



“Revision of Korea REACH and New K-BPR (Biocides Safety Act)”

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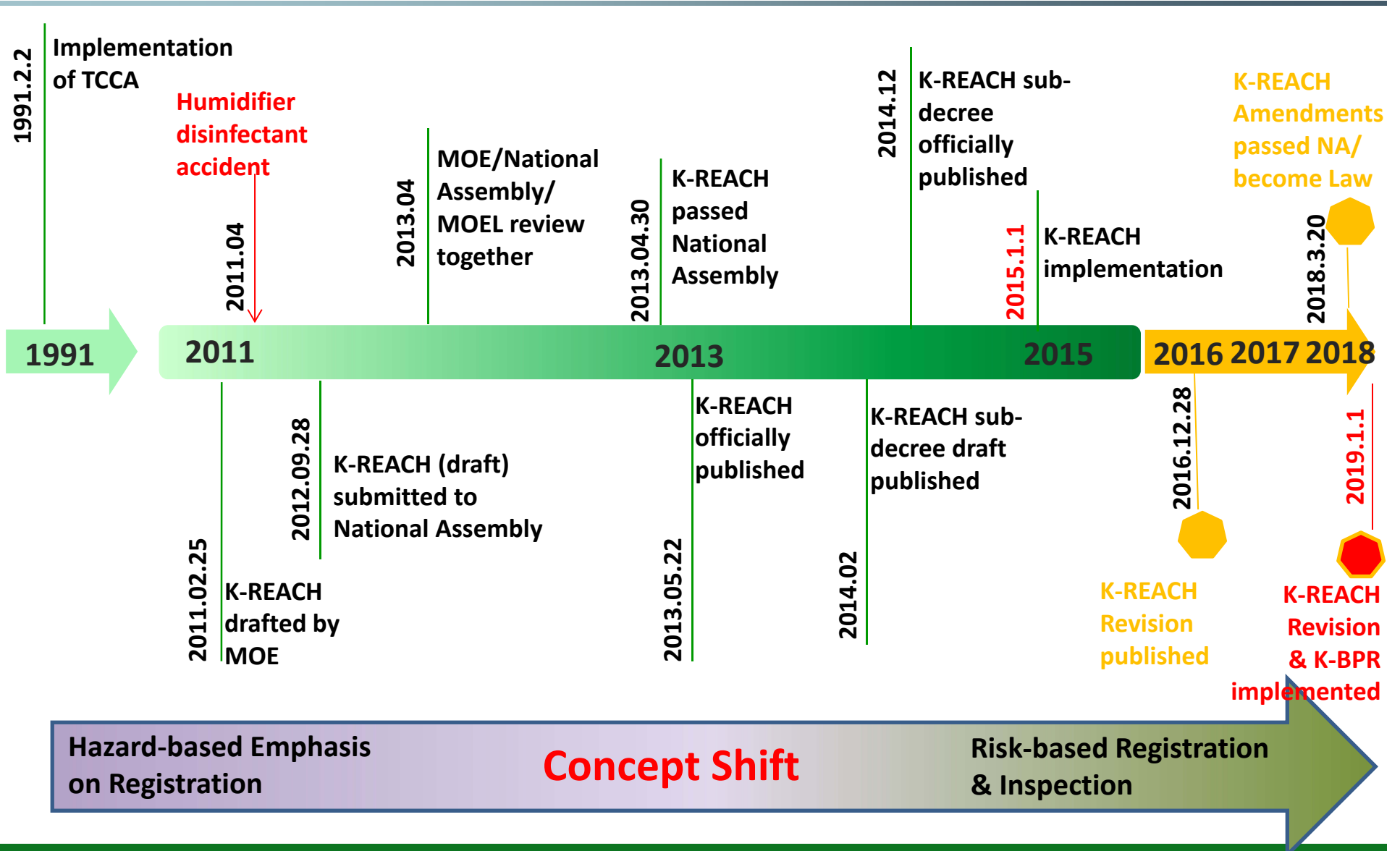


