

Revised Regulations on Chemical Management in China

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Chemical Registration Center of MEP

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Contents

- Regulation on Safety Management of Hazardous Chemicals
- Measures on Environmental Management of New Chemical Substances

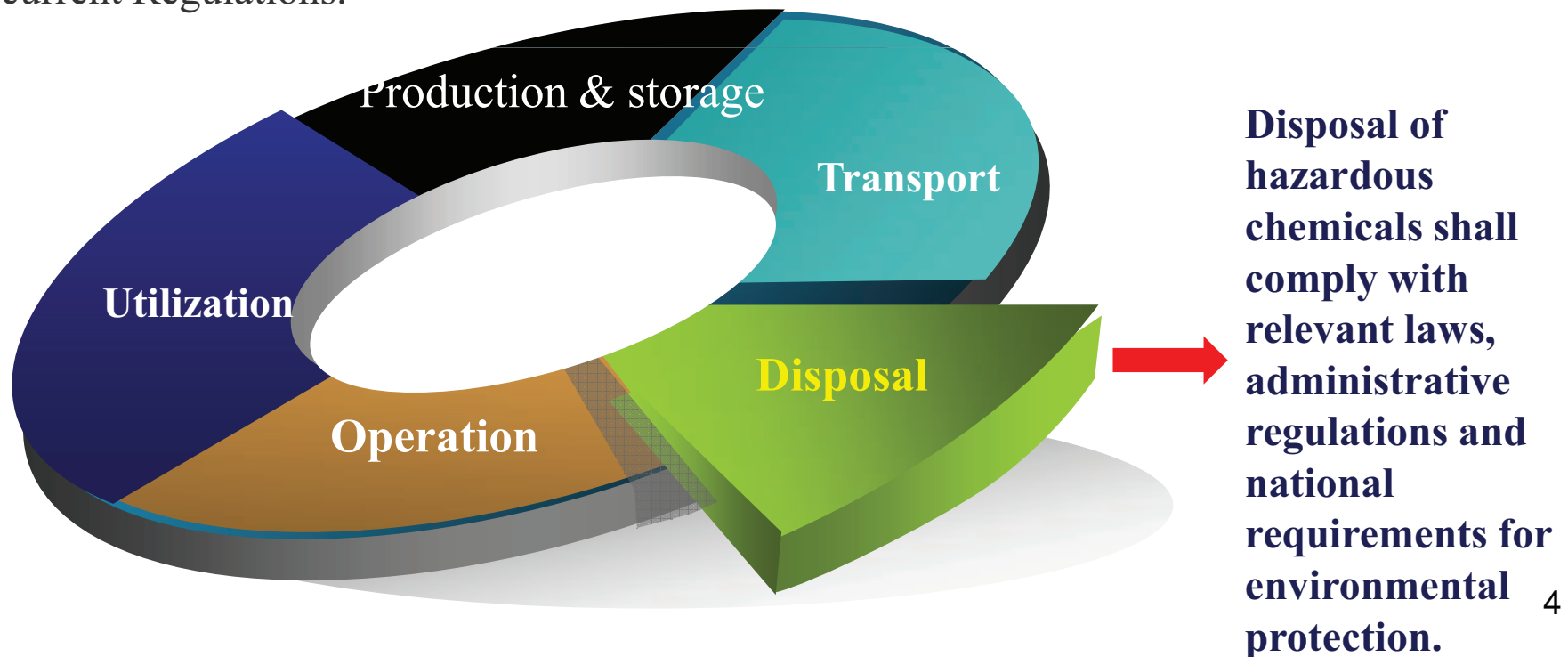
Regulation on Safety Management of Hazardous Chemicals

- Adopted at the 144th session of the Standing Committee of the State Council on Feb. 16, 2011
- Signed by Premier Wen Jiabao on Mar. 2
- State Council Decree No. 591
- Be executed from Dec. 1, 2011
- Be officially made public on Mar. 11
- Chapter I General Provisions (Article 1-10)
- Chapter II Safety of Production and Storage (Article 11-27)
- Chapter III Utilization Safety (Article 28-32)
- Chapter IV Operation Safety (Article 33-42)
- Chapter V Transportation Safety (Article 43-65)
- Chapter VI Registration of Hazardous Chemicals and Emergency Response (Article 66-74)
- Chapter VII Legal Liability (Article 75-96)
- Chapter VIII Supplementary Provisions (Article 97-102)

