



# New Chemical Substance Registration under K-REACH and KOSHA(Amendment)

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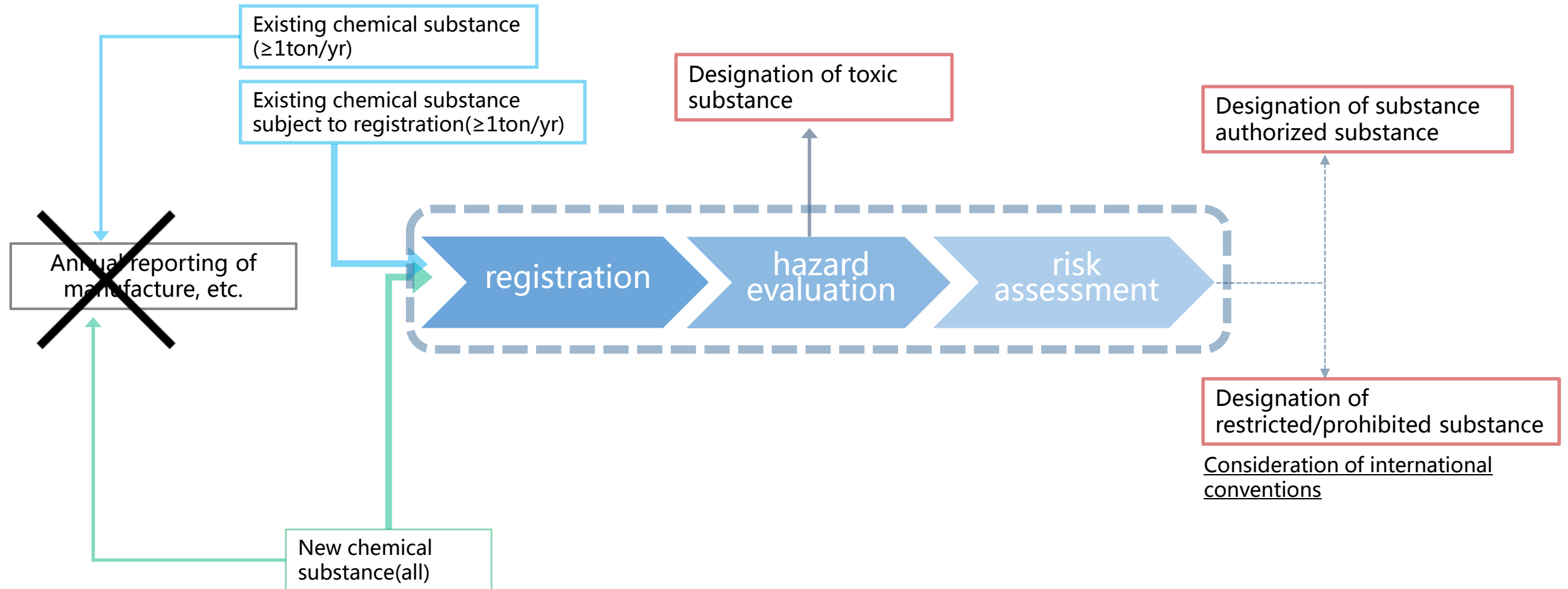
- I. What are the changes to the type and method of registration for a new chemical substance under K-REACH Amendment?
- II. How to identify the subject to registration of a polymer.
- III. Registration and Hazard Evaluation of a New chemical substance under K-OSHA .