K-REACH &
K-BPR

Overview of Chemical Regulation in South Korea

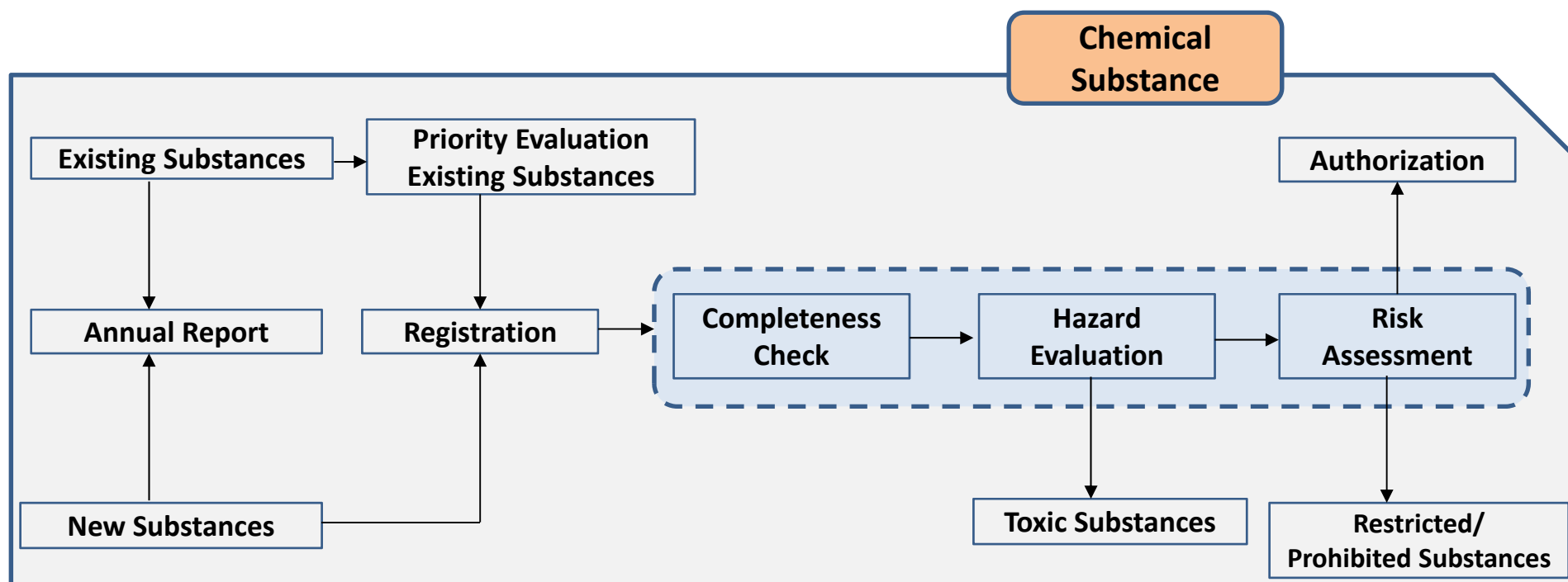
Products	Laws	Competent Authority
Industrial Chemicals	Act on Registration and Evaluation of Chemical Substances (K-REACH or AREC)	Ministry of Environment (MOE)
	Chemical Control Act (CCA)	Ministry of Environment (MOE)
	Occupational Safety and Health Act (OSHA)	Ministry of Employment and Labor (MOEL)
Cosmetics	Cosmetics Law	Ministry of Food and Drug Safety (MFDS)
Pharmaceuticals	Pharmaceutical Affairs Law	Ministry of Food and Drug Safety (MFDS)
Food Additives	Food Sanitation Law	Ministry of Food and Drug Safety (MFDS)
Pesticides	Agrochemicals Control Act	Ministry of Agriculture
Dangerous Materials/Substances	Dangerous Substance Safety Control Act (DSSCA)	Ministry of Public Security
	Transport Safety Rule (TSR) and Civil Air Act (CAA)	Ministry of Land, Infrastructure and Transport (MOLIT)
Household Chemical Products & Biocides	Act on Safety Management of Household Products and Biocides (K-BPR)	Ministry of Environment (MOE)

