Systematization for Registration and Evaluation of Chemical Substances

Nov. 2014

Ministry of Environment
Chemical Management Division

CONTENTS

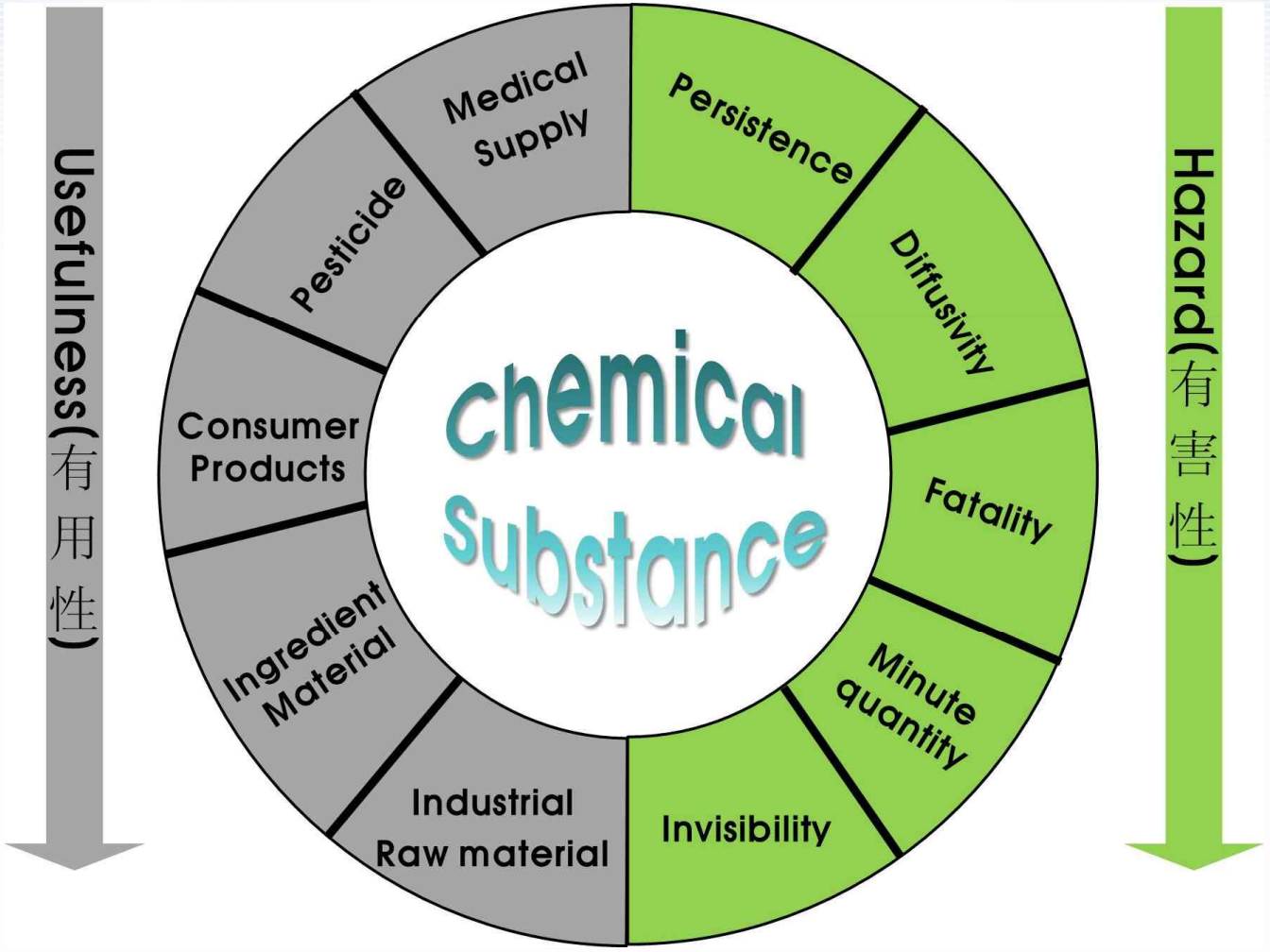
Background and Progress

Global Status: Chemicals

At a global level,

- 8.8 million chemicals developed
- 120,000 chemicals commercially distributed
- 2,000 new chemicals registered per year

1. Background and Progress



- Essential for modern times, but hazardous to human health and environment ☞ Precautionary measures needed

DDT(1939~1973)

✓ Substance of Miracles (1939)

- Malaria prevention, pest eradication, etc
- A developer (P.H.Muller) won Nobel prize(1948)

✓ Adverse effects on Ecosystem
(e.g. red-tailed robin, trout, etc)

- Rachel Carson, Silent Spring (1962)
- Prohibition of use in U.S. (1973)

✓ Still used for prevention of Malaria and typhus in several countries

Damage from thalidomide (1957~1961)

✓ Morning sickness inhibitor

- No adverse effects from animal testing

✓ 12,000 infants with birth defects from 50 countries

- 4 years spent to identify causes

※ U.S. was the only country without damages
(Sales not authorized based on toxicity analysis data)

✓ Reused for chemotherapy

- 2.5 billion dollars earned per year

Damage from humidifier disinfectant (2011~2013)

✓ Carpet antibacterial agents, etc('97)

- Water + PGH / PHMG (0.01%)
- Reused as humidifier disinfectant agents

✓ Unidentified lung damage (e.g. acute respiratory failure)

- Frequently occurred in the pregnant, infant/babies

✓ Suspected cases (April,14)

- Of 361 patients examined, 27 confirmed to have lung damage; 41 with high possibility; 42 with low possibility

Chemicals, difficult to know …

Especially, their HAZARD !!

If we use them well,

If we use them wrong

Introduction of EU REACH (June‘07)

Protect public health and the environment
- Secure chemical substance information before market release -

Strength competitiveness of EU chemical industry
- Armed with the latest technology and service -

Obtain human•physical resources
- developed IT system, established ECHA -

EU, U.S, Japan, China…

No Data

No Market !!

…..Global Standard

1. Background and Progress

Needs for Korea Act on Registration and Evaluation, etc of Chemical Substances

1	Protect human health and the environment from unknown chemicals
2	Obtain chemical safety data Promote occupational safety management
3	Chemical accident of humidifier disinfectant Prevention of repeated chemical accident

⇒ Needs for advancing chemical registration and evaluation system

1. Background and Progress

Definition of the Korea Act

- Develop a system for securing advanced chemical information
  - EU REACH(introduced in June'07) "No Data, No Market"
- Chemical management based on 綠色化學
  - Expect for developing eco-friendly substances and risk management methods

Details

- Annual reporting; registration prior to manufacture / import; information provision
  - Extended to existing chemicals (prior public notice, grace period for registration)
- Examination/evaluation of registered substances, designation of hazardous substances
  - Hazard assessment by National Institute of Environmental Research
- Safety management of household chemical products and biocide
  - Declaration of product containing hazardous chemicals, Safety standard labeling for risk-concerned product, etc

Current Status

'11.4.	'12.9.	'13.5.	'13.8	'14.2~4	'14.6.	Present
Chemical accident of humidifier disinfectant	Chemical accident in Gu-mi	Legislation · announcement of the Korea Act	Legislation of subordinate laws	Public notice	Regulatory examination completed	**Ongoing review by Legislative Office**

