Korea Chemical Regulation & 2024 Updates

GCCM Training

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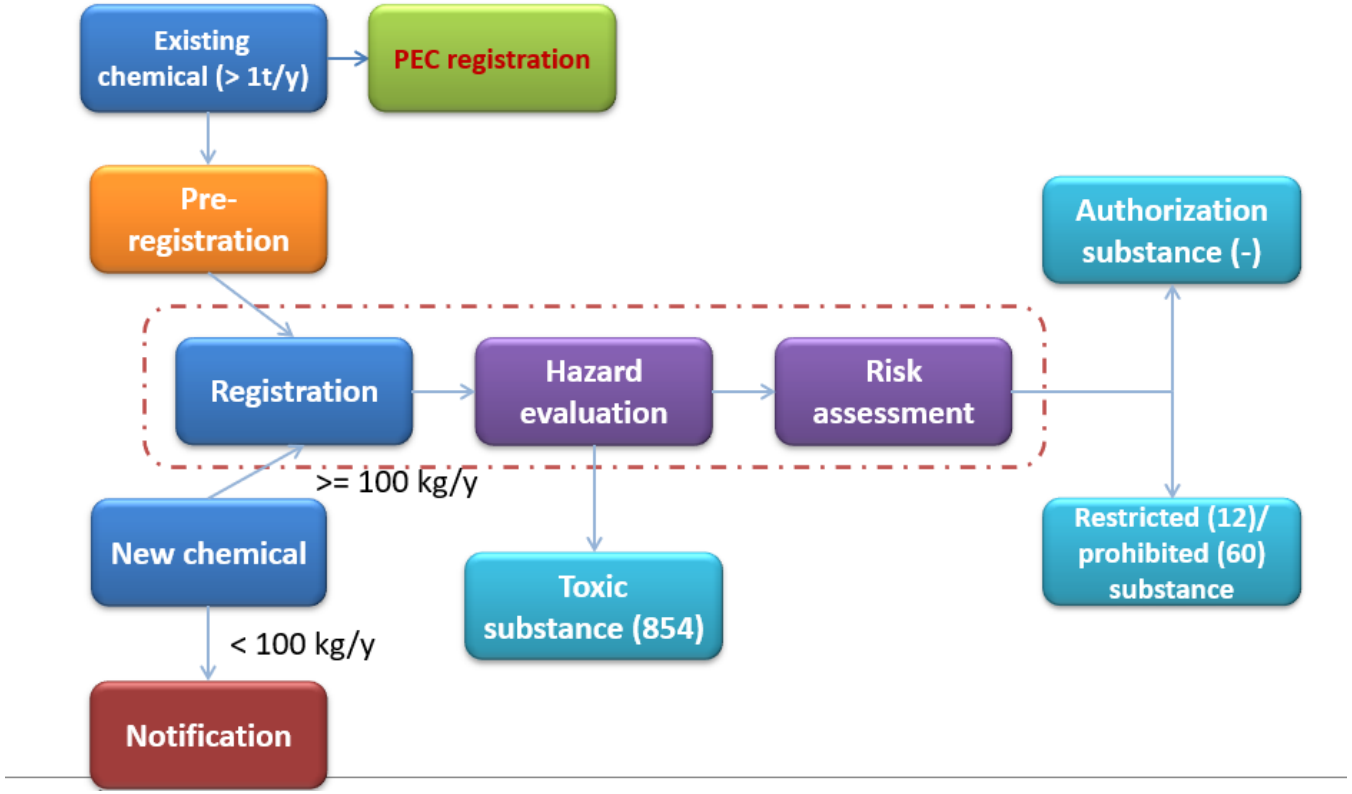
CONTENT

1. K-REACH System

- K-REACH (ARECS): ACT ON REGISTRATION, EVALUATION, ETC. OF CHEMICALS
- Enforcement date: 2015.1.1
- Implementation of New K-REACH: 2019.1.1
- Authority: Ministry of Environment (MOE)
- Registration body: Manufacturer or importer in Korea; Foreign manufacturer (OR)
- Cooperative association: National Institute of Environmental Research(NIER);
- Korea Environment Corporation (KECO)



1. K-REACH Substance Type

Existing Substance

- >1t/a:
  Pre-registration
  Registration

Priority Existing Substance (phase-in substance subject to registration)

- >1t/a: Registration
- 510 PEC Substances, has to be registered before manufacture or import after July 1, 2018.

New chemical Substance

- ≥0.1t/a: Registration
  <0.1t/a: Notification （no data requirement）

1. K-REACH Inventory

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

Korea Existing Chemicals List (KECL)
> 43,000 substances

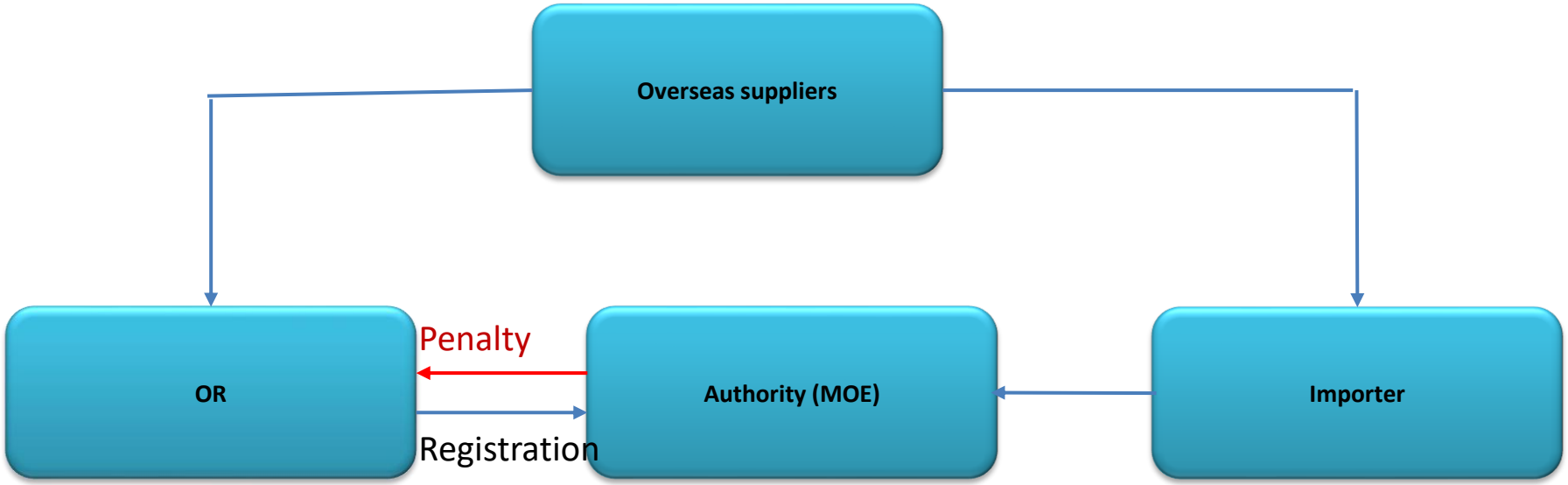
Chemical Search

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	View info
13150-00-0	Sodium 2-[2-[2-(dodecyloxy)ethoxy]ethoxy]ethyl sulfate	KE-31442						

