

## IV

# Legislation and Amendment of Chemicals Management Act

1. **TCCA**
2. **Act on Registration and Evaluation, etc. of  
Chemical Substances (K-REACH)**
3. **Chemicals Control Act (CCA)**

# 1-1. Current Toxic Chemicals Control Act

## ➤ History of TCCA

<b>History</b>	<b>Main Contents</b>
Poison and Toxin oriented management (1963~1990, Act on Poisons and Toxins)	Acute toxic substance based regulation to prevent poisoning accidents
Beginning of full-scale chemicals management policy (1990~1996, Toxic Chemicals Control Act)	Systematic management including examination of toxicity etc.
Setting up basis of advanced chemicals management (1996~2005, OECD accession)	Joining of OECD in 1996, introduction of advanced system such as GLP, TRI etc.
Policy shift to advanced chemicals management (2006~, Receptor oriented precautionary management)	Restricted · Banned substance designation (Proceeding risk assessment based scientific regulation)
Separation of toxicity evaluation and risk assessment ( expected in 2 <sup>nd</sup> half of 2013)	Legislating Act on Chemicals Evaluation and Registration etc.

# 1-2. Purpose of TCCA and Contents

## ➤ Purpose

- Enable all people to live in a healthy and comfortable environment by properly controlling toxic chemicals

## ➤ TCCA Exemption

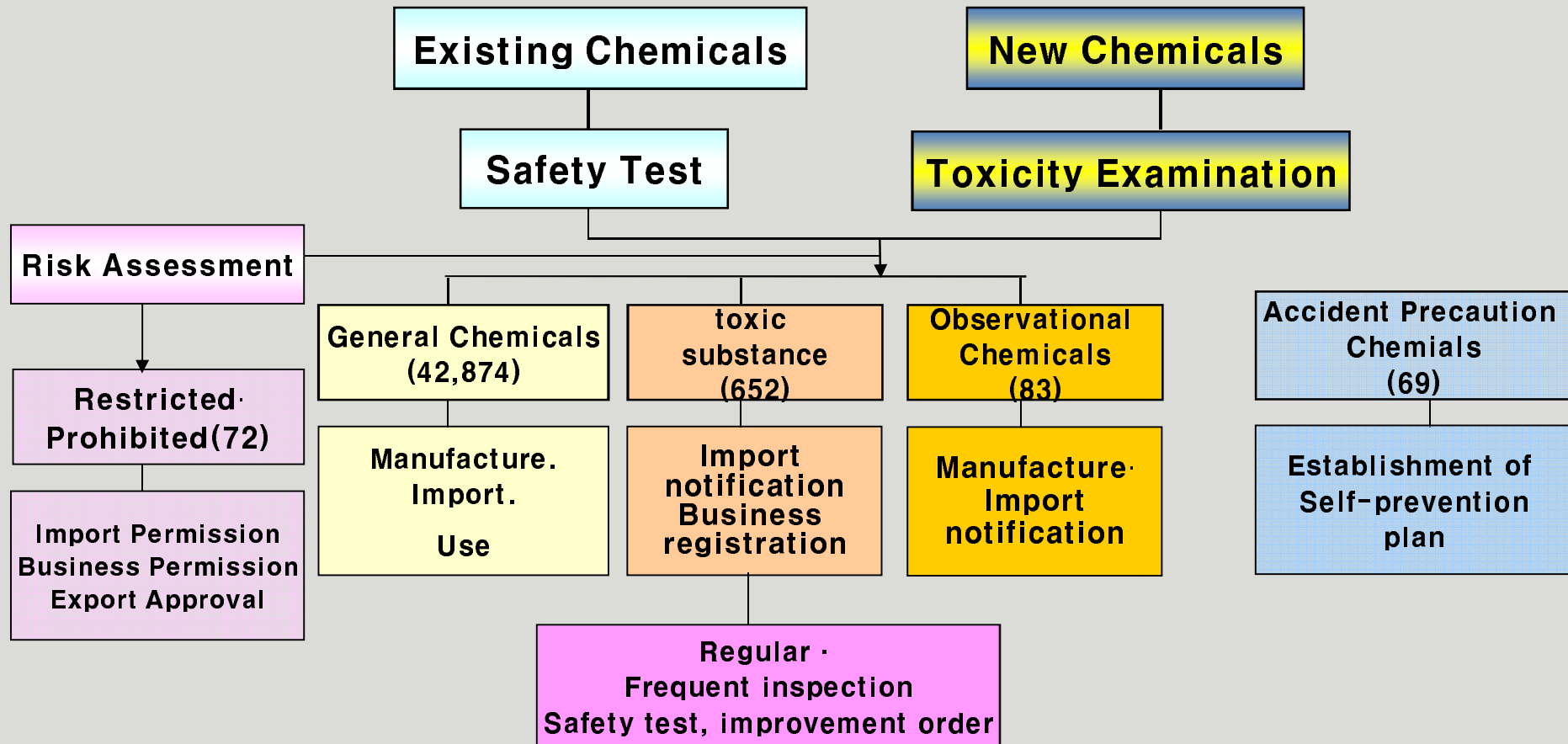
- ✓ Atomic Energy Act (radioactive substance)
- ✓ Pharmaceutical Affairs Act (Medicines and non pharmaceutical drugs)
- ✓ Act on the Control of Narcotics (Narcotics)
- ✓ Cosmetics Act (Cosmetics)
- ✓ Agrochemicals Control Act (Technical ingredients and agrochemicals)
- ✓ Fertilizer Act (Fertilizers)
- ✓ Food Sanitation Act (Food and food additives)