•Formation/operation of consultative body among stakeholders

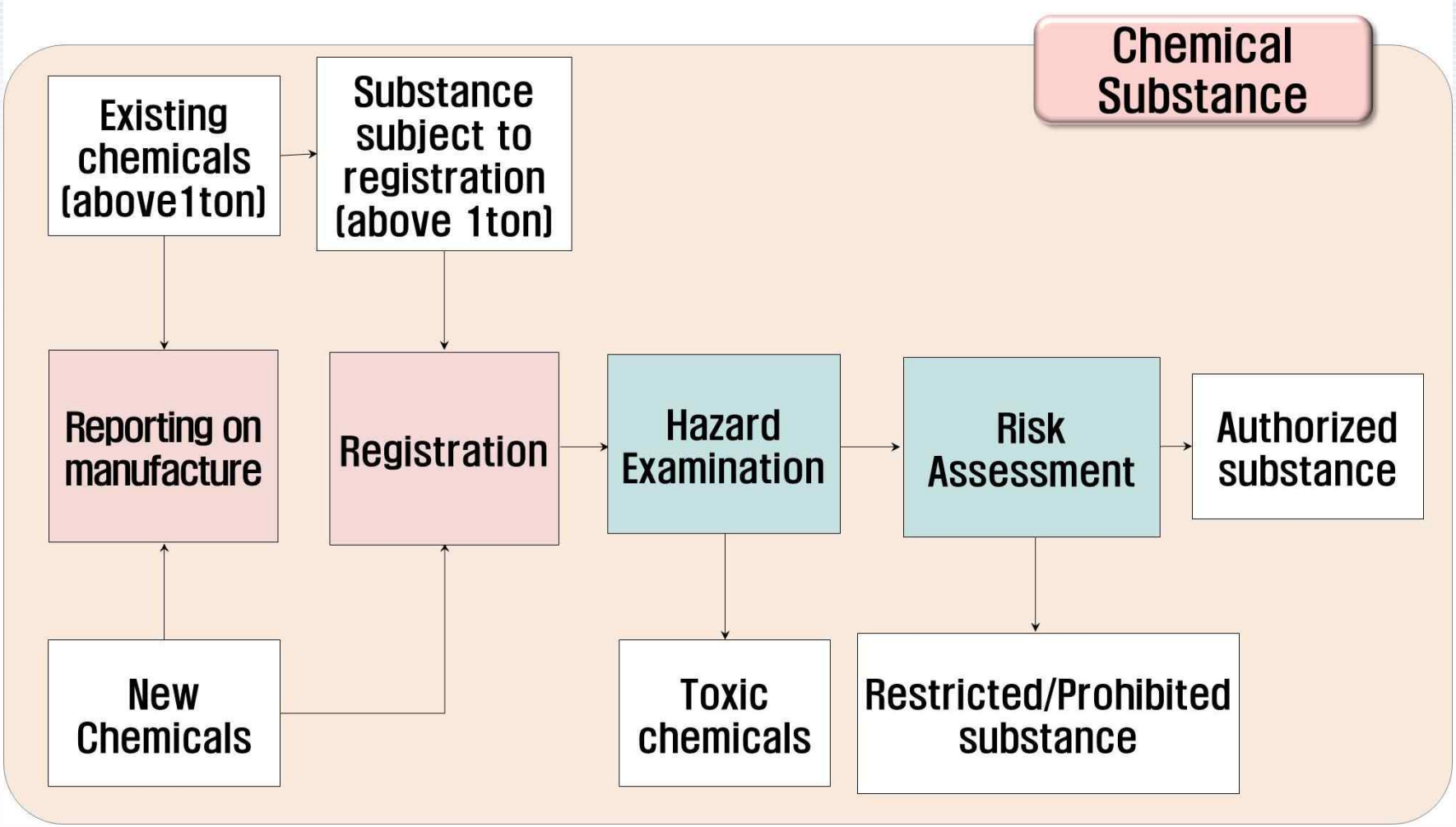
* The original law unchanged if its opinion violates the intent of the law
-Prolong grace period for registration of small-medium enterprises, not subject to confirmation of exemption of R&D substances below 1 ton

Issue	Draft subordinate law
① Exemption from registration of R&D substance	Maintain the current law (exemption); add safety measure(submission of management plan, etc)
② Registration of small volume new chemicals	**Small volume to be registered**, simplify submission data, shorten registration period, etc

Overview of the Act

2A. Overview of the Act

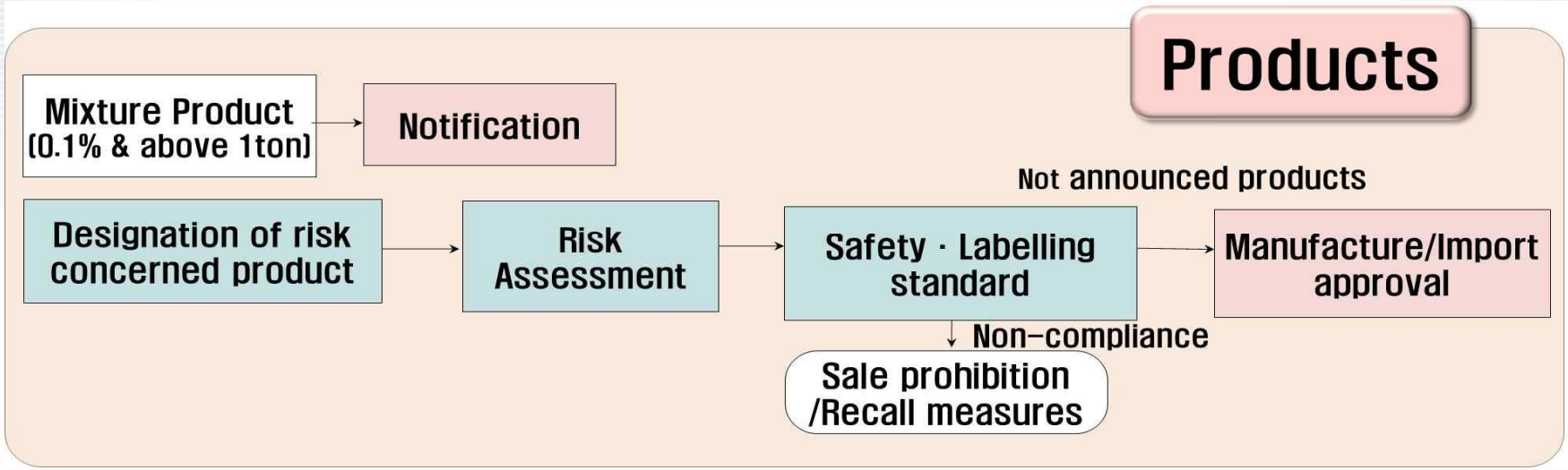
- (Chemical substance)
  Registration → Evaluation/Assessment → Designation of hazardous chemicals



2A. Overview of the Act

(Chemical substance)

