

How to Export Chemical Substances to China

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About REACH24H

- **Offering one-stop global market access services**
- **Headquarters in Hangzhou, China and global offices in Ireland, United Kingdom, United States, South Korea, and Taiwan, China.**
- **Support on a broad range of industries including industrial chemicals, agrochemicals, cosmetics, food and food contact materials, and consumer products.**
- **Service content includes product registration and consulting, regulatory data and news alerts, conferences, workshops and webinars, software and regulatory database services.**



Catalogue



01 Overview of Chemical Regulation

Regulation Interpretation
and Supervision 02



03 Summary and Suggestion

Part 1 Overview of Chemical Regulations

- Responsible authority
- Regulation system

Responsible authority

Regulatory authorities:
customs department

Regulatory authorities:
Emergency management department,
Competent traffic management department
(port area)

Regulatory authorities:
Environmental Protection
Department

**Export and
import**

Transport

Warehousing

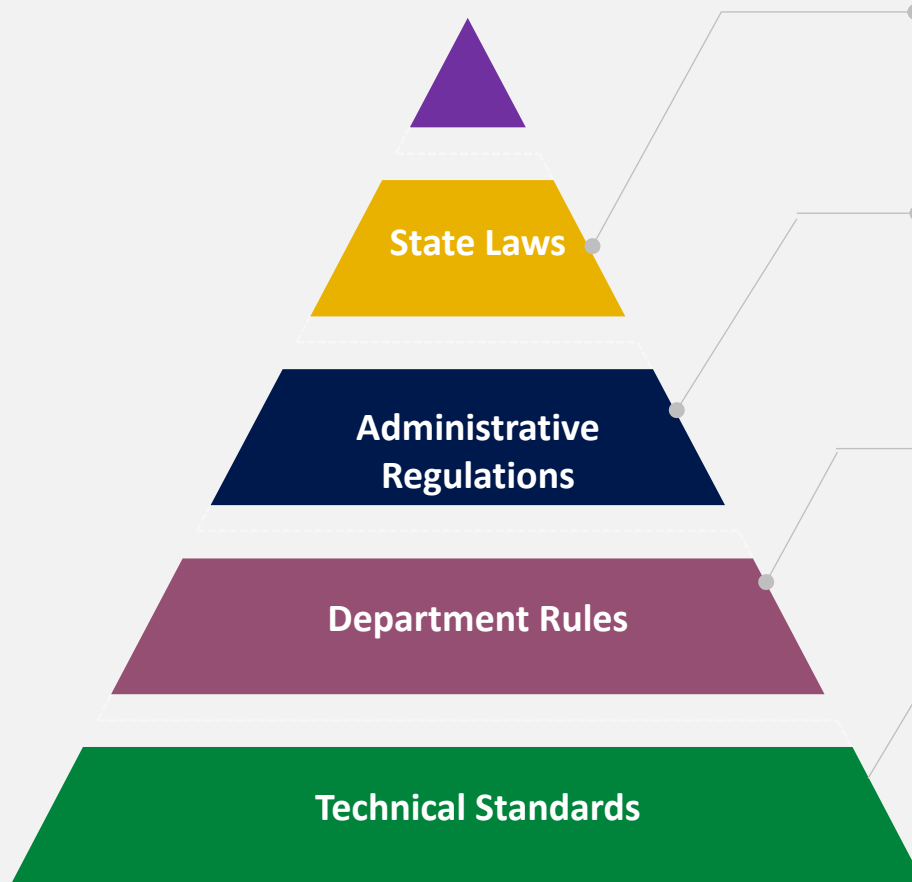
Use/sale

Discard

Regulatory authorities:
public security bureau,
competent traffic management department,
competent railway management department,
competent civil aviation management department

Regulatory authorities:
Market supervision and management
department, emergency management
department, public security bureau

Regulation System



Level 1 – State Laws

Law of the People’s Republic of China on Safety of Hazardous Chemicals (Draft)
Production Safety Law of the People’s Republic of China

Level 2 – Administrative Regulations

Regulations on the Control over Safety of Hazardous Chemicals (Decree No. 591 of the State Council)
Regulations on the Administration of Precursor Chemicals (Decree No. 445 of the State Council)

