

# New trends in the development of occupational exposure limits for airborne chemicals in China

You-xin Liang,<sup>a,\*</sup> Zhi Su,<sup>b</sup> Wei-ai Wu,<sup>c</sup> Bo-qin Lu,<sup>c</sup> Wei-zu Fu,<sup>d</sup>  
Lei Yang,<sup>e</sup> and Jin-yu Gu<sup>b</sup>

<sup>a</sup> Fudan University School of Public Health, 138 Yixueyuan Road, Shanghai 200032, China

<sup>b</sup> Ministry of Health, P.R. China, Beijing 100044, China

<sup>c</sup> China Center for Disease Control and Prevention, Beijing 100050, China

<sup>d</sup> Shanghai Municipal Center for Disease Control and Prevention, Shanghai 200336, China

<sup>e</sup> Tongji Medical College, Huazhong University of Science and Technology, Wuhan 430022, China

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## Abstract

Occupational exposure limits (OELs) are well established in many countries, which serve occupational professionals as benchmarks of industrial hygiene practice at workplaces worldwide. Starting in the mid-1950s, the central government of China began promulgating OELs for hazardous substances at workplaces. This paper discusses the historical basis, philosophical principles and schematic protocols of developing and setting OELs in China. The underlying principles include: (1) protection of human health being the first and the most important criterion; (2) the use of quantitative epidemiological studies in humans being given top priority; (3) integration and full use of all information sources, including animal experimental data for new chemicals or chemicals with new toxicity concerns; (4) considerations of socioeconomic and technological feasibilities in the country; and (5) amending existing standards based on new evidence. The strategy of the World Health Organization's "Two-step Procedure" is applied to convert health-based recommendations to law-based operational OELs, with considerations for national technological and socioeconomic conditions and priorities. As a result of the recent passage of the new law *Occupational Diseases Prevention and Control Act of the People's Republic of China* (ODPCA), an official document *Occupational Exposure Limits for Hazardous Agents in the Workplace* containing a comprehensive list of new and amended OELs has been issued, which has now become one of the most essential regulations affiliated with the ODPCA. This paper provides a brief summary of the salient features of the new law ODPCA and the principles and processes of developing or amending OELs. This paper also discusses the challenges that lie ahead in enforcing the new regulations in China.

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## 1. Introduction

Occupational health in China has undergone many changes and has improved gradually over the past decades. These changes and improvements came about as a result of the recognition, regulation and reduction of exposures to hazardous materials at work. In China, as in many other countries, occupational exposure limits (OELs) are mandatory standards designed to control

exposures to hazardous agents and to provide a safe environment for workers. In this paper we will describe the historical basis, the scientific parameters considered in setting and amending OELs, and the application of the World Health Organization's (WHO's) "Two-step Procedure" in developing OELs in China. We will report and discuss the latest development and implementation of OELs, including the new comprehensive law on occupational health, the *Occupational Diseases Prevention and Control Act of the People's Republic of China* (ODPCA), which became effective on May 1, 2002 (the Labor Day in China).

\* Corresponding author. Fax: +86-021-64043069.

E-mail address: [yxliang@shmu.edu.cn](mailto:yxliang@shmu.edu.cn) (Y. Liang).

## 2. Historical basis

In the mid-1950s the central government of China began promulgating the adoption and implementation of OELs for chemical substances, dusts, and physical agents in the workplace. The first official document *Provisional Hygienic Standards for the Design of Industrial Premises (Standard 101-56)* was issued in 1956, which contained a list of maximum allowable concentrations (MACs) for 53 chemical agents and dusts. This was followed by a period of gradual development, that resulted in a 1962 document entitled *Hygienic Standards for the Design of Industrial Premises (GBJ 1-62)*, containing a list of MACs for 92 chemical substances and dusts. A further expanded and updated version of *Hygienic Standards for the Design of Industrial Premises (TJ 36-79)* was not released until 1979, containing a list of 120 MACs and representing the most comprehensive document on OELs prior to China's economic reform in the 1980s (Liang et al., 1995).

The systematic development of OELs began in 1981 after the establishment of the National Technological Committee of Health Standards Setting (NTCHSS), under the Ministry of Health. As an affiliate to the NTCHSS, the Subcommittee of Occupational Health Standards Setting (SCOHSS) comprises approximately 20 members selected from the Ministry of Health and its executive agencies; the Centers for Diseases Control and Prevention at state, provincial and municipal levels; industrial ministries; medical universities, and institutes of industrial hygiene and occupational medicine. The membership of SCOHSS covers a range of expertise, including toxicology, epidemiology, occupational health and medicine, analytical chemistry, and industrial hygiene. The SCOHSS acts as a consultative body, prioritizing research projects for setting occupational standards, advising and reviewing proposals for new and amended OELs, and providing education and training. The SCOHSS holds annual committee meetings to evaluate the appropriateness of recommended OELs by reviewing written submissions and presentations made at the annual meetings. This organizational framework is recognized as a milestone of the development of occupational health standards setting in China (Gang, 2000). Since the 1990s, more sophisticated approaches to the use of data aimed at setting and amending OELs have been developed, and the pace of promulgating standards has been greatly accelerated. As a result, two volumes of *Compilations of National Occupational Standards*, containing 123 further developed OELs were published in 1992 (Standards Division, Chinese Academy of Preventive Medicine, 1992) and 1997 (Standards Division, Chinese Academy of Preventive Medicine, 1997), respectively (Fig. 1).

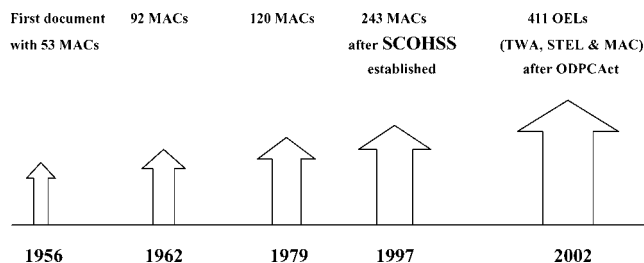


Fig. 1. Chronology of occupational exposure limits (OELs) in China.