Designation of Risk concerned product → Evaluation → Management standard

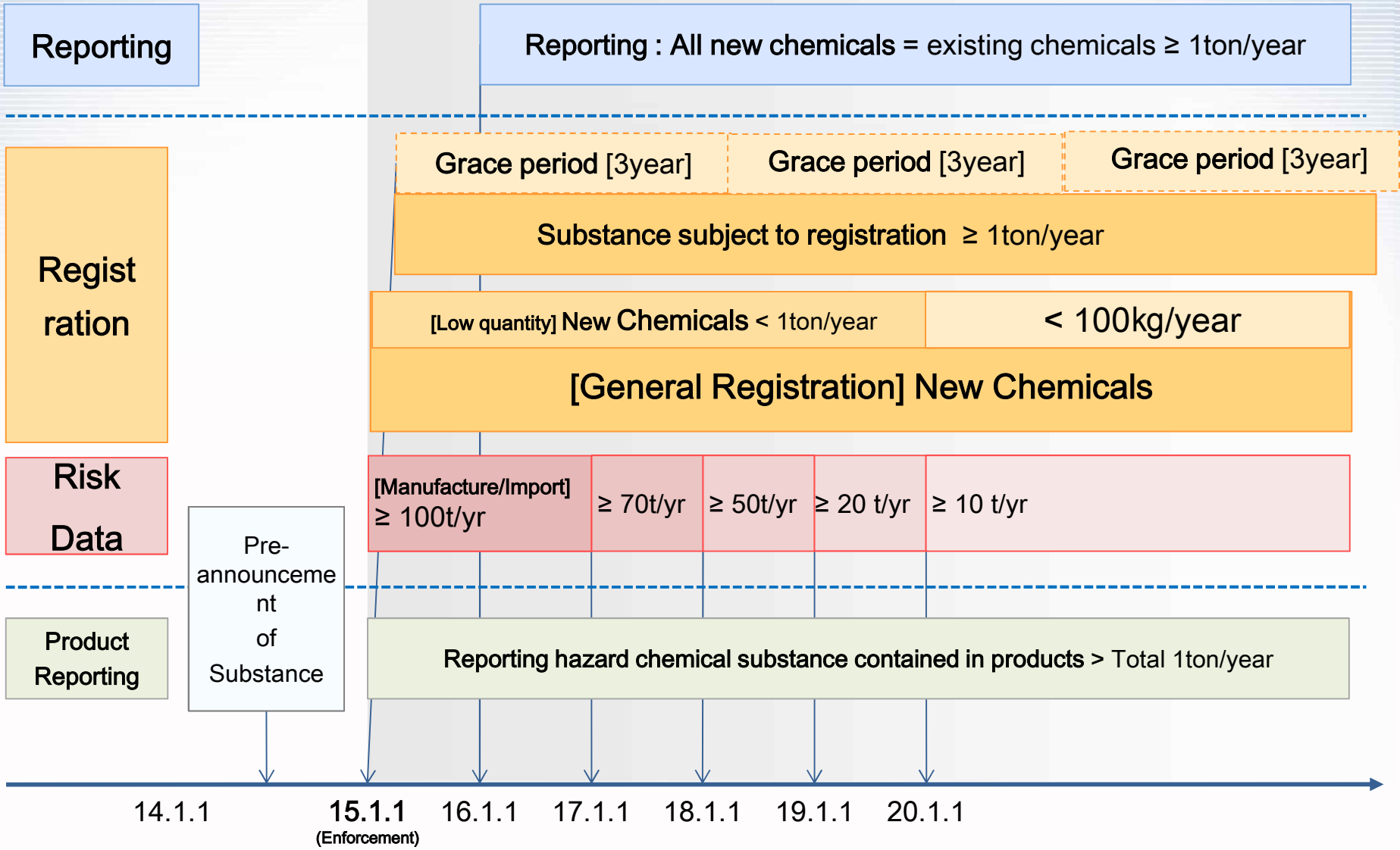


Enforcement Date: 2015.1.1

- Risk data submission criteria to be strenghened

Date	2015.1.1	2017.1.1	2018.1.1	2019.1.1	2020.1.1
Criteria	100t/year	70t/year	50t/year	20t/year	10t/year

2A. Overview of the Act



Main Contents

2B-1. Reporting of Manufacture etc.

2B-1-1. Meaning of Reporting System

Meaning of Reporting

① Understanding in advance of an obligator of joint submission , Fundamental data for designation of existing chemicals subject to registration

② Understanding status of obligator's performance , Use of substance after registration, Confirm the fact of volume change

Reporting Method

- Report the status of chemicals of the preceding year by June 30 of the following year

Obligator of Report

- A person responsible for reporting the manufacture, importing and selling of chemicals etc. of chemicals ⇒ Except for users in business, sales to consumers

Contents of Reporting

- ① Report Company Name, ② Name of the chemical substance, Identity number, ③ Quantity of manufacture, use/sales, ④ Detailed use
- In case of seller, Product name, Buyer, If report composition elements, ②, ③, ④ can be omitted

Exemption of Reporting

- Low effectiveness of existing chemical substance in terms of risk

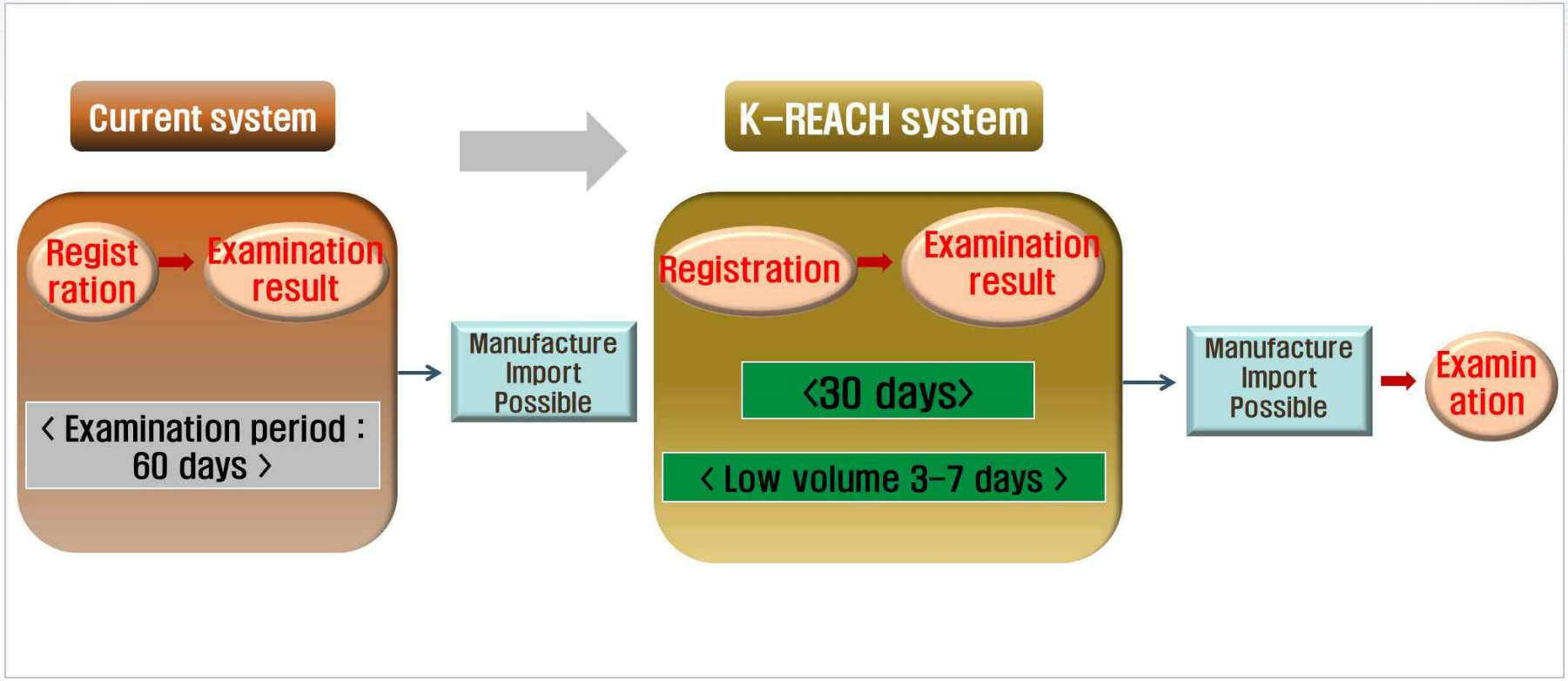
  * Since reporting is to understand the status of registration performance, except existing chemical substance which have no possibility to be applicable to registration(Notification)

2B-2. Registration of Chemical Substance

2B-2-1. Registration Procedure

Division of Registration and Evaluation Procedure (Similar to EU)

- Division between Review procedure of submission data(Registration) and Review of contents(Evaluation)



2B-2-2. Substance subject to registration

Designation System of Existing Chemicals Subject to Registration

- Every 3 years Designation and Announcement of Existing Chemicals Subject to Registration

  - Result of Report and Statistical survey, Consideration of domestic/overseas data regarding hazard &risk

- Grant 3 year Registration Grace period

  - 3 year registration grace period referring to EU REACH registration period

  * REACH Fermentation('07.6) after First : '10.12(3yr6mth), Second : '13.5(6yr), Third : '18.5(11yr)

- Prior notice for Designation

  - Prior notice schedule('14yr) before enforcement

2B-2-3. Substance subject to registration

Chemical Substance subject to registration by type

- Impurities · By-product except from registration
  - Fill in the application registration(Similar to EU)

*** Impurities :** By chance or Unintended, Non-commercial purpose or Non-commercial value to other chemical substances

- Different types of intermediates
  - Non-isolated: Exemption / Isolated: Registration

*** Intermediate :** A substance that is manufactured for and consumed in or used for chemical processing in order to be transformed into another substance.