Level 3 – Department Rules

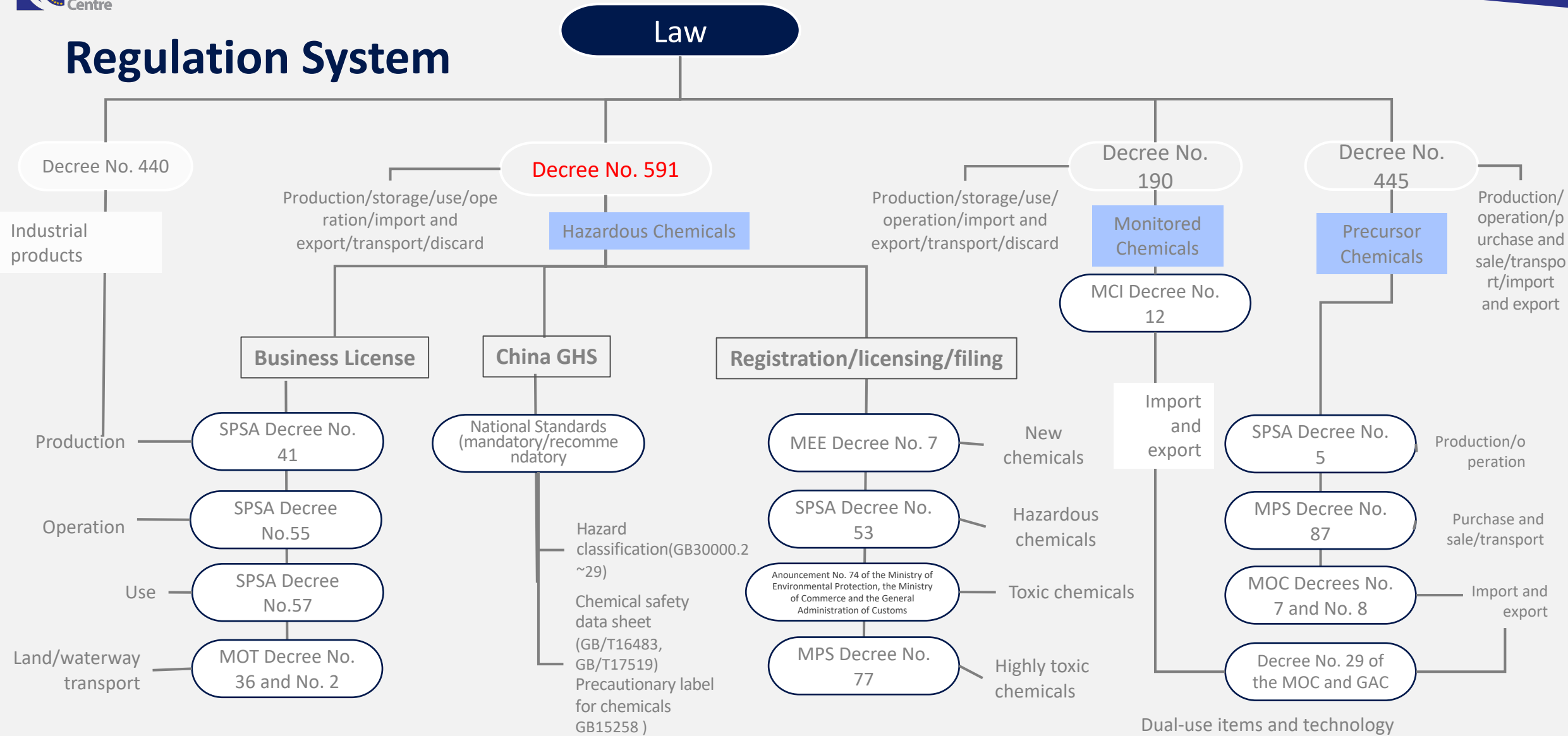
Measures for the Administration of Hazardous Chemicals Registration (SAWS Order No. 53)
Measures on the Administration of Physical Hazard Identification and Classification for Chemicals (SAWS Order No. 60)

Level 4 – Technical Standards

Rules for Classification and Labelling of Chemicals (GB 30000.2~29-2013);
General Rules for Preparation of Precautionary Label for Chemicals (GB 15258-2009);
Safety Data Sheet for Chemical Products - Content and Order of Sections (GB/T 16483-2008);
Guidance on the Compilation of Safety Data Sheet for Chemical Products (GB/T 17519-2013)

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Regulation System



Part 2 Regulation Interpretation and Supervision

- Supervision target
- Mainly inventory

(New substance chemical and hazardous chemical)