Focus of Amendment of the Regulations

(I) Adjustment of the application scope

- The former Regulations are applicable to six links, that is, production , operation, storage, transport, utilization and disposal of hazardous chemicals.
- The applicable scope of the amended Regulations no longer include **disposal of waste hazardous chemicals**. The New Regulations stipulates: Safety management of production , storage, utilization, operation and transport of hazardous chemicals is applicable to the current Regulations.



Focus of Amendment of the Regulations

(II) Change of definition of hazardous chemicals based on GHS

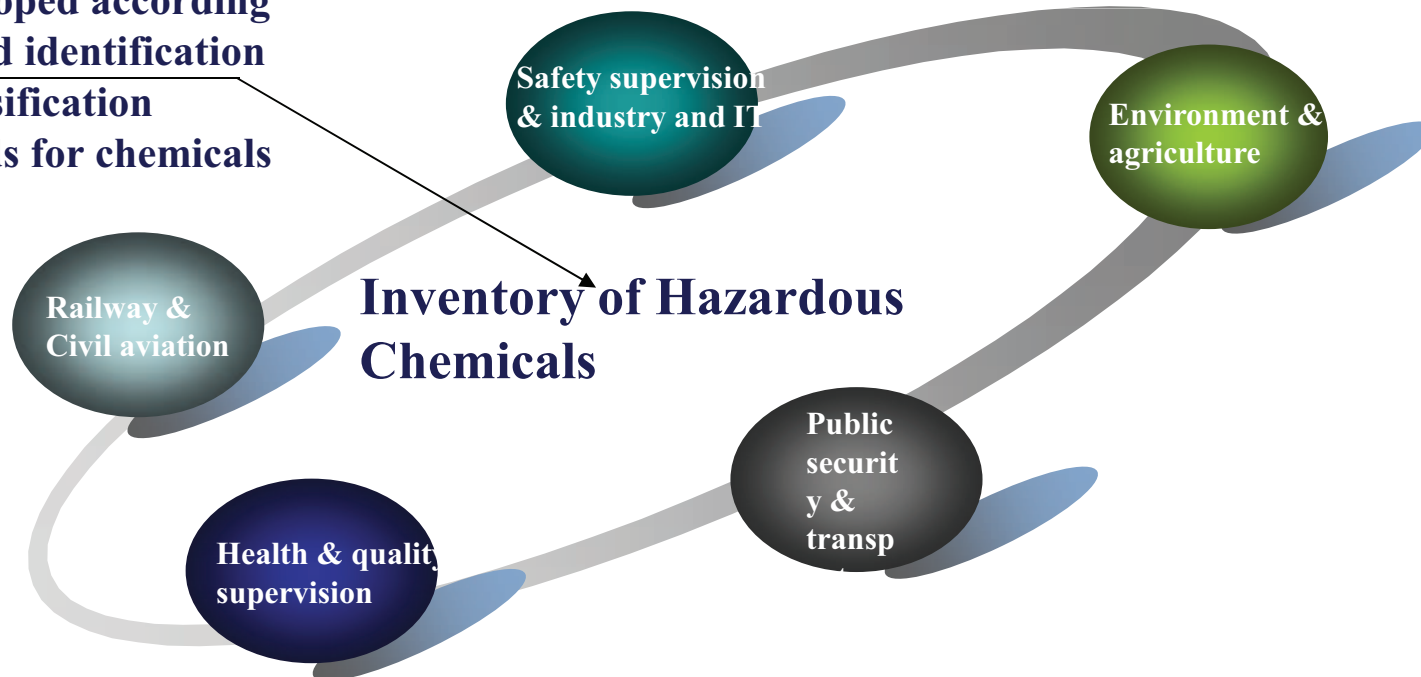
- The former definition is that for hazardous goods. The definition in the amended Regulations is based on the definition of GHS.
- The definition of hazardous chemicals in the former Regulations: It refers to explosives, compressed and liquefied gas, combustible liquid and solid, self-ignition substances and substance emitting flammable gases when in contact with water, oxidant and organic peroxides, toxic and corrosive substances and so on.
- The definition of hazardous chemicals in the amended Regulations: It refers to the chemicals with features such as toxicity, hazard, corrosion, explosion, combustibility and supporting combustion as well as deadly poisonous and other chemicals with hazards to humans, facilities and the environment.

