

The development and regulation of occupational exposure limits in China

Youxin Liang^{a,*}, Otto Wong^{a,b,c,d,e}, Lei Yang^f, Tao Li^g, Zhi Su^h

^a School of Public Health, Fudan University, Shanghai, China

^b Applied Health Science, Inc., San Mateo, California, USA

^c Department of Epidemiology, Tulane University, New Orleans, Louisiana, USA

^d Department of Community Medicine, Chinese University of Hong Kong, Hong Kong

^e Department of Community Medicine, University of Hong Kong, Hong Kong

^f Tongji Medical College, Huazhong University of Sciences and Technology, Wuhan, China

^g National Institute of Occupational Health and Poison Control, China Center for Diseases Control and Prevention, Beijing, China

^h Department of Health Law Enforcement and Supervision, Ministry of Health, Beijing, China

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Abstract

Of the 700 million workers in China, approximately 200 million workers are potentially exposed to industrial hazards. Although the promulgation and implementation of occupational exposure limits (OELs) in China began in the mid-1950, a systematic approach was not formalized until the formation of the Subcommittee of Occupational Health Standards Setting (SOHSS) in 1981. More recently, the 2002 Occupational Disease Prevention and Control Act of the People's Republic of China created the legislative framework for the development and enforcement of OELs. The SOHSS, whose members are primarily health professionals, is the organization responsible for the development of recommended standards, under the auspices of the Ministry of Health. The philosophy of OEL development of the SOHSS consists of a two-step approach: (1) an initial health-based recommended standard is established based on scientific data, and (2) a final law-based standard takes into consideration both socioeconomic and technological feasibility. Governmental agencies such as the Centers for Diseases Control and Prevention and the Institutes of Public Health Supervision at the state, provincial or municipal levels are charged with the responsibilities of the enforcement of OELs. The process and challenges in the enforcement of OELs are discussed. A comparison is made between selected Chinese OELs and those in other countries. The OELs for benzene and industrial dusts (including silica) are discussed in some detail.

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1. Introduction

China, with a population of 1.3 billion, is the most populous country in the world. Approximately 700 million Chinese people are in the active workforce and most of them are blue-collar workers. According to the latest government estimates, approximately 200 million workers are potentially exposed to industrial hazards. China is going

through a unique transitional period of economic transform from primarily an agricultural country to a major manufacturer on the global market. The current changes include labor reorganization, employment structure, and economy globalization. These changes have created a dramatic decrease of employment at state-owned enterprises, an overwhelming increase of foreign-invested enterprises, and a steady increase of town- or village-owned enterprises, as well as private enterprises. These much welcomed economic transformations and expansions, however, might have also created some unintentional burdens on factory inspections, worker health monitoring

* Corresponding author. Fax: +86 21 64043069.

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

and occupational health services. The workers in small- and medium-scale industries are affected by these changes the most (Liang and Xiang, 2004). This paper provides readers a framework as to how the regulation of occupational health standards develops and its roles in controlling occupational hazards in China.

Occupational exposure limits (OELs), which serve occupational professionals as benchmarks of occupational hygiene in workplaces, are well established in many countries. The central government of China began the promulgation, adoption, and implementation of OELs for chemical substances, dusts, and physical agents in the mid-1950s. However, a systemic development of OELs was not formalized until 1981 with the founding of the National Technological Committee of Health Standards Setting (NTCHSS) and its affiliated Subcommittee of Occupational Health Standards Setting (SOHSS), under the Ministry of Health. Since then, more sophisticated approaches of setting and amending OELs have been rapidly developed. The first comprehensive national law on occupational health, the Occupational Diseases Prevention and Control Act of the People's Republic of China (ODPCA) was adopted by the Standing Committee of the National People's Congress in October 2001, and went into effect on May 1, 2002. The ODPCA has now become the legislative backbone for the development and enforcement of OELs. At the end of 2002, NTCHSS and SOHSS were renamed National Committee of Health Standards Setting (NCHSS) and National Committee of Occupational Health Standards Setting (NCOHSS).

