



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**

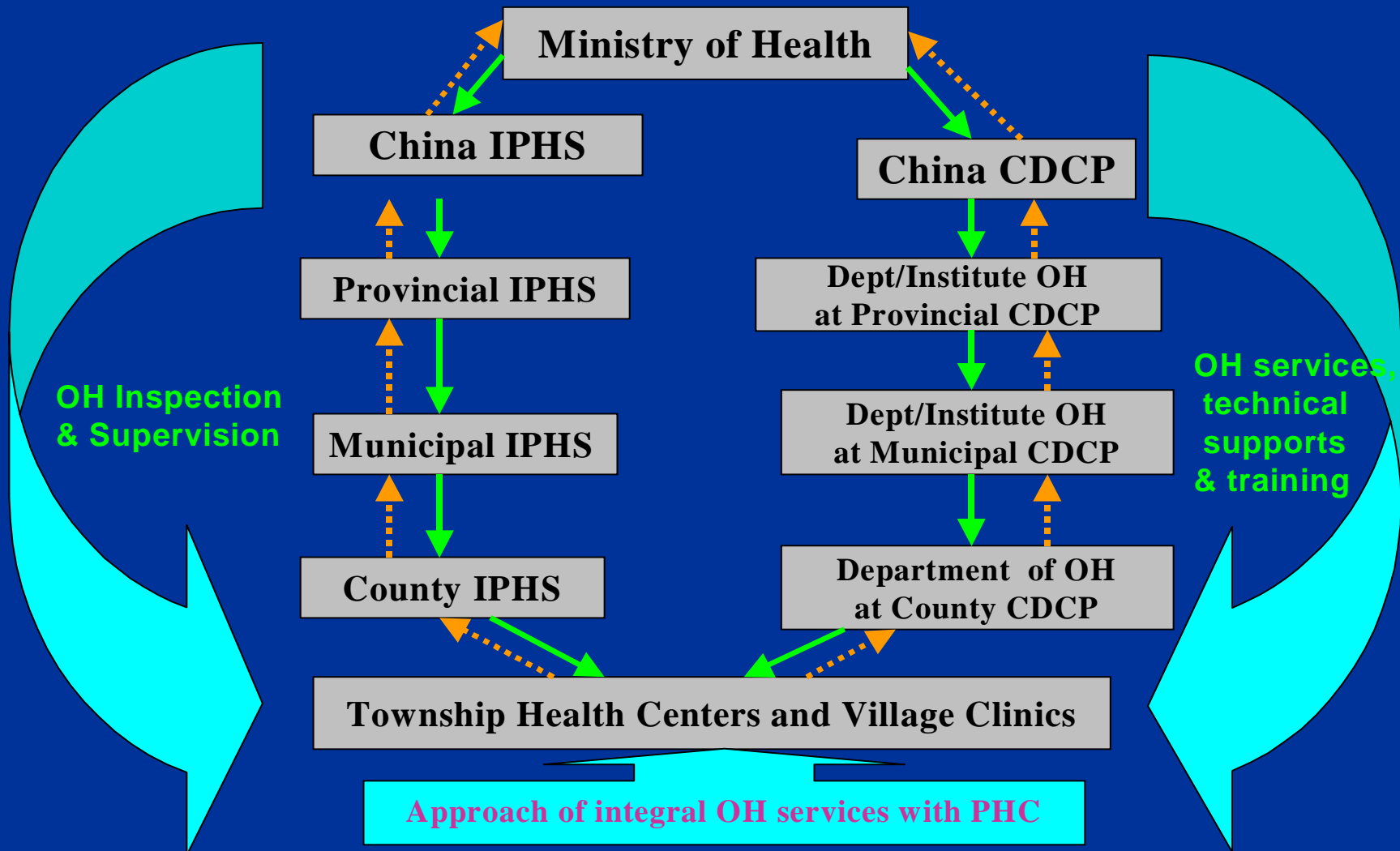
**Employees:
Protective rights for
occupational health;
Awareness of self-protection**

**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



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 courses offered to popularize knowledge on risk reduction and to elevate public awareness in implementing ODPCAAct, 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
LD₅₀, LC₅₀; 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**