## 3. Philosophy and protocols in setting OELs

### 3.1. The philosophical principles

The development of OELs for airborne contaminants is based on the premise that, although exposure to all chemical substances is toxic above certain concentration over a certain period of time, a concentration (e.g., dose) exists for all substances below which no injurious effects should result no matter how often the exposure is repeated.

In China, protocols for setting health standards are based on the following principles: (1) protection of human health being the first and the most important criterion; (2) the use of quantitative epidemiological studies in humans being given top priority; (3) integration and full use of all information sources, including animal experimental data for new chemicals or chemicals with new toxicity concerns; (4) considerations of socioeconomic and technological feasibilities in China; and (5) amending existing standards based on new evidence.

The scientific criteria used to develop OELs may include morphological, functional, or biochemical changes, as well as miscellaneous factors such as nuisance, cosmetic irritation, etc. Whenever possible, more sensitive and specific indicators are preferred, such as changes in cholinesterase (ChE) activity for organophosphate pesticides exposure, sensory irritation for irritants, neurobehavioral changes for neurotoxic substances, as well as other relevant biomarkers. Whenever possible, OELs are based on primarily human data, i.e., effects observed in workers chronically exposed. Consequently, most existing OELs have been set based on the results of workplace monitoring, with qualitative and quantitative observations of human response. OELs for new chemicals, however, have been based on primarily animal studies and international standards with considerations for national conditions and priorities.

At the SCOHSS, health-based OELs are developed through specific research projects. Each research project that will result in a proposal for health-based OELs is required to submit to the SCOHSS a standardized document entitled "Scientific Basis for the Proposed OELs" with the following information:

- Substance identification with chemical name, formula, molecular weight, CAS number, and technical data on purity of the substance;
- Chemical and physical properties including information on form, color, melting and boiling points, and solubility of the chemical in water and other solvents;
- Production and use at workplace, emphasizing the specific working conditions with significant exposures;
- Exposure and effect assessments describing qualitative and quantitative information on exposure from environmental and biological monitoring to facilitate the establishment of dose–response/effect relationships;
- Toxicological and epidemiological databases providing dose–response/effect data from both animal experiments and human epidemiological studies, the biological threshold level derived from the lowest observable adverse effect level (LOAEL), and the safety margin considered;
- Mutagenic, carcinogenic and teratogenic properties; and
- Up-to-date literature review with complete references.

As evident from the above list, the philosophical principles of developing health-based OELs used by the SCOHSS in China are quite similar to those used by other international bodies. Once the health-based OELs have been developed and having communicated the proposal with health administrators and industrial managers, the principal investigators of the project are required to provide information regarding technological and socioeconomic considerations of converting the health-based recommendations into law-based operational OELs.

### 3.2. The schematic protocols

Under the SCOHSS, protocols for setting OELs have been structured in accordance with the World Health Organization's (WHO's) "Two-step Procedure" aimed at generating: (1) recommended health-based OELs, and (2) law-based operational OELs (Mikheev, 1995). Collaboration among scientists, policymakers, industry and occupational health care professionals is required to balance toxicological and epidemiological considerations with socioeconomic and technological feasibilities. The two-step procedure keeps the researchers and policymakers in a state of balance between "How safe is safe?" and "How safe can we afford?" The procedure takes the development of OELs from hazard and exposure considerations to law-based guidelines for good industrial hygiene practice (Fig. 2).

In general, the underlying methodologies of developing health-based OELs and generating law-based operational OELs are common to all international bodies for standard setting. The common methodological features

include the basic criteria used, the core data sets, the scientific rationales, the socioeconomic feasibilities, and the logical processes established. Although the actual values of many OELs differ from country to country, with the rapid economic globalization, there is a widespread perception of a requirement for and a commitment to international harmonization of OELs. Vincent (1998) has pointed out that, in view of the vast differences in technological feasibility and social environment among various countries, full harmonization of OELs may not necessarily be a good solution for improving the environments for all workers and that intermediate or rudimentary harmonization may be more "incremental," thus providing more promising and realistic approaches to the reduction of international differences. In reviewing the current status of setting and implementing OELs in China, we believe that China is approaching a stage of intermediate harmonization both in a theoretical and a practical sense, in which OELs are developed using criteria, methods and data commonly found in the international literature but also taking into account national considerations and priorities. For example, labor-intensive work is common in many industries in China, which makes it possible to draw a direct link between exposures and effects from relatively large populations of exposed workers, rather than extrapolations from animal experiments. Therefore, we put strong emphasis on the use of quantitative epidemiological studies in human populations in developing OELs.

## 4. Latest legislative approaches to occupational health

### 4.1. The new law on the prevention and control of occupational diseases

The *Occupational Diseases Prevention and Control Act of the People's Republic of China* (ODPCA) is the first comprehensive law on occupational health adopted at the national level (Occupational Diseases Control and Prevention Act, 2001). It was approved by the Standing Committee of the National People's Congress in 2001, and put into effect on May 1, 2002. Similar to the impact of the 1970 Occupational Safety and Health Act (OSHAct) on occupational health and safety in the USA, the ODPCA is expected to vastly improve occupational health in China. In fact, the new law has now become a legislative backbone for enforcing OELs. According to the new law, every employer is obligated to comply with the requirements related to work environment, hazards control and implementation of OELs. The ODPCA is comprised of seven chapters with 79 articles, and its salient features are briefly summarized below:

Chapter 1. *General principles*. This Act is enacted based on the Constitution of the People's Republic of