- Supervision measure

Supervision target

China Chemical Management

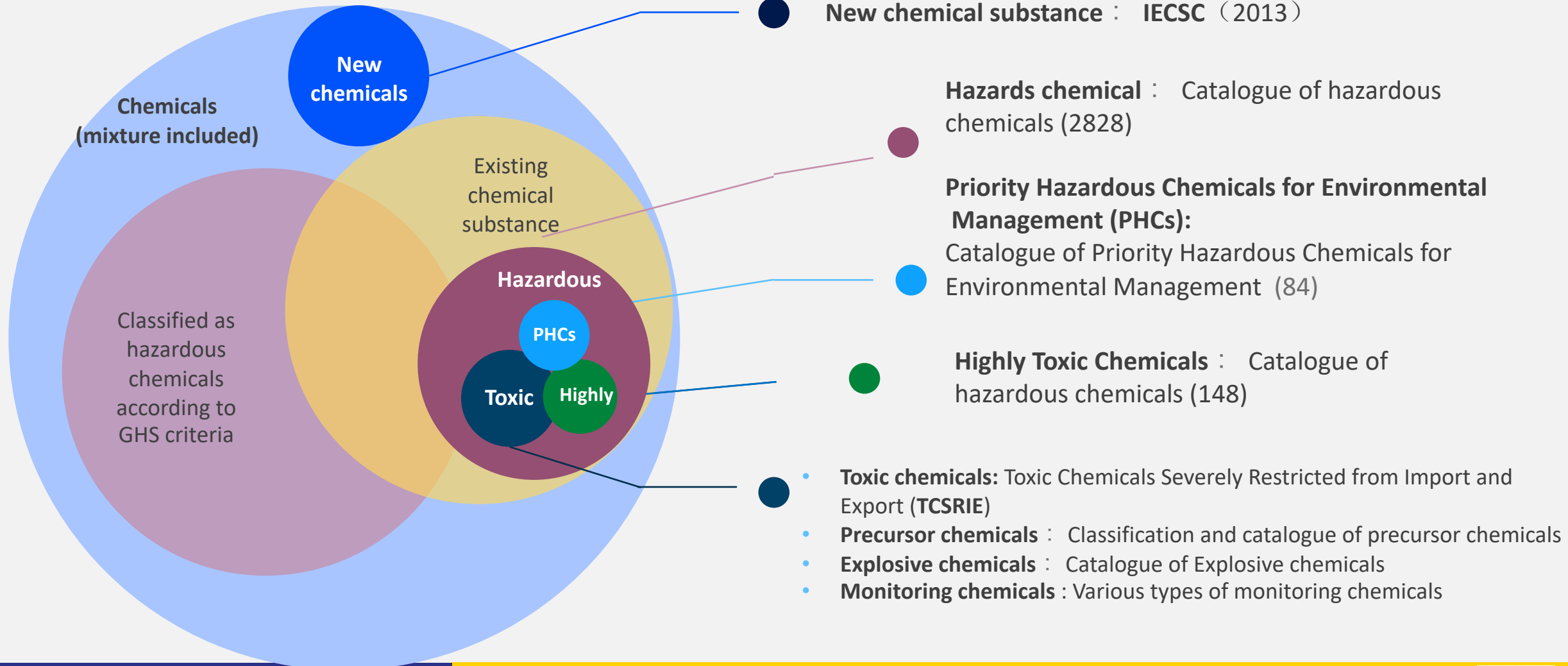
New chemical
substance

Hazardous chemical

Dangerous Goods

Other Controlled
Chemical

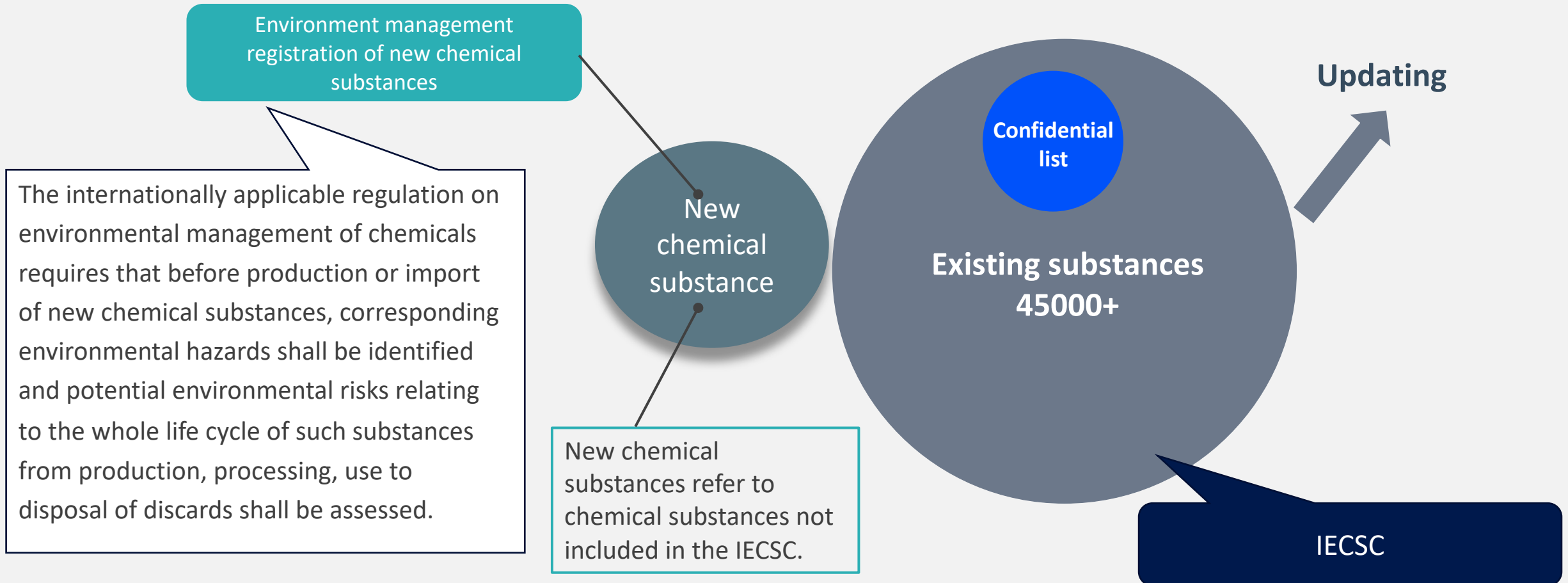
Mainly inventory



| Chemicals | Management inventory | Management method | Regulations |
|------------------------|---|--|---|
| New Chemical Substance | Not listed in the IECSC | <ul style="list-style-type: none"> Environmental management Registration Production and import license Risk evaluation China GHS | <ul style="list-style-type: none"> Decree 591; Measures for Environmental Management of New Chemical Substances |
| Hazardous Chemicals | <ul style="list-style-type: none"> Inventory of hazardous chemicals (2015) Hazardous chemicals with GHS hazard classification | <ul style="list-style-type: none"> Production, import and export registration Production/operation, use, transport permit China GHS | <ul style="list-style-type: none"> Decree 591; Measures for registration of hazardous chemicals; Chemical physical hazard identification and classification management methods |
| Highly toxic | <ul style="list-style-type: none"> Catalogue of hazardous chemicals (2015) Remarks "highly toxic" | <ul style="list-style-type: none"> Purchase, transport permit China GHS | <ul style="list-style-type: none"> Decree 591; Administrative measures on the purchase of toxic chemicals and the administration of road transport permits |