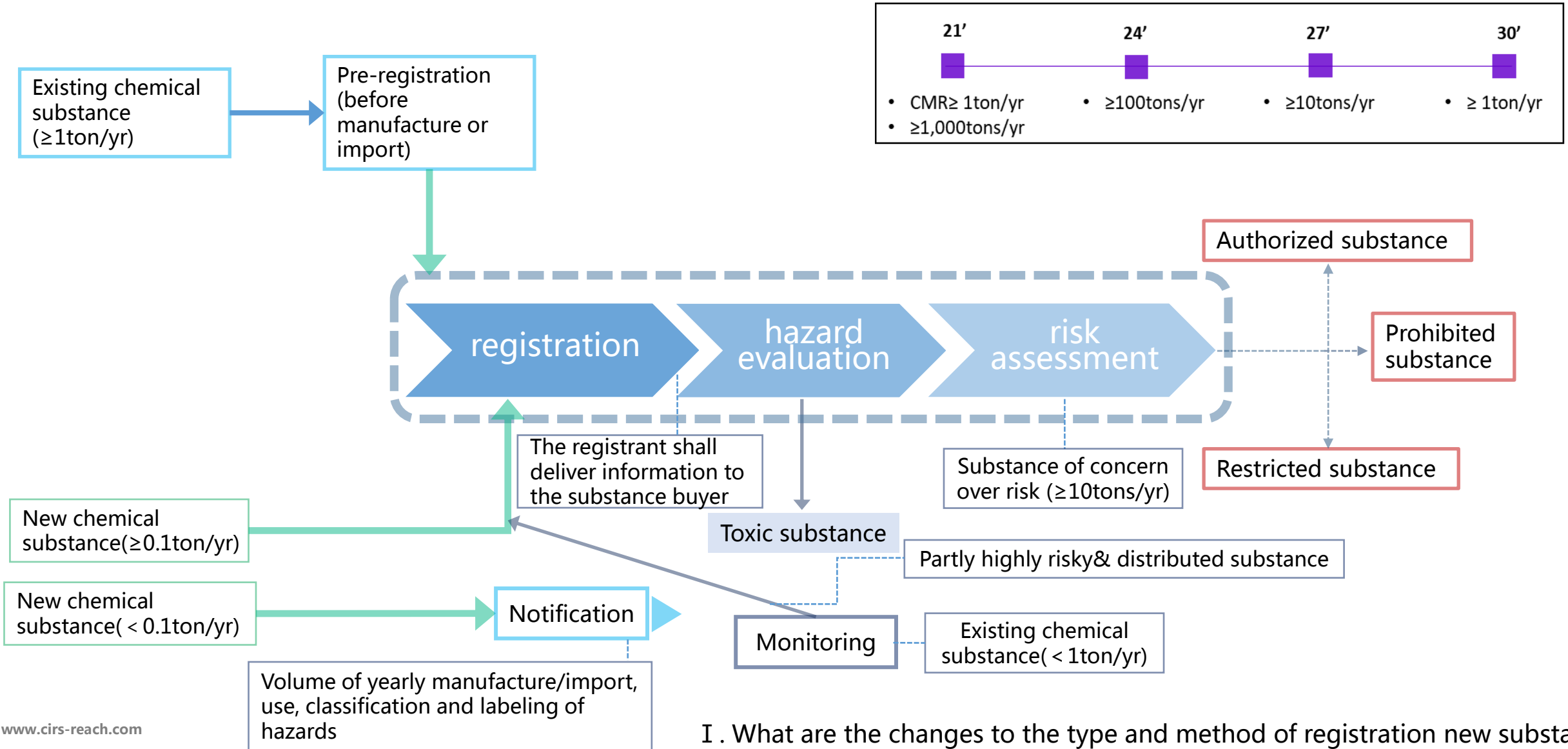
## I. What are the changes to the type and method of registration for a new chemical substance under K-REACH Amendment?

1. Before Amendment( '15- '18)
2. After Amendment( '19,1.1-)
3. The type of New chemical registration
  - i . Registration Flow of New chemical substance
  - ii . (< 0.1tons)Notification of a new chemical substance  
(Article 10(4) of the Act)
  - iii.  $\geq 0.1$ ton Registration (Article 10(1) of the Act)
  - iv. Polymer Registration(Article 10(1) of the Act)
  - v . Transitional Measures