As a result of the ODPCA, the Ministry of Health has issued two important documents regarding occupational health standards: Hygienic Standards for the Design of Industrial Premises (GBZ 1-2002) and Occupational Exposure Limits for Hazardous Agents in the Workplace (GBZ 2-2002) (Ministry of Health, 2002). Document GBZ 2-2002 contains both updated and newly developed OELs for more than 400 chemical agents, dusts, physical agents, biological agents, and other occupational hazards (Ministry of Health, 2002). There were several noticeable changes. Instead of maximum allowable concentrations (MACs) only, for chemicals and dusts, the limit values are expressed as: (1) Permissible Concentration-Time Weighted Average (PC-TWA), which is defined as the average concentration for a conventional 8-h work shift; (2) Maximum Allowable Concentration (MAC), defined as the ceiling level of chemical substances with certain acute toxicological properties requiring the use of such "ceiling" that should not be exceeded at any representative sampling; and (3) Permissible Concentration-Short Term Exposure Limit (PC-STEL), defined as the 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 which is aimed at controlling the magnitude of short-term excursions above the PC-TWA.

2. Procedure of OEL development

2.1. Agencies and organizations responsible for the development of OELs

The National Committee of Occupational Health Standards Setting (NCOHSS) is recognized as the key organization responsible for OELs setting, consisting of some 20 members recommended by the governmental health agencies including the Department of Health Law Enforcement and Supervision of MOH, Centers for Diseases Control and Prevention (CDCPs), Institutes of Public Health Supervision (IPHSs), Institutes of Occupational Health and Occupational Medicine, Industrial Ministries, All China Federation of Trade Union, and medical universities. The NCOHSS members are composed of a wide range of expertise of occupational health, toxicology, epidemiology, industrial hygiene, sanitary analytical chemistry, and health inspection and supervision. Acting as a consultative body, the primary role of NCOHSS is to prioritize research projects for setting occupational standards, providing scientific or technical advice, and reviewing and evaluating study outcomes for both developing new and amending existing OELs. For example, to ensure the implementation of existing OELs, NCOHSS, authorized by MOH, has drafted and issued two occupational health standards entitled "Specifications of Air Sampling for Hazardous Substances Monitoring in the Workplace" (GBZ159-2004) and "Methods for Determination of Occupational Hazards in the Air of the Workplace" (GBZ160.1-160.81-2004) in 2004. To implement the Occupational Diseases Prevention and Control Act of 2002, NCOHSS focuses on the following activities: developing and updating OELs, establishing guidelines for workers health protection and workplace risk assessment, and promoting the enforcement of occupational health standard. Acting as a "standing committee," the secretariat office of the NCOHSS stands as the primary agent responsible for organizing annual meetings, education and training, expert consultation, and documenting and publicizing OELs.

The other agencies and organizations involved in the development of OELs are governmental agencies (CDCPs and IPHSs under the MOH at the state level, and Bureaus of Health, at provincial or municipal levels), Chinese National Federation of Trade Unions, industrial ministries (primarily large state-owned enterprises such as the Sino Petrochemical Company), scientific institutions (institutes of occupational health and occupational medicine at the state, provincial or municipal levels); and universities (mainly medical or public health schools).

2.2. Scientific basis for generating health-based recommendation of OELs

The scientific endpoints for developing a health-based OEL may include: morphological, functional, or biochemical changes, as well as miscellaneous factors (nuisance,

cosmetic irritation, etc.). For setting a safer OEL, 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, and some other relevant biomarkers. Whenever possible, OELs have been based mainly on human data, i.e., effects observed in workers chronically exposed to particular substances. This means that most existing OELs have been set based on the results of workplace health monitoring as well as qualitative and quantitative epidemiologic investigations. However, some OELs, particularly in the case of new chemicals for which human data are limited or unavailable, have been based primarily on the results of animal studies, and some adapted from international standards (primarily TLVs recommended by the American Conference of Governmental Industrial Hygienists, ACGIH).

The information prepared by NCOHSS for the development of OELs includes the following categories:

- *Substance identification* contains chemical name and formula, molecular weight, CAS number, and technical data on purity of the substance.
- *Chemical and physical properties* include information on form, color, melting and boiling points, solubility of the chemical in water and other solvents, and other information of relevance.
- *Production and use at workplace* describe the working conditions that may result in a significant occupational exposure.
- *Exposure and effect assessments* describe the qualitative and quantitative information on exposure from environmental and biological monitoring to facilitate the establishment of dose–response and dose–effect relations.
- *Toxicological and epidemiological evidence* summarizes the data demonstrating the dose–response relation from animal experiments, and/or exposure–response relation from human epidemiological studies. These data are used to establish a biological threshold level, derived from the lowest observable adverse effect level (LOAEL) and adjusted with safety margins. For the majority of the non-carcinogenic chemicals that were established after 1990s, the safety factors range from 2 to 10.
- *Mutagenic, carcinogenic, and teratogenic properties* for some chemicals are considered as specific potential indicators for more stringent safety margins.