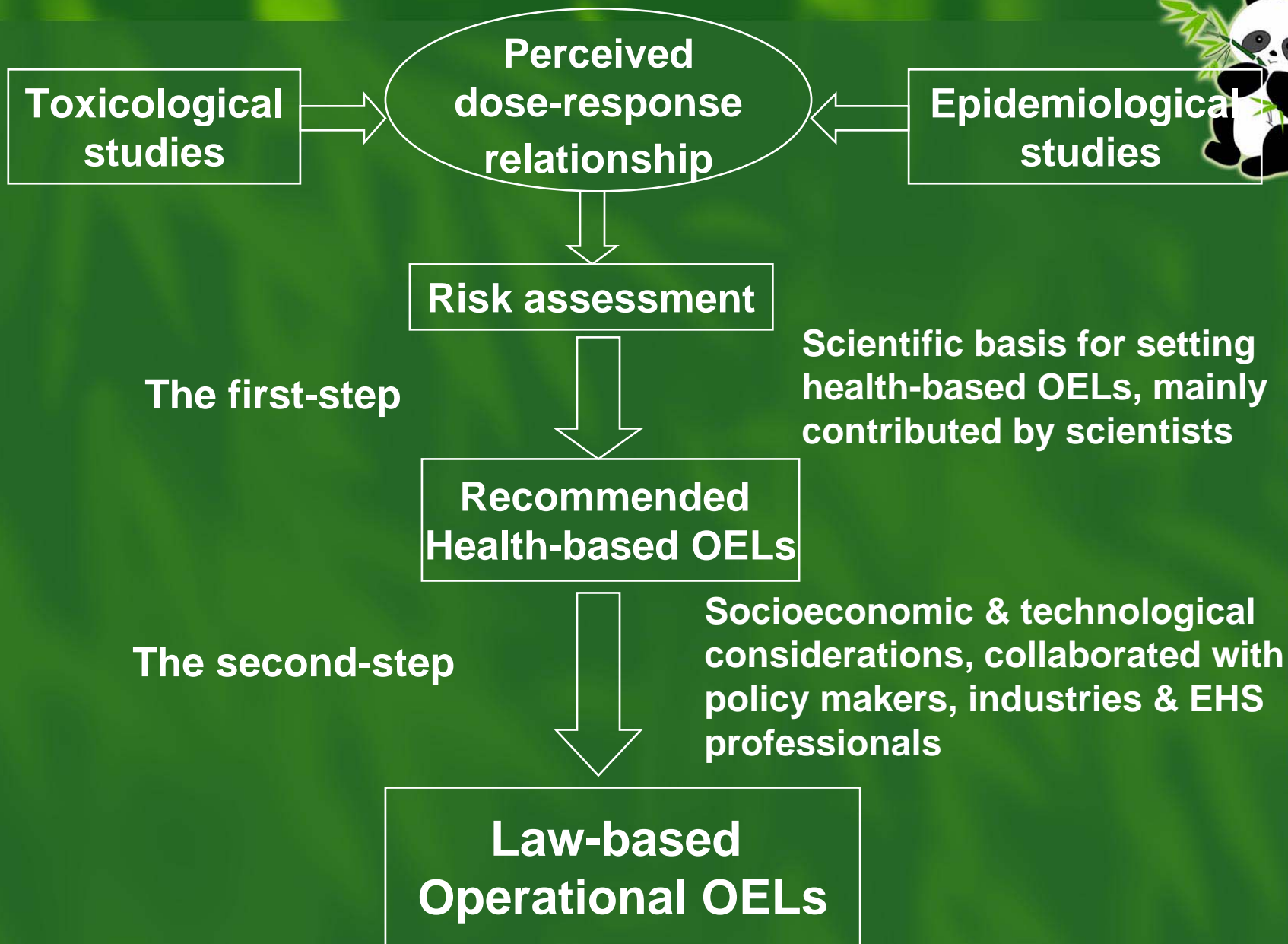
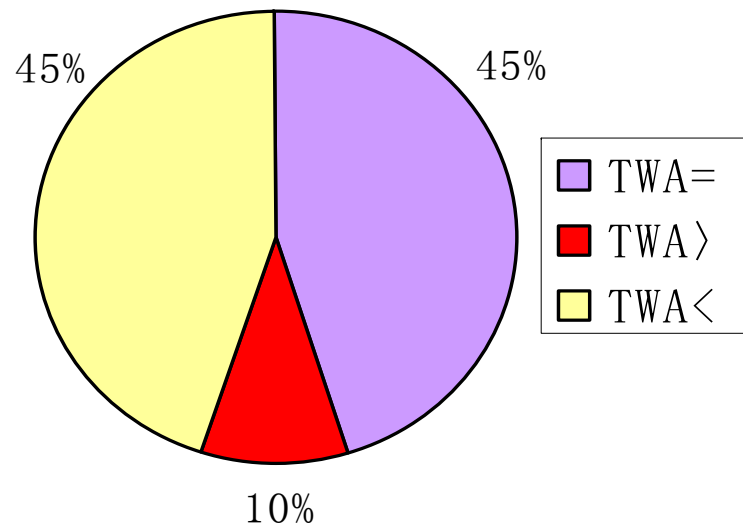