| PHCs | Catalogue of Priority Hazardous Chemicals for Environmental Management (2014 Version) | <ul style="list-style-type: none"> China GHS | <ul style="list-style-type: none"> Decree 591; |

| Chemicals | Management inventory | Management tool | Registration |
|--|--|---|---|
| Toxic Chemicals Severely Restricted | List of toxic chemicals severely restricted to be imported into or exported from china | <ul style="list-style-type: none"> • Environmental management Registration • Import and export liscence • Risk evaluation • China GHS | <ul style="list-style-type: none"> • Decree 591; • MEP Notice No.113 (2009): Notice on Reinforce Environmental Management of Import and Export of Toxic Chemicals • MEP,CUSTOMS Joint Announcement No.85 (2014) • MEP,CUSTOMS Joint Announcement NO.86 (2016) |
| precursor chemicals | Catalogue of Explosive chemicals | <ul style="list-style-type: none"> • Production, operation, purchase, transportation, import and export license • China GHS | <ul style="list-style-type: none"> • Decree 445 |
| Explosive chemicals | Catalogue of Explosive chemicals (2011) | <ul style="list-style-type: none"> • Purchase, transport permit • China GHS | <ul style="list-style-type: none"> • Decree 591 |
| Monitoring chemicals | Various types of monitoring chemicals | <ul style="list-style-type: none"> • Production, operation or use permit • China GHS | <ul style="list-style-type: none"> • Decree 190 |