# 1-2. Purpose of TCCA and Contents

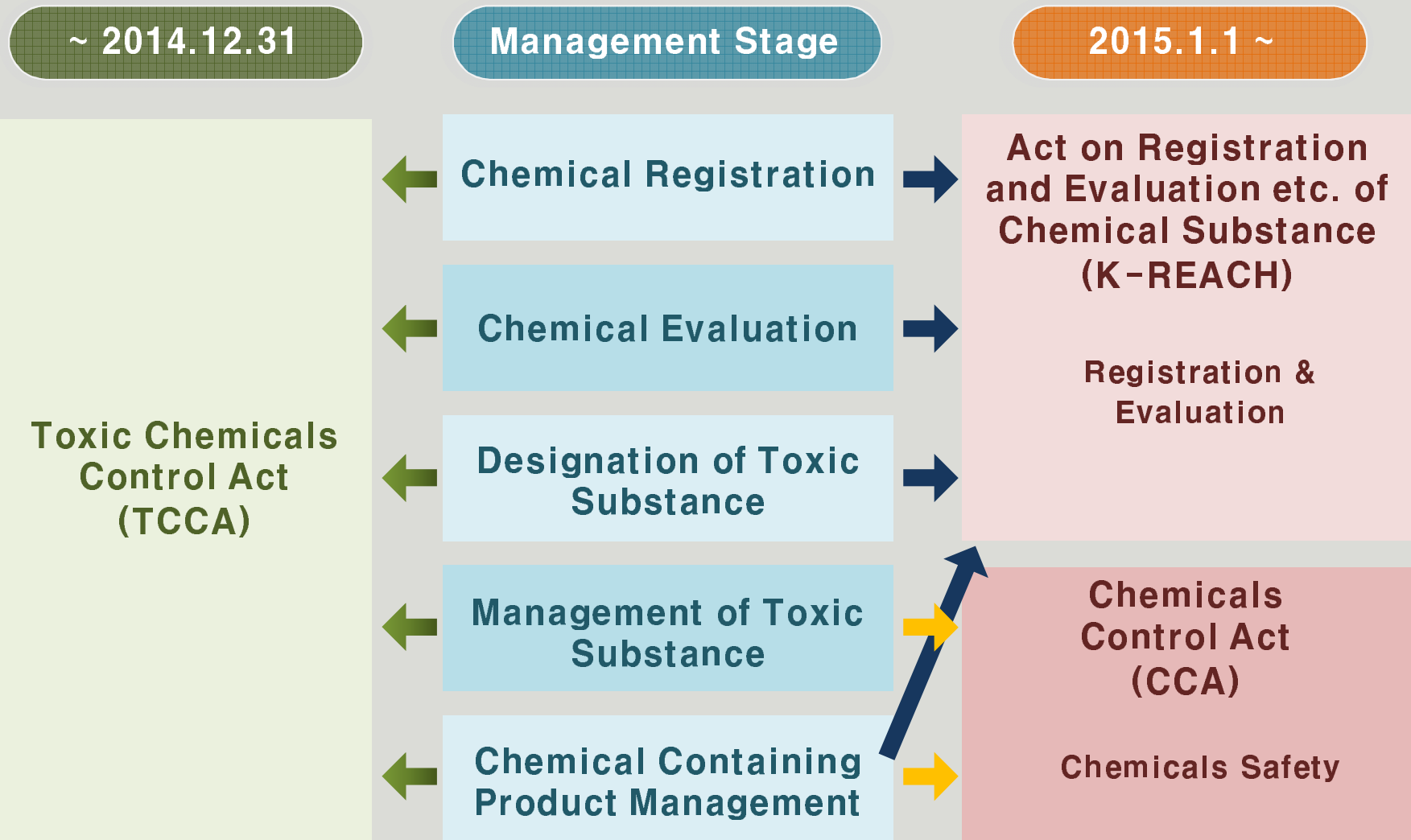
## ➤ Main Content

- Confirmation of chemical manufacture, import, toxicity examination of new chemicals, risk assessment
- Investigation of circulation and TRI
- Toxic Chemicals Safety Management
  - \* Toxic chemicals: Import report, Business registration, facility inspection, Toxic chemicals labeling etc.
  - \* Restricted · Banned substance: Import · Business approval
  - \* Accident Precaution chemicals: comply regulation standard, self-prevention plan, accident report and effect analysis

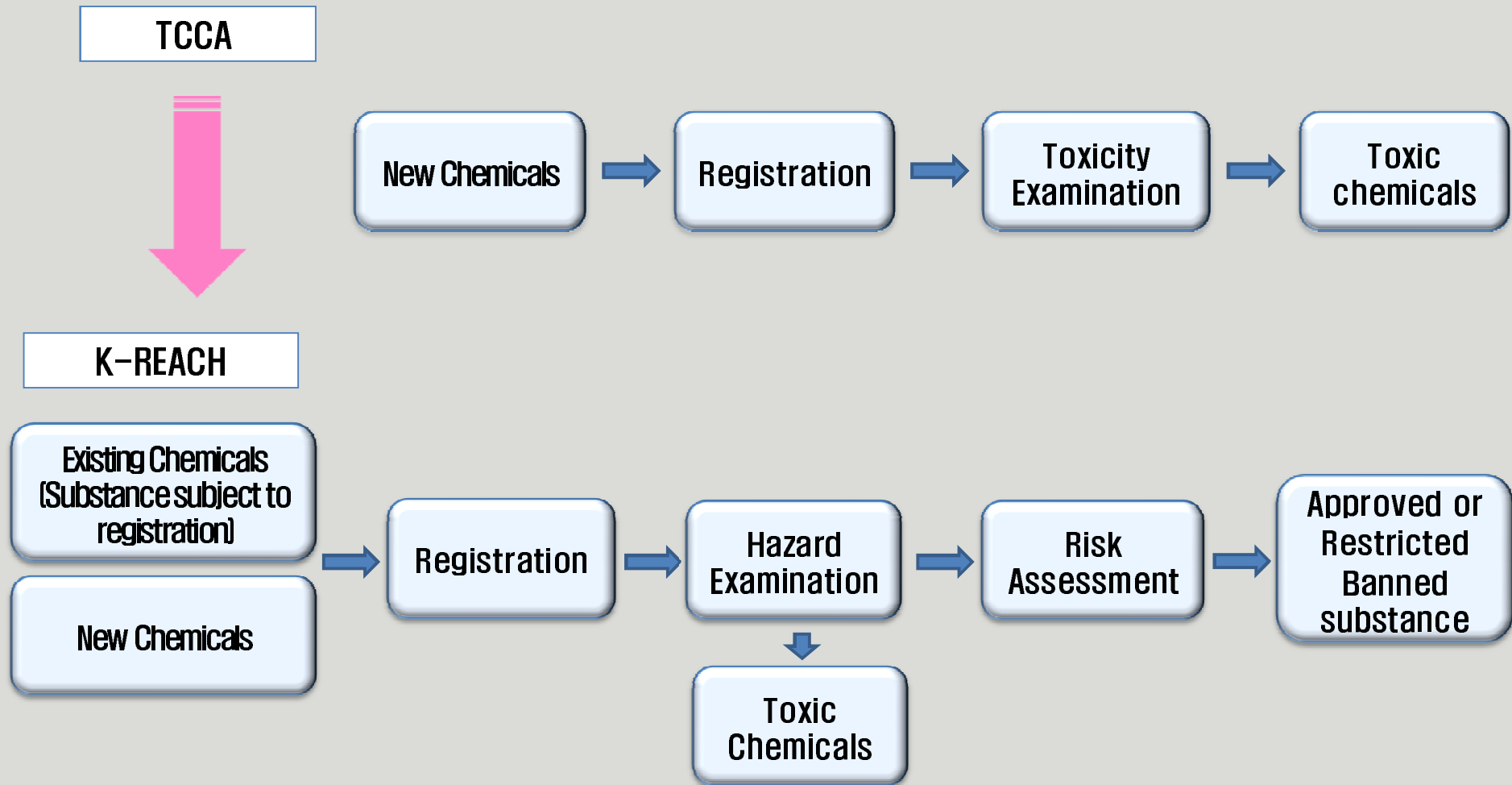
# 1-3. Classification / Management System under TCCA