# 1. Before Amendment( '15- '18)

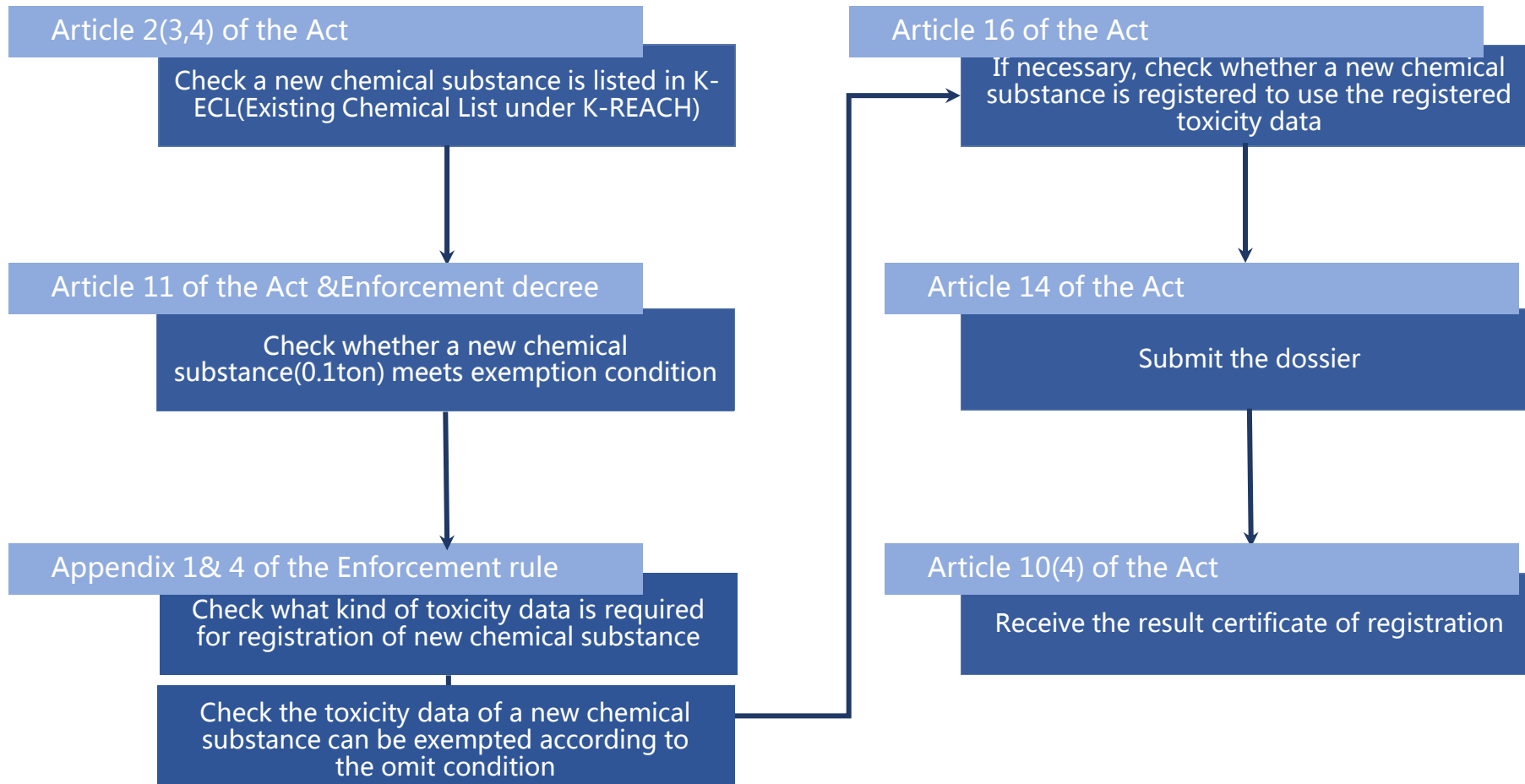


## 2. After Amendment( '19,1.1-)



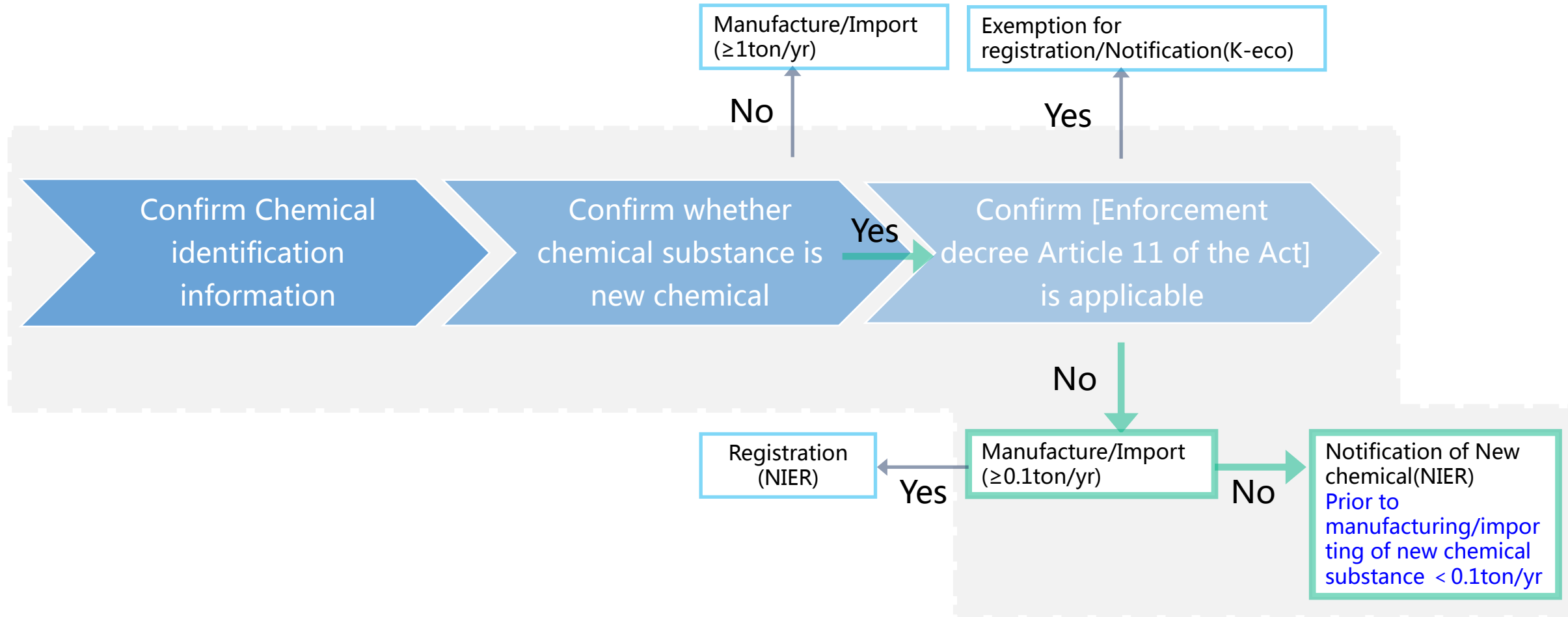
# 3. The type of New chemical registration

## i . Registration Flow of New chemical substance



### 3. The type of New chemical registration

#### ii. (< 0.1tons)Notification of a new chemical substance (Article 10(4) of the Act)



### 3. The type of New chemical registration



#### ii. (< 0.1tons)Notification of a new chemical substance (Article 10(4) of the Act)

- A. Subject and period of Notification of a new chemical substance
  - manufacture or import a new chemical substance less than 0.1ton per year
  - The new chemical substances which have been confirmed to be exempted from the hazard evaluation under the previous TCCA shall be notified within 2yrs(Until Dec.31, 2020)
  - prior to manufacturing or importing
- B. Method of Notification and Notification of any change in new chemical substances
  - Any change of applied notification shall be submitted to the NIER via K-REACH IT System