- Low concern Polymer is exempted from registration
  - Exceptions: Cationic polymer, etc.

2B-2-4. Substance subject to registration

Registration of Small Quantity New chemical Substance

- Simplification of Registration Below 1 ton/year('20yr 0.1t)

- Submission Data : Business information, Use, Identification information, Purpose of Use related to exposure information

- Period : Notification within 3 days after registration

  (If necessary additional review:7 days)

- In case of concerning of consumer exposure and exceeding accumulation of small quantity standard, submit additional data

2B-2-5. Exemption of Chemical Registration

Exemption of Chemical Registration

① Chemicals in imported machineries

② Chemicals in imported machineries devices for test-run

③ Chemicals contained in solid form product that is not released during use

Chemicals subject to Registration Exemption Confirmation

1. Chemicals that are intended for manufacture or import for scientific experiment, analysis such as reagents (Annual Basis)
2. For the purpose of research and development (R&D plan Basis)
3. Low concern polymers (For the first time)
4. Chemically surface-treated chemicals that are intended for manufacture/import in which both the substances subject to surface-treating agent are not new chemicals or existing chemicals subject to registration (For the first time)
5. Chemicals such as manufactured or imported in amounts that are no more 10 tons for the purpose of exporting the entire quantity abroad (Annual Basis)
6. Chemicals such as manufactured or imported in amounts that are no more 10 tons for the purpose of exporting the entire quantity abroad to manufacture other chemicals (Annual Basis)
7. Non-isolated intermediate and isolated materials of certain condition (For the first time)

2B-2-6. Chemicals subject to Registration Exemption Confirmation

Chemicals for Experiment analysis, Research and Development

- Regulation of Chemicals subject to Registration Exemption Confirmation

  (Same as current hazard regulation)

  - Process development, Reagent, Demonstration manufacture before product, For test etc. Materialization

- Permit transfer out of a place of business, Reinforce of Safety

  - Submission of proof data for research and development, safety plan, post processing plan etc.

2B-2-7. Data apply for Registration

Specific Data apply for Registration (Similar to EU)

- Materialization of Data of identification information, use, classification, labelling, characteristic, Hazard, Risk,etc

	Information	Registration Criteria	Remarks
1	Information of manufacturer or importer	○ New chemicals ○ Existing chemicals subject to registration (Above 1 ton/year)	- Name, Address & Representative person
2	Chemical substance identification information		- Identity information including name, molecular formula, chemical structure etc.
3	Use		- Use classification system, known use, prohibited use
4	Classification and Labeling		- International classification, Materialization of GHS items
5	Physical-chemical properties		- Differentiation according to tonnage(46 Max.) - Submission of Full data or test summary
6	Hazard Information		
7	Safe use guidance		- Protective equipment, Emergency measures
8	Risk	○100 ton or more per year (Gradually strengthened)	- 1) Hazard assessment, 2) Exposure assessment(Exposure scenario / Exposure prediction), 3) Safety confirmation
9	Exposure information, Estimated Volume		

2B-2-8. Data apply for Registration

Submission of testing date (Differential according to annual manufacturing import volume)

- 1ton above~10ton below : Max 14 items (A)
- 10ton above~100ton below : Max 25 items (A+B)
- 100ton above~1,000ton below : Max 36items (A+B+C)
- 1,000ton above : Max 46 items (A+B+C+D)

Will announce test exemption criteria by type

Ex) When result of Bacterial Reverse Mutation Test and chromosome aberration test is negative, accept gene mutation test instead of animal test

Type	A	B	C	D
Physico-chemical properties	1) State of the substance, 2) water solubility 3) melting/freezing point, 4) boiling point 5) vapour pressure, 6)Partition coefficient n-octanol/water 7) Relative density , 8) Granulometry	1) Flammability 2) Explosiveness 3) Oxidising propperties	1) Viscosity 2) Dissociation constant	
Toxicology properties testing	1) Acute oral toxicity, if exposure path determines to be inhalation, acute inhalation toxicity 2) Bacterial Reverse Mutation Test 3)Skin irritation/corrosion 4)Skin sensitisation	1) Acute toxicity by oral route or Acute toxicity by inhalation 2) Eye irritation/corrosion 3) *in vitro* Mammalian Chromosome Aberration Test 4) *in vivo* Mammalian Cell Gene Mutation Test 5) Repeated Dose 28-day Oral Toxicity Study in Rodents 6) Reproduction/Developmental Toxicity Screening Test	1) Additional Mutagenetic toxicity (Germ cell mutagenicity tests)	1) Subchronic oral toxicity test (90 days) 2) Teratogenicity 3) Two-Generation Reproduction Toxicity Study 4) Carcinogenicity
Ecotoxicology property testing	1) short-term toxicity testing on fish 2) Ready Biodegradability 3) short-term toxicity testing on invertebrates	1) Alga growth inhibition test 2) Hydrolysis as a Function of pH	1) Inherent biodegradability test 2) Information of decomposition products 3) Chronic toxicity test in fish 4) Daphnia magna Reproduction Test 5) Terrestrial Plants, Growth Test 6) Earthworm, Acute Toxicity Tests 7) Activated Sludge, Respiration Inhibition Test 8) Adsorption/Desorption screening	1) Additional information of environmental fate and distribution 2) Terrestrial Plants Reproduction Test 3) Earthworm Reproduction Test 4) Additional information of Absorption/ Desorption screening 5) Sediment-Water Chronomid Toxicity 6) Bioconcentration: Flow-through Fish Test 7) Additional information of decomposition products

2B-2-9. Data apply for Registration

Rationalization of Registration data (Similar to EU)

- Acknowledgment of 非Test data(QSAR, read-across) and test plan substitute
- Omit test, in case of experiment execution Impossibility and no possible damages that may cause exposure to human body or the environment

