



Overview of The Act on the Registration and Evaluation of Chemicals(K-REACH) and Korea GHS



*Enabling Chemical Compliance
for A Safer World*

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Table of Content



Korean Chemical Regulatory Framework	1
Korea REACH	3
- Definition & Scope	4
- Timeline & Overview	5
- Annual Report/Registration	6
- Management of Products	20
- Comparison with EU & China	23
- How to Comply with K-REACH	25
Korea GHS	28
Summary	33

Korea: Chemical Regulatory Framework



Chemicals	Ministries	Regulations
Industrial Chemicals	Ministry of Environment	Toxic Chemicals Control Act (à K-REACH and CCA)
Hazardous chemicals in workplaces	Ministry of Employment & Labor (MoEL)	Industrial Safety and Health Act (ISHA)
Explosive, Oxidizing & Flammable materials	National Emergency Management Agency	Dangerous Material Management Act
Medical Supplies	Ministry of Health & Welfare	Pharmaceutical Affairs Act
Narcotics		Narcotics control Act
Cosmetics		Cosmetic Act
Food additives		Food Sanitation Act
Agricultural Chemicals	Ministry for Food, Agriculture, Forestry & Fisheries	Agricultural Chemicals Control Act
Fertilizer		Fertilizers Control Act
Livestock and Fish feed		Control of Livestock and Fish feed Act
High Pressure Gas	Ministry of Knowledge Economy	High Pressure Gas Safety Control Act
Radioactive Substances	Ministry of Education science and technology	Atomic Energy Act

Toxic Chemicals Control Act(TCCA)

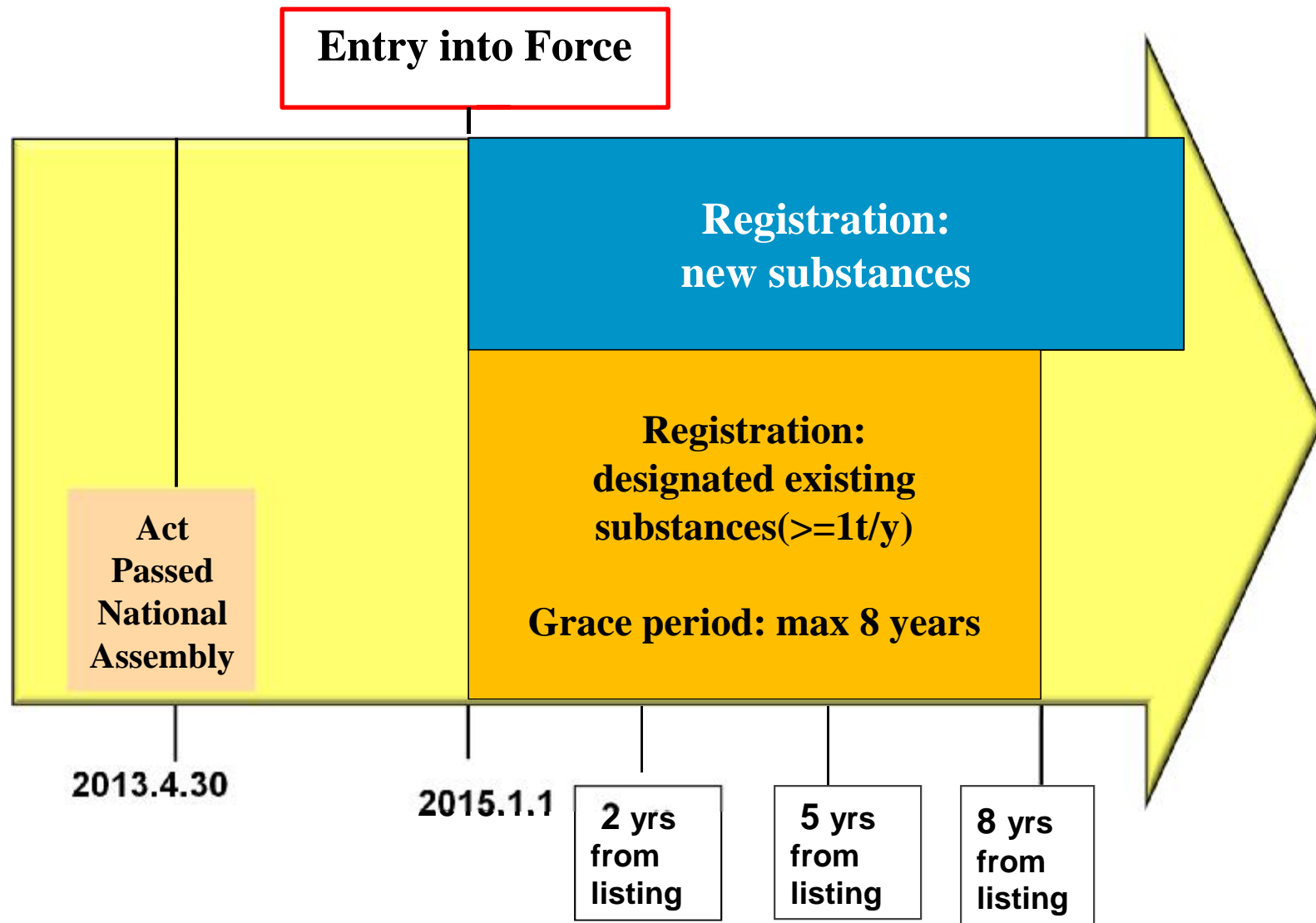
K-REACH, 1 Jan 2015	Chemical Control Act(CCA), 1 Jan 2015
<ul style="list-style-type: none">Registration of chemical substancesHazard and risk assessmentsListing as authorization substancesSharing of info on chemical substancesControl of risk concerned products	<ul style="list-style-type: none">Statistical survey of chemical substancesSafety control of hazardous substancesLicense related to toxic substancesImposing chemical accident reporting obligations and establishing emergency response system.

