities, and amending recommended standards based on the new evidence raising questions about the safety and feasibility of the standard (Liang and Gu, 1991).

The OELs set under the system are officially promulgated by the government as legislative requirements for the work environment and are notated with "GB," the initials of the phonetic alphabet meaning "National Standards" in Chinese, and intended for use in the practice of industrial hygiene for the control of relevant occupational hazards and the prevention of occupational diseases. In most cases, OELs are effectively implemented toward improvement in working conditions. However, further enforcement of these health standards remains to be intensified in certain circumstances, particularly for small-scale industries in rural areas, which has become a greater challenge since the early 1980s (Liang *et al.,* 1994).

PROTOCOL FOR SETTING HEALTH STANDARDS

The protocol for setting health standards under the system is structured in a multistep manner. Taking

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TABLE 1

Maximum Allowable Concentration for Chemical Substances in the Air of Workplaces (Standard TJ 36-79)

Substance	Adopted MAC (mg/m^3)
1.1 Toxic chemicals	
Acetone	400
Acetonitrile	3
Acrolein	0.3
Acrylonitrile (skin)	2
Ammonia	30
Amyl acetate	100
Amyl alcohol	100
Aniline, methylaniline, and dimethylaniline (skin)	5
Arsenic trioxide and pentoxide	0.3
Arsine	0.3
Benzene (skin)	40
Beryllium and compounds	0.001
Bromomethane (skin)	1
Butyl acetate	300
Butyl alcohol	200
Butyl aldehyde	10
Butylene	100
Cadmium oxide	0.1
Carbon disulfide (skin)	10
Carbon monoxide[a]	30
Caprolactam	10
Carbon tetrachloride (skin)	25
Caustic alkali (as NaOH)	0.5
Chlorine	1
Chlorobenzene	50
Chloroethylene (vinyl chloride)	30
Chloronaphthalene and chlorodiphenyl (skin)	1
Chloropicrin	1
Chloroprene (skin)	2
Chromium trioxide, chromate, and dichromate (as CrO$_3$)	0.05
Cyclohexane	100
Cyclohexanol	50
Cyclohexanone	50
Dinitro- and trinitrobenzene and homologs (dinitrobenzene, trinitrotoluene, etc.) (skin)	1
Decalin (decahydronaphthalene) and tetralin (tetrahydronaphthalene)	100
Dichlorodiphenyltrichloroethane (DDT)	0.3
1,2-Dichloroethane	25
1,3-Dichloropropanol (skin)	5
Dichlorovos (DDVP) (skin)	0.3
Dimethoate (Rogor) (skin)	1
Dimethylamine	10
Dimethyl dichlorosilane	2
Dimethyl formamide (DMF) (skin)	10
Diphenyl diphenyl ether	7
Divinyl (biethylene)	100
Epichlorohydrin (skin)	1
Ethyl acetate	300
Ethylene oxide	5
Ethyl ether	500
Formaldehyde	3
Furfural (furfuraldehyde)	10
Hexachlorocyclohexane	0.1
r-Hexachlorocyclohexane	0.05
Hydrogen chloride and hydrochloric acid	15
Hydrogen cyanide and cyanates (as HCN) (skin)	0.3
Hydrogen fluoride and fluorides (as F)	1
Hydrogen sulfide	10
Iodomethane (skin)	1
Lead	
Lead (dust)	0.05
Lead (fumes)	0.03
Lead sulfide	0.5
1.1 Toxic chemicals (Continued)	
Malathion (skin)	2
Manganese and compounds (as MnO$_2$)	0.2
Mercuric chloride	0.1
Mercury, elemental vapor	0.01
Mercury, organic compounds (skin)	0.005
Metasystox (skin)	0.2
Methyl acetate	100
Methyl alcohol	50
Methyl parathion (skin)	0.1
Monomethylamine	5
Mononitrobenzene and homologs (nitrobenzene, nitrotoluene, etc.) (skin)	5
Molybdenum, insoluble compounds	6
Molybdenum, soluble compounds	4
Nickel carbonyl	0.001
Nitrochloro- and dinitrochlorobenzene compounds (nitrochlorobenzene, dinitrochlorobenzene, etc.) (skin)	1
Nitrogen oxide (as NO$_2$)	5
Ozone	0.3
Parathion (skin)	0.05
Pentachlorophenol and its sodium salts	0.3
Phenol (skin)	5
Phosgene	0.5
Phosphine	0.3
Phosphorus pentoxide	1
Propenol (skin)	2
Propyl acetate	300
Propyl alcohol	200
Pyridine	4
Selenium dioxide	0.1
Solvent gasolines	350
Styrene	40
Sulfuric acid and sulfur trioxide	2
Sulfur dioxide	15
Systox (Demeton) (skin)	0.02
Tetraethyl lead (skin)	0.005
Thimet (skin)	0.01
Toluene	100
Toluene-2,4-diisocyanate (TDI)	0.2
Trichlorfon (Dipterex) (skin)	1
Trichloroethylene	30
Trichlorosilane	3
Triethyltin chloride (skin)	0.01
Tungsten and tungsten carbide	6
Turpentine	300
Vanadium and compounds	
Vanadium–ferroalloy	1
Vanadium pentoxide (dust)	0.5
Vanadium pentoxide (fumes)	0.1
Xylene	100
Yellow phosphorus	0.03
Zinc oxide	5
Zirconium and compounds	5
1.2 Dust (total dust)	
Aluminum, aluminum oxide, and aluminum allow dusts	4
Asbestos or asbestos-containing dust (asbestos >10%)	2
Cement dust (SiO$_2$ <10%)	6
Coal dust (SiO$_2$ <10%)	10
Glass fiber and slag fiber dusts	5
Dust containing more than 10% SiO$_2$ (quartz, quartzite, etc.)	2
Other dusts[b]	10
Talc dust (SiO$_2$ <10%)	4
Tobacco dust and tea dust	3