Timeline of K-REACH Legislation



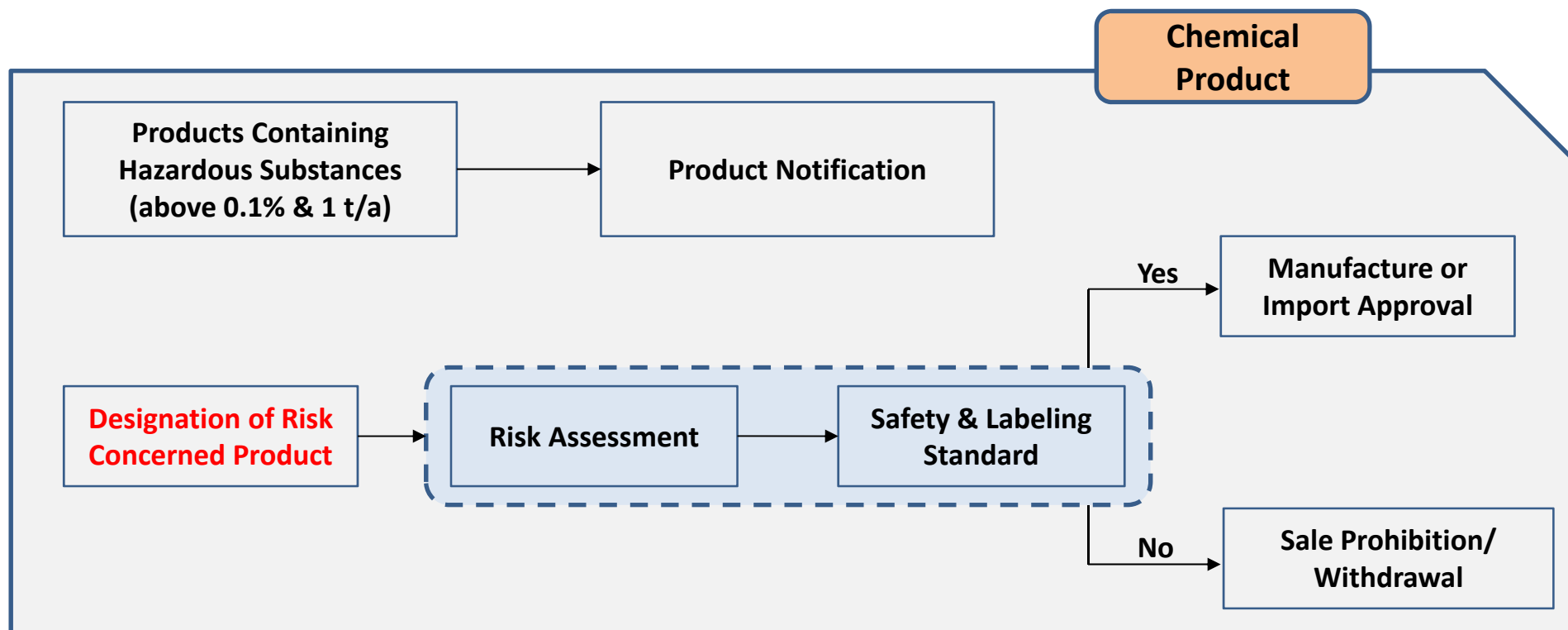
Main Obligations under Current K-REACH

Obligations	Applicable Scope	Who to Comply	Notes
Annual Reporting	All new chemicals (regardless of tonnage) Existing chemicals (≥ 1 tpa)	Manufacturers, Importers (OR), Sellers	Volume during 1 Jan – 31 Dec of the previous year shall be reported until 30 Jun every year (Abolished after 30 Jun 2018)
Apply for Exemption from Registration	<ol style="list-style-type: none"> 1) Export Only (≤ 10 tons per year); 2) Reagents for scientific study, analysis or research; 3) R&D purpose; 4) Isolated intermediates which are not released and are blocked from exposure; 5) Surface treatment material; 6) Polymer of Low Concern (PLC) 	Manufacturers, Importers (OR)	<p>Korea Environment Corporation (KECO) is responsible for exemption registration.</p> <p>Information requirements are different for each exemption type.</p> <p>Normal audit time is 15 days.</p>
Registration	New substance (no volume limit) Priority existing chemical (PEC) substances subject to Joint Registration (≥ 1 tpa)	Manufacturers, Importers (OR)	<p>NIER - New substances should be registered before manufacture or import.</p> <p>PECs subject to joint registration granted 3-year transition period until 30 Jun 2018 deadline.</p>
Product Notification	Required if total amount of each hazardous chemical contained in a manufactured or imported product ≥ 1 ton/year and content of the hazardous chemical contained in a product $\geq 0.1\%$ (w/w)	Producers, Importers (OR)	Local environment agency notification prior to manufacture or import; Hazardous chemical refers to Toxic chemical, Chemicals for authorization, Restricted/Prohibited chemicals
Supply Chain Communication	Information communication for annual report, registered substances and notified products.	Transferor	Providing chemical substance safety information to transferee.



Note:

- 3 year grace period for PEC substances; Joint Registration required for same PEC;
- Even less than 1 ton/year, registration is required for substances with high hazard to human health and the environment as designated by MOE through discussion of relevant ministries;
- Supply chain communication;
- Import can start after authority approves completeness check and issues the certificate. However, additional information might be requested during completeness check and hazard evaluation.



Note:

- Risk Concerned Product designated by MOE (e.g., such as products for daily use and as biocides)
- Product Safety & Labeling Standard (final) is published and updated for specific product types
- Application of exemption from product notification when exception conditions met

Legal Entity to Comply with Obligations under K-REACH (and K-BPR)

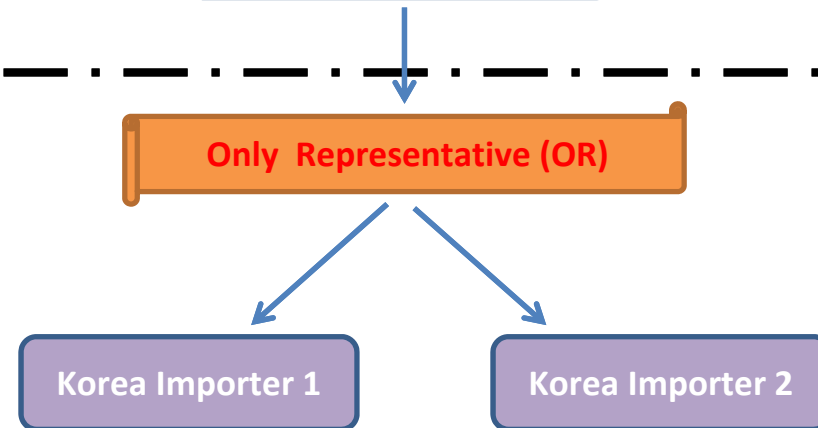
Outside of Korea



In Korea



Competent Authority
Customs



◆ Note:

- 1) Article 38 of K-REACH states that 'Only manufacture and producer' can appoint OR for K-REACH.
- 2) Either Foreign manufacturer of the substance or Foreign downstream producer (formulator) can appoint OR for K-REACH compliance on behalf of the Korean importers of one's own.
- 3) Foreign manufacturer can appoint OR and apply for registration on behalf of Korea importers of its foreign downstream formulator.
- 4) MoE has clearly stated that trade corporations which are not involved in manufacture or produce (formulate) of the substance cannot be entitled to appoint OR for their K-REACH compliance.

Only Representative appointed by overseas manufactures (Article 38, 49-54)

A foreign manufacturer who intends to fulfill obligations is required to appoint OR to fulfill the obligation of the importer;

- Annual reporting, reporting update
- Application of registration, etc. Registration update , exemption application, inquiry,
- Product notification, exemption application, information communication of hazardous substance in product
- Supply chain communication
- CBI application

OR Notification

- Power of Attorney (POA) is required to prepare dossier and submit to authority for OR nomination confirmation, prior to reporting, registration dossier submission.
- Each substance is required to submit one application dossier for OR nomination.
- Application for OR nomination and get permission from KCMA for each substance is 3 workdays, max 7 days.

Analysis of the First Batch Joint Registration of PECs

First Batch PEC List (510 substances)

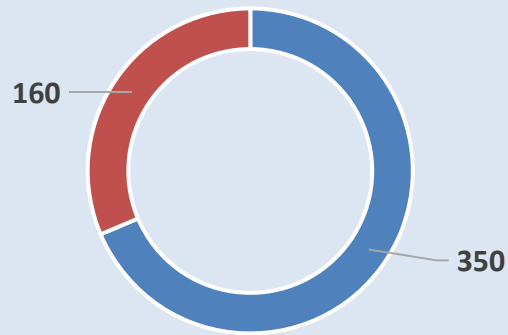
Chemical Name	CAS No.	Revised in Final PEC List Compared to Draft Version
Hydrazine	302-01-2	Added as entry No.190 of the final list
Disodium tetraborate decahydrate; Borax	1303-96-4	Deleted
Lead oxide phosphonate (Pb3O2(HPO3)), hemihydrate	1344-40-7	Deleted
(R)-1-Methyl-4-(1-methylethenyl)cyclohexene; D-Limonene	5989-27-5	Incorporated into entry No.177 of the final list
Hydrazine hydrate	7803-57-8	Deleted
Cobalt nitrate	10026-22-9	Deleted
Chromium oxide	11118-57-3	Deleted
Disodium tetraborate pentahydrate	12179-04-3	Deleted
(R)-Glycidyl butyrate	60456-26-0	Incorporated into entry No. 275 of the final list
(S)-Glycidyl butyrate	65031-96-1	