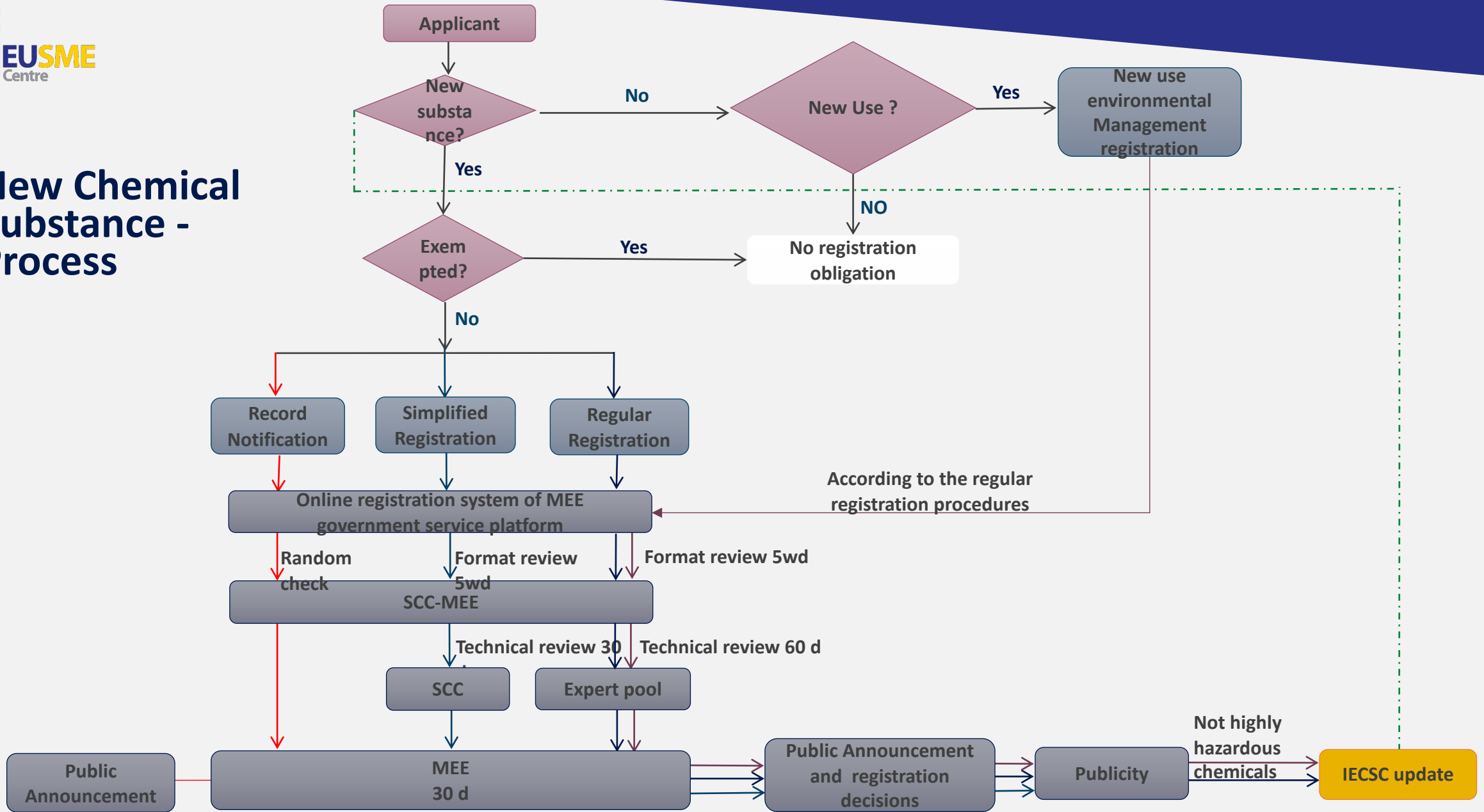
Mainly inventory - New Chemical Substance



New Chemical Substance - Type

| Registration Types | Substance | Volume Limit | Timeline | Evaluation Points | Certificate |
|-------------------------|----------------------|------------------|--------------|--|-------------|
| Record Notification | Non-polymer | Less than 1 MT/y | 1-2 weeks | Statement/proof for clarification and confirmation | No |
| | Polymer 2% or PLC | No limit | | | |
| Simplified Registration | Not specified | 1-10 MT/y | 8-12 months | <ol style="list-style-type: none"> Physical Chemical Property Biodegradation Bioaccumulation Acute toxicity (and long-term) toxicity to aquatic species | Yes |
| Regular Registration | Not specified | > 10 MT/y | 14-20 months | <ol style="list-style-type: none"> Physical Chemical Property Toxicological Property Eco-Toxicological Property <p>Most importantly, Biodegradation, and Bioaccumulation,</p> | Yes |