Current

No exception for test data

K-REACH

Test data can be omitted

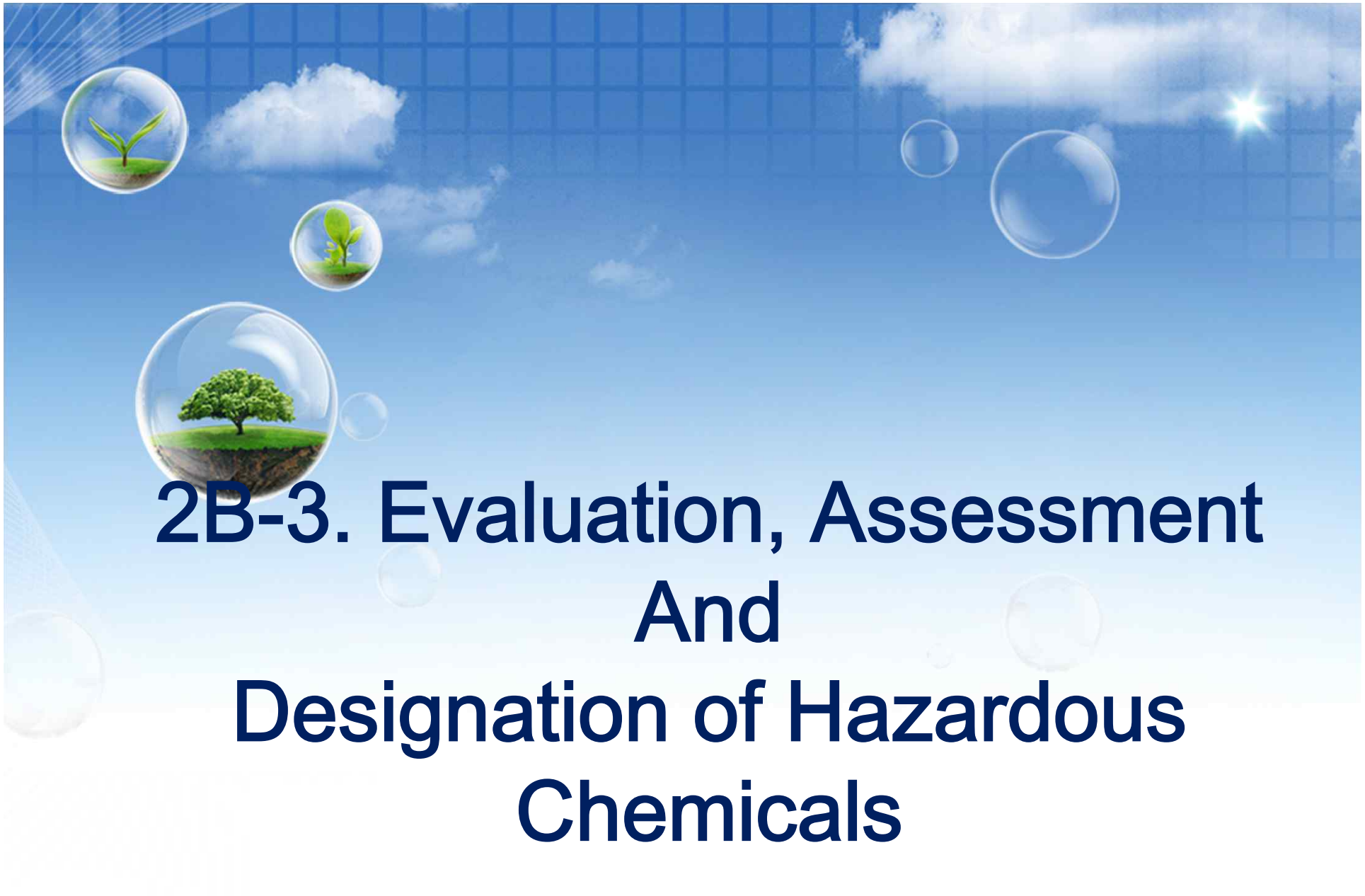
⇒ Small quantity

⇒Dramatically expansion of non-Test data
· QSAR , read-across(Structure Similarity)

⇒ In case of impossibility of technical test

⇒ In case of non-exposure to human, environment

⇒ Acknowledgment of Test plan substitute
· No structure of test base, Long-time required



2B-3. Evaluation, Assessment And Designation of Hazardous Chemicals

2B-3-1. Evaluation, Assessment System

- Hazard Evaluation : Notification of Result of Registered hazardous chemicals

  - Review of test data submitted by manufacturer and Property data

  - Additional data can be required for submission regarding consumer hazardous chemical substance and Biocide

    ◇ Grounds for additional date can be ordered for submission

    - As a result of review of propriety and reliability, require revision, supplement

    - Concerns about exposure to human body and environment based on use and exposure information

    - Small quantity of existing chemicals which were manufactured, imported accumulation amount is exceed 1 ton

    - Possibility of designation as hazardous chemical substance

    - Biocide, Products containing hazardous chemical substance

    - In case of need of test data specialty

- Hazard Assessment : Government self-assessment of International organization evaluation substance and entire quantity export substance etc.

- Risk Evaluation : Implement of evaluation and Notification of result based on the result of hazard examination

  - Selection of evaluation substance, Preparation of hazard assessment report

2B-3-2. Designation of Hazardous substances

- Designation : Evaluation· Assessment Result, Hazardous Substance, Authorized Substance, Restricted Substance, Prohibited Substance

Category	Designation Criteria	Remarks
Hazardous	○ Hazard examination Result - Possible damage to human body· Ecotoxicology substance	- Name, Classification, whether the chemical substance is a hazard substance
Authorized	○ Hazard examination + Risk evaluation result - Risk-concerned substance	- Carcinogenic· Mutation· Bio accumulative etc. - Name, Classification, Authorized use, Grace period etc. - prior notice + Acceptance of an opinion procedure - Prepare risk evaluation plan, socio-economic analysis plan(If needed)
Restricted/ Prohibited	○ Hazard examination + Risk evaluation result - Admitted risk substance	- International organization, International agreement etc. - Name, Classification, prohibited use - Prior notice + Acceptance of an opinion procedure -Prepare risk evaluation plan, socio-economic analysis plan (If necessary)

- Management : According to 「Chemical Control Act('15.1.1 Enforcement)」

- Strengthen business authorization and standard use management of handling facilities etc.

2B-3-3. Designation of Risk-posing substances

Designation of toxic substance

- Toxic substance according to TCCA

  *** Current status of designation of toxic substance according to harmful regulation**(May 2014) :

  687 chemicals included in Benzene, Toluene, Sodium peroxide etc.

  ⇒ regard as toxic substances according to K-REACH(Additional clause Article 2)

- Supplement to correspond with UN GHS

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

- Repeated exposure toxicity, Mutagenicity, Carcinogenicity, reproductive toxicity(Health Hazard)

- Aquatic acute ecotoxicity, Aquatic chronic ecotoxicity (Environment Hazard) establishment or improvement

* Repeated exposure toxicity requires additional aquatic ecology toxicity item about algae, a water flea, exclusion of specific exposure period

*** Maintain Acute oral · Dermal and Inhalation toxicity · Skin corrosion etc. which is coincident with GHS**

* Low item of toxicity level(Eye damage etc.) and No reflection of items which is not standard of GHS(Aquatic plant growth inhibition test, etc.)

2B-3-4. Designation of Hazardous Chemical Substances

Designation of Authorized Chemicals

- Significance: In case of Restriction·prohibition of Manufacture·Import·Use, will cause chaos in industry

  * **Restricted**·Prohibited Chemicals : Prohibition of manufacture, import, use as a special or all use

    * Current status of designation of restricted·prohibited substances(‘14.5mth) :

      Handling prohibited substances(60 DDT, PCBs, Current asbestos etc. substances), **Handling restricted substances**

      (12 Malachite green, Nonylphenol etc. substances)

⇒ In spite of high hazardous chemicals, If industry’s cost burden is higher than benefit of national health care for a certain period, It is allowed to manufacture, import, use for a certain period

⇒ Proper management of high risk concerned substances, Induce development of substitute substance gradually

◇ EU REACH :

- Development promotion of substitute substance, For the purpose of gradual market liquidation of risk-posing substances
- Designation of 134 authorized candidate substances(‘13.12),
- Currently Designation of Musk xylene, MDA, HBCDD, DEHP, BBP, DBP etc.31 as authorized object substance (‘14.6)

