



**CIRS**

# Global GHS Training Course

## No.3 - Korea GHS Feature and Local Regulations



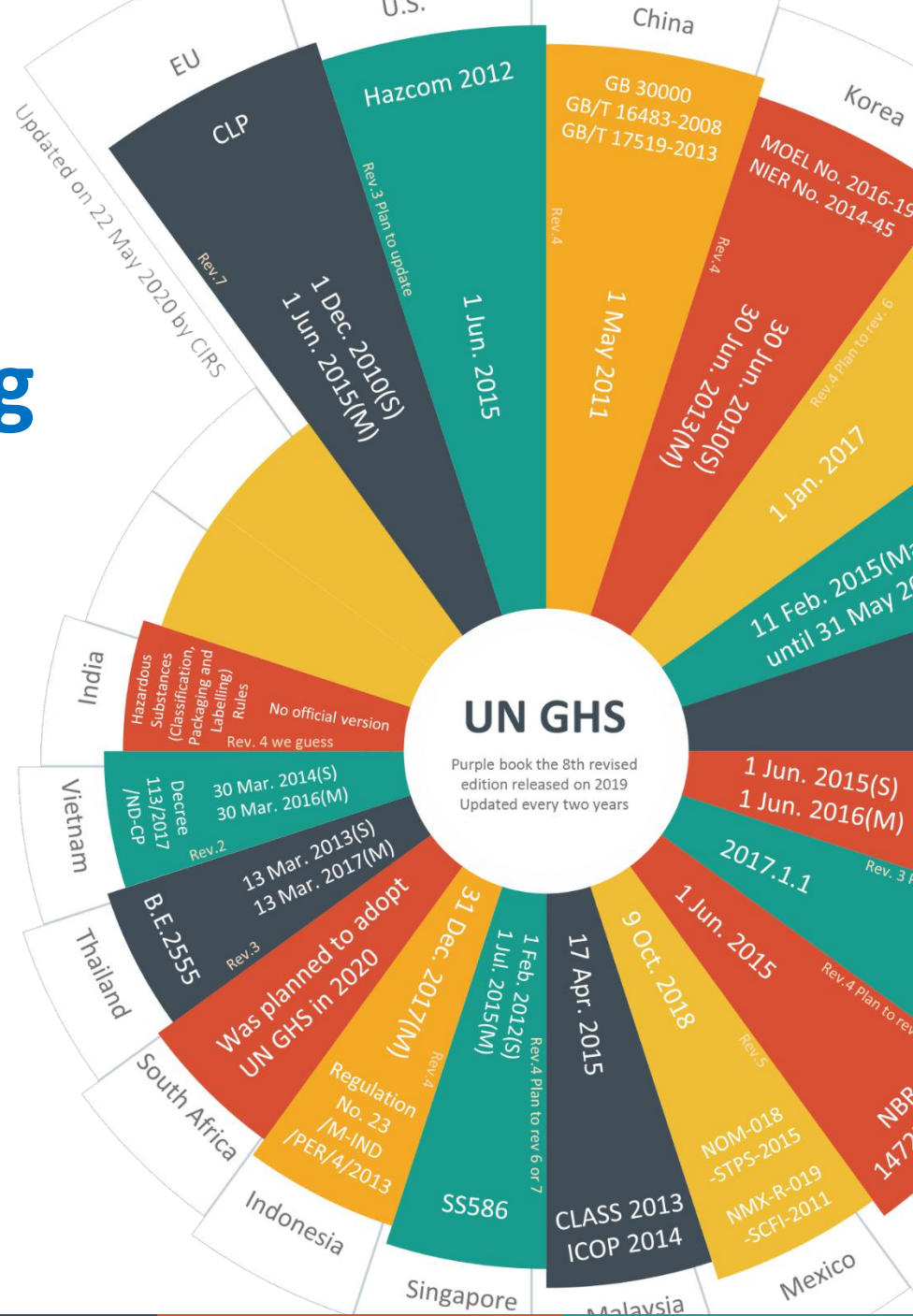
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- CIRS is an individual consulting firm founded in 2007 and headquartered in China;
- Has 350+ employees and annual revenue approximately 50 M USD;
- Has branch offices in Dublin(Ireland), Arlington(US), Seoul ( Korea ) , Nanjing(China), Beijing(China), Hangzhou(China);
- CIRS provides regulatory compliance consulting, testing and training services.
- CIRS shares more than 70% Chinese consulting markets;
- Has 4000+ Clients including 300+ oversea companies

#### **CIRS China (HQ)**

Add: 11/F., Bldg 1, Dongguan Hi-Tech Park, 288 Qiuyi Rd, Binjiang District, Hangzhou, China

#### **CIRS Europe**

Add: CIRS, Regus Harcourt Centre D02 HW77, Dublin, Ireland

#### **CIRS US**

Add: #200-092, 3100 Clarendon Blvd., Arlington, VA 22201

#### **CIRS Korea**

Add: B-2310, 583, Yangcheon-ro, Gangseo-gu, Seoul, Republic of Korea

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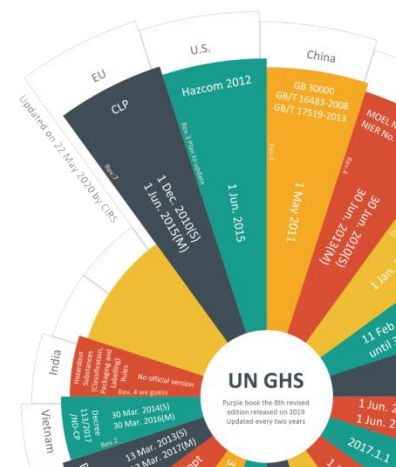


