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Required Test Data

- up to 1 ton ~ less than 10 tons : max. 15 items (A)
- up to 10 tons ~ less than 100 tons : max. 26 items (A+B)
- up to 100 tones ~ less than 1,000 tons : max. 37 items (A+B+C)
- up to 1,000 tons : max. 47items (A+B+C+D)

	A	B	C	D
Physicochemical Properties	1) State of substance 2) Solubility in water 3) Melting/freezing point 4) Boiling point 5) Vapor pressure 6) Octanol-water partition coefficient 7) Density 8) Grain-size analysis	1) Combustible 2) Explosive 3) Corrosive	1)Viscosity 2) Dissociation constant	
Hazards to Human	1) Acute oral toxicity but, acute inhalation toxicity when main exposure path is deemed to inhalation given the substance's physicochemical properties and use 2) Reverse mutation 3) Skin irritation/corrosion 4) Skin hypersensitivity	1) Acute dermal toxicity or acute inhalation toxicity 2) Eye irritation/corrosion 3) In vitro Mammalian Chromosomal Aberration Test 4) genetic toxicity test w/ test animals 5) Repeated Dose Toxicity (28days) 6) Reproductive & Developmental Toxicity screening	1) Additional genotoxicity (genotoxicity to reproductive cells, etc.)	1) Repeated-dose toxicity (90days) 2) Teratogenecity 3) Second-generation reproductive toxicity 4) Carcinogenicity
Hazards to Environment	1)Fish acute toxicity 2) Easily-biodegradable 3) Acute Toxicity to daphnia magna	1) Growth inhibition of Freshwater algae 2) Hydrolysis according to pH values	1) Inherent Biodegradability 2)Confirmation of degradation product 3) Chronic fish toxicity 4) Chronic toxicity to daphnia magna 5) Acute toxicity to land plant 6)Acute toxicity to invertebrates 7)Respiratory inhibition caused by activated sludge 8) Adsorption & desorption	1)Additional information on environmental fate & dynamics 2) Chronic toxicity to land plant 3)Chronic toxicity to invertebrates living on land 4) Additional information on adsorption & desorption 5) Chronic toxicity to benthos 6) Bioaccumulation

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Exceptions

Exceptions for Biocide

Biocide	Test items
1≤ T <10 ton	Tests for 10≤ T <100 ton substance
10≤ T <100 ton	Tests for 100≤ T <1000 ton substance
100≤ T	Tests for ≥ 1000 ton substance
0.1≤ T <1 ton *(Required from Jan. 1, 2020)*	Tests for 1≤ T <10 ton substance

Exceptions for Polymer

Polymer	Test items
1≤ T <10 ton	1) Appearance 2) Water solubility 3) Meting point/Freezing point 4) Boiling point 5) Vapor pressure
10≤ T <100 ton	1) Acute oral toxicity 2) Ames 3) Acute fish toxicity 4) Ready biodegradation
100≤ T <1000 ton	Tests for 1≤ T <10 ton substance
1000≤ T ton	Tests for 10≤ T <100 ton substance

※ Polymer data should be submitted additionally
1) Mn & molecular weight distribution
2) Monomers information (chemical name, CAS No., %)
3) Residue of monomers (%)
4) Percentage of Mn < 1,000
5) Acid/base stability

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Rational Requirement of Test Data

TCCA

No exception regarding test data

K-REACH

Possible omission of test data submission

⇒ omit test data when registering small quantity
⇒ expand the scope of non-test-data
· **QSAR , read-across (structural similarity)**
⇒ omit test data when it is impossible to conduct technical test
⇒ omit test data when there's no exposure to human and the environment
⇒ admit replacement w/ test plan
· **If test infra is not built, test must take long time**

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Simplified Registration for Small Quantities

“ALL” Non-phase-in chemicals should be registered, even in very small quantities

◆ **Simplified registration for less than 1ton/yr (0.1 ton, '20)**

- **Simplified data** : identity of business operator, intended use, identity info. of substance., exposure data

- **Expedited process**: notifying within 3 days after application (7 days if additional review needed)

◆ **Additional data can be ordered at a time of hazard examination and risk assessment**

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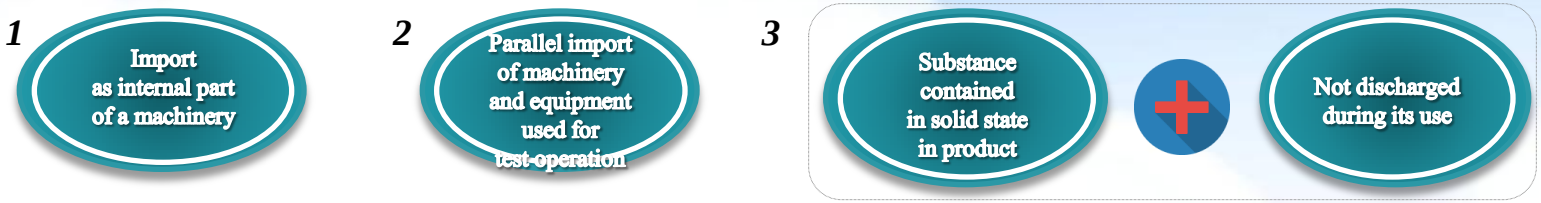
Exemption from the Registration

