「Act on Registration and Evaluation, etc. of Chemical substance(K-REACH)」 : Current Status

2014.12

Korea Chemicals Management Association

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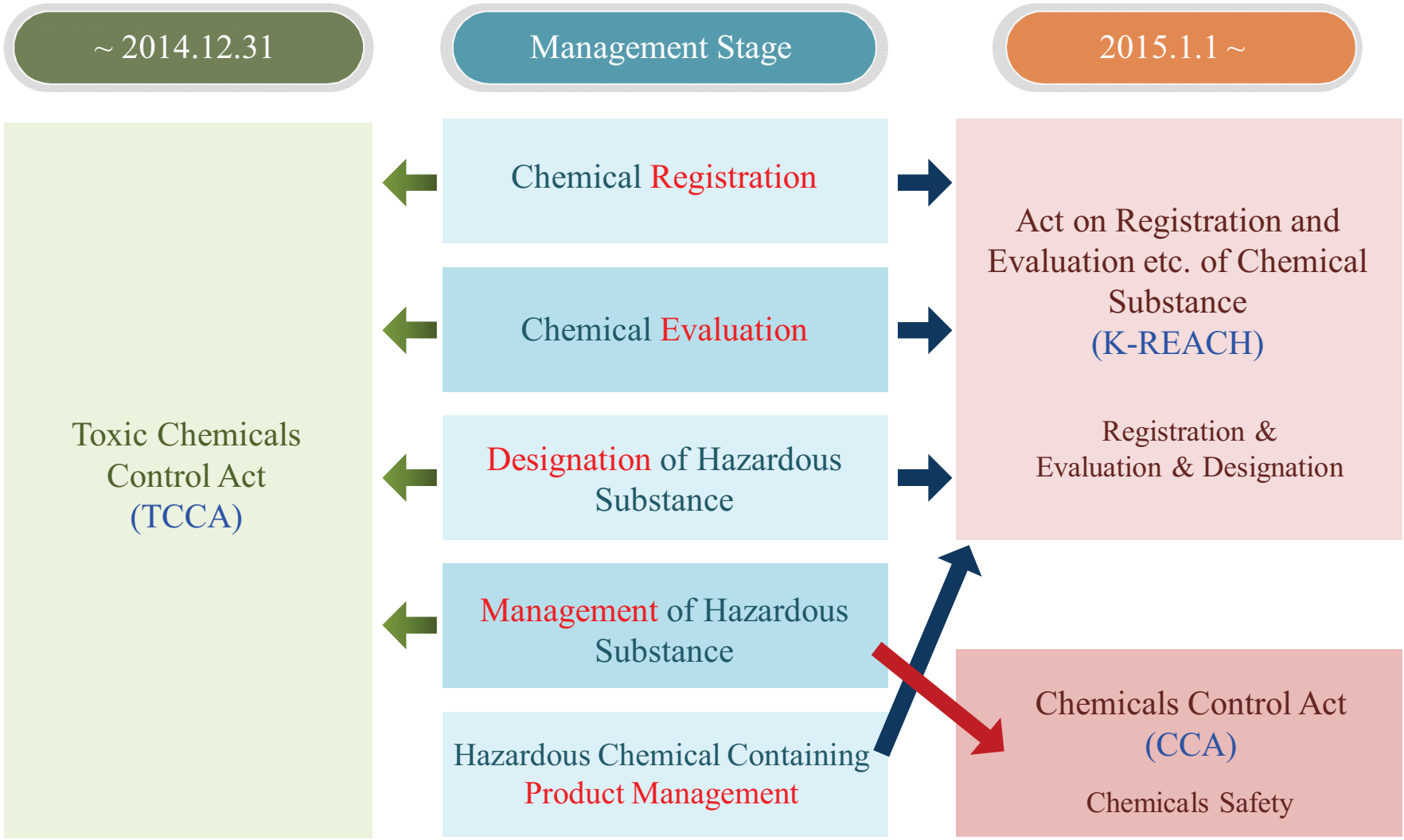
CONTENTS