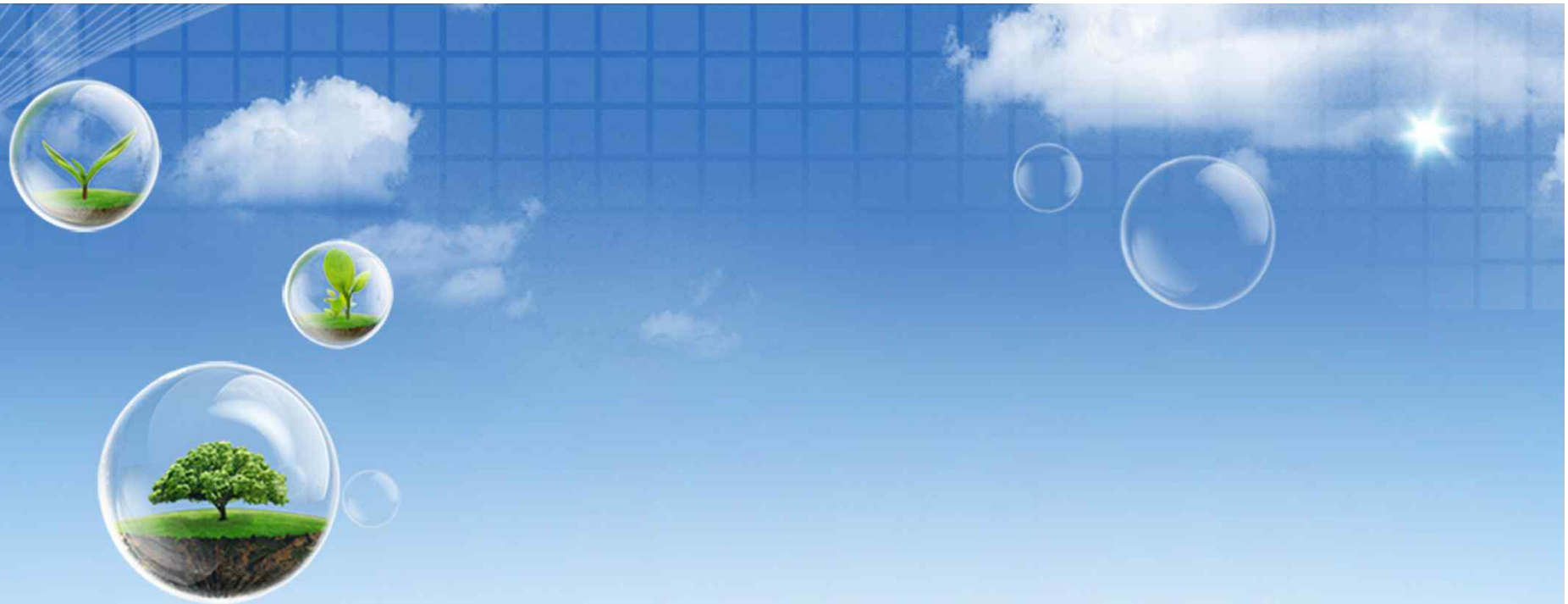
2B-3-5. Designation of Hazardous Chemical Substances

- Authorization Grace Period : Manufacture, Import, Use without authorization

  * Considering the use, manufacture and usage cycle of the relevant chemical subject to authorization

- Criteria of designation of chemicals subject to Authorization : Similar to EU REACH

Category	EU REACH Criteria	K-REACH
Cancer	“Directive 67/548/EEC”Carciogenic Category1/2 Substance	Table4. 1, Ga mok
Mutation	“Directive 67/548/EEC”Mutagenic Category1/2 Substance	Table4. 1, Na mok
Reproductive toxicity	“ Directive 67/548/EEC”Reproduction toxicity Category1/2 Substance	Table4. 1, Da mok
Endocrine system disorder	Endocrine Disruptor	Table4. 1, Ra mok
Residual-prone/Living organism accumulatise/Toxicity	Annex 1 PBT Substance	Table4. 2
High residual-prone/High living organism accumulatise	Annex 13 vPvB substance	Table4. 3



2B-4.Chemical Substances • Mixtures Information offering

2B-4-2. Chemical substances •Preparation Information offering

- Registered chemical substances, Contained mixtures Information offering : Substance·mixtures

Transferor ⇒ Transferee

- Registration Number, Name, Hazard·Risk Information, Safety use information etc.

  (In case of occurrence of change item : within 1 month)

- In case of repeated transfer: At the first time of transfer

- 「Occupational Safety and Health Act.」 Acceptance of information for MSDS

- Bilateral Information Offering : Provide within 1 month from the date of opposite party's request

- Downstream user·Seller⇒ Manufacturer·Importer : Use, Exposure information, Volume of usage · sale, safety use etc.

- Manufaturer· Importer⇒ Sub-user·Seller : Use, Characteristic, manufacture·import quantity, Safety use information etc.

- Notification by Minister of Environment : If modification to the information, notification to registered person.

2B-4-3. Specific contents of Information Offering

"Chemical Substance Safety Information" Offering

- Name, Hazard, Limited Use, Precaution etc. Mainly offer chemical substance safety information etc.
  - Component, Content etc. Except for business confidential information, Quantity of manufacture·Import·sale can be omitted

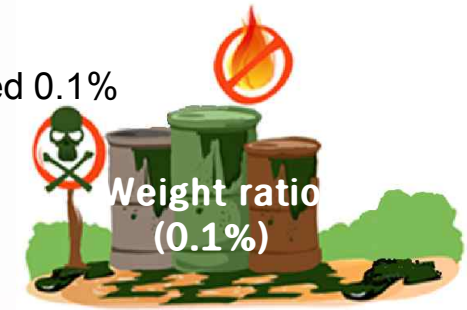
Content	- Offering Registration content relevant to classification, Labeling, Hazard etc.
Period	- Offering according to simplified form before transfer or concurrently

2B-5. Chemical Product Management

2B-5-1. Reporting of Products Containing Hazardous Chemical Substances

Reporting Requirements

- (Total quantity criteria) **Product production and Importer base**, total quantity exceeds 1ton per year by chemical substance
- (Content criteria) Weight ratio of products containing chemical substance: Exceed 0.1%
  (Similar to EU REACH)
- (Preparation product) Except for product in Article 2, 15ho, na mok



※ Article 2.15. "Product" mean goods that are ultimately used by consumers or parts or components of such goods, and which fall under the following with the possibility of exposing consumers to chemical substances.

Ga. Products consisting of preparation

Na. Products where chemical substances are not released during use, but perform a certain function while in the form of a certain solid form.

- (For consumer) For consumer product subject to report, **Except for industrial product**

2B-5-3. Risk-Posing Products

- Risk-posing products : Concerns about posing risk to people's health or the environment, Announcement of Ministry of Environment

① Products such as cleaners, air fresheners, adhesives, polishes, odor removers, synthetic detergents ,bleach, fabric softners, etc., used by the general consumer primarily for household use

② Biocide such as insect repellents, disinfectants, preservatives, etc.

- Risk Evaluation : Evaluation risk-posing products for each type

-Enforcement of government self risk evaluation without submitting producer· importer's hazard data

- If necessary, require data submission, Collect sample

- In case of incident of domestic/overseas hazardous concern, Emergency enforcement, Determine whether hazardous or not

<Method of hazard examination of products containing hazardous chemical substances>

plan	- Basic plan should be established every 2 years by President of National Institute of Environmental Research
Object	- **International regulation product**, Detection products containing hazardous chemical substance
Evaluation Method	-Confirmation of product containing hazardous chemicals → **Computation of exposure allowable tolerance → Evaluation of degree of exposure→Risk etc. process**

2B-5-4. Risk-posing Products

- Safety• Labeling Standards : According to risk evaluation, announce the safety and labeling standards regarding risk for each type

  - Registration• Examination•Evaluation of chemicals(⇒ Hazard•Risk Information), Set the standard by making use of status of product reporting etc, synthetically

  - Designation of unserviceable hazardous chemical substance or Set the safety standard such as volume of content yield of water evapotranspiration etc. of product containing hazardous chemical substance(including container packaging)

- Prohibition of Sales, etc. : No selling or presenting as a import of products unsuitable according to the safety and labeling standards

  - A person Intending to produce or import risk-posing products that do not have safety or labeling standards shall submit data by preclearance of the Minister of Environment

- Withdraw Order, etc. If products doesn't meet the standard, risk concerned product whose standard are not notified:

  - Possible damages to health or the environment → Collect, Withdraw, Prohibition of Sales, Scrapping, Order to take a improvement • correct

  - Order to take emergency measures to prevent spread of damage

System Implementation

3A. System Implementation

Selection of Existing Chemical Substance subject to Registration

Overview

- Designation. Announcement considering ①Domestic volume, ②Hazard. Risk among existing chemical substances