Exemption



Can be exempted, but to be confirmed

1. Whole amount of substances, which is exported to other countries (less than 10 tons per year) (annual-based)
2. Reagent used for testing, analysis or chemical research (annual-based)
3. Substance used for R&D (by R&D project) 4. Polymer of low concern (ONLY at the first time)
4. Surface treatment substance (ONLY at the first time)
5. Non-isolated intermediate & isolated intermediate that is blocked from any release w/ technical measures (ONLY at the first time)

Most of the exempted substances are:

1. **Chemicals for scientific testing**
2. **Chemicals for R&D**

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Designation of Chemicals (Article 20, 25, 27)

- ✓ Hazard Examination: **Review test data and characterization data submitted by businesses**
- ✓ Hazard Evaluation : **Government's evaluation on substance subject to evaluation by international organizations, substance exported as a whole**
- ✓ Risk Assessment : **prepare risk evaluation report after designating substance to be evaluated**

● Designation

Classification	Criteria for Designation	Note
Toxic Substances	○ As the result of hazardous examination - substance w/ toxic properties to human or eco-toxicity	- Make a public announcement w/ name, classification & labeling, hazards
Authorization/ Restricted/ Prohibited Substances	○ As the result of hazardous examination & risk assessment - substance of risk concern	- name, classification& labeling, permitted use , grace period, etc. - Pre-notice + Consultation - Written risk assessment and socio-economic assessment

● Management : pursuant to the Chemicals Control Act (enforced in Jan 1, 2015)
- Used for permission of business, facility safety standards etc

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Toxic Substances

- Toxic substances under TCCA ⇒ **Deemed as toxic substances under AREC**

  * **Number of toxic substances under TCCA**(as of DEC 2014) : **723 chemicals** i.e., benzene, toluene, etc

- Revised to be compatible with UN GHS

  * GHS : Globally Harmonized System of Classification and Labeling of Chemicals

- **Repeated exposure, carcinogenic, mutagenic, and reproductive toxicity**(health)
- Acute and chronic toxicity to aquatic ecosystem(environment) → newly introduced or revised

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Authorization/Prohibited/Restricted Substances

- Prohibited & Restricted Substances : Not allowed for all or certain purposes of manufacture, import, and use

*** Number of prohibited and restricted substances(as of Apr 2014)**

Prohibited Substances	Restricted Substances
60 Substances including DDT, PCBs, Asbestos	12 substances including malachite green, nonylphenol

- Substances subject to Authorization :
  - If the cost of prohibition exceeds the benefit, and the industry is not ready for prohibition.
  - The possible high risk is specially managed, while encouraging the industry to come up with new and better substances

*** No authorization substances announced as of May 2015**

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Sharing of Information (Article 29, 30)

- **Transfer & sharing Safety Info. throughout the supply chain**

1. Substance information grasped from its registration is transferred to a downstream users, and then is utilized for safe management in a workplace
2. Support compliance w/ report and registration obligation of manufacturer and importer
3. Sharing safety data between downstream user/seller & manufacturer/importer

- **Protection of Confidential Business Information :**
  - Pursuant to『Unfair Competition Prevention and Trade Secret Protection Act』
  - Component, content, etc.
  - Submitter must claim the information as confidential business information

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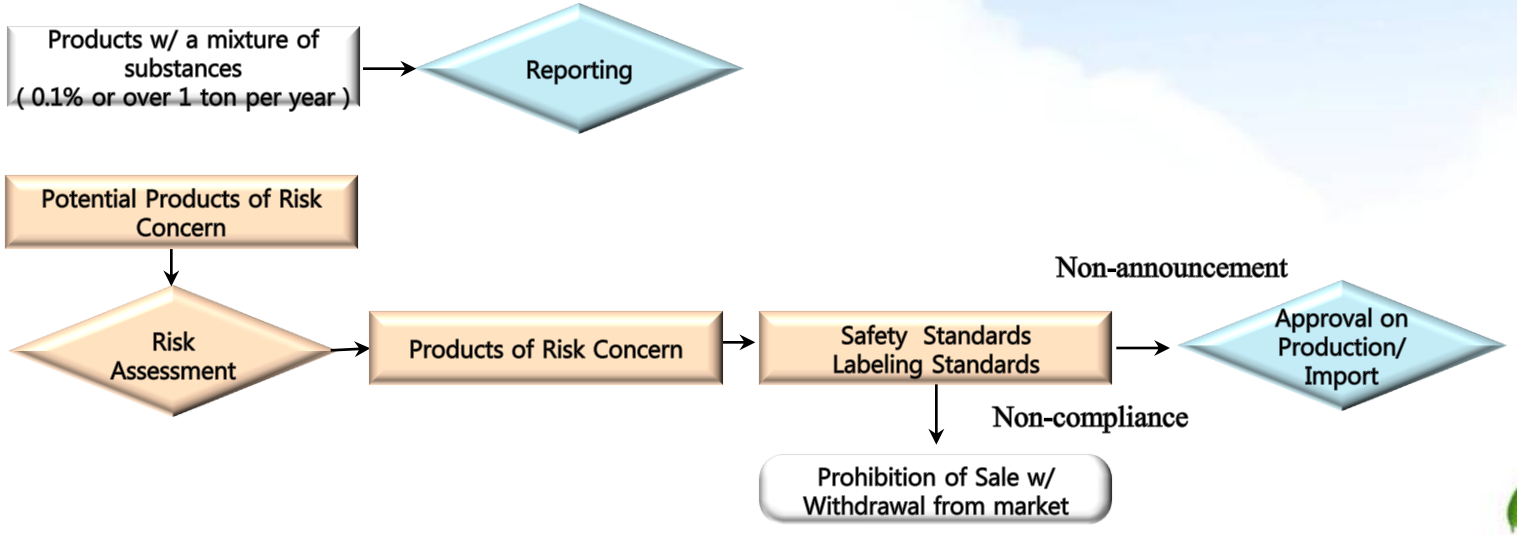
Overview of Chemical Products Management



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Reporting of Products containing Hazardous Chemical Substances (Article 32)

- (By total amount) ≥ **1 ton/year/substance** for manufacturer/importer
- (By content) ≥ **0.1% by weight**
- (Target user) Only for consumer products. Products for industrial uses are excluded
- (Hazardous Chemical Substances) Toxic substances, Authorization/Restricted/Prohibited substances under AREC
- (Exemption) No leakage or exposure under conventional usage
- (How to report) If ≥ 1 ton/year ☞ Prior to manufacture/import
  Not sure about the annual tonnage ☞ Prior Reporting prior to manufacture/import

Reporting by the next April

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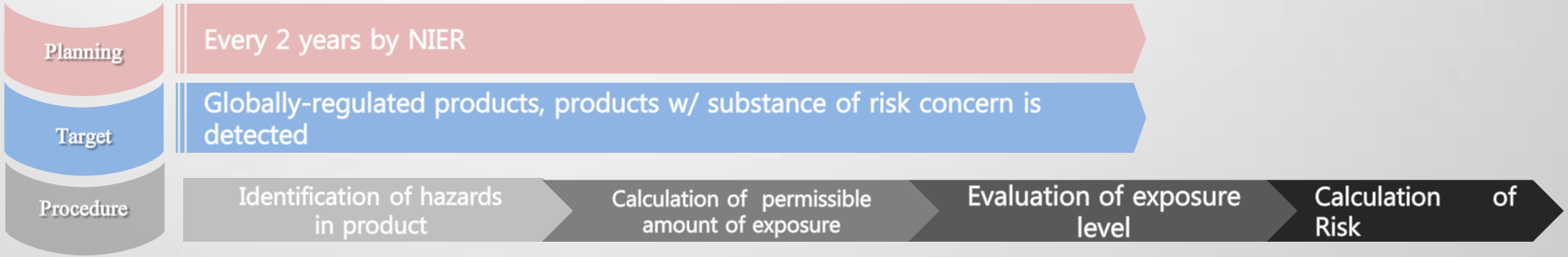
Designation of Products of Risk Concern & Application of Safety/Labeling Standards (Article 34)

- Potential Products of Risk Concern → (Risk Assessment) → Products of Risk Concern, Safety/Labeling Standards

Products for daily uses		Biocides
Previously regulated under QC Act(8 categories)	Not previously regulated(7 categories)	
Detergents, fragrances, adhesives, polishes, deodorants, synthetic detergents, bleaching agents, fabric softeners	Rust inhibitor, anti-fogging agents, colorant/decolorant, tatoo colorant	insecticides, disinfectants, preservatives

- Risk Assessment

- Government carries out risk assessment when risk data is not submitted by manufacturer/importer
- If necessary, the government may order submission of data



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Designation of Products of Risk Concern & Application of Safety/Labeling Standards 2

- **Risk Assessment → Safety/Labeling Standards for each product category**

  - (**Safety Standards**) Prohibited substances, Content-restricted substances, Obligatory Labeling substances

    ※ Substances of high risk, such as humidifier sterilizer substances(PHMG, PGH), or carcinogens are prohibited substances

  - (**Labeling Standards**) Content and toxicity information is specified on the surface of the packaging for Hazardous Chemical Substances under AREC, or internationally accepted CMRs, etc

- **Prohibition of sales/import for the products failing the standards**

  - Health and environmental risk → Retrieval, Ban on sales, Disposal of products
  - Emergency measures to prevent expanded damages

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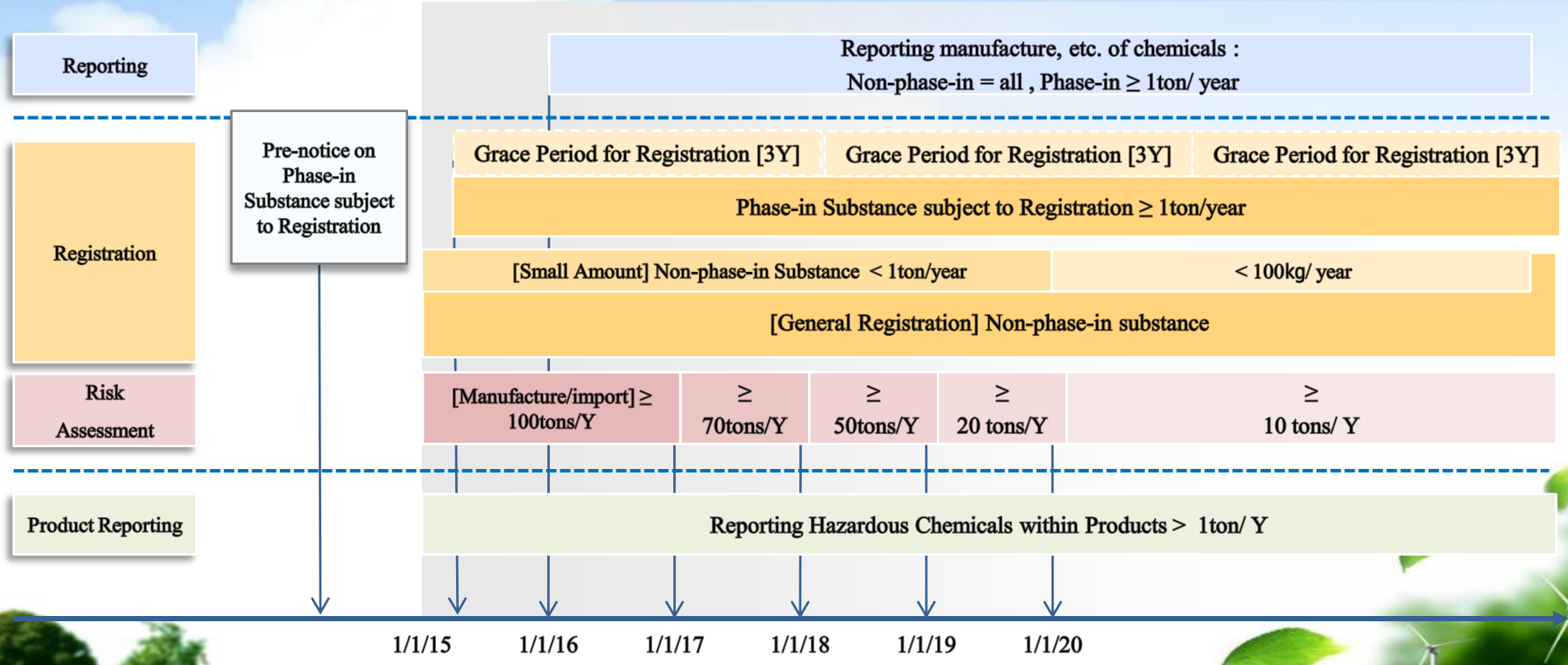
Timeline



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Revision of Enforcement Rules

- Purpose : To address challenges businesses face when implementing the law

- Details of Revision

✓ Eased burden of confirmation on registration exemption for chemical reagents (annual → `first time only)

✓ Only Representative (OR)
- ▪Simplification of procedure, when OR is changed(submit written dismissal & appointment respectively → submit integrated one)
- ▪ Enhancement of notification form (e.g. name of chemical substance can be replaced with name of product)

✓ Deletion of Duplicated Items in the Form
- ▪ imported quantity in the forms of report, registration, etc.
- ▪ exposure data in application form for small-volume registration

✓ Improvement of the way how a representative is appointed for joint registration (majority → autonomous appointment), etc.