New Chemical Substance - Process



Mainly inventory - Hazardous Chemical

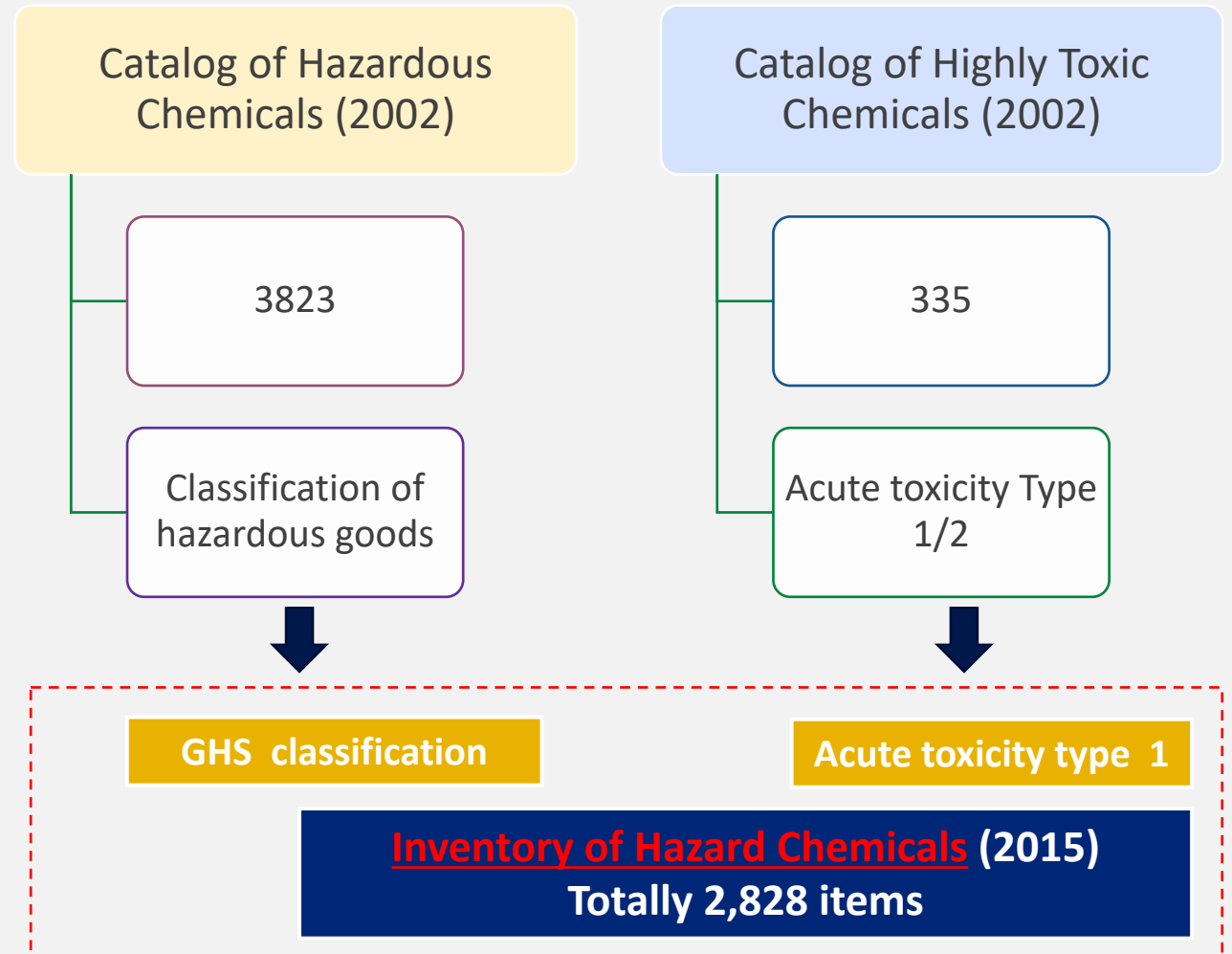
国家安全生产监督管理总局 中华人民共和国工业和信息化部
 中华人民共和国公安部 中华人民共和国环境保护部
 中华人民共和国交通运输部 中华人民共和国农业部
 中华人民共和国国家卫生和计划生育委员会
 中华人民共和国国家质量监督检验检疫总局
 国家铁路局 中国民用航空局

公告
 2015年 第5号

依照《危险化学品安全管理条例》(国务院令591号)有关规定,安全监管总局会同工业和信息化部、公安部、环境保护部、交通运输部、农业部、国家卫生计生委、质检总局、铁路局、民航局制定了《危险化学品目录(2015版)》,现予公布,请自行下载(网址: www.chinasafety.gov.cn)。《危险化学品目录(2015版)》于2015年5月1日起施行。《危险化学品名录(2002版)》(原国家安全生产监督管理局公告2003年第1号)、《剧毒化学品目录(2002年版)》(原国家安全生产监督管理局等8部门公告2003年第2号)同时废止。

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 国家卫生计生委 质检总局 铁路局
 民航局

2015年2月27日





Determination Principle(81 classification with gray background)