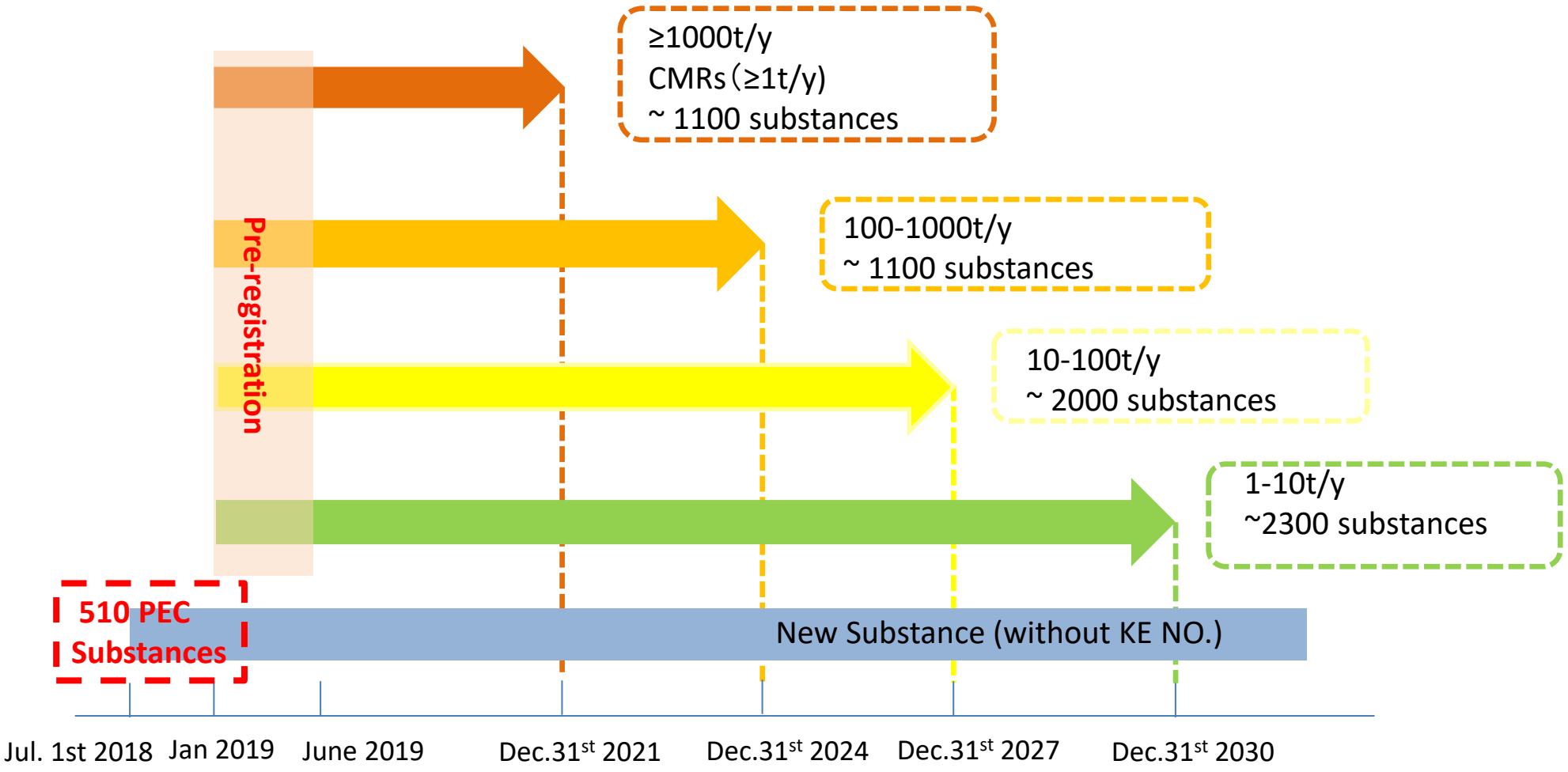
1. K-REACH Only Representative



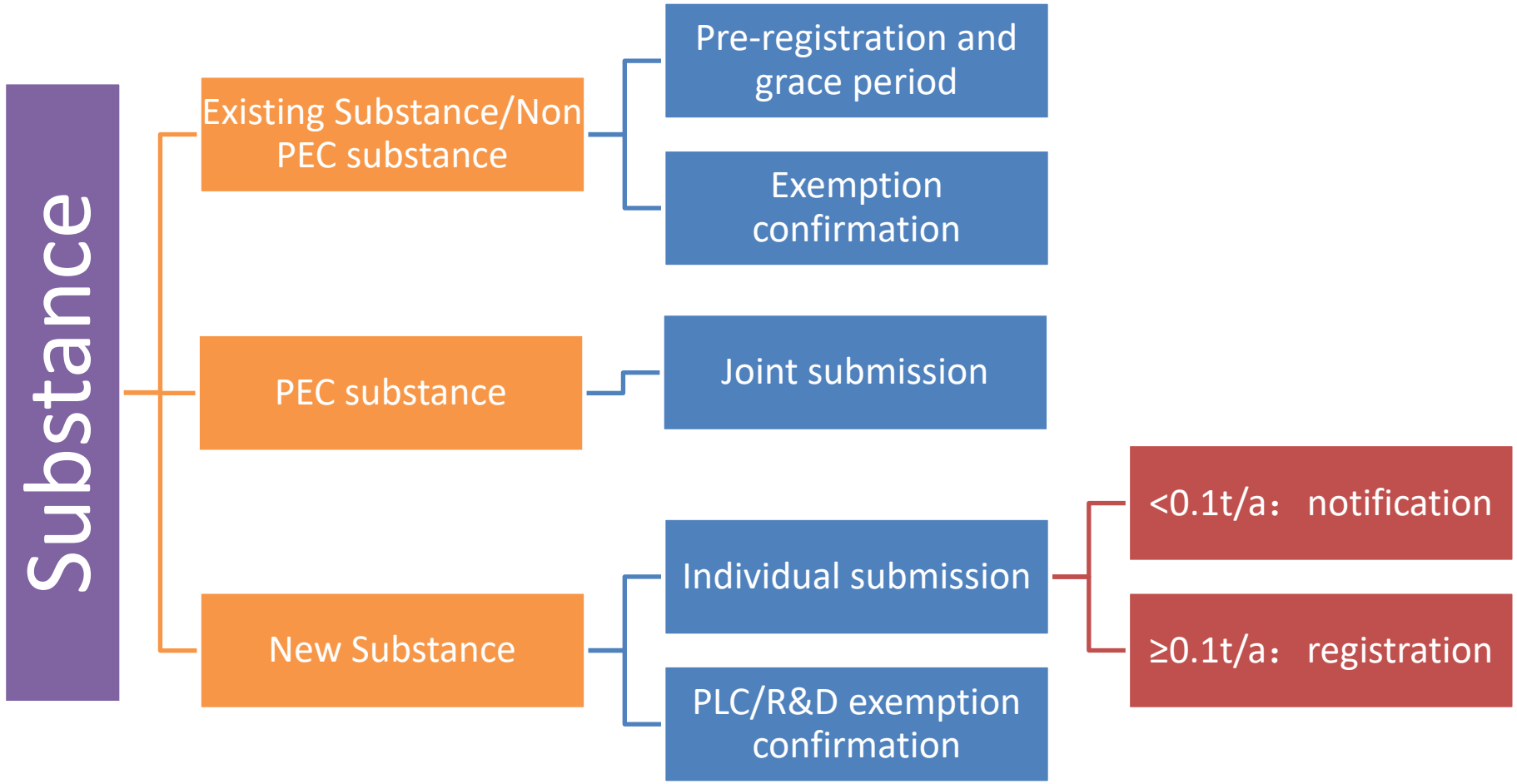
- If OR is appointed, all penalties will belong to OR!
- OR Change is not available under K-REACH currently