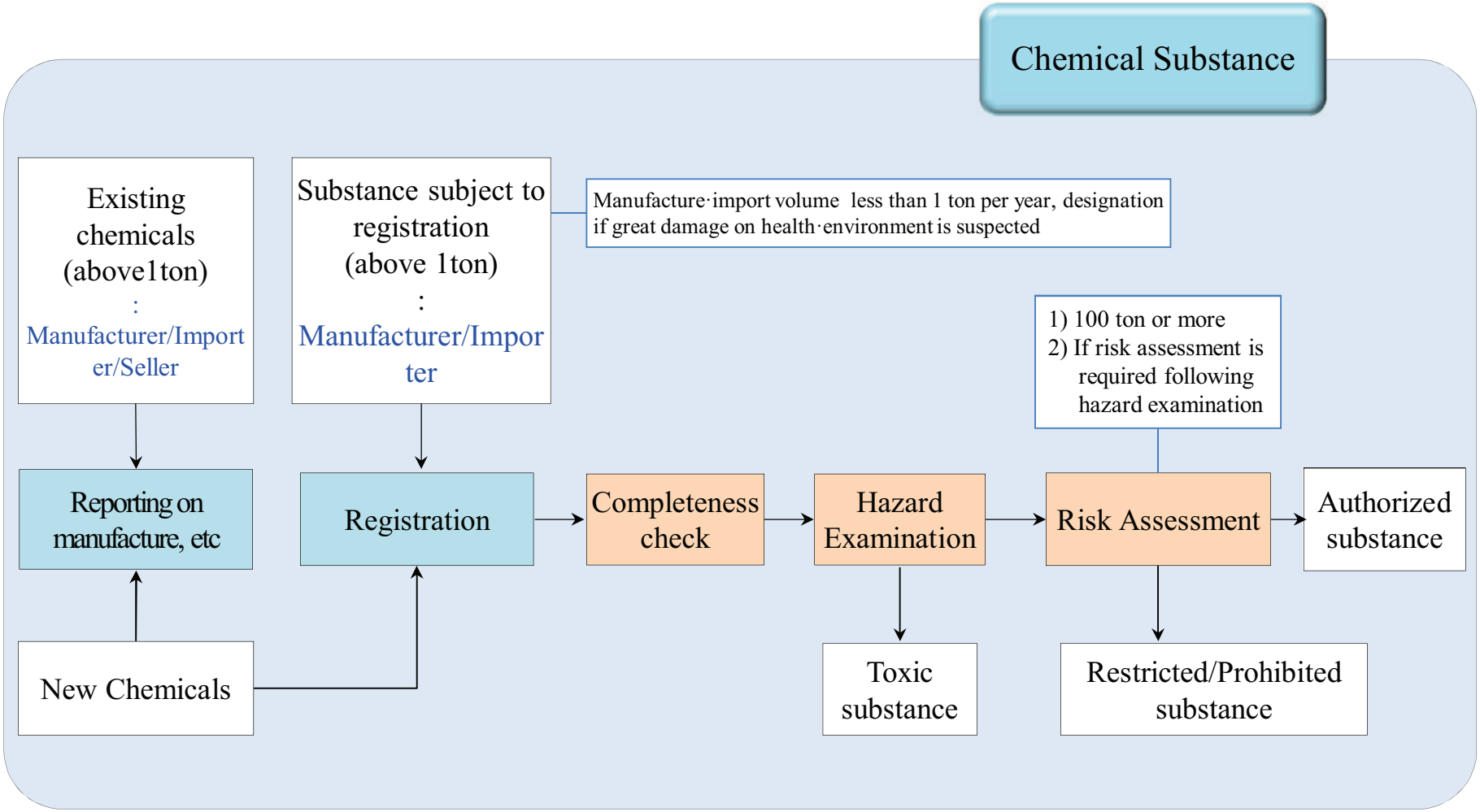
I. Overview

1. Reformed TCCA System



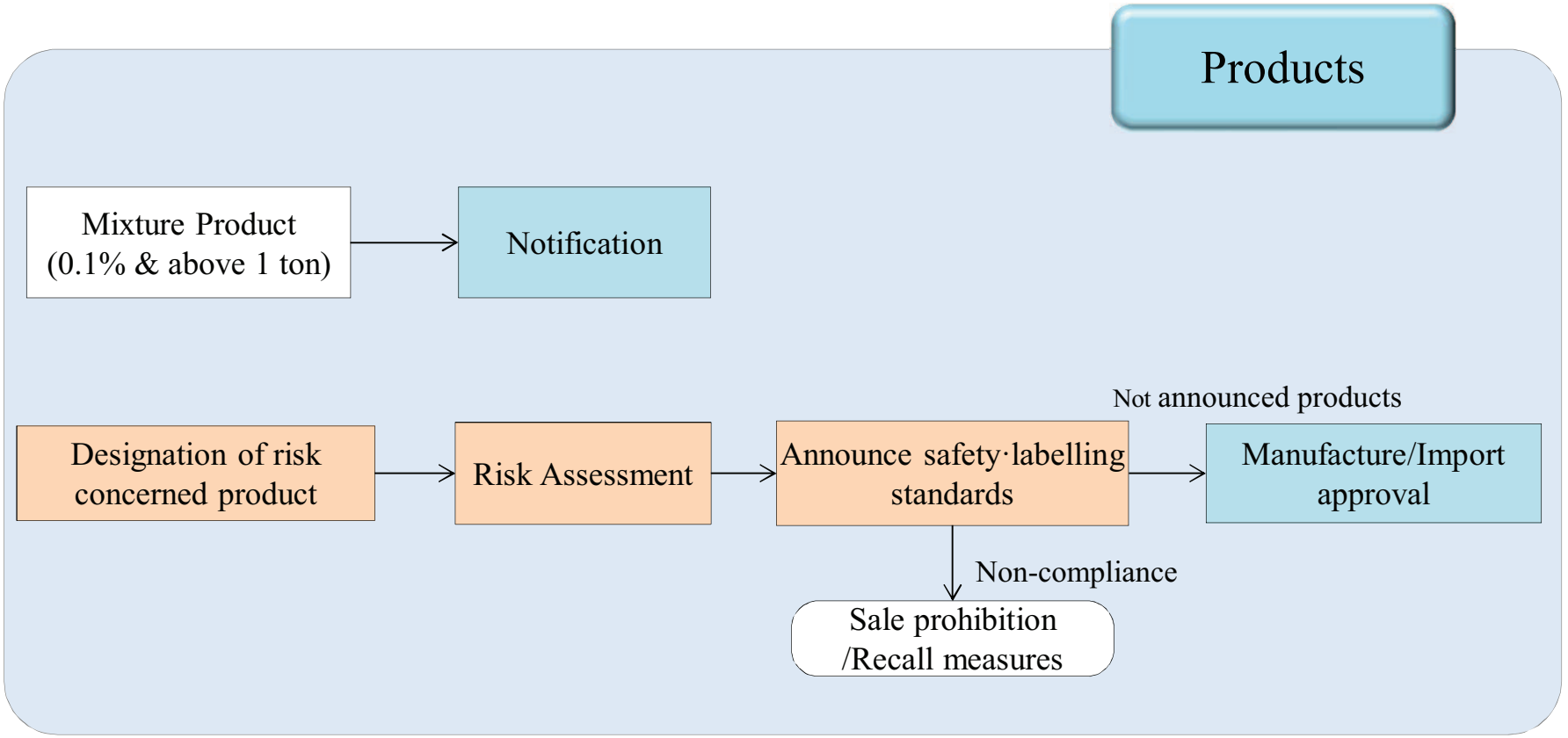
2. K-REACH Flowchart _ Chemical Substance