Figure 1 Two-step Strategy for OELs Setting

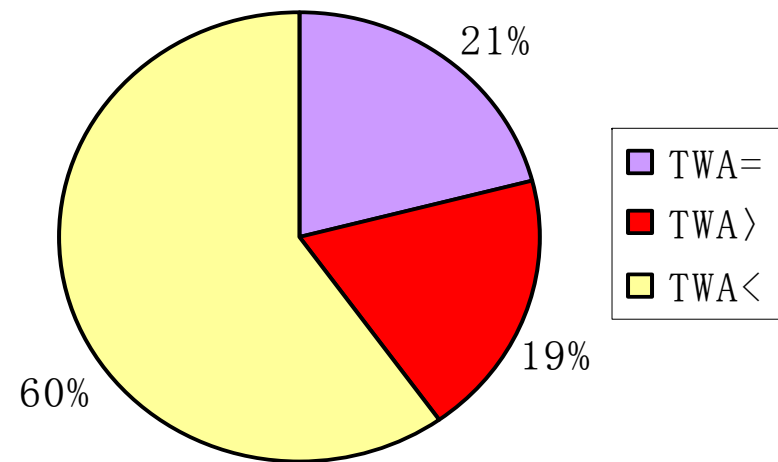
5. How are the regulations synchronized among neighboring countries?