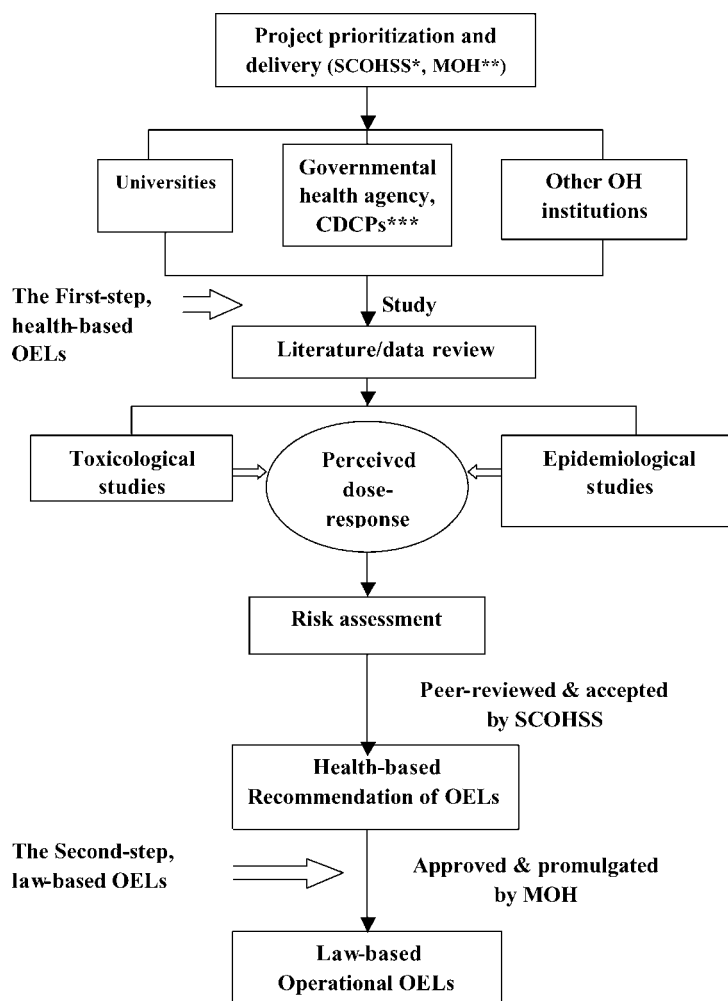


Fig. 2. Schematic protocols in setting OELs. \*SCOHSS: Subcommittee of Occupational Health Standards Setting; \*\*MOH: Ministry of Health; \*\*\*CDCPs: Centers for Disease Control and Prevention.

China towards: (1) protecting workers' health and safety at work; and (2) promoting workers' health by providing a healthy and safe workplace, together with good industrial hygiene practice and management to achieve a sustainable development of the national economy.

Chapter 2. *Pre-production prevention*. The Act emphasizes the national strategy of "Prevention First" through proactive measures at the beginning of each industrial production project being established. It is aimed at creating a safer process during the development of a new industrial project, or renovation or expansion of existing industrial process.

Chapter 3. *Preventive and protective measures, and management at work*. This chapter describes detailed measures for hazards control in the workplace and emphasizes that labor employment units (LEUs) are obligated to take managerial and technological measures to comply with the legal requirements. These measures may include work organization and industrial hygiene engineering, such as ergonomic layout of

workstation, ventilation, enclosure, automation and the use of personal protection equipment.

Chapter 4. *Diagnosis of and compensation for occupational diseases*. The chapter outlines requirements for conducting periodic medical surveillance, early pre-clinical detection of health effects on workers, and provisions for proper medical facilities for disease diagnosis, treatment, and rehabilitation. It also specifies the process for compensation and pension for workers with occupational diseases. One hundred and fifteen (115) work-related diseases due to over exposures to occupational hazards have been identified as compensable occupational diseases (Table 1). Workers who are diagnosed with occupational diseases are fully covered by medical insurance offered by LEUs.

Chapter 5. *Supervision and inspection*. Based on the requirements of the ODPC Act, the affiliated regulations and the national OELs, health inspectors from the Institutes of Health Supervision and Inspection at county level and above are responsible for carrying out workplace health inspections, evaluations and worker health

Table 1  
Types of compensable occupational diseases in China

| Type of the diseases                                 | No. notified diseases |
|--|-----------------------|
| (1) Pneumoconiosis                                   | 13                    |
| (2) Ionizing radiation-induced occupational diseases | 11                    |
| (3) Occupational poisonings                          | 56                    |
| (4) Physical agents-induced occupational diseases    | 5                     |
| (5) Biological agents-induced occupational diseases  | 3                     |
| (6) Occupational dermatoses                          | 8                     |
| (7) Occupational eye diseases                        | 3                     |
| (8) Occupational ear, nose, throat and oral diseases | 3                     |
| (9) Occupational cancers;                            | 8                     |
| (10) Other occupational diseases                     | 5                     |
| Total  | 115                   |

surveillance, and for enforcing occupational health standards. An inspection can also be triggered by an employee complaint or an accident involving a serious chemical poisoning or fatality.

Chapter 6. *Penalty*. Any infraction of the ODPCAct is considered a violation of the law. During an inspection, a LEU found to be in violation of the law would first receive a warning, together with consultation on developing a plan of action to improve the working conditions within a certain period of time. Further penalty may include: fines, revocation of business license or even criminal charges if a warning has been ignored and no remedial action has been taken within the specified time period. Monetary fines can range from ¥ 5000 to 500,000 RMB.

Chapter 7. *Supplemental provisions*. Definitions of technical terms frequently used in the text of the ODPCAct are listed as an appendix to clarify terminology used in the regulations.

## 5. Scientific developments affiliated with the new law

### 5.1. Renewed definitions of OELs in China

The following three categories of OELs for chemical substances have been recently adopted in China, including: (1) Permissible Concentration-Time Weighted Average (PC-TWA), which is defined as an average concentration for a conventional 8-h workday; (2) Maximum Allowable Concentration (MAC), defined as the ceiling level of chemical substances that should not be exceeded at any representative sampling; and (3) Permissible Concentration-Short Term Exposure Limit (PC-STEL), defined as an average of a 15-min TWA exposure which should not be exceeded at any time during a workday even if the 8-h TWA is within the limit of PC-TWA.

### 5.2. Newly developed documents of relevance under the ODPCAct

Two important documents regarding occupational health standards (OHSs), i.e., *Hygienic Standards for the Design of Industrial Premises (GBZ 1-2002)* and *Occupational Exposure Limits for Hazardous Agents in the Workplace (GBZ 2-2002)*, have been issued by the Ministry of Health, to facilitate the implementation of the new ODPCAct. Document *GBZ 1-2002* focuses on: (1) workplace selection and design; (2) ergonomic layout of workstation; (3) guidelines of sanitation facilities and emergency needs; and (4) health-based meteorological requirements in the workplace (Ministry of Health, 2002a). Document *GBZ 2-2002* contains updated and newly developed OELs (Ministry of Health, 2002b). Selected OELs of chemicals and dusts are shown in Tables 2 and 3, with a comparison to the corresponding ACGIH-TLVs. Comparing the Chinese PC-TWAs to ACGIH TLV-TWAs for 68 identical chemicals indicates that 33 (49%) are exactly the same, 27 (40%) are lower, and 8 (12%) have higher limit values.