➢ Registration → Examination/Assessment → designation of hazardous chemicals

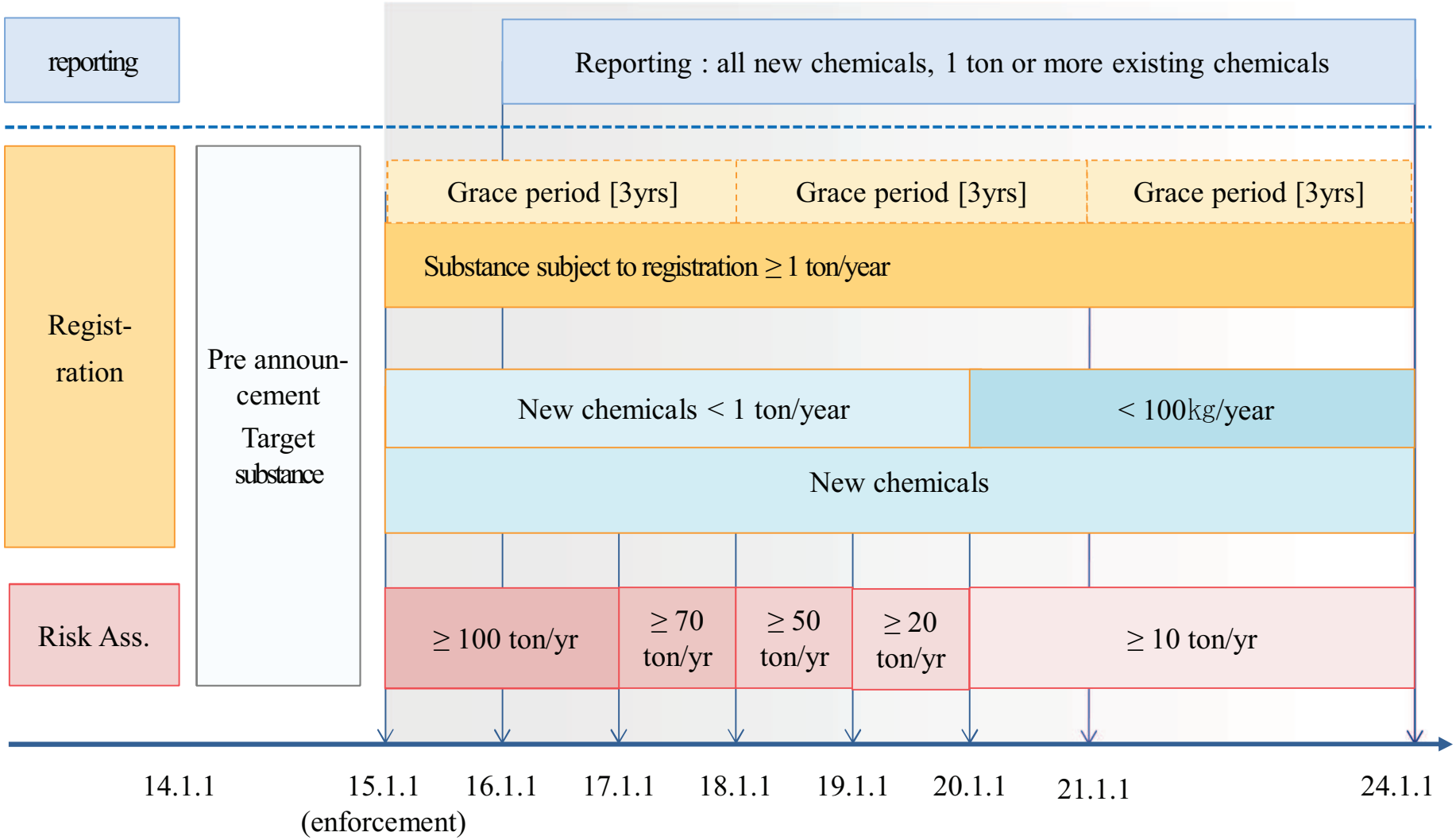


2. K-REACH Flowchart _ Products

- Products containing hazardous chemical substances → Notification
- Designation of risk concerned product → Risk assessment → Management standard



3. K-REACH implementation schedule



II. Main Contents

1. Reporting

➢ Purpose : Identification of obliged registrants in advance, confirmation of any changes after registration etc.

- Encourage joint-submission

  * Similar to EU REACH "Pre-registration"

➢ Reporting : Anyone who manufactures, imports or sells new chemicals and 1 ton or more existing chemicals annually

➢ Required information: Use and Tonnage of chemical substances

- Any changes (i.e. use) need to be notified

➢ 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

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

< Substances exempted from reporting >

- Chemicals in imported machineries
- Chemicals in imported machinery devices for test-run
- Chemicals contained in solid form product that is not released during use
- Manufactured/imported substances for the purpose of research and studies
- Substances for test, Non isolated intermediates
- Low effectiveness of existing chemical substance in terms of risk , etc.

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

2. Registration of Chemical substance

Target : Manufacturer or importer of all new chemicals & existing chemicals (above1ton/yr).