| | | | | | | | | |
|-----------------------|---|----------------|---------------|----------------------------|---------------|----------|----------|----------|
| Physical Hazards | 1. Explosive | Unst. Expl. | Div. 1.1 | Div. 1.2 | Div. 1.3 | Div. 1.4 | Div. 1.5 | Div. 1.6 |
| | 2. Flammable gases | Cat. 1 | Cat. 2 | Unst. Gas A | Unst. Gas B | | | |
| | 3. Aerosols | Cat. 1 | Cat. 2 | Cat. 3 | | | | |
| | 4. Oxidizing gases | Cat. 1 | | | | | | |
| | 5. Gases under pressure | compressed gas | liquefied gas | Refrigerated liquefied gas | Dissolved gas | | | |
| | 6. Flammable liquid | Cat. 1 | Cat. 2 | Cat. 3 | Cat. 4 | | | |
| | 7. Flammable solid | Cat. 1 | Cat. 2 | | | | | |
| | 8. Self-reactive substance/mixture | Type A | Type B | Type C | Type D | Type E | Type F | Type G |
| | 9. Pyrophoric liquid | Cat. 1 | | | | | | |
| | 10. Pyrophoric solid | Cat. 1 | | | | | | |
| | 11. Self-heating substance/mixture | Cat. 1 | Cat. 2 | | | | | |
| | 12. Substance/mixture which in contact with water, emit flammable gases | Cat. 1 | Cat. 2 | Cat. 3 | | | | |
| | 13. Oxidizing liquid | Cat. 1 | Cat. 2 | Cat. 3 | | | | |
| | 14. Oxidizing solid | Cat. 1 | Cat. 2 | Cat. 3 | | | | |
| | 15. Organic peroxides | Type A | Type B | Type C | Type D | Type E | Type F | Type G |
| | 16. Corrosive to metal | Cat. 1 | | | | | | |
| Health Hazards | 1. Acute toxic - oral/inhalation/dermal | Cat. 1 | Cat. 2 | Cat. 3 | Cat. 4 | Cat. 5 | | |
| | 2. Skin corrosion/irritation | Cat. 1 | Cat. 1A | Cat. 1B | Cat. 1C | Cat. 2 | Cat. 3 | |
| | 3. Serious eye damage/irritation | Cat. 1 | Cat. 2 | Cat. 2A | Cat. 2B | | | |
| | 4. Respiratory/Skin Sensitization | Cat. 1 | Cat. 1A | Cat. 1B | | | | |
| | 5. Germ cell mutagenicity | Cat. 1A | Cat. 1B | Cat. 2 | | | | |
| | 6. Carcinogenicity | Cat. 1A | Cat. 1B | Cat. 2 | | | | |
| | 7. Reproductive toxicity | Cat. 1A | Cat. 1B | Cat. 2 | Lactation | | | |
| | 8. STOT - single exposure | Cat. 1 | Cat. 2 | Cat. 3 | | | | |
| | 9. STOT - repeated exposure | Cat. 1 | Cat. 2 | | | | | |
| | 10. Aspiration hazard | Cat. 1 | Cat. 2 | | | | | |
| Environmental Hazards | 1.1 Hazardous to the aquatic environment - Acute | Cat. 1 | Cat. 2 | Cat. 3 | | | | |
| | 1.2 Hazardous to the aquatic environment - Chronic | Cat. 1 | Cat. 2 | Cat. 3 | Cat. 4 | | | |
| | 2. Hazardous to the ozone layer | Cat. 1 | | | | | | |

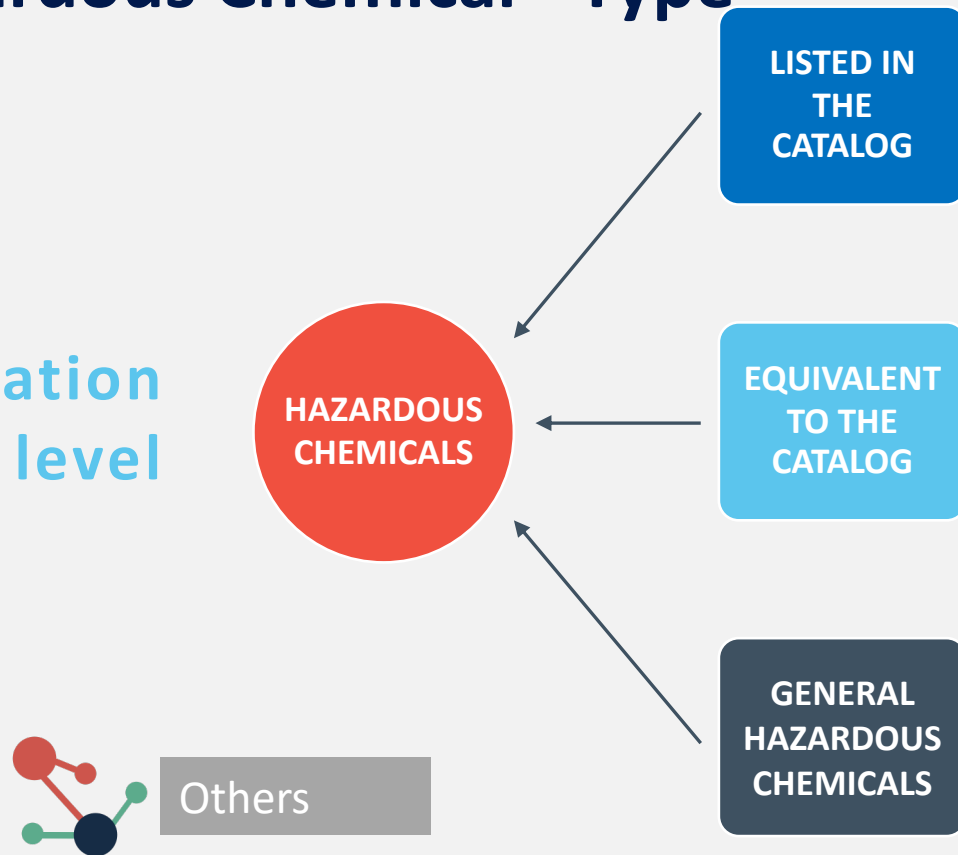
14 GHS classifications un-adopted by Inventory (excluded from the inventory):