In addition to OELs, biological monitoring provides supplemental means to assess exposure and health risk to workers. In China, the biological exposure limits (BELs) have been developed as recommended standards rather than mandatory OELs. Currently, listed in Document *GBZ 2-2002* are 11 BELs that have been promulgated by the SCOHSS as recommended values for an individual's "uptake" of chemical(s). Most of these are not directly derived from the OELs but closely related to the development of adverse effects and correlated with the OEL to a certain extent (Table 4).

### 5.3. The relationship between STEL and TWA

To control the magnitude of excursion in a workplace with fluctuating exposure levels in a conventional 8-h workday, the average of 15 min PC-TWA, i.e., PC-STEL, is set as a supplemental limit to PC-TWA. For a number of chemical substances, the PC-STEL was set either based on toxicological and epidemiological data, or derived from existing international standards. However, for hazardous substances lacking adequate toxicological and epidemiological data for directly generating PC-STELs, the values (PC-STEL\*) were set in accordance with the proposed Excursion Limits for chemical substances with various levels of adopted PC-TWA (Table 5).

## 6. Amending or revising existing standards

Amendments may be initiated either on the basis of emerging knowledge in toxicology, new findings from field surveys or industrial practice. The lowering of the

Table 2  
Comparison of OELs adopted in China with ACGIH TLVs for selected chemicals in mg/m<sup>3</sup>(ppm)

| Substances (CAS no.)  | MAC   | PC-TWA | PC-STEL | ACGIH TLVs   |              |
|---|-------|--------|---------|--|--------------|
|   |       |        |         | TWA  | STEL         |
| Acetaldehyde [75-07-0]  | 45    | —      | —       | —  | C 45 (25)    |
| Acetic acid [64-19-7]   | —     | 10     | 20      | 25 (10)  | 37 (15)      |
| Acetic anhydride [108-24-7]                                       | —     | 16     | 32*     | 21 (5)   | —            |
| Acetonitrile [75-05-8]  | —     | 10     | 25*     | 34 (20)  | —            |
| Ammonia [7664-41-7]   | —     | 20     | 30      | 17 (25)  | 24 (35)      |
| Ammonium chloride fume [12125-02-9]                               | —     | 10     | 20      | 10   | 20           |
| Aniline [62-53-3] (skin)  | —     | 3      | 7.5*    | 7.6 (2)  | —            |
| Antimony and compounds, as Sb [7440-36-0]                         | —     | 0.5    | 1.5*    | 0.5  | —            |
| Arsenic and inorganic compounds as As [7400-38-2]                 | —     | 0.01   | 0.02    | 0.01   | —            |
| Arsine [7784-42-1]  | 0.03  | —      | —       | 0.16 (0.05)  | —            |
| Asphalt (petroleum) fume, as benzene soluble matter (8052-42-4)   | —     | 5      | 12.5*   | 0.5 <sup>†</sup>   | —            |
| Benzene [71-43-2] (skin)  | —     | 6      | 10      | 1.6 (0.5)  | 8 (2.5)      |
| Beryllium and compounds, as Be [7440-41-7]                        | —     | 0.0005 | 0.001   | 0.002  | 0.01         |
| Biphenyl [92-52-4]  | —     | 1.5    | 3.75*   | 1.3 (0.2)  | —            |
| Boron trifluoride [7637-07-2]                                     | 3     | —      | —       | —  | C 2.8 (1)    |
| Bromine [7726-95-6]   | —     | 0.6    | 2       | 0.66 (0.1)   | 1.3 (0.2)    |
| 1,3-Butadiene [106-99-0]  | —     | 5      | 12.5*   | 4.4 (2)  | —            |
| Cadmium and compounds, as Cd [7440-43-9]                          | —     | 0.01   | 0.02    | 0.01<br>0.002 <sup>R</sup>   | —            |
| Calcium cyanamide [156-62-7]                                      | —     | 1      | 3       | 0.5  | —            |
| Calcium oxide [1305-78-8]   | —     | 2      | 5*      | 2  | —            |
| Carbon disulfide [75-15-0] (skin)                                 | —     | 5      | 10      | 31 (10)  | —            |
| Carbon monoxide [630-08-0]  | —     | —      | —       | 29 (25)  | —            |
| Normal altitude   | —     | 20     | 30      | —  | —            |
| High altitude: 2000–3000 m  | 20    | —      | —       | —  | —            |
| >3000 m   | 15    | —      | —       | —  | —            |
| Carbon tetrachloride (skin) [56-23-5]                             | —     | 15     | 25      | 31 (5)   | 63 (10)      |
| Carbonyl fluoride [353-50-4]                                      | —     | 5      | 10      | 5.4 (2)  | 13 (5)       |
| Cesium hydroxide [21351-79-1]                                     | —     | 2      | 5*      | 2  | —            |
| Chlorine dioxide [10049-04-0]                                     | —     | 0.3    | 0.8     | 0.3 (0.1)  | 0.8 (0.3)    |
| Chlorine trifluoride [7790-91-2]                                  | 0.4   | —      | —       | —  | C 0.4 (0.1)  |
| bis (chloromethyl) ether (542-88-1)                               | 0.005 | —      | —       | 0.0047 (0.001)   | —            |
| Chloromethyl methyl ether [107-30-2]                              | 0.005 | —      | —       | — <sup>L</sup>   | —            |
| Chromium trioxide, chromate, dichromate, as Cr [7440-47-3]        | —     | 0.05   | 0.15*   | 0.5 (metal and Cr III compounds)<br>0.05 (water-soluble Cr VI compounds)<br>0.01 (insoluble Cr VI compounds) | —            |
| Coal tar pitch volatiles, as benzene soluble matters [65996-93-2] | —     | 0.2    | 0.6*    | 0.2  | —            |
| Cobalt and oxides, as Co [7440-48-4]                              | —     | 0.05   | 0.1     | 0.02 (cobalt and inorganic compounds, as Co)   | —            |
| Copper, as Cu [7440-50-8]   | —     | —      | —       | —  | —            |
| Copper fume   | —     | 0.2    | 0.6*    | 0.2 (fume)   | —            |
| Copper dust   | —     | 1      | 2.5*    | 1 (dust/and mist)  | —            |
| Cresol [1319-77-3] (skin)   | —     | 10     | 25*     | 22 (5):all isomers   | —            |
| Cyanamide [420-04-2]  | —     | 2      | 5*      | 2  | —            |
| Cyanogen chloride [506-77-4]                                      | 0.75  | —      | —       | —  | C 0.75 (0.3) |
| DDT (dichlorodiphenyltrichloroethane) [50-29-3]                   | —     | 0.2    | 0.6*    | 1  | —            |
| Decaborane [17702-41-9] (skin)                                    | —     | 0.25   | 0.75    | 0.25 (0.05)  | 0.75 (0.15)  |
| Dichlorobenzene   | —     | —      | —       | —  | —            |
| o-Dichlorobenzene [95-50-1]                                       | —     | 50     | 100     | 150 (25)   | 301(50)      |
| p-Dichlorobenzene [106-46]  | —     | 30     | 60      | 60 (10)  | —            |
| Dimethyl sulfate [77-78-1] (skin)                                 | —     | 0.5    | 1.5*    | 0.52 (0.1)   | —            |
| Dinitrobenzene [582-29-0; 99-65-0; 100-25-4] (all isomers) (skin) | —     | 1      | 2.5*    | 1 (0.15)   | —            |
| 4,6-Dinitro-o-cresol [534-52-1] (skin)                            | —     | 0.2    | 0.6*    | 0.2  | —            |
| Dinitrotoluene (skin) [25321-14-6]                                | —     | 0.2    | 0.6*    | 0.2  | —            |
| Ethylamine [75-04-7]  | —     | 9      | 18      | 9 (5)  | 27 (15)      |