- Persons jointly submitting registration application data are all in agreement, they may jointly submit test data in 3 years of grace period

Future Direction

- Pre-announcement 518 substances
  - Official announcement after gathering the opinions in 2016

- Will review the criteria to select substance for notification after 3 yrs

3A. System Implementation

Transfer of control of household use chemical products

Overview

Transfer of control for household product('12.11)

Reflect applicable provision(Chapter 6)

Discussing the time of transfer

- Apply Product under Quality management and industrial safety law before the announcement of safety standard

Household product		Biocide
Product under Quality management and industrial safety law (8)	Uncontrolled product(7)	
cleaners, air freshners, adhesives, polishes, odor remover, synthetic detergents, bleach, fabric softners	rustinhibitor, antifogging agent, colorant·decoloring agent, dye for tatoo	Insect repellents, disinfectants, preservatives

Future Direction

Develop Safety. Labeling standards(Regulation) this year based on hazard assessment

- (Safety standard) use ban substance & set of substance content, reinforcement of substance standard
- (Labeling standard) Labeling of hazardous substance contents, Review of duty of indication partly all ingredient
- Negative method regulation(Exception : positive regulatory scheme for biocidal ingredient

Routine checkup, Reinforcement of market monitoring etc. construct of follow-up system

- Arranging follow-up guideline such as watchdog and operation of accident investigation center

3A. System Implementation

Composition of Evaluation Committee

Overview

Established to deliberate on K-REACH main system(Article7)

- (Matters of deliberation) formation of the basic plan, designation of existing chemical subject to registration, designation of chemicals subject to restricted and prohibited, safety and labeling standards of risk-posing products

Composition of Specialized Committee

- ①Risk Evaluation Committee, ②Governing Committee for risk-posing products, ③Social Economy Analysis Committee

Future Direction

Composition of Evaluation Committee(Within 30 people) and Specialized Committee by field(Within 10 people) in a year

- (Evaluation Committee) Equal ratio of expertise and experience in the fields of chemistry ,environment, health, toxicity, economy and policy
- (Specialized Committee by Field) organized with **private member**

After enforcement, management of evaluation committee according to appointment

Establishing Management Basis

3B. Establishing Management Basis

Securement of Management Manpower

Overview

Necessary to increase personnel for Evaluation and Assessment at the National Institute of Environment Research personnel(currently 4 people)

- Increase of Registration Substance(330substances/yr→About 2thousand substances/yr), Increase of test data submission items(16→46items), Implementation of New System(hazard evaluation etc.)

- New chemical substance(0.1ton →all), Existing chemical substance(Regulated →1ton/year)

Future Direction

Until '**15 year-end 30~40people(including temporary position) level manpower securement**

Additional securement of manpower according to transfer of Life chemicals management

3B. Establishing Management Basis

Securement of Management Manpower

Overview

Type	A	B	C	D
Physico-chemical properties	1) State of the substance, 2) water solubility 3) melting/freezing point, 4) boiling point 5) vapour pressure, 6)Partition coefficient n-octanol/water 7) Relative density , 8) Granulometry	1) Flammability 2) Explosiveness 3) Oxidising propperties	1) Viscosity 2) Dissociation constant	
Toxicology properties testing	1) Acute oral toxicity, if exposure path determines to be inhalation, acute inhalation toxicity 2) Bacterial Reverse Mutation Test 3)Skin irritation/corrosion 4)Skin sensitisation	1) Acute toxicity by oral route or Acute toxicity by inhalation 2) Eye irritation/corrosion 3) *in vitro* Mammalian Chromosome Aberration Test 4*) in vivo* Mammalian Cell Gene Mutation Test 5) Repeated Dose 28-day Oral Toxicity Study in Rodents 6) Reproduction/Developmental Toxicity Screening Test	1) Additional Mutagenetic toxicity (Germ cell mutagenicity tests)	1) Subchronic oral toxicity test (90 days) 2) Teratogenicity 3) Two-Generation Reproduction Toxicity Study 4) Carcinogenicity
Ecotoxicology property testing	1) short-term toxicity testing on fish 2) Ready Biodegradability 3) short-term toxicity testing on invertebrates	1) Alga growth inhibition test 2) Hydrolysis as a Function of pH	1) Inherent biodegradability test 2) Information of decomposition products 3) Chronic toxicity test in fish 4) Daphnia magna Reproduction Test 5) Terrestrial Plants, Growth Test 6) Earthworm, Acute Toxicity Tests 7) Activated Sludge, Respiration Inhibition Test 8) Adsorption/Desorption screening	1) Additional information of environmental fate and distribution 2) Terrestrial Plants Reproduction Test 3) Earthworm Reproduction Test 4) Additional information of Absorption/ Desorption screening 5) Sediment-Water Chronomid Toxicity 6) Bioconcentration: Flow-through Fish Test 7) Additional information of decomposition products

※1t～10t: 14 items(A), 10t～100t: 25items(A+B), 100t～1,000t: 36items(A+B+C), 1,000 t above: 46items(A+B+C+D)

3B. Establishing Management Basis

Completion of Evaluation System

Overview

- Requiring specific Testing data preparation method regarding test items(Max.46) according to K-REACH
  - Currently announce testing methods of 33 testing items according to hazard regulation
- Promotion of hazard evaluation core-technology development business('12.3 ~'14.12)
  - Arranging evaluation skill of hazardous item, Korea environment behavior model, Consumer exposure coefficient and evaluation model, Workshop exposure evaluation etc. related manual

Future Direction

- OECD test guideline reference, Total Test Method Supplementation· Organization
  - Arrangement of testing method and data preparation method regarding the rest of 13 items
- Announcement of Hazard data preparation method, Preparation of related technical manual
  - "Joint Registration demonstration project" pilot written & applicability evaluation schedule

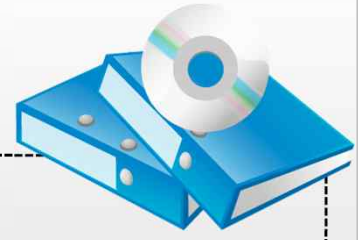
3B. Establishing Management Basis

Establishment· Operation of IT System

Overview

To support performance. operation of the entire process system(K-REACH Article 39)

①Development of report preparation system, ②Development of registration evaluation system ③Portal system, ④Development of product registration evaluation system



◇ **Current status of IT system related to EU REACH**

- Consisting of REACH-IT, IUCLID5, ECHA Portal etc.
- Development from '07, launched in June '08 and '09 Completed(20.5 billion KRW during 3 yrs)

Future Direction

Chemical Substance information processing system
Open('14.12), Completion of Establishment('15yr)

- '14yr Establishment of Basic System(2.5billion KRW), '15yr Budget 2.8billion KRW)

Consideration of Integration of existing SYSTEM(NCIS) and System of Chemical Substance Management

- For convenience of Civil compliant, NCIS system operates separately, Integration until '15yr

3B. Establishing Management Basis

Establishment of GLP test base

Overview

Currently, Minister of Environment designates GLP testing Institution : 15

- K-FDA(Medicine and Medical supplies Field 19)and Rural Development Administration(Agricultural pesticide Field 16)

◇ **GLP(Good Laboratory Practice) : Good laboratory operational standard**
- Standards regarding operating system, manpower, facilities etc., which are to be equipped as testing institution to secure reliability of all kinds of chemical substance's toxicity testing

Undesignated item(12) among testing items required by K-REACH

- 30 items out of 46 testing items required by K-REACH, Invertebrate chronic toxicity, Plant acute toxicity etc, 12 items are not designated.