According to the philosophy of the NCOHSS, ideally a ‘health-based’ standard is established on the basis of

the following: (1) reliable data from relevant human populations exposed to known levels of the substance, with at least one exposure level being a clear no-effect level for health effects that can be monitored; and (2) considerations from physicochemical and toxicological perspectives for other possible health effects that are difficult to monitor directly in humans (e.g., mutagenicity, reproductive toxicity). In practice, however, the toxicological information available on the substances of interest is often inadequate, in extent or quality, to allow the direct determination of such a standard. One is often faced with challenges of arriving at specific values based on the extrapolation from experimental and epidemiological data (Fairhurst, 1995).

The conventional approach adopted in standard setting in dealing with this situation is to identify from available information a reference point, usually a ‘no observed adverse effect level’ (NOAEL) or a ‘lowest observed adverse effect level’ (LOAEL) from experimental animal studies or human epidemiological studies. From this reference point, a standard is set at a lower level of exposure which is considered to meet the stipulated health protection criteria. The safety margin between the reference point (referred to the above as NOAEL or LOAEL) and the standard recommended has been termed the ‘Uncertainty Factor’ or ‘Safety Factor.’ The rationale of this approach is based on the assumption that a chemical has a threshold and that lowering the observed reference point by a safety margin can provide an acceptable level of exposure (Galer et al., 1992). However, there are several statuses that might influence the size of the uncertainty factor. The availability of toxicological information, such as amount of data, species studied, route of exposure, quality of data, and the availability of an identified LOAEL and/or NOAEL; nature and severity of principal adverse effects; availability of human exposure data; and the degree of control achievable (Fairhurst, 1995). Table 1 shows that the most stringent safety factor (50) was introduced into those chemical substances with severe nature of principal adverse effects in experimental animals; the intermediate ones (10–20) were used for those chemicals with less severe adverse effects in animals; and the smallest safety factor (2) was adopted for a chemical with LOAEL indicating minor adverse effect directly obtained from an occupational epidemiological study in the pesticides manufacturing. It also shows a historical downward tendency of safety factors introduced with the improved availability of toxicological and epidemiological data.

Table 1
Examples of safety factors adopted for selected chemical substances while OELs setting

Chemical substance	Indicators of LOAEL	Safety factor	Period OEL set
Triethyltin chloride	Histopathological brain edema in rabbits	50	1960s
Acrylonitrile	Liver function deficiency (SGPT > 40 IUs) in rats	20	1970s
Hexafluoropropylene	Elevated fluorides in the bone in rats	10	1980s
Trichlorfon (Dipterex)	Cholinesterase 30% inhibited in the pesticide producing workers	2	1980s

2.3. Consideration of socioeconomic and technological feasibility

Under the NCOHSS, the protocol for setting OELs has been formulated in accordance with the principles of the World Health Organization's (WHO's) two-step procedure aimed at generating: (1) a health-based recommendation for OELs and (2) the law-based operational OELs (Mikheev, 1995). Accordingly, a close and harmonious collaboration among scientists, policy makers, industry and occupational health professionals is required to balance toxicological and epidemiological considerations with socioeconomic, and technological feasibility. The two-step procedure keeps the researchers and policy makers in a state of logical equilibrium between the scientific desirability in terms of "how safe is safe" and the practical reality of "how safe can we afford." This two-step approach is summarized in Fig. 1.

2.4. Harmonization with other countries or organizations

The development of health-based OELs and the subsequent modifications into law-based operational OELs have many generic features that are common to all international bodies for standard setting. These features include the basic criteria used, the core data set, the rationales frequently considered from the scientific viewpoint and on the basis of socioeconomic feasibility, and the logical processes established.