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

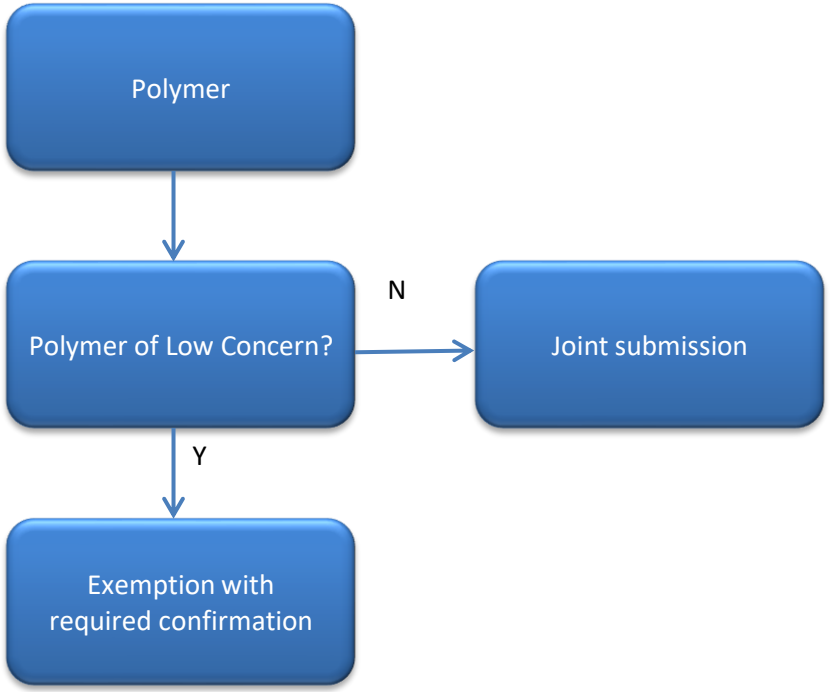
1. K-REACH Registration Timeline

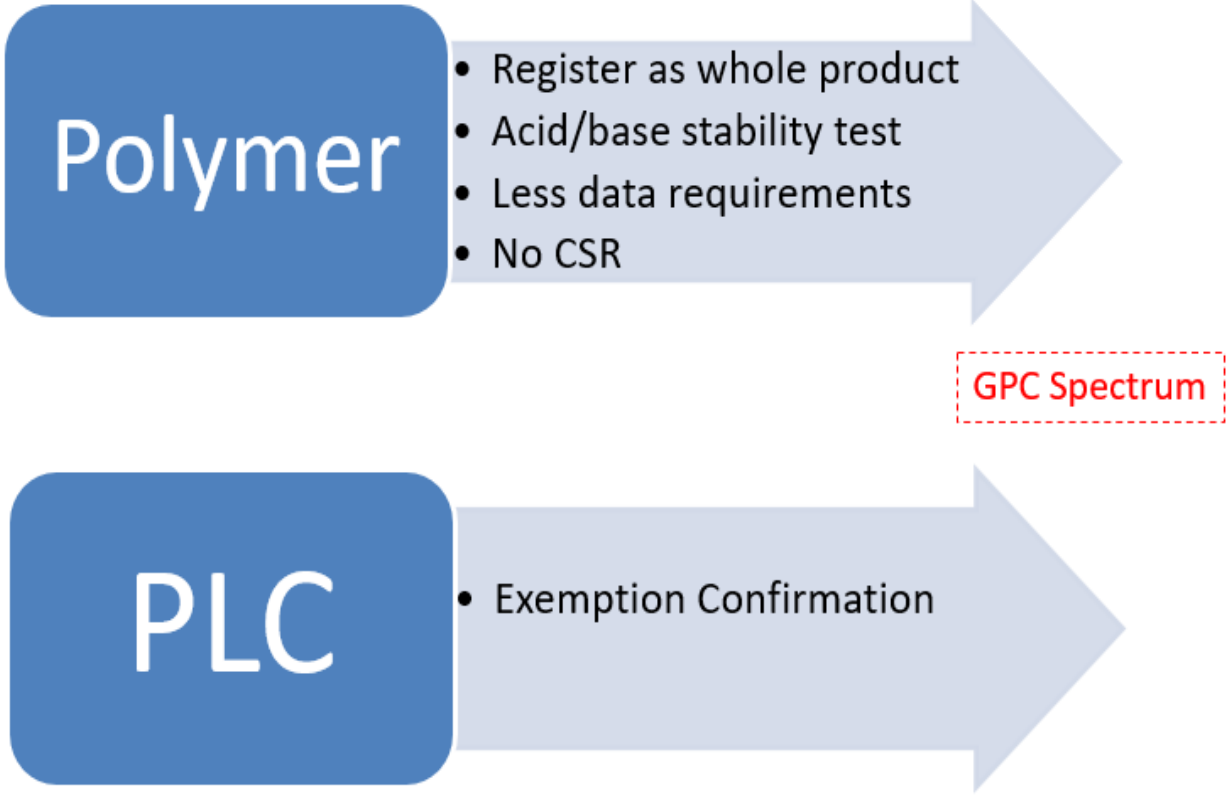


1. K-REACH Registration Procedure



1. K-REACH Polymer Registration



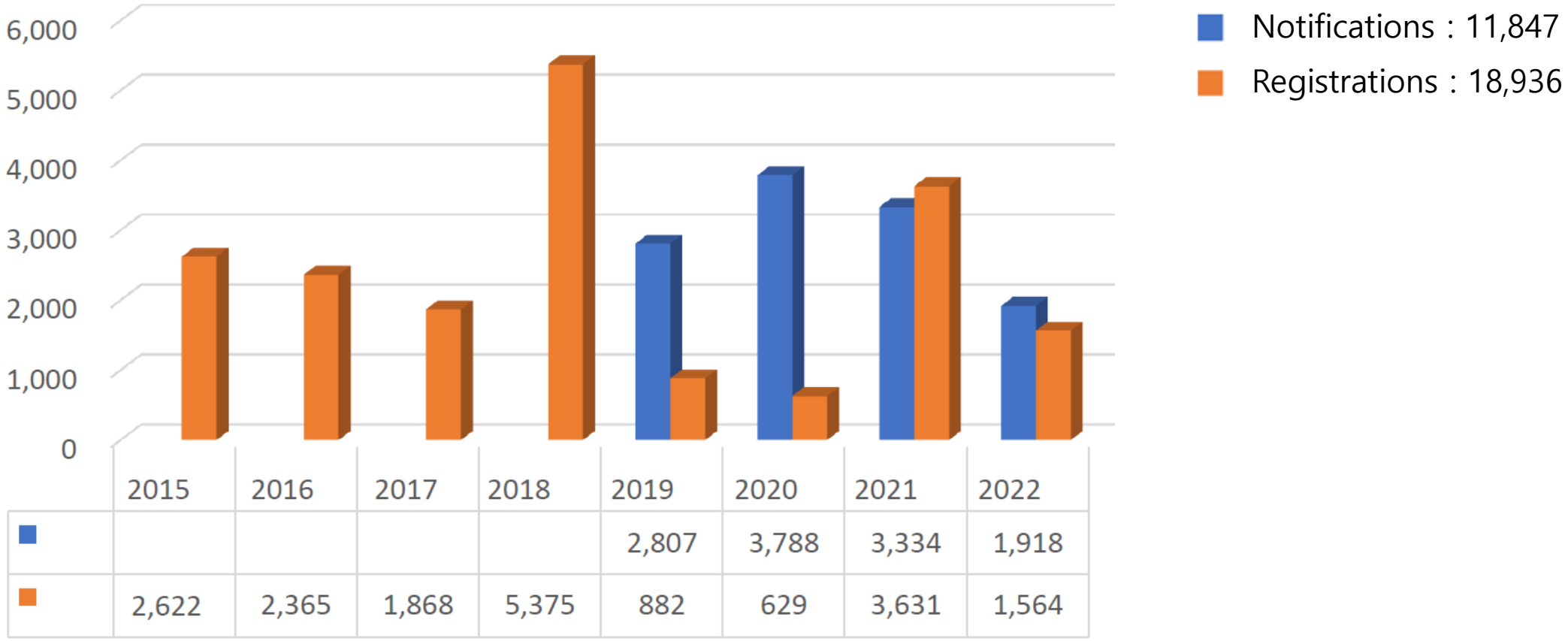


➢Unlike EU REACH, polymer itself is required to take basically joint registration under K-REACH!

➢Some polymer compounds subject to hazard review exemption under previous TSCA (Toxic Substances Control Act in Korea) should be notified to authority.

1. K-REACH Progress

K-REACH Registrations and Notifications (as of Sept, 2022)