- ◆ Final list of **510 priority existing chemical substances (PECs)** was officially published on 1 July 2015 (MoE Announcement No. 2015-92).
- ◆ From this date, individuals and companies have a three (3) year grace period to register the listed PEC substances (≥ 1 t/y) until **30 Jun 2018 deadline**.
- ◆ Joint Registration is **MANDATORY**.
- ◆ Please note that under K-REACH, ~40 pesticide active ingredients (AIs) are identified as PECs subject to Registration.

K-REACH LR PEC Registration Statistics

LR Selection of 510 PEC Substances (as of 3 Jul 2018)

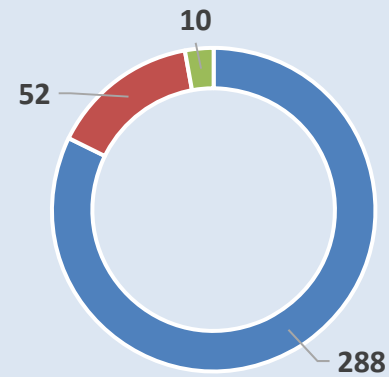
510 PECs



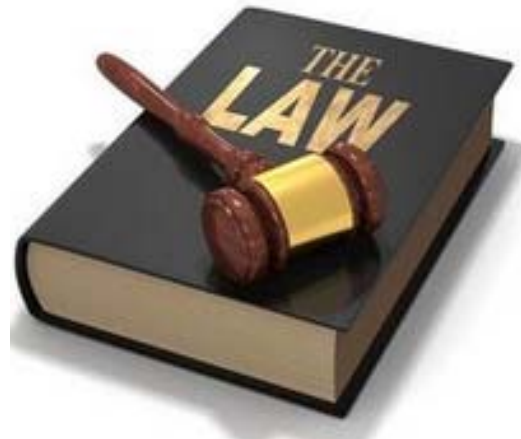
■ LR ■ NO LR

LR Registration (as of 13 Sep 2018)

LR Registration



■ LR dossier passed ■ LR dossier to be evaluated
 ■ LR dossier unsubmitted



New Revision of K-REACH

Background

Problems with K-REACH Implementation



1. Slow progress in the Joint Registration of 510 PECs; registration work cannot be completed on schedule.
2. Companies do not know the following list of substances to be registered so cannot prepare ahead of time.
3. Any tonnage of new chemical is subject to registration which is a burden to small and medium-sized enterprises (SMEs). This rule is different from EU REACH and would possibly result in trade disputes.

K-REACH: Amendments published 20 Mar 2018; **implementation date 1 Jan 2019**.
Subsidiary Regulation published on 30 May 2018, consultation closed on 9 Jul 2018.

Key Milestones under Revised K-REACH

Late 2017	<ul style="list-style-type: none">• MOE published the amended K-REACH after NA approval• Sub-decree drafted but not finalized
Late 2018	MOE expected to enforce amended K-REACH on 1 Jan 2019 Launch pre-registration for 7000 phase-in substances (> 0.1 t/y)
Late 2019	Close of Pre-Registration period (1 Jan 2019 - 30 Jun 2019) Grace period for different tonnage tier of joint registration from the date
31 Dec 2021	Deadline for CMR and >1000 t/y substances (1170 phase-in substances)
31 Dec 2024	Deadline for 100-1000 t/y substances (1096 phase-in substances)
31 Dec 2027	Deadline for 10-1000 t/y substances (2075 phase-in substances)
31 Dec 2030	Deadline for 1-10 t/y substances (2642 phase-in substances)

Summary of Technical Changes

Phase-in Substance Subject to Registration

← ~~PEC~~ > 1 tpa

- Phase-in substances >1 tpa (about 7000 substances)
- Introduce Pre-registration

LVE/PLC under Former TCCA

- Ver 1 - Repeated registration under K-REACH
- Ver 2 - Introduce notification for LVE and PLC under K-REACH

Annual Report

- All non phase-in (new) substances
- All phase-in (existing) substances > 1 tpa
- Annual report before 30 Jun 2018 should be submitted

Product Notification

- Hazardous substance/risk concern substance (CMR/PBT/EDC)
- Total tonnage >1 tpa and content > 0.1% (total or individual??)

Authorization List

- Publish the authorization substance list and grace period
- Publish specific use to authorization
- Publish specific use exempt from authorization

Supply Chain Communication

- When transfer registered substance or mixture containing this substance (Without % limit)
- When transfer hazardous substance or mixture containing hazardous substance (Without % limit)

Pre-Registration of Existing Chemicals

K-REACH Revision

Only existing chemicals that are pre-registered can have a grace period.

Pre-registration will start from **1 Jan 2019** and complete before **30 Jun 2019**.

Details

- Name of manufacturers/importers, representative
- Chemical name
- Annual production/import volume
- Classification & label
- Classification of purpose of use



Tonnage of import/manufacture

Declare in advance if there's any change



Classification label

Classification of use

Declare within a month if there's any change

Pre-Registration of Existing Chemicals



To manufacture/import existing chemicals (>1 t/y), companies should complete registration before 2030 in accordance to varied grace period for different tonnages.

