Risk assessment and OELs (BELs) Setting in China

At the Workshop on the Priority in Chemical Risk Assessment and Management in the PR China (Beijing, 2004-2-20)

You-xin Liang, M.D.

Fudan University School of Public Health, Shanghai 20032, China

E-mail: yxliang@shmu.edu.cn
Contents

- Introduction
- History of OEL Setting in China
- Health Risk Assessment in OEL Setting
- Occupational Diseases Prevention and Control Act, P.R. China 2001
- Scientific Development of OELs under the New Law
- Risk Assessments in Setting and Amending Existing OELs: Case Studies
- Conclusions
Introduction
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 and reduction of exposures to hazardous materials at work.
Introduction

», Occupational exposure limits (OELs) serve occupational professionals as benchmarks for a healthy workplace.

», In China, as in many other countries, OELs are mandatory occupational health standards (OHSs) designed to control exposure to hazardous agents at workplace.
Introduction

This presentation shares with you:

- The latest development of OELs for airborne chemicals in China
- The role of risk assessment has played in promoting OELs and BELs setting
Historical Background
Historical Overview (1950s-1970s)

In China, airborne standards at workplace were established for a few chemical substances and dusts in the 1950s

- 《Standard 101-56》 contains a MAC list of 53 chemical agents and dusts at workplace documented in 1956

Followed by a gradual development between the 1960s and 1970s

- 《GBJ 1-62 》 contains 92 MACs, 1962
- 《TJ 36-79》 contains 120 MACs, 1979, which became a backbone of OHSs before 1980s
The systematic development of OELs began in 1981:

- After the establishment of National Technological Committee of Health Standards Setting (NTCHSS), MOH;
- The affiliated Subcommittee of Occupational Health Standards Setting (SCOHSS)
Historical Overview (1980s-1990s)

- The SCOHSS acts as a consultative body responsible for:
- Prioritizing research projects for setting OELs
- Advising and reviewing proposals for new and amended OELs
- Providing education and training
Historical Overview (1980s-1990s)

- SCOHSS holds annual committee meeting to evaluate appropriateness of recommended OELs by reviewing written submissions & presentations made at the annual meetings.

- This organizational framework is regarded as a milestone of the development of OELs in the country.
As a result, two compilations of National Occupational Standards with 119 newly developed OELs were published in 1992 & 1997 (Table 1)
Table 1 The adopted National OELs (up to 2000)

<table>
<thead>
<tr>
<th></th>
<th>TJ 36-79</th>
<th>Comp vol 1</th>
<th>Comp vol 2</th>
<th>Others</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemicals</td>
<td>111</td>
<td>25</td>
<td>51</td>
<td>3</td>
<td>180</td>
</tr>
<tr>
<td>Dusts</td>
<td>9</td>
<td>14</td>
<td>17</td>
<td>1</td>
<td>41</td>
</tr>
<tr>
<td>Physical agents</td>
<td>6</td>
<td>1</td>
<td></td>
<td></td>
<td>7</td>
</tr>
<tr>
<td>OEGs</td>
<td>5</td>
<td></td>
<td></td>
<td></td>
<td>5</td>
</tr>
<tr>
<td><strong>Subtotal</strong></td>
<td><strong>120</strong></td>
<td><strong>50</strong></td>
<td><strong>69</strong></td>
<td><strong>4</strong></td>
<td><strong>243</strong></td>
</tr>
</tbody>
</table>
Health risk assessment in OELs setting
The Philosophical Principles

- Use of quantitative epidemiological studies in humans being given the top priority;
- Review of EHCs/CICADs and OELs of other countries or organizations (e.g., IPCS, ACGIH)
- Integration and full use of all information sources, including animal data for new chemicals, or chemicals with new toxicity concerns;
- Considerations of socioeconomic and technological feasibility in China; and
- Amendment of existing standards based on new evidence
Parameters to consider when setting OELs:

- The most useful animal studies for setting OELs:
  - Multiple dose studies to determine NOAEL, LOEAL; or BMD, LBMD
  - Development of reference level
  - Selection of endpoints: most sensitive endpoint, biologically relevant to man
  - Selection of safety factors, SF

- A recommended OEL can be derived as:
  \[ OEL = \text{Reference level} / \text{SF} \]
Safety factors

- Uncertainty factors (UFs) and safety factors (SFs) are used to account for the uncertainty in extrapolating toxicity data:
  - ↑ Dose to ↓ dose (LOAEL → NOAEL)
  - Intra- & inter-species difference
  - Different routes of administration
- To our knowledge, for non-carcinogens’ OELs, UFs or SFs are generally small (2-10), accounting for about 75-80% of OELs established.
In accordance with WHO two-step strategy, the protocol being structured to generate (Fig 1):

- Recommended health-based OELs; and
- Law-based Operational OELs:
  -- In collaboration with scientists, policymakers, industry & OH care professionals
  -- Considerations of economic and technological feasibility
Perceived dose-response relationship

Recommended Health-based OELs

Law-based Operational OELs

Toxicological studies

Epidemiological studies

Risk assessment

Scientific basis for setting health-based OELs, mainly contributed by scientists

Socioeconomic & technological considerations, collaborated with policy makers, industries & EHS professionals