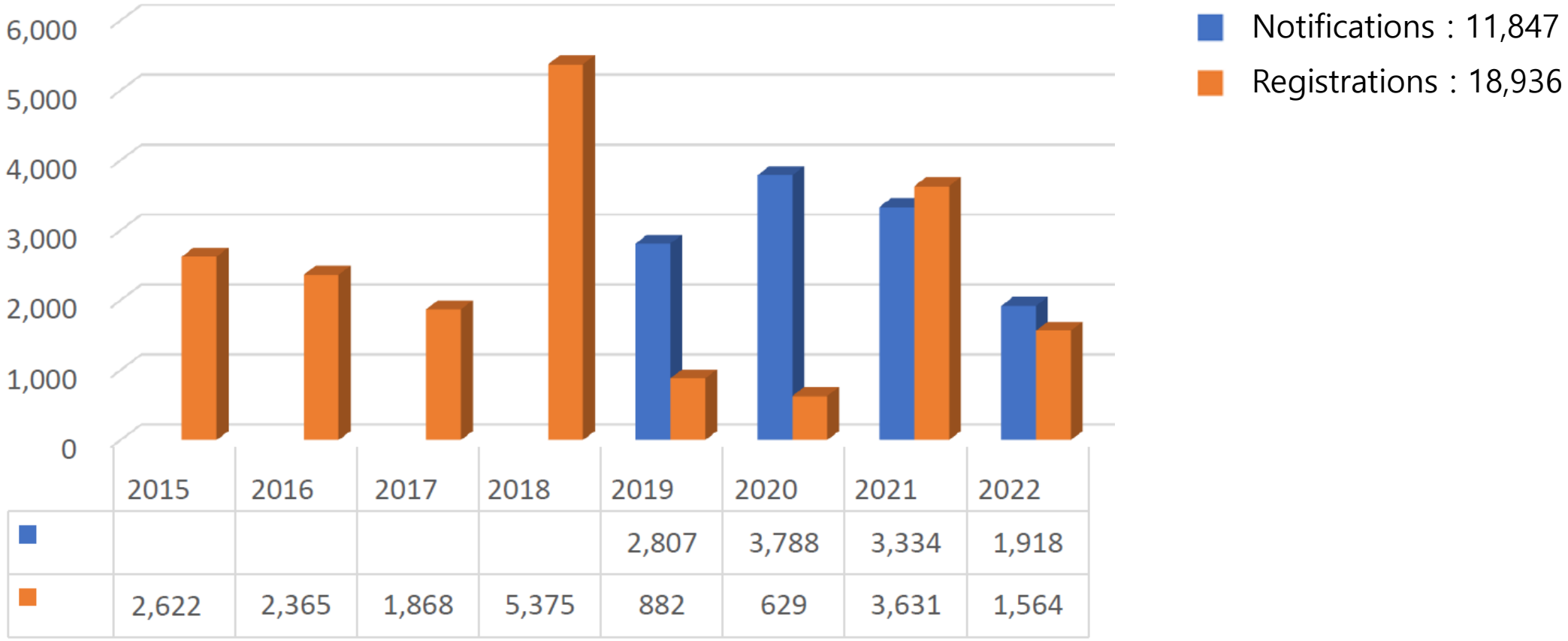
	2015	2016	2017	2018	2019	2020	2021	2022
■					2,807	3,788	3,334	1,918
■	2,622	2,365	1,868	5,375	882	629	3,631	1,564

1. K-REACH Progress

	Korea			EU
	TCCA	K-REACH	K-REACH Amendment	REACH
Subject to Registration	New chemicals	Designated Existing All New Chemicals and Polymers	All existing (>1t) All New Chemicals and Polymers	All existing(>1t) New Chemicals(>1t)
Annual Report	X	O	X	X
Pre-Registration	X	X	O	O
Registrants	Manufacturer, Importer	Manufacturer, Importer, Representative	Manufacturer, Importer, Representative	Manufacturer, Importer, Representative
Chemical Notification			<0.1T (<1T)	
Chemical Registration	0.1~1T >1T	<1T 1~10T 10~100T 100~1000T >1000T	0.1~1T 1~10T 10~100T 100~1000T >1000T	1~10T 10~100T 100~1000T >1000T
Priority Substances	X	X	O	O (SVHC)
Product Notification	X	O (Chemical Product)	O (Chemical Product)	O (Article)
Evaluation	All	All	All	5%
Evaluation criteria	Hazards	Risks	Risks	Risks
Listing as existing	After 3 years	X	X	X
Authorizatino	X	O	O	O

1. K-REACH Progress

K-REACH Registrations and Notifications (as of Sept, 2022)

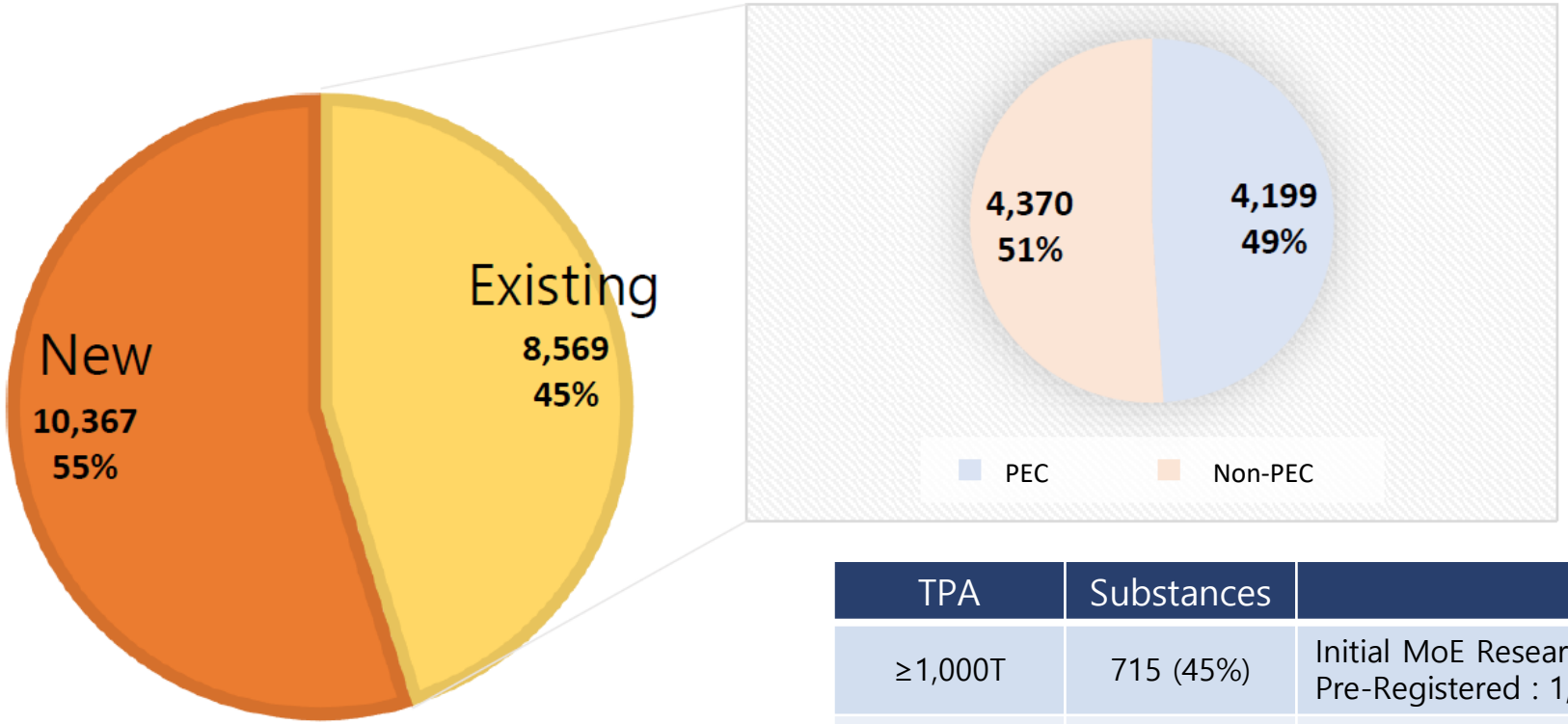


	2015	2016	2017	2018	2019	2020	2021	2022
■					2,807	3,788	3,334	1,918
■	2,622	2,365	1,868	5,375	882	629	3,631	1,564

1. K-REACH Progress

K-REACH Registrations (as of Sept, 2022)