Detail

▶ **10~100t**
Need to complete registration by 2027

▶ **1~10t**
Need to complete registration by 2030



31 Dec 2021

31 Dec, 2024

31 Dec, 2027

31 Dec, 2030

High-risk carcinogenic substances (>1 t) and substances >1000 t (1,100+ substances)

100-1000t (1,100+ substances)

10-100t (2,000+ substances)

1-10t (2,300+ substances)

New Chemical Registration

**K-REACH
Revision**

- 1 New Chemicals < 0.1t
- 2 Exempted new chemicals according to TCCA
- 3 New chemicals $\geq 0.1t$ should register



**Subject to
Notification**

Detailed Regulation

➔ **NIER will release results of notification within 7 days
(if further assessment needed – 14 days)**

Notification

1. Enterprises name & legal person of manufacturers/
importers
2. Chemical name
3. Classification and labels of chemicals
4. Classification of use and scope
5. Hazard information



Designation of Chemical for Registration



Even if tonnage of a chemical does not meet the standard for registration, the chemical still might be designated to be registered if the total tonnage of the chemical in Korea exceeds the standard prescribed by the presidential decree.

MOE might designate a chemical for registration after the assessment by Chemical Substance Evaluation Committee

Details

	Tonnage	Total production/import volume in Korea
Existing chemicals	> 1 t/year	> 10 t/year (enterprise < 1t/year)
New chemical	> 0.1 t/year	> 1 t/year (enterprise < 0.1t/year)

MOE may designate a chemical based on its **hazard or risk**

Number of Testing Items Under K-REACH

Data Requirement	0.1 – 1 t/y (from 1 Jan 2020 for new chemical only)	1 – 10 t/y	10 – 100 t/y	100 – 1000 t/y	>1000 t/y
Physical & Chemical Properties	5	8	11	13	13
Human Health Hazards	2	4	10	11	15
Environmental Hazards	2	3	5	13	19
TOTAL	9	15	26	37	47

Simplified Data Requirements for Low-Concern Chemicals

Beginning in **June 2018**, MOE plans to reduce the data requirements for 3 types of chemicals to ease the registration burden for industry:

1. Existing chemicals determined to be non-hazardous (without GHS label of health/environmental hazard except for consumer use)
 - Unlimited tonnage; data requirements will be reduced from 47 to 15 test items (Tier 1)
2. “Transported isolated intermediates” that are produced during the manufacture of other chemicals, transported to other production sites, and is entirely consumed.
 - If the intermediate is <1000 t/y, then no extra tests are needed for K-REACH Registration;
 - If the intermediate is >1000 t/y, then the enterprise could submit a Simplified Registration dossier contains only 15 test items
 - * Enterprises should provide documentation to support that the chemical is transported and used with strict safety control
3. Chemicals with similar properties can be registered together

Reagent Exemption

► Current KR

Use of reagent should apply for exemption before manufacture/import.



► KR Revision

Can be manufactured/imported first, and apply reagent exemption within 30 days.

A reagent product may contain ≥ 1 substances

→ A representative substance can be used for exemption.
(information of other substances should be recorded too)



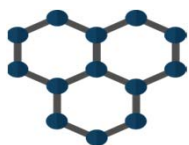
Changes to PLC Exemption Requirements

► Current KR



Monomer

(A, B)



Polymer

(A-B-A-B)

1000-10000 Dalton, a polymer needs registration if its monomer contains more than 2% hazardous or new chemical.

► KR Revision



Number-average molecular weight <10,000;
Residual monomer content (> 0.1%)

Consumer Products Containing Hazardous Chemicals

K-REACH
Revision

Priority Management Chemical

Definition: a chemical that meets one of the following conditions, assessed by chemical substance assessment committee, and published by the director of MOE:

1. Carcinogenic to humans or animals, sudden variation, harmful to reproductive capacity and endocrine;
2. High accumulation in humans, animals or plants, and remains in the environment for long period of time;
3. When exposed, it can damage people's lungs, liver, heart or other organs;
4. Substance that would cause the same extent of harm as above.

Details

Condition

1. Each product contains more than 0.1% of *Priority Management Chemical*
2. The total amount of each substance containing *Priority Management Chemical* in the product exceeds 1 ton.

Exemption

1. A product will not expose to human and the environment.
2. A product that pre-registered or registered officially.
3. Substance contained in a facility and import with the facility.
4. Chemicals used to run testing facilities or machines.
5. Chemicals function in a certain solid form and no chemicals separate during use.



Products containing *Priority Management Chemical* should notify to MOE before manufacture and import.

Notification:

Chemical name
Content & hazard information
Exposure information
Use of the *Priority Management Chemical*

Re-Definition of “*Authorized Chemical*”

K-REACH
Revision

“*Authorized Chemical*” -

a chemical’s hazard evaluated by Chemical Substance Assessment Committee, and designated to be authorized by MOE prior to its manufacture or import.

Details

Currently, authorized chemicals need to be authorized for particular uses; no restriction for other uses.



After revision, authorized chemical can **only** be used for its authorized use.

Chemical Information Transfer

► KR Revision

For registered, notified, or hazardous chemicals, the distributor should transfer related safety information to its downstream users.

“CMR” Chemical Information

If a chemical contains a CMR substance, related enterprises must provide safety information.

For enterprises that refuse to do so, they should apply in advance.



Established New Penalty Basis



Enterprises who manufacture or import chemicals before Registration or Notification



Penalty up to 5% of sales.

Details

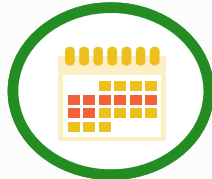
Total Sales

The average annual sales of the previous three years before the violation; if it is circulated in the market less than 3 years, calculate the average annual sales.

