

# ChemExpo India 2024

Compare and contrast chemical registration systems in the Asia-Pacific

April 2024

**MEET US**  
**Hall 2**  
**2C20**

**RAMBOLL**

Ramboll is a global architecture, engineering and consultancy company with more than 18,000 experts, creating sustainable solutions for governments and companies all over the world.

### Sourcing

- Raw material extraction
- End-of-waste criteria
- Product legislation

### Overarching services

- LCA
- Circularity assessments
- Regulatory mapping
- Substance/Product registration
- Hazard/Risk Assessments
- Auditing
- Permitting

### End-of-Life management

- Separate/efficient waste collection
- Waste Classification
- Recycling
- Safe Recyclates
- Waste-to-Energy



### Design and Production

- Safe and sustainable materials
- Product Stewardship
- Circular Design

### Extending product lifecycles

- Product safety in case of repair and refurbishment

### Waste prevention

- Zero waste to landfill studies
- Standard operation procedures
- Educational tools

- Founded in Denmark in 1945
- 300 offices across 35 countries
- Over EUR 2.1bn revenue
- > 1,900 experts in APAC & India

# Speaker



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Regional Director, Health Sciences, APAC

With over 30 year's experience in the chemical industry Willi supports Ramboll's clients across the Asia Pacific in product compliance and stewardship matters.

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# Agenda

1. China
2. Taiwan
3. Vietnam
4. Thailand
5. Korea
6. Japan

# China

| Registration Type       | MEE Order 12   | MEP Order 7           |   |
|-------------------------|--|-----------------------|---|
| Regular registration    | > 10 t/a   | Level I               | 1 - 10 t/a  |
|                         |  | Level II              | 10 - 100 t/a  |
|                         |  | Level III             | 100 - 1000 t/a  |
|                         |  | Level IV              | > 1,000 t/a   |
| Simplified Registration | 1 - 10 t/a   | Regular               | < 1 t/a   |
|                         |  | Special Circumstances | <ol style="list-style-type: none"> <li>1. Intermediate or for export &lt; 1 t/a</li> <li>2. Scientific research, 0.1 - &lt; 1 t/a</li> <li>3. R&amp;D, &lt; 10 t/a (max. 2 years)</li> <li>4. PLC or Polymers with &lt; 2% monomer</li> </ol> |
| Record Notification     | <ol style="list-style-type: none"> <li>1. &lt; 1 t/a</li> <li>2. PLC or Polymers with &lt; 2% monomer</li> </ol> | Filing                | <ol style="list-style-type: none"> <li>1. R&amp;D, &lt; 0.1 t/a</li> <li>2. Sample testing</li> </ol>   |



- MEP Order 7 entered into force in 2010  
Ministry of Environmental Protection  
Replace previous regulation (2003)
- MEE Order 12 was released 10 years later  
Entered into force 1st January 2021  
Ministry of Ecology and Environment
- Chinese competent authority (SCC)  
Solid Waste and Chemical Management Center