It is not surprising that many actual values of OELs differ from country to country because of considerable differences in socioeconomic and technological consideration based on each country's development stage and its philosophy for OELs setting. However, with the rapid

development of economic globalization, there is a widespread perception of a requirement for and a commitment to international harmonization. Vincent (1998) has pointed out the following scenarios: (1) full harmonization among countries, with common criteria, development methods, exposure assessment methods, strategies, and OELs; (2) intermediate harmonization, with common criteria and methods and common primary database, but with local OELs based on national considerations and priorities; and (3) rudimentary harmonization, with better understanding among countries about factors that underpin the local OELs. In scrutinizing the current status of OEL setting in China, we believe that China is approaching a stage of intermediate harmonization both in a theoretical and 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 comparison, the Chinese OELs in term of PC-TWAs for 100 selected airborne chemicals are contrasted with those adopted or recommended by ACGIH (USA), Australia, Germany, and UK. It shows that almost 50% (51–53%) of Chinese OELs are lower, 20% (12–29%) are higher, and 30% (20–35%) are exactly the same as the TLVs-TWA in these other countries (Table 2). The comparison demonstrates that the majority of OELs set in China is on a par with those in developed countries (Ministry of Health, 2002; and ACGIH, 2003).

2.5. OELs for occupational carcinogens

In accordance with the classification schemes of the International Agency for Research on Cancer (IARC), eight chemicals have been classified as occupational carcinogens, and the malignant neoplasms induced by these carcinogens have been designated as compensable occupational cancers in China. To investigate the carcinogenic effects of these chemicals, comprehensive nationwide epidemiological studies were conducted among workers who were exposed to chloromethyl ether, asbestos, inorganic arsenic compounds, chromates, benzene, benzidine, vinyl chloride, and coke oven emissions. The results of these studies have been summarized in a previous paper (Liang et al., 1995). The overall data provide strong evidence for an association between cancer and exposure to these carcinogens at the workplace, which eventually led to the development of OELs that would adequately protect exposed workers (Table 3). These OELs, however, need periodic reevaluations to reaffirm or to amend the currently adopted limit values.

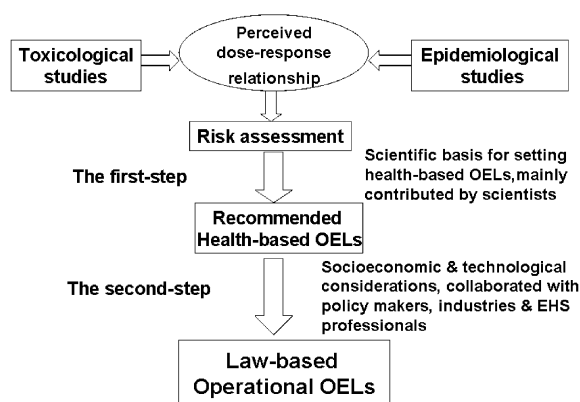


Fig. 1. Two-step Strategy for OELs Setting.

Table 2
Comparison of OELs for 100 selected airborne chemicals adopted in China vs. those of other countries

OELs in China vs. other countries	No. Lower PC-TWA	No. Identical PC-TWA	No. Higher PC-TWA	Total
USA (ACGIH)	50	35	15	100
Australia	54	34	12	100
Germany	51	20	29	100
UK	53	31	16	100

Table 3
Chemicals that identified as occupational carcinogens in China

Chemical carcinogens	Associated neoplasm	Exposure limits (mg/m ³)	
		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)	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

3. Enforcement and communication of OELs

The adoption of the 2002 ODPCAct and the subsequent renewal of OELs signify the central government's commitment to improve work environment and to eliminate or reduce avoidable occupational diseases. The ODPCAct reaffirms the authority of the Ministry of Health to set OELs, and specifies that occupational exposures to hazardous substances at the workplace must be within the OELs. When exposures exceed the OELs, failure to make proper remediation within the specified time will result in fines up to ¥500,000 (US\$61,000).

Furthermore, serious violations will result in the revocation of business license and the shutting-down of operations, and individuals responsible may be subjected to criminal prosecution (Liang et al., 2003a; Wong, 2003).

Governmental agencies such as IPHSs and CDCPs at national, provincial or municipal levels are responsible for worksite inspection, environmental monitoring, worker health surveillance, and systematic health risk assessment, if necessary. By law, occupational health inspections to any worksite can be performed anytime without advance notice. Such inspections can also be initiated by an employee complaint or an accident involving a serious chemical poisoning or fatality. The medical surveillance data are kept at CDCPs and the authorized hospitals, and occupational health inspection and industrial hygiene monitoring data are kept at IPHSs. In principle, these surveillance and monitoring data are potentially useful in reaffirming or amending the adopted OELs and in assessing the effectiveness of the 2002 ODPCAct. In practice, with a few exceptions, these data are not adequate for such evaluations. Therefore, improvements in the collection of both surveillance and monitoring data conducive to a better enforcement and evaluation of OELs are imperatively needed. Risk communication, health education, and routine inspections are all appropriate means for increasing the enforcement of occupational health standards to a broader extent.