- Although less than 1ton, registration obligation applies to substance that have high risk concern to human health and the environment.

Existing chemical 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

- Target : 518 chemical substances(Pre-announcement, 14.10.31)

[Toxic chemicals(318), Observational chemicals(45), Restricted chemicals(4), PRTR(42), Substances requiring preparation for accidents(12), CMR(33), Aquatic environment(45), Etc(19)]

- Grace period : manufacture/import possible for 3 years from notification date
- Joint submission : same chemical substances are subject to joint submission
- Data sharing : under consent from owner who have previously submitted data
- Test data selected/produced : one test data of each test items

2. Registration of Chemical substance

Exemption of Chemical Registration

① Chemicals in imported machineries

② Chemicals in imported machinery devices for test-run

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

Requires "Confirmation of Registration Exemption" from the KCMA

① Manufactured/imported chemicals for the purpose of chemical reagent for scientific experiment, analysis or research (yearly)

② Manufactured/imported chemicals for the purpose of R&D (R&D unit)

③ Low concern polymers (first time)

④ Chemically surface-treated substances which both base substance and surface-treating substance do not fall into new chemicals or substances subject to registration (first time)

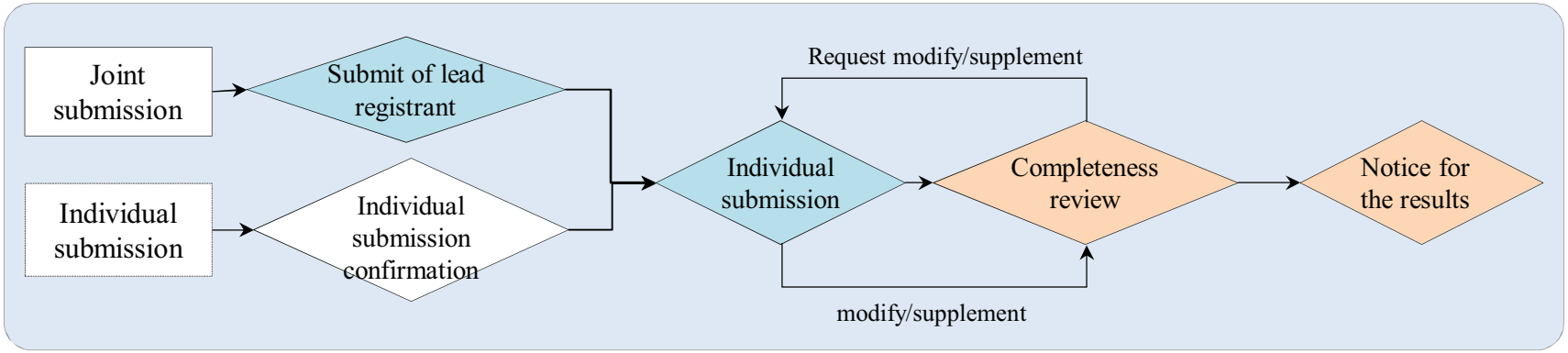
⑤ Chemicals manufactured or imported 10 tons or less per year for the purpose of export only (yearly)