# China – MEE Order #12

## Registration

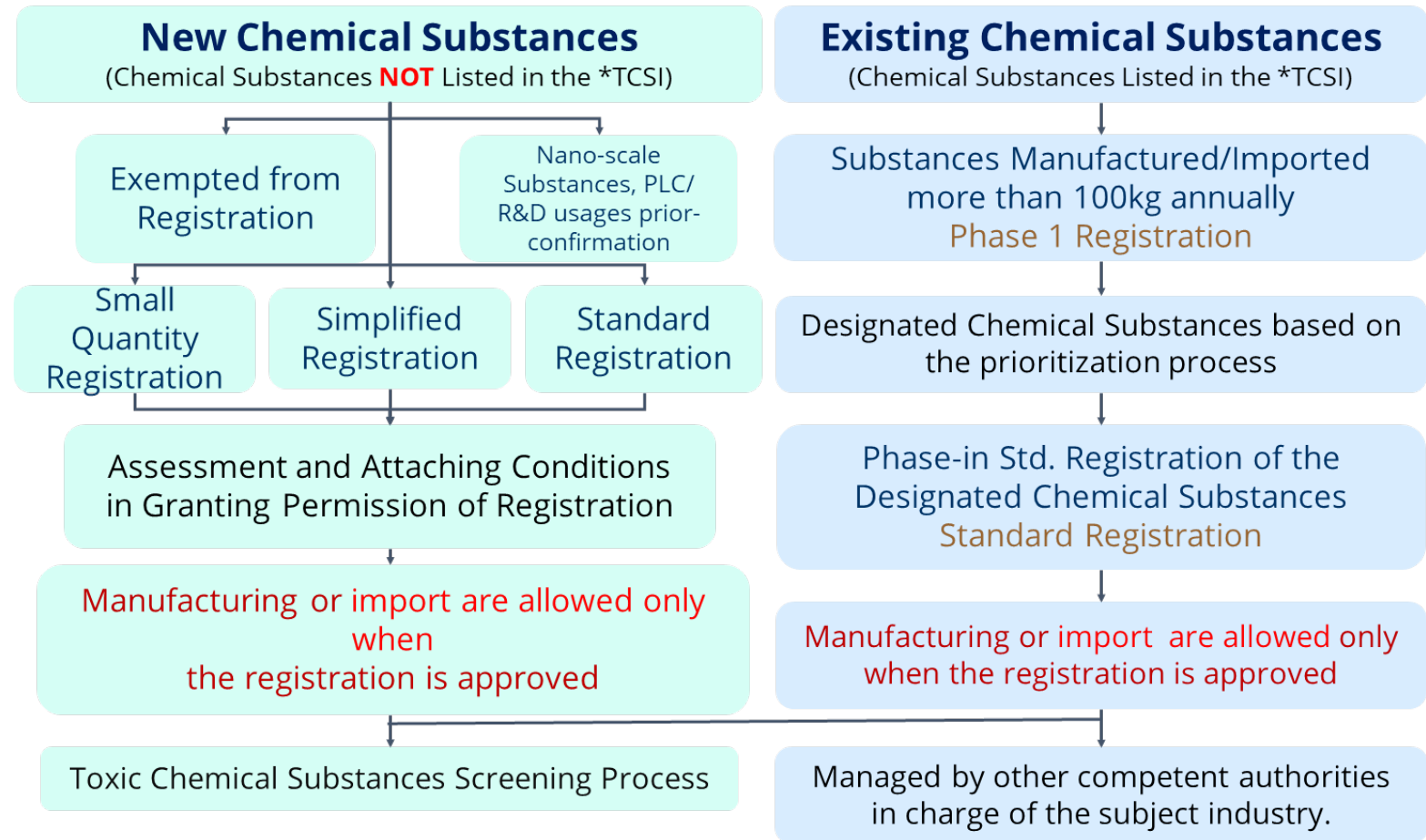
- New Substances
- New uses of Existing Substances
- Re-registration
  - Change of registered activities
  - Change of environmental risk control measures
  - Increase of environmental risks

## Requirements

- Data focus on environmental endpoints
- Required data depends on P/B/T
- New concept of **‘Highly hazardous New Chemical Substances’**
  - analysis of the social and economic benefits required

# Taiwan

- Toxic and Chemical Substances of Concern Control Act (TCSCCA) entered into force 2014
- All existing substances need a 'Phase I' registration
  - Similar to EU REACH pre-registration
- Data requirements for registration based on annual tonnage
  - 1-10, 10-100, 100-1000. >1000 t/a
- Registration of Existing Substances subject to designation by EPA
  - List approach
- 106 PEC need to be registered by 31<sup>st</sup> Dec. 2024

