

Chemicals management policies in Some Asian countries/Regions

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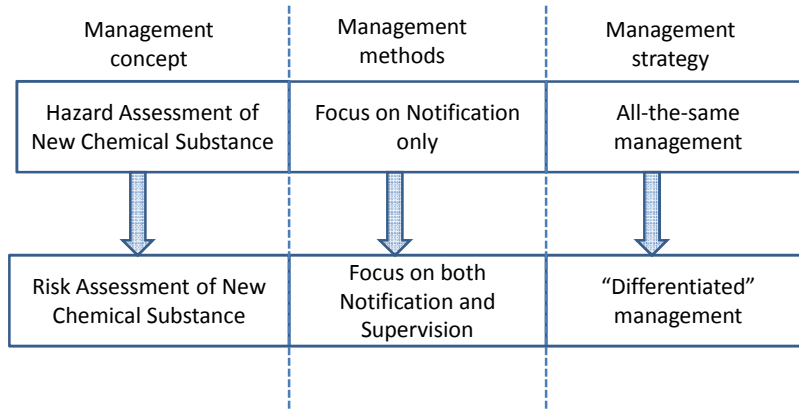
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China – Regulation on New Chemical Substances



The management of new chemicals is the **starting point**. The final goal is to promote the management of all chemicals.

China – Regulation on New Chemical Substances

- ◆ Having come into Force: October 15th, 2010.
- ◆ Qualified registrants: Entities registered within Chinese Mainland jurisdiction.
Entities outside can appoint an representative inside the jurisdiction.
- ◆ New chemical substances: not listed in the Inventory of Existing Chemical substances of China (IECSC)

| Items | Nickel Substances |
|---|---|
| Nickel substances in web version of IECSC | Nickel metal (7440-02-0); Nickel sulphate (7786-81-4); Nickel chloride (7718-54-9); Nickel nitrate (13138-45-9 and 14216-75-2); Nickel oxide (1313-99-1); Nickel (hydroxy)carbonate (12607-70-4 and 3333-67-3); Nickel dihydroxide (12054-48-7); Nickel sulphamate (13770-89-3); Ni subsulphide (12035-72-2); |
| Nickel substances not in web version of IECSC | Nickel oxide (11099-02-8); Nickel (hydroxy)carbonate (12122-15-5); Nickel acetate (6018-89-9); Ni sulphide (16812-54-7); Nickel sinter oxide; Nickel matte (69012-50-6); Ni hydroxide precipitate; Ni Ash; Mixed hydroxycarbonate; Sludge |

Note: Nickel substances not in web version of IECSC do not indicate they are not regarded as the existing substances. If necessary, we can ask the Register Center of MEP to check nickel substances from their internal version of IECSC.

China – Regulation on New Chemical Substances

- Tier-Mode registration (according to the tonnage band)

1. Putting on records

2. Simplified registration

3. Normal registration includes:

- serial registration
- combined registration
- combined serial registration

Re-registration is allowed.

China – Regulation on New Chemical Substances

| Registration | Step-mode | Requirement |
|-------------------------|-------------------------|--|
| Recording | | Scientific research and <100kg; imported samples for eco-toxicological test. |
| Simplified registration | No data notification | Scientific research and 100~1000kg; intermediate product and <1000kg; export only and <1000kg; technical development and <10000kg and < 2 years; low-concern polymer |
| | Test data notification* | Other < 100kg |
| Normal Registration | Grade 1 | 1-10t |
| | Grade 2 | 10-100t |
| | Grade 3 | 100-1000t |
| | Grade 4 | 1000t or more |

China – Regulation on New Chemical Substances

Minimum Requirements for data on physical-chemical properties:

- **Physical state** under normal temperature and pressure.
- Corresponding physical and chemical data:
 - **Gaseous state:** oxidizability, self-ignition temperature, combustibility, explosion limit and threshold.
 - **Liquid state:** boiling point, density, vapor pressure, n-octanol/water partition coefficient, water solubility, pH value, surface tension, flash point, oxidizability, self-ignition temperature, flammability and explosibility.
 - **Solid state:** melting point, density, n-octanol/water partition coefficient, water solubility, particle size, oxidizability, self-ignition temperature, flammability and explosibility.
 - **Other:** data on items applicable for testing, in addition to the above-mentioned items.

China – Regulation on New Chemical Substances

➤ **Substances – Minimum Requirements for data on Toxicology Test**

| Data requirement | Grade 1 1-10t/a | Grade 2 10-100t/a | Grade 3 100-1000t/a | Grade 4 ≥1000t/a |
|--|--------------------|----------------------|------------------------|---------------------|
| Acute toxicity | √ | √ | √ | √ |
| 28-day Repeated contamination toxicity | √ | √ | √ | √ |
| Mutagenicity | √ | √ | √ | √ |
| 90-day repeated contamination toxicity | | √ | √ | √ |
| Reproduction/growth toxicity | | √ | √ | √ |
| Toxic substances dynamics | | √ | √ | √ |
| Chronic toxicity | | | | √ |
| carcinogenicity | | | | √ |
| other | | | | |

China – Regulation on New Chemical Substances

➤ Substances--Minimum Requirements for data on **Eco-toxicology Test**

| Data requirement | Grade 1 1-10t/a | Grade 2 10-100t/a | Grade 3 100-1000t/a | Grade 4 ≥1000t/a |
|---|--------------------|----------------------|------------------------|---------------------|
| Algal growth inhibition toxicity | √ | √ | √ | √ |
| Daphnia acute toxicity | √ | √ | √ | √ |
| Fish acute toxicity | √ | √ | √ | √ |
| Active sludge respiration inhibition toxicity | √ | √ | √ | √ |
| Absorption/desorption | √ | √ | √ | √ |
| Degradability | √ | √ | √ | √ |
| Earthworm acute toxicity test | √ | √ | √ | √ |
| Fish 14-day protracted toxicity test | | √ | | |
| Daphnia magna reproduction test | | √ | √ | √ |
| Bio-accumulative | | √ | √ | √ |
| Fish chronic toxicity test | | | √ | √ |
| Seed germination and root growth test | | | √ | √ |



China – Regulation on New Chemical Substances

➤ The Requirements of **testing institutions**

- The testing institutions in China
 - **authorized** and supervised by **MEP**
 - **complying with the guidelines for the qualified laboratories**
 - carrying out the tests in accordance with relevant guidelines and national standards.

- The foreign testing institutions
 - **must pass the authorized examination in their own jurisdictions**
 - complying with the relevant standards of qualified laboratories.



China – Regulation on New Chemical Substances

➤ The Requirements of **Risk Assessment**

- Risk assessment report should include
 - Hazard assessment
 - Exposure predicting assessment and risk control measure
 - RA results on environment and human health
- Technological audit on the RA reports
 - The degree of exposure
 - The risk to human health and environment
 - Appropriate risk control measure

China – Regulation on New Chemical Substances

➤ The Requirements of **Classification**

- The normal application form should include
 - Classification
 - Labeling
 - MSDSin accordance with national standards of Chinese GHS.
- Technological audit carried out on
 - the physical-chemical hazards
 - hazards on human health and environment

China – Regulation on New Chemical Substances

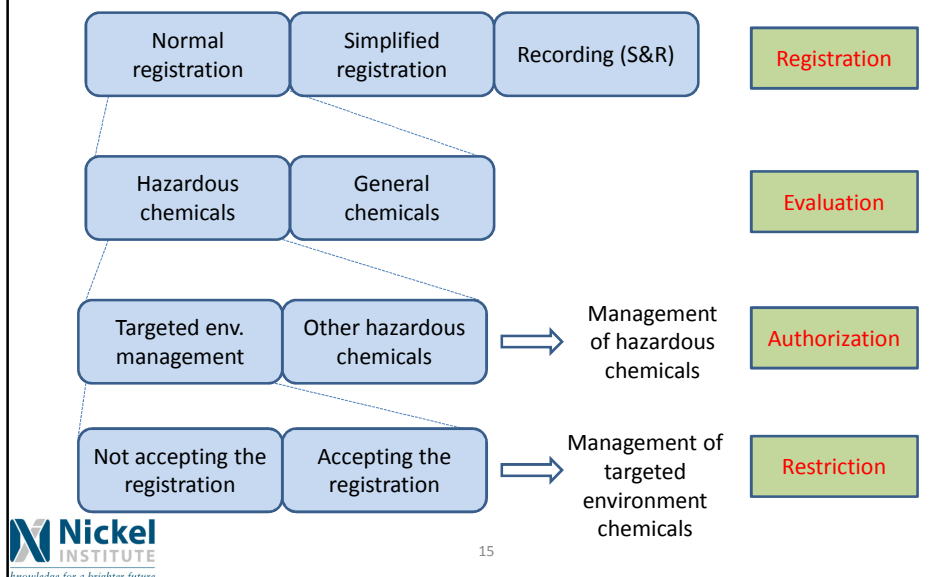
- Registration report includes:
 - Registration sheet;
 - Risk assessment report
 - Testing report.