⑥ Chemicals manufactured or imported 10 tons or less per year for the purpose of manufacturing other only export chemicals (yearly)

⑦ Non-isolated intermediate and isolated materials of certain condition (first time)

2. Registration of Chemical substance

❖ Registration procedure

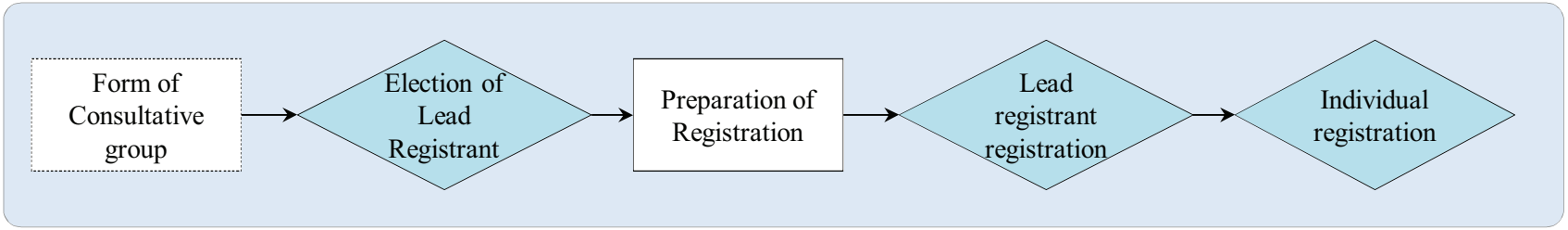


❖ Notice for the results

	Date
Low volume new chemicals	**within 3 days**[less then 1ton/y(15~19), less then 0.1ton/y(20~)]
	within 7 days(If necessary additional review)
General registration	**within 30 days**(from the application of registration)
	within 3 months from an expiration date of grace period(in case of an application submitted by a person who manufactures/imports a priority existing chemical substance during the period of 2 month prior to an expiration date of grace period)

2. Registration of Chemical substance

❖ Procedure and Method of Joint Data Submission



- Procedure : After completing registration of Lead Registrant, member registrants should apply for registration by preparing their own required documents. Other information needs to be submitted by all registrants individually.
- Election of Lead Registrant :"Agreement among parties" → "Election by the majority decision"
- Responsibility of Lead Registrant
  - Tasks for the selection/production of test data for submission
  - Tasks concerning the share of cost for registration data submission
  - Other tasks regarding joint preparation and data submission
- Share of cost : "Agreement among parties" → "equally shared based on the numbers of people need to submit the data and manufacturing/import volume"

2. Registration of Chemical substance

❖ Joint Submission Data

1. Classification and Labeling of chemical substance
2. Physico-chemical properties of chemical substance
3. Hazard information of chemical substance
4. Test plan
5. In case all members of joint submission agree
   - Risk of chemical substance
   - Data regarding the guidance of safe use

❖ Individual submission

1. In case that it is anticipated to cause significant commercial damages due to the disclosure of confidential business information
2. In case that it costs more if submitted jointly than individually
3. In case chemical classifications of substance are different for the same toxicity studies to be submitted
4. In case that individuals disagree with the lead registrant on the selection of test data for the same test item to be submitted jointly

3. Data apply for Registration

❖ Specific Data apply for Registration

	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(47 Max.) - Submission of Full data or test summary
6	Hazard Information		
7	Risk		- 1) Hazard assessment, 2) Exposure assessment(Exposure scenario / Exposure prediction), 3) Safety confirmation
8	Safe use guidance		- Protective equipment, Emergency measures
9	Exposure information, Estimated Volume		

◆ Hazardous data(general registration)

Category	1≤ - <10t	10≤ - <100t	100≤ - <1,000t	≥ 1,000t	0.1≤ - <1t (From 2020.1.1)
Physico-chemical properties	8	11	13(2)	13(2)	5
Toxicology properties	4	10(1)	11(2)	15(6)	2
Ecotoxicology properties	3	5	13(8)	19(14)	2
Total	15	26(1)	37(12)	47(22)	9

* Number in the bracket shows the number of test that can be replaced with test plan

3. Data apply for Registration

❖ Exceptions for biocide

Manufacture• import volume	Toxicity data
1≤ - <10t	Test data of 10-100 t for general registration
10≤ - <100t	Test data of 100-1000t for general registration
≥ 100t	Test data over 1000t for general registration
0.1≤ - <1t (From 2020.1.1)	Test data of 1-10t for general registration

❖ Exceptions for polymer

Manufacture• import volume	Toxicity data
1≤ - <10t	Physico-chemical properties of 0.1-1t test data for general registration
10≤ - <100t	Test data of 0.1-1 t for general registration
100≤ - <1,000t	Test data of 1-10 t for general registration
≥ 1,000t	Test data of 10-100 t for general registration
0.1≤ - <1t (From2020.1.1)	Physico-chemical properties of 0.1-1t test data for general registration