Table of Content



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Summary	33

K-REACH: Timeline



8 Chapter, 54 Articles and an addendum

- n General Rules (article 1 ~ 7) – Definition & scope etc
- n Registration of chemical Substances (article 8 ~ 17)
- n Hazardous Evaluation and Risk Assessment of chemical substances (article 18 ~ 24)
- n Listing and changing authorization substances (article 25 ~ 28)
- n Communication of chemical substance information (article 29 ~ 31)
- n Management of Risk Concerned products (article 32 ~ 37)
- n Supplementary Provisions (article 38 ~ 48)
- n Penalties (article 49 ~ 54)
- n Addendum (article 1 ~ 7)

1) Existing Substance

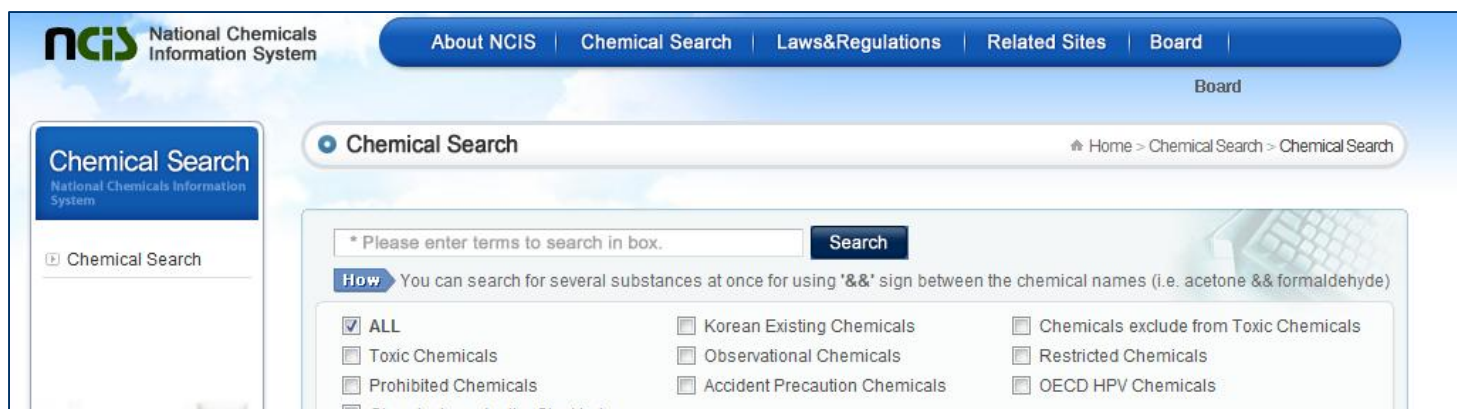
- n Chemical substances distributed for commercial uses in Korea prior to February 2, 1991 and published by MoE;
- n New substances notified and published by MoE under Toxic Chemicals Control Act after February 2, 1991.
- n ~42,652 substances(up to Jan 2013).

2) New Substance

- n Other than above;
- n i.e, new substance notified between 2012-2014 but not published.

3) Hazardous Substance Includes:

- n Toxic chemical substance: published by MOE as hazardous;
- n Authorization substance: published by MoE due to high risks, prior authorization required for use;
- n Restricted substance: published by MoE, restricted for certain uses;
- n Prohibited substance: published by MoE, banned for all uses;
- n other substances with potential hazards or risks;



<http://ncis.nier.go.kr/totinfo/TotInfoList.jsp?sub=02>

4) Product

Means each of following that are likely to result in the exposure of chemicals to consumers as final consumer goods or parts thereof and accessories.

- n Product consisting of a mixture.
- n Product of which the chemicals are not released during the course of uses and perform a certain function in a particular solid form.

5) Risk-concerned products

Mean the ones published by MoE as they are concerned to pose risks to public health or environment:

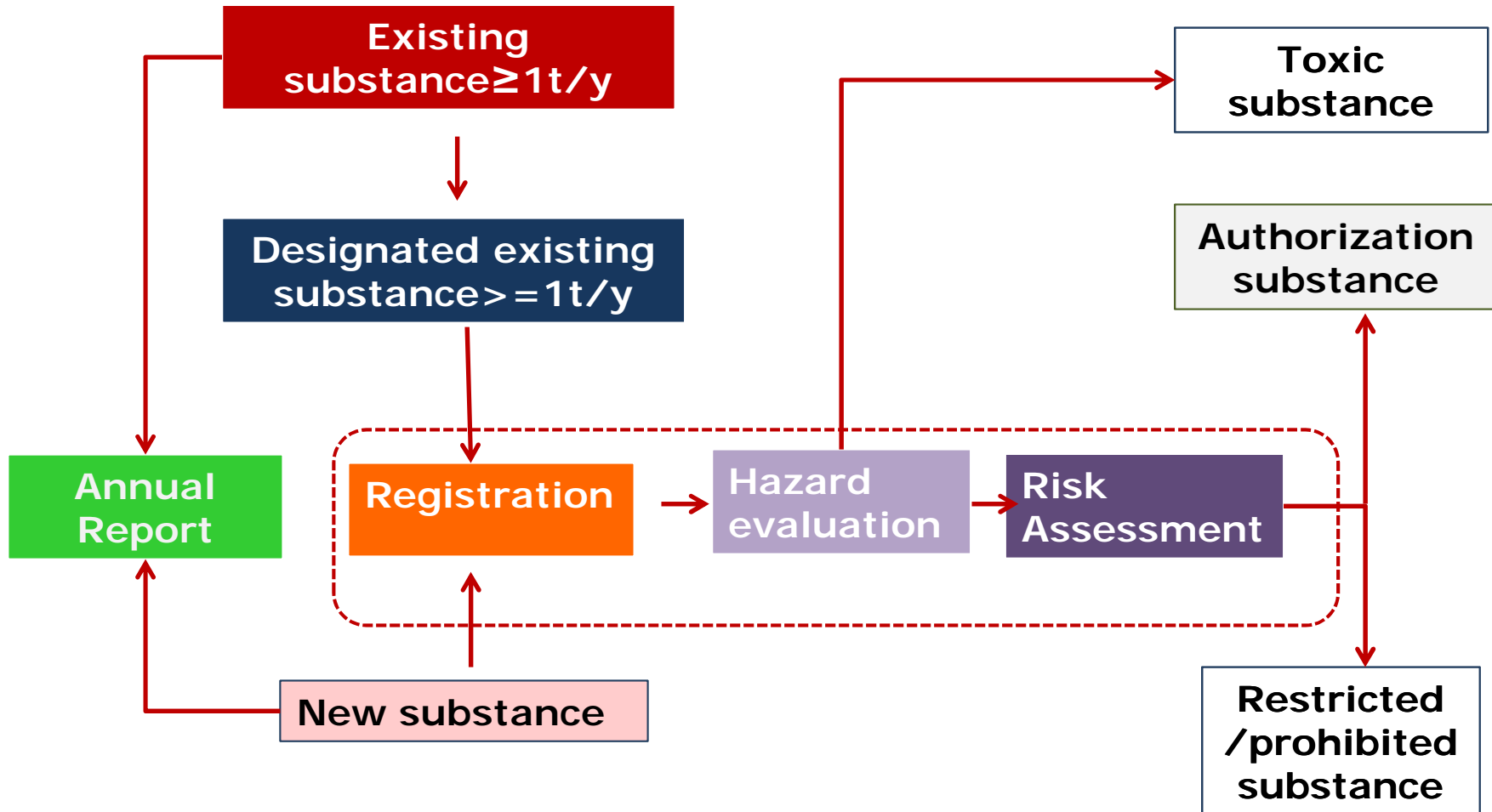
- n Consumer product(cleaner, detergent, adhesive, etc);
- n Biocidal products(disinfectant, insect repellent, preservative, etc)

1) K-REACH does not apply to:

- n Radioactive substances;
- n Pharmaceutical products and quasi-drugs;
- n Narcotics;
- n Cosmetics and raw materials for cosmetics;
- n Pesticides and active ingredients for pesticides;
- n Fertilizers;
- n Food, food additives, food device & food packaging;
- n Feeds;



K-REACH: Overview



1) Notifier:

Manufacturer/Importer/Only Representative;

2) Target Substance

§ New substance;

§ Existing substance $\geq 1\text{t/y}$;

3) Information To Be Reported

§ Volume;

§ Use;

4) Reporting of Changes

§When substance is used for other purposes;

5) Exemptions from Reporting

§Substance imported as an internal component of machinery.

§Substance imported with machinery/equipment for trial operation;

§Substance contained in a product in a solid form to perform a certain function without being released during normal use.

§Other substances manufactured/imported for investigation and research purposes, which are prescribed in the Presidential Decree.

1) Registrant:

Manufacturer/Importer/Only Representative;

2) Target Substance

- § New substance irrespective of volume;
- § Designated existing substance $\geq 1\text{t/y}$;
- § $< 1\text{t/y}$ but causing serious damage to public health and environment

3) Exemptions from registration (☞ does not require confirmation)

- § Substance imported as an internal component of machinery;
- § Substance imported with machinery or equipment for trial operation;
- § Substance contained in a product in a solid form to perform a certain function with no intention of being released normal conditions of use.

4) Confirmation of exemption required

- § $M/I \leq 10\text{t/y}$ in/into Korea and to be exported in its entirety

5) Documents Required:

- § Legal entity information & substance identity;
- § Use information;
- § Classification and Labeling of chemical substance
- § Physico-chemical properties of chemical substance
- § Hazard information of chemical substance
- § Risk information including exposure scenario (For $\geq 10\text{t/y}$ substance, different deadlines apply).
- § Guidance on safe uses
- § Other data prescribed by the Ministerial Decree

6) Reduced Requirements

§ Available for some substances(<1t/y new substance, PLC, R&D substance etc.) listed in the Presidential Decree;

7) Joint submission:

§ Mandatory;

8) Opt-out;

§ Allowed(approval from MOE required;)

9) Testing proposal;

§ Accepted.

10) Submission of Data for Risk Assessment

Tonnage	Deadline of Submission
≥100 ton per year	1st Jan 2015
70 ~100 ton per year	1st Jan 2017
50 ~70 ton per year	1st Jan 2018
20 ~50 ton per year	1st Jan 2019
10 ~20 ton per year	1st Jan 2020

K-REACH: Transitional Measures



1) Period: Between now and 1 Jan 2015;

2) Transitional Measures:

§Any person who had received an exemption confirmation of hazard examination pursuant to current TCCA shall be deemed to have received an exemption confirmation of registration under K-REACH.

§ Applicable to: small volume(<100kg/y, R&D substance, new polymer of low concern, 2% polymer rule, surface treatment substance).

§Any person who made new substance notification pursuant to current TCCA shall be deemed to have completed registration of substance under K-REACH.

1) Notifier:

M/I of products containing hazardous substance $\geq 1\text{t/y}$;

2) Information to be notified

§ name of chemical substance, content

§ information on its hazards and use

3) Exemptions from notification (☞ does not require confirmation)

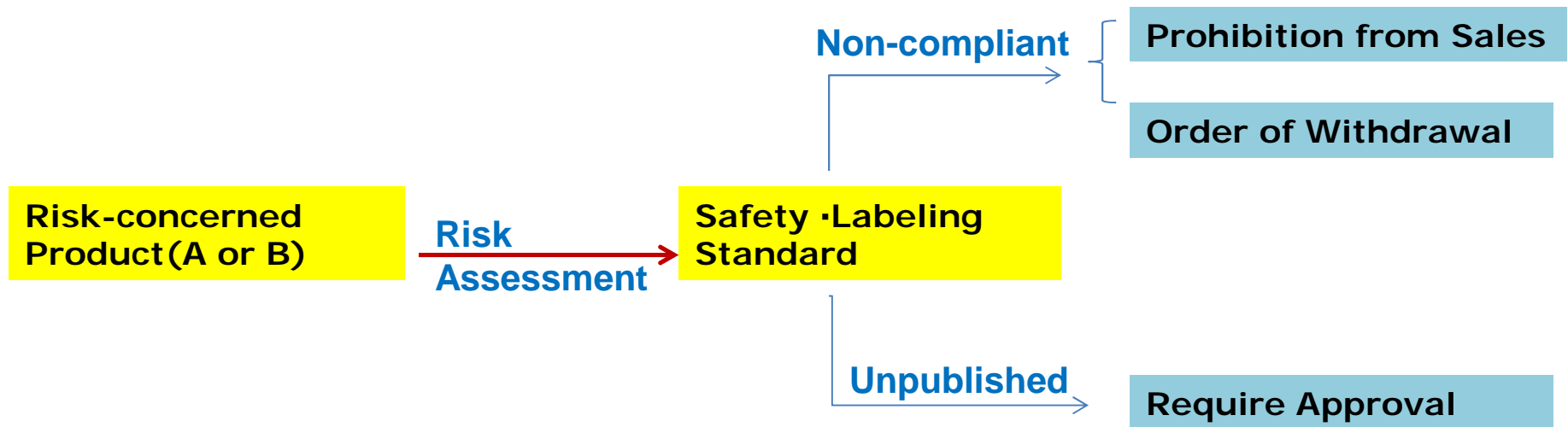
§ A product in which the substance is contained in solid form to perform a certain function and is not released under normal use;

4) Confirmation of notification exemption required

§ Exposure to human/environment can be excluded

§ Chemical substances already registered for that use

K-REACH: Risk Assessment of Risk-concerned Product



A. Household consumer product

- | Cleaner
- | Perfumery
- | Adhesives
- | Polish
- | Fabric softener
- | ...

B. Biocidal product

- | Insect repellents
- | Disinfectants
- | Preservatives
- |

- 1) **Appointed by:** a foreign manufacturer;
- 2) **Qualification of OR:** to be specified by MoE;
- 3) **Responsibilities of the representative**
 - § annual reporting under Article 8;
 - § registration under paragraph 3 of Article 10;
 - § product notification under Article 32;
 - § other activities as specified in the Presidential Decree

Comparison between EU, Korea and China



Items	Korea REACH	EU REACH	China REACH
Registration Object	New substance; Designated existing substance \geq 1t/y;	New substance \geq 1t/y; Existing substance \geq 1t/y;	New substance
Who can register	M/I/OR	M/I/OR	M/I/OR
Type of Registration	Wait for guidance (full/reduced)	PPORD, intermediate, full	R&D; simplified; full
Tonnage Level	1-10, 10-100, 100-1000, 1000+(expected)	1-10, 10-100, 100-1000, 1000+	1-10, 10-100, 100-1000, 1000+
Polymer	Registration of polymer itself	Registration of monomer & reactant(\geq 2%)	Registration of polymer itself
Risk Assessment	\geq 10t/y	\geq 10t/y	1-10t: qualitative; \geq 10t: quantitative
Submission of Risk Info	Can be separated from dossier	In dossier	In dossier

Comparison between EU, Korea and China



Items	Korea REACH	EU REACH	China REACH
Joint submission	Mandatory	Mandatory	Not Mandatory
Inquiry Process	Yes	Yes	No
Testing Proposal	Accepted	Accepted	No
Administrative fee to authority	Yes	Yes	No
Restriction /Authorization	Yes	Yes	No
Annual Report	Yes	No	Yes
Cosmetic ingredients	Exempt from registration	Not exempt	Not exempt
Other Issues	Product notification Risk Assessment of risk-concerned products	SVHC notification	Some eco-toxicology tests must be done in China

How to Comply with Korea REACH & GHS(1/2)



Item	What to do
Annual reporting	<ul style="list-style-type: none">- Draw up a list of substances exported to Korea & volume;- Decide who will do annual reporting : Korean importer or OR;- OR can keep your confidential business information.
Registration	<ul style="list-style-type: none">- Track the list of designated existing substances sub. to registration- Track the guidance on registration;- Application of exemption confirmation under TCCA or submit new substance notification under TCCA.
Toxic, authorization, restricted, prohibited substances	<ul style="list-style-type: none">-Obtain relevant lists from http://ncis.nier.go.kr and check it against your products;- Keep track of designation of authorization substances.

How to Comply with Korea REACH & GHS(2/2)



Item	What to do
Sharing of information on chemical substances	<ul style="list-style-type: none">- Update your SDSs after registration;- Check the format to be given by authorities.
Products containing hazardous chemical substances	<ul style="list-style-type: none">- Identify if your products contain hazardous substances ($\geq 1\text{t/y}$);- Choose between Korean importer or OR;- Keep track of the notification requirements to be issued
Risk concerned products	<ul style="list-style-type: none">- Identify if any of your products is a risk concerned product;- Make sure that your products comply with the relevant safety and labeling standards.

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1) Main Standard:

Standards on classification and labelling of chemical substances and the Material Safety Data Sheet (MoEL Notice No. 2012-14)

2) Implementation Period

§ Substance: 1 July 2010; Mixture: 1 July 2013;

3) Building Blocks vs UN GHS Rev 4

§CHEMICALLY UNSTABLE GAS Category A/B

§AEROSOLS Cate. 3

§FLAMMABLE LIQUIDS Cate. 4

§ SKIN CORROSION / IRRITATION Cate. 3

§ACUTE TOXICITY Cate. 5

§AQUATIC TOXICITY (ACUTE) Cate. 2 & 3

4) Compulsory Classification List

§ Mandatory to follow C&L conducted by NIER for toxic chemicals(>620);

§ http://ncis.nier.go.kr/ghs/board/list_1_view.jsp?board_id=00202&seq=6



유독물 GHS 지원시스템
Globally Harmonized System of Classification and Labelling of Chemicals

정보마당

HOME > 정보마당 > 공지사항

공지사항

HWP viewer

제목	The amended list of GHS classification and labelling for Toxic Chemicals(3rd)				
작성자	시스템관리자	작성일	2011-05-06	조회수	1709
첨부파일					

NIER(National Institute of Environmental Research) notice No. 2011-7 dated April 15, 2011.

Amending NIER notice # 2011-3 on classification and labelling of Toxic Chemicals.

For amended list of GHS classification and labelling list of Toxic Chemicals, **please click here.**

Label system, **please click here.**

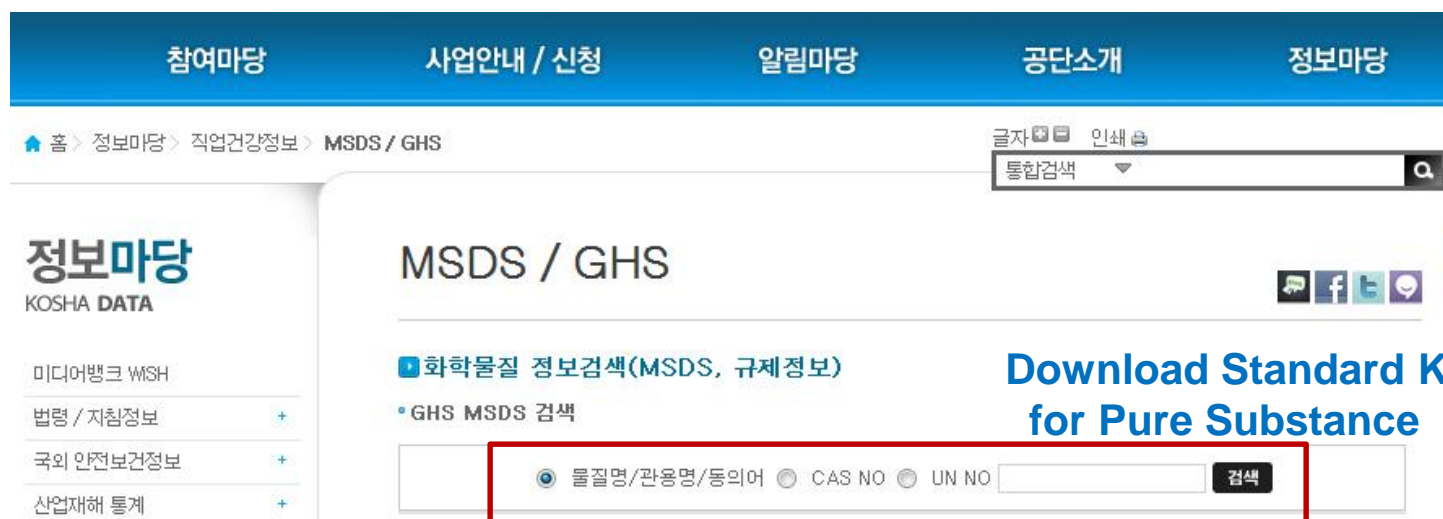
목록

**Download Compulsory
GHS Classification List !**

5) SDS

- § Section 3: $\pm 5\%$; if the contents are less than 5%, the lower limit shall be indicated as " $\geq 1\%$ (0.1% for carcinogens and germ cell mutagens, 0.2% for respiratory sensitizers, and 0.3% for reproductive toxicants);
- § Section 3: substance name, CAS or content may not be shown in case of confidential data.

<http://www.kosha.or.kr/msds/msdsMain.do?menuId=69>




**Download Standard Korean SDS
for Pure Substance**

6) Labelling

- § Standard GHS labelling elements;
- § Supplier info must be a supplier based in Korea;
- § 4 pictograms & 6 p-statements limits: Not compulsory;
- § Container $\leq 100\text{ml}$: h&p statements can be omitted;

암 모 니 아



선 호 어 : 위험
유해 · 위험 문구
극원화성가스
폭발하면 유해 함
수생생물에 유독함

예방조치 문구
 예방 : 열 · 스파크 · 화염과 같은 점화원으로부터 격리하십시오 - 금연, 화경으로 배출하지 마십시오
 대응 : 누출성 가스 화개시 누출을 안전하게 막을수 없다면 불을 끄려하지 마시오, 필요하면 모든 점화원을 제거하십시오, 누출물을 모으시오
 저장 : 직사광선을 피하고 환기가 잘 되는 장소에 보관하십시오
 폐기 : 관련법규에 명시된 경우 규정에 따라 내용물 · 용기를 폐기하십시오

