Ministry of Environment

Act on Registration and Evaluation, etc. of Chemical Substances

Subordinate Laws
- Draft Amendment -

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Ⅰ. Background

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K-REACH : amended and promulgated (Mar. 20, 2018)
will be enforced (Jan. 1, 2019)

➡ **Its subordinate laws also need to be amended.**

e.g.) grace periods of existing substances, penalty criterion

Amendment of subordinate laws includes some elements of "Measures to Support Industry's Compliance (incl. SMEs)"

(This measure was developed jointly by relevant ministries on Sep. 28, 2017)

e.g.) simplified data requirements of low risk-concerned substances

Improve several lacks witnessed while operating K-REACH since Jan. 2015

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II. Main Contents

1 Revision Under K-REACH Amendment

1-1 Grace period for existing substance registration (Decree, Article 10)

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K-REACH Amendment

Manufacturer/importer of existing substance over 1ton/y should submit hazard data and complete registration by 2030, based on the tonnage bands and hazards.

>100 ton/y

By 2024

1~100ton/y

Within 2030 under subordinate laws

Amendment of Subordinate Laws

▶ 10~100 ton/y
Registration by 2027
(grace period of 3 years)

▶ 1~10 ton/y
Registration by 2030

Dec.31,'21 (K-REACH)
Over 1ton/y CMRs, Over 1,000 ton/y
(1,100 substances)

Dec.31,'24(K-REACH)
Over 100ton/y
(1,100 substances)

Dec.31,'27(Decree)
Over 10ton/y
(2,000 substances)

Dec.31,'30(Decree)
Over 1ton/y
(2,300 substances)

1-2 Pre-notification of existing substance
(Decree, Article 10(2) / Rule, Article 3 & Article 51)

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K-REACH Amendment

Grace period is provided only after manufacturer/importer notifies of basic information* before manufacturing or importing existing substance. * e.g. chemical name, the amount manufactured/imported

When the Amendment comes into force, person who already manufactures or imports existing substance should pre-notify it **by June 30, 2019.**
When non-compliance, its manufacture, import, use will be banned.

Details of pre-notification & notification on changed information in the subordinate laws

Amendment of Subordinate Laws

Submit a notification to KECO through Chemicals Information Processing System (IT)

➡ KECO reviews/accepts it or not, and report current status and progress to ME every quarter

- Manufacturing/Importing company's name, representative
- Chemical substance's name
- Annual amount manufactured/imported
- Classification & labelling
- Substance's use category & scope

Tonnage band manufactured/imported

Notify before the change is applied

Classification/labelling, Use category, etc.

Notify within 1 month

1-3 Designation of Substance subject to Registration based on annual tonnage band (Decree, Article 10(3))

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K-REACH Amendment

Even though it is not subject to registration based on the amount per company, when its total annual amount manufactured in or imported to Korea exceeds the limit decided by the Presidential Decree,

ME may designate it as subject to registration (PEC) after a deliberation of Chemical Substance Evaluation Committee.

Amendment of Subordinate Laws

	Registration criteria of each manufacturer/importer	Total amount manufactured/imported in Korea
Existing Substance	Over 1 ton/y	Over 10 ton/y (< 1ton/y per company)
New Substance	Over 0.1ton/y	Over 1 ton/y (< 0.1ton/y per company)

ME decides PEC designation/announcement by considering hazards/risks

1-4 How to notify of new substance less than 100kg (Decree, Rule, Article 6(2))

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K-REACH Amendment

1. New substance < 0.1ton/y
2. Already confirmed exemption from hazard review under previous 「TCCA」

» **Should notify**

Amendment of Subordinate Laws

Submit a notification to NIER
through Chemical Substance Information Processing System

➡ NIER informs its acceptance or not within 7 days (max. 14days)

Notify changes within 1 month

- Changes in classification and labelling, use category, consumer use
- New use by consumers

1-5 How to calculate and impose fine, etc.
(Decree Article 15(2), Article 15(3), etc.)