Focus of Amendment of the Regulations

(III) Administration based on the Inventory of Hazardous Chemicals

- Requirement of the former Regulations: Hazardous chemicals shall be included in the List of Hazardous Goods (GB12268) released as a national standard.
- Requirement of the amended Regulations: The Inventory of Hazardous Chemicals shall be developed and release by relevant departments of the State Council according to the hazard identification and classification standards for chemicals with adjustment at appropriate time.

Be developed according to hazard identification and classification standards for chemicals



Focus of Amendment of the Regulations

Other inventories:

- The Inventory of Deadly Poisonous Chemicals will be marked in the Inventory of Hazardous Chemicals, which is determined by 10 departments.
- The Inventory of Hazardous Substances Easy to Make Explosives ” should be developed by public security department.
- The Inventory of Hazardous Chemicals Subject to Key Environmental Management should be developed by environmental protection department.
- The Inventory of Hazardous Chemicals (deadly poisonous chemicals and other hazardous chemicals) Prohibited from Transportation in Inland Rivers shall be developed and released by the competent transportation department in cooperation with competent environmental protection department, competent department of industry & information technology and work safety department of the State Council.

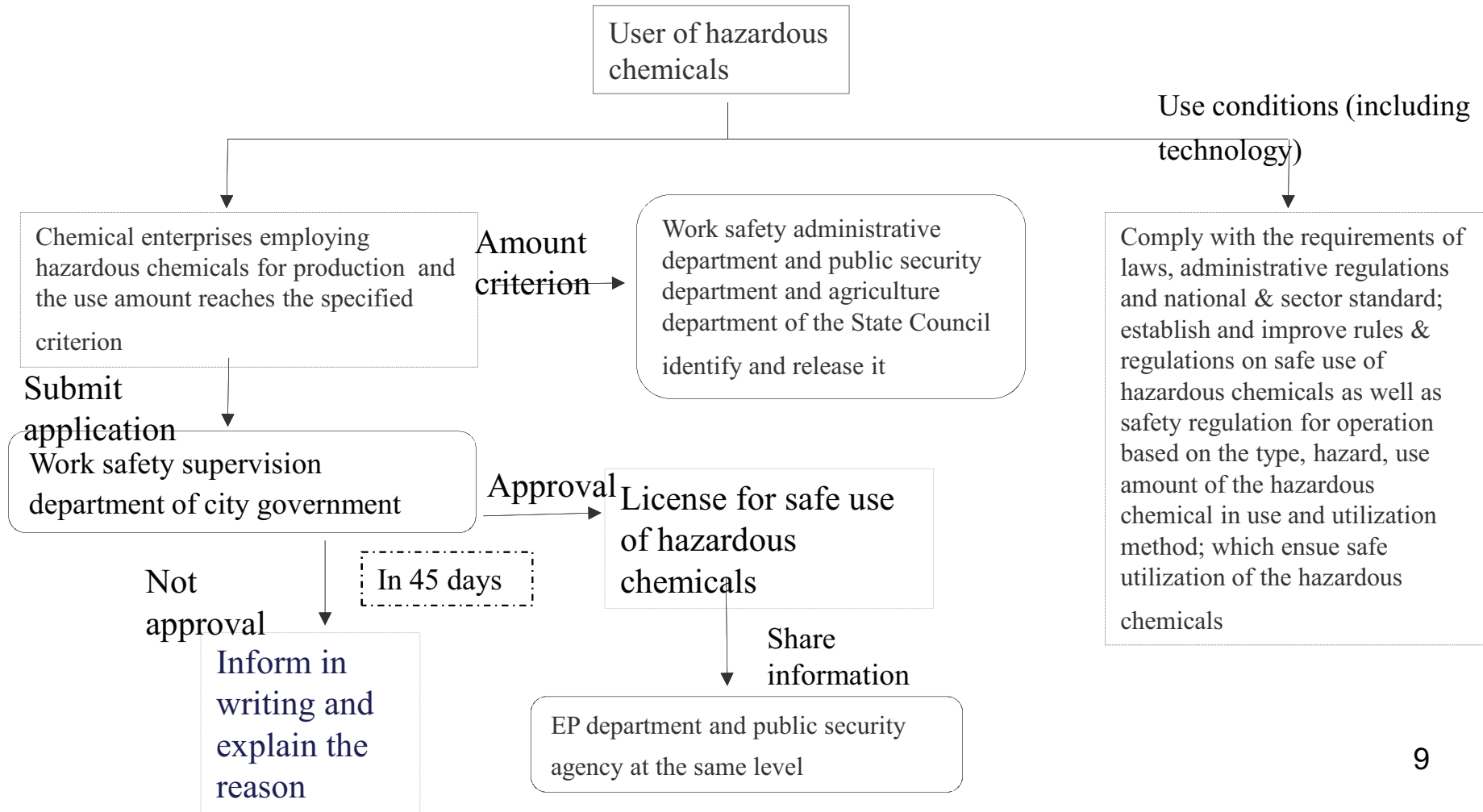
Focus of Amendment of the Regulations

(IV) Further standardize safety assessment system

Content	New Regulations (Decree No.591)	Former Regulations (Decree No. 344)
Assessment frequency	Once in every 3 years	<ol style="list-style-type: none"> 1. Deadly poisonous chemicals: Once a year 2. Other chemicals: Once in every 2 years
Assessment target	Safe production conditions of the current enterprise	Production and storage facilities of the current unit
Assessment institution	Have the qualification required by the State	Nil
Record unit	Safety supervision department of the government at county level	The department in charge of comprehensive work on supervision on the safety of hazardous chemicals of the government at city level