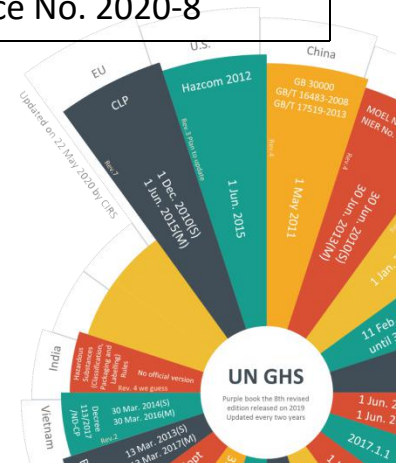
## 5. Summary

# 01

## PART

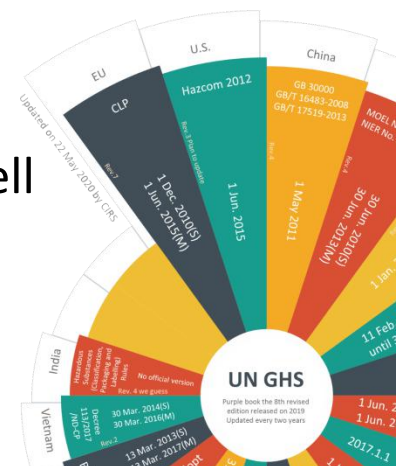
# Korean GHS



Global GHS Training Courses 2020 CIRS

## SDS Requirements

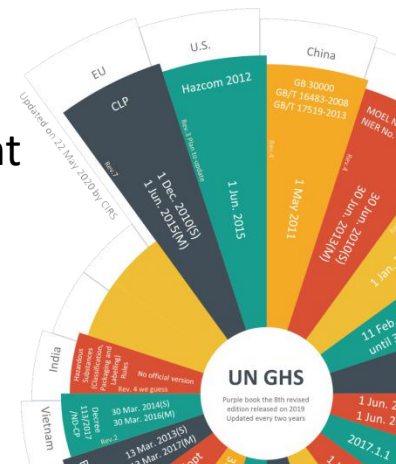
- Korea has also adopted standard 16-section SDSs
- Confidential business information (CBI): Substance name, CAS or Content (%)
- Hazardous substances must be fully disclosed in Section 3
- If there is any changes in SDS, the supplier must provide the latest version of the SDS to the buyer
- Must indicate the concentration range within 5%
- If the contents are less than 5%, the lower limit shall be indicated as follows:  $\geq 1\%$  "(0.1% for carcinogens and germ cell mutagens, 0.2% for respiratory sensitizers, and 0.3% for reproductive toxins



# SDS Requirements

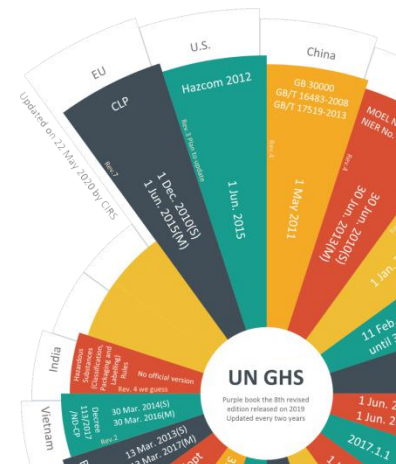
## OSHA 2019 Amendment

- Submit safety data sheets to MoEL before production or import (enforcement 15<sup>th</sup> January 2021)
- Composition info
- **Option 1:** 100% composition information (including non-hazardous substances)
- **Option 2:** Hazardous substances only + separate document with non-hazardous substances
- **Option 3 (imported products):** Hazardous substances + statement signed by foreign companies stating all non-disclosed substances are non-hazardous



## Label Requirements

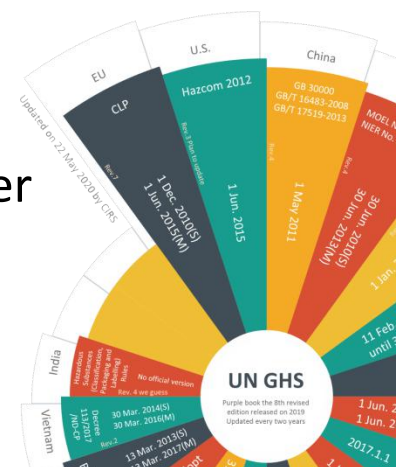
- Labelling requirements issued by the MoEL's (For Dangerous Goods, can refer to RTDG)
- Product identifier must be consistent with SDSs
- Signal word: Warning or Danger
- Up to 4 pictograms can be attached (if more than 5)
- Hazard statements are required, similar statements are combined and repeated statements are removed





## Label Requirements

- Precautionary statements: Up to 6 p-statements required. Refer to the SDS
- Must contain the contact info of Korean legal entity
- In general the Korean language must be required. But this is not required for lab and research chemicals
- Substance name and foreign supplier's contact info can be written in English.
- For a package less than 100ml or 100g the hazard and precautionary statements can be omitted by letting reader refer to the SDS.



## Label Size Requirements

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

# Label Example

아밀 아세테이트

경고

유해·위험 문구  
H226 - 인화성 액체 및 증기.


예방조치 문구  
예방  
P210 - 열·스파크·화염·고열로부터 멀리하시오 - 금연.  
P233 - 용기를 단단히 밀폐하시오.  
P240 - 용기와 수용성비늘 접촉시키거나 절지하시오.  
P241 - 폭발 방지용 전기·원기·조명 장비를 사용하시오.  
P242 - 스파크가 발생하지 않는 도구만을 사용하시오.  
P243 - 정전기 방지 조치를 취하시오.  
P280 - (보호장갑·보호의·보안경·안전보호구)를(을) 착용하시오.

대응  
P303 + P361 + P353 - 피부(또는 머리카락)에 묻으면 오염된 모든 의복은 벗으시오.  
피부를 물로 씻으시오/샤워하시오.  
P370 + P378 - 화재 시 불을 끄기 위해 적절한 소화제를 사용하시오.

저장  
P403 + P235 - 원기가 잘 되는 곳에 보관하고 저온으로 유지하시오.

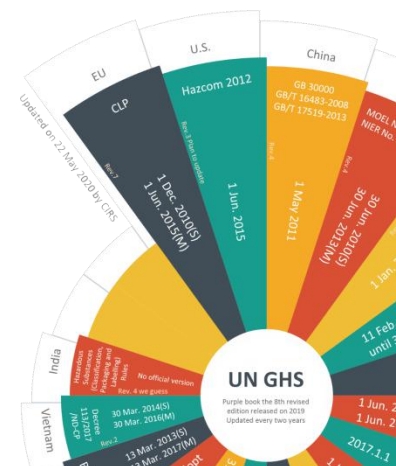
폐기  
P501 - (관련 법규에 명시된 내용에 따라) 내용물과 용기를 폐기하시오.

보충정보  
본 물질의 100%는 급성 경구 독성이 알려지지 않은 성분으로 구성됨. 본 물질의 100%는 급성 피부 독성이 알려지지 않은 성분으로 구성됨. 본 물질의 100%는 급성 흡입 독성이 알려지지 않은 성분으로 구성됨. 본 물질의 100%는 급성 수생 환경 유해성이 알려지지 않은 성분으로 구성됨. 본 물질의 100%는 장기간 수생 환경 유해성이 알려지지 않은 성분으로 구성됨.  
추가 정보는 물질안전보건자료를 참고할 것.  
위험물안전관리법에 의한 규제 :  
제4류 제2석유류 (비수용성액체)

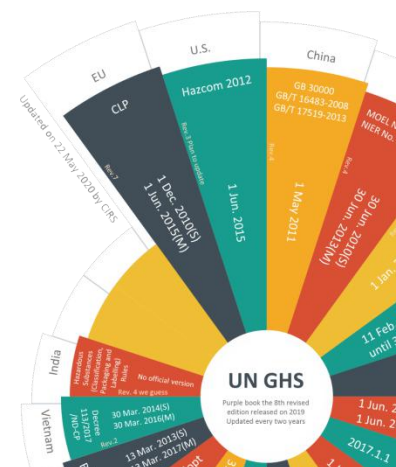


- Chemical Name
- Signal Word
- Hazard Statements
- Precautionary Statements
- Prevention Information
- Response Information
- Storage Information
- Disposal Information
- Supplemental Information