The first-step

The second-step

Figure 1 Two-step Strategy for OELs Setting
The Occupational Diseases Prevention and Control Act, P.R. China, 2001 (ODPCAct)
**General Principles**, based on the Constitution of the PR China towards protecting workers’ health; and promoting national economy

**Pre-production Prevention**, emphasizing “Prevention First” through proactive measures at the beginning of a project being established

**Preventive/Protective Measures, and Management at Work**, describing control measures, emphasizing labors employment units’ (LEUs) obligation of complying with OH/IH requirements

According to the new law, employers are obligated to comply with OELs
ODPCAct

- **Diagnosis of Occupational Diseases and Compensation**, including medical surveillance, early detection, diseases diagnosis, treatment, rehabilitation; & management of compensation or pension

- **Supervision & Inspection**, i.e., health supervision and inspection at county and above levels

- **Penalty**, including fines (5,000-500,000 RMB), revocation of business license or criminal charges

- **Supplemental Provisions**, defining technical terms frequently used in ODPCAct
Scientific Developments of OELs under the New Law
Scientific Development of OELs under the New Law

Two important updated documents:

- **Hygienic Standards for the Design of Industrial Premises (GBZ 1-2002)**;
- **Occupational Exposure Limits for Hazardous Agents in the Workplace (GBZ 2-2002)**
National Occupational Health Standards, P.R. China

Occupational Exposure Limits for Hazardous Agents in the Workplace

The Ministry of Health, P. R. China

Issued on 2002-04-08
The GBZ 2-2002 contains lists pertaining updated and newly developed OELs for:

- Chemical agents (340/329)*
- Dusts (70/47)*
- Physical agents (12)
- Biological agents (1)
- Others

Note: * (No. of OEL’s values/No. of items)
Definitions adopted to the OELs:

- **Permissible Concentration-Time Weighted Average, PC-TWA:**
  Time-weighted average concentration for a conventional 8-h workday

- **Maximum Allowable Concentration, MAC:**
  Ceiling level which should not be exceeded at any representative sampling

- **Permissible Concentration-Short Term Exposure Limit, PC-STEL:**
  Average 15-min TWA exposure which should not be exceeded at any time during a workday even if the 8-h TWA is within the PC-TWA
<table>
<thead>
<tr>
<th>Agents</th>
<th>No. Items</th>
<th>No. OEL values</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemicals</td>
<td>329</td>
<td>340</td>
</tr>
<tr>
<td>Dusts</td>
<td>47</td>
<td>70</td>
</tr>
<tr>
<td>Bioaerosol</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td><strong>Subtotal</strong></td>
<td><strong>377</strong></td>
<td><strong>411</strong></td>
</tr>
</tbody>
</table>
### Table 2 Distribution of OEL categories (2002-04-08)

<table>
<thead>
<tr>
<th>Category</th>
<th>MAC</th>
<th>PC—TWA</th>
<th>PC—STEL</th>
<th>PC—STEL*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemicals</td>
<td>59/54</td>
<td>314/285</td>
<td>112/102</td>
<td>174/166</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>(286/268)</td>
</tr>
<tr>
<td>Dusts</td>
<td></td>
<td>70/47</td>
<td>70/47</td>
<td></td>
</tr>
<tr>
<td>Biological agent</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Physical agents</td>
<td>80</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Chronology of Occupational Exposure Limits (OELs) in China

1956: 53
1962: 92
1979: 120
1997: 242
2002: 411
Risk assessment in amending existing OELs and BEIs

-- Selected case studies
The amending may be initiated either by the new knowledge of toxicology or industrial practice.

- Under-estimation might lead to a greater risk of exposure, for example, OELs for benzene and CS$_2$.
- Over-estimation might cause an increased constraint, hinder the enforcement of OELs and economy development, for example, Hg OEL.

A great number of OELs have been adjusted/re-notified after having the new law implemented recently (50% same as ACGIH adopted, 40% lower, and 10% higher) (Liang, et al, 2003).
Lowering of Benzene OELs

- Benzene has been heavily utilized in numerous industries, e.g., shoe, suitcase, toy, furniture, paint manufacturing and printing process.
- A number of studies on risk assessment of leukemogenic effects of benzene conducted in China demonstrating that workers are at ‘significant risk’ of harm at the old OEL, which was set 40 mg/m3 (12ppm) as MAC.
Based on the studies, integrated with an overview of the scientific literature, a decision was made to significantly lower the benzene OELs from 40 mg/m$^3$ (12ppm) to 10 mg/m$^3$ (3ppm) as PC-STEL and 6mg/m$^3$ (2ppm) as PC-TWA in 2001.
Adjusting over estimation of risk

- On the contrary, over-estimation of the risk associated with exposure may actually mislead and hinder the enforcement of OELs, for instance:

- A stringent MAC value of 0.01mg/m3 was set for mercury vapor in China between the 1950s and late 1880s.
Studies showed that only the incidence of mild chronic effects of CNS was increased (<2% higher) among workers who had been exposed to Hg vapor ranging from 0.02 to 0.03 mg/m³ for more than 30 years.

Therefore, a recommendation to elevate Hg MAC from 0.01 to 0.02 mg/m³, which is now converted into a PC-TWA of 0.02 mg/m³ and a PC-STEL of 0.04 mg/m³ (Table 4).
Table 6 Examples of amended occupational exposure limits (mg/m$^3$) and scientific basis

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Carbon disulfide</td>
<td>10</td>
<td>5</td>
<td>10</td>
<td>Menstrual disorders found in female workers at 10mg/m$^3$</td>
</tr>
<tr>
<td>Mercury (vapor)</td>
<td>0.01</td>
<td>0.02</td>
<td>0.04</td>
<td>Negligible/acceptable risk at 0.02 mg/m$^3$</td>
</tr>
</tbody>
</table>

* No longer being used
Risk assessment for pesticide: Chlorodimeform

- Chlorodimeform (CDM) was used as a pesticide for pest control in cotton and rice during 1970s-1980s

Chlorodimeform (CDM)
Risk assessment for pesticide: Chlorodimeform

- It became a major concern soon after its marketing because of carcinogenic effects found in animals
- An extensive study on risk assessment of manufacturing and using Chlorodimeform (CDM) was carried out in China (Xue et al, 1989)
Table 6: Estimated mortality of urinary bladder cancer among populations exposed to CDM via various routes

<table>
<thead>
<tr>
<th></th>
<th>Manufacturing workers in CDM plant</th>
<th>Farming sprayers in areas used CDM</th>
<th>Residence intake CDM from residue in rice</th>
</tr>
</thead>
<tbody>
<tr>
<td>Estimated intake dose (mg/kg BW/d)</td>
<td>$1.922 \times 10^{-3}$</td>
<td>$5.465 \times 10^{-4}$</td>
<td>$2.143 \times 10^{-5}$</td>
</tr>
<tr>
<td>Risk estimated upon animal data</td>
<td>$24.2 \times 10^{-5}$</td>
<td>$7.3 \times 10^{-5}$</td>
<td>$1.04 \times 10^{-5}$</td>
</tr>
<tr>
<td>Risk estimated upon Stasik model</td>
<td>$22.0 \times 10^{-5}$</td>
<td>$6.2 \times 10^{-5}$</td>
<td>$0.82 \times 10^{-5}$</td>
</tr>
<tr>
<td>Risk estimated upon US-EPA data</td>
<td>$30.6 \times 10^{-5}$</td>
<td>$8.68 \times 10^{-5}$</td>
<td>$1.14 \times 10^{-5}$</td>
</tr>
<tr>
<td>Estimated size of exposed population</td>
<td>3000</td>
<td>$1.5 \times 10^{6}$</td>
<td>$1.34 \times 10^{8}$</td>
</tr>
<tr>
<td>No. expected case of urinary bladder cancer</td>
<td>0.726</td>
<td>109.5</td>
<td>1394</td>
</tr>
</tbody>
</table>
Risk of CDM inducing urinary bladder cancer

- $24.2 \times 10^{-5}$, in CDM manufacturing worker
- $7.3 \times 10^{-5}$ in farming sprayers, substantially higher than the background rate ($1.04 \times 10^{-5}$)

Based on the studies, authors suggested that:
1) setting up more stringent regulations for the production and use of CDM;
2) minimizing all unnecessary and avoidable exposures;
3) carrying out worksite and biological monitoring for exposure control; and
4) banning the use of CDM as soon as a substitute pesticide is available (it achieved since 1993)
In accordance with IARC, the following eight chemicals, in our OELs list, have been classified as occupational carcinogens:

- Arsenic
- Asbestos
- Benzene
- Benzidine
- Chloromethyl ether
- Chromium (VI) compounds
- Coke oven emissions, and
- Vinyl chloride
Occupational carcinogens

- A nationwide epidemiological study was carried out among workers who had been exposed to the above 8 carcinogens.
- The overall data had shown strong evidence or an association between cancers and workers’s exposures.
- Malignant neoplasms associated with exposures to these carcinogens were notified as compensable occupational cancers in China.
The current adopted carcinogens’ “OELs” (mainly genotoxic?) are based on, technological feasibility for achieving the lowest possible exposure level, or “virtually safe occupational exposure levels”

However, it is not necessarily referred as zero risk, as no exposure level to carcinogen is safe

Systematic risk assessments remain to be further carried out and validated
CONCLUSIONS

- Great efforts have been devoted to the setting and amending of OELs in accordance with Intermediate principles, criteria and methods, but with national considerations & priority in China;
- Recent adoption of DPCAct has substantially improved the enforcement of occupational health standards
CONCLUSIONS

- Important gaps of the implementation of law still exist between the developed and less developed areas, and the established and incipient work sectors
CONCLUSIONS

- Enhanced risk communication and risk management may be of crucial to the success of achieving the goal of risk assessment and health standards setting.

- As pointed out: “legislation and guidelines themselves mean little without means and willingness to enforce them” (Aitio, 2003)
Think globally, Act locally!

-- The theme of the United Nation on Environment and Development (UNECD)

Rio De Janeiro, 1992