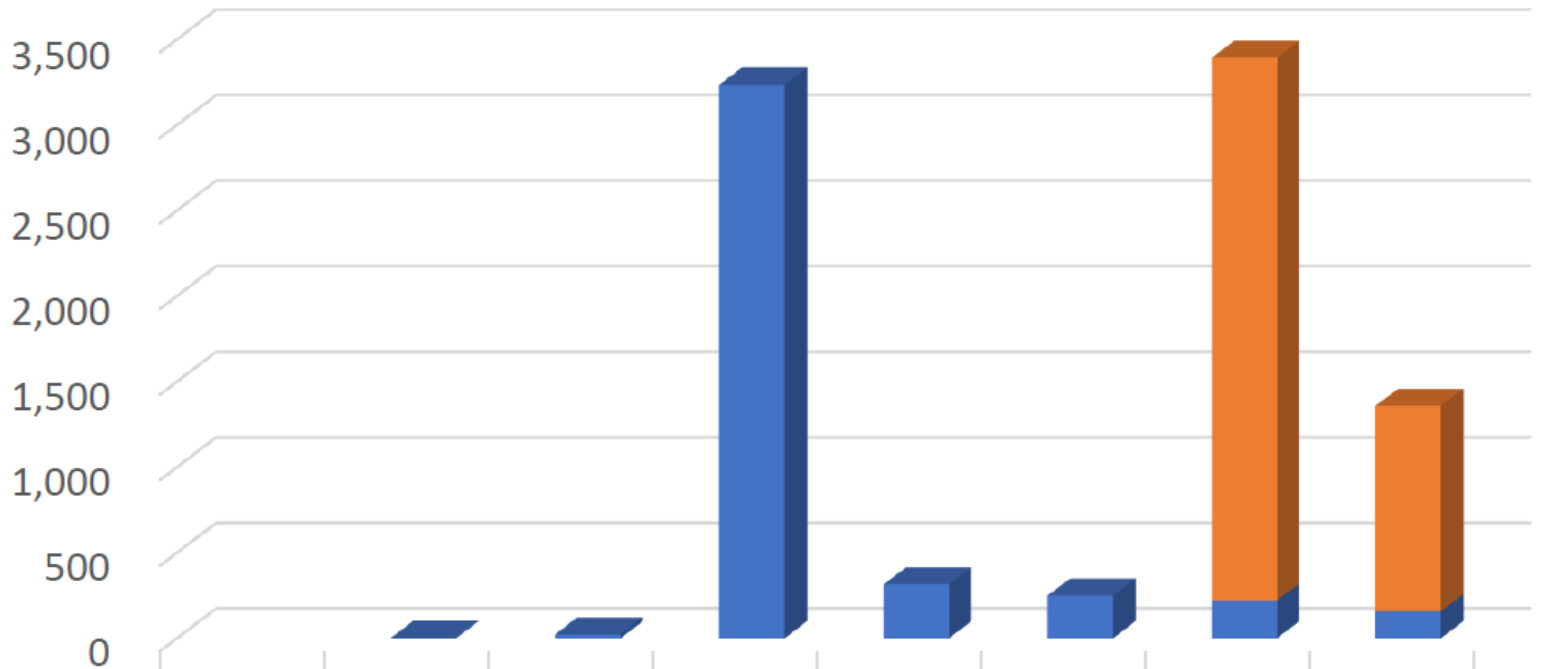
- New Vs Existing
- Within Existing : PEC(2018) Vs non-PEC(after 2018)



TPA	Substances	Remark
≥1,000T	715 (45%)	Initial MoE Research : 1,170 Substances Pre-Registered : 1,580 Substances
<1,000T	73	

1. K-REACH Progress

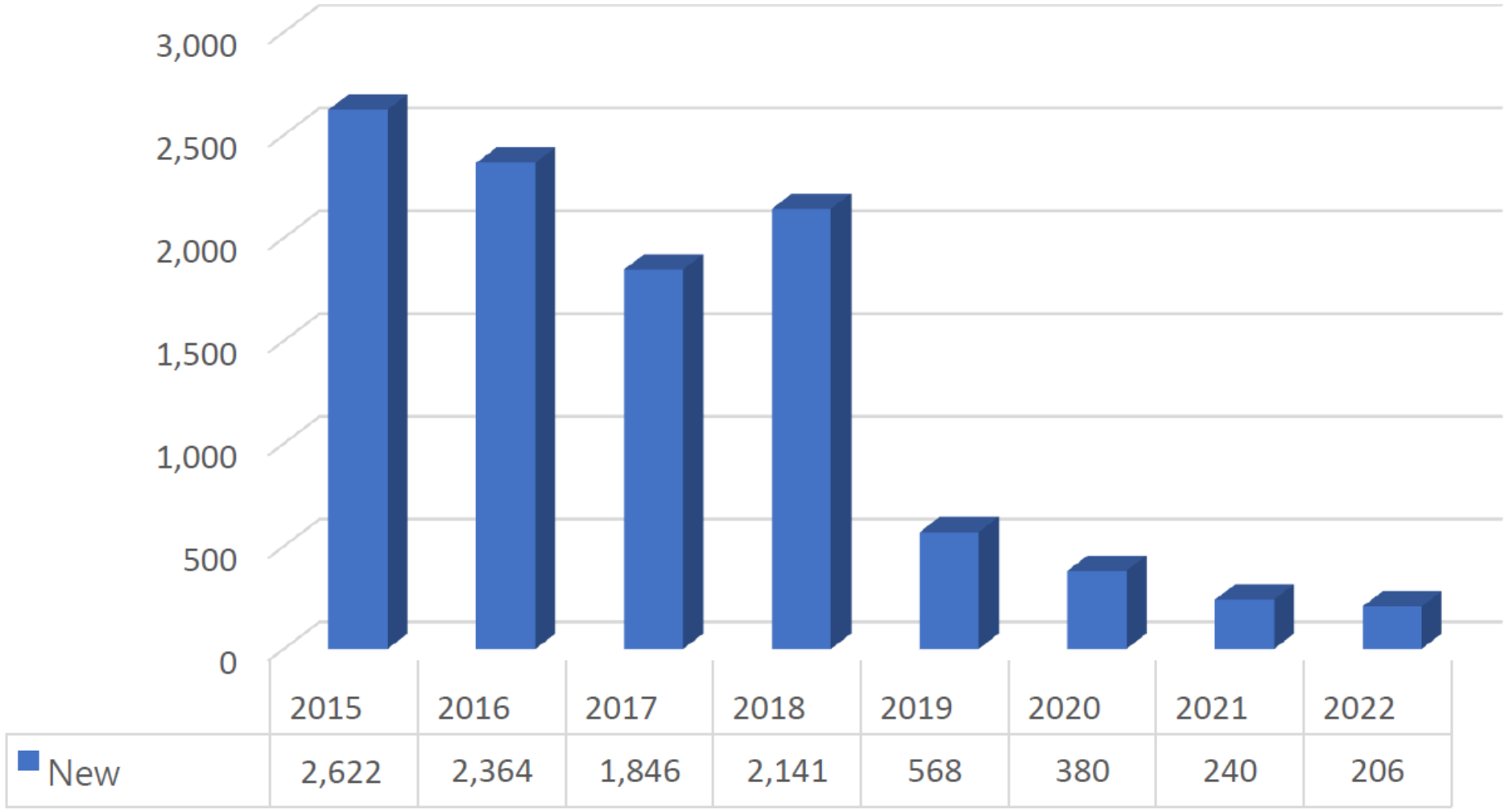
K-REACH Existing Chemical Substances Registrations (as of Sept, 2022)



	2015	2016	2017	2018	2019	2020	2021	2022
non-PEC							3,170	1,200
PEC		1	22	3,234	314	249	221	158

1. K-REACH Progress

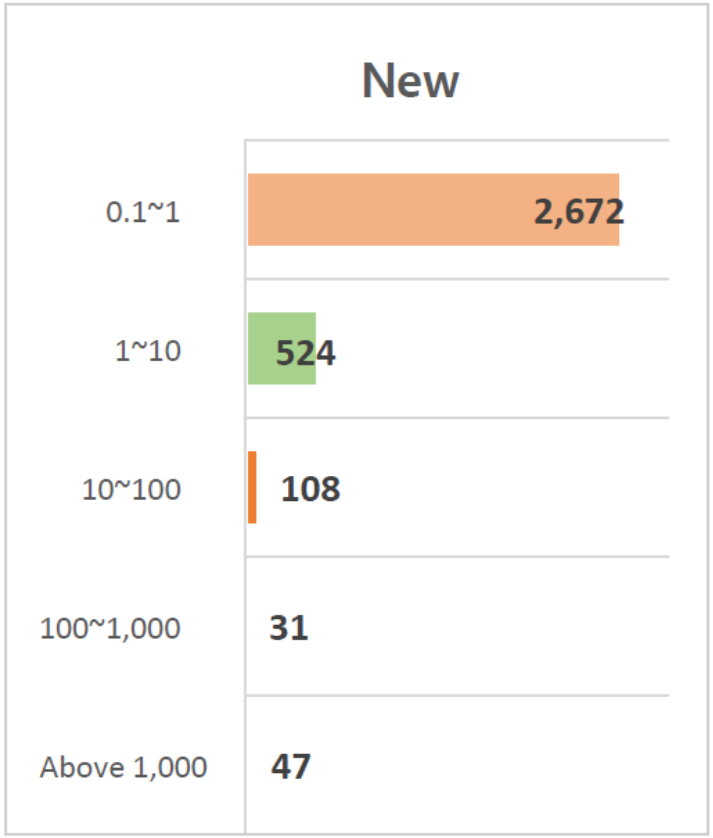
K-REACH New Chemical Substance Registrations (as of Sept, 2022)