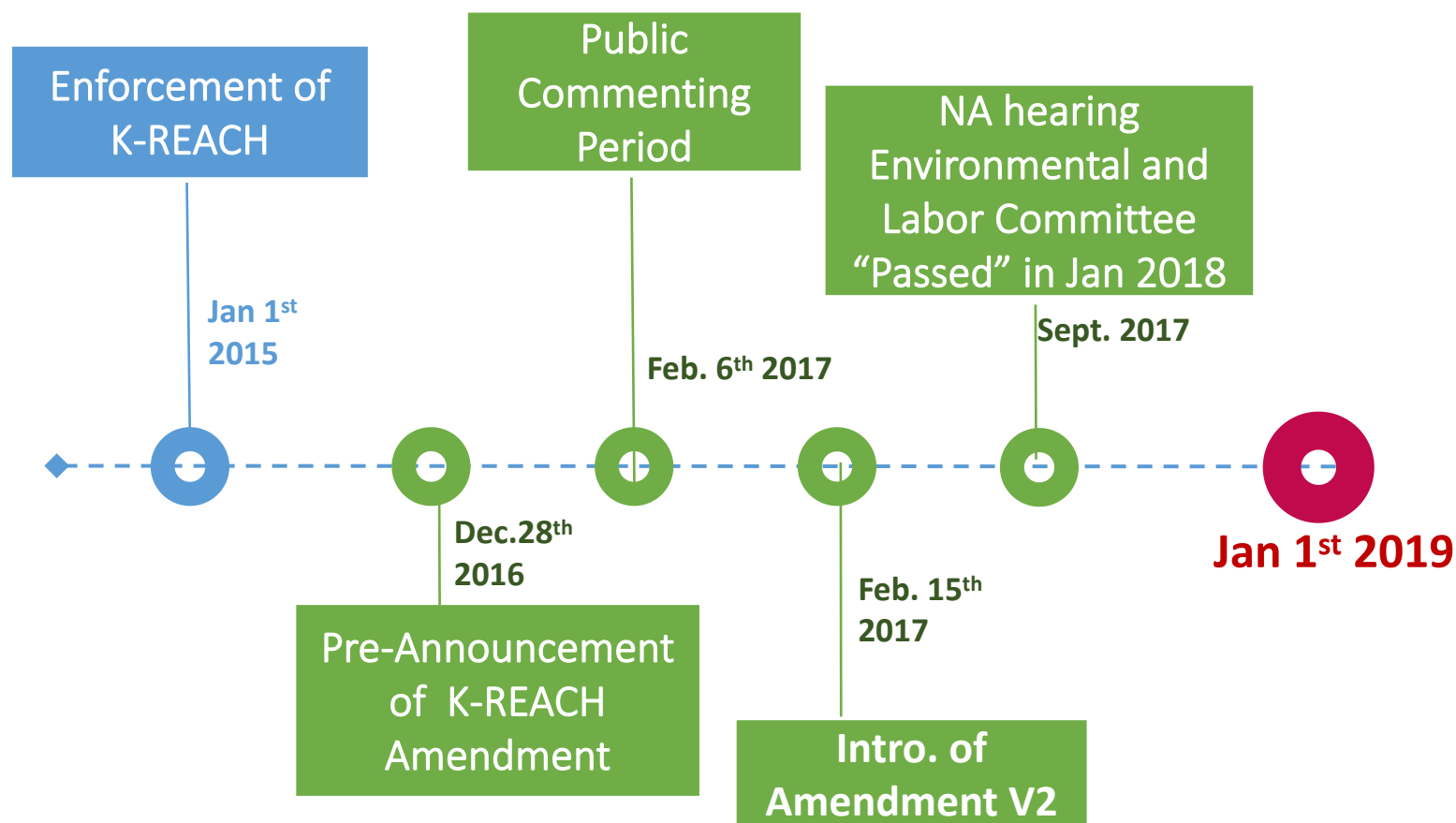
Pictogram



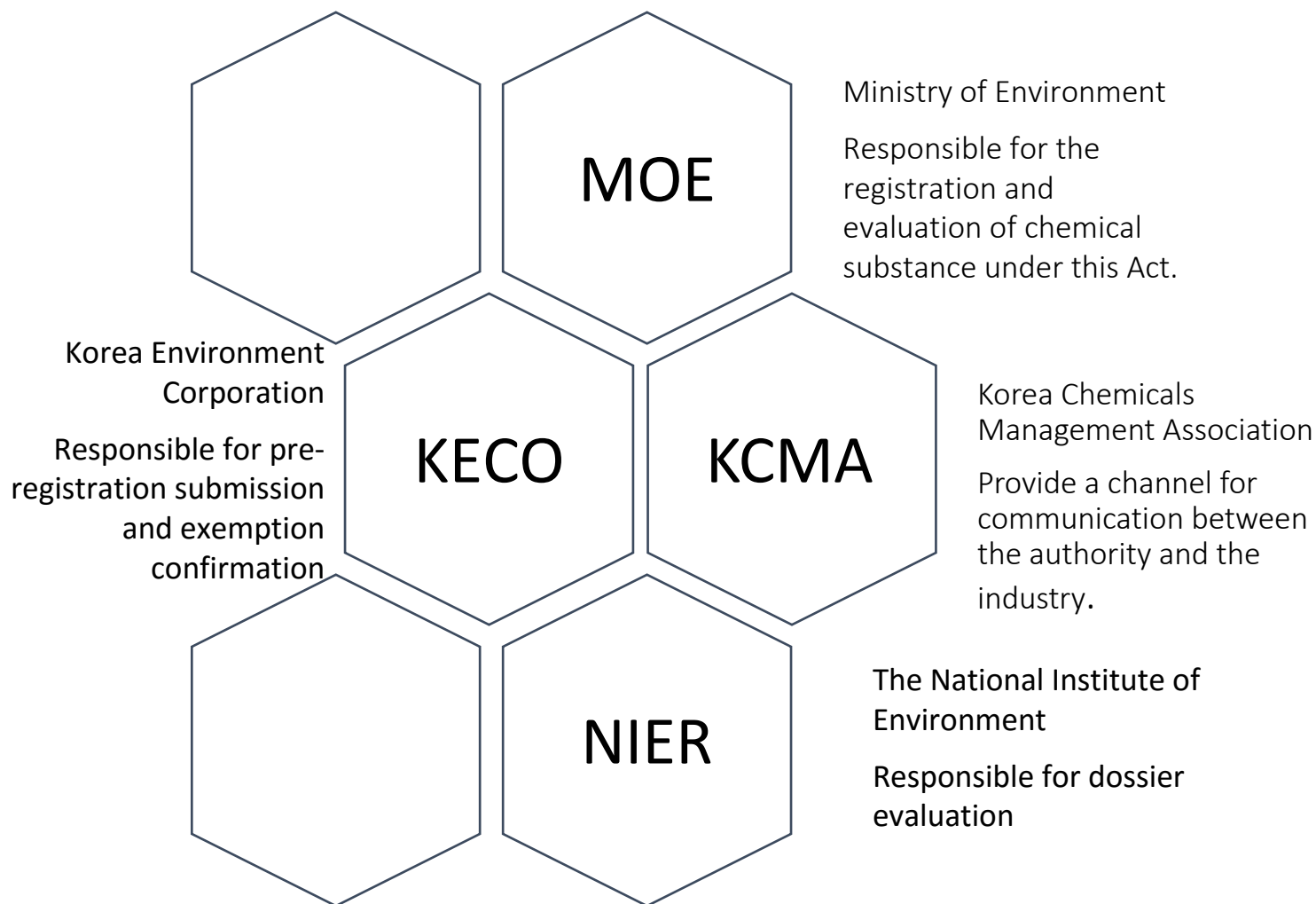
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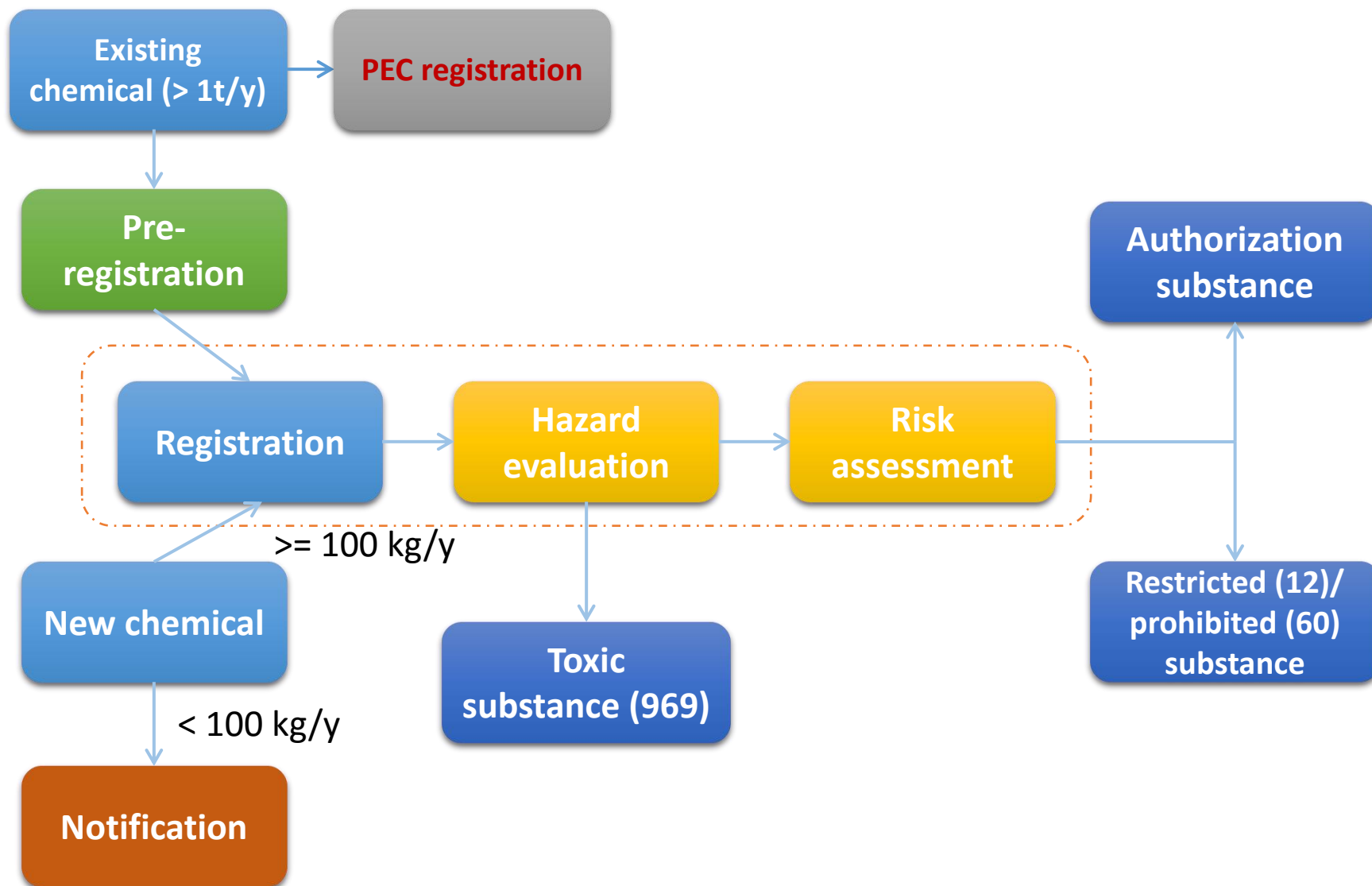
# Legislation History of K-REACH



## K-REACH Key Authorities



# K-REACH System



# Substances Exempt Under K-REACH

**Substances controlled by other laws and regulations (confirmation not required)**

1. Radioactive substances under the 「Nuclear Safety Act」
2. Medicines and non-pharmaceutical items under 「the Pharmaceutical Affairs Act」
3. Narcotics under 「the Narcotics Control Act」
4. Cosmetics and raw materials used for cosmetics under 「the Cosmetics Act」
5. Pesticides and technical ingredients under 「the Pesticide Control Act」
6. Fertilizers under 「the Fertilizer Control Act」
7. Foods, food additives, appliances, containers, and packages under 「the Food Sanitation Act」
8. Livestock feed under 「the Control of Livestock and Fish Feed Act」
9. Explosives under 「the Control of Firearms, Knives, Swords, and Explosives, etc. Act」
10. Military supplies (excluding conventional items) under 「the Act on the Management of Military Supplies」
11. Functional health foods under 「the Functional Health Foods Act」
12. Medical devices under 「the Medical Devices Act」
13. Hygiene products under 「the Hygiene Products Control Act」
14. Biocidal substances and biocidal products defined in subparagraphs 7 and 8 of Article 3 of 「the Act on Safety Management of Chemical Products for Daily Use and Biocides」



# Chemicals Exempt from K-REACH Registration

Substances exempt from registration (no confirmation required)	Substances exempt from registration (confirmation required)
Chemical substance imported together with relevant machineries or equipment for the purpose of trial operation	Chemical substance imported/manufactured for export-only use, including substance imported/manufactured to make export-only products (Note: needs to be done on annual basis)
Chemical substance imported as already equipped machinery	Chemical reagents (PEC or New Substances tested in Korea)
Chemical substances in articles with no intended release	Substances for R&D use
Chemicals excluded from registration or notification (MoE Notice No. 2018-234) Impurities and By-product	Surface treated substances
	Non-isolated intermediates
	On-site isolated intermediates (which can be technically blocked from leakage or exposure)
	Polymer of low concern(PLC).