Table 2 (continued)

| Substances (CAS no.)  | MAC   | PC-TWA               | PC-STEL              | ACGIH TLVs                      |  |
|---|-------|----------------------|----------------------|---------------------------------|--|
|   |       |                      |                      | TWA                             | STEL   |
| Ethylene chlorohydrin [107-07-3] (skin)                                   | 2     | —                    | —                    | —                               | C 3 (1)  |
| Ethylene oxide [75-21-8]  | —     | 2                    | 5*                   | 1.8 (1)                         | —  |
| Fenthion [55-38-9] (skin)   | —     | 0.2                  | 0.3                  | 0.2                             | —  |
| Fluorides (except HF), as F   | —     | 2                    | 5*                   | 2.5                             | —  |
| Formaldehyde [50-00-0]  | 0.5   | —                    | —                    | —                               | 0.45 (C 0.3)   |
| Formic acid [64-18-6]   | —     | 10                   | 20                   | 9 (5)                           | 19 (10)  |
| <i>n</i> -Hexane [110-54-3] (skin)  | —     | 100                  | 180                  | 180 (50)                        | —  |
| Hydrazine [302-01-2] (skin)   | —     | 0.06                 | 0.13                 | 0.01 (0.01)                     | —  |
| Hydrogen bromide [10035-10-6]   | 10    | —                    | —                    | —                               | C 10 (3)   |
| Hydrogen chloride and chlorhydric acid [7647-01-0]                        | 7.5   | —                    | —                    | —                               | C 7 (5)  |
| Hydrogen cyanide, as CN [74-90-8] (skin)                                  | 1     | —                    | —                    | —                               | C 5 (4.7)  |
| Hydrogen fluoride, as F [7664-39-3]                                       | 2     | —                    | —                    | —                               | C 2.5 (3)  |
| Hydrogen peroxide [7722-84-1]   | —     | 1.5                  | 3.75*                | 1.5 (1)                         | —  |
| Hydrogen selenide, as Se [7783-07-5]                                      | —     | 0.15                 | 0.3                  | 0.2 (0.05)                      | —  |
| Hydrogen sulfide [7783-06-4]  | 10    | —                    | —                    | 14 (10)                         | 21 (15)  |
| Iodine [7553-56-2]  | 1     | —                    | —                    | —                               | C 1 (0.1)  |
| Lead and inorganic compounds, as Pb [7439-92-1]                           |       |                      |                      |                                 | —  |
| Lead dust   | 0.05  | —                    | —                    | 0.05                            | —  |
| Lead fume   | 0.03  | —                    | —                    | —                               | —  |
| Magnesium oxide(fume) [1309-48-4]   | —     | 10                   | 25*                  | 10                              | —  |
| Malathion [121-75-5] (skin)   | —     | 2                    | 5*                   | 10                              | —  |
| Manganese and inorganic compounds, as MnO <sub>2</sub> [7439-96-5]        | —     | 0.15                 | 0.45                 | 0.2                             | —  |
| Mercury [7439-97-6]   |       |                      |                      |                                 | —  |
| Element mercury (vapor)   |       | 0.02                 | 0.04                 | 0.025                           | —  |
| Mercury organic compounds (skin), as Hg                                   |       | 0.01                 | 0.03                 | (elemental and inorganic forms) | —  |
| Molybdenum and compounds, as Mo [7439-98-7]                               |       |                      |                      |                                 | —  |
| Molybdenum and insoluble compounds  |       |                      |                      | 10 <sup>I</sup>                 | —  |
| Soluble compounds   |       | 6                    | 15*                  | 3 <sup>R</sup>                  | —  |
| Soluble compounds   |       | 4                    | 10*                  | 0.5 <sup>R</sup>                | —  |
| Nickel and inorganic compounds, as Ni [7440-02-0]                         |       |                      |                      |                                 | —  |
| Elemental nickel and insoluble compounds                                  | —     | 1                    | 2.5*                 | 1.5 <sup>I</sup> (elemental)    | —  |
| Soluble compounds   | —     | 0.5                  | 1.5*                 | 0.1 <sup>I</sup> (soluble)      | —  |
| Nickel carbonyl, as Ni [13463-39-3]                                       | 0.002 | —                    | —                    | 0.2 <sup>I</sup> (insoluble)    | —  |
| Nitric oxide (nitrogen monoxide) [10102-43-9]                             | —     | 15                   | 30*                  | 0.1 (0.05)                      | —  |
| <i>p</i> -Nitroaniline [100-01-6] (skin)                                  | —     | 3                    | 7.5*                 | 30 (25)                         | —  |
| Nitrobenzene [98-95-3] (skin)   | —     | 2                    | 5*                   | 3                               | —  |
| <i>p</i> -Nitrochlorobenzene [100-00-5]/dinitrochlorobenzene [25567-67-3] | —     | 0.6                  | 1.8*                 | 1                               | —  |
| Oxalic acid [144-62-7]  | —     | 1                    | 2                    | 0.6 (0.1)                       | —  |
| Ozone [10028-15-6]  | 0.3   | —                    | —                    | ( <i>P</i> -nitrochlorobenzene) | —  |
|   |       |                      |                      | 1                               | 2  |
|   |       |                      |                      | —                               | 0.1 (0.05):<br>Heavy work<br>0.16 (0.08):<br>Moderate work<br>0.2 (0.10):<br>Light work<br>0.4 (0.20): ≤ 2 h |
| Parathion [56-38-2] (skin)  | —     | 0.05                 | 0.1                  | 0.1                             | —  |
| Phosgene [75-44-5]  | 0.5   | —                    | —                    | 0.4 (0.1)                       | —  |
| Phosphorus (yellow) [7723-14-0]   | —     | 0.05                 | 0.1                  | 0.1                             | —  |
| Subtilisins (1395-21-7; 9014-01-1)  | —     | 15 ng/m <sup>3</sup> | 30 ng/m <sup>3</sup> | —                               | C 60 ng/m <sup>3</sup>   |
| Sulfur dioxide [7446-09-5]  | —     | 5                    | 10                   | 5 (2)                           | 10 (5)   |
| Thallium and soluble compounds [7440-28-0] (skin), as Tl                  | —     | 0.05                 | 0.1                  | 0.1                             | —  |
| Toluene (skin) [108-88-3]   | —     | 50                   | 100                  | 188 (50)                        | —  |
| Toluene-2,4-diisocyanate (TDI) [584-84-9]                                 | —     | 0.1                  | 0.2                  | 0.04 (0.005)                    | 0.15 (0.02)  |
| 2,4,6-Trinitrotoluene [118-96-7] (skin)                                   | —     | 0.2                  | 0.5                  | 0.1                             | —  |
| Tungsten and insoluble compounds, as W [7440-33-7]                        | —     | 5                    | 10                   | 5                               | 10   |