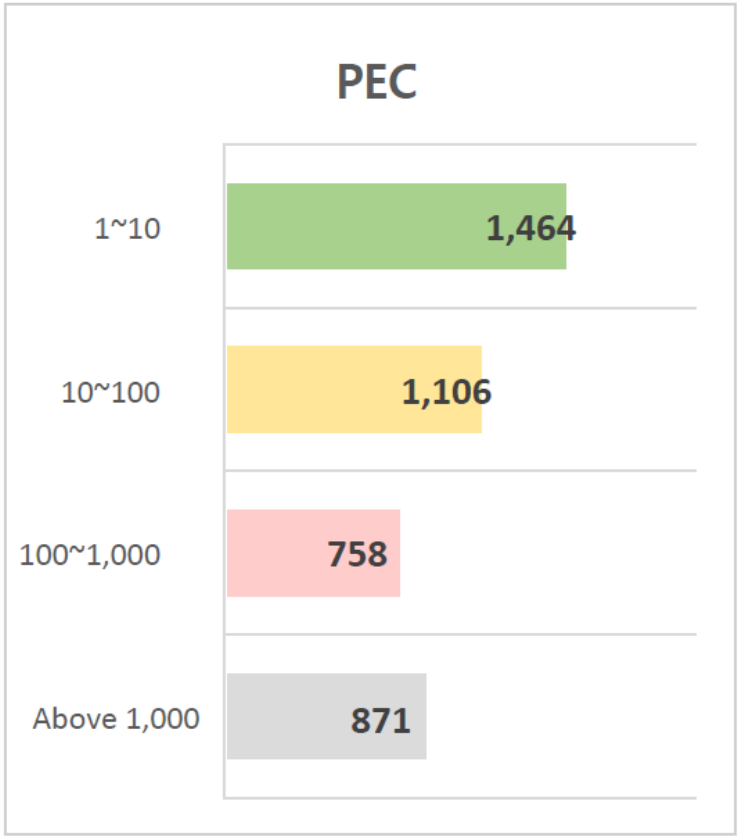


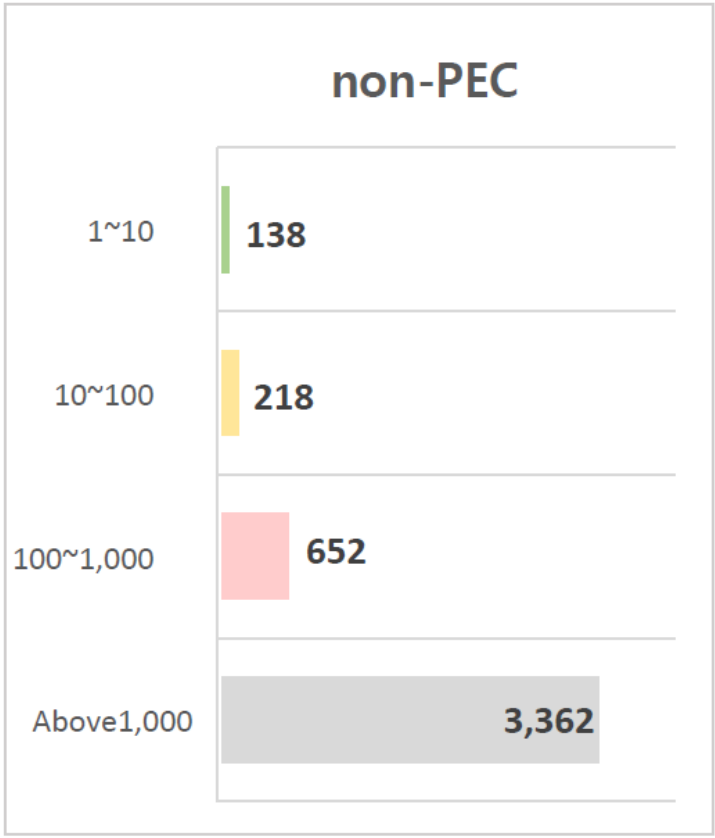
	2015	2016	2017	2018	2019	2020	2021	2022
New	2,622	2,364	1,846	2,141	568	380	240	206

1. K-REACH Progress

K-REACH Registrations (per Tonnage Band) (as of Sept, 2022)

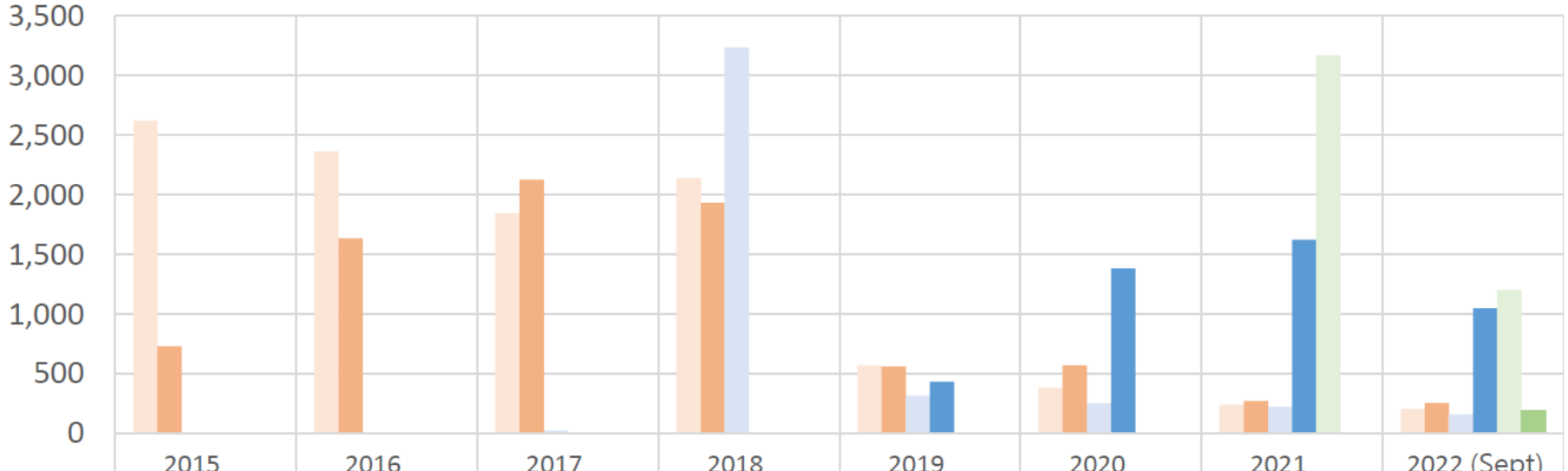






1. K-REACH Progress

K-REACH Hazardous Assessment (as of Sept, 2022)



	2015	2016	2017	2018	2019	2020	2021	2022 (Sept)
New Reg.	2,622	2,364	1,846	2,141	568	380	240	206
New Reg. Assess.	731	1,636	2,126	1,933	561	569	269	253
PEC Reg.		1	22	3,234	314	249	221	158
PEC Reg. Assess.					433	1,381	1,624	1,049
Non-PEC Reg.							3,170	1,200
Non-PEC Assess.								192

1. K-REACH Progress

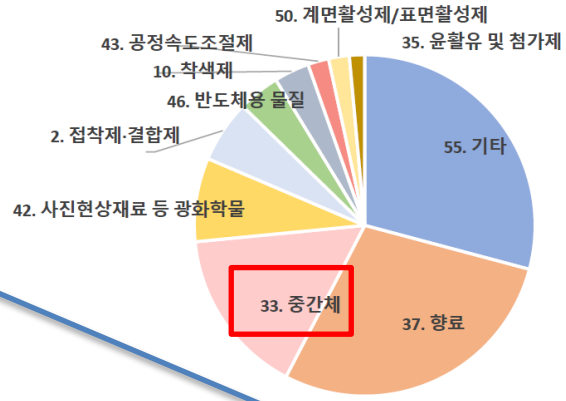
Government's efforts to reduce burdens for Industry, with below considerations