- Technological audit by the audit committee:
 - Identification of chemicals;
 - Physical-chemical properties;
 - Hazard to human health;
 - Hazard to environment;
 - Exposure, risk and the appropriate risk control measure.

China – Regulation on New Chemical Substances

- **The comments of the Audit Committee:**
 - on the classification of chemicals, i.e. **general chemicals, hazardous chemicals, chemicals of targeted environmental management.**
 - on risk to **human health and environment;**
 - on appropriateness of **risk control measure.**
 - Conclusion on accepting the registration or not.

China – Regulation on New Chemical Substances



Taiwan – Existing Chemical Substance Nomination

- Companies manufacturing chemical substances in Taiwan or exporting chemical substances to Taiwan **can** nominate their chemical substances to Chemical Substance Registration Office of Taiwan (NCSR)
- Deadline: Dec. 31, 2010
- **Voluntarily**
- Information submitted:
 - The basic information of the company
 - Properties of chemical substances
 - Tonnage
 - Usage
 - Etc.
- Up to Dec. 31, 2010, more than 2,000 companies nominated about **30,000** chemical substances.

Taiwan – Existing Chemical Substance Nomination

- On this basis, [the first list of existing chemical substances](#) will be developed, becoming the foundation of Taiwan's chemical management. The list will be published in July, 2011.
- According to the list, [a screening project based on risk will be implemented](#). In this project, data on both hazard and risk will be provided.
- [Labor Safety and Health Law](#) and [The Toxic Chemical Substance Control Act](#) of Taiwan are under revision. Notification requirement and restriction & authorization requirement of chemical substances may be introduced.

Japan – Chemical Substance Control Law (CSCL)

- CSCL was amended in 2009 and has been adopted, indicating that the hazard-based management has been shifted to risk-based management.
- From April 1st, 2011, companies manufacturing or importing general chemical substance over than 1 t/a, **should** notify the [data on hazard and application](#) of chemical substance to Japanese government [annually](#).
- Based on the notified data, Japanese government will pre-evaluate the environmental exposure of the chemicals. Then [risk screening](#) will be implemented according to the outcome of the pre-evaluation.
- Additionally, [List of Priority Assessment Chemical Substance \(PACs\)](#) will be developed according to the available hazardous information of chemical substances.

Japan – *Chemical Substance Control Law (CSCL)*

Useful URLs for the Information on CSCL

- Ministry of Economy, Trade and Industry
http://www.meti.go.jp/policy/chemical_management/index.html
- Ministry of the Environment
<http://www.env.go.jp/chemi/kagaku/index.html>
- Ministry of Health, Labour and Welfare
<http://www.nihs.go.jp/mhlw/chemical/kashin/kashin.html>
- Public Comment (Ministry of Economy, Trade and Industry)
<http://www.meti.go.jp/feedback/index.html>

Korea – *Act on the Registration and Evaluation of Chemicals*

- On February 25th 2011, the Ministry of Environment (MOE) preannounced the legislation of *the draft Act on the Registration and Evaluation of Chemicals*.
- The following concepts and requirements will be introduced:
 - Pre-registration followed by Registration
 - Authorization
 - Restriction
 - The Only Representative
 - Data sharing
 - Joint submission
 - Annual notification
 - Communication on the supply chain
 - Etc.
- After the Act is formally published, the industries will have a **transition period of 2 years**.

For more information please visit the National Chemical Information Portal Service (NCIPS) : http://ncis.nier.go.kr/eng/index_Eng.jsp

Thanks for your attention!

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