Table 2 (continued)

| Substances (CAS no.)                                | MAC | PC-TWA | PC-STEL | ACGIH TLVs                       |                |
|---|-----|--------|---------|----------------------------------|----------------|
|   |     |        |         | TWA                              | STEL           |
| Vanadium and compounds, as V [7440-62-6]            |     |        |         |                                  |                |
| Vanadium pentoxide fume, dust                       |     | 0.05   | 0.15*   | 0.05 <sup>R</sup> (dust or fume) |                |
| Ferrovanadium alloy dust                            |     | 1      | 2.5*    |                                  |                |
| Vinyl chloride [75-01-4]                            | —   | 10     | 25*     | 10 (5)                           | —              |
| Xylene (all isomers) [1330-20-7; 95-47-6; 108-38-3] | —   | 50     | 100     | 435 (100)                        | 655 (150)      |
| Yttrium and compounds, as Y [7440-65-5]             | —   | 1      | 2.5*    | 1                                | —              |
| Zinc chloride fume [7646-85-7]                      | —   | 1      | 2       |                                  | 1–2            |
| Zinc oxide [1314-13-2]                              | —   | 3      | 5       | 5 (fume)<br>10 (dust)            | 10 (fume)<br>— |
| Zirconium and compounds, as Zr [7440-67-7]          | —   | 5      | 10      | 5                                | 10             |

\*STELs were calculated based on the Excursion Limits (See Table 5).

<sup>R</sup>Respirable fraction.

<sup>I</sup>Inhalable fraction.

Exposure by all routes should be carefully controlled to levels as low as possible.

benzene standard illustrates these points. Historically, benzene has been heavily utilized in numerous Chinese industries, e.g., shoe, suitcase and paint manufacturing. Based on an evaluation of the scientific literature, a decision was made to significantly lower the benzene standard from 40 mg/m<sup>3</sup> (13 ppm) to 10 mg/m<sup>3</sup> (3 ppm) as PC-STEL and 6 mg/m<sup>3</sup> (2 ppm) as PC-TWA. Scientifically, this decision was based on a consideration of more recent data and investigations in China and other countries. These new standards are more compatible with the regulatory levels in North America and the European Union (ACGIH, 2002). In addition, the Chinese government has clearly articulated a strong position on compliance and enforcement of the new benzene standards. This demonstrates that the process of scientific re-evaluation of standards can lead to regulatory changes and subsequent emphasis on enforcement. It should also be pointed out that in some industries (particularly the small ones), workers in China are still exposed to unacceptably high levels of benzene, with quite a few in excess of 300 mg/m<sup>3</sup> (Wong, 2002). For benzene exposure, therefore, increased enforcement of OELs may be of equal or greater importance than lowering the standard.

On the contrary, over-estimation of the risk associated with exposure may actually mislead and hinder the enforcement of OELs. For example, a stringent MAC value of 0.01 mg/m<sup>3</sup> was set for mercury vapor in China between the 1950s and the late 1980s. Results of an extensive epidemiological study conducted in the early 1990s showed that only the incidence of mild chronic effects was increased (less than 2%) among workers who had been exposed to mercury vapor ranging from 0.02 to 0.03 mg/m<sup>3</sup> for more than 30 years. Therefore, a recommendation to elevate Hg MAC from 0.01 to 0.02 mg/m<sup>3</sup> was accepted by the SCOHSS in 1993 (Fu et al., 1993), which is now converted into a PC-TWA of 0.02 mg/m<sup>3</sup> and a PC-STEL of 0.04 mg/m<sup>3</sup>. Similarly, a

number of OELs have been adjusted and/or re-evaluated in the wake of the new law substantially bridging the gap between OELs in China and those adopted in other countries, thus approaching intermediate harmonization (Liang and Wu, 2002a,b).