[a] The exposure limits for carbon monoxide are allowed to be contingent on working hours, viz., within a working period of 1 hr, the exposure limit of CO is allowed to reach 50 mg/m^3; within half an hour, 100 mg/m^3; 15–20 minutes, 200 mg/m^3. The interval between exposures should not be less than 2 hr.

[b] Other dusts refer to mineral or vegetable dusts containing less than 10% free silica and nontoxicants.

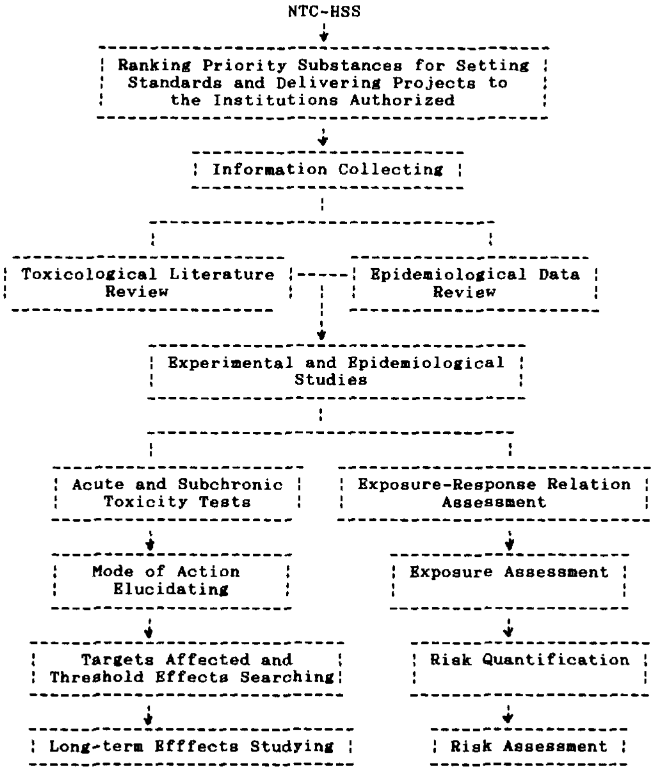

FIG. 1. First step in setting OELs.

examples from setting OEL for chemical agents, the two major steps of the procedure somewhat follow the "Two-Step Policy" recommended by WHO (1980). As schematically represented in Fig. 1, the first step focuses on searching for a health-based exposure limit by means of information collection, toxicological and epidemiological studies, and exploration of risk assessments. The second step mainly investigates the technological and economical feasibilities of enforcing the standards through a field survey of the present status, negotiation with professionals and administrators of the industries concerned, and other forms of communication (Fig. 2). A tentative recommendation for occupational exposure limits, expressed as the maximum allowable concentration, is then recommended to the NTC-HSS to be reviewed and discussed at the annual meeting of the Subcommittee, at which aspects regarding both health-based and socioeconomic and technological considerations are taken into account. The accepted recommendations will be approved and finally promulgated by the Ministry of Health and the State Standards Bureau as the national operational occupational exposure limits (Gang and Liang, 1993).

This procedure explicitly permits full input from health workers and administrative professionals. Based on this protocol, 100 new or revised MACs have been set for chemical substances, including dusts, since the founding of the NTC-HSS and have been or are being promulgated as an integral part of the MACs list of Standard TJ 36-79 (Table 2).

PHILOSOPHY OF HEALTH-BASED RECOMMENDATION AND ITS FEASIBILITY

In China, the occupational exposure limits for chemical substances are expressed as maximum allowable concentrations, which are defined as the airborne concentrations of chemical substances in the workplace air to which it is believed that all workers may be repeatedly exposed without observed adverse health effects. Herein, the MAC values refer to a ceiling level of chemical substances that should not be exceeded at any representative sampling. Therefore, health-based considerations have primarily predominated the first stage of the process of setting health standards. However, the level of MACs depends highly upon the definition of "health" that was chosen as the basic criterion. As stated by WHO, "Health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity" (1978). In this sense, the health standard is oriented toward playing an important role in the preservation and promotion of health and not merely the prevention of disease or death.

Accordingly, we have devoted our efforts to making the basic approach to setting health standard be the protection of workers from detected adverse effects rather than the definition of suffering from a definite organic damage. To set a safer level of OELs, more sensitive and specific indicators, which may reflect early and reversible effects, are preferably chosen as the basic evidence of adverse effects. Examples are changes in cholinesterase activity for organophosphate exposure, sensory irritations for irritants, and neurobehavioral alterations for neurotoxic substances (Zhuang *et al.*, 1993).

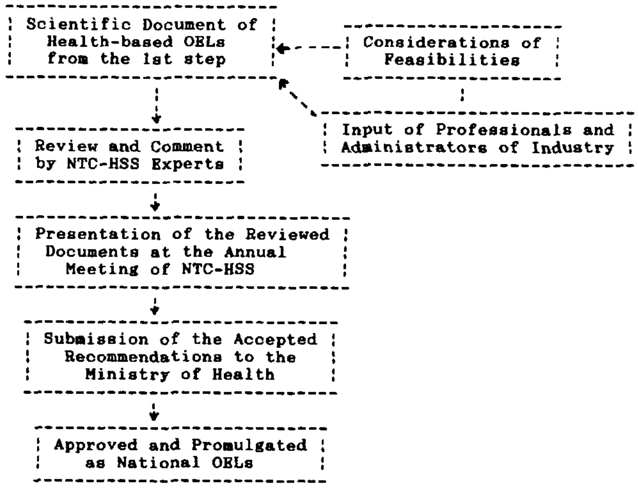

FIG. 2. Second step in setting OELs.