Content of Notification	Content of a Notification of any change
<ul style="list-style-type: none"><li>• Name, location and representative</li><li>• Identification information of the chemical substance such as the name, molecular formula, structure and etc.</li><li>• Classification and labelling</li><li>• Use, detailed use description</li><li>• Hazard data and etc. possessed by the manufacturer or importer of the relevant new chemical substance</li></ul>	<ul style="list-style-type: none"><li>• <b>&lt;within 1 month from the date any change has occurred&gt;</b></li><li>• Any change in the trade name, location or representative</li><li>• In the case of a person appointed by foreign manufacturer/importer, importer of the relevant chemical substance shall be added/deleted</li><li>• <b>&lt;within 1 month from the date any change has been known&gt;</b></li><li>• Use, classification system, change in consumer' s use, new confirmation of consumer' s use</li><li>• Confirmation of hazard information that changes classification and labelling, confirmation of new information concerning risks</li></ul>



# 3. The type of New chemical registration



## iii. $\geq 0.1$ ton Registration (Article 10(1) of the Act)

- A. Subject and period of registration of a new chemical substance
  - manufacture or import a new chemical substance  $\geq 0.1$ ton
  - prior to manufacturing or importing
- B. Data to be submitted when applying for Registration of New chemical substances  $\geq 0.1$ tons(Article 14 of the Act)

#.	Information to be submitted	Details	Remarks
1	Information on manufacturer or importer	<ul style="list-style-type: none"><li>• Name, location, representative</li></ul>	
2	Information on a chemical substance	<ul style="list-style-type: none"><li>• Name, information on the identification (e.g. molecular formula, structure and etc.)</li></ul>	
3	Use of a chemical substance	<ul style="list-style-type: none"><li>• Use classification system, detailed use description</li></ul>	
4	Classification and labeling	<ul style="list-style-type: none"><li>• World-wide standard items for classification and labelling (e.g. GHS)</li></ul>	
5	Physico-chemical properties	<ul style="list-style-type: none"><li>• Differentiation by range of tonnage(max 47items)</li><li>• Submission of abstract of test data(submit full report if owned)</li></ul>	
6	Hazards		
7	Guidance on safe use	<ul style="list-style-type: none"><li>• Personal protective equipment, emergency measures etc. at the time of explosion, fire or leakage</li></ul>	
8	Risks	<ul style="list-style-type: none"><li>• An exposure scenario describing operational methods, exposure controls and management measures during its life-cycle</li></ul>	Annual volume $\geq 10$ tons

# 3. The type of New chemical registration



## iii. ≥ 0.1ton Registration (Article 10(1) of the Act)

### C. Method of registration and registration of any change in new chemical substances

- Any change of applied registration shall be submitted to the NIER via K-REACH IT System

Notification of any change by the enterprise who has registered	Registration of any change by the enterprise who has registered		
<within <b>1 month</b> from the date any change has <b>occurred</b> >	<within <b>1 month</b> from the date any change has <b>occurred</b> >	<within <b>1 month</b> from the date any change has been <b>known</b> >	<within <b>6 month</b> from the date any change has been <b>known</b> >
<ul style="list-style-type: none"><li>Any change in the trade name, location or representative</li><li>In the case of a person appointed by foreign manufacturer/importer, importer of the relevant chemical substance shall be added/deleted</li></ul>	<ul style="list-style-type: none"><li>Any change in the range of tonnage of the yearly volume manufactured or imported</li></ul>	<ul style="list-style-type: none"><li>Use classification system, change in consumer' s use, new confirmation of consumer' s use</li></ul>	<ul style="list-style-type: none"><li>Confirmation of hazard information that changes classification and labelling, confirmation of new information concerning risks</li></ul>

### 3. The type of New chemical registration



#### iv. Polymer registration(Article 10(1) of the Act)

- A new polymer substance registration requires toxicity data on lower tonnage of non-polymer

Volume of yearly	Common data requirement on property of polymer	Toxicity data requirement	Remarks
0.1-1tons	<ul style="list-style-type: none"> <li>• GPC report</li> <li>• Monomer information</li> <li>• Acid/Base stability study</li> <li>• Testing contents of residual monomer</li> </ul>	<ul style="list-style-type: none"> <li>• physical state</li> <li>• water solubility</li> <li>• melting/freezing point</li> <li>• boiling point</li> <li>• vapour pressure</li> </ul>	*No need submission until Dec 31, 2019
1-10tons			
10-100tons		1-10tons toxicity data requirement of non-polymer	
100-1,000tons		10-100tons toxicity data requirement of non-polymer	
≥ 1,000tons		100-1,000tons toxicity data requirement of non-polymer	

# 3. The type of New chemical registration



## v . Transitional Measures

- A. Of New chemical substance registration from 2015 to 2018(Article 3 of the Addenda(Enforcement decree), Article of 4 of the Addenda(Enforcement rule)
- According to the previous K-REACH(No.13891), an Enterprise who has registered a planned amount of new chemical manufacture/import of less than 0.1 tons of new chemical substance annually is required to submit to those who manufacture/import of less than 1tons, more than 0.1tons of new chemical substance to the authority by end of June

\*The authority may request to submit the toxicity data required for hazard evaluation, whom submitted  $\geq$  information

- B. Of New chemical notification before January 1<sup>st</sup>, 19' (Article 5 of the Addenda(Act))
- Those who registered before 19' .1.1 to manufacture and import new chemical substances less than 0.1 tons per year notified under the amended regulations
  - The new chemical substances which have been confirmed to be exempted from the hazard evaluation under the previous TCCA shall be notified within 2yrs(Until Dec.31, 2020)



## II. How to identify the subject to registration of a polymer.

### 1. Existing chemical substance under K-REACH

i . Definition of Existing chemical substance (Article 2(3) of the Act)

### 2. Polymer Definition

i . In accordance with Article 2 of the Enforcement decree of Korea regulation

### 3. Naming of Polymer

i . Naming of Homopolymer

ii . Naming of Copolymer

# 1. Existing chemical substance under K-REACH



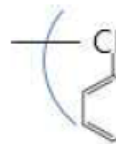
## i . Definition of Existing chemical substance (Article 2. 3 of the Act)

In accordance with	Definition
Article 2. 3. a.	<ul style="list-style-type: none"><li>▪ Chemical substances publicly notified by the Minister of Environment in consultation with the Minister of Employment and Labor, which were domestically distributed for commercial purposes before February 2, 1991;</li><li>▪ KE-XXXXX</li></ul>
Article 2. 3. b.	<ul style="list-style-type: none"><li>▪ Chemical substances publicly notified by the Minister of Environment, the hazard reviews thereof have been conducted pursuant to the former Toxic Chemicals Control Act after February 2, 1991.</li></ul>

## 2. Polymer Definition

i. In accordance with Article 2 of the K-REACH Enforcement Decree

- It shall be composed of molecules in which at least one monomer unit is repeated;
- It shall show the characteristic distribution of molecular weight numbers of monomer units in each molecule;
- Its molecules that at least three monomer units form a covalent unit or other reactants shall be at least 50 percent;
- Its molecules of the same molecular weight shall be not more than 2%.



	sample1	sample2	sample3
n=1	30%	0%	5%
n=2	30%	10%	5%
n=3	15%	75%	40%
n=4	13%	15%	30%
n=5	12%	0%	20%
Total	100%	100%	100%

ii. 2% Rule

- In such cases, where a high molecular compound consisting of monomers excluding monomers whose weight ratio does not exceed 2% falls under existing chemicals, such high molecular compound shall be deemed an existing chemical

Polymer X	
Monomer	Contents(%)
A	60
B	30
C	9.5
D	0.5

Polymer X :  
Existing chemical

Polymer Y	
Monomer	Contents(%)
A	60
B	30
C	10

Polymer Y :  
Existing chemical

II. How to identify the subject to registration of Polymer.

# 3. Naming of Polymer

i . Naming of Homopolymer : composed of one type of monomer

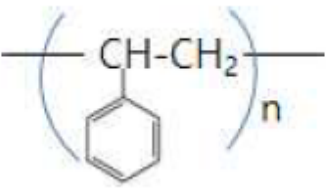
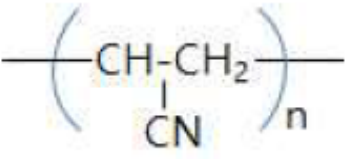
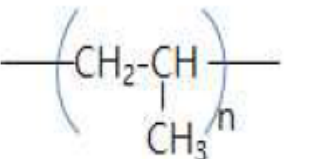
e.g. In case ; polymer containing only one monomer A → Poly A or Poly(A)