## 7. Occupational carcinogens

Carcinogen classification approaches and risk assessment methodologies are key elements to assessing risk from environmental and occupational exposure to chemical carcinogens. The classification of carcinogens serves several purposes, including setting OELs, labeling, and establishing product use restrictions (Seeley et al., 2001). The risk assessment for carcinogens began in the mid-1980s in China. For example, chlordimeform (CDM) was used as a pesticide for pest control in cotton and rice. However, the use of CDM became a major concern soon after its marketing. A research group at the Fudan University Medical Center (formerly Shanghai Medical University) conducted a risk assessment of occupational exposure to CDM in the mid- and late-1980s. The risk of developing urinary bladder cancer was reported as  $24.2 \times 10^{-5}$  in CDM manufacturing workers and  $7.3 \times 10^{-5}$  in farming sprayers, substantially higher than the background rate. Based on these results, the authors recommended that: (1) setting-up more stringent regulations for the production and use of CDM; (2) minimizing all unnecessary and avoidable exposures; (3) conducting worksite and biological monitoring for exposure control; and (4) banning the use of CDM once a substitute pesticide is available (Xue et al., 1988; Guo, 2000).

In accordance with the classification schemes of the International Agency for Research on Cancer (IARC), eight chemicals have been classified as occupational carcinogens, and malignant neoplasms induced by



Table 3  
Comparison of OELs in China to ACGIH TLVs for selected dusts in mg/m<sup>3</sup>

| Dusts (CAS No.)  | PC-TWA   | PC-STEL  | ACGIH TLVs TWA   |
|--|----------|----------|--|
| Asbestos fiber, and dust-containing > 10% of asbestos [1332-21-4]    |          |          | 0.1 f/cc <sup>F</sup> (all forms)                          |
| Total dust   | 0.8      | 1.5      |  |
| Asbestos fiber   | 0.8 f/ml | 1.5 f/ml |  |
| Carbon black dust [1333-86-4] (total)                                | 4        | 8        | 3.5  |
| Cement dust (free SiO <sub>2</sub> < 10%)                            |          |          |  |
| Total dust   | 4        | 6        |  |
| Respirable dust  | 1.5      | 2        |  |
| Coal dust (free SiO <sub>2</sub> < 10%)                              |          |          |  |
| Total dust   | 4        | 6        | 0.4 <sup>R</sup> (anthracite)                              |
| Respirable dust  | 2.5      | 3.5      | 0.9 <sup>R</sup> (bituminous)                              |
| Cotton dust (total)  | 1        | 3        | 0.2 <sup>G</sup>   |
| Diatomite dust (free SiO <sub>2</sub> < 10%)<br>[61790-53-2] (total) | 6        | 10       | 10 <sup>E,1</sup><br>3 <sup>E,R</sup>                      |
| Graphite dust [7782-42-5]  |          |          |  |
| Total dust   | 4        | 6        |  |
| Respirable dust  | 2        | 3        | 2 <sup>R</sup>   |
| Mica dust [12001-26-2]   |          |          |  |
| Total dust   | 2        | 4        |  |
| Respirable dust  | 1.5      | 3        | 3 <sup>R</sup>   |
| Perlite dust [93763-70-3]  |          |          | 10 <sup>E</sup>  |
| Total dust   | 8        | 10       |  |
| Respirable dust  | 4        | 8        |  |
| Silica dust [14808-60-7]   |          |          |  |
| Total dust   |          |          |  |
| Free SiO <sub>2</sub> containing 10–50%                              | 1        | 2        |  |
| Free SiO <sub>2</sub> containing 50–80%                              | 0.7      | 1.5      |  |
| Free SiO <sub>2</sub> containing >80%                                | 0.5      | 1.0      | 0.1 <sup>R</sup> (triboli)                                 |
| Respirable dust  |          |          |  |
| Free SiO <sub>2</sub> containing 10–50%                              | 0.7      | 1.0      | 0.05 <sup>R</sup>  |
| Free SiO <sub>2</sub> containing 50–80%                              | 0.3      | 0.5      | (cristobalite, quartz and tridymite)                       |
| Free SiO <sub>2</sub> containing >80%                                | 0.2      | 0.3      |  |
| Silicon carbide dust [409-21-2]                                      |          |          | 10 <sup>E</sup>  |
| Total dust   | 8        | 10       |  |
| Respirable dust  | 4        | 8        |  |
| Talc dust (free SiO <sub>2</sub> < 10%) [14807-96-6]                 |          |          | 2 <sup>E,R</sup> (containing no asbestos fibers)           |
| Total dust   | 3        | 4        | Use asbestos TLV <sup>K</sup>                              |
| Respirable dust  | 1        | 2        | (containing asbestos fibers)                               |
| Welding fumes/dust (total)   | 4        | 6        | 5  |
| Wood dust (total)  | 3        | 5        | 1 (certain hard woods)<br>5 mg/m <sup>3</sup> (soft woods) |

<sup>R</sup> Respirable fraction.

<sup>G</sup> As measured by the vertical elutriator, cotton sampler.

<sup>E</sup> For particulate matter containing no asbestos and <1% crystalline silica.

<sup>1</sup> Inhalable fraction.

<sup>K</sup> Should not exceed 2 mg/m<sup>3</sup> respirable particulate.

these carcinogens have been classified as compensable occupational cancers in China (Table 6). To meet the needs for data in amending OELs of confirmed human carcinogens, a comprehensive nationwide epidemiological study was conducted among workers who had been exposed to chloromethyl methyl ether, asbestos, inorganic arsenic compounds, chromates, benzene,

benzidine, vinyl chloride, and coke oven emissions. Results of the study have been reported in a previous paper (Liang et al., 1995). The overall data had shown strong evidence for an association between cancers and workers' exposures, which eventually led to the setting of "virtually safe occupational exposure levels" (Table 6).