Future Direction

Forwarding domestic testing basis establishment &Business of manpower training continually

- Testing basis establishment : Environment damage field test. Evaluation skill, Testing facilities management guideline, Testing item field, Construction facilities, Equipment standardization etc.(Annually 15 Million)
- Training of Professional manpower : Environment damage field(19 items), GLP Institutional related

Utilize the test plan submission(Article14 3)

Cooperation & Support of Stakeholders

3C. Cooperation & Support of Interested parties

Support of Small and Medium Enterprises

Overview

Legal system of small and medium enterprise's Implementation capacity is the outcome of the settlement system

- Domestic distribution by SMEs 26%(110 million tons/470 million tons), number of SMEs 96%(15,905companies/16,547companies)

Launched “industry support group”(‘14.4)

To increase capacity of SME’s chemical safety management”(‘14.6.25, Minister’s meeting)

Future Direction

K-REACH First in line(~’17yr) small and medium enterprises supporting business propulsion

◇ **’15yr Support budget(Submission of National Assembly)**

- (Test data support) Small and medium-sized enterprises **chemical substance registration· hazard evaluation support**(28Milliom)
  * offer national test data after produce· secure → foreign test data purchasing cost savings
- (1:1 consulting expert **support**) small and medium-sized enterprises the whole system implementation procedures support(20Million)
  * Confirmation of chemical substance, Preparation of registration data, Registration procedure etc. support
- (Hazard evaluation support) Small and medium-sized enterprises **hazard evaluation system implementation consulting** (20Million)
  * Hazard evaluation report preparation support → Writing ability Enhancement and cost savings

3C. Cooperation & Support of Interested parties

Development of Green Chemistry Technology

Overview

New paradigm“Green Chemistry”

▣ 12 Principals, Anatas & Warner

(3) Less Hazardous Chemicals Syntheses
(4) Designing Safer Chemicals
(5) Safer Solvents and Auxillaries
(10) Design for Degradation
(11) Real-time analysis for Pollution Prevention
(12) Inherently Safer Chemistry for Accident Prevention

Main Function of Green Chemical Center is to develop technology in relation to risk evaluation of chemical substances and reduction and prevention of risks posed by main function of chemical substances(Article40)

Future Direction

Business promotion of Hazardous chemical substance reduction technology development

- Select the project for pre-research project for joint planning project with related government(‘14.8)

▣ Main Technology

① Development of substitute substance and production of prototype regarding domestic/overseas chemical substance regulation object substance

② Use of hazardous chemical substances. Emission reduction process development and substantiation

3C. Cooperation & Support of Interested parties

Establishment of communication system of chemical product risk information

Overview

To increase public reliability for K-REACH, needs sound communication between government and society

ECHA "Communication Strategy"
(Goal : involve, cooperate, consult, inform)

MFDS “Communication advisory committee”(regular meeting with media, NGO, experts)

Needs of cooperation measure between Government and civil organization

Future Direction

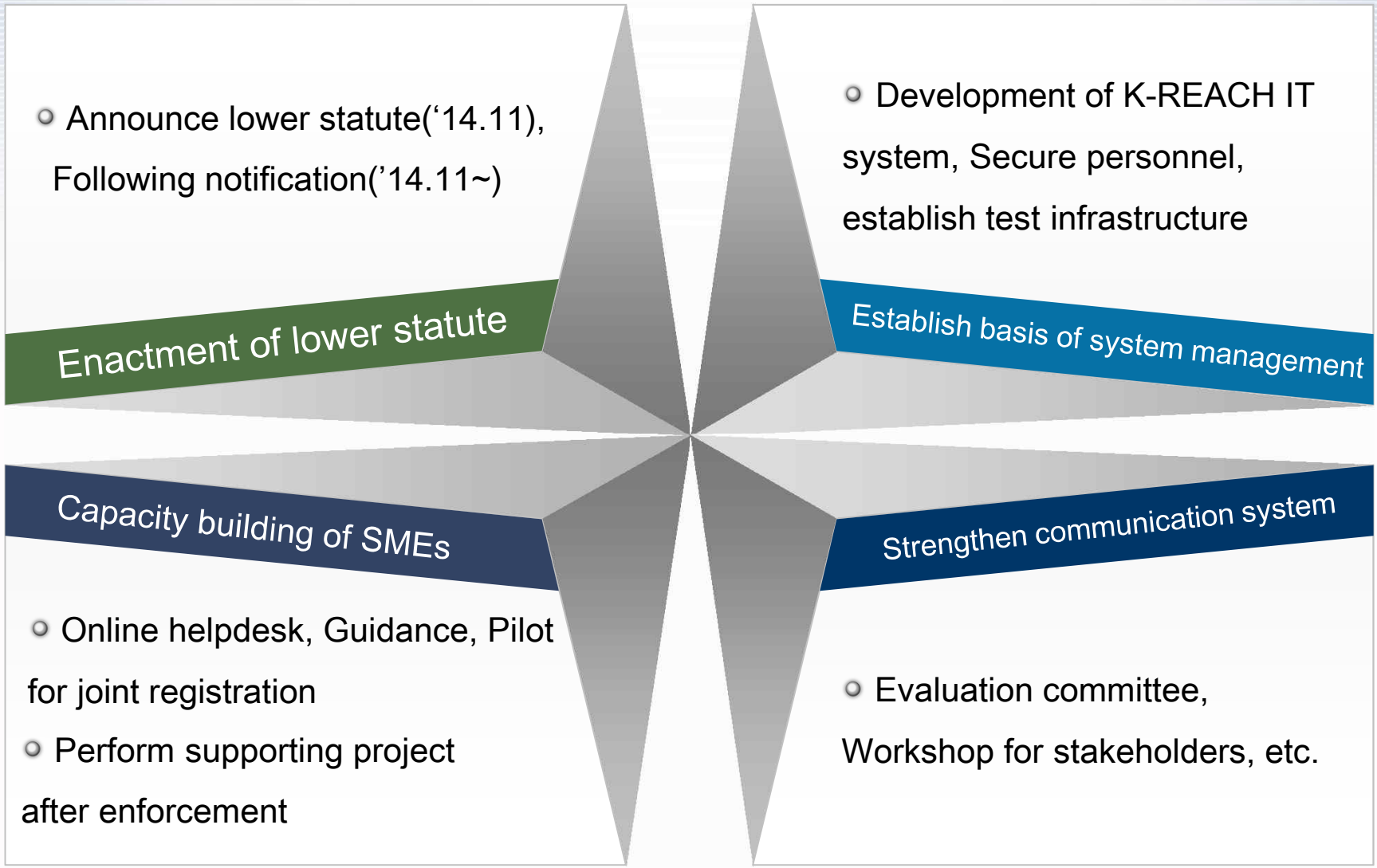
Inducing participation in the system of K-REACH

- Composition of Evaluation Committee, Participation in establishing basic plan, Monitoring related to risk-posing product safety, Cooperation of monitoring system

Vitalization of Communication regarding chemical product safety management

- Review regular meeting & holding workshop among interested parties
  - Share hazardous chemical product information, Discussion of consumer problem presentation items

4. Future Plan



4. Future Plan

Public health protection
&
Strengthen industrial competitiveness

K-REACH

Registration·Evaluation
(All new chemicals including existing chemicals

Authorization·restriction·probihited :
Restrict manufacture, import and use of chemicals

Information sharing :
Apply to safety use of chemical in society as a whole

Induce to develop alternatives to reduce use of hazardous chemicals

4. Future Plan

Sustainable growth of Chemistry Industry through realization Green Chemistry

Enhancement of Substance information service

- Management of chemical substance safety information
- Settlement of public concern and enhance of corporate image

- Foster chemical substance information manager
- Consultant etc. Service industry
- Expansion of Domestic test capacity

Improvement of Chemistry Industry competitive

- Promotion of higher value-added chemistry industry viable
- Innovation of eco-friendly management system

- Expansion of R&D investment
- Advancement of hazardous substance substitute technology
- Promotion of developing chemicals with cutting-edge technology


감사합니다.
Thank you