4. Examples of OEL development

4.1. Benzene

Benzene is one of the most widely used industrial chemicals in China. A wide variety of industries and occupations

Table 4
Past and current benzene occupational exposure limits in China

Years	Standards
1956–1979	50 mg/m ³ , Area breathing zone concentration
1979–2002	40 mg/m ³ , Area breathing zone concentration
2002-present	10 mg/m ³ , Permissible concentration, short-term exposure limit 6 mg/m ³ , Permissible concentration, time-weighted average

particularly the shoe and luggage industries in China use benzene or benzene-containing solvents and adhesives. Industries in China have been regulated with OELs for benzene since the 1950s. These limits have gone through revisions over the years as shown in Table 4. The development of benzene OELs in China has been discussed in a number of recent articles (Liang et al., 2003a; Liang et al., 2005; Wong, 2003).

The current standard (10 mg/m³ STEL and 6 mg/m³ TWA), reduced from the previous MAC of 40 mg/m³, was developed based on primarily epidemiologic data and a consideration of safety margin. The new OEL is in general agreement with benzene standards in most other countries.

2002 ODPCAct is one of the most significant and comprehensive legislatures in occupational health in China (Liang et al., 2003b; Wong, 2003). Along with the 2002 Act, new or revised OELs were introduced. The OEL for benzene was reduced substantially. Although it may still be too early to see the full impact of the new reduced OEL, early insights are encouraging. Table 5 shows that benzene exposure levels in the shoe industry in China reported in 2002–2004 (mean of 69.7 mg/m³) were substantially lower than that of proceeding years 1991–2001 (mean of 293.1 mg/m³). However, the data indicate that the current benzene exposure levels were still high, exceeding the current OEL by several fold (Wang et al., 2006) (in press).

4.2. Industrial dusts (including silica and asbestos)

A large number of Chinese workers engaged in construction, mining, and many other occupations are potentially exposed to industrial dusts (including silica and asbestos). Pneumoconiosis has long been the most serious and yet preventable occupational disease in China. Occupational health studies have demonstrated that dust controls are

Table 5
Arithmetic means of reported benzene concentrations (mg/m³) at workplaces of the shoemaking industry by time periods

Time periods	No. paper	Minimum		Average ^a		Maximum	
		No. papers	Mean	No. papers	Mean	No. papers	Mean
1978–1990 (A)	24	17	339.4	12	405.3	18	2074
1991–2001 (B)	129	81	63.0	62	293.1	91	730.1
2002–2004 (C)	24	16	31.0	12	69.7	18	490.7
Total	177	114		86		127	

^a A vs. B, $p > 0.05$; A vs. C, $p < 0.05$; B vs. C, $p < 0.05$.

effective measures in reducing both the number of pneumoconiosis and the associated economic burden (Liang et al., 2003b).

A total number of 47 OELs for a variety of industrial dusts appear in the newly updated version of Chinese Occupational Exposure Limit for Hazardous Agents in the Workplace (GBZ 2-2002). Of these, 22 substances can be found in the ACGIH TLVs and BEIs booklet (ACGIH, 2003). A comparison of selected silica-containing dusts and asbestos is shown in Table 6.

It is shown that the limit values of asbestos, coal dust, and crystalline silica adopted in China are higher than those of ACGIH. For example asbestos limit value in China is 0.8 f/cc but 0.1 f/cc in the US. Although it is difficult to judge which limit is more appropriate or reasonable, the fact remains quit clear that for confirmed human carcinogens, such as asbestos, the exposure limits must be as low as technologically achievable, and that working condi-

tions in developing country such as China should be further improved to make a better harmonization with international standards.