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K-REACH Amendment

When manufacturing/importing without substance registration, registration of changed information, impose fine and penalty

Amendment of Subordinate Laws

Total Sales = Annual sales of three business years just prior to the business year that the company violates the law.

Adjustment


Seriousness


How long
How many times


Economic profits from violation


Capacity to afford fine

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II. Main Contents

2 Industry Supporting Measures (incl.SMEs)

2-1 Simplified registration dossier for low risk-concerned substance (Enforcement Decree, Article 13)

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▶ Reason

For 'low risk-concerned substances',
Reasonable operation of legislation

▶ Amendment

After review, " Simplified Data Requirements"

Existing substance, not classified as hazardous based on pre-notification results

- Only 15 data are required regardless of the amount manufactured or imported, which is usually asked for 1~10ton/y

Substance (transported isolated intermediate) that is produced in the course of manufacturing other substance, and then transported, and used and dissipated during subsequent processing as a whole.

- Substance 〈 1,000 tons : exempted from data submission
- Substance 〉 1,000 tons : needs to submit 15 data
  * company should submit documents confirming the substance is transported and used under strictly-controlled condition, and should record and keep a management record.

2-2 Improved registration system based on substance properties (Decree, Article 11)

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▶ Reason

A B

Monomer

–A–B–A–B–

Polymer

Even though Monomer – Polymer has different properties, When Monomer is

'Hazardous' or 'New',

Polymer should be also registered.

▶ Amendment

Hazardous Substance

Priority Substance

New Substance

As residual monomer (〉 0.1%),

When impacting on polymer's hazards, it should be registered

* For surface-treated substance C = (A) B

If Substance A's weight accounts for most of total weight, and if Substance A and B are not new substance and already registered, Substance C is exempted from registration.

2-3 Improved method to form consortium for joint registration (Enforcement Rule, Article 17)

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▶ Reason

Manufacture/Import of Same Substance

Joint registration
by forming/operating consortium

Manufacture/Import of Same Substance (Different Use/Property)

'Issue Raised'

▶ Amendment

Manufacturer/Importer can establish separate consortium if manufacturing/importing for " Consumer Use"

When two substances have same name but it is hard to consider them as same, ME allows to form separate polymer consortium

※ ME develops new provision to facilitate early registration
: when lead registrant completes joint submission, it should inform member registrant in the consortium within 15 days.

2-4 Improved system for registration exemption confirmation (Enforcement Rule, Article 7)

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▶ Reason

For 'Reagent that is not placed on the market', Less regulation on registration exemption confirmation

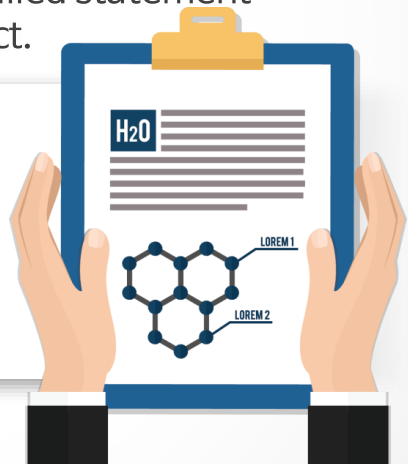
▶ Amendment

Submit within 30 days after manufacture/import

- ME extends the period, which is same with the period to submit "detailed statement of verification" of imported substance under the Chemicals Control Act.

Dozens/hundreds of substances are imported at once as reagent in product unit

➡ **registration exemption confirmation can be prepared with representative substance of the product.**
(also should specify other substances in the product)



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II. Main Contents

3 Improvement & Supplement

3-1 Extended information provision of hazardous substance (Decree, Article 20(2) / Rule, Article 35)

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▶ Reason

Seller provides purchaser with registered substance information (K-REACH, Article 29)

But, seller may not provide it by claiming CBI, except hazardous substances (Rule, Article 35)

Insufficient information provision of hazardous substances!

▶ Amendment

Carcinogenic /Mutagenic/Reprotoxic Substances Information should be provided

* Substances announced as subject to registration by 2021

Other substances classified as hazardous : ME's approval* in advance in order not to provide the information as CBI.