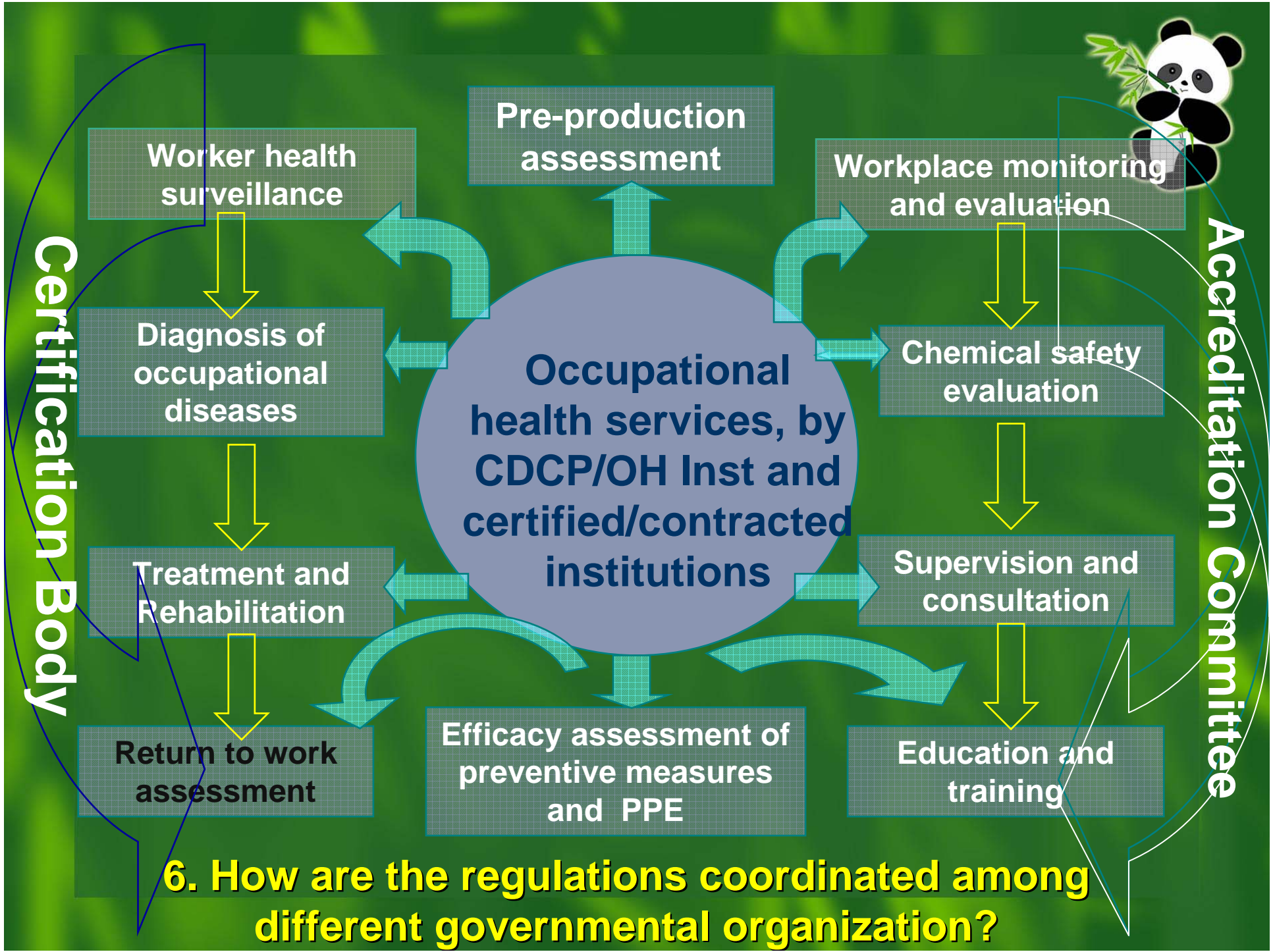


CHINA (n=330) VS AUSTRALIA (n=643)



