「Act on Registration and Evaluation of Chemical substance (Draft)」

Chemicals Management Division,
Environmental Health Policy Office,
Ministry of Environment

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Contents

1 Background

Background

- Background of legislation

- Increase of public interest in safety of chemical substances

→ Public interest in safety management of chemical substance is increasing

But government evaluated only 15% of existing chemicals(total 43,000 kinds)

- Promoting chemical industry to turn to green chemistry

→ By reducing and restriction・prohibition of substances of very high concern

- Need to participate in international goals on chemical management

→ To minimize the adverse effects of chemicals on human health and the environment by 2020 (SAICM)

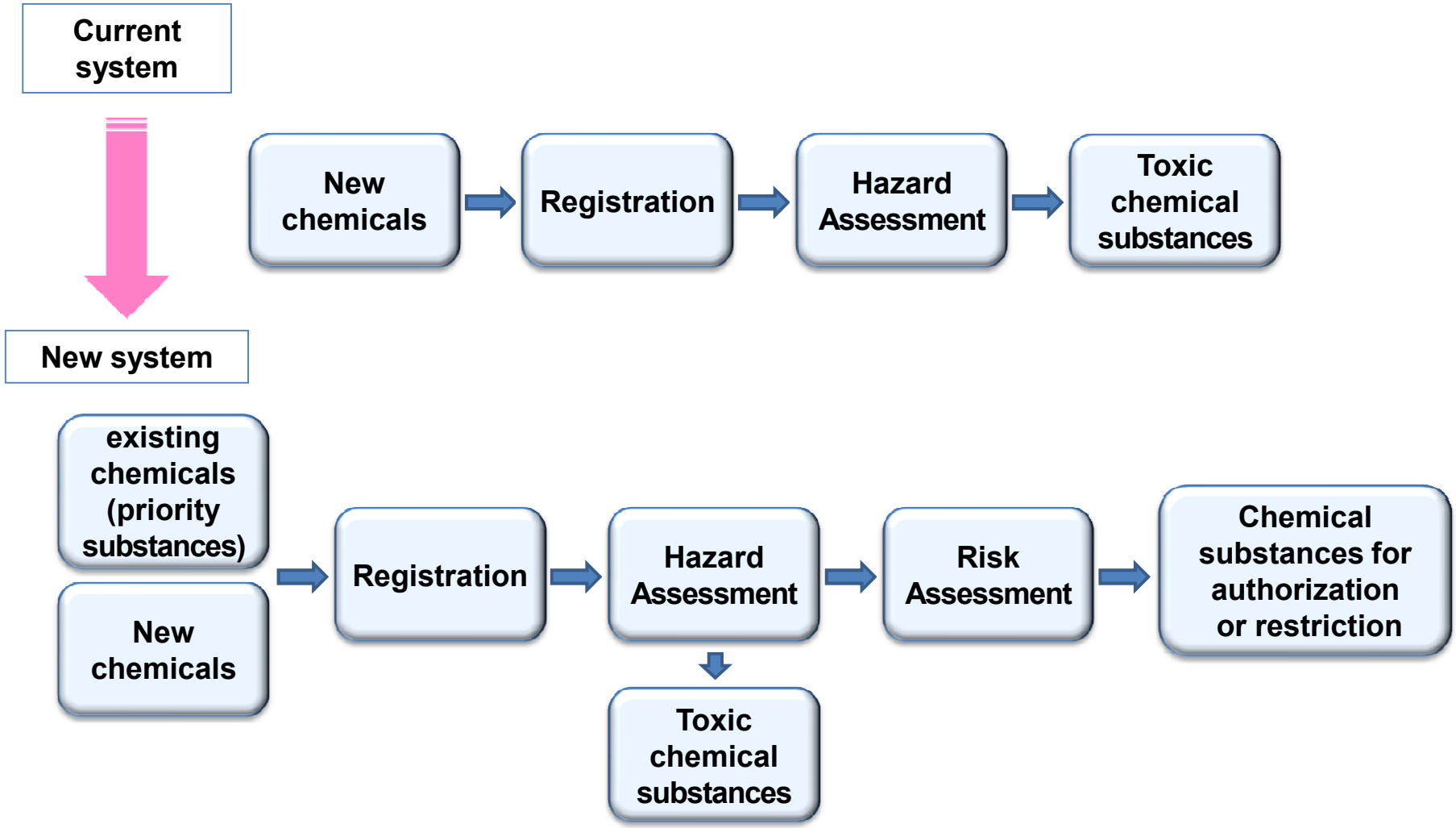
※ SAICM(Strategic Approach to International Chemicals Management)

2 Overview of Act

「Act on Registration and Evaluation of Chemicals」

Target of Registration	- Not all existing chemicals are required to register - For priority assessment substance, Registration is required
Pre-registration & Grace period	- Priority assessment substances can be pre-registered - If pre-registered, grace period is given to priority substances
Joint Submission	- When register the same chemical substance with other companies, it is required to submit information jointly
Authorization & restriction	- Phase-out substance of very high concern in market by authorization and restriction・prohibition

