Chemical Safety and Risk Management: case studies in China

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Chemical Safety and Risk Management in OELs setting
Introduction

Major types of health regulations using or based on risk assessment in China

- OELs at workplaces (GBZ-2 2002)
- MAC of pollutants in ambient environment
  (SEPA-air, -water standards, etc)
- ADI of chemical residues in foods
- MEL of Radiation/chemical carcinogen exposure
- This presentation takes OELs as examples describing roles of RA and RM in promoting (OELs/MAC) setting
The OELs Setting

- Occupational exposure limits (OELs) are established on a basis of “safe level” of exposure at workplaces, to which no injurious effects should result no matter how often the exposure is repeated.
1. Types of information needed for developing OELs, a kind of laws/regulations

- Scale of a chemical being utilized in industries
- Physicochemical properties associated with potential for exposure: gas, vapor, mist, or inhalable dust, that are most likely causing pollution in work & ambient environment
- Estimated population being exposed
- Toxicity and human health effects
- Public perception and awareness
- Literature info on Toxicol, Epi & RA
2. To what scenarios should the regulations apply?

_**Rights, roles and accountabilities among different stakeholders, that constitute a harmonizing and collaborating scenarios in enforcing and performing the regulations**_
Institute of Public Health Supervision (IPHS):
Health inspection and administration

Employees:
Protective rights for occupational health; Awareness of self-protection

Employers/LEUs:
Liability to ensure workers’ right to know, and a safe and healthy workplace for all

CDCP & affiliated institutions:
OH services & technical supports on preventive control, medical surveillance & education

Rights and accountabilities among stakeholders
Network of Occupational Health Services in China

- Ministry of Health

  - China IPHS
  - Provincial IPHS
  - Municipal IPHS
  - County IPHS
  - Township Health Centers and Village Clinics

- China CDCP
  - Dept/Institute OH at Provincial CDCP
  - Dept/Institute OH at Municipal CDCP
  - Department of OH at County CDCP

OH services, technical supports & training

Approach of integral OH services with PHC

OH Inspection & Supervision
3. How are regulations communicated to those that enforce and apply?

Multiple stakeholders often have conflicting views on how to assess/manage risks and failed to build general trust and acceptance

- Governments, facing increasingly complex issues, with limited budgets
- The general public, becoming increasingly risk averse as affluence rises and poverty and other threats diminish
- Companies, it reduces their freedom to operate and ability to maximize their profit
- Governmental agencies (CDCP, IPHS), NGOs (Federal TU, industry representatives, EHS professionals, etc) are recruited as member or invited to attend annual meeting of OELs setting committee.
- Training causes offered to popularize knowledge on risk reduction and to elevate public awareness in implementing ODPC Act, OELs/related regulations.
- MSDS available for workers at worksite.
- Publications disseminated for professionals.
4. What methods should be included in the regulation? What have worked? What have not?

In accordance with WHO two-step strategy, protocols being structured to generate:

- Recommended health-based OELs; and
- Law-based Operational OELs:
  -- In collaboration with scientists, policymakers, industry, trade union, OH/EHS professionals
  -- Consideration of economic/technological feasibility
Parameters to consider when setting OELs

- **Toxicity data**
  - Acute (oral, dermal, inhalation lethality data
    \( \text{LD}_{50}, \text{LC}_{50}; \) irritation, LOAEL, NOAEL, BMD, LBMD)
  - Subacute/subchronic/chronic toxicity
    (14, 28, 90 days or up to 6 months, targeted organ and mode of action)
  - Reproductive effects and genotoxicity

- **Human health effects from occupational exposures**
- **Epidemiological survey data**
Reviews of EHCs and OELs of other countries or organizations (e.g., IPCS, ACGIH/US-OSHA, EU, etc)

Use of quantitative epidemiological studies in human beings given the top priority

Integrated information sources, including animal data for either new chemicals or chemicals with new toxicity concerns

Feasibility in developed and developing regions

Selection of safety factors

Amending existed standards on new evidence
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
5. How are the regulations synchronized among neighboring countries?