# Exemption of Very Low Risk Substances



Current	New Added
Impurities, by-products	Substance which is gained from other substance in the nature by using manpower, machine, water solubility/ floating (in case of physical application or simple mixing)
Compost, biofuel, hydrogen, oxygen	
Substances which exists in the nature and its chemical structure is not changed (e.g. Minerals)	Constituent chemicals of human body (e.g. amino acid, bases of which DNA or RNA is composed)
Substance which is gained from nature resources and its chemical structure is not changed (e.g. vegetable, animal fat)	

Substances excluded from registration, notification: 44 substances

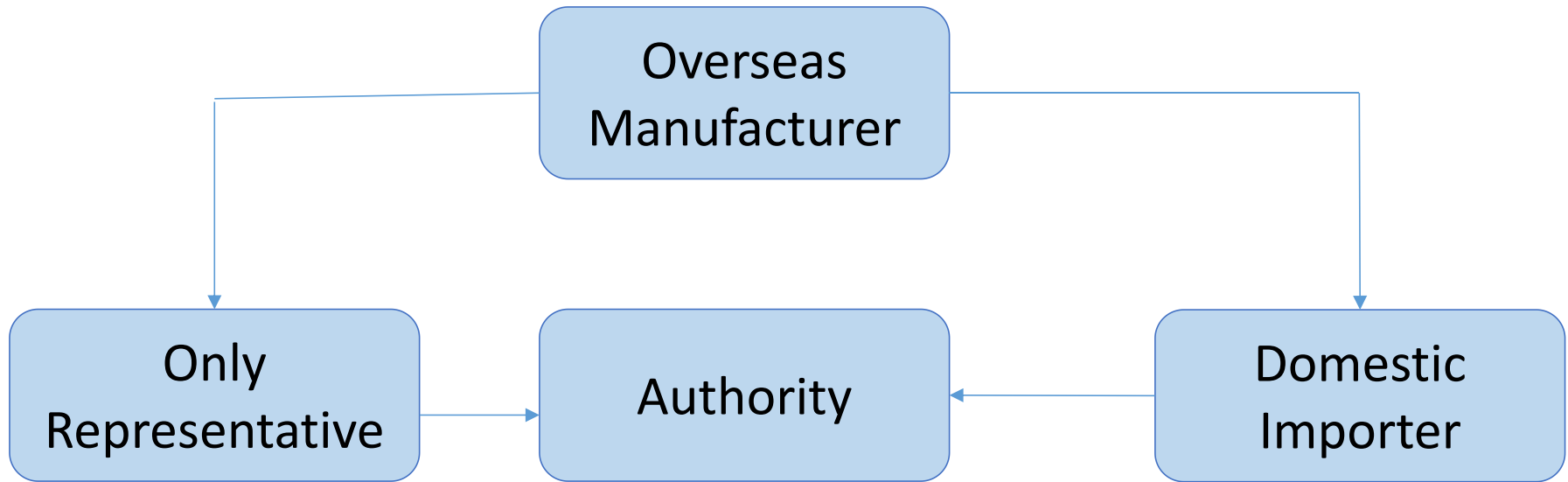
## K-REACH

Korea Manufacturer

Korea Importer

Non Korea Manufacturer or Formulator (appoint an OR in Korea)

# OR Responsibility



- **OR Change is not available under K-REACH currently**
- **OR Appointment takes 7 working days**

**OR → Importer:**

- Registration/ Notification confirmation letter
- Pre-notification
- MSDS
- Notification result of Priority Management chemicals
- OR confirmation letter

## Post registration

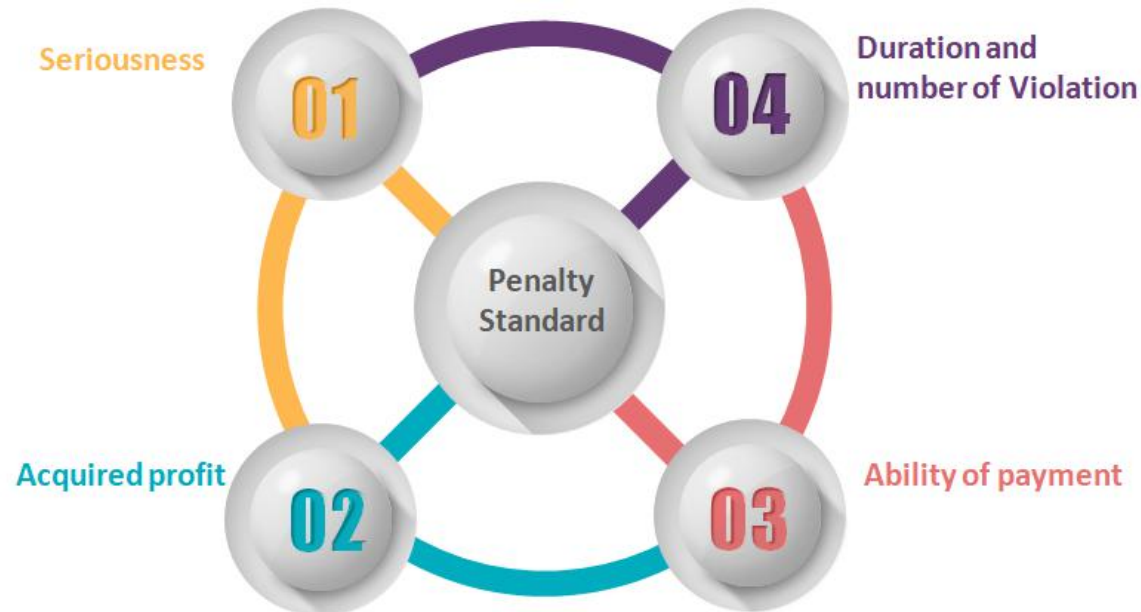
- ~~Annual reporting~~
- Update importer list and relevant use information
- Communication with Korean importers and non-Korean exporter
- Data recording and Keeping for registration
- Supplement of materials
- Update the submitted information
- SDS update
- Change of registrant-the change in company name, address, representative, etc.

# Penalty

**5% of Total Sales or less** will be fined if manufacturer/ importer doesn't comply with K-REACH!

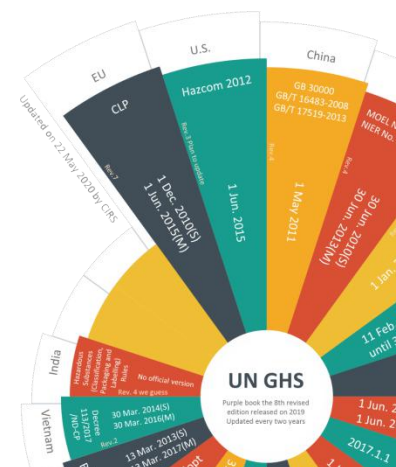
\* Total sales = Average three-year annual sales before violation.

\* If it's hard to estimate total sales, it may be charged up **to one billion won**.



# 03 PART

## Korea REACH Registration



# K-REACH Registration

<http://ncis.nier.go.kr/en/main.do>

## Chemical Search

All

50-00-0



Search









Search Results 3

Search within results

Search

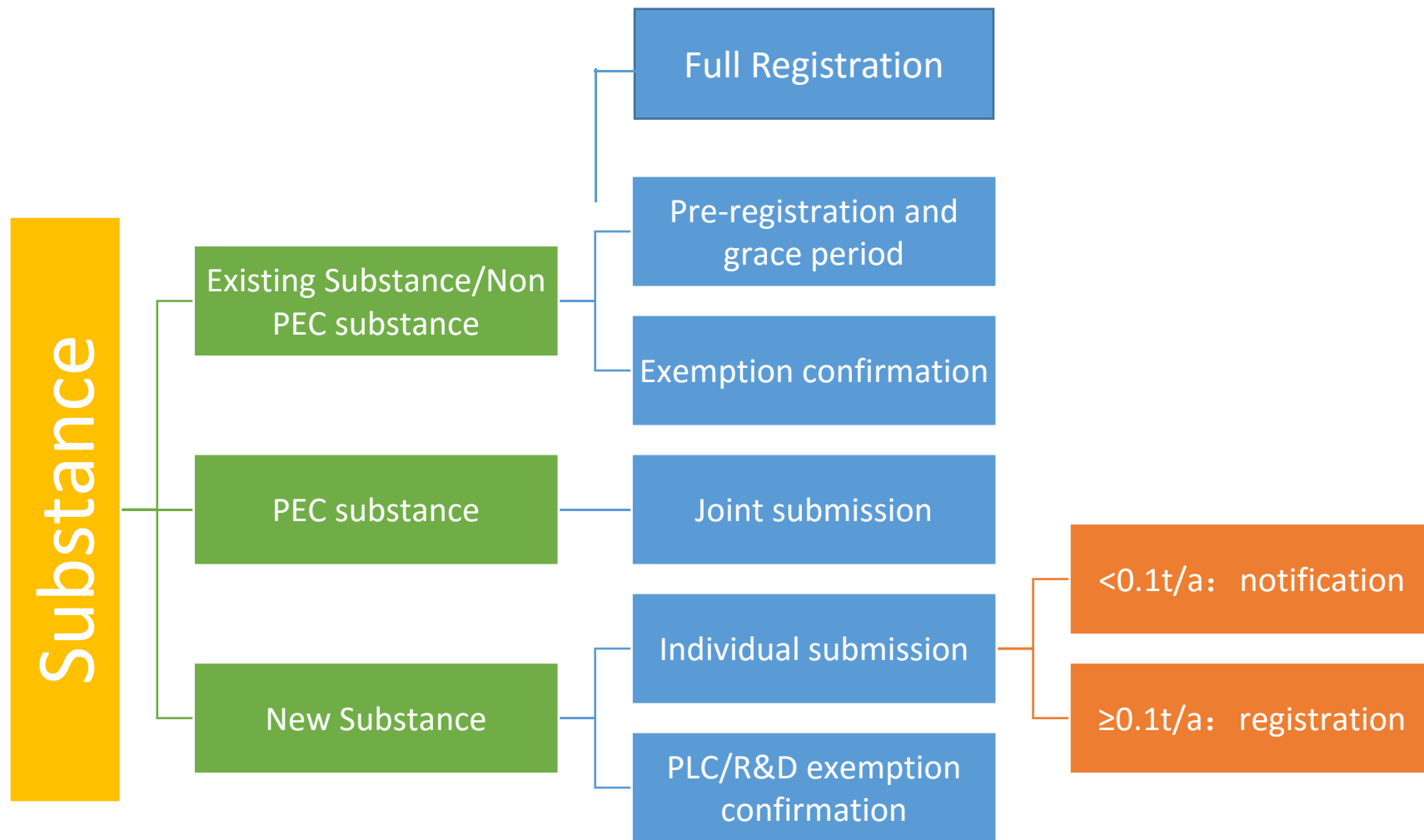


10 Items per Page

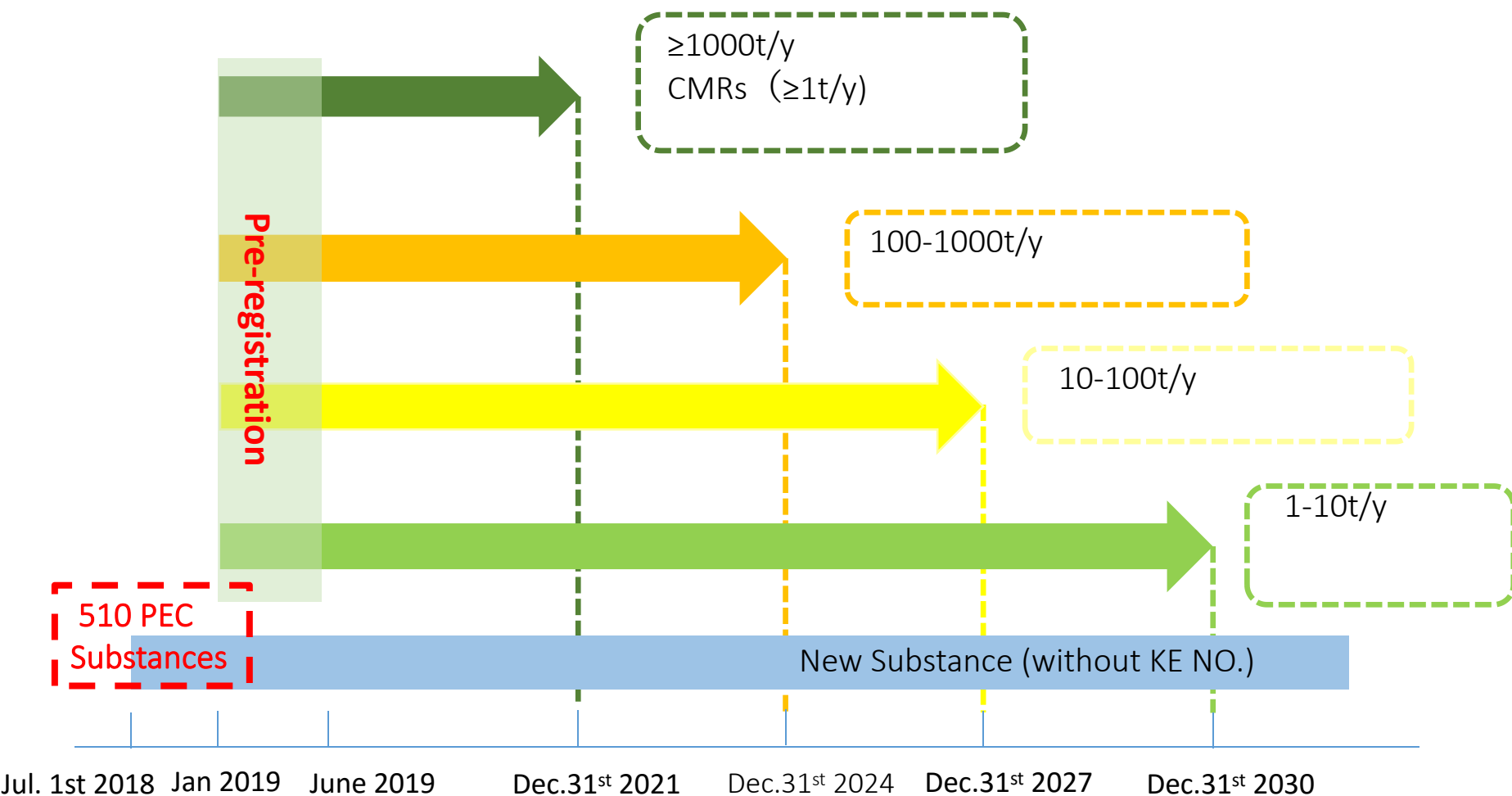
CAS No. 	Chemical Name 	NIER's No.						Percentage & Regulatory Information
		KE No. 	Phase-in substance subject to registration 	Toxic substance 	Restricted substance 	Prohibited substance 	Substance requiring preparation for accidents 	
68650-00-0	Fatty acids, tall oil polymers with pentaerythritol, phthalic anhydride and tung oil, oxidized	KE-16170						
50-00-0	Formalin [Other names : Formaldehyde: ]	KE-17074	1	97-1-345	06-5-5		1	<a href="#">View info</a>
13150-00-0	Sodium 2-[2-(dodecyloxy)ethoxy]ethyl sulfate	KE-31442						