TABLE 2
Newly Developed/Revised MACs after Standard TJ 36-79

Substances	Adopted MAC (mg/m^3)
2.1 Toxic chemicals	
Acetic acid	20
Acrylamide (skin)	0.3
Acrylic acid (skin)	6
Allyl chloride	2
Antimony and compounds	1
Beauveria spores	3
Cadmium dust (as Cd)[a]	0.05
Carbon dioxide	18,000
Carbon disulfide[a]	5
Chloroform	20
Chloromethane	40
Chloroprene (skin)[a]	
Producing	6
Processing	1
Chlorothalonile	0.4
Cobalt and oxides (as Co)	0.1
Cortisone	3
Copper (as Cu)	
Dust	1
Fumes	0.2
Cresol, all isomers (skin)	10
Cyctonite (RDX) (skin)	3
Deltamethrin	0.03
Dibutyltin dilaurate (skin)	0.2
Dibutyl phthalate	2.5
Dichloromethane	200
1,2-Dichloroethane[a]	15
m-Dihydroxybenzene (Resorcinol)	10
Dimethyl acetamide (skin)	10
Dimethyl sulfate (skin)	0.5
Ethylamine	18
Ethyl benzene	50
Ethylene chlorohydrin (skin)	2
Ethylene diamine	4
1,2-Ethylene dichloride	15
Ethylene glycol	10
Ethylene oxide	2
Ethylene tetrachloride	200
Fenvalerate	2
Furan	30
Glycidyle methacrylate	5
Hydrazine	0.13
Hydrazoic acid	0.2
Hydrazoic sodium azide	0.3
Hydrogene fluoride and fluorides (as F)[a]	0.5
Isophorone diisocyanate	0.1
Isopropyl alcohol	750
p-Kitazin (skin)	1
Liquified petroleum gas	1000
Lithium hydride	0.05
Magnesium oxide (fumes)	10
Mercury, elemental vapor[a]	0.02
Methyl acrylate (skin)	20
Methyl methacrylate	30
Monochloromethane	40
Monocrotophos (skin)	0.05
Monomethyl hydrazine (skin)	0.08
Naphthalene	50
Nickel and compounds (as Ni)	
Metal and insoluble compounds	1
Soluble compounds	0.5
p-Nitroaniline (skin)	3
Nitroglycerine	1
Omethoate (skin)	0.3
Oxalic acid	2
Phosphamidon (skin)	0.02
2.1 Toxic chemicals (Continued)	
Phosphorus trichloride	0.5
Phthalic anhydride	1
Raffinate (50–220°C)	300
Selenium	0.2
Sodium azide	0.3
Solvent gasolines[a]	300
Sulfur hexafluoride	6000
Sulfuryl fluoride	20
Sumithion (skin)	1
Tetrahydrofuran	300
Tetrachloroethylene	200
Thallium (skin)	0.01
Tin dioxide (as Sn)	2
Trichlorfon (Dipterex) (skin)[a]	0.5
Triocresyl phosphate (skin)	0.3
Trifluoromethylhypofluoride	0.2
Tungsten (as W)	6
Unsymmetric dimethylhydrazine (skin)	0.5
Vanadium and compounds (as V)[a]	
Metal, vanadium–ferroalloy and carbides	1
Vanadium pentoxide (dust)	0.1
Vanadium pentoxide (fumes)	0.02
Zinc chloride (fumes)	2
2.2 Dusts (total dust)	
Aluminum (dust)	
Metal	4
Oxides	6
Alloys	4
Asbestos	1.5 f/cc
Carbon black	8
Cement dust, respirable	2
Charcoal carbon	10
Coal dust, respirable	3.5
Cotton dust ($SiO_2 < 10\%$)	3
Diatomite	2
Dolomite	10
Fur ($SiO_2 < 10\%$)	10
Grain dust	8
Graphite ($SiO_2 < 10\%$)	6
Grinding wheel dust ($SiO_2 < 10\%$)	10
Gypsum dust	10
Hemp fiber ($SiO_2 < 10\%$)	
Flax dust	3
Jute dust	4
Ramie dust	6
Limestone	10
Marble dust	6
Mica ($SiO_2 < 10\%$)	4
Mixed dust from fluorspar ($SiO_2 > 20\%$)	2
Molybdenum (mixed dust)	2
Natural silk dust ($SiO_2 < 10\%$	10
Perlite ($SiO_2 < 10\%$)	10
Polyethylene dust	10
Polypropylene dust	10
Pyrophyllite ($SiO_2 < 80\%$)	2
Rare-earth dusts ($SiO_2 < 10\%$)	5
Silica fused	3
Silicon carbide ($SiO_2 < 10\%$)	10
Silicon dioxide (SiO_2, 50–80%)	1.5
Silicon dioxide ($SiO_2 > 80\%$)	1
Titanium dioxide	10
Vermiculite ($SiO_2 < 10\%$)	5
Welding dust and fume	6
Wood dust ($SiO_2 < 10\%$)	8

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[a] Denotes recently revised MAC.

Therefore, it is not surprising that most of OEL values in terms of MACs adopted in China are much lower than those of TLVs, expressed in TLV–TWAs, even in STELs or ceilings, recommended by the ACGIH. Comparisons of 71 identical chemicals with 74 paired values of MACs and TLV–TWAs and 28 paired MACs and STELs/ceilings revealed that 50 of 74 MACs were lower than TLV–TWAs, accounting for 67.5% (ratios ranged from 1/120 to 1/1.2); 18 were higher than TLV–TWAs, accounting for 24.3%; and only 6 MACs (8.2%) appeared to be exactly the same as the two. With respect to "momentary peak values," 78.5% (22/28) of MACs were even lower than the recommended STELs/ceilings, and only 21.5% (6/28) of MACs had relatively higher values (Table 3) (Ministry of Health, 1979; ACGIH, 1994–1995). The conflict between safety and feasibility is, thus, encountered during enforcement of some of the OELs.

Realistically, questions regarding "How safe is safe" and "How safe can we afford" should always be kept in mind when effectively translating health-based permissible levels into operational exposure limits, which are accepted as economically and technologically feasible measures for protecting workers' health.