3. Data apply for Registration

❖ Standard of Hazard data

- Level of data – any one of the following

- The whole testing data describing test result without modification of process & procedure etc., which is performed to produce Physico-chemical properties, hazard information of chemical substance

- Testing summary which is descripting sufficient information like purpose, method, result and conclusion sufficient information to perform of evaluation regarding testing result by minimizing the whole testing data

- Test data produced by designated domestic testing Institute or foreign testing Institute following GLP standard

- 1 item for physico-chemical properties, 15 items for Toxicology properties, 14 items for Ecotoxicology properties
- When submitting Foreign testing Institute Implementation testing date, GLP certificate or document required for the verification of following GLP standard

❖ Submission of test plan

- (Applicant) Preparation &submission of test plan - name of test data, name of testing institute, test method, test schedule, expected submission date of test data
- (National Institute of Environment Research) Review the completeness and notify the result - submission due date, test condition/ method, supplement request
- (Applicant) Test execution and submission of test data – Submission due date can be extended if test data cannot be submitted by the due date due to the force majeure reason of domestic testing institute
- If test data is not submitted by the due date, it will considered as not registered

3. Data apply for Registration

❖ Submission of Risk data

- Phased reinforcement of submission standard

Category	≥ 100t	≥ 70t	≥ 50t	≥ 20t	≥ 10t
Enforcement date	2015.1.1	2017.1.1	2018.1.1	2019.1.1	2020.1.1

- Items for data preparation

1. Chemical substance identification information & Physico chemical properties
2. Confirmed use in manufacture & in the supply chain
3. Hazard assessment for human health
4. Physico-chemical risk assessment
5. Hazard assessment for the environment
6. Assessment of persistent and bioaccumulative
7. Exposure assessment
8. Confirmation of safety

❖ Data related to guidance for safety use

1. Handling measures(Storage method, handling precautions etc.)
2. Fire fighting measures(fire extinguish method, fire-extinguishing agent, fire extinguishing equipment)
3. Control measures for leakage(Control chemicals, equipment, control method etc.)
4. Protective equipment, disposal method etc.
5. Regulation information according to relevant legislation
6. Other safety use guidance such as emergency measures

3. Data apply for Registration

❖ Isolated Materials

1. Information of manufacturer• Importer – company name, address, president
2. Chemical identification information – chemical name, molecular formula/structure, identity no., product name, purity(%), name/content of impurity/byproduct
3. Main use – Classified use, explanation of specific use, inapplicable use
4. Classification & Labeling
5. Physico-chemical properties
6. Others- Submission of hazard data, exposure data, risk data, safety use data if possess them

❖ Cases when data for registration can be omitted

- Corresponding test data among Physico-chemical properties, hazard data, data submission can be omitted for the cases below

1. Chemicals manufactured/imported below 10 tons per year and can be judged of hazard to human health & environment through result from QSAR internationally recognized Quantitative structure activity relationship program
2. Chemicals can be judged of hazard to human health & environment through result from internationally qualified and recognized in vitro test
3. Chemicals can be judged of hazard to human health & environment as similarly structured chemicals
4. Chemicals which is not possible to be tested technically

4. 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

5. 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
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)」

6. Information provision

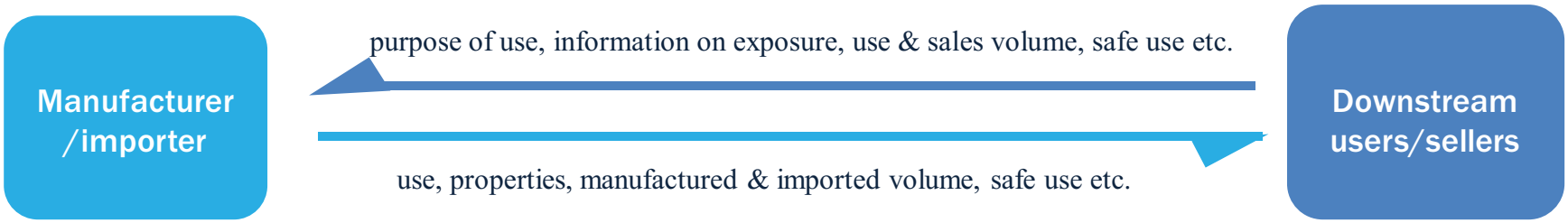
➢ Registered chemical substances, Contained mixtures Information offering : Substance·mixtures Transferor ⇒ Transferee

- 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



⇒ Component, Content etc. Except for business confidential information, Quantity of manufacture·Import·sale can be omitted

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

7. Products Management

➢ Notification of Mixture Products

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

➢ Risk Concerned Products : Concerns about posing risk to people's health or the environment, Announcement of Ministry of Environment

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

7. Product Management

- Safety·Labelling Criteria : announcement on product specific Safety & Labelling criteria in accordance to assessment result

  - chemicals banned in Risk Concerned Products, threshold level of content, migration and evaporation etc. (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