ii . Naming of Copolymer :

consisting of more than one type of monomers

e.g. In case ; polymer containing 4 monomers A, B, C and D

- A, polymer with B,C, and D
- B, polymer with A,C, and D
- C, polymer with A,B, and D
- D, polymer with A,B, and C

Polymer	Naming focused on monomer	Naming focused on structure
	polystyrene	Poly(1-phenylethene)
	Poly(acrylonitrile)	Poly(1-cyanoethene)
	polypropylene	Poly(1-propene)





### III. Registration and Hazard Evaluation of a New chemical substance under K-OSHA .

1. KOSHA(Occupational Safety and Health Act) Amendment
  - i .  $\geq 0.1$ ton Registration (Article 108(1) of the Act)
  - ii . a new Polymer Registration (Article 89-2(1) of the Enforcement rule)

# 1. KOSHA(Occupational Safety and Health Act) Amendment



## i . ≥ 0.1ton Registration (Article 108(1) of the Act)

Article 86 of the Enforcement rule has been amended on Jan 31, 2019 in accordance with the K-REACH Amendment.

Item	After KOSHA amendment		
Tonnage	0.1-1ton	1-10tons	≥ 10tons
Obligation	Registration for hazard assessment Since 2020, no obligation under KOSHA if a new chemical is registered under K-REACH		
	Completion before manufacture/import		
Processing period	14 working days	30 working days	
Toxicity data requirement	<ul style="list-style-type: none"> <li>Acute Oral(Inhalation) Toxicity</li> </ul>	<ul style="list-style-type: none"> <li>Acute Oral(Inhalation) Toxicity</li> <li>AMES test</li> </ul>	<ul style="list-style-type: none"> <li>Acute Oral(Inhalation) Toxicity</li> <li>AMES test</li> <li>(in-vivo)genotoxicity(single sex)test</li> </ul>
Remarks	<ul style="list-style-type: none"> <li>Registration is required until December 31, 2019</li> <li>Since 2020, no obligation under KOSHA</li> </ul>	<ul style="list-style-type: none"> <li>Only if AMES result is positive, (in-vivo)genotoxicity(single sex)test is required</li> </ul>	

# 1. KOSHA(Occupational Safety and Health Act) Amendment



## ii. a new Polymer Registration (Article 89-2(1) of the Enforcement rule)

Even if a new polymer is applied for PLC(Polymer Low Concerned) exemption under K-REACH, a new polymer is also required to check whether a new polymer substance meets with MoEL Notice. 2017-2(Hazard/Risk assessment of a new chemical substance)

Item	KOSHA			
	< 10tons	10-100tons	100-1,000tons	≥ 1,000tons
Obligation	Registration for hazard/risk assessment			
Times of submission	Once before manufacture/import			
Processing period	30 working days **14 working days( < 1tons)			
Data requirement on property of polymer	<ul style="list-style-type: none"> <li>• GPC report</li> <li>• Monomer information</li> <li>• Acid/Base stability study</li> </ul>			
Toxicity data requirement	n/a	<ul style="list-style-type: none"> <li>• Acute Oral(Inhalation) Toxicity</li> <li>• AMES test</li> </ul>	<ul style="list-style-type: none"> <li>• Acute Oral(Inhalation) Toxicity</li> <li>• AMES test</li> <li>• Only if AMES result is positive, (in-vivo)genotoxicity(single sex)test is required</li> </ul>	<ul style="list-style-type: none"> <li>• Acute Oral(Inhalation) Toxicity</li> <li>• AMES test</li> <li>• (in-vivo)genotoxicity(single sex)test</li> </ul>

# Thank You!



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