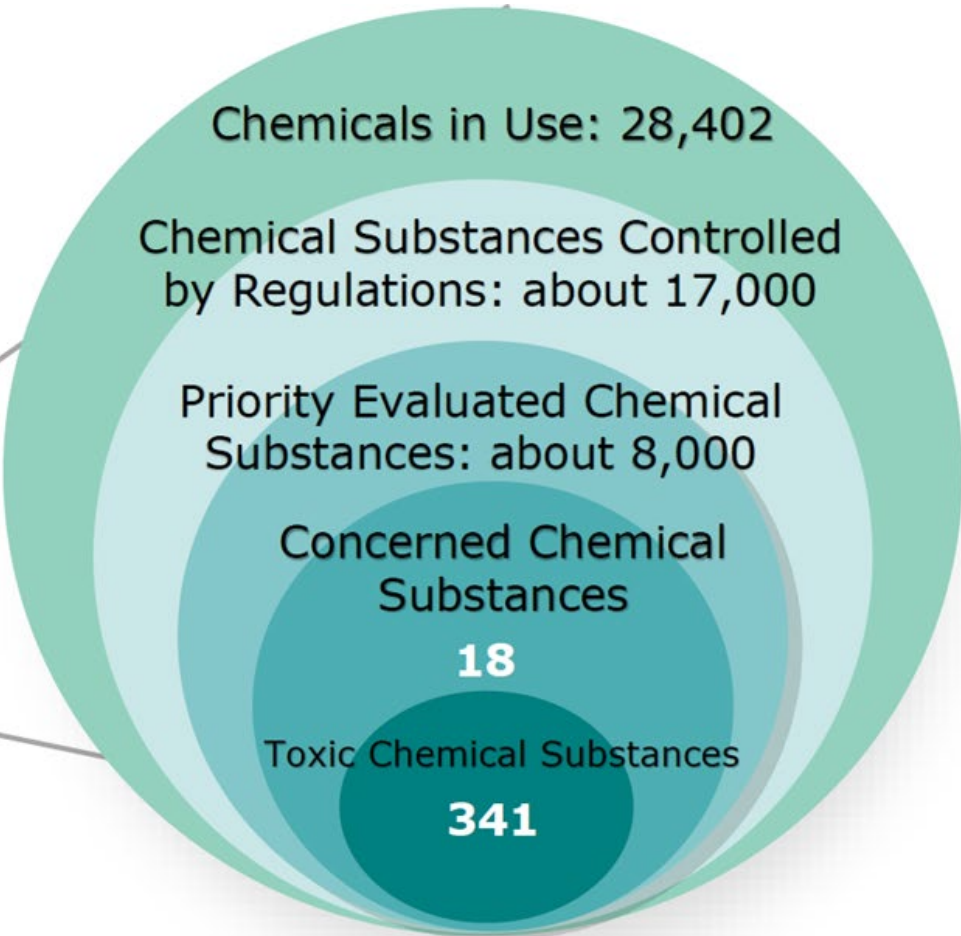


\*TCSI: Taiwan Chemical Substance Inventory



# Taiwan

From Toxic and Concerned Chemical Substances to Harmonize Different Regulations under 14 Different Authorities