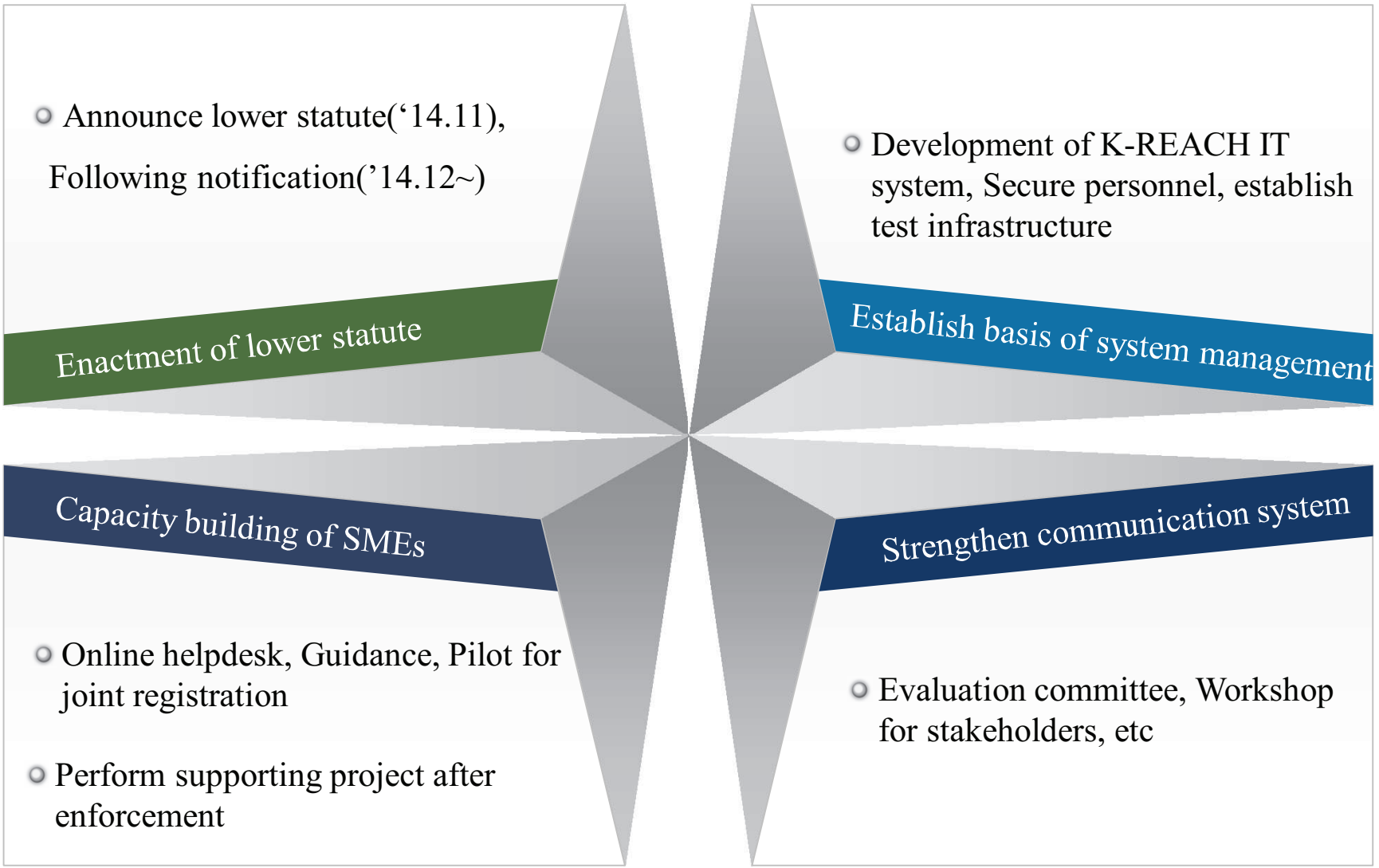
  - Order to take emergency measures to prevent spread of damage

8. Activities of appointee

Activities of appointee by overseas manufacturer and producer

1. Reporting of the use, quantity, etc. of chemical substances under Article 8
2. Application for registration under Article 10(3)
3. Notification under Article 32
4. Modification Report under Article 8(3)
5. Application for Exemption of Chemical Registration under Article 11(2)
6. Modification Registration, Modification Report of Chemicals under Article 12
7. Confirmation of Individual Submission under Article 15(1)
8. Inquiry of Chemical Registration under Article 16(2)
9. Confirmation of consent to use of Vertebrate Animal Testing Data under Article 17(2)
10. Provision of Information on Chemical Substances under Article 29
11. Provision of Information under Article 30(2)
12. Application for Exemption of Chemical Notification under Article 32(3)
13. Provision of Information on product containing a hazardous substance under Article 35
14. Submission of data for approval of manufacture. Import of risk-posing products that do not have safety or labeling standards under Article 36(2)
15. Application for data protection under Article 45