# K-REACH Registration Procedure



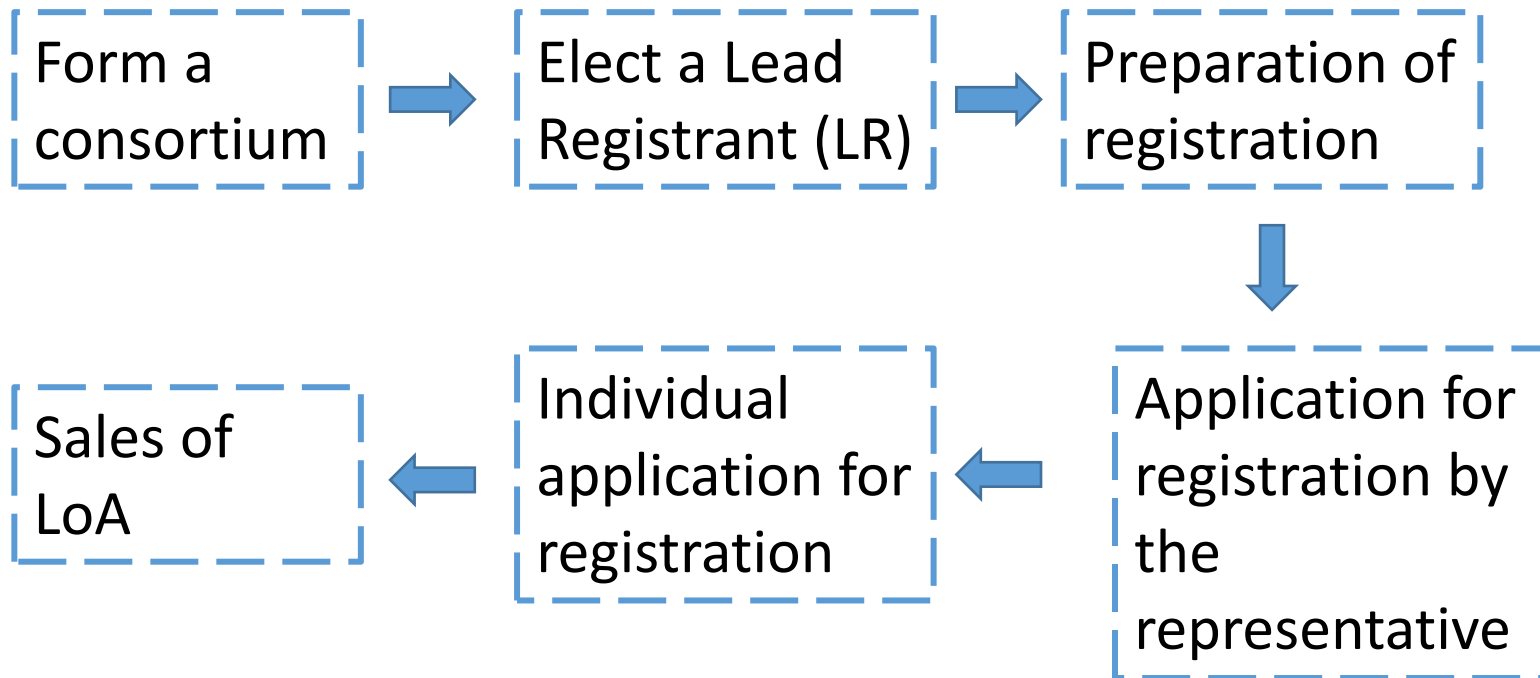
# K-REACH Registration Timeline



## Process of K-REACH Late Pre-registration

- Self-declaration on the export volume during last three years;
- Filling in Substance Information Survey;
- Confirming Contract and POA (non-Korean enterprise);
- Preparing Late Pre-registration dossier;
- Sending Late Pre-registration number and completion notice;
- Maintaining Late Pre-registration and updating information (if necessary).

## K-REACH-Joint Submission



# Data Requirement

	0.1-1 ton/year	1-10 ton/year	10-100 ton/year	10-100 ton/year	> 1000 ton/year
<b>Physicochemical data</b>	5	8	11	13	13
<b>Health hazard data</b>	2	4	10	11	15
<b>Environmental hazard data</b>	2	3	5	13	19
<b>Total</b>	9	15	26	37	47

- GLP (Good Laboratory Practice) institutes are required;
- There are 18 GLP institutes in Korea;
- Tests reports from EU GLP lab should be acceptable under K-REACH.

## K-REACH Registration- Polymer Registration vs PLC

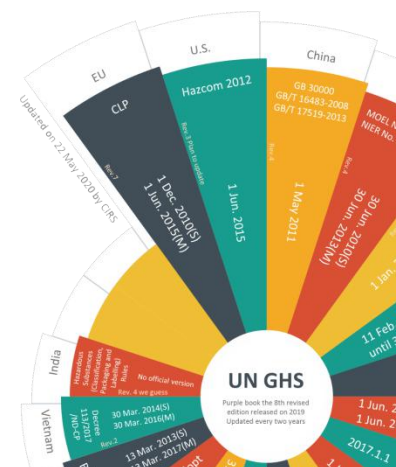
### Polymer

- Register as whole product
- Acid/base stability test
- GPC test
- Residual monomer content Analysis
- Less data requirements

### PLC

- Exemption Confirmation
- GPC test
- Residual monomer Content Analysis

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# New Chemical Substances Registration or Notification

## Registration

- New chemical substances manufactured or imported  $\geq 0.1$  t / a



**Registration before manufacture or import**

### > Physicochemical and toxicological test data (new chemical substances)

Test	0.1~1 t/a ( 9 )	1+ t/a ( 15 ~ 47 )
Physicochemical	<ol style="list-style-type: none"> <li>1. Physical State</li> <li>2. Water Solubility</li> <li>3. Melting/freezing</li> <li>4. Boiling Point</li> <li>5. Vapor Pressure</li> </ol>	<ul style="list-style-type: none"> <li>- Data requirements are the same with existing chemical substances</li> <li>- New substances do not apply data reduction standards</li> </ul>
Health Toxicological	<ol style="list-style-type: none"> <li>1. Acute Tox. Oral or Inhalation</li> <li>2. AMES</li> </ol>	
Ecotoxicology	<ol style="list-style-type: none"> <li>1. Acute Tox. Fish or Daphnia</li> <li>2. Rapid biodegradability</li> </ol>	