*After "Application not to provide information" is submitted to ME, ME should inform the applicant of its decision whether it accepts the application or not based on deliberation of Information Provision Deliberation Committee **within 60 days** (a subcommittee under Chemicals Evaluation Committee).

3-2 Disclosure of hazard test summary of registered substance (Rule, Article 5, Attachment 1)

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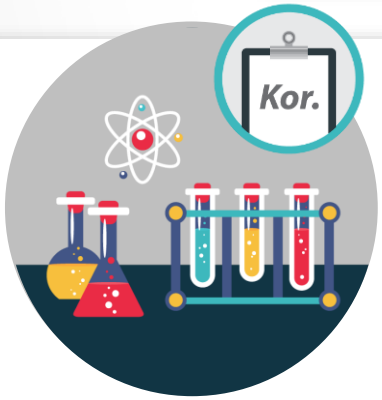
▶ Reason

To make people accessible to substance information on Korean market more swiftly!

Need to disclose hazard data submitted by industry

▶ Amendment

Disclose Test Summary, except CBI



Existing — Submit full paper/summary

Amendment — **Submit "test summary" in Korean**

* If submitter has original paper of test summery, the original paper should be submitted along with the test summery.
* If submitter owns the full paper, the full paper should be submitted.

3-3 Improved hazard review method for registered substance (Rule, Article 23)

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▶ Reason

1. Lack of legal ground for reviewing higher risk-concerned substances first among other substances
2. Unclear when ME performs hazard review on existing substances

▶ Amendment

Priority criteria for hazard review

Consider the amount manufactured/imported into Korea, hazards, damages

Existing substance's joint registration

- Once after lead/member registrants submit registration dossier, and grace period is expired, ME carries out hazard review.

3-4 Strengthened penalty for violation of hazard testing institute (GLP) (Rule, Article 31, Attachment 10)

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▶ Reason

Insufficient penalty
(business suspension, designation cancellation, etc.)

If testing institute issues undesignated test results, only warnings are given.

▶ Amendment

**Strong penalty for testing institute,
Similar to penalty under Pesticide Control Act & Pharmaceutical Affairs Act**

Violation		1st	2nd	3rd	over 4th
① When testing institute fails to fulfil designation criteria, or violates management criteria	Before	Order of improvement	Order of improvement	1month suspension	3months Suspension
	After	1month suspension	3months suspension	6months suspension	Cancellation (designation)
② When it has no performance on designated test item for over 2 years	Before	warning	1month suspension	1month suspension	6months suspension
	After	warning	Cancellation (test item)		
③ When it issues undesignated test result	Before	warning	1month suspension	3months suspension	Cancellation (test item)
	After	Cancellation (designation)			
④ When it does not submit a performance report of previous year	New	Order of improvement	Order of improvement	1month suspension	3months suspension

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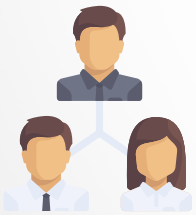
ME's Notice : Registration : Notification on Changed Information

Many applications will be submitted around expiration date of grace period

(Keep existing provision) "within 30 days" from the date when the registration dossier is submitted

Extends the period less than 30 days, maximum twice (Rule, Article 6)

Registrant's Notification on Changed Information



When adding/changing importer,
When changing OR appointed by overseas manufacturer/producer

* OR on behalf of importer (Korean corporate, etc.) has all liabilities.
It is important to understand and manage a list of importers precisely.

Ⅲ. Plan

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Consultation with relevant Ministries,

Pre-announcement of legislation

This will be done with draft subordinate laws of K-BPR that provisions of K-REACH is transferred to.

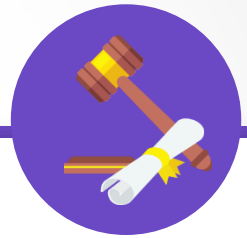
May ~July

Review by ME, & Regulatory Reform Committee

June~Aug.

Review by Ministry of Government Legislation

Aug.~Oct.



Deliberation by Vice-Ministers' meeting & Cabinet Meeting,

Promulgation of subordinate laws

Nov.

Thank you

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