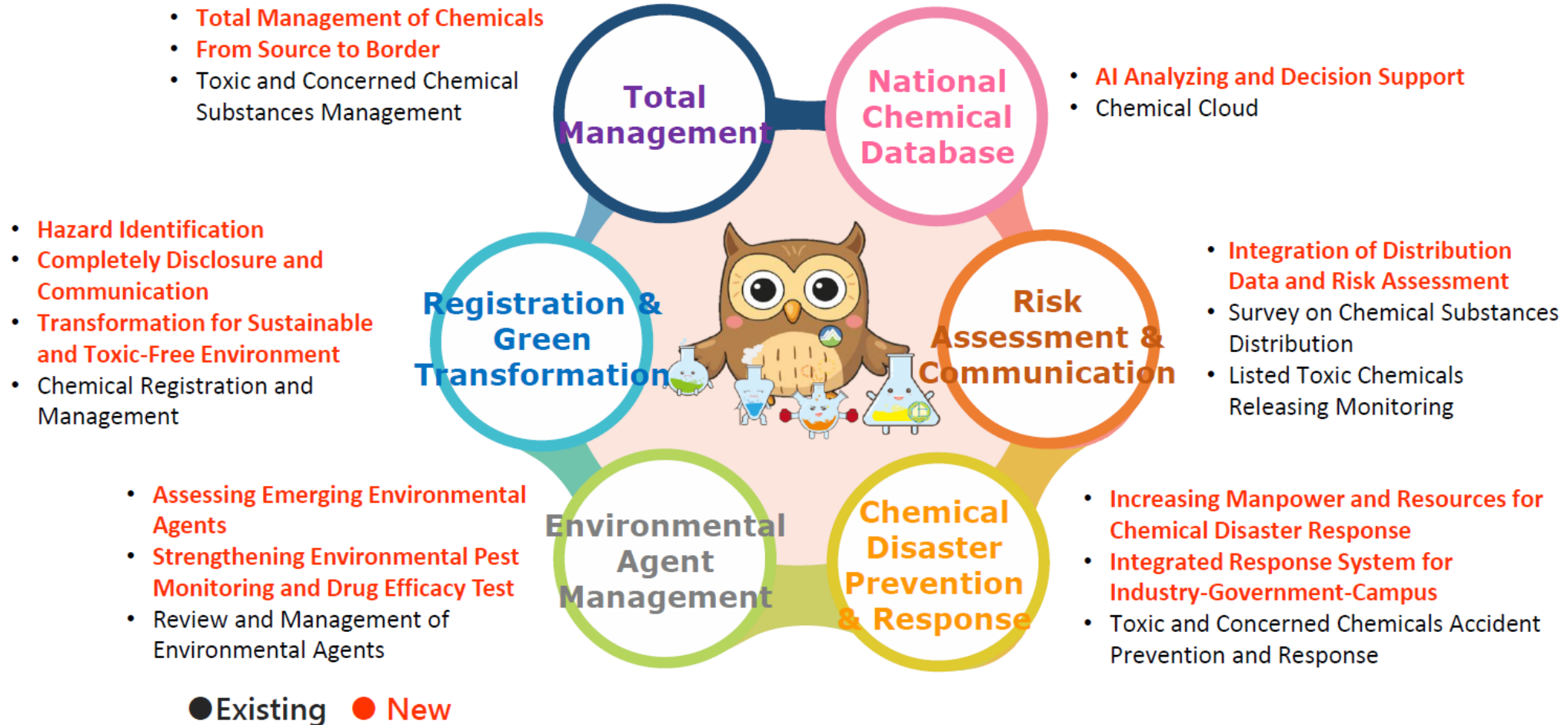


Taiwan's EPA has become Ministry of Environment (MOENV) on August, 22<sup>nd</sup> 2023

- Climate Change Administration
- Resource Circulation Administration
- Environmental Management Administration
- Chemicals Administration (TCHA)
- National Environmental Research Academy



# Taiwan



# Vietnam

- Restricted chemicals
  - Decree no. 82/2022/ND-CP (Appendix II), for example, aldicarb (CAS No. 116-06-3)
- Conditional chemicals
  - Decree no. 113/2017/ND-CP (Appendix I) and Decree no. 82/2022/ND-CP (Article 1.19), for example, acetonitrile methyl cyanide (CAS No. 75-05-8)
- Industrial precursors
  - Decree no. 113/2017/ND-CP (Appendix I), such as acetic anhydride (CAS No. 108-24-7)
- Schedule chemicals
  - Governed by the Chemical Weapons Convention clarified under Decree no. 38/2014/ND-CP
- Other hazardous chemicals
  - Clarified under the [Law on Chemicals](#)
  - Based on GHS classification
  - Explosive
  - strongly oxidizing
  - strongly corrosive
  - Flammable
  - acutely toxic
  - chronically toxic
  - causing irritation to humans
  - causing cancer or posing threats of causing cancer
  - causing genetic mutation, reproductively toxic
  - bio-accumulative
  - organically polluting and hard to decay, and environmentally toxic



- Legal Document No. 76/HC-QLHC (19<sup>th</sup> February 2024)
- Companies producing, importing, exporting, distributing, transporting, storing, or using
- Annual report by 15<sup>th</sup> February via National Chemical Database System
- <https://chemicaldata.gov.vn>

# Vietnam - Law on Chemicals

- Vietnam's Ministry of Industry and Trade (MOIT) has finalized the draft of the [revised](#) Law on Chemicals in March 2024
  - Draft will be submitted to the Government in June
  - 11 Chapters and 95 Articles
  - clarify definitions and the scope of the regulation
  - make the chemical industry more sustainable and modern
  - develop consistent chemicals management throughout the entire lifecycle
  - increase management of chemicals in products
  - regulations on chemical information – such as classification, labelling, packaging, safety sheets, and [the registration and evaluation of new chemicals](#).
- Submit to the National Assembly in May 2025 and have it passed end of 2025



# Thailand

## B.E. 2565 (2022)

- Hazardous Substances >1t/a, based on the **substance** across all products
- None classified substances and substance < 1t/a can be notified voluntarily
- Previous declarations stay valid
- New online tool (or manual)

- Information to submit (WoAo/AoKo32)
  - Substance ID
  - GHS classification
  - Form of use (consumer/commercial/industrial/intermediate)
  - Volume (1-10; 10-100; 100-1,000; 1,000-10,000; >10,000 t/a)

Hazardous Substance Lists regulate classified and restricted chemicals.

Hazardous Substance List 5.6 regulates all hazardous chemicals not controlled via any of the other lists

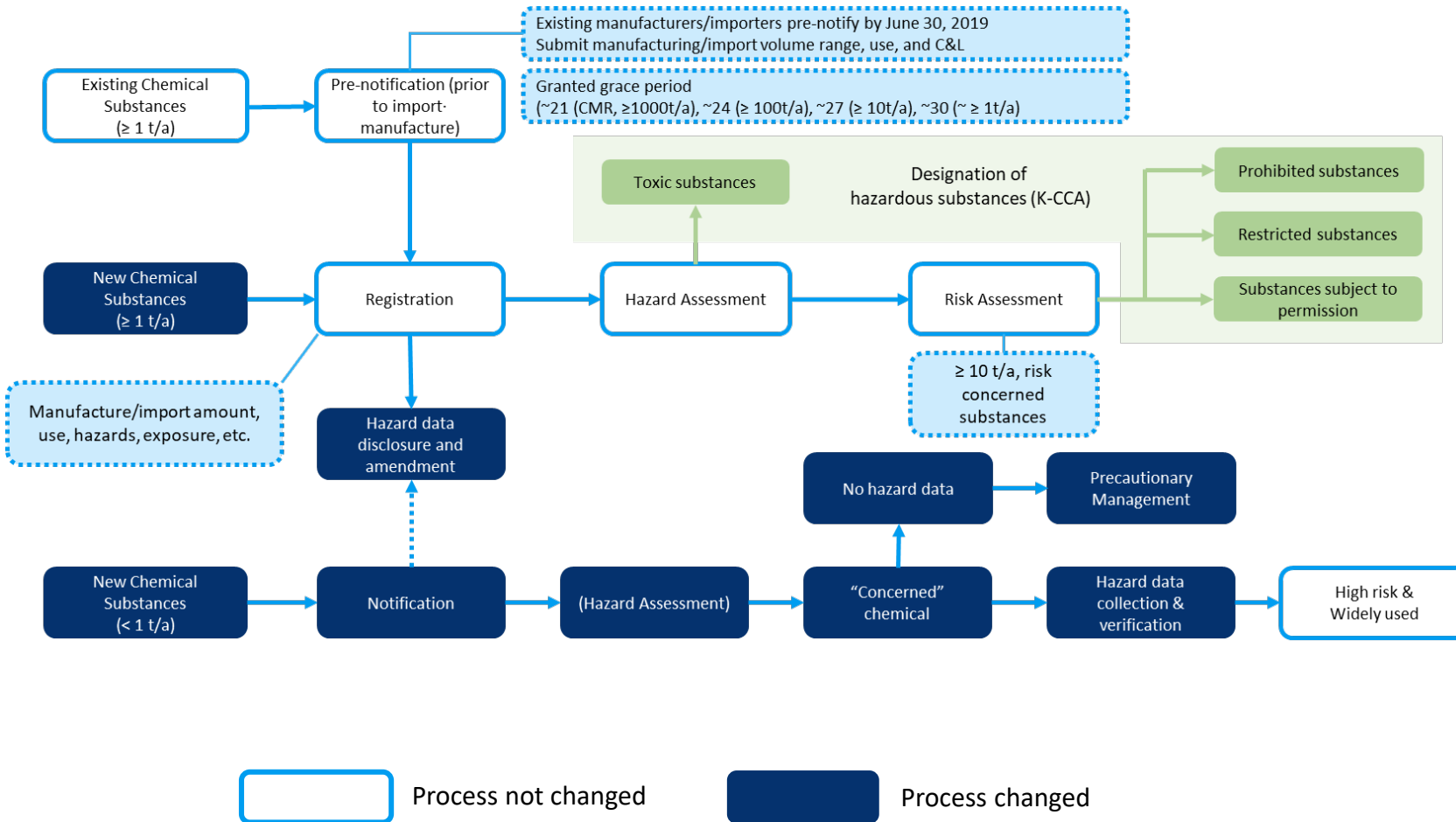
Thailand published an MOI Notification in June 2022, which took effect on 26<sup>th</sup> September 2022 related to the declaration of List 5.6 substances