5. Discussion

The central government of China began the promulgation, adoption and implementation of OELs for chemical substances, dusts, and physical agents in the mid-1950s. The recent passage and implementation of the Occupational Diseases Prevention and Control Act in 2002 has legally granted the OELs legislative power and has hence significantly improved the enforcement of occupational health standards. However, the implementation of the new law is met with many challenges. Several major obstacles are apparent as described below. First, a general trust and perception of the risk of occupational hazards and the adverse effects on workers' health and negative impact on the

Table 6
OELs of dusts in part adopted in China vs. ACGIH TLVs

Dust [CAS No.]	ACGIH		Dust	China	
	TWA	STEL		TWA	STEL
Asbestos, all forms [1332-21-4]	0.1 f/cc	—	Asbestos in fiber, and in dust containing 10% or more asbestos Dust Fiber	0.8 mg/m ^{3d} 0.8 f/cc	1.5 mg/m ^{3d} 1.5 f/cc
Coal dust			Coal dust (SiO ₂ < 10%)		
Anthracite	0.4 mg/m ^{3c}	—		4 mg/m ^{3d}	6 mg/m ^{3d}
Bituminous	0.9 mg/m ^{3c}	—		2.5 mg/m ^{3c}	3.5 mg/m ^{3c}
Portland cement [65997-15-1]	10 mg/m ³	—	Cement (SiO ₂ < 10%)	4 mg/m ^{3d} 1.5 mg/m ^{3c}	6 mg/m ^{3d} 2 mg/m ^{3c}
Silica, amorphous-diatomaceous earth (uncalcined) [61790-53-2]	10 mg/m ^{3a,b} 3 mg/m ^{3a,c}	— —	Diatomaceous earth- (SiO ₂ < 10%) [61790-53-2]	6 mg/m ^{3b}	10 mg/m ^{3b}
Silica, crystalline-			Silica-contained dust [14464-46-1]		
Cristobalite [14464-46-1]	0.05 mg/m ^{3c}	—	10–50% silica	1 mg/m ^{3d}	2 mg/m ^{3d}
Quartz [14808-60-7]	0.05 mg/m ^{3c}	—	50–80% silica ≥ 80%	0.7 m ^{3d} 0.5 m ^{3d}	1.5 m ^{3d} 1.0 m ^{3d}
			10–50% silica 50–80% silica ≥ 80%	0.7 mg/m ^{3c} 0.3 mg/m ^{3c} 0.2 mg/m ^{3c}	1.0 mg/m ^{3c} 0.5 mg/m ^{3c} 0.3 mg/m ^{3c}

^a For particulate matter containing no asbestos and <1% crystalline silica.

^b Inhalable fraction.

^c Respirable fraction.

^d Total dust.

sustainable development of national economy have not been commonly accepted by local governments, industries or workers. Second, the functions of trade unions have not been effectively utilized. In many situations, the appropriate communicating channels between employers and employees have not been well developed, and trade unions have not been adequately empowered to deal with the disputes during the critical period of economy transition. Third, the arrival of vast number of untrained farmers in industries such as coal mining, construction, and manufacturing has had a negative impact on the enforcement of OELs. Ironically, these workers are often the people most vulnerable and with the least control over their own workplace safety.

Finally, it should be pointed out that occupational health problems in some small-scale industries in rural areas are of major concern as the 2002 Occupational Diseases Prevention and Control Act and its related 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 rural areas. Therefore, there is vast room for improvement in a few aspects: (1) enhancing risk communication, occupational health and safety education, mandatory inspection, and professional supervision; (2) integrating occupational health services with primary health care for small-scale industries in the rural areas; and (3) keeping pace of occupational health legislation and implementation with the economy development. All these measures are strongly recommended to further prompting the enforcement of ODPCAct and its related regulations.

6. Conclusion

Over the past 50 years, great efforts have been devoted to developing, setting, implementing, and amending occupational health standards in China. Since the early 1980s, the OELs have been developed based on the protocol set forth by the Sub-committee of Occupational Health Standards Setting, SOHSS (presently the National Committee of Occupational Health Standards Setting, NCOHSS), under the auspices of the Ministry of Health, and more than 400 OELs have been set for chemical substances, dusts and physical agents. Of these, approximately 60% are independently developed by our own experimental study and epide-

miological survey data; 20% developed mainly by literature survey with appropriate scale of field surveys for validation in this country; and the remaining 20% are equivalently adopted from existing standards set by other countries, dominantly ACGIH-TLVs. Along with the implementation of national law on occupational health and safety, acting as one of the most important legislative regulations, the occupational exposure limit for hazardous agents has been playing a vital role in controlling occupational hazards and preventing avoidable occupational diseases although the enforcement of OELs, in terms of regional gap between the developed and less developed areas, remains to be further bridging.

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