CHINA (n=330) VS AUSTRALIA (n=643)

- TWA = 45%
- TWA > 10%
- TWA < 45%

CHINA (n=330) VS JAPAN (n=252)

- TWA = 21%
- TWA > 60%
- TWA < 19%
Pre-production assessment

Workplace monitoring and evaluation

Worker health surveillance

Diagnosis of occupational diseases

Chemical safety evaluation

Treatment and Rehabilitation

Supervision and consultation

Return to work assessment

Education and training

Efficacy assessment of preventive measures and PPE

Occupational health services, by CDCP/OH Inst and certified/contracted institutions

Certification Body

Accreditation Committee

6. How are the regulations coordinated among different governmental organization?
7. How is risk assessment used in developing regions?

In China, significant gaps of enforcing and implementing regulations exist between:

- Developed and developing regions
- Established and incipient industrial sectors
- OH problems in SSIs are of major concern

Therefore, increased risk communication, education and management in developing regions are obviously greater importance.
Newly developed documents under ODPCAct

- **Hygienic Standards for the Design of Industrial Premises (GBZ 1-2002);**
- **Occupational Exposure Limits for Hazardous Agents in the Workplace (GBZ 2-2002)**
Occupational Exposure Limits for Hazardous Agents in the Workplace

The Ministry of Health, P. R. China
Issued on 2002-04-08
Chronology of Occupational Exposure Limits (OELs) in China

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

-- Selected case studies
Lowering of Benzene OELs

- Benzene has been heavily utilized in numerous industries, e.g., shoe, suitcase, toy, furniture, paint manufacturing, printing, etc.
- 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 previous OEL (MAC) of 40 mg/m³ (12ppm)
Based on the studies, integrated with scientific literature review, benzene OEL has been significantly lower from 40 mg/m³ (12ppm) to 10 mg/m³ (3ppm) as PC-STEL and 6mg/m³ (2ppm) as PC-TWA since 2001
### Table 5 Currently adopted Benzene OELs in selected countries

<table>
<thead>
<tr>
<th>Country</th>
<th>TWA (ppm)</th>
<th>STEL (ppm)</th>
<th>MAC (ppm)</th>
<th>TRK (ppm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>China</td>
<td>2 (6mg/m³) (2001- )</td>
<td>3 (10mg/m³) (2001-)</td>
<td>12 (40 mg/m³) (1950s- 2001)</td>
<td></td>
</tr>
<tr>
<td>Germany</td>
<td></td>
<td></td>
<td></td>
<td>5</td>
</tr>
<tr>
<td>Sweden</td>
<td>0.5</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>United Kingdom</td>
<td>5</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>US-NIOSH</td>
<td>0.1(REL)</td>
<td>1 (ceiling)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>US-OSHA</td>
<td>1(PEL)</td>
<td>5 (ceiling)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
A number of OELs have been adjusted and/or reaffirmed in the wake of the new law, thus:

- Substantially bridging the gap between OELs in China and those adopted in other countries, and
- Approaching into an intermediate harmonization
Table 6 Examples of amended occupational exposure limits (mg/m³) and scientific basis

<table>
<thead>
<tr>
<th></th>
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</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/m³</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/m³</td>
</tr>
</tbody>
</table>

* No longer being used
3. Risk assessment for pesticide: Chlorodimeform

- Chlorodimeform (CDM) was used as a pesticide for pest control in cotton and rice during 1970s-1980s
- 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>Estimated intake dose (mg/kg BW/d)</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>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 has been achieved since 1993)
7. Future perspectives

International harmonization

- Full harmonization among countries, with common sets of criteria, exposure assessment methods, and strategies and OELs;

- Intermediate harmonization, with common criteria and methods and a common primary database, but with local OELs based on national considerations & priority;

- Rudimentary harmonization, with better understanding among countries about all the factors that underpin the local OELs