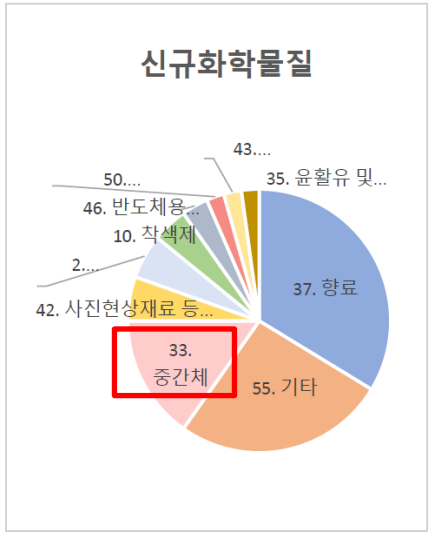
- Current Economy Situations in Korea
- Not forgetting the background of the legislation of the Regulation
  - Safety use of Chemical substance; and also
  - Social and Political
- Not to discriminated from those who are (or had) registered under the Regulations
  - PEC Substances (by 2018)
  - >1,000T Substances (by 2021)
  - 100-1,000T Substances currently under preparations (by 2024)
- Many years of discussions, and now with draft approaches
  - E.g. 0.1-1T New Chemical Substance Registration ⇒ 0.1-1T New Chemical Substance Notification

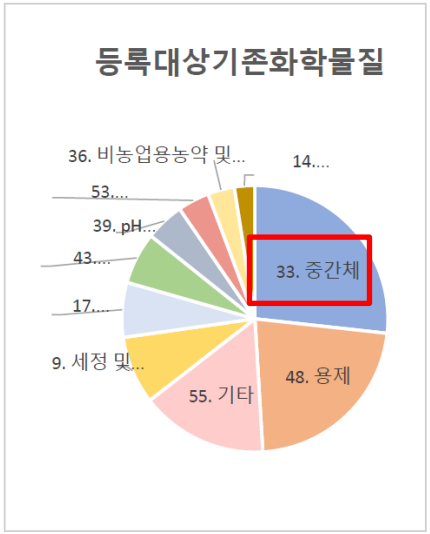
2. Transported Isolated Intermediates (TII) Registration

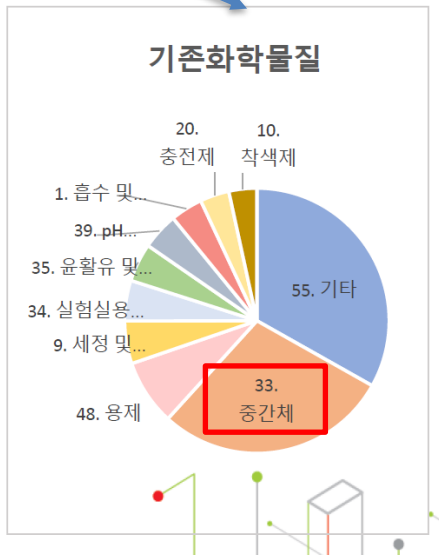
Use no 33. Intermediate

- Top 10 Use for New Chemical Substance Notification (<0.1)
- Top 10 Use for Non-PEC Existing Chemical Substance Registration
- Top 10 Use for PEC Registration
- Top 10 Use for New Chemical Substance Registration









2. Transported Isolated Intermediates (TII) Registration

CIRS

TII Registration - Data Requirement

	0.1-1 ton	1-10 ton	10-100 ton	100-1,000 ton	1,000-ton
Physico-Chem	1) Physical State 2) Water Solubility 3) Melting/freezing 4) Boiling Point 5) Vapor Pressure	1) Partition coefficient n-octanol/water 2) Density 3) Granulometry	1) Flammability 2) Explosive properties 3) Oxidizing properties	1) Viscosity 2) Dissociation constant	
Toxicity					1) Acute Tox. Oral or Inhalation 2) AMES 3) Skin Irritation /Corrosion 4) Skin Sensitization
Eco Toxicity					1) Acute Tox. Fish 2) Ready biodegradability 3) Acute Tox. Daphnia

2. Transported Isolated Intermediates (TII) Registration

TII Registration – Downside

- "TII Justification" required with Registration
  - Proving that the substance satisfies the TII requirement
    - All users of the substance must satisfy the requirements

Additional obligation after the completion of TII Registration

- Users : Administrative Obligations
  - Record on use of the substance are required

- Registrant : Registrant Update with new DU
  - Update TII Justification covering the new user satisfying the requirements
  - Registration Update with updated TII Justification

2. Transported Isolated Intermediates (TII) Registration

What is TII

Below is what is explained in text

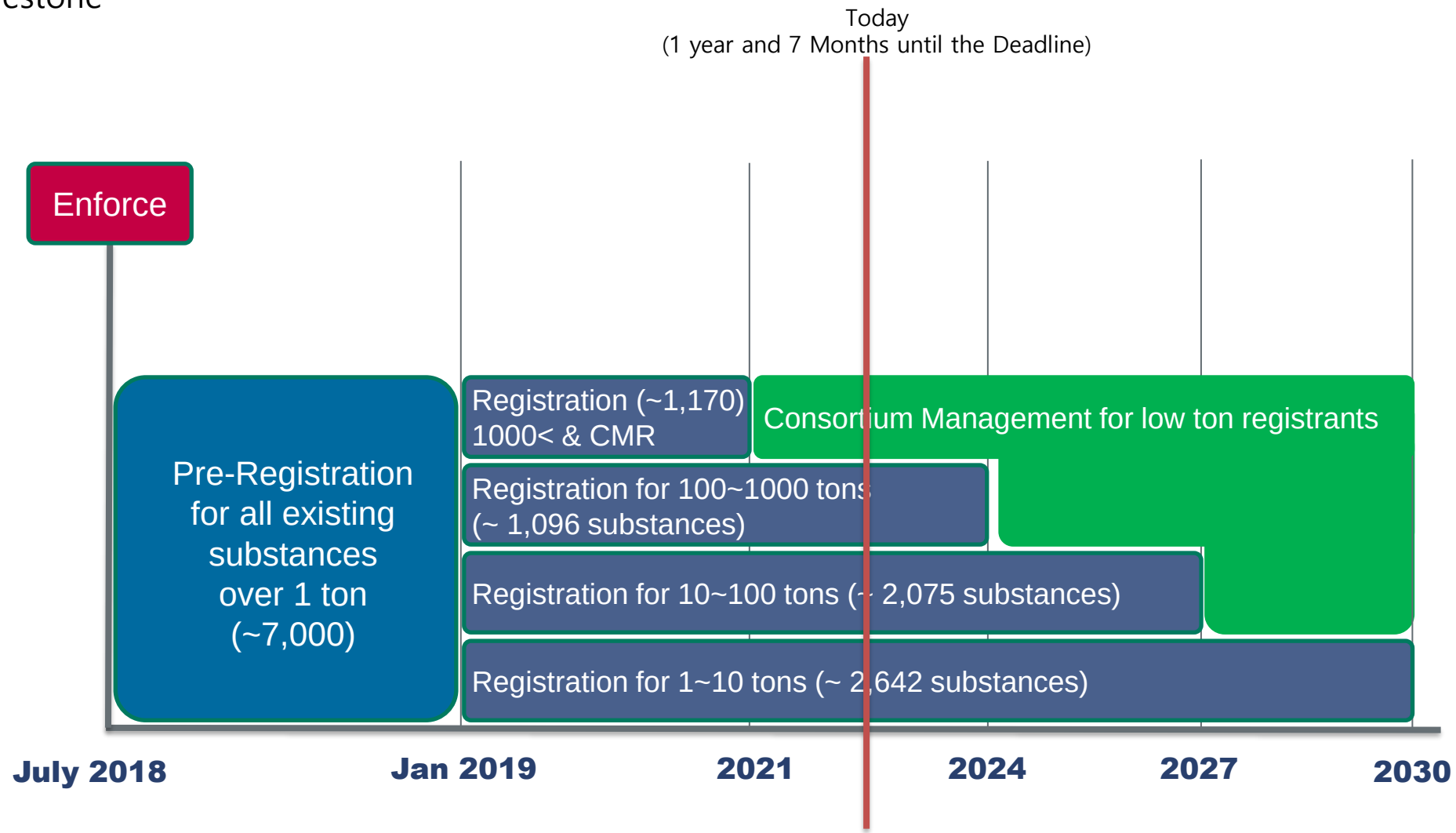
1. Intermediate
   - The substance is manufactured to be used to manufacture another substance
   - All amount manufactured must be consumed·used to manufacture the other substance

2. Strictly Controlled Conditions
   - Substance must be under SCC for whole life cycle

3. Administrative requirement for the use of TII
   - Must be handled by trained personnel
   - Use of TII must be documented

3. 100-1,000T Registration Deadline

K-REACH Milestone



3. 100-1,000T Registration Deadline

K-REACH Milestone (Backward from the deadline, only with the essential procedures)