EPIDEMIOLOGICAL STUDY

For many reasons, field and epidemiological studies merit full emphasis in health standard setting. First, for most chemicals for which we are now intending to set OELs, the scientific information, in particular, voluminous toxicological data, is already available in publications from industrialized countries or in WHO documents on health-based exposure limits. For these chemicals, therefore, our major task is to observe the health effects on exposed Chinese workers through routine environmental monitoring and health surveillance rather than to duplicate all of these toxicological data by laborious animal experimentation. Second, the uncertainties that exist between the susceptibilities of animals and humans make it difficult to extrapolate animal data directly to the human population. The emphasis on epidemiological studies and the integration of toxicological and epidemiological data seem to be an effective way to narrow the gap between animal and human studies.

An excellent example of this is provided by one of our recent studies. MATDA [*N′*,*N″*-methylene-bis-(2-amino-1,3,4-thiodiazole] has been widely used as pesticide for more than a decade. It was synthesized in the 1970s in this country as a bactericide for controlling *Xanthomonus oryzae* on rice. Unfortunately, MATDA proved to be highly teratogenic in rodents. The TD_{50}s for MATDA in rats and mice were 3.8 (2.53–6.68) and 26.9 (20.0–35.9) mg/kg body wt, respectively (Li *et al.*, 1986).

To compare the differences between animals and humans, an epidemiological study of pregnant women within the period from January 1, 1979 through December 31, 1981 in two counties that had used the pesticide and in two other counties where the pesticide had never been used was conducted. Surprisingly, the results showed no evidence of birth defects attributable to the use of the pesticide. Furthermore, no teratogenic effects were observed in rats and mice fed rice harvested from the MATDA-treated fields.

These findings may, at least, lead to the following two assumptions: (1) There are species differences in the teratogenic effects of MATDA; and (2) the residue of the pesticide in rice was far below the threshold dose for teratogenic effects. It is estimated that the ratio of human exposure level to the threshold for inducing teratogenic effects ranged from 1/3600 to 1/4400, and the ratio to the no-observed-effect level ranged from 1/1200 to 1/1400 (Gu *et al.*, 1988). The study has truly shed light on the need to minimize the discrepancy between animal and human data in setting health standards.

INITIATIVE APPROACH TO AMENDING STANDARDS

Ideally, requests for amending a documented standard should be initiated by either grass-root health units or industries if a strong suspicion of the appropriateness of the documented level occurs. For example, 10 mg/m^3 (3 ppm) has been the MAC of carbon disulfide (CS_2) for decades in China. However, a retrospective cohort study of 265 exposed and 291 nonexposed female workers in five viscose rayon factories in Shanghai showed that female workers exposed to CS_2 at a level around 10 mg/m^3 for mostly less than 10 years had a higher risk of menstrual disturbance than those in the nonexposed group (35.9% vs 18.2%, $R^2 = 2.0, P < 0.01$). The total incidence rate of the menstrual disturbance as well as some of the specific symptoms of the disturbance exhibited a close exposure–response relationship (Zhou *et al.*, 1988).

Given the existence of such an association between menstrual disorders and exposure, it is worth reconsidering the safe level of CS_2 exposure, in particular, for female workers of reproductive age. Based on the results from the above study and similar findings of other studies, we have recommended lowering the current MAC of CS_2 from 10 to 5 mg/m^3 for both male and female workers. This recommendation has been accepted by the NTC-HSS. A WHO Expert Group concluded that there is reason to recommend a tentative health-based exposure limit of CS_2 at a lower level of 3 mg/m^3 (8 hr TWA) (WHO, 1981).

In contrast, overestimation of the risk related to the exposure may mislead, causing an increased constraint hindering the enforcement of standards. This must also be a strong point in initiating an amendment. A good example is the proposal for elevating the current MAC

TABLE 3

Comparison of MACs and TLVs from 71 Chemicals

	MAC adopted in China (mg/m^3)	TLV recommended by ACGIH (mg/m^3)		Ratio	
Substance	Ceiling (1)	8 hr TWA (2)	STEL/ceiling (3)	2/1	3/1
Acetone	400	1780	2380	4.5	6.0
Acetonitrile	3	67	101	22.3	33.7
Acrolein	0.3	0.23	0.69	0.8	2.3
Acrylonitrile	2	4.3	—	2.2	—
Ammonia	30	17	24	0.6	0.8
Amyl acetate	100	532	—	5.3	—
Aniline	5	7.6	—	1.5	—
Arsine	0.3	0.16	—	0.5	—
Benzene	40	32	—	0.8	—
Beryllium and compounds	0.001	0.002	—	2.0	—
Butyl acetate	300	713	950	2.4	3.2
Butyl alcohol	200	152	—	0.8	—
Cadmium oxide	0.1	0.01	—	0.1	—
Carbon disulfide	10	31	—	3.1	—
Carbon monoxide	30	29	—	1.0	—
Carbon tetrachloride	25	31	63	1.2	2.5
Chlorine	1	1.5	2.9	1.5	2.9
Chlorobenzene	50	46	—	0.9	—
Chlorodiphenyl	1	1	—	1.0	—
Chloropicrin	1	0.67	—	0.7	—
Chromium(VI) compounds	0.05	0.5	—	10	—
Cyclohexane	100	1030	—	10.3	—
Cyclohexanone	50	100	—	2.0	—
DDT	0.3	1	—	3.3	—
Demeton (Systox)	0.02	0.11	—	5.5	—
1,3-Dichloroethane	25	40	—	1.6	—
Dichlorvos	0.3	0.9	—	3.0	—
Dinitrobenzene	1	1	—	1.0	—
Ethyl acetate	300	1440	—	4.8	—
Ethyl ether	500	1210	1520	2.4	3.0
Formaldehyde	3	—	C 0.37	—	0.1
Furfural	10	7.9	—	0.8	—
Hydrogen cyanide	0.3	—	C 11	—	36.7
Hydrogen fluoride	1	—	C 2.6	—	2.6
Hydrogen sulfide	10	14	21	1.4	2.1
Lead		0.15			
Dust	0.05		—	3.0	—
Fumes	0.03		—	5.0	—
Malathion	2	10	—	5.0	—
Manganese and compounds	0.2				
Dust		5	—	25	—
Fume		1	3	5	15
Mercury					
Inorganic vapor	0.01	0.025	—	2.5	—
Alkyl compounds	0.005	0.01	0.03	2.0	6
Methyl acetate	100	606	757	6.1	7.6
Methyl alcohol	50	262	328	5.2	6.6
Methyl bromide	1	19	—	19	—
Methyl iodide	1	12	—	12	—
Methyl parathion	0.1	0.2	—	2	—
Molybdenum					
Soluble compounds	4	5	—	1.3	—
Insoluble compounds	6	10	—	1.7	—
Nickel carbonyl	0.001	0.12	—	120	—
Nitrogen oxide	5	31	—	6.2	—
Nitrobenzene	5	5	—	1.0	—
Nitrotoluene	5	11	—	2.2	—

TABLE 3—*Continued*

Substance	MAC adopted in China (mg/m^3)	TLV recommended by ACGIH (mg/m^3)		Ratio	
	Ceiling (1)	8 hr TWA (2)	STEL/ceiling (3)	2/1	3/1
Ozone	0.3	—	C 0.2	—	0.7
Parathion	0.05	0.1	—	2	—
Pentachlorophenol	0.3	0.5	—	1.7	—
Phenol	5	19	—	3.8	—
Phosgene	0.5	0.4	—	0.8	—
Phosphine	0.3	0.42	—	1.4	—
Phosphorus (yellow)	0.03	0.1	—	3.3	—
Propyl acetate	300	835	1040	2.8	3.5
Selenium dioxide	0.1	0.2	—	2.0	—
Solvent gasolines	350	890	1480	2.5	4.2
Styrene	40	213	426	5.3	10.7
Sulfur dioxide	15	5.2	13	0.3	0.9
Tetraethyl lead	0.005	0.1	—	20	—
Toluene	100	188		1.9	
Toluene diisocyanate (TDI)	0.2	0.036	0.14	0.2	0.7
Trinitrotoluene (TNT)	1	0.5	—	0.5	—
Tungsten	6				
Insoluble compounds		5	10	0.8	1.7
Soluble compounds		1	3	0.2	0.5
Vanadium, as V_2O_5					
Dust	0.5	0.05	—	0.1	—
Fumes	0.1		—	0.5	—
Vinyl chloride	30	13	—	0.4	—
Xylene	100	434	651	4.3	6.5
Zinc oxide	5				
Dust		10	—	2.0	—
Fume		5	10	1.0	2.0
Zirconium and compounds	5	10	—	2.0	—

Note. C, ceiling limit.

of mercury. Based on previous studies, 0.01 mg/m^3 has been the MAC of elemental mercury vapor in China. However, a survey of the thermometer manufacturing industry, where mercury is believed to be the major chemical hazard in the work environment, showed that the current MAC of Hg seems to be too conservative and too strict to be enforced in most phases of the production process.

To clarify the true extent of mercury exposure and health effects, an extensive epidemiological study was carried out in thermometer manufacturing and other mercury-using industries. The results showed that the expected incident rate of chronic mercurialism at the mild stage is less than 2% among workers who had been exposed to mercury vapor, ranging from 0.02 to 0.03 mg/m^3, for more than 30 years. To weigh the pros and cons, a recommendation to elevate the current value of Hg MAC from 0.01 to 0.02 mg/m^3 was accepted by the NTC-HSS (Fu *et al.*, 1993).

At least six documented MACs have been revised in recent years according to the periodic verification and reappraisal of the documented standard (Table 4) (Hu *et al.*, 1986; Zhou *et al.*, 1988; Division of Health Standards Setting, Chinese Academy of Preventive Medicine, 1992; Fu *et al.*, 1993).

OCCUPATIONAL CARCINOGENS

In contrast to the widely accepted concept of a biological threshold for noncarcinogenic chemicals, its existence for chemical mutagens and carcinogens remains a matter of scientific debate. Currently, no documented exposure limits in China derived from a possible threshold of carcinogenic effects have been set. Proven carcinogens, such as benzene and vinyl chloride, on the existing MAC list are still treated as noncarcinogens rather than as carcinogens.

To meet the real need, several steps are being taken to find effective ways for setting socially acceptable levels of OELs for some proven carcinogens frequently encountered in production processes. For example, an epidemiological investigation of occupational cancer incidences in workers exposed to chloromethyl ether, asbestos, inorganic arsenic compounds, chromates, benzene, benzidine, vinyl chloride, and coke oven emissions was conducted by a nationwide expert collab-

TABLE 4
Revised Exposure Limits and Scientific Basis

Substance	MAC (mg/m^3) TJ 36-79	MAC (mg/m^3) Revised	Scientific basis
Being lowered			
Carbon disulfide	10	5	Menstrual disorders found in female workers at 10 mg/m^3
Trichlorfon (dipterex)	1	0.5	ChE inhibited in workers at 0.9–1.0 mg/m^3
1,2-Dichloroethane	25	15	Neurosis found in workers at 25 mg/m^3
Solvent gasolines	350	300	Neurosis and respiratory symptoms found in workers at 350 mg/m^3
Vanadium			
V_2O_5 dust	0.5	0.1	Adverse effects observed in workers at current MACs of dust and fumes
V_2O_5 fumes	0.1	0.02	
Being elevated			
Mercury, vapor	0.01	0.02	"Negligible/acceptable risk" at 0.02 mg/m^3

orative group. The number of exposed workers totalled 93,500 (988,572 person-years) and controls 63,000 (646,744 person-years). Statistical analysis showed that the standardized mortality rate (SMR) of lung cancer for workers exposed to chloromethyl ether was 1546, to asbestos in asbestos factories was 633, to asbestos in asbestos mines was 940, and to inorganic arsenic compounds was 660. These figures were all significantly higher than those of controls ($P < 0.01$). Workers engaged in the production of chromate also showed a higher SMR of lung cancer. In addition, the SMR of benzene-induced leukemia, the SIR (standardized incidence ratio) of bladder cancer in benzidine production workers, and the SRR (standardized relative risk) of lung cancer in workers exposed to coke oven emissions were also significantly higher than those of controls (Joint Group of Occupational Cancer Study, 1986).

Findings from the study seemed not only to show strong evidence of the association between cancer and occupational exposure to carcinogens in the workplaces but also to provide a sound scientific basis for conducting risk assessments of the exposures, which will eventually lead to setting virtually safe "occupational exposure levels" for these substances that probably cause cancer.

FURTHER CONSIDERATIONS

1. MAC and TWA. As mentioned above, the OELs in China are defined as maximum allowable concentrations, which refer to the ceiling values that should not be exceeded at any representative sampling. However, in most field surveys, environmental monitoring of toxic agents at the workplace is expressed as some kind of "mean" and its biased deviation rather than as the "momentary peak." This has created much controversy in evaluating the quality of the work environment as well as in describing the exposure–response relationship. The majority of the NTC-HSS members believe that data for MAC obtained from grab sampling do not precisely reflect the real exposure level of workers, while the time-weighted average, TWA, seems to be a more reliable and reasonal criterion for assessing exposure.