- Explosive Cat. 1.5
- Explosive Cat. 1.6
- Aerosols Cat. 2
- Aerosols Cat. 3
- Flammable liquid Cat. 4
- Self-reactive Type F
- Self-reactive Type G
- Organic peroxides Type G
- Acute Toxic Cat. 4
- Acute Toxic Cat. 5
- Skin Corr./Irrit. Cat. 3
- Aspiration hazard Cat. 2
- Aquatic hazard - Acute Cat. 3
- Aquatic hazard - Chronic Cat. 4



Hazardous Chemical - Type

Regulation level



- Chemicals of low hazard according to GHS classification
- Non-hazardous chemicals

Inventory of Hazardous Chemicals 2015

- ✓ Items 1-2827
- ✓ Item 2828: 88 sub-items

Conforming to the Determination Principle & 70% principle

- ✓ Conforming to the Determination principle: 81 items of GHS classification
- ✓ Conforming to the 70% principle, constituents listed in the Catalog $\geq 70\%$

Only conforming to the Determination Principle

- ✓ Conforming to the Determination Principle: 81 items of GHS classification
- ✓ **Nonconforming to the** 70% principle, constituents listed in the inventory **<70%**

Hazardous Chemical - Supervision Measure

| | In-inventory management | | | Out-inventory management | |
|-----------------------------------|---|---|---|--|---|
| | ①Entry 1-2827 | ②Entry 2828 | ③Classification conforming to the catalog-defined principle and the $\geq 70\%$ requirement | ④Classification conforming to the catalog-defined principle but nonconforming to the $\geq 70\%$ requirement | ⑤Classification nonconforming to the catalog-defined principle |
| Classification and identification | Classification according to the Implementation guidelines in combination with GB30000 standards | Determination of hazard risks and classification according to GB30000 standards | Determination of hazard risks and classification according to GB30000 standards | Determination of hazard risks and classification according to GB30000 standards | Determination of hazard risks and classification according to GB30000 standards |
| SDS and GHS label | Required | Required | Required | Required | Required |
| Hazardous chemical registration | Required | Required | Required | Required | Not required |
| Production/operation permit | Required | Required | Required | Not required | Not required |
| Import and export supervision | Required | Required | Required | Required | Sample inspection |
| Hazardous chemical warehouse | Required | Required | Required | According to local requirements | Not required |

Hazardous Chemical - Supervision Measure

Hazard identification

Classification and determination

Risk assessment

Information transfer

SDS

Label

Registration/filing/ permit

Hazardous chemical registration

New substance registration

Production/operation/use/purchase/transport/import and export permit

Restriction/elimination

Forbidden, limited and controlled

Industrial restructuring

Substitute products

Part 3 Summary and suggestion

- New chemical substance declaration
- Hazardous chemical registration
- Release order of toxic chemicals for import or export
- Import and export permit for dual-use items
- GHS



- New chemical substance declaration
- Hazardous chemical registration
- Production/operation/use permit for hazardous chemicals
- Purchase permit/filing for highly toxic chemicals
- Production permit for precursor chemicals
- Production permit for industrial products
- GHS

- Operation permit for hazardous chemicals
- Technical precautions for highly toxic chemicals
- Operation permit for precursor chemicals
- Special permit for production of monitored chemicals
- GHS

- Transport permit for highly toxic chemicals
- Transport permit for precursor chemicals
- JT/T 617

- Determination of hazardous waste
- Declaration of hazardous waste for registration
- Operation permit for hazardous waste
- Transfer sheet for hazardous waste
- VOC

Suggestion

- Many laws and regulations
- Local management difference



Policy warning
Reasonable control

- Wide distribution of factories/suppliers
- Involvement of diverse industries



- Establish chemical regulations database of “enterprise”
- Fully understand management requirements of regulations (scope of materials, activity range, key management points)
- Have sound communication with local management departments
- Seek external exchange and help from industrial peers or consulting agencies

- Highly specialized
- Experience requirement

Thanks for listening !



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