Record contents	Safety Assessment Report and the implementation of the correction program	Safety Assessment Report

Focus of Amendment of the Regulations

(V) Further improve safety management and license system for use of hazardous chemicals



Responsibility of environmental protection department specified in the Regulations

- In charge of environmental management registration of hazardous chemicals and new chemical substances
- Organize identification of environmental hazards of hazardous chemicals and assessment of their environmental risks
- Identify the hazardous chemicals under key environmental management

Article 16 Any enterprise manufacturing the hazardous chemicals under key environmental management shall report relevant information such as environmental release of the chemical to competent environmental protection department according to the requirements of the competent environmental protection department of the State Council. The competent environmental protection department may take corresponding environmental risk control measures if necessary.

Responsibility of environmental protection department specified in the Regulations

- Investigate environmental pollution accidents and ecological damages by relevant hazardous chemicals based on its responsibility and work division
- In charge of emergency environmental monitoring of the site of hazardous chemical pollution accident
- In charge of supervision on the disposal of waste hazardous chemicals



Measures on Environmental Management of New Chemical Substances

- Issuing institution: MEP
- Issuing date: January 19, 2010
- Implementation date: October 15, 2010
- Form: MEP Order No. 7
- Title: Measures on Environmental Management of New Chemical Substances
- Framework: 6 chapters with 52 articles

Chapter 2 Notification Procedures (11 Articles)



Chapter 5 Legal Liability (7 Articles)

Notification Types

- **Normal notification**

Four levels

- Level I: $1\text{t} \leq \text{notified quantity} < 10\text{t}$
- Level II: $10\text{t} \leq \text{notified quantity} < 100\text{t}$
- Level III: $100\text{t} \leq \text{notified quantity} < 1000\text{t}$
- Level IV: $\text{notified quantity} \geq 1000\text{t}$