9. Future Plan



III. Current Status

1. Pilot project

- **Pilot project on 7 substances**

No.	Substance name	CAS No.	No. of companies	No. of domestic manufacturers
1	Diisocyanatomethylbenzene(TDI)	26471-62-5	7	2
2	Benzoyl peroxide	94-36-0	10	-
3	Hydrogen bromide	10035-10-6	10	-
4	p-xylene	106-42-3	11	8
5	1-Chloro- 2,3-epoxypropane(Epichlorohydrin)	106-89-8	7	2
6	Trichloroethylene	79-01-6	9	-
7	Hydrogen chloride	7647-01-0	10	8

➢ (Content) From consortium formation to actual registration

Consortium formation	Registration Preparation	Registration Application	Registration Completion
• Substance identification • Representative selection	• Dossier preparation • Cost sharing	• Registration dossier submission	• Submission of required additional data

2. Development of Guidance

Development of 4 dossiers for K-REACH Guidance

Identification

Confirmation of Substance name and identification

- Confirmation standard system
- Confirmation and naming
- Substance identification confirmation standard
- Examples, etc

Registration Preparation

Data exchange and cost sharing

- Basic principle of data exchange
- Inquiry procedure
- Data sharing standard
- Protection of business confidentiality, etc

Registration

Registration

- Registrant obligation
- Registration application procedure
- Preparing Registration dossier , etc

Products notification

Notification

- **Notification obligation**
- **Notification procedure and method**
- **Examples, etc**

3. Help desk operation by MoE

- (Purpose) Consultation system for domestic and foreign industries to support implementation of K-REACH
- (Online) Homepage (www.chemnavi.or.kr) (2014.8)
- (Offline) Experts available for consultation with domestic companies (2014.4)

3. Establishment of Joint-registration support system

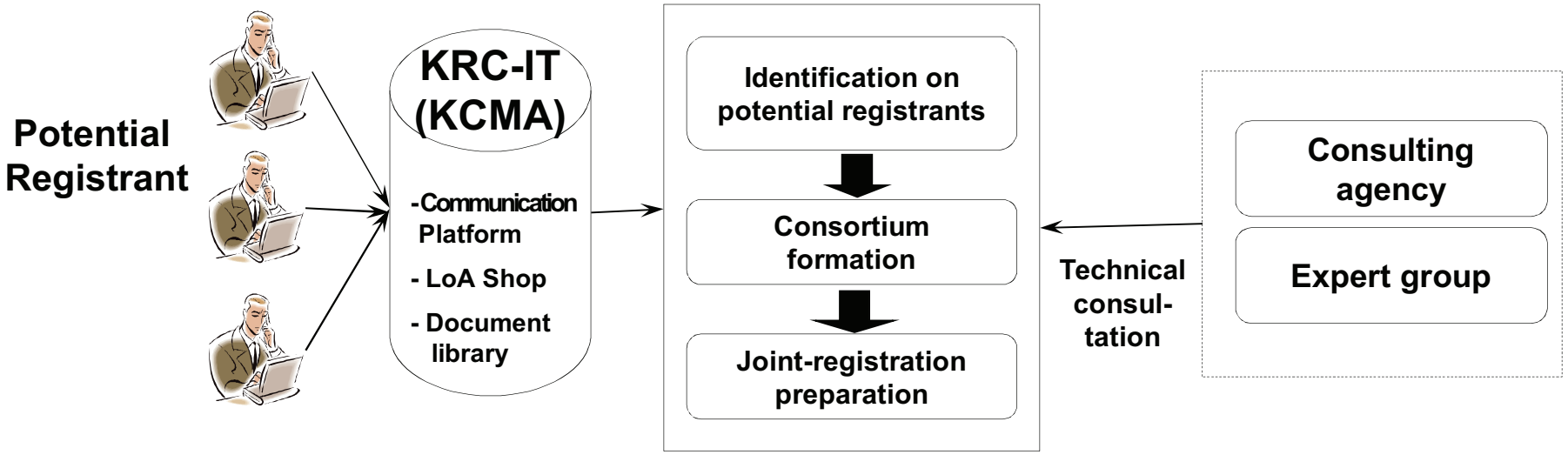
- (Purpose) To identify potential registrants beforehand, and provide support in preparing for joint registration (Similar to EU REACH_SIEF)
- (Period) ~2015.3
- (User) Korean manufacturer/importer, Only Representative
- (Content) Room per substance(registrants of same substance to know each other), group e-mail/SMS(communication between joint registrants)

4. Joint-registration Support by KCMA

➢ Installation of Joint-registration Center (K-REACH Center; KRC), support in formation/operation of potential registrants consortium

- Potential registrants who wants jointly register needs to join KRC. Through KRC-IT, potential registrants of same substance are identified and consortium is formed.

- KRC will support joint registration through mutual cooperation and dividing function among consulting agency and experts from relevant field (chemistry/toxicity/ legal/ tax)



Thank You for your attention

Korea Chemicals Management Association