Table 4  
Recommended biological exposure limits (2002)

| Chemicals                            | Sampling time                              | BELs  |
|--------------------------------------|--|---|
| Cadmium                              |  |   |
| Cadmium in blood                     | Not critical                               | 5 µg/L  |
| Cadmium in urine                     | Not critical                               | 5 µg/g Cr.  |
| Carbon disulfide                     |  |   |
| TTCA in urine                        | End of shift                               | 2.2 mg/g Cr.  |
| Carbon monoxide                      |  |   |
| HbCO                                 | End of shift                               | 5% Hb   |
| Fluorine and fluorides               |  |   |
| Fluorides in urine                   |  | 7 mg/g Cr. (post-shift)<br>4 mg/g Cr. (pre-shift)     |
| <i>N</i> -Hexane                     |  |   |
| 2,5-Hexanedione in urine             | End of shift                               | 4.0 mg/L  |
| Lead                                 |  |   |
| Lead in blood                        | Any time after having exposed for 3 weeks  | 40 µg/dL  |
| Organophosphate P pesticides         |  |   |
| AChE activity in blood               | Any time after having exposed for 3 months | 70%   |
| Styrene                              |  |   |
| Mandelic acid in urine               |  | 300 mg/g Cr. (post-shift)<br>120 mg/g Cr. (pre-shift) |
| Phenylglyoxylic acid in urine        |  | 100 mg/g Cr. (post-shift)<br>40 mg/g Cr. (pre-shift)  |
| Toluene                              |  |   |
| Hippuric acid in urine               |  | 1.5 g/g Cr. (post-shift)<br>2.0 g/L (post-shift)      |
| Trichloroethylene                    |  |   |
| Trichloroacetic acid in urine        |  | 50 mg/L (post-shift)                                  |
| Trinitrotoluene                      |  |   |
| 4-Amino-2,6-dinitrotoluene-Hb adduct | Any time after having exposed for 4 months | 200 ng/g Hb   |

Table 5  
Relationships among PC-TWA, Excursion limit and PC-STEL\*

| PC-TWA<br>(mg/m <sup>3</sup> ) | Excursion limit | Proposed PC-STEL*<br>(mg/m <sup>3</sup> ) |
|--------------------------------|-----------------|---|
| ≤1                             | 3               | ≤3  |
| ~10                            | 2.5             | ~25                                       |
| ~100                           | 2.0             | ~200                                      |
| ≥100                           | 1.5             | ≥150                                      |

## 8. Enforcement and communication

Risk communication, health education and routine inspections are all appropriate means for increasing enforcement of occupational health standards. Since the promulgation of the ODPCAct on May 1, 2002, the Ministry of Health has sponsored a number of training courses in several developed areas in the country. To further disseminate the new regulations, a series of

Table 6  
Chemicals that identified as occupational carcinogens in China

| Chemical carcinogens      | Related neoplasm            | Exposure limits (mg/m <sup>3</sup> ) |               |
|---------------------------|-----------------------------|--------------------------------------|---------------|
|                           |                             | TWA                                  | STEL          |
| Arsenic                   | Lung cancer, skin carcinoma | 0.01                                 | 0.02          |
| Asbestos                  | Lung cancer, mesothelioma   | 0.8 f/ml                             | 1.5 f/ml      |
| Benzene                   | Leukemia                    | 6                                    | 10            |
| Benzidine                 | Bladder cancer              | Not available                        | Not available |
| Chloromethyl methyl ether | Lung cancer                 |                                      | 0.005 (MAC)   |
| Chromium (VI) compounds   | Lung cancer                 | 0.05                                 | 0.15          |
| Coke oven emissions       | Lung cancer                 | 0.1                                  | 0.3           |
| Vinyl chloride            | Liver angiosarcoma          | 10                                   | 25            |

related publications have been issued. However, it is recognized that significant gaps still exist between developed areas, mainly the East and Southeast coastal regions, and less developed areas, mainly the North, Northwest and Southwest provinces, and between the established and incipient industrial sectors. Occupational health problems in some small-scale industries are of major concern as the ODPAct and affiliated occupational health standards have not been effectively implemented by grass-root health units that are responsible for the inspection and supervision of small-scale industrial sectors in the rural areas. Recently, a devastating episode of acute benzene poisoning occurred in a township-owned suitcase manufacturing in Hebei Province, resulting in 17 cases of serious benzene poisoning and five deaths. Industrial hygiene measurements, taken shortly after the incident, reported air concentrations of benzene as high as 949–2040 mg/m<sup>3</sup>; which were 95- to 204-fold higher than the currently adopted PC-STEL and 158- to 340-fold higher than the PC-TWA (Zhang et al., 2002; Wong, 2003). Although this incident was one of the worst cases, similar incidents are frequently found in other small-scale industries. As a result, the State Council has taken serious actions, including shutting down workshops, bringing lawsuits against violators and issuing additional regulations. One of the actions was the release of the document *Administrative Rules of Labor Protection Regarding the Use of Toxic Substances in the Workplace* (The State Council, 2002). It is evident that only through appropriate legislation and effective inspection systems, including the integration of occupational health services with primary health care for small-scale industries in the rural areas, will the new ODPAct and its affiliated regulations be effectively enforced.

## 9. Conclusions

Over the past 50 years, great efforts and resources have been devoted to setting, implementing and amending occupational health standards in China. Occupational exposure limits or industrial hygiene guidelines dealing with occupational hazards have become a valuable tool for good industrial hygiene practice: through routine workplace inspections, and environmental monitoring and health surveillance aimed at controlling hazards in the workplace. The adoption and implementation of the recently passed ODPAct has substantially improved the enforcement of occupational health standards. However, it is recognized that important gaps still exist between the developed and less developed areas, and between the established and small-scale industrial sectors in the country. Education and appropriate legislation together with effective supervision and inspections, including the integration of occu-

pational health services with primary health care for small-scale industries in the rural areas, will improve the enforcement of the ODPAct and its affiliated regulations for the protection of all workers in making the WHO's global objective of "Occupational Health for All" a reality (WHO, 1995).

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