Therefore, action is being taken to develop a "bi-track system" for the OELs. For chemicals that are most likely to have cumulative and chronic effects, mainly TWA levels will be monitored. However, MAC values are intended to be the criteria for monitoring the acute-acting substances to which even a one time peak exposure may be hazardous. Both OELs in MAC and TWA might simultaneously be used for a substance that has both acute and chronic effects. To facilitate international exchange, the system is expected to be applied to OELs in the near future in China.

2. Selection of safety factors. The safety factor concept was originally suggested by Lehman and Fitzhugh and modified and adopted by WHO (Lehman and Fitzhugh, 1954; WHO, 1958). Commonly, a factor of 10 is intended to represent interindividual variation and a further factor of 10 to represent interspecies variation, resulting in a combined factor of 100, as a "margin of safety" between the maximum ineffective dose in animals and the permitted dose in humans, in particular, to estimate the acceptable daily intake (ADI) of food additives and pesticides residues for a large human population. Detailed descriptions of the selection of safety factors are available in the literature (Dourson and Stara, 1983; Lu, 1983, 1985, 1988). However, a similar safety factor is not normally applied in the workplace when setting OELs, perhaps mainly because (1) workers are relatively healthy even when occupationally exposed and (2) it is easier to monitor exposure, to medically examine workers' health, and to remove

TABLE 5
Examples of Safety Factors Selected

Substance	Indicators of threshold	SF	MAC
Triethyltin chloride	Edema of brain white matter found in animals chronically exposed to 0.5 mg/m^3	50	0.01
Acrylonitrile	Change of serum GPT in animals at 40 mg/m^3 for 3 months	20	2
Dibutyltin dilaurate	Neurosis and irritation of respiratory tract found in workers at 0.8 mg/m^3	4	0.2
Trichlorfon (dipterex)	ChE inhibited in workers at 0.9–1.0 mg/m^3	2	0.5

Note. SF, safety factor.

them from exposure when ill health occurs (Illing, 1991).

In our experience, the safety factor between the LOAEL (lowest-observed-effect level) and an OEL will generally be 5–20, which accounts for 90% of the safety factors introduced. As other authors have pointed out, the actual magnitude of a safety factor will depend on the type of the toxicity, the severity and reversibility of the toxic effects, the sample size studied, the source of data available, the nature of the indicator denoting the biological threshold, and the shape of the exposure–response relationship. For example, a smaller safety factor might be convincingly chosen for threshold effects on human populations per se or the end point of the LOAEL may merely reflect the "negligible risk" of neurobehavioral or other functional alterations rather than the definite pathological damages. However, a larger factor should be introduced for a more serious effect or a threshold effect that was extrapolated mainly from animal tests. Several examples that demonstrate some of the criteria that we used in selecting a suitable safety factor are presented in Table 5 (Liang and Gu, 1991). Furthermore, we should be cautious; some genotoxic effects may be linked to a potential risk of cancer. In practice, this would require a very low risk level (e.g., 1×10^{-6} year^{-1}) for excess deaths due to exposure and reducing the exposure limits as low as reasonably practicable (Illing, 1991).

3. *Biological exposure limits.* Biological exposure limits (BELs) are developed to correlate occupational exposure to relevant levels of the toxicant or its metabolites in biological tissues or fluids. In China, the BELs have been preliminarily set for several toxicants of heavy metals, organic solvents, and organophosphate pesticides to illustrate the relationship between internal exposure level and health effects and to provide a biological basis for setting the diagnostic guidelines of occupational diseases.

To standardize the methods of determining a toxicant and its metabolites in biological materials, a guidebook titled *Recommended Methods for Analysis of Hazardous Substances in Biological Materials* has recently been published (Institute of Occupational Medicine and Division of Health Standards Setting, Chinese Academy of Preventive Medicine, 1994). The guidebook describes 51 analytical methods for determining 25 commonly used industrial toxic substances and their metabolites in blood, urine, and exhaled air and provides not only the scientific but also the legal basis for establishing the biological exposure limits in China, it is hoped in the near future.

4. *Enforcement and education.* Finally, enforcement and education are two of the major means of regulating the documented health standards. The serial publication *Advances in Health Standards Setting,* sponsored by the Chinese Academy of Preventive Medicine, has been published since 1984. This publication has created a channel for providing both domestic and international information pertaining to setting and enforcing health standards. It has been much appreciated by health professionals, hygienists, and managers of enterprises for its up-to-date information on the scientific achievements in setting health standards and the latest exposure limits adopted in industrialized countries, as well as the new concepts of health standards and their implementation. These are truly beneficial in improving the legislative process of setting health standards and in upgrading public awareness on this issue.

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