Registration · Evaluation Process



3 Details on Act

「Act on Registration and Evaluation of Chemicals」

Chapter	Provision
Ch.1	General Provision (Article 1~8)
Ch. 2	Registration of Chemicals(Article 9~23)
Ch. 3	Evaluation of Chemicals (Article24~29)
Ch. 4	Authorization and Restriction of Chemicals (Article 30~36)
Ch. 5	Communication on Chemicals (Article 37~40)
Ch. 6	Supplemental (Article 41~51)
Ch. 7	Penalties (Article 52~57)

Ch. 1. General Provision (Article 1~8)

Purpose (Article 1)

- To prevent adverse effects of chemical substances on human health and the environment by the registration and evaluation of chemical substances

Definitions (Article 2)

- To define priority assessment substances and chemical substances for authorization, restriction·prohibition

※ (Priority assessment substances) Amongst existing chemical substances, designated by the Ministry of the Environment based on trading volume and use, etc

※ (Substances for authorization) a substance of high concern which requires permission by the MOE prior to manufacture, import and use

※ (Substances for restriction · prohibition) a substance of high risk which is restricted or prohibited from manufacture, import, use and sale in certain or all use

Scope of Act (Article 3)

- The act is not applicable to chemical substances whose registration*evaluation is subject to other acts such as pharmaceuticals and pesticides and so on.

Only representative (Article 6)

- A foreign manufacture who intends to perform obligations required to a importer under this act shall appoint a legal entity in Korea as an only representative.

Ch. 2. Registration of Chemical substances (Article 9~23)

- Reporting of Manufacture or Import of Chemical Substances (Article 9)
  - In the case of existing chemicals(≥0.5ton/y), companies(manufacture or importer) are required to report the volume of manufacture or import of the previous year to MOE

- Designation of Priority Assessment Substances (Article 10)
  - Amongst existing chemicals, assessment chemical substance shall be designated based on use and trading volume, etc. and published them.

- Pre-registration and Grace Period (Article 12~13)
  - Priority assessment substance shall be subject to pre-registration.
  - Maximum 8 years grace period shall be granted to pre-registered chemical substances.

- Registration (Article 15~16)
  - Manufacturer or importer of new chemical or priority substance shall submit a registration to the Ministry of the Environment
  - In case of registration, information on hazard, risks of chemical substance and other information(e.g use) shall be submitted

Ch. 2. Registration of Chemical substances (Article 9~23)

- Modification of Registration (Article 19)
  - In case of modification to registration due to increased manufacture or import volume or confirmation of new uses, modified or added data shall be submitted

- Joint Submission of Registration Dossiers (Article 20~21)
  - Companies of the same chemical substances are required to submit registration data jointly
  - Existing data may possibly be submitted with the approval of data owner

- Prohibition on Repetitive Generation of Test Data (Article 22)
  - Duplication of vertebrate animal test for registration is prohibited.

- Measures on Dispute over Data sharing (Article 23)
  - In case of refusal or forced approval of data sharing without justification, the submission of data for registration can be banned

Ch. 3. Evaluation of Chemical substances (Article 24~29)

- Hazard assessment and notice of hazard assessment results (Article 25~26)
  - MOE(NIER) conducts hazard assessment of registered chemical substances
  - Notice of hazard assessment results by MOE

- Risk assessment (Article 27)
  - MOE(NIER) conducts risk assessment

    For ① substances manufactured or imported more than 100t/y and

    ② substances considered to be in need of risk assessment after hazard assessment

  - Chemicals of very high concern based on a risk assessment shall be designated as substances for authorization by use or for restriction or prohibition

Ch. 4. Authorization and Restriction of Chemical stances (Article 30~36)

Authorization of chemical substances (Article 30~33)

- Companies who intend to manufacture, import and use of substances for authorization are required to obtain prior permission from MOE
- The authorization is valid only during the authorization period

Restriction or prohibition of chemical substances (Article34~36)

- Based on a risk assessment, substance of high risk is designated as substance for restriction or prohibition by MOE
- Compliance with restriction·prohibition is mandatory in case of manufacture, import, sale, use of substances for restriction or prohibition.
- In the case of product containing a certain level of substance for restriction, the name·content and use of the substance need to be reported to MOE.

Ch. 5. Communication on Chemical substances (Article 37~40)

Provision of Chemical Evaluation Result (Article 37~39)

- In supplying priority assessment substances, some information concerning their hazard shall be provided to the recipient.
- In supplying a substance for authorization, details of authorization, etc shall be provided to the recipient.
- In supplying substances for restriction·prohibition, details of restriction or prohibition shall be provided to the recipient.

Modification of Information Provided (Article 40)

- In case of modification to provided information, modifications shall be notified to the relevant supplier
- MOE may request submission or modification of information for prevention of risk

4 Main issues

Main Issues

1. Priority assessment substances

- The draft list are planned to be released publicly in early 2013 and will be decided officially 6 months(or more) before the start of pre-registration
- Criteria for prioritization : exposure level → quantity(national level), use
  hazard level → CMR, PBT, H410, Toxic substance(under TSCA)

2. Data requirements and tonnage level

- We are now studying reasonable data requirements and tonnage level.(the draft may be released next year)
- Registration limit(0.5t/y) is more reasonable than 1t/y in Korean market,
  But we are considering some ways to minimize the burden to registrants below 1t/y

3. Exemption

- R&D, un-isolated intermediate and polymer of low concern will be exempted from reporting, registration, authorization and restriction

Main Issues

4. Reporting(Article 9)

- Reporting is a very essential factor for designation of priority assessment substances
- Considering the possible difficulties to industry caused by reporting,
  we are searching for more rational ways to remove unnecessary burden

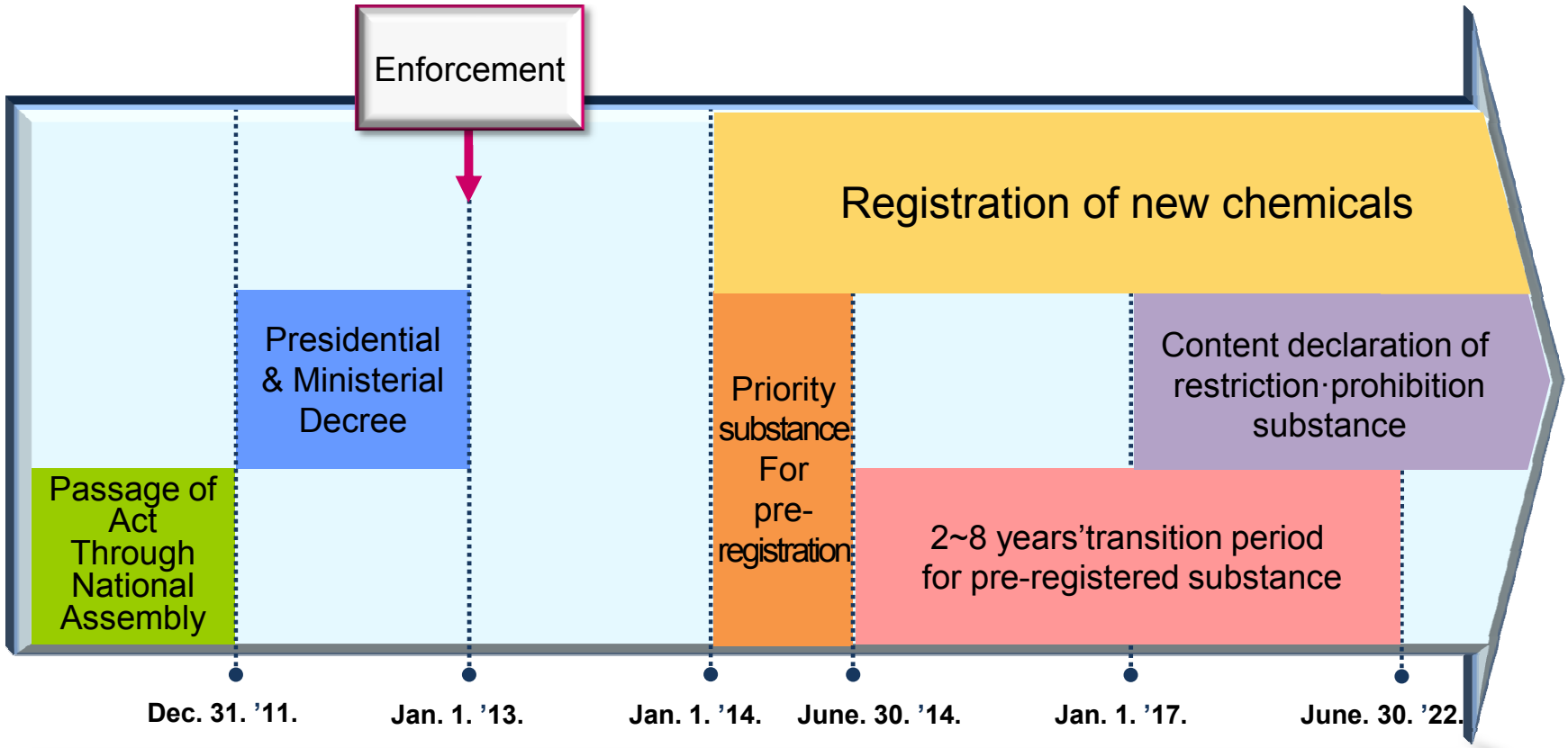
5. Grace period for priority 1 substance(2 years)

- Priority 1 substance is the most urgent one for assessment
  → We are not considering to expand grace period for priority 1
- There will not be too many priority 1 substances
- Total number of priority 1, 2, 3 substances may be 2,000~3,000 .

※ Designating priority 4 substances by reviewing information gathered from reporting

5 Enforcement Plan

Enforcement Plan (draft)



Thanks

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