## Notification

- New chemical substances manufactured or imported  $< 0.1$  t / a

\* Annual manufacture / import volume, classification and labeling, use, etc. (including application for confidentiality, proof of exemption from harmful examination, etc., if applicable)

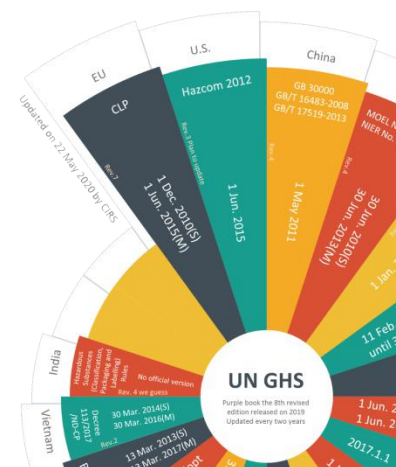


**Notification before manufacture or import**



05  
PART

# Summary



## Summary

- Build an internal inventory system for your products in Korea
- Ensure you choose a competent Only Representative
- Be aware of Late Pre-Registration
- Monitor regulation updates and consortium progress
- Make sure your Korean SDS/ label compliant
- Contact us for future questions

## Useful Links

1. Asia-Pacific Chemical Inventory Search System (APCISS):

<http://apciss.cirs-group.com/?l=en-us>

2. Regulatory Related Materials Download:

<http://freedoc.cirs-group.com/en>

3. Free Webinar Information:

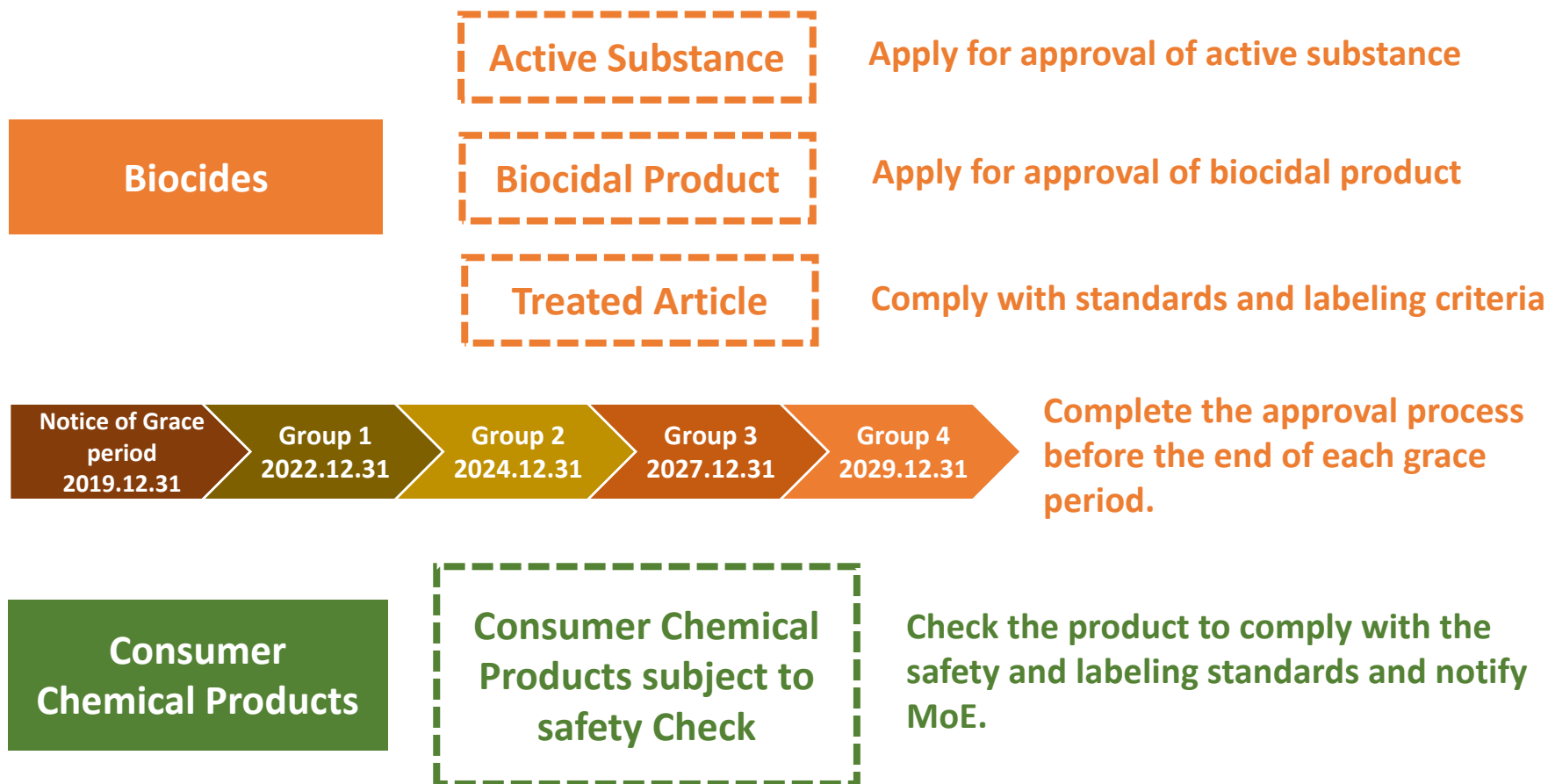
<http://www.cirs-reach.com/events>

4. Regulatory News Updates:

<http://www.cirs-reach.com/>



## Consumer Chemical Products and Biocides Safety Act



More information about K-BPR can be found by clicking the below link:  
<http://www.cirs-reach.com/news-and-articles/K-BPR-Consumer-Chemical-Products-and-Biocides-Safety-Act.html>

# Q&A Session

Following our event, please always click

<http://www.cirs-reach.com/news-and-articles/2020-CIRS-Training-Courses-Global-GHS.html>

to find further updates

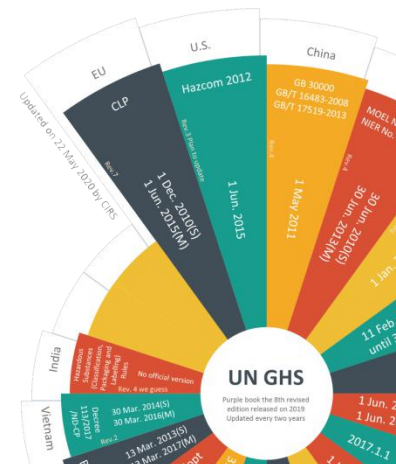
Contact Email: [service@cirs-reach.com](mailto:service@cirs-reach.com)

For our Consultation

**Next Webinar:** China GHS features and local regulations

**Time & Date:** (GMT+1) 15:00, July 22nd

Registration still Available





# Thank you for your attention