Three forms: serial notification, joint notification and repeat notification

- **Simplified notification**

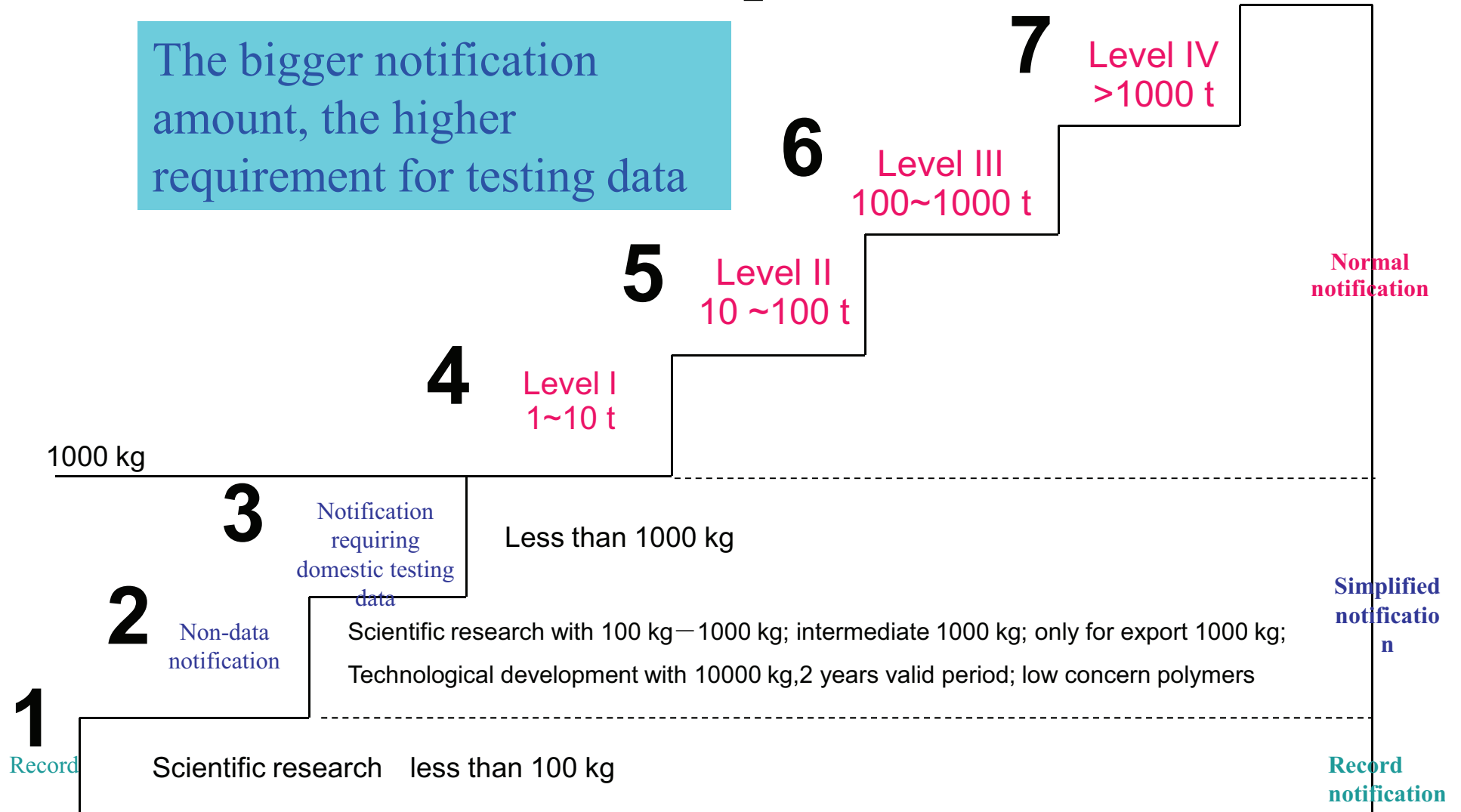
- Basic circumstance: $\text{notified quantity} < 1\text{t}$
- Specific circumstances
 - Intermediates or exportation only, $\text{notified quantity} < 1\text{t}$
 - For scientific research, $0.1\text{t} \leq \text{notified quantity} < 1\text{t}$
 - Polymers containing new chemical monomers of 2% or lower, or polymers of low concerns
 - Process and product R&D, $\text{notified quantity} < 10\text{t}$ (within 2 years)