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





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 ODPCA Act



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

中华人民共和国国家职业卫生标准

GBZ 2-2002

National Occupational Health Standards, P.R. China

GBZ 2-2002

工作场所有害因素职业接触限值

Occupational Exposure Limits for Hazardous

Agents in the Workplace

*Occupational Exposure Limits for Hazardous
Agents in the Workplace*

The Ministry of Health, P. R. China

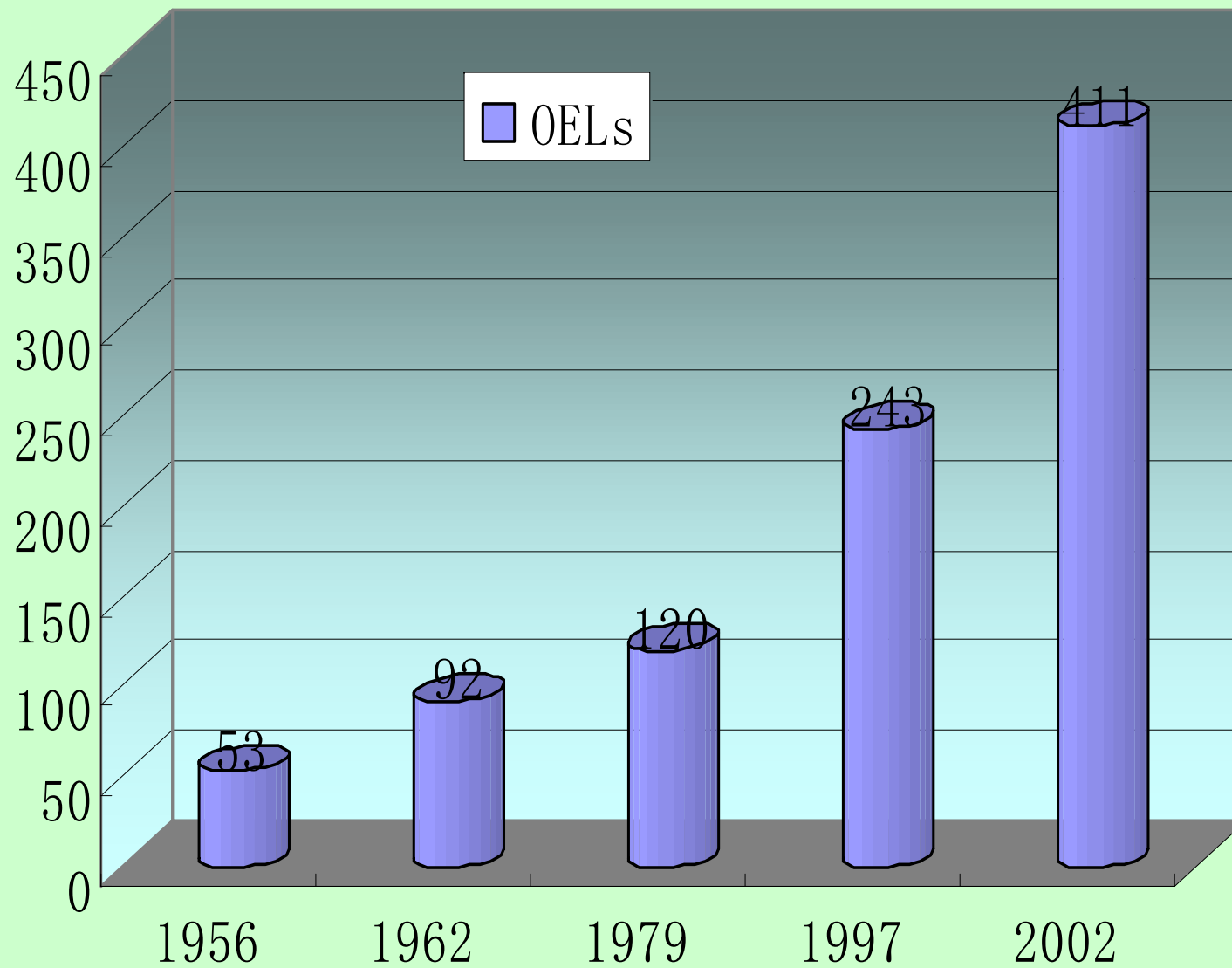
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Chronology of Occupational Exposure Limits (OELs) in China



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-STEEL and 6mg/m³ (2ppm) as PC-TWA since 2001**

Table 5 Currently adopted Benzene OELs in selected countries



| | TWA (ppm) | STEL (ppm) | MAC (ppm) | TRK (ppm) |
|-----------------------|---|---|---|--------------|
| China | 2 (6mg/m³) (2001-) | 3 (10mg/m³) (2001-) | 12 (40 mg/m³) (1950s- 2001) | |
| Germany | | | | 5 |
| Sweden | 0.5 | | | |
| United Kingdom | 5 | | | |
| US-NIOSH | 0.1(REL) | 1 (ceiling) | | |
| US-OSHA | 1(PEL) | 5 (ceiling) | | |



- ❖ **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



| Substance | MAC* (-2002) | PC-TWA (2002-) | PC-STEL (2002-) | Scientific basis |
|------------------|-------------------------------|-------------------|--------------------|--|
| Carbon disulfide | 10 | 5 | 10 | Menstrual disorders found in female workers at 10mg/m ³ |
| Mercury (vapor) | 0.01 | 0.02 | 0.04 | Negligible/acceptable risk at 0.02 mg/m ³ |

* 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



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

Risk of CDM inducing urinary bladder cancer



- ❖ 24.2×10^{-5} , in CDM manufacturing worker
- ❖ 7.3×10^{-5} in farming sprayers, substantially higher than the background rate (1.04×10^{-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