Factors



Severity of the Violation



Frequency of Violations



Illegal Profit



Capability to Afford Penalty





Risk Concerned Products and Biocides (K-BPR)

Designation of Risk Concerned Products

Designated Products of Risk-Concern	Detergent Products	Coating Adhesive Products	Air Freshener Products	Dye Products	Biocidal Products	Others
(MOE Notice No. 2015-41)	(1) Cleaners	(1) Coating agents	(1) Air fresheners	(1) Colorant/ de-colorant agents	(1) Disinfectants	(1) Candle
(Updated 22 Aug 2017)	(2) Synthetic detergents	(2) Anti-rust additives	(2) Deodorizing agents	(2) Tattoo inks	(2) Insect repellents	(2) Dehumidifying agent for home use
	(3) Bleaching agents	(3) Anti-fogging agents		(3) Ink cartridges and toners	(3) Preservatives	(3) Engine antifreeze coolant
	(4) Fabric softeners	(4) Adhesives				
	(5) Windshield washer fluids	(5) Ironing auxiliaries				
		(6) Gap and crack fillers				

Safety & Labeling Standards

- The Safety & Labeling Standards for each product type usually consist of 4 parts:
 - 1) Restriction (e.g., concentration limits)
 - 2) Ban
 - 3) Labeling
 - 4) Packaging (e.g., child resistant packaging)
- MOE issued updated version which came into effect [22 Aug 2017](#).
- List of approved biocidal active substances with newly corresponding % threshold are provided for three products:
 - [26 approved biocidal active substances for cleaners](#)
 - [23 approved biocidal active substances for air fresheners](#)
 - [22 approved biocidal active substances for deodorants](#)
- Manufacture or importation of risk concerned products require product testing in one of [eight \(8\) qualified labs](#) every three (3) years to verify compliance with the safety standards and keep testing reports for inspections.
- For products containing biocidal active substances already on the market, a grace period for testing can be granted by submitting a proposed testing plan to the MoE before [22 August 2018](#).
 - However, if a product contains a biocidal active substance which is not on the white list, the manufacturer must submit data before use for safety assessment by the MoE in advance.

Safety & Labeling Standards

In addition, MOE set out a timetable for full compliance with the updated Safety & Labeling Standards:

- Windshield washer fluids for automobiles
 - 30 Dec 2017 for safety and labeling standards
- Dehumidifying agent for home use and candle:
 - 30 Dec 2017 for safety standards
 - 29 Jun 2018 for labeling standards
- Spray cleaners, air fresheners, deodorants, and gap and crack fillers:
 - 22 Feb 2018 for safety standards
 - 29 Jun 2018 for labeling standards
- Engine antifreeze coolants:
 - 29 Jun 2018 for safety and labeling standards

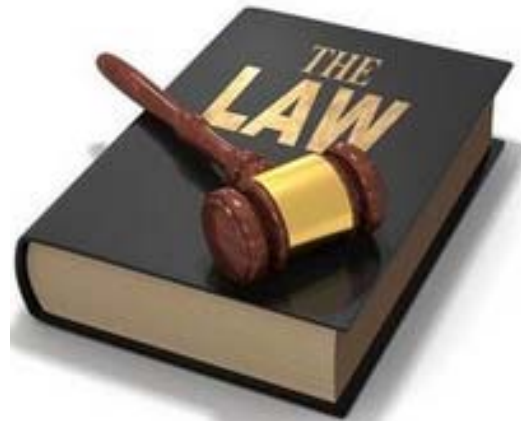
Exposure Factors for Risk Assessment

Risk assessment of risk concerned products is required under K-REACH. To assess exposure and risk to consumers, the exposure factors of the risk concerned products are provided by the authority. Issued on 15 Nov 2017 by NIER Notice 2017-401, exposure factors for four (4) risk concerned products were newly provided for public comments until 5 Dec 2017 including:

- Windshield washer fluids for automobiles
- Candle
- Dehumidifying agent for home use and candle:
- Engine antifreeze coolants:

In addition, more exposure factors supplemented for the six (6) risk concerned products listed below are also under public consideration:

- Cleaners
- Adhesives
- Coating Agents
- Synthetic Detergents
- Bleaching Agents
- Fabric Softeners



Revision of K-REACH & New K-BPR

New “Act on Safety Management of Consumer Chemical Products and Biocides (aka “K-BPR”)

- MOE notified the WTO Committee on TBT on 12 Jan 2017 of draft proposal
- Passed by South Korea’s Cabinet on 8 Aug 2017
- Approved by National Assembly on 28 Feb 2018
- The **K-BPR Law 15511** was promulgated on 20 Mar 2018 and will take effect on 1 Jan 2019.
- The regulation governs the labeling, approval, authorization and post-management of household chemical products, biocidal products and biocide-treated articles.
- **The K-BPR sub-regulation drafts (Enforcement or Presidential Decree and Implementation Rules or Ministerial Decree) were published on 30 May 2018 for a 40-day public consultation (until 9 Jul 2018). Expected to be published in Nov 2018.**

Major Contents:

I. Safety Management of Consumer Chemical Products

- Risk Concerned Products currently managed under K-REACH will be covered by the new Act.
- Name of “Risk Concerned Product” will be changed to “Consumer Chemical Products Subject to Safety Confirmation” (or Safety Confirmation Products).
- Under K-BPR, corresponding products expected to cover more items and include not only products used in household, but also products used in living spaces such as office and multi-use facilities.
- Manufacturer or importer of household chemical products should request specialized institutes entrusted by MOE to perform safety risk assessment on products every 3 years including:
 - Safety & labeling criteria; threshold for substance content; migration or evaporation, etc.
- New MOE Commission specialized in household chemical products to be established.