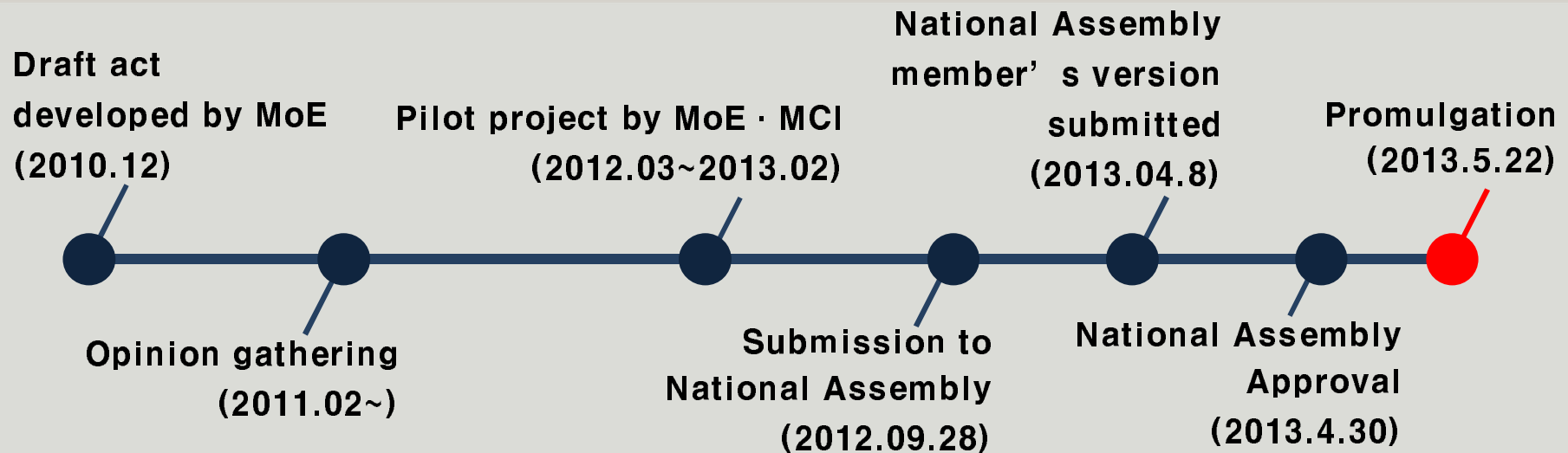
# 1-4. Reformed TCCA System



# 2-1. Comparison of TCCA & K-REACH



# 2-2. Instigating Enactment Procedure of K-REACH



## MoE · MCI Pilot Project (2012)

### Implementation and Guidance

- Registration · Evaluation draft guidance development (4 in total)
- Consortium per substance, cost calculation · sharing etc.

### Stakeholders' Forum

- Opinion gathering among relevant Ministries
- Opinion gathering among industry, government, NGO

### Support Measures for Industry

- awareness, confirmation of test data accessibility (survey)
- Professional training education, support for test cost according to company size

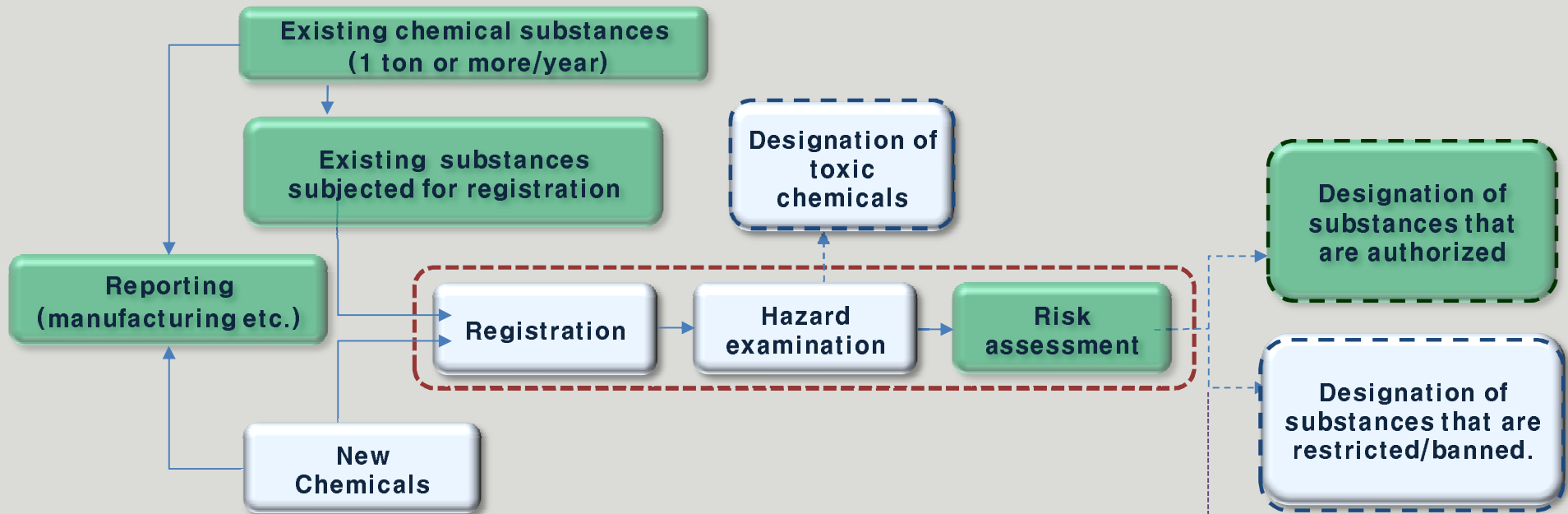


## 2-3. Changes During K-REACH Introduction

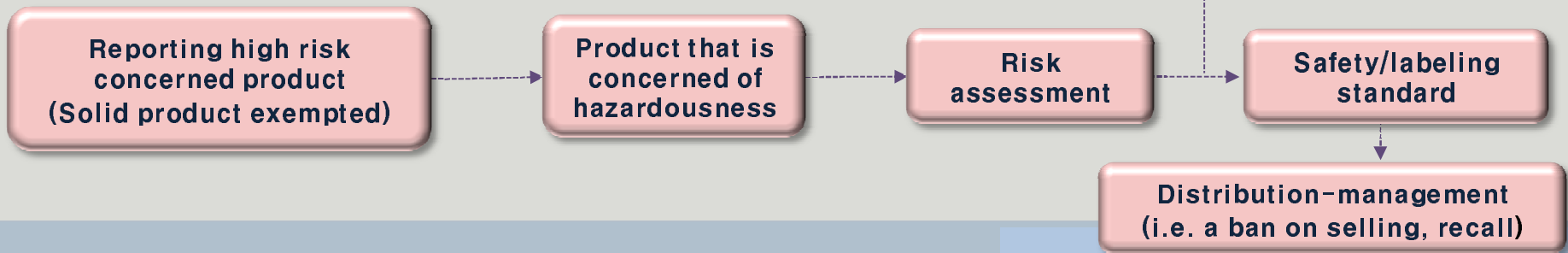
Main Scheme	MOE Proposal	private member's Proposal	Final version
Reporting (manufacture etc.)	<ul style="list-style-type: none"> <li>▶ Both new and existing chemicals in 1 ton or more (yearly basis)</li> <li>▶ Reporting every 2 yr</li> <li>▶ Manufacturer &amp; importer</li> </ul>	<ul style="list-style-type: none"> <li>▶ All new and existing chemicals in 1 ton or more (yearly basis)</li> <li>▶ Every year</li> <li>▶ Manufacturer, importer, seller, user</li> </ul>	<ul style="list-style-type: none"> <li>▶ All new and existing chemicals in 1 ton or more (yearly basis)</li> <li>▶ Every year</li> <li>▶ Manufacturer, importer, seller</li> </ul>
Registration	<ul style="list-style-type: none"> <li>▶ Both new and existing chemicals in 1 ton or more (yearly basis)</li> </ul>	<ul style="list-style-type: none"> <li>▶ All new and existing chemicals</li> </ul>	<ul style="list-style-type: none"> <li>▶ All new and existing chemicals in 1 ton or more (yearly basis)</li> </ul>
Submission of risk assessment	<ul style="list-style-type: none"> <li>▶ Both new and existing chemicals in 100 tons or more (yearly basis)</li> </ul>	<ul style="list-style-type: none"> <li>▶ Both new and existing chemicals in 10 tons or more (yearly basis)</li> </ul>	<ul style="list-style-type: none"> <li>▶ Both new and existing chemicals in 100 tons (yearly basis)</li> <li>* gradually tighten up to 10 tons until Year 2020)</li> </ul>
Information provision	-	<ul style="list-style-type: none"> <li>▶ Information provided by downstream user and product sellers</li> </ul>	<ul style="list-style-type: none"> <li>▶ Only upon requests from manufacturers/importers</li> </ul>
High Risk Concerned products	-	<ul style="list-style-type: none"> <li>▶ Product reporting, hazard examination etc.</li> </ul>	<ul style="list-style-type: none"> <li>▶ Article is exempted</li> </ul>
Penalty	-	<ul style="list-style-type: none"> <li>▶ No set value</li> <li>* Certain amount paid in a ratio of company' s sales</li> </ul>	<ul style="list-style-type: none"> <li>▶ Default</li> </ul>

# 2-4. K-REACH Flowchart

<Chemical substance & mixture >



<Product>



## 2-5. K-REACH content (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

### < Substances exempted from reporting >

- 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
- ④ Manufactured/imported substances for the purpose of research and studies
- ⑤ Others chemicals listed in Presidential Decree etc.

## 2-5. K-REACH content (Subject to Registration)

### ◆ Existing Chemical Substances

- Designation and Notification of existing chemical substances subject to Registration
- Chemicals manufactured or imported 1 ton or more annually are subject to register prior to manufacture or import
- Allow manufacturing & importing without registration given a grace period

#### \* Existing chemicals :

- ① All substances domestically circulated since Feb.2.1991 (37,021 types)
- ② Substances that have been examined for its hazardousness and published by the MoE in according to 「TSCA」 since Feb 2 1991 (assumed 6,878 as of Dec.2012)

### ◆ Subject to registration even its volume less than 1 ton per year

- Designation and Notification of chemical substances subject to Registration if recognized to cause serious damage to public health and environment

### ◆ All New chemicals

#### < Substances exempted from reporting >

- 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
- ④ Chemicals manufactured 10 tons or less per year for the purpose of export only, and those chemicals listed in Presidential Decree (requires “Confirmation of Registration Exemption” from the Minister of Environment)

## 2-5. K-REACH content (Registration data)

- ◆ Information of chemicals, hazard examination and risk assessment etc.
  - Submit a risk assessment including Exposure Scenario for chemical substances manufactured and imported 100 tons or more per year.
  - \* **Submission date of risk assessment data**  
 100 tons('15) → 70 tons ('17) → 2018 : 50 tons → 2019 : 20 tons → 2020 : 10 tons

	Information	Registration criteria	Remarks
1	Information of manufacturer or importer	-New chemical substance  -Existing chemical substance (1 ton or more per year)	- Name, address, representative person
2	Chemical substance Identification information		- Name, identification information (i.e. molecular formula and chemical structure)
3	Use		
4	Classification and Labeling		
5	Physico-chemical properties		
6	Hazard information		
7	Guidance on safe use		- protective equipment, emergency measures in a case of explosion, fire and leakage
8	Risk	- New & existing (100 tons or more per year) * gradually phase-in	- exposure scenario describing overall handling measures, exposure control and management
9	Test plan (substitution acceptable)	- details to be specified in subordinate legislation	- May submit relevant references used in the registration as a replacement
10	Confidentiality data (upon request)		- K-REACH Article 45 (Data protection)

## 2-5. K-REACH content (Registration)

- ◆ **Registration confirmation : check if subject to registration or exemption**
- ◆ **Data preparation:**
  - **new chemical substances: prior to the legislation enforcement**
  - **existing chemical substances: in time with registration grace period**
    - \* **only accept hazardous data produced by GLP or government approved testing laboratories**
- ◆ **Joint-submission : Manufacturer or importers registering same substances subject to registration**
- ◆ **Data sharing : under consent from owner who have previously submitted data**
- ◆ **Foreign manufacturers & producer (overseas) : shall appoint an appropriate person in Korea who fulfills the requirement specified in the Ministerial Decree; and the person will act on behalf to complete required duties**

## 2-5. K-REACH content (Hazard Examination & Risk Assessment)

- ◆ **Hazard** : Notification of hazard examination result to the registrants
  - Review testing data and references submitted by companies
    - \* MOE will directly conduct hazard assessment for substances identified by international organizations.
  
- ◆ **Risk** : Risk Assessment based on the result of hazard examination, and notification of the result
  - Risk assessment of chemicals manufactured or imported 10 tons or more per year

Tonnage	Submission date of risk information
100 or more ton/year	1 <sup>st</sup> Jan. 2015
70 or more ton/year	1 <sup>st</sup> Jan. 2017
50 or more ton/year	1 <sup>st</sup> Jan. 2018
20 or more ton/year	1 <sup>st</sup> Jan. 2019
10 or more ton/year	1 <sup>st</sup> Jan. 2020

## 2-5. K-REACH content (Designation of Hazardous Chemicals Substances)

- ◆ Designation of chemicals through Examination & evaluation result
  - toxic substance, authorization substance, prohibited/restricted substance

Classification	Designation standard	Remarks
Toxic substance	<ul style="list-style-type: none"> <li>○ Result of hazard examination               <ul style="list-style-type: none"> <li>- substances recognized as toxic to human body and ecology based on the result of hazardous examination</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>- Notification of name, toxic status etc.</li> </ul>
Authorized substance	<ul style="list-style-type: none"> <li>○ Result of hazard examination &amp; risk assessment               <ul style="list-style-type: none"> <li>- Substances concerned to be hazardous</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>- Carcinogenesis, mutation, biological concentration etc.</li> <li>- Notification of name, use, suspended term of permission</li> </ul>
Restricted/ Banned substance	<ul style="list-style-type: none"> <li>○ Result of hazard examination &amp; risk assessment               <ul style="list-style-type: none"> <li>- Substances identified as hazardous</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>- Substances banned/restricted by International institutes and international treaty</li> <li>- Announcement of name, expected date etc.</li> </ul>

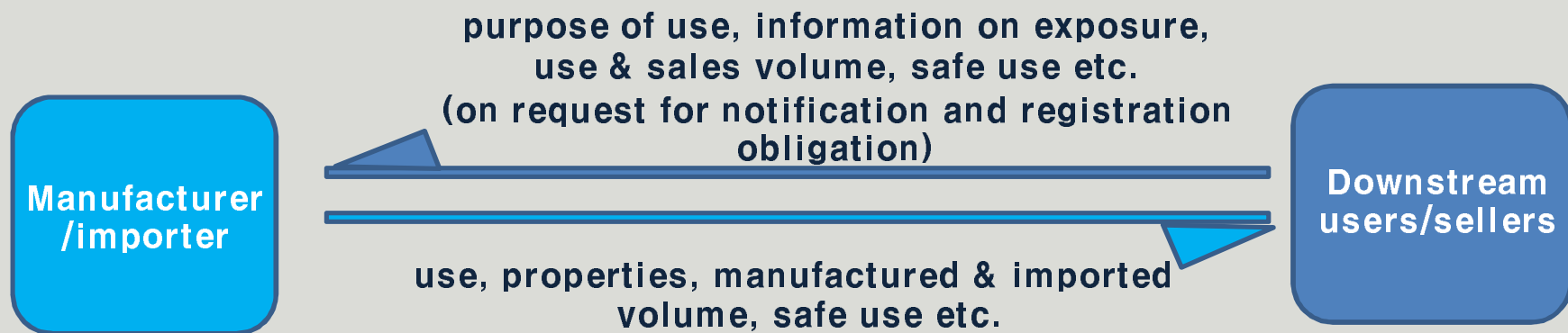


## **2-5. K-REACH content (Designation of Hazardous Chemicals Substances)**

- ◆ **removal from designation list when substitute substances developed; or new technology is commercialized; or there is no identified hazard**
- ◆ **Management : 「Act of Chemical Substance Management)」  
(enforcement Jan. 01. 2015)**
  - **Permit for business, a standard on facility of handling, control purposes of use etc.**

## 2-5. K-REACH content (Information provision)

- ◆ Manufacturer to provide information on Registered substance & mixture to downstream user (**Manufacturer/Importer** ⇒ **User**)
  - Registration number, name, hazardous & risk information, safe use etc. (any changes to be informed within 1month )
- ◆ Information provision within the supply chain:



- ◆ MoE to notify any changes on the information to the registrant

## 2-5. K-REACH content (Notification of Product Containing Hazardous Substance )

- ◆ **Products** : Any final products or parts which may expose chemical substance to the consumers
- ◆ **Subject to Notification** : In case chemical substances exceed one tons per year in total contained in products
  - Name, volume, hazardous information, purpose of use in the product
- ◆ **Exemption from notification** : hazard chemical substance is not released during use, and performs specific function in a solid form.
- ◆ **Confirmation on the exemption** : release of hazardous chemical substance is controlled and the use of chemical substance in the product is already registered.
- ◆ **Provision of information** : **Manufacturer/Importer** ⇒ **Customer**
  - name, use, condition
  - Provide safe use information of the product upon request of customers

## 2-5. K-REACH content (High-Risk Concerned Product )

- ◆ Risk concerned product : Published by the MoE as it is concerned to pose risks to public health or environment
  - \* Household products such as detergent, air freshener, adhesives, synthetic detergents, bleaches etc.
  - \* Biocides such as non-agricultural insecticide, disinfectants, preservatives etc.
- ◆ Risk Assessment : Category specific evaluation of risk concerned product
- ◆ Safety & Labeling criteria : chemicals banned, threshold level of content, migration and evaporation etc.
- ◆ Circulation management : selling & importing of products which fail to meet criteria are banned, or recalled back
  - If Safety & Labeling criteria are not published, they must get a prior approval authorized by the Minister of Environment before being used or imported.

## 2-5. K-REACH content (Time of Enforcement & Interim Measures)

- ◆ **Enforcement date : Jan.01.2015**
  - **Different active dates for provision of risk information**
  
- ◆ **Interim Measures**
  - **Person who have already received hazard examination under “Korea Toxic Chemicals Control Act”**
    - ⇒ **classified as “completed” for Registration and Hazard examination**
  
  - **Violation prior to legislation enforcement**
    - ⇒ **subject to administrative disposition, penalty/fine may be charged under “Korea Toxic Chemical Control Act”**

## **2-6. Legislation schedule of K-REACH Subordinate law**

- **Instigating Enactment Procedure (Jan.2014~)**
- **Enforcement of “K-REACH” (Jan.1.2015)**
- **Implementation measures**
  - **Develop technical guidance and standard (2013-2014)**
  - **Develop and distribute brochure for industry about K-REACH**
  - **Develop a tool for “K-REACH”, conduct national education**
  - **Give an advance notice regarding existing substances that are subjected to registration**

# 3-1. Chemicals Control Act (Background)

## Public Anxiety Arising From Chemical Accidents

### Frequent chemical accidents

- After hydrofluoric acid accident in Gumi ('12.09.27) **series of chemical accidents occurrence**



### Facility Deterioration

- Industrial complex installation before 90's **Facility deterioration**
- Concern for possibility of large scale chemical accident in future

Industrial Death Highest in OECD,  
Economic Cost due to Industrial Accident (including indirect costst)  
18trillion Won per year

**Urgency to TCCA Amendment Rise**

**Revised TCCA Pass National Assembly ('13.5.7)**

**' 15.1.1 enforcement**

## 3-2. Chemicals Control Act (amendments)

### ➤ Amendment for chemical accident prevention, preparedness and response

Classification	Before	Amendment
<p style="text-align: center;"><b>Facility Management</b></p>	<ul style="list-style-type: none"> <li>- Toxic chemicals business Register (local government)</li> <li>- Restricted substance, Banned substance business approval system(MoE)</li>   <li>- No registration or approval for accident precaution chemicals</li>   <li>- Regular and frequent inspection, safety inspection management (local government)</li> </ul>	<ul style="list-style-type: none"> <li>- Hazardous Chemicals(Toxic chemicals, Restricted substance, Banned substance, accident precaution chemicals) Business approval (MoE)</li>   <li>- Business approval after submission of off-site consequence analysis, and confirmation of facility safety management inspection result</li> <li>- Business operator of precaution chemicals submits risk management plan</li> <li>- Regular and frequent inspection, safety inspection management(MoE)</li> </ul>



# 3-2. Chemicals Control Act (amendments)

Classification	Before	Amendment
<p><b>Chemicals Management</b></p>	<ul style="list-style-type: none"> <li>- Toxic chemicals import notification and management(local government)</li> <li>- Investigation of chemicals every 4 years (MoE)</li> <li>- Classification and Labeling for toxic chemicals(MoE)</li> </ul>	<ul style="list-style-type: none"> <li>- Toxic chemicals import notification and management (MoE)</li> <li>- Management of approved substance (MoE)</li> <li>- Submission of Toxic Chemicals transport Plan and confirmation notification (MoE)</li> <li>- Investigation of chemicals every 2 years (MoE)</li> <li>- Classification and Labeling for toxic chemicals(MoE)</li> </ul>
<p><b>OEM Management</b></p>	<p>No relevant regulation</p>	<ul style="list-style-type: none"> <li>- OEM Notification (MoE)</li> <li>- Contractor guidance and inspection (MoE)</li> </ul>

# 3-2. Chemicals Control Act (amendments)

Classification	Before	Amendment
<p><b>Safety Education and Training</b></p>	<ul style="list-style-type: none"> <li>- Toxic substance manager education (MoE)</li> </ul>	<ul style="list-style-type: none"> <li>- Toxic chemicals manager, user, transporter, contractor education (MoE)</li> </ul>
<p><b>Penalty</b></p>	<ul style="list-style-type: none"> <li>- Fine up to 300 million (local government)</li> </ul>	<ul style="list-style-type: none"> <li>- <b>Fine up to 5% of annual income (MoE)</b></li> <li>- <b>If a business faces 3 times suspension in 2 years period, business license cancelled (MoE)</b></li> </ul>
<p><b>Information Disclosure system</b></p>	<ul style="list-style-type: none"> <li>- Announcement to regional community on self prevention plan of accident precaution chemicals (MoE)</li> </ul>	<ul style="list-style-type: none"> <li>- Annual announcement to regional community on risk management plan of accident precaution chemicals (MoE)</li> </ul>

## 3-2. Chemicals Control Act (amendments)

Classification	Before	Amendment
<b>Chemical Accidents Preparedness</b>	<ul style="list-style-type: none"><li>- Notification if any risk concerned to human health or environment (MoE)</li></ul>	<ul style="list-style-type: none"><li>- <b>Immediate notification</b> on every chemical accidents (MoE)</li><li>- Management and designation of <b>special regulation area</b> for chemical accident prevention (MoE)</li></ul>
<b>Response to Chemical Accidents</b>	<ul style="list-style-type: none"><li>- Research on effects after accidents (MoE)</li></ul>	<ul style="list-style-type: none"><li>- Dispatch <b>field control coordinator</b> to accident site (MoE)</li><li>- Research on cause of accident, resident health and effect on environment (MoE)</li><li>- Command measures including recovery, removal, etc. to person responsible for the cause of the accident (MoE)</li></ul>

V

## Domestic Industry Action Plan

1. **K-REACH**
2. **Chemicals Control Act**

# 1-1. Industry Participation in Legislating K-REACH Subordinate Law

## ➤ Background

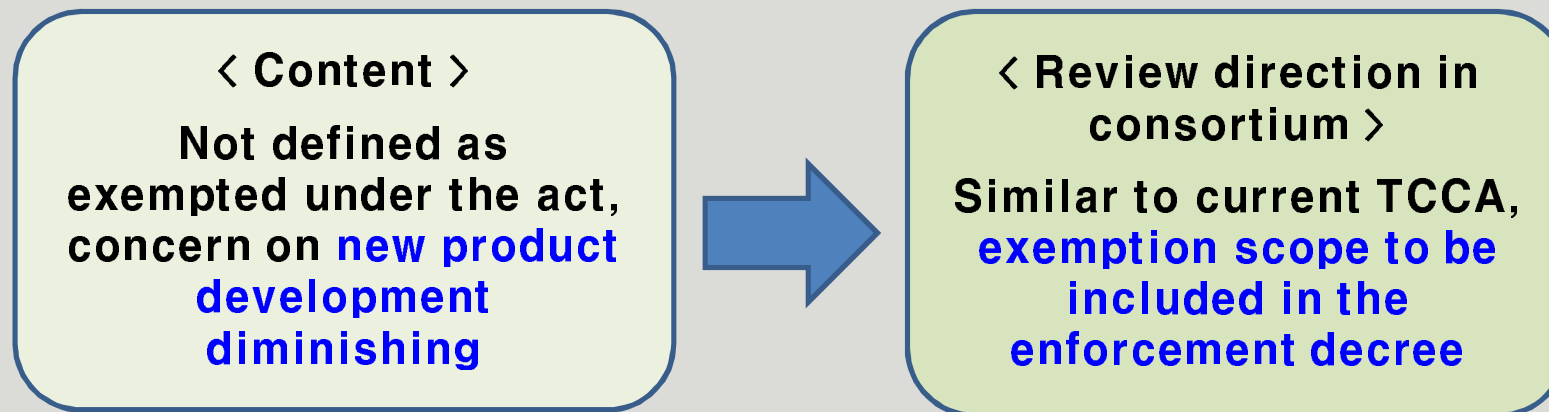
- Dissatisfaction of industries regarding K-REACH, promulgated on '13.5.22
  - \* Increase in burden on industries with all new chemicals becoming subject to registration
  - \* Increase in interest of R&D substance exemption

## ➤ Participation in Working Group for legislation of subordinate law

- MoE formed WG consisting of chemical industry organization, experts, NGOs, relevant GOs
- In process of draft subordinate law development through WG discussion
- Discussion on draft legislation in WG with opinions of chemical industries as the basis

# 1-2. Progress of Discussion on main Issues of K-REACH

## ● Issue 1 : Registration Exemption of **R&D substance**

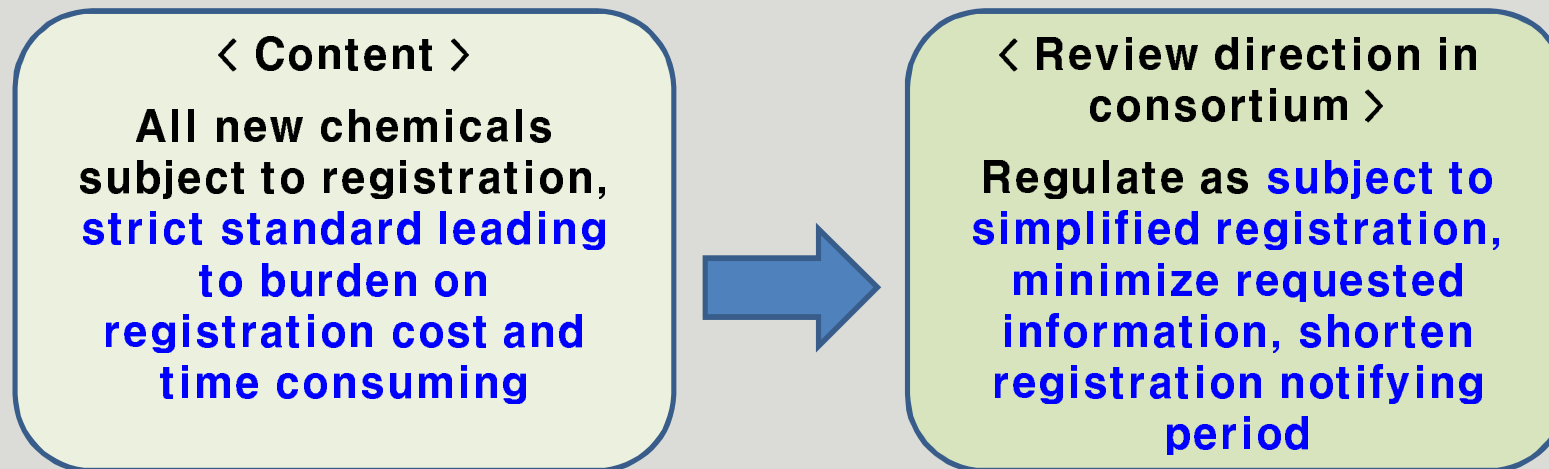


### <Note>

In case of foreign policies, exemption given under strict condition such as restriction on manufactured/imported volume or notification/exemption registration process, expert implementation etc.

# 1-2. Progress of Discussion on main Issues of K-REACH

## ● Issue 2 : **Low Volume New Chemicals Registration**

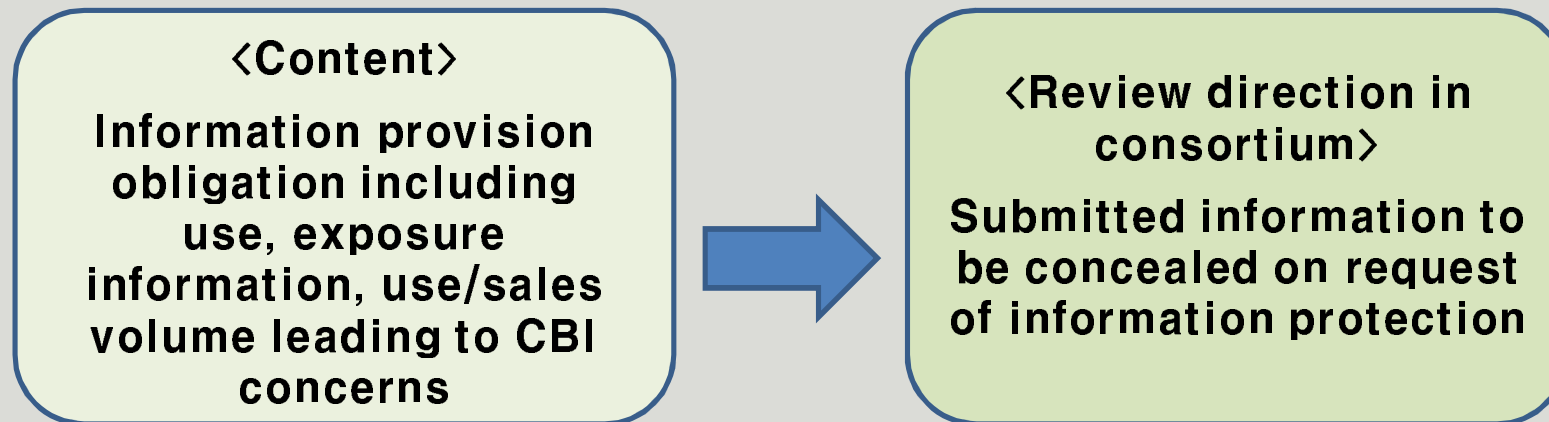


### <Note>

In case of foreign policies, different level of registration(notification) standard and information request according to possessing information

# 1-2. Progress of Discussion on main Issues of K-REACH

## ● Issue 3 : **CBI related concerns**



### <Note>

In case of similar foreign policies, CBI is protected, safety information including name/hazard/health effect is disclosed



# 1–3. Support for K-REACH implementation Preparation

- **Education, advertisement for industries' better implementation on K-REACH enacting from 2015**
  - MoE and KCMA conducting education on K-REACH implementation measures for industries
  - Additional education appropriated for SME
- **Development of detailed K-REACH guide line**
  - MoE and KCMA developing guid lines on areas needed in implementing K-REACH including reporting, registration, risk assessment etc.
  - Improvement and modification in guidance through pilot project when needed
- **Education and training for managers on new policy implementation**
  - Technical education on new policy including risk assessment, ecotoxicology test, etc.

# 1-4. KCMA Industry Support Plan

- **IT based consortium Formation and Operation**
  - Preparation of joint registration and advanced communication among domestic and international companies
  - Provide support on toxicity, legal affairs and administration by forming an expert group
  - Match making substance data holder and data user
- **Toxicity data Trading System**
  - Network building with domestic and international data possessor is under plan to be operated in later 2014
  - Through toxicity with domestic and purchase among domestic and overseas chemical industries, we aim to reduce registration cost by the means of price fairness
- **K-REACH help desk setup (2014.7 [www.kreach.or.kr](http://www.kreach.or.kr))**
  - KCAM help desk to be setup to provide K-REACH implementation support for domestic and international companies
  - Policy Q&A and consulting in Korean and English

# 2-1. Participation in legislating Subordinate Law of CCA

## ➤ Background

- Dissatisfaction of industries regarding revised Chemicals Control Act promulgated on 2013.06.04
  - \* Excessive fines, indefinite notification period

## ➤ Participation in WG for legislation of subordinate law

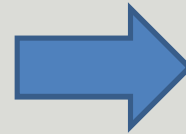
- MoE formed WG consisting of chemical industry organization, experts, NGOs, and relevant GOs
- In process of draft subordinate law development through WG discussion
- Discussion on draft legislation in WG with opinion of chemical industries as the basis

# 2-2. Progress of Discussion on main Issues of CCA

## ● Issue 1 : Excessive Fines

### <Industry Concern>

- Fine up to 5% of annual income upon occurrence of chemical accident
- Fine imposed for simple errors, uncontrollable condition, natural disasters, slight violation of regulation



### <Communication through WG>

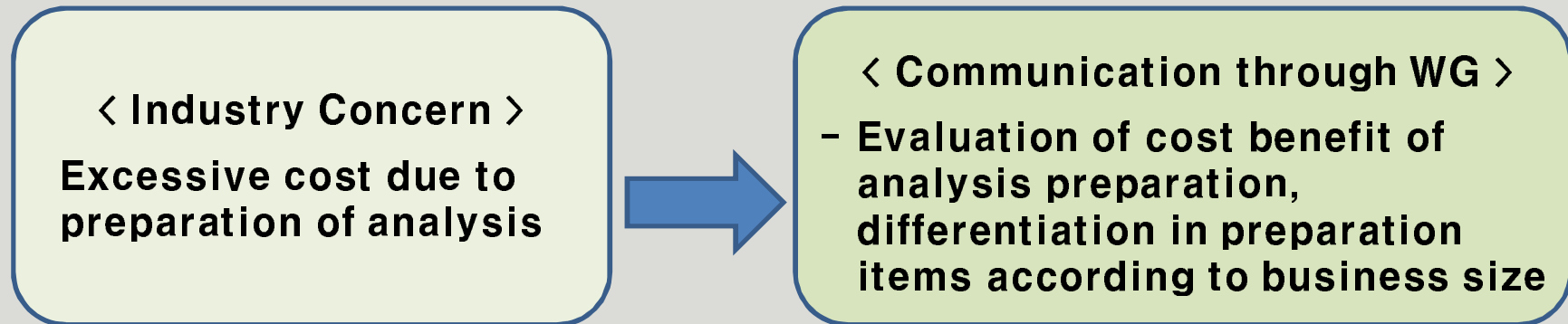
- Fine imposed considering condition, not on occurrence discretely
- Encouraging and educating for vulluntary compliance
- \* Preventive effort, measurement order implementation considered

### <Note>

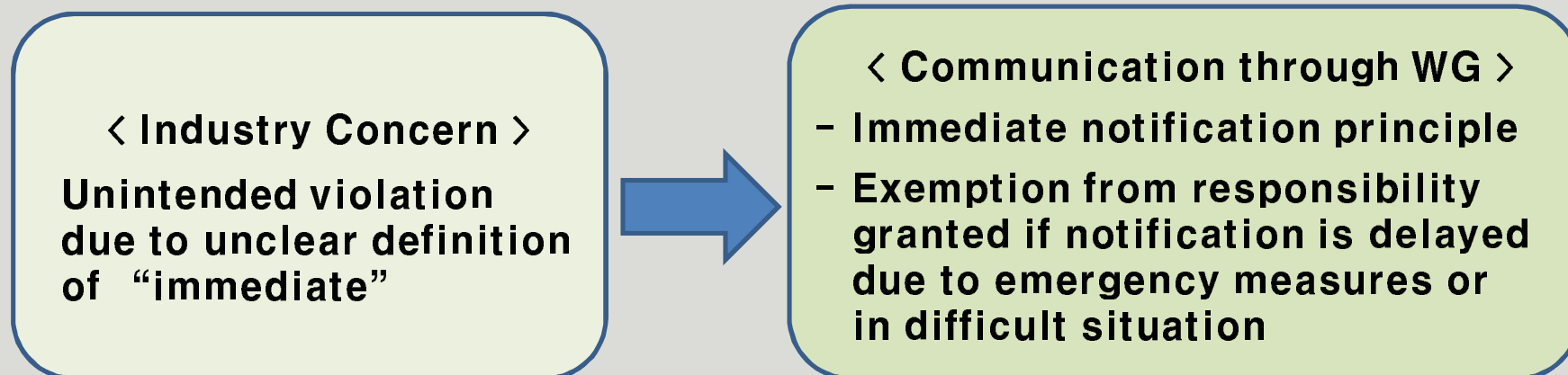
**intentional, duplicative, gross negligence, incompliance to measurement order face fine equivalent to business suspension (business operator selectable)**

## 2-2. Progress of Discussion on main Issues of CCA

### ● Issue 2 : Off-site Consequence Analysis



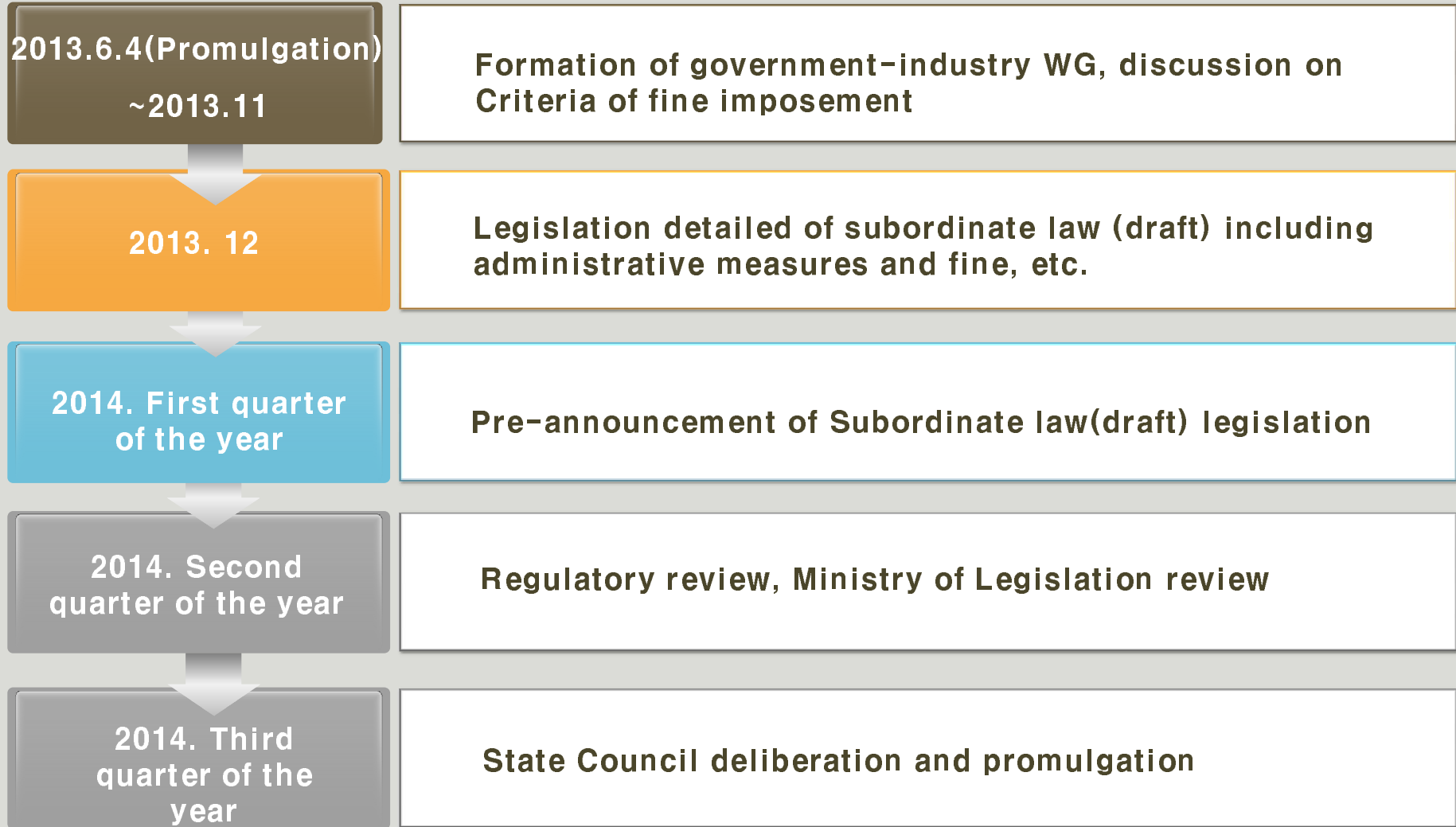
### ● Issue 3 : Unclear regulation of “immediate” notification on chemical accident occurrence



## 2–3. Support for CCA Implementation Preparation

- **Education, advertisement for industries' better implementation on CCA enacting from 2015**
  - **MoE and KCMA conducting education on CCA implementation measures for industries**
  - **Additional education appropriated for SME**
  - **Technical education on new policy including Off-site Consequence Analysis, Risk Management Plan, etc.**
- **Development of detailed CCA guide line**
  - **MoE and KCMA developing guide line on areas needed in implementing CCA including facility safety management, safety management of hazardous substances etc.**
- **Education and training for managers on new policy implementation**
  - **Safety Management check on chemicals used and facilities**
  - **Direction / Guidance for new policy compliance**

# 2-5. CCA Subordinate Law Legislation Schedule



**First step of  
flourishing chemical industry  
starts with  
safe management of  
chemicals**