# Thailand

List of Hazardous Substances No. 7 B.E. 2565 has been published (Dec.2022)

- [4th Draft of the Chemical Substance Act](#) published on 7<sup>th</sup> January 2021
  - Chemical lifecycle from manufacturing through recycling
  - Risk based, not hazard
  - Will replace Hazardous Substance Act (HSA)
  - Only Representative concept
  - Requirements for chemicals will depend on the risk assessment of National Chemical Policy Committee, Chemical Assessment Committee (CAC)

# South Korea



Korea improves the coherence of chemical related regulations

- K-REACH hazard assessment outcome is used for the inclusion into the 'Toxic Substance List' under K-CCA
- New substance registration to start  $>1$ t/a
- Mutual acceptance of licenses between MoE (CCA) and MoEL (OSHA)
- Tattoo inks moved from K-BPR to the Hygiene Products Act

# K-REACH amendment

**Threshold for new substance notification changes to < 1 t/a**

## **Notification of new substances**

- Notification includes name, use, C&L with sufficient evidence
- Submitted information can be amended with evidences
- Authority review of notified C&L
- Yearly disclosure of certain information to the public

## **Hazard-undetermined substances**

- Substances without hazard information
- Assumed to be hazardous until evidence is provided
- Reason for no classification need to be communicated in the supply chain

## **Exemption**

- Full export and intermediates



- Announced on 6<sup>th</sup> February 2024
- Effective from 7<sup>th</sup> August 2025
- Additional amendments on enforcement rule, enforcement decree and related regulations are planned in 2024.



Japan's Chemical Management Regulation (CSCL) is in force since 1972

# Japan

## CSCL

- Substances on the inventory (CSCL)
  - annual reporting
  - CSCL number allocation is done by industry
  - Legally binding assessment only from METI
- New Substances
- Pre-marketing Notification
  - < 1 t/a, PLC, intermediates
- Notification
  - > 1 t/a
  - Data/Information depending on hazard, especially environmental

## Safety Data Sheets

- GHS rev.6 SDS and Label requirements
  - Pollutant Release and Transfer Registration Law (PRTR)
  - Industrial Safety and Health Law (ISHL)
  - Poisonous and Deleterious Substances Control Law (PDSCL)
- Added 667 substances (Aug. 2023)
  - More substance are planned
- 860 substances will have workplace exposure limits by 2025
  - 120 (2022), 170 (2023)
  - 180 (2024), 390 (2025)



# Conclusion

- Focus shift to environmental hazard/risks
- Inclusion of the entire life cycle in the Chemical Management
- Closing 'gaps': Worker protection, regulatory cohesion, supply chain communication
- All regulations require DATA
- Wider acceptance of alternative data (in-vitro, QSAR...)

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