- Co-Registrants can only submit their registration, once the LR has completed theirs (expect 1~2 months with NIER)
- Lead-Registrant will require around 3 months with NIER

Milestone | Year	2023								2024											
Month	5	6	7	8	9	10	11	12	1	2	3	4	5	6	7	8	9	10	11	12
1. Preparation of Lead Registrations																				
- Submission and Completion of Lead-Registrations																				
2. Preparation of Co-Registrations																				
- Submission and Completion of Co-Registrations																				

3. 100-1,000T Registration Deadline

K-REACH Milestone (Back from the deadline, only with the essential procedures)

Testing

- 28d Repeat Tox. (oral) will be the most time critical (if there are no available data), requires 6 months
- Pre-requisite for 28d Repeat Tox. (oral) : Acute Tox. (oral), requires 3 months
- Pre-requisite for Acute Tox. (oral) : Skin irritation, requires 3 months

Milestone | Year	2023								2024											
Month	5	6	7	8	9	10	11	12	1	2	3	4	5	6	7	8	9	10	11	12
1. Preparation of Lead Registrations																				
- Testing Skin Irritation																				
- Testing Acute Tox. (oral)																				
- Testing 28d Repeat Tox. (oral)																				
- Submission and Completion of Lead-Registrations																				
2. Preparation of Co-Registrations																				
- Submission and Completion of Co-Registrations																				

- Beware, the lab capacity are quite full (consider the needs from ~500 substances)
  - Especially eco tox : acute fish/daphnia (expect at least 12 month waiting period)

3. 100-1,000T Registration Deadline

K-REACH Milestone (Back from the deadline, only with the essential procedures)

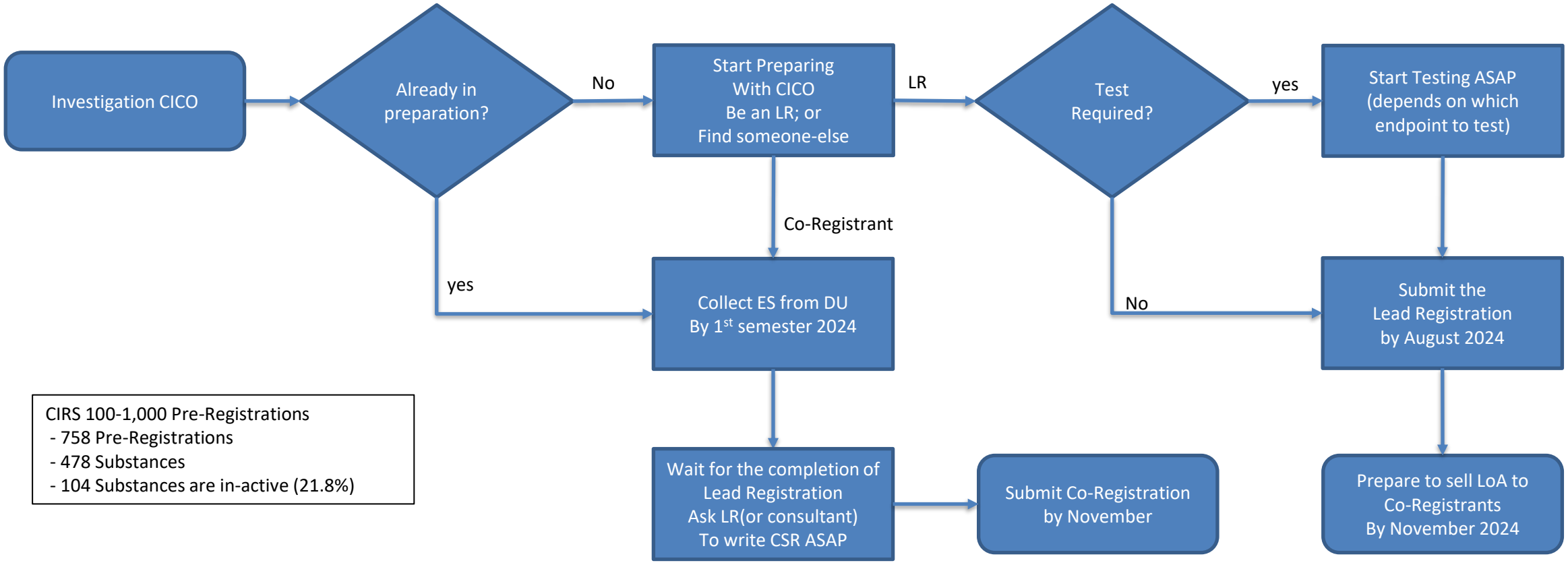
Writing CSR

- Will assume that Exposure Scenario from DU are already collected
- For Lead Registrants : Expect 1 month to write CSR
- For Co-Registrants : Expect at least 1 month to write CSR
  - There will be other Co-Registrants from at least 500 substances, who will also have to write CSR

Milestone | Year	2023								2024											
Month	5	6	7	8	9	10	11	12	1	2	3	4	5	6	7	8	9	10	11	12
1. Preparation of Lead Registrations																				
- Testing Skin Irritation																				
- Testing Acute Tox. (oral)																				
- Testing 28d Repeat Tox. (oral)																				
- Write CSR																				
- Submission and Completion of Lead-Registrations																				
2. Preparation of Co-Registrations																				
- Write CSR																				
- Submission and Completion of Co-Registrations																				

3. 100-1,000T Registration Deadline

What to do from today.



CIRS 100-1,000 Pre-Registrations
- 758 Pre-Registrations
- 478 Substances
- 104 Substances are in-active (21.8%)

4. Authorization

(Pilot Project) Public Comment Period for the designation of Candidate List (Dec, 2021)

- This was to test run the procedure to designate Candidate List for Authorizations
- Deadline to submit comments : 20th January 2022

	Substance Name	CAS No	Priority Substance	
			Identification	Hazardous
1	Benzo[def]chrysene (Benzo[a]pyrene)	50-32-8	Appendix 1-2	CMR, PBT
2	Benz[a]anthracene	56-55-3	Appendix 2-7	CMR, PBT
3	Formamide	75-12-7	Appendix 1-16	CMR
4	p-(1,1-dimethylpropyl)phenol	80-46-6	Appendix 1-28	Endocrine Disruptor
5	Tris(2-chloroethyl) phosphate	115-96-8	Appendix 1-67	CMR
6	Sodium peroxoborate	7632-04-4	Appendix 1-125	CMR
7	Perboric acid, sodium salt	11138-47-9	Appendix 1-161	CMR
8	Sodium Tetraborate, Pentahydrate	12179-04-3	Appendix 1-164	CMR
9	2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (DOTE)	15571-58-1	Appendix 1-175	CMR
10	Trixylyl phosphate	25155-23-1	Appendix 1-181	CMR

4. Authorization

Public Comment Period for the 1st designation of Candidate List (Nov, 2022)

- Deadline to submit comments : 13th February, 2023
  - Deadline was postponed to 28th February
- Information to submit
  - Name, contact no., e-mail
  - Type of organization
  - Comments on open information toxicity, usage, exposure, substitutable substances, users, socio-economic impact, use amount or any reason why such substance should not be subject to authorization

	Substance Name	CAS No
1	Benzene	71-43-2
2	Bisphenol A; 4,4'-isopropylidenediphenol	80-05-7
3	Dibutyl phthalate; DBP	84-74-2
4	Benzyl butyl phthalate; BBP	85-68-7
5	4,4'-methylenebis[2-chloroaniline]	101-14-4
6	Di-(2-ethylhexyl)phthalate; DEHP	117-81-7
7	Orange lead	1314-41-6
8	Lead monoxide	1317-36-8
9	Chromium trioxide	1333-82-0
10	Lead sulfochromate yellow 1344-37-2	1344-37-2
9	Strontium chromate	7789-06-2

4. Authorization

Procedure to designate Substances subject to Authorizations

Steps	Procedure	Remark
1	Designation of Candidate Substances	Current Stage
2	Risk Assessment / Market Research / Announcement of Candidate List with public comment	
3	Set priorities to designate Substances Subject to Authorizations	
4	Collect comments from industry, and Discussion with industry	
5	Develop and announce Strategies to designate as Substances Subject to Authorizations	
6	deliberation by the Evaluation Committee	
7	Announcement of Substances Subject to Authorizations(draft) with public comment	

THANK YOU !

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