- **Record notification**

- Scientific research, $\text{notified quantity} < 0.1\text{t}$
- Imported for conducting eco-toxicity tests of new chemicals within Chinese territory by using Chinese target organism

Terraced Data Requirements

The bigger notification amount, the higher requirement for testing data



Main Additions of Contents and Requirements

——General provisions and applicable scope

General provisions	Conduct prohibition
	Role models are encouraged
	Public supervision
	Hazard information shall not be confidential
Report the fact	Submit all known information
	Report on new characteristics
Areas	Bonded area and export processing zone included
Substance type	(Intentionally release) Articles
Conduct	Processing and use (key category)
Applicant	Oversea exporter should not directly make notification.

—Information requirement and review

Normal notification	GB classification (GHS)
	MSDS
	Risk assessment report
	Joint, serial and repeat notification are graded based on accumulated volumes
Review contents	Exposure extent
	Health and environment risks
	Risk control measures
	Management categories

—— Owner of Registration Certificate

First production /import report	Period: 30 days
	Report to: CRC-MEP
	Frequency (general, hazardous): Only once
	Frequency (key category): Each time
Annual report	Simple notification: Actual production/import
	Hazardous category: Implementation of risk control measures, actual impacts
	Key category: Annual plan
	Information reservation: 10 years
Information transfer	Normal notification
	Normal notification for key category: Monitoring or estimate emission

— Others (1)

Contents of Registration Certificate	Management type, risk control measures
Inclusion in the Inventory	Period: 5 years
	Hazardous and key category: Submit actual activity report
Re-notification	Alteration of use of key category
	Processor and user
Inter-department reporting	Hazardous and key category
	Announcement/Public notice

——Others (2)

Supervision	Supervision Notice: Key and hazardous categories
	Period: 30 days after the first production/ import report
	Contents: Management type, risk control measures, administration requirement and main points for supervision specified in the registration certificate
Check new chemical	Once in every 5 years

—— Others (3)

Handling period	Normal notification: Maximum 90 days
	Simplified notification (basic situation): Maximum 60 days
	Simplified notification (Special situation): Maximum 30 days
Re-notification	Rise of amount level
Scientific research	Use limit: Only for scientific research
	Waste: Disposal as hazardous waste
Testing institution	MEP check and announcement
	GLP Guidelines
	Testing method

Relevant Events

- MEP released the following 6 supporting documents on September 16, 2010
 - *Guidance for Notification of New Chemical Substances*
 - *Specifications on Supervision, Management and Inspection of New Chemical Substances*
 - *Application Form for Normal notification of New Chemical Substances and Filling Out Explanations*
 - *Application Form for Simplified Notification of New Chemical Substances and Filling Out Explanations*
 - *Scientific Record Form for New Chemical Substances and Filling Out Explanations*
 - *Initial Report Form for New Chemical Substances and Filling Out Explanations*

Relevant Events

- The Third Phase of Chemicals Review Expert Committee has been established, November 16, 2010, with members going up to 100
- MEP has issued and implemented the Measures on Management of Environmental Management Experts on Chemical Substances on May 11, 2011
- MEP carried out inspection and examination on institutions for chemical testing since July 2011.

Relevant Events

- Relevant technical norms
 - *Expert Technical Review Process for Normal notification of New Chemicals*
 - *Expert Technical Review Process for Simplified Notification of New Chemicals*
 - *Technical Requirements on Substance Identity Information in New Chemical Substance Notification*
 - Standardizing information of substance identity submitted by applicant
 - Improving the quality of substance identity
 - As criteria for export review

Status of Implementation

- Many applications of specific circumstances of simplified notification and record notification cases
 - Relatively many applications of basic circumstances of simplified notification
 - Relatively less applications of normal notification
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- ◆ Report and approval specific circumstances of simplified notification and record notification
 - ◆ Regularly carry out review on basic circumstances of simplified notification
 - ◆ Carry out normal notification review when necessary

THANK YOU !