공급자 정보 : ○○화학(주), 경기도 과천시 중앙동 345번지 ☎ 02-1234-5678

Capacity	Size of label	Size of pictogram
500 L \leq Capa.	450 cm ²	ü 1/40 of surface area; ü Min. 0.5cm ²
200 L \leq Capa. \leq 500L	300 cm ²	
50 L \leq Capa. \leq 200L	180 cm ²	
5 L \leq Capa. \leq 50L	90 cm ²	
Capa. \leq 5L	>5% of area	

7) Languages

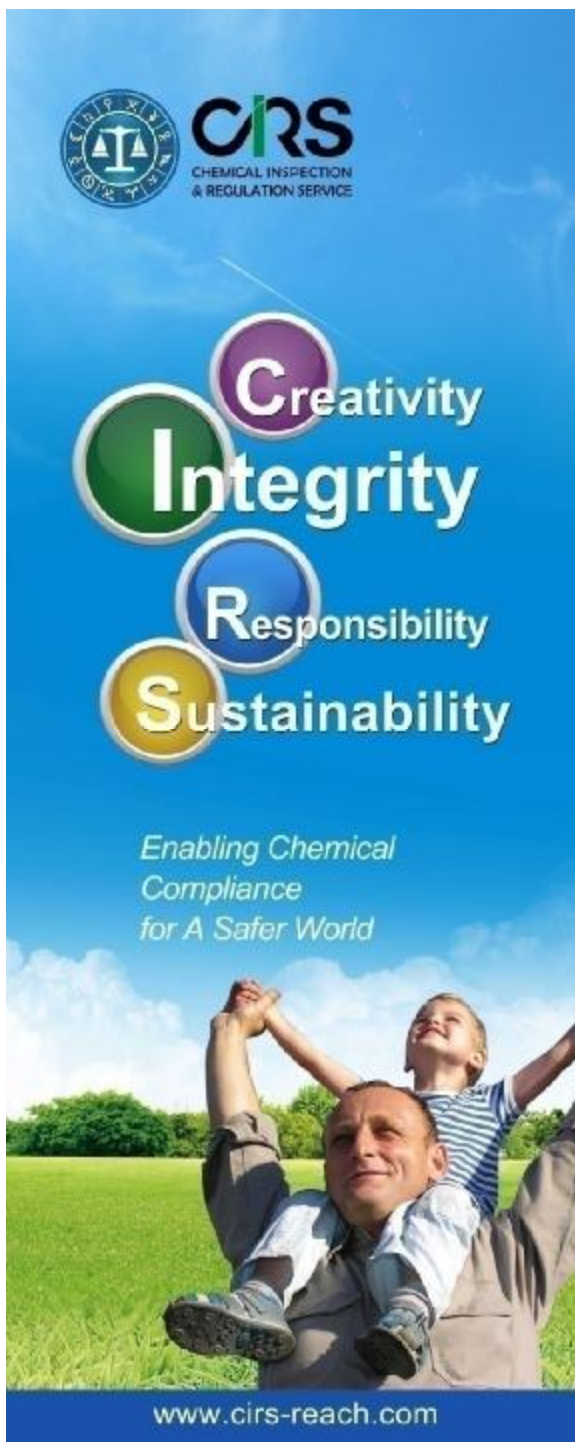
- § Korean(not required for an imported chemical reagent for lab use & research purpose);
- § English accepted for chemical name & foreign company name;

8) Impact of K-REACH on Korea GHS

- § More harmonized classifications (for tox. chemicals) published;
- § When transferring registered substance, companies will need to provide the following information in SDSs;
 - ü registration number;
 - ü name;
 - ü information on its hazards and risks;
 - ü information on safety control and others;

Summary

- | *Korean Chemical Regulatory Framework;*
- | *Korea REACH Introduced & Advice Given;*
- | *Korea GHS Summarized.*



Thank You!

谢谢！