New “Act on Safety Management of Consumer Chemical Products and Biocides (aka “K-BPR”)

Major Contents (Cont’d):

II. Approval of Biocidal Substances (Active Substances)

- Application for grace period to MOE for approval of active substance contained in a biocidal product.
- For active substances already on the market before **31 Dec 2018**, a ten (10) year grace period will be granted after notifying such situation to the authority;
- Notification period for existing Biocidal Substances is **1 Jan 2019 - 30 Jun 2019**;
- A Positive List of active substances approved for use will be issued by **31 Dec 2019** based on notified active substances/products. Biocidal products using unlisted active substances will be removed from the market by **January 2020**;
- Dossiers should be submitted within the grace period to get approval;
- **Exempted products include: preservatives used in food and cosmetics; technical materials, formulation and device governed by Pesticide Control Act; food additives governed by Food Sanitation Act; feeds governed by Livestock and Fish Feed Control Act; cosmetics and raw materials governed by Cosmetic Regulations; and water treatment chemicals governed by Drinking Water Management Act.**

III. Authorization of Biocidal Products

- Only approved biocide actives can be used for biocidal products;
- Biocidal products such as disinfectants and insecticides must obtain authorization before they are placed on the market;
- Authorization is based on its safety, effect, and efficacy information.

New “Act on Safety Management of Consumer Chemical Products and Biocides (aka “K-BPR”)

Major Contents (Cont’d):

IV. Safety Management of Treated Articles

- Articles can only be treated with biocidal products containing active substances approved by the authority.
- Treated articles should be labeled accordingly.

V. Data Protection and Sharing

VI. Distribution [Post-] Management of Consumer Chemical Products and Biocides

- Restriction on Advertising - ban the use of phrases such as “Safe”, “Non-toxic”, “Eco-friendly”, etc. which may misdirect consumers or cause misunderstanding.
- Child Safety Packaging
- Market Surveillance
- Prohibition of sales, intermediation and purchase of goods for illegal products
- Mandatory Reporting of newly discovered risks & other side effects
- Household products found to be in violation maybe subject to bans, recalls or fines.
- Duty to Report – Manufacturers or Importers of Safety Confirmation Products or Biocides shall report to MOE every 2 years regarding name and volume of substances and products.
 - First Report Period after K-BPR enactment is ~31 Mar 2020;
 - Report Period after 2020 is by 31 Mar of every 2 years (e.g., 2022, 2024, etc.)



Key Aspects of Sub-Regulation Drafts

1. Data Requirements of Approval of Biocide A.I. and Biocidal Products

- **Approval for Biocide A.I.**: 13 types of data requirements total (physicochemical properties, biological characteristics, efficacy, health hazards and environmental hazards, etc.)
- **Approval for Biocide Product**: 13 types of data requirements total (physicochemical properties, biological characteristics, efficacy, health hazards and environmental hazards, data verifying that applicants complied with manufacturing/storage facility standard, etc.)

2. K-BPR Product Types

- MOE specifies biocidal product types
- By establishing biocide product types, biocide A.I. cannot be used in unauthorized product types
- K-BPR's product types are classified into 4 Categories and 15 specific types (whereas EU BPR has 22 product types)

New K-BPR Product Types

Classification	Korea BPR Product Types
Disinfectants	(1) Disinfectants
	(2) Algaecide
Pest Control	(3) Rodenticides
	(4) Control of other vertebrates
	(5) Insecticides
	(6) Control of other non-vertebrates
	(7) Repellents
Preservatives	(8) Product preservatives
	(9) Product surface treatment preservatives
	(10) Fabric, leather preservatives
	(11) Wood preservatives
	(12) Construction material preservatives
	(13) Material/equipment preservatives (Preservatives for liquid-cooling and processing systems, working or cutting fluid preservatives)
	(14) Embalming or taxidermist fluids
Others	(15) Antifouling agents

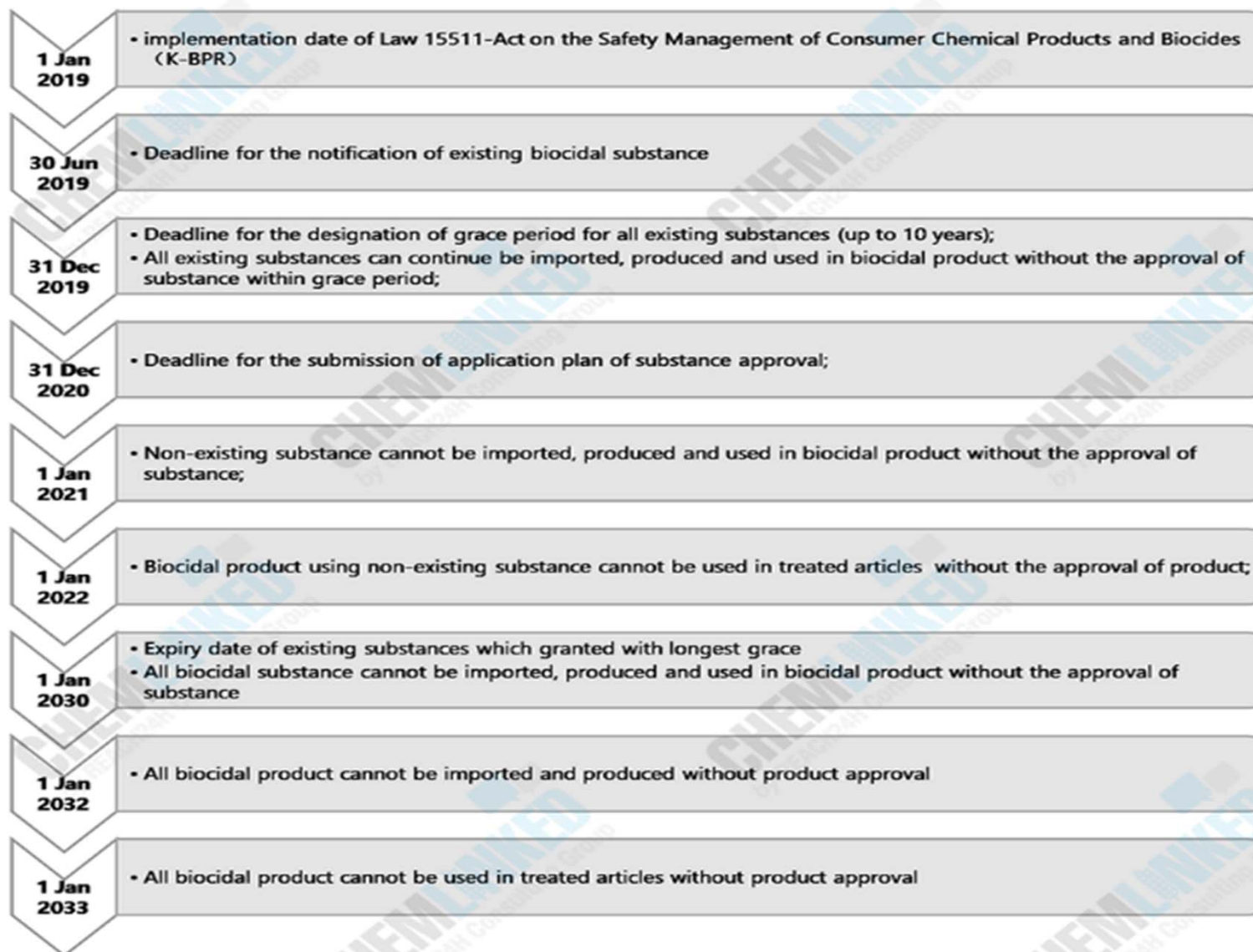
Key Aspects of Sub-Regulation Drafts

3. Grace Period of Approval of Existing Biocide Active Ingredient

- Existing biocide A.I. means one contained in biocidal products that is circulated domestically before 31 Dec 2018.
- Existing biocide A.I. are assigned grace period for approval by setting different deadlines which can be up to 10 years according to product types where the biocide A.I. is used
- For product types which have a high possibility of being used everyday by consumers, grace period for approval of existing A.I. will be relatively shortened.

Classification	Group 1	Group 2	Group 3	Group 4
Grace Period of Biocide A.I. Approval	3 yrs. (31 Dec 2022)	5 yrs. (31 Dec 2024)	8 yrs. (31 Dec 2027)	10 yrs. (31 Dec 2031)
Product Type	<ul style="list-style-type: none"> - Disinfectants - Algaecides - Rodenticides - Insecticides - Repellants 	<ul style="list-style-type: none"> - Wood preservatives - Control of other vertebrates - Control of other non-vertebrates 	<ul style="list-style-type: none"> - Product preservatives - Product surface preservatives - Fabric, leather preservatives 	<ul style="list-style-type: none"> - Construction material preservatives - Material/equipment preservatives - Embalming or taxidermist fluids - Antifouling agents

New K-BPR Timeline



Key Aspects of Sub-Regulation Drafts

4. Label Claims of Biocidal Products

- Only biocidal products whose main function is removing or eliminating harmful organisms are allowed to label or advertise its 'biocidal effect' such as "disinfection", "insecticide", "preservation", etc.
- For biocide-treated articles whose biocidal function is a secondary one, these products are restricted to indirect claims such as "disinfected", "antimicrobial" and "preservative", etc.
- Consumer chemical products determined as "Product of Concern" or subject to safety confirmation are prohibited from misleading labels such as "non-toxic", "harmless", "environmental friendly" and "animal friendly" leading to consumer misconception about the safety of the product.

5. Support to Industry

- Government can support SMEs to generate relevant data by offering financial aid or directly generating the required data for these companies.
- In an effort to streamline administrative procedures, conformity notification of consumer chemical products subject to safety confirmation, and the application for the approval of biocidal substance and biocidal products will be processed electronically.

New K-BPR Fees

Classification	Base Amount (₩ KRW)
1. Application for Approval of Substances in accordance with Article 13 (1) and (3) of the Act	200,000
2. Application for approval of change of substance approval in accordance with Article 15 of the Act	100,000
3. Application for recognition of substance equivalence under Article 16 (1) of the Act	50,000
4. Application for product approval under Article 21, Paragraphs 1 and 3 of the Act	200,000
5. Application for change approval of product approval pursuant to Article 23 of the Act	100,000
6. Application for product approval pursuant to Article 24 (2) of the Act (special product approval)	50,000
7. Application for recognition of product similarity pursuant to Article 25 (1) of the Act	50,000
8. Request for information provision or inspection pursuant to Article 30 (information disclosure on biocidal product used on treated article, requested by the buyer of the treated articles)	20,000

Reduction of tax base - For medium and small enterprises under Article 2 (2) of the Framework Act, 50% of the standard amount for medium enterprises and 80% of the standard amount for small enterprises.

[NOTE: \$1 USD = 1095 KRW]

Industry Key Considerations

- Check if any biocide A.I. is contained in manufactured or imported products;
- Understand the obligation, if applicable, depending on the biocidal product type;
- Foreign manufacturer or producers may appoint an Only Representative (OR) to fulfill K-BPR obligations;
- Two options are feasible in order to ensure current compliance requirements are met:
 - 1) Submission of dossiers of biocidal substances under K-REACH prior to 31 Dec 2018;
 - 2) Extension of the grace period by timely notification of existing substance and submission of application plan



Thanks for your attention!

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