



# **“Asia-Pacific HazCom/Chemical Control Update”**

**Robert J. Kiefer**

**SCHC Fall Meeting, 2020**



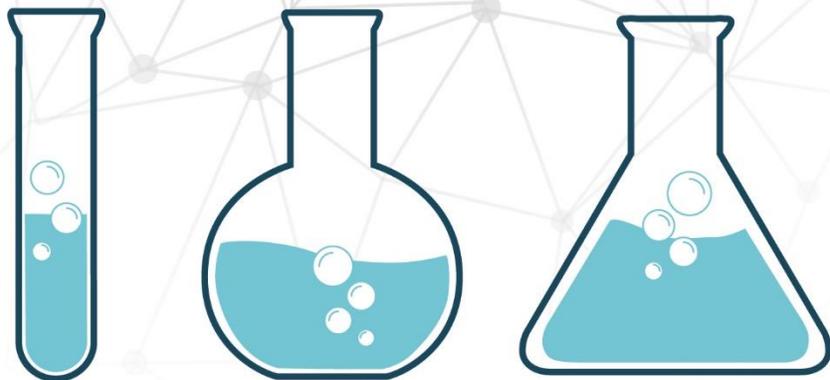
# Intellectual Property Statement

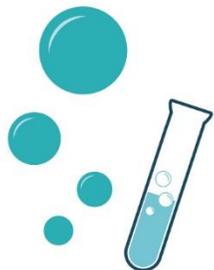
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# “Asia-Pacific HazCom/ Chemical Control Update”

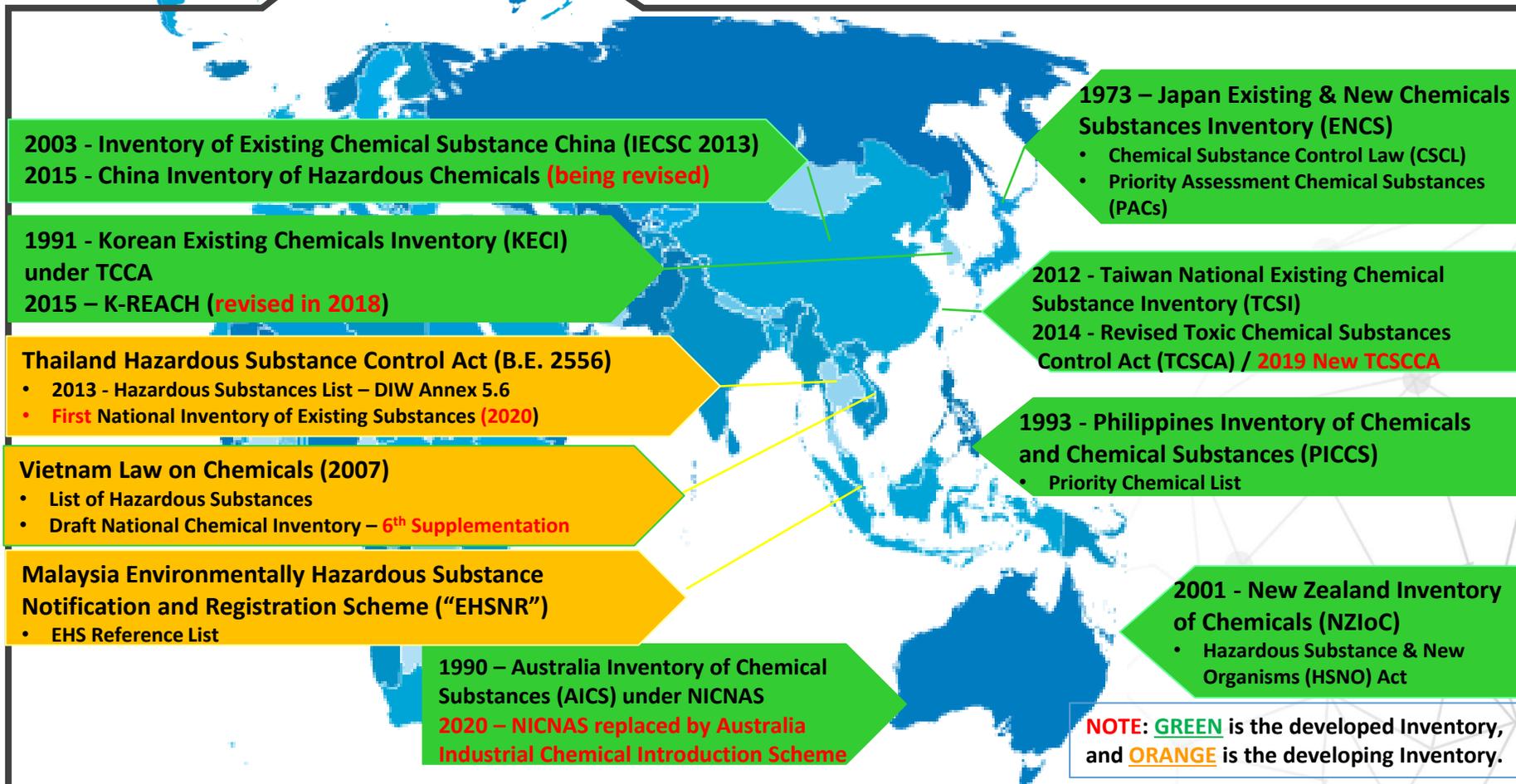
**Robert J. Kiefer**  
General Manager  
REACH24H USA Inc.

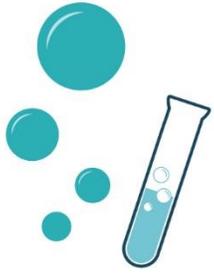
SCHC 2020 Fall Virtual Meeting  
November 9, 2020





# Asia-Pacific Inventories





# Contents

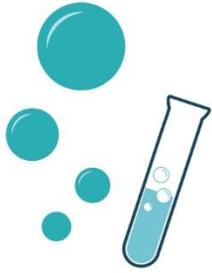
- 1. China MEE Order No. 12**
- 2. Korea REACH**
- 3. Taiwan PEC Standard Registration**
- 4. Australia AICIS**
- 5. India Draft Chemicals Rule**
- 6. Thailand Existing Chemicals Inventory**
- 7. Vietnam National Chemical Inventory**
- 8. A-P GHS Updates**



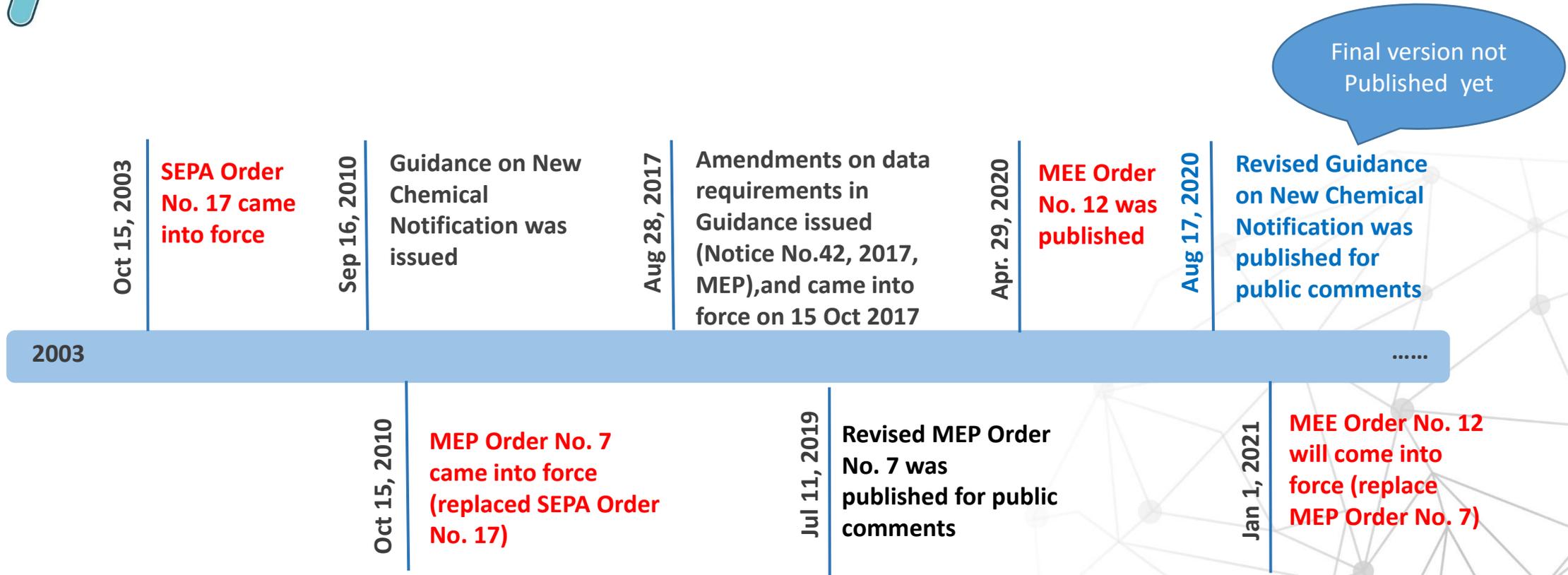


# China

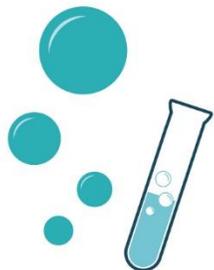




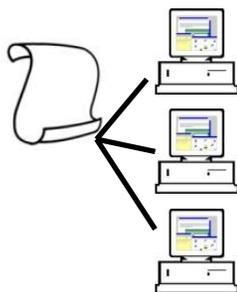
# 1 Legislation Evolution



Final version not Published yet



## 2.1 Key Points—Scope of Application



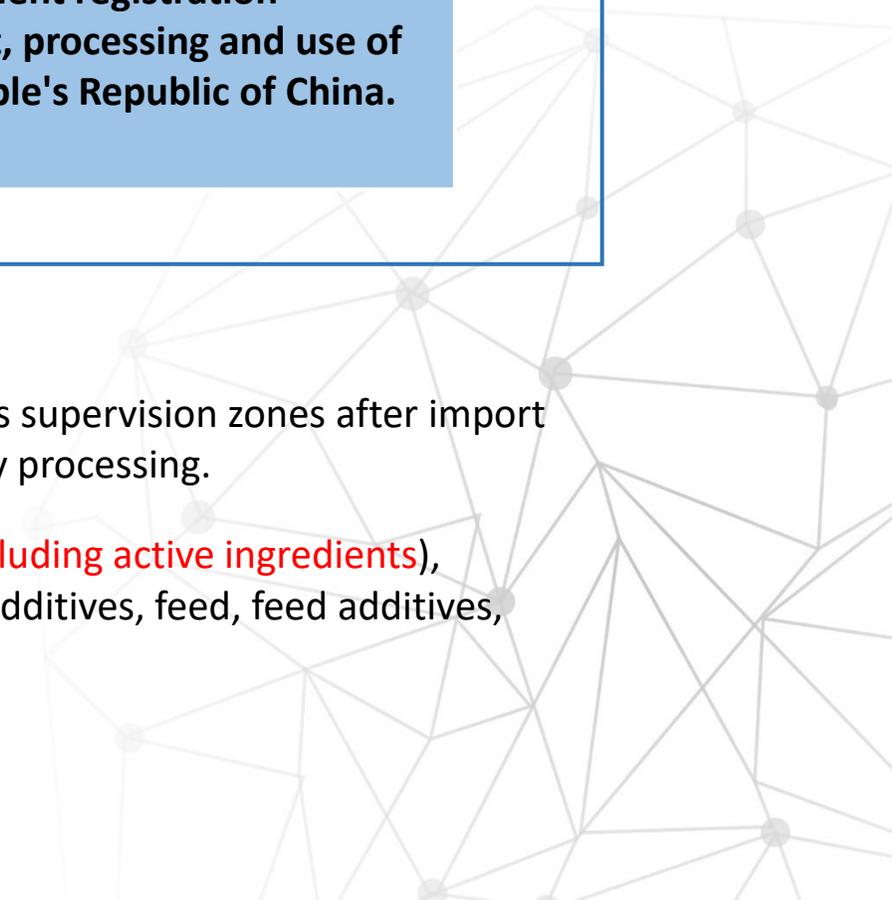
The Measures are applicable to environmental management registration of the activities regarding research, manufacture, import, processing and use of new chemical substances within the territory of the People's Republic of China.

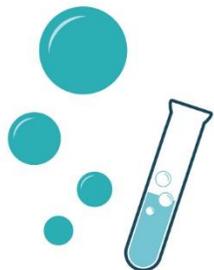


Scope of Application

### Not Applicable:

- Temporarily stored in the special customs supervision zones after import and all designated for export without any processing.
- Medicines (**including API**), pesticides (**including active ingredients**), veterinary drugs, cosmetics, food, food additives, feed, feed additives, **fertilizers**, etc.





## 2.2 Key Points—Information Protection



### When to apply for CBI protection

- Along with dossier



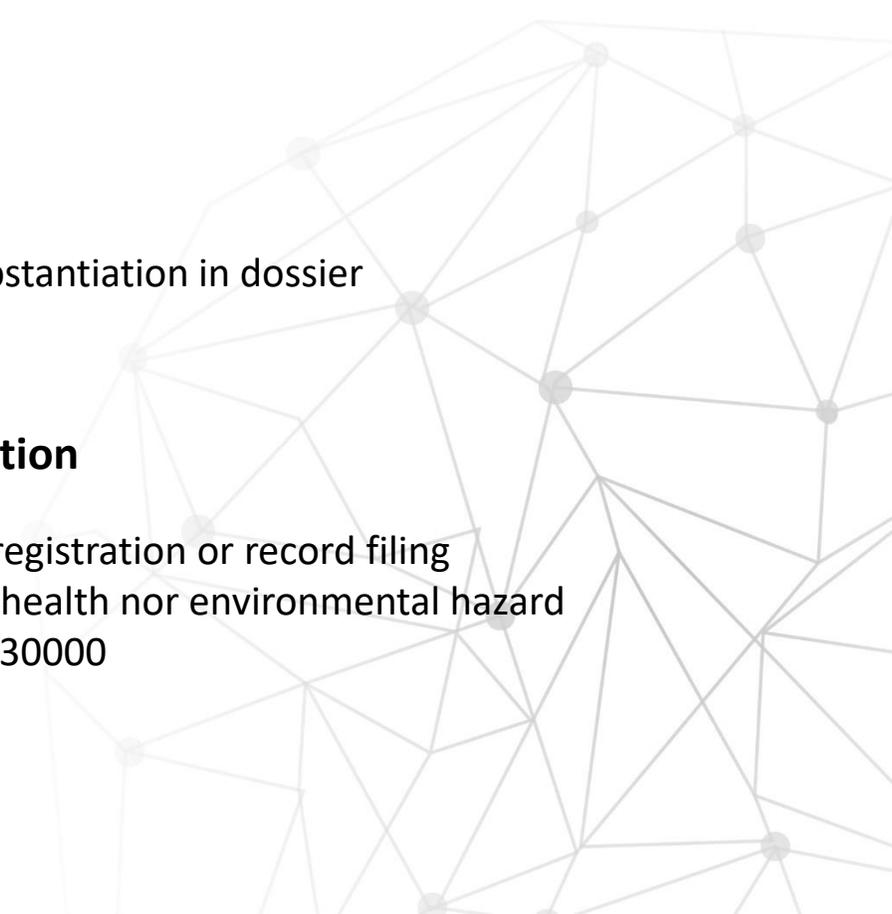
### Requirement

- 12 items for clarification/substantiation in dossier
- Generic Name



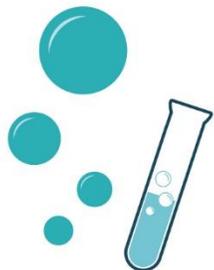
### When to apply for CBI protection

- 5 years from the date of first registration or record filing
- 5-year extension without any health nor environmental hazard classification according to GB 30000



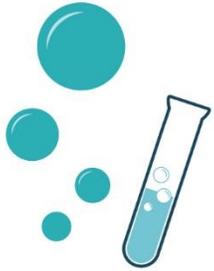
## 2.3 Key Points—Qualification of Testing Institutes

	Properties	MEP Order No. 7	MEE Order No. 12
Domestic	Physical Chemical	CMA, CNAS, GLP-Ministry of Agriculture	CMA, and conform to the laws, regulations and the requirement of national authorities
	Toxicology	GLP of National Food and Drug Administration Standards for Quality Control of Non-Clinical Drug Research; Accreditation Institute of Ministry of Health for Chemical Toxicity; CNCA GLP	CMA, GLP of National Food and Drug Administration Standards for Quality Control of Non-clinical Drug Research; Institute of Chemical Toxicity qualified by China CDC; Pesticide registration and testing institutes announced by the Ministry of Agriculture and Rural Affairs; CNCA GLP
	Eco-Toxicology	Testing institutes announced by MEE	CMA, conform to GLP and management requirement of chemical testing institutes by MEE
Overseas	Physical Chemical	-	ISO 17025 or GLP
	Toxicology/ Eco-Toxicology	Conform to the inspection of the national authorities or GLP (only for eco-toxicology)	Internationally accepted GLP



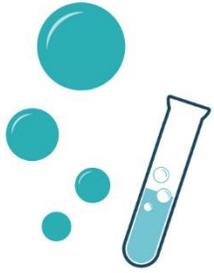
## 2.4 Key Points—Registration Types and Requirements

MEP Order No.7	MEE Order No.12
Scientific Research Record Notification (SRRN) (<0.1 T/y)	<b>Record Notification</b>
Simplified Notification - Basic Case (<1 T/y)	<b>Record Notification</b>
<b>Simplified Notification – Special Case:</b> 1. Intermediates manufactured/imported at an annual volume of less than 1 T 2. Manufactured for the sole purpose of export at an annual volume of less than 1 T; or 3. Substances manufactured/imported at an annual volume of 0.1-1 MT for scientific research purposes; or 4. Any new chemical substance classified as a polymer of low concern (PLC), or a polymer with the concentration of monomer below 2% (w/w)	<b>Record Notification</b>
<b>Simplified Notification – Special Case:</b> Substances manufactured/imported for the purpose of product and process orientated research and development (PPORD) at an annual volume of below 10 T for no more than two years	<b>Simplified Registration</b>
Regular Notification (Band 1) 1-10 MT/y	<b>Simplified Registration</b>
Regular Notification (Band 2, 3 and 4) ≥10 MT/y	<b>Regular Registration</b>

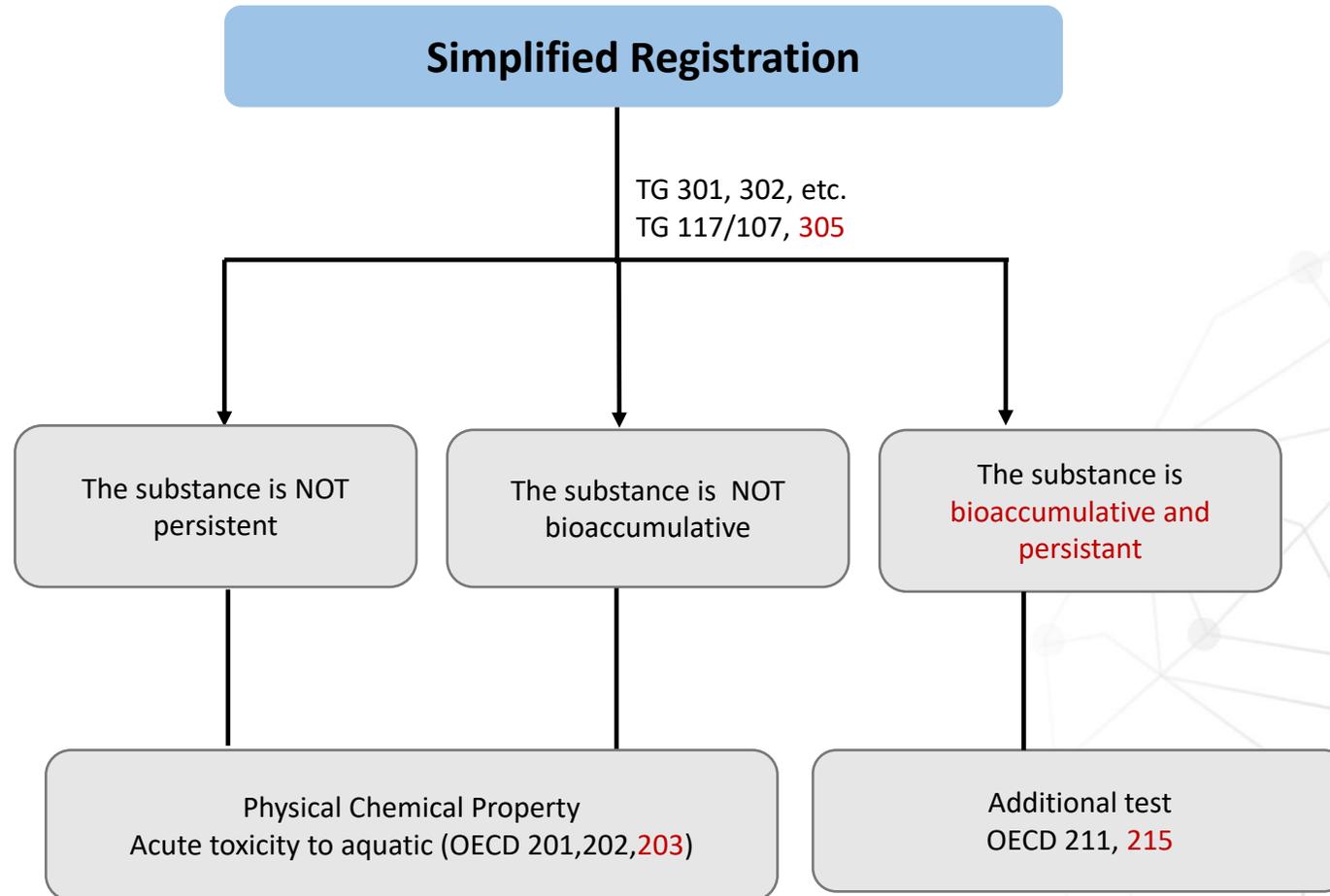


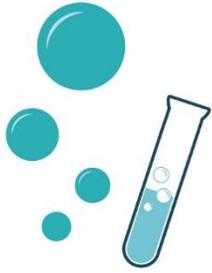
## 2.4 Key Points—Registration Types and Requirements

<b>Record Notification</b>	<ul style="list-style-type: none"><li>◆ Certification materials that meet the corresponding conditions</li><li>◆ Already known data concerning physical and chemical properties, health toxicology and ecotoxicological properties of the known new chemical substances</li></ul>
<b>Simplified Registration</b>	<ul style="list-style-type: none"><li>◆ Testing reports or materials of physicochemical properties, persistence, bioaccumulation and toxicity on aquatic environment, etc. of the new chemical substances.</li></ul>
<b>Regular Registration</b>	<ul style="list-style-type: none"><li>◆ Testing reports or materials of physicochemical properties, toxicological and ecotoxicological characteristics of new chemical substances, and risk assessment reports and other application materials.</li><li>◆ Socio-economic analysis materials shall be submitted when applying for regular registration of PBT substances, vPvB substances, or substances with the same hazards as theirs (<b>Highly Hazardous Chemical Substances</b>).</li></ul> <p><input type="checkbox"/> Physico-chemical properties + Basic endpoints</p> <ol style="list-style-type: none"><li>Health Toxicology</li><li>Ecological Toxicology</li></ol> <p><input type="checkbox"/> Persistent, Bioaccumulation, Toxicity Properties Evaluation</p> <p><input type="checkbox"/> Further data requirements and materials</p>

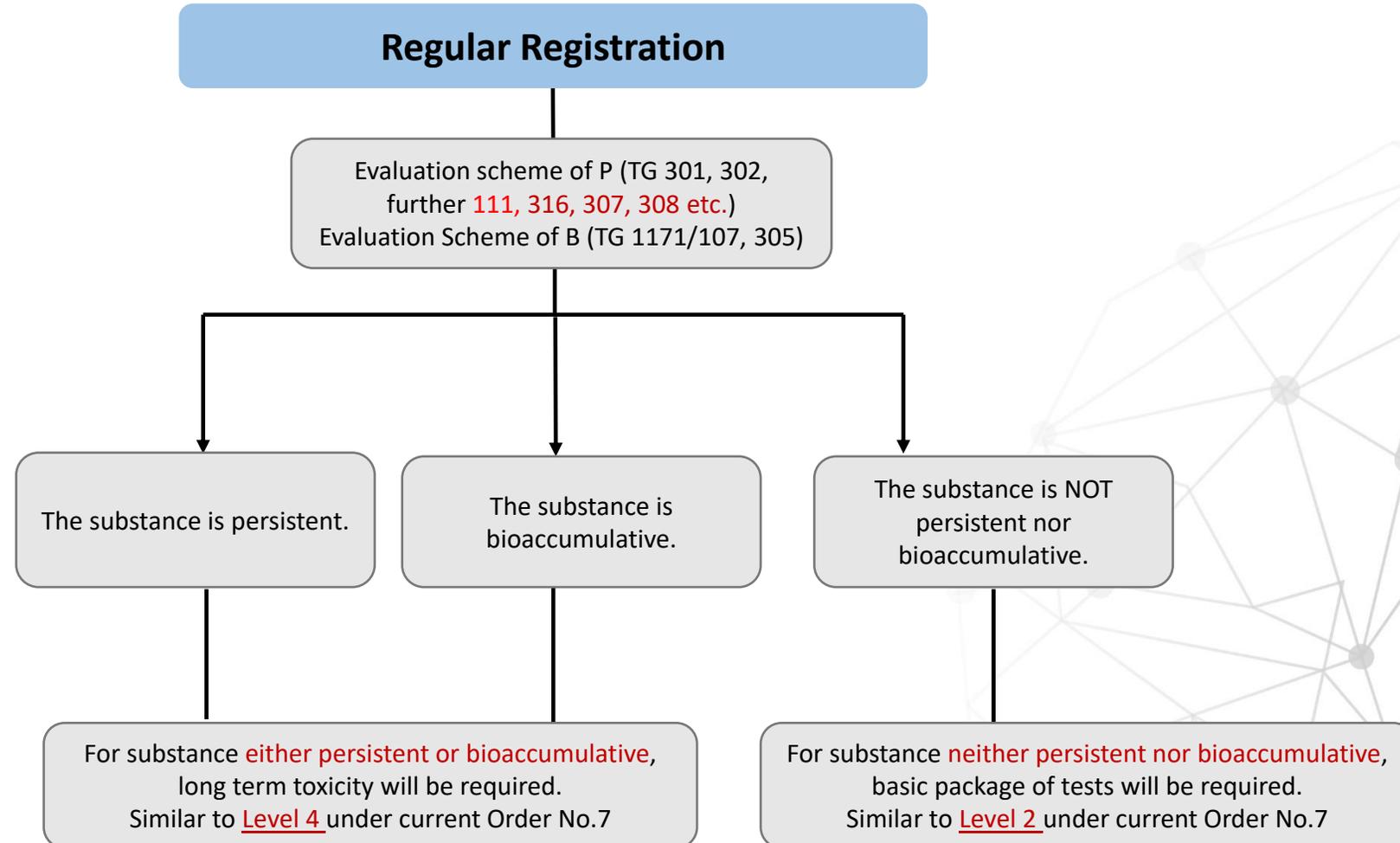


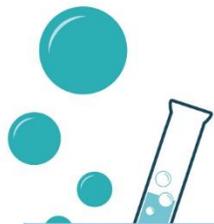
## 2.5 Key Points—Flow of Evaluation Process for Simplified Registration





## 2.6 Key Points—Flow of Evaluation Process for Regular Registration





## 2.7 Key Points—Special Rules on Polymer (Definitions)

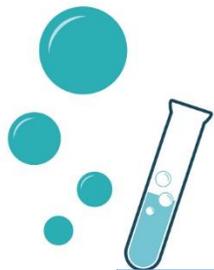
Item	Order No. 12
<b>Definition</b>	3 Criteria
<b>Naming Rules</b>	1) Naming based on the exact Molecular Structure 2) 2% Naming rule
<b>2% Polymer</b>	1) The polymer itself is not included in the IECSC, but all monomers/reactants (w/w) which are new chemical substances are with a content less than or equal to 2% in the polymer; 2) The polymer itself is not included in the IECSC, but all monomers/reactants of the polymer are included in the IECSC.
<b>Polymer of Low Concern (PLC)</b>	<p>1) The polymer's <b>number-average molecular weight</b> is between 1,000 and 10,000 Daltons. The content of oligomers in the polymer with molecular weight &lt;500 Daltons is less than 10% (w/w) and the content of oligomers with molecular weight &lt;1000 Daltons is less than 25% (w/w). At same time, the polymers must not contain functional groups of high concern or high reactivity, such as heavy metals, cyano, acrylate, aziridine, isocyanate, thio-isocyanate, vinyl sulfone, <b>alkoxy silane (methyl or ethyl), amine, helicene amine, halogenosilane, hydrazine, <math>\alpha/\beta</math>-lactone, methacrylic acid (ester) groups, etc.</b></p> <p>2) The polymer's <b>number-average molecular weight</b> is <math>\geq 10,000</math> Dalton. The content of oligomers in the polymer with molecular weight &lt;500 Daltons are less than 2% (w/w) and the content of oligomers with molecular weight of &lt;1,000 Daltons are less than 5% (w/w).</p> <p>3) The polymer is a polyester polymers, whose <b>main chain is the monomers bonded by ester bonds or whose main chain exhibits the characteristics of ester bonds.</b></p>



## 2.7 Key Points—Special Rules on Polymer (Exclusions)

### Exclusions Circumstances for Polymer Record (NEW)

- 1 **Cationic polymers** or **polymers expected to become cationic polymers** in natural water environment, such as polymers covalently bonded with phosphonium ion, sulfonium ion, ammonium ion, and polymers containing amidogen and isocyanate.
- 2 **Degraded or unstable polymer**, including polymers that are easily degraded, decomposed and depolymerized, and polymers that decompose after production or uses.  
Degradation, decomposition, or depolymerization refers to chemical changes that decompose polymers into simpler and smaller molecular weight substances through oxidation, hydrolysis, heat, light, solvents or microorganisms.
- 3 **Water-absorbing polymer** with number-average molecular weight is more than 10,000 Daltons.  
Water-absorbent polymers refer to polymers that can absorb their own weight of water, excluding water-soluble polymers and water-dispersible (including self-dispersed or dispersed) polymers.
- 4 **Perfluoroalkyl polymer** contains covalent bonding with carbon or sulfur atoms, such as polymers containing perfluoroalkyl sulfonic acid groups, perfluoroalkyl carboxylic acid groups, fluorine-containing telomers, etc.
- 5 Polymers containing elements other than the following permitted elements, excluding impurities:  
A polymer **must contain at least two** elements of carbon, hydrogen, nitrogen, oxygen, sulfur or silicon (C, H, N, O, S or Si).  
Additional elements: fluorine, chlorine, bromine and iodine (F, Cl, Br and I) covalently bounded to carbon, and chloride, bromide and iodide in the form of single ions (Cl<sup>-</sup>, Br<sup>-</sup> and I<sup>-</sup>)  
Other permitted single-ion elements include sodium, magnesium, aluminum, potassium and calcium (Na<sup>+</sup>, Mg<sup>+2</sup>, Al<sup>+3</sup>, K<sup>+</sup> and Ca<sup>+2</sup>), and lithium, boron, phosphorus, holmium, manganese, iron, nickel, copper, zinc, tin and zirconium (Li, B, P, Ti, Mn, Fe, Ni, Cu, Zn, Sn and Zr) with a weight percentage (w/w) less than 0.20%.



## 2.7 Key Points—Special Rules on Polymer (Simplified/Regular Registration)

Health Toxicology, Eco-Toxicology and Environmental Risk Assessment Report are exempted when all the following conditions are met:

1	Does not contain metals other than sodium, magnesium, potassium, calcium in structure; (used to be <b>Heavy metals</b> or <b>their cations</b> under Order No. 7)
2	Insoluble in water, lipophilic solvents (n-octanol, n-heptane) and general solvents ( <del>isopropanol, 1,2-dichloroethane, toluene, THF, methyl isopropyl ketone, DMF</del> );
3	Stable under acid or base conditions, stability tests carried out under the conditions of pH 4.0, 7.0, 9.0 and 1.2 (if physiologically important) have shown stability.
4	<del>Whether belongs to PLC</del>

1. Under Order No. 7, there's no need for **Environmental Risk Assessment Report** for Polymer Regular Notification, and **Health Toxicology** and **Eco-toxicology** could be exempted if it meets the above criteria.

2. Under Order No. 12, both Simplified and Regular Registrations need to **fill in more data gap** and **CSR may be required** in accordance to the registration type, if it doesn't meet all above criteria.

RISK ASSESSMENT,  
YES

## 2.7 Key Points—Special Rules on Polymer (Evaluation Flow)



**New Polymer**

2% Rule  
PLC

NO

YES

Five Exclusions  
one by one

NO

YES

**Record Filing**

Manufacture  
/import  
volume

Over 1 MT/y

Volume less than 1 MT/y

Simplified  
or Regular  
Registration  
based on  
the volume

Does not contain  
metals other than  
Na, Ma, K, Ca in  
structure;

Insoluble in Water,  
Lipophilic solvents,  
THF, DMF

Chemical  
composition does  
not change in  
neutral, acid, and  
alkaline water.

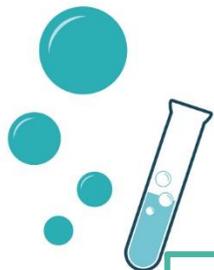
Does the  
new  
polymer  
meet all  
three  
conditions?

NO

YES

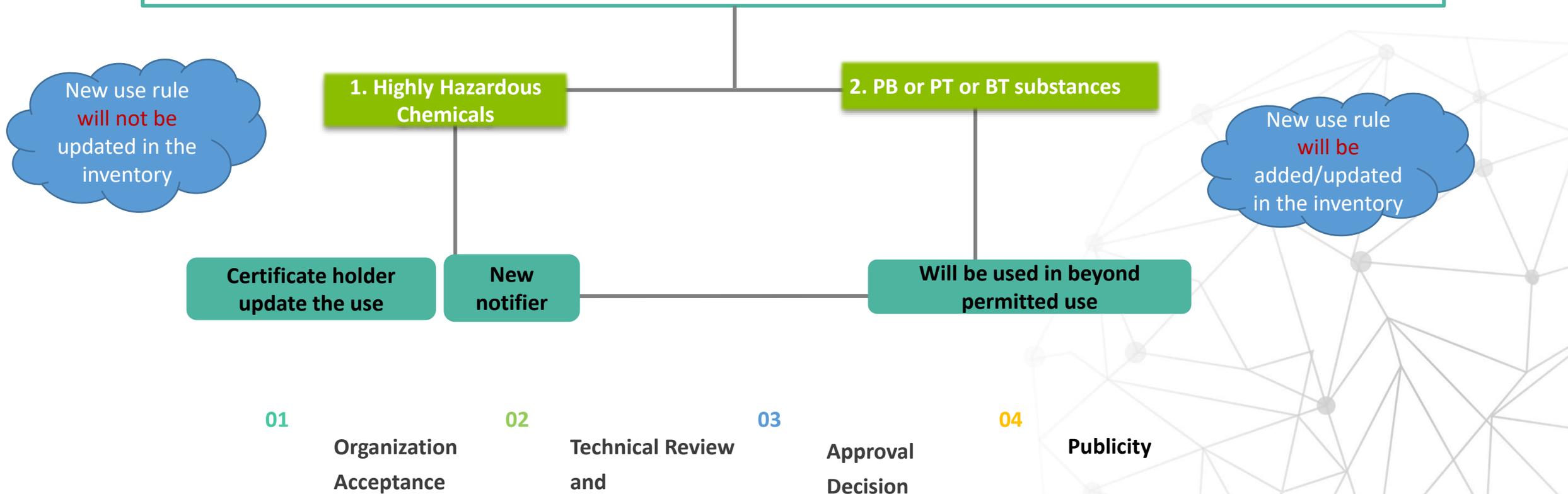
Toxicology  
Eco-toxicology  
CSR (if needed)

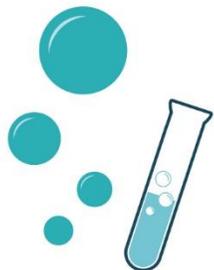
No further  
data, but  
follow  
registration  
work



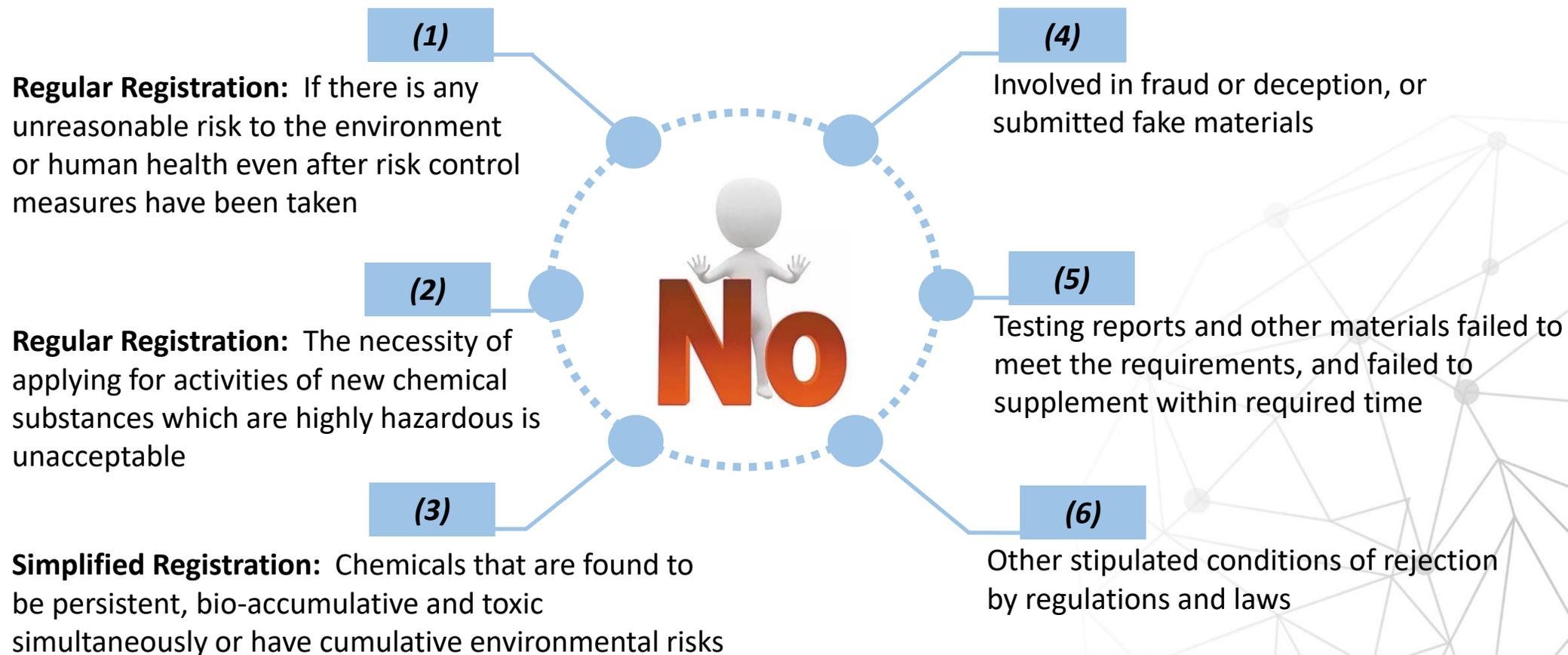
## 2.8 Key Points—New Use Management

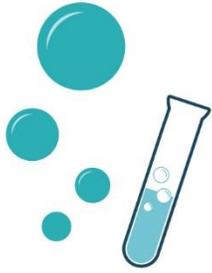
- 1) The substance has been listed into the IECSC and with a new usage environmental management identification;
- 2) The substance is to be used for industrial applications other than those permitted in the IECSC; for highly hazardous chemical substances, the applicant has not obtained the Regular Registration Certificate for the intended usage.





## 2.9 Key Points— Conditions of Rejection





## 2.10 Key Points—Activity Reporting



### Cancelled

- Every time transfer activity report;
- Five-year actual activity reports



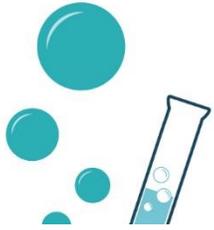
### First Time Activity Report

- Within **60 days** of first-time production activity;
- Within **60 days** of first-time import and transport to the processors and users, shall submit a first activity report
- Apply for both Simplified Registration and Regular Registration

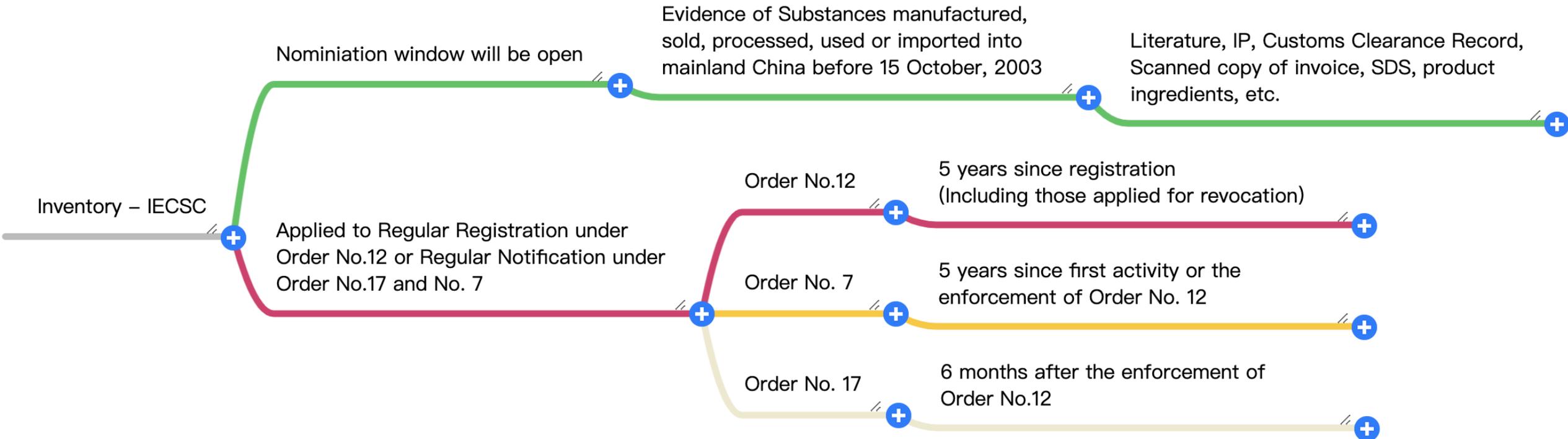


### Annual Reports

- Submit Annual Report if required to be submitted according to the environmental management requirements in the Regular Registration Certificate
- Submit before **April 30 annually** (currently Feb 1)
- Regular Notification certificate obtained under MEP Order No. 7 and the substance was categorized as Hazardous Chemical of Priority Environmental Concern, Annual Report is still required

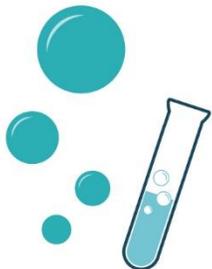


## 2.11 Key Points—Listing Into IECSC



MEE lists the above substances into IECSC through public announcements.

Use scope will be restricted for Highly Hazardous Substances and PB/PT/BT substances.



## 2.12 Key Points—Transitional Measures (Oct 27, 2020)

名称	关于新化学物质环境管理登记有关衔接事项的公告		
索引号	000014672/2020-01349	分类	固体废物与化学品管理
发布机关	生态环境部	生成日期	2020-10-27
文号	公告 2020年 第46号	关键词	

**关于新化学物质环境管理登记有关衔接事项的公告**

《新化学物质环境管理登记办法》(生态环境部令12号,以下简称12号令)将自2021年1月1日起施行,2010年1月19日原环境保护部发布的《新化学物质环境管理办法》(环境保护部令7号,以下简称7号令)同时废止。为保证新化学物质环境管理登记工作的有序延续,现将有关衔接事项通知如下。

一、常规申报衔接规定

自12号令生效之日起,根据7号令取得新化学物质环境管理常规申报登记证的新化学物质:

(一) 环境风险控制措施落实

登记证持有人和相应的加工使用者,应当按照登记证的规定采取环境风险控制措施。

(二) 信息传递报告和记录保存

登记证持有人应当按照12号令第二十八条、第二十九条、第四十一条、第四十二条规定进行信息传递、资料记录及保存、首次活动情况报告和新危害信息报告;其中,属于7号令第三条规定的重点环境管理危险类新化学物质的,还应当按照12号令第四十一条规定提交年度报告。

(三) 申请撤销登记证

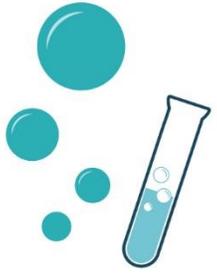
登记证持有人可以按照12号令第三十三条规定,向国务院生态环境主管部门申请撤销登记证。

(四) 新用途登记规定



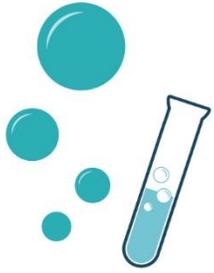
### MEE Order No. 12

- ❑ MEE Order No. 12 will replace current MEP Order No. 7 when it comes into force.
- ❑ Regular Notification Certificates obtained under current MEP Order No. 7 will remain valid, and the notified substances will be listed into the inventory by MEE after 5 years since first activity or 5 years since MEE Order No. 12 comes into force.
- ❑ Simplified Notification (Basic & Special Case) Certificates obtained under current MEP Order No. 7 will stay valid.
  - ❑ PPORD period of validity is two (2) years after first-time activity
- ❑ Notification Certificates obtained under SEPA Order No. 17 (precursor to MEP Order No. 7) will stay valid, and the notified substances finished Normal Notification will be listed into the inventory by MEE within 6 months of implementation of MEE Order No. 12.
- ❑ Registration certificate holders shall apply for new record notification or registration if any information in original certificate changes which will raise the risk
- ❑ For new chemical registrations that are accepted before MEE Order No. 12 enters into effect, they will be handled according to MEP Order No. 7 until Jun 30, 2021; where a certificate cannot be obtained for such applications before Jun 30, 2021, they will be handled according to MEE Order No. 12.

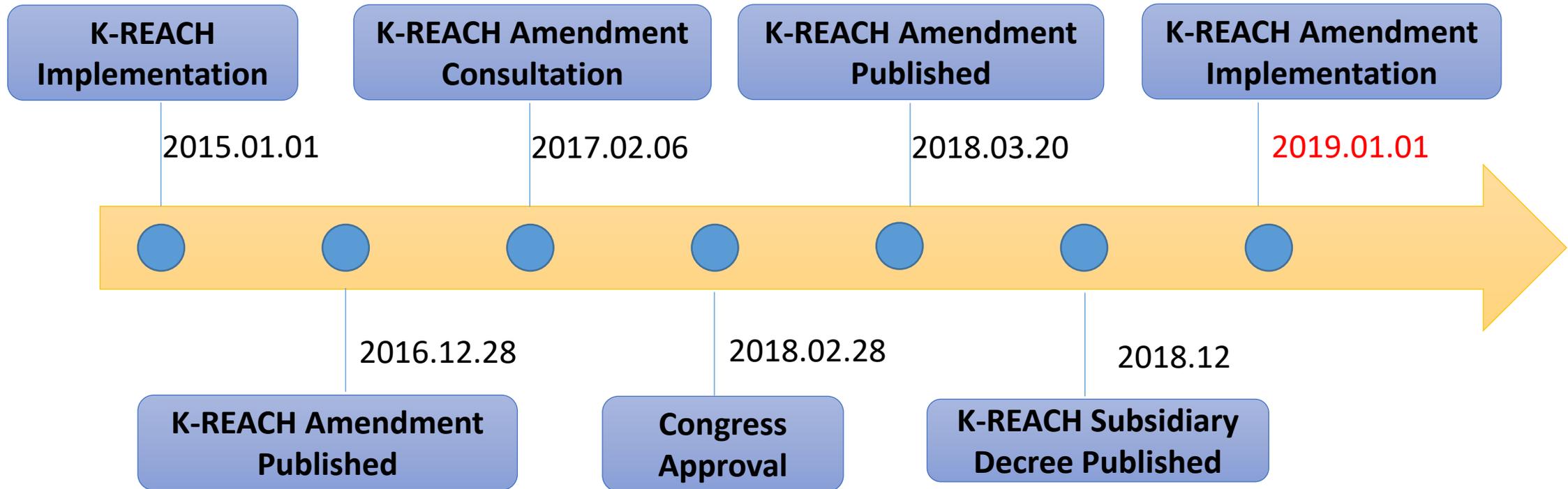


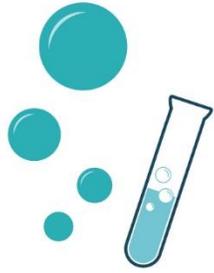
# Korea



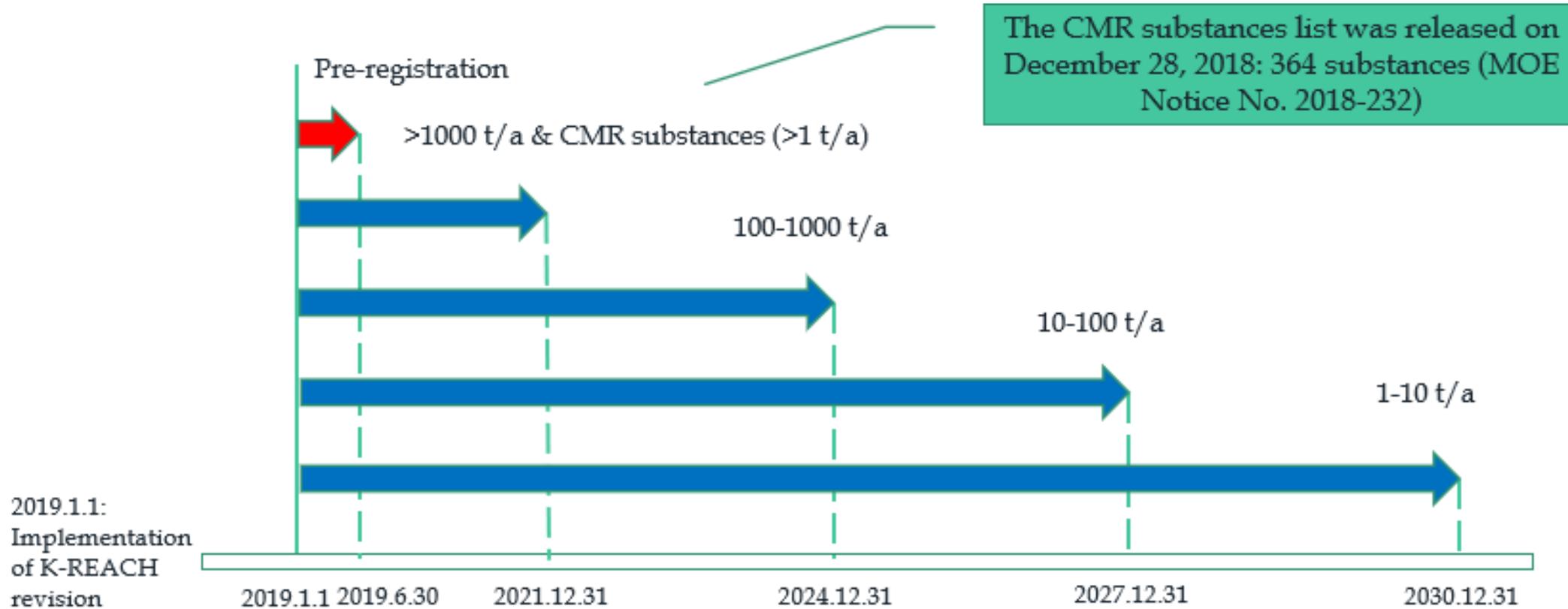


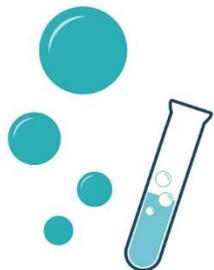
# K-REACH Development





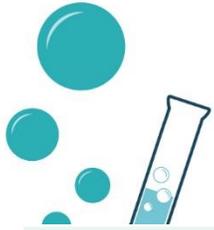
# Registration Deadlines of Different Tonnage Bands





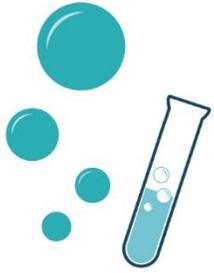
## Status of K-REACH (Late) Pre-Registration (as of July 23 , 2020)

As of July 23, 2020		~2021 (1t+CMR, 1000t+)	~2024 (100-1000t)	~2027 (10-100t)	~2030 (1-10t)
Substances	16941	1963 (11%)	2681 (16%)	5581 (33%)	6716 (40%)



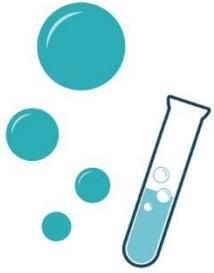
# 1000+t/a Registration Schedule

Contents		2019.4Q	2020.1Q	2020.2Q	2020.3Q	2020.4Q	2021.1Q	2021.2Q	2021.3Q	2021.4Q	2022
Formation of CICO	LR election										
	Kick off meeting										
	CICO Survey										
	Agreement signing										
	SIP confirmation										
Preparation of materials for joint registration	Data gap analysis										
	Data acquisition										
	CSR preparation										
	Dossier preparation										
Registration dossier submission	LR dossier submission										
	AM dossier submission										
	Sell LoA to PM										
	PM dossier submission										
Late-registration management	Cost settlement										
	Sale of LoA to late registrants										
	Response to Authority's request										



# Taiwan

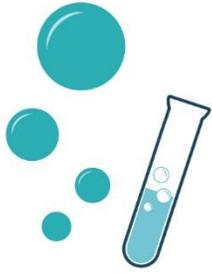




## Priority Existing Chemicals (PECs) Subject to Standard Registration

The **Registration Regulation** is under revising, in which a big change is that the Registration deadline for 106 PECs will be postponed

		Current	After Revision
PECs which completed pre-registration/late pre-registration before 2020	1-100 t/a	Deadline: 31 Dec 2022	<b>Deadline: 31 Dec 2023</b>
	>100 t/a	Deadline: 31 Dec 2021	<b>Deadline: 31 Dec 2023</b>



# Priority Existing Chemicals (PECs) Subject to Standard Registration

## Taiwan Releases **Guidance for Priority Existing Chemical Substances Registration** on June 9

### *Key Points*

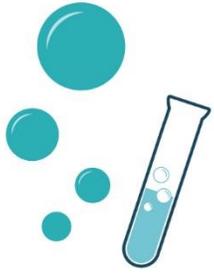
#### □ **Priority of Accepted Data**

International public databases → Testing proposal → Non-testing method (QSAR, Read across, systematic review) → Testing

Totally 16 International public databases

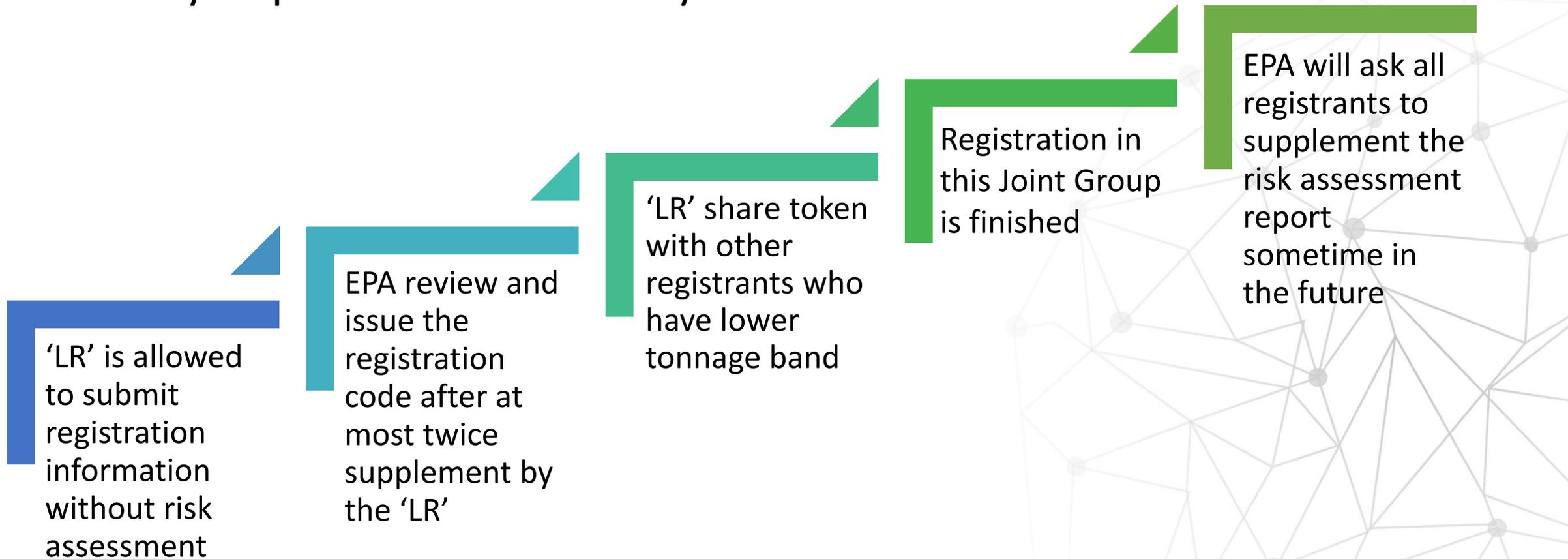
Including ILO ICSC, IPCS, IARC, WHO, OECD SIDS, EC Joint Research Center, EU RAR, US EPA, ATSDR, NTP, ChemIDplus, CCRIS, GENE-TOX Data, NITE-CHRIP, NICNAS-Priority Existing Chemical (PEC) assessment

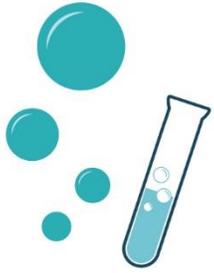
National Industrial Chemicals Notification and Assessment Scheme



## Priority Existing Chemicals (PECs) Subject to Standard Registration

The Risk Assessment (Hazard & Exposure Assessment) is **NOT** necessarily required at the time of your submission





# Annual Reporting

Year 2020 is the first year which requires registrants to submit annual report



## Who shall report?

- Local importers and manufacturers
- TPRs (after authorized by the Local importers and manufacturers through IT platform)
- ~~Overseas suppliers are not allowed to report~~



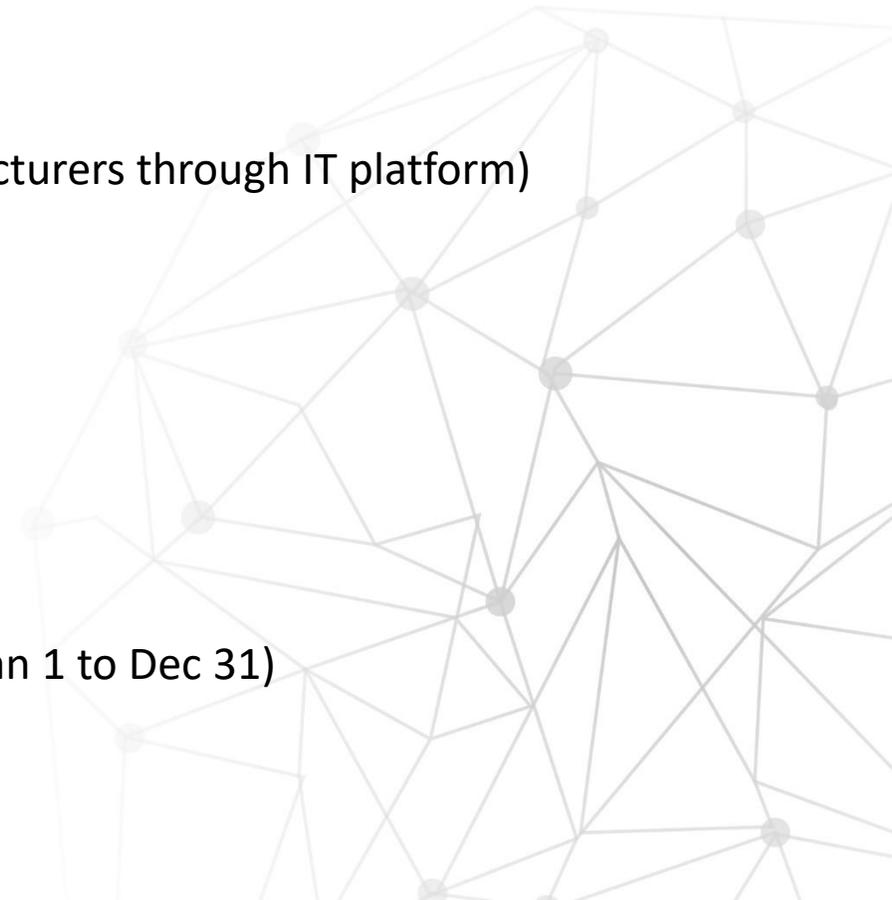
## When to report?

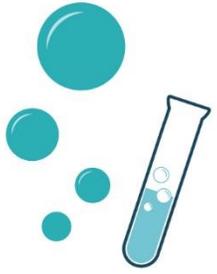
- April 1 to September 30



## What to report?

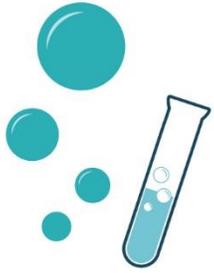
- The manufacture and import volume in last calendar year (Jan 1 to Dec 31)
- If no manufacture or import, submit '0' on the platform





# Australia





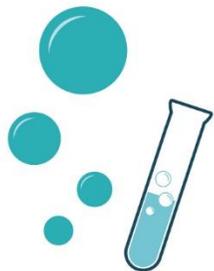
# Australian Industrial Chemicals Introduction Scheme (AICIS)

National Industrial Chemicals Notification  
and Assessment Scheme (NICNAS)



Australian Industrial Chemicals Introduction Scheme (AICIS)

Effective on July 1, 2020

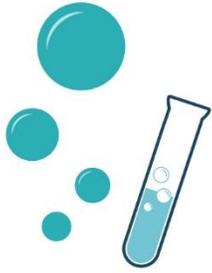


# Australian Industrial Chemicals Introduction Scheme (AICIS)

## Principles and Key Functions of the New Scheme

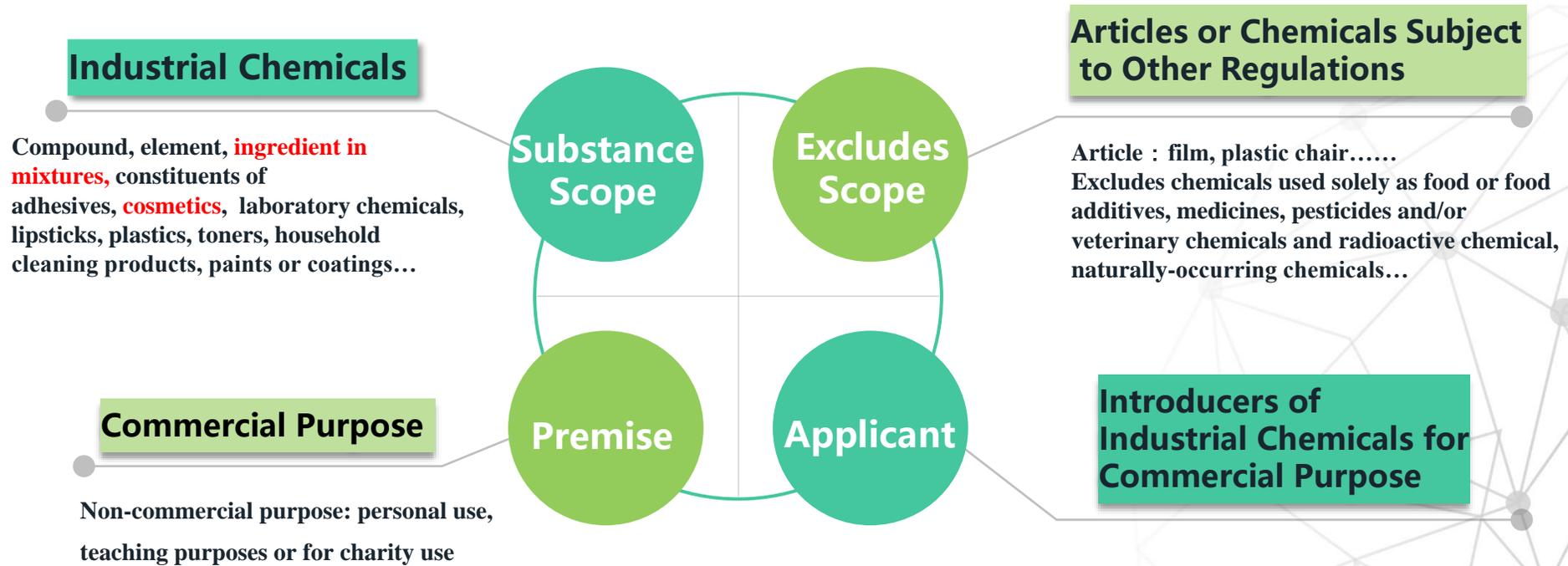
- Risk-Proportionate Regulation → **Six (6) Categories of Introduction**
- Rebalanced Pre-Introduction versus Post-Introduction Controls
- Incentivized Lower Risk Chemical Introductions
  - ❑ Less pre-introduction assessment by focusing on assessing higher risk introductions
  - ❑ More post-introduction monitoring and evaluation
- Flexible and responsive process for evaluating chemicals on the market

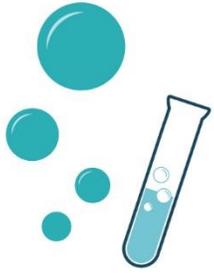




# Australian Industrial Chemicals Introduction Scheme (AICIS)

## AICIS Management Scope

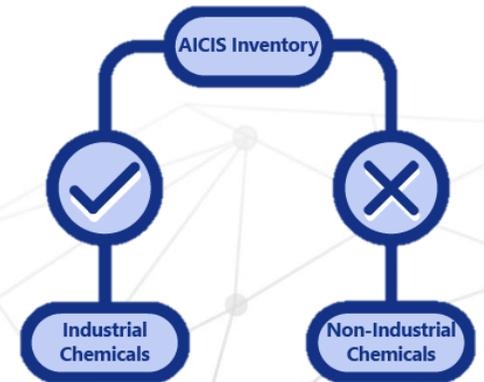




# Australian Industrial Chemicals Introduction Scheme (AICIS)

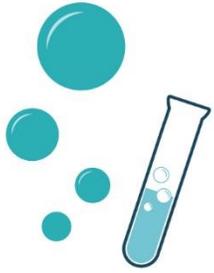
## AICIS Inventory

- The Australian Inventory of Industrial Chemicals (AIIC)
- Basis for the notification of new substances and the criteria for distinguishing non-listed substances from listed substances
- Chemicals that have **never had an industrial use** will not be included in the AIIC Inventory
- **No confidential inventory under AIICS**, chemical will be marked as confidential on public
  - no disclosure of chemical details



### List of chemicals with non-industrial uses that were removed from the old NICNAS Inventory (AICS):

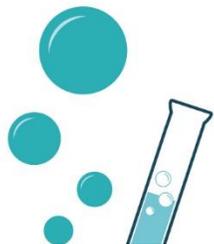
<https://www.industrialchemicals.gov.au/news-and-notice/chemicals-non-industrial-uses-removed-australian-inventory-chemical-substances-old-inventory>



# Australian Industrial Chemicals Introduction Scheme (AICIS)

## Introducer Obligations





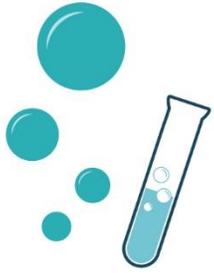
# Australian Industrial Chemicals Introduction Scheme (AICIS)



## AICIS Business Registration

- Legal requirement for all Introducers (importers or manufacturers) of industrial chemicals in Australia
- Pay annual fee and a charge – according to **total value** of the industrial chemicals you imported or manufactured in the **previous financial year** (8 levels)
- Amounts to change – cost recovery consultation

Value of industrial chemicals introduced in the previous financial year	Fee (AUD) GST does not apply	Charge (AUD) GST does not apply	Total (AUD) GST does not apply
Level 1 - \$0 to \$49,999	\$72	nil	\$72
Level 2 - \$50,000 to \$74,999	\$72	\$75	\$147
Level 3 - \$75,000 to \$99,999	\$72	\$100	\$172
Level 4 - \$100,000 to \$249,999	\$72	\$250	\$322
Level 5 - \$250,000 to \$499,999	\$72	\$500	\$572
Level 6 - \$500,000 to \$2,999,999	\$72	\$3,000	\$3,072
Level 7 - \$3,000,000 to \$4,999,999	\$72	\$5,000	\$5,072
Level 8 - \$5,000,000 or more	\$72	\$40,000	\$40,072

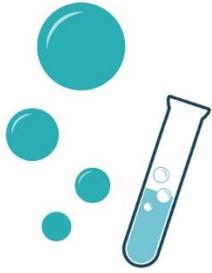


# Australian Industrial Chemicals Introduction Scheme (AICIS)

## Know What You're Introducing

- Work out the 'Category' of each Introduction
- The Category determines what other regulatory obligations apply to the Chemical Introduction
- Check all your ingredients against the Inventory
- Ignorance can be an offense





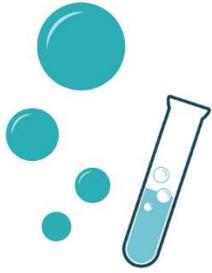
# Australian Industrial Chemicals Introduction Scheme (AICIS)

## Understand Your Introduction Category

- Six (6) Categories of Introduction:

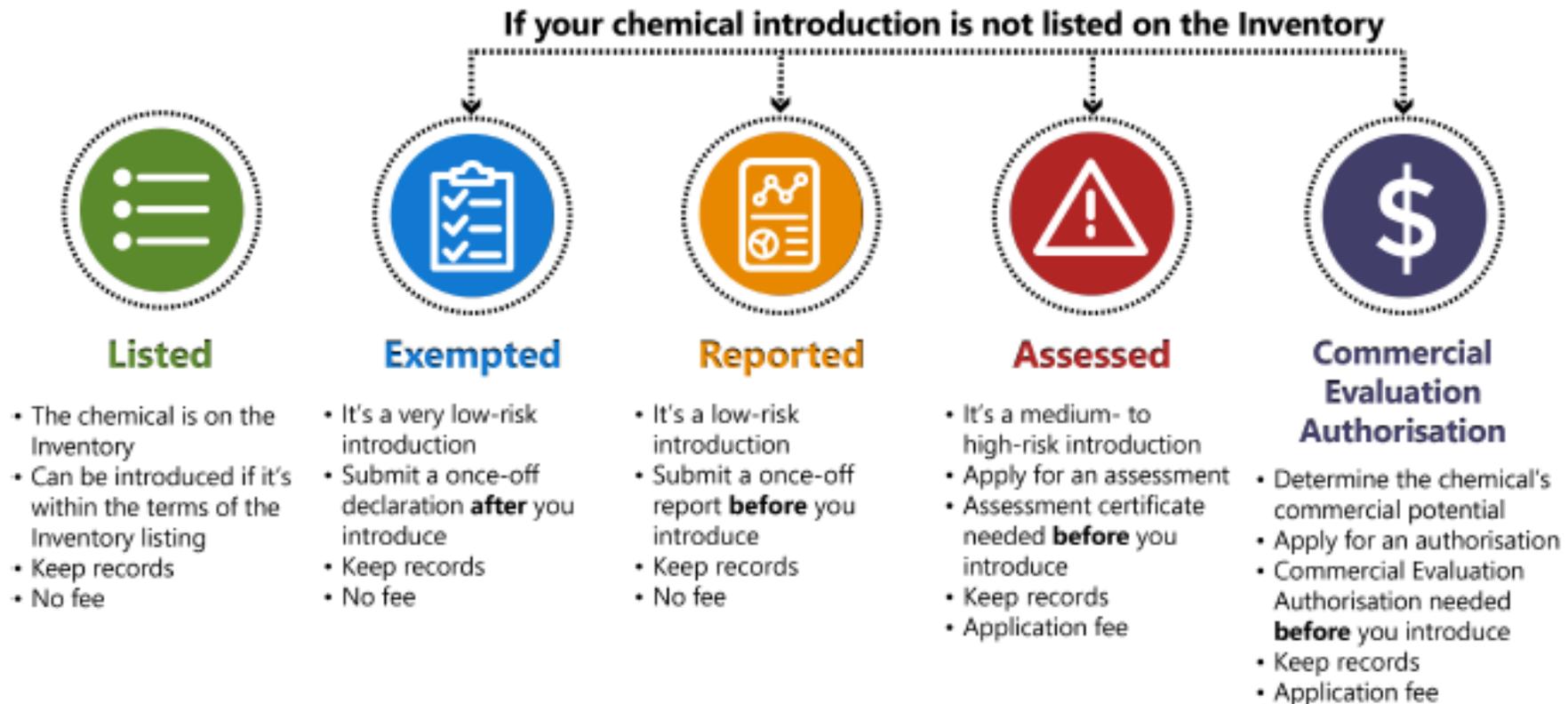


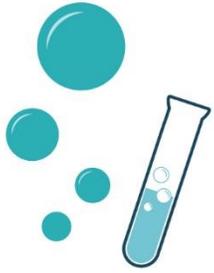
Category	Scope
Listed Introductions	Chemicals listed on the Inventory and Introduction is within the terms of the listing (if any)
Exempted Introductions	Chemicals with <b>very low risk</b>
Reported Introductions	Chemicals with <b>low risk</b>
Assessed Introductions	Chemicals with <b>medium to high risk</b>
Commercial Evaluation Introductions	Time Limited Authorizations granted for testing the market viability of the chemical before full introduction
Exceptional Circumstances Introductions	Ministerial Authorization to allow urgent introduction to protect public health or the environment



# Australian Industrial Chemicals Introduction Scheme (AICIS)

## Different Category/Different Obligations





# Australian Industrial Chemicals Introduction Scheme (AICIS)

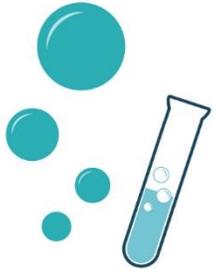
## Work Out Your Introduction Category

**Information you might need if your Introduction is NOT in the listed category**

- Introduction volume
- Introduction concentration
- End use concentration
- End use
- Hazard information

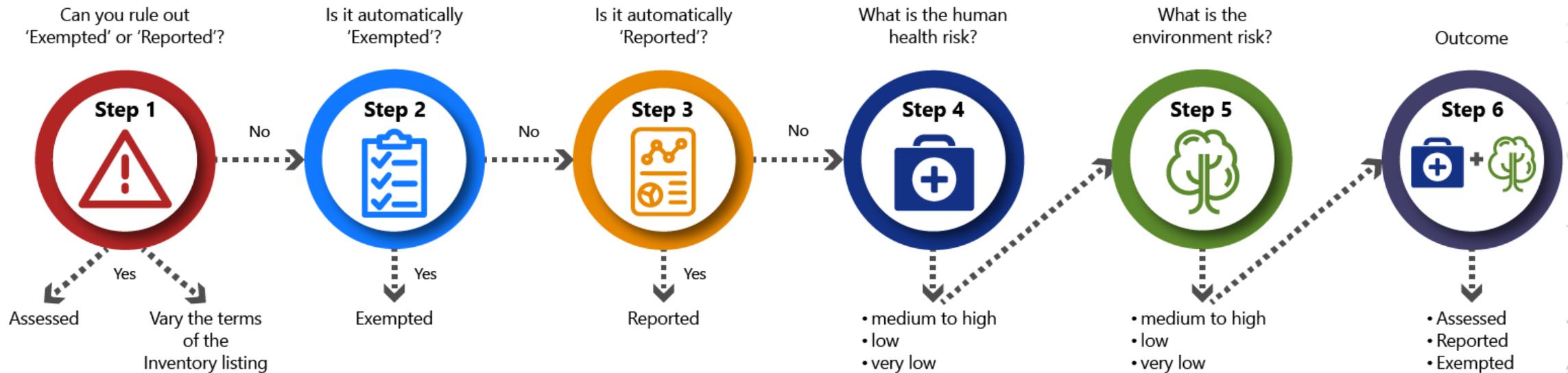
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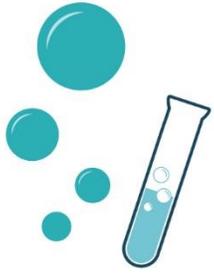




# Australian Industrial Chemicals Introduction Scheme (AICIS)

## Work Out Your Introduction Category



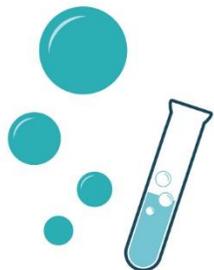


# Australian Industrial Chemicals Introduction Scheme (AICIS)

## Record-Keeping

- Information necessary to demonstrate:
  - ❑ What industrial chemicals you introduced and what category
  - ❑ How you determined categories
  - ❑ How you determined your registration charge
- Information about animal testing
- Information if required by a term of an Inventory listing
- Post-assessment information obligations
- Records must be kept for 5 years



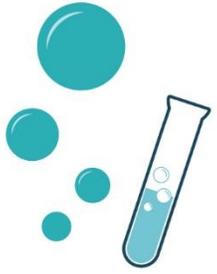


# Australian Industrial Chemicals Introduction Scheme (AICIS)

## Giving Information to AICIS

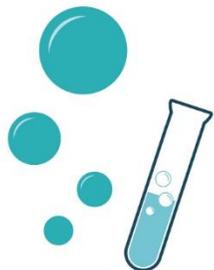


- Executive Director can request information in various circumstances:
  - ❑ Any information required to be kept (record-keeping)
  - ❑ In relation to a risk assessment (pre- or post-introduction)
  - ❑ As part of monitoring and compliance activity
- Requests must be in writing
- Requests will have a deadline of at least 20 working days



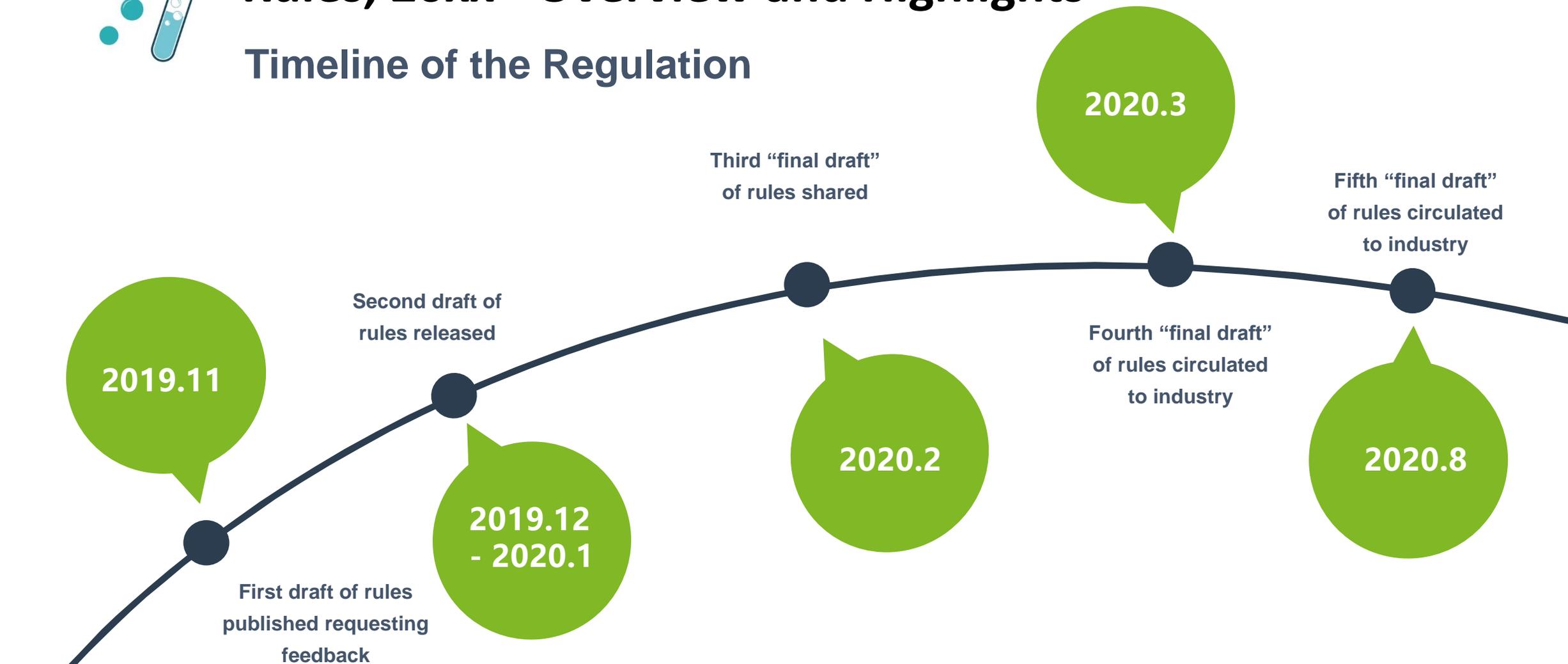
# India

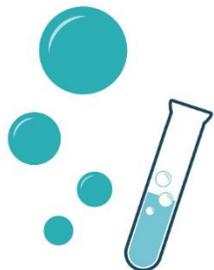




# India Draft Chemicals (Management & Safety) Rules, 20xx - Overview and Highlights

## Timeline of the Regulation





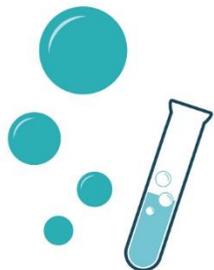
# Chemical Regulatory Division Structure of Responsibilities (under National Chemical Authority)

## Units of the Chemical Regulatory Division (8):

- 1) Chemistry Unit
- 2) Toxicology Unit
- 3) Chemical Accidents Unit
- 4) Packaging and Labelling Unit
- 5) Techno-Legal Unit
- 6) Priority Substance Unit
- 7) Information Technology Unit; and
- 8) Socio-Economic Unit



In addition, three (3) committees will be set up, including: Steering Committee, Scientific Committee, and Risk Assessment Committee.



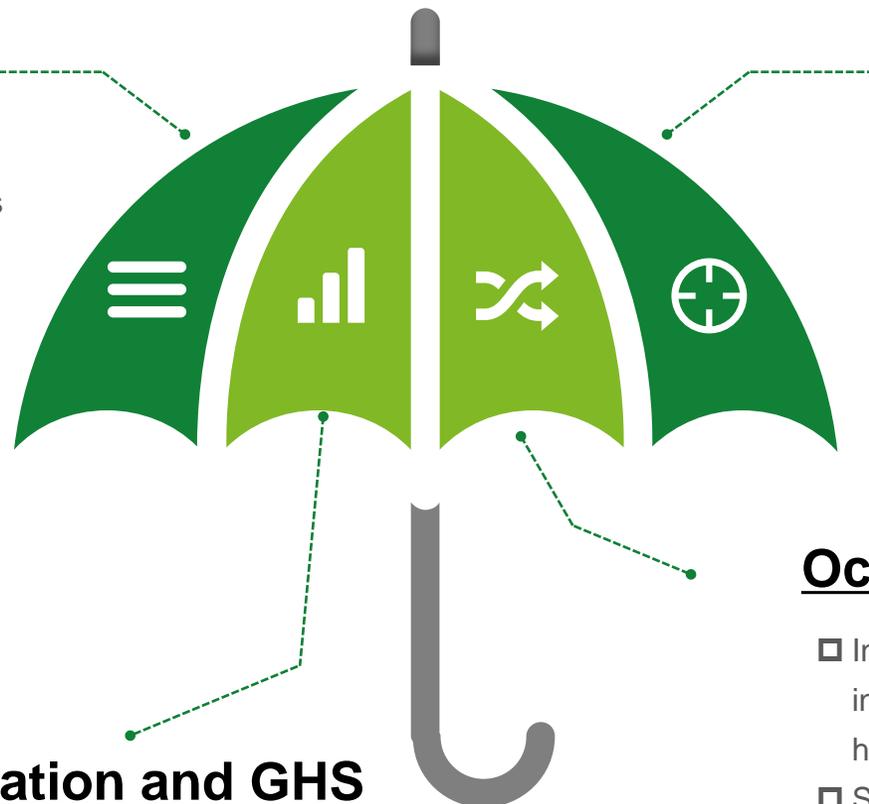
## Highlights of The Rule

### Initial-Notification and Notification

- ❑ Initially notify the Division of all existing substances that have been placed in Indian market (>1 t/a, 1 year after the rule enactment, 180 days period);
- ❑ Notify the division of any new substance **60 days** before manufacture or import;
- ❑ Notify the division of any existing substance >1t/a after the initial period.
- ❑ Exemptions:
  - ❑ Special rules for intermediates
  - ❑ Include identity, **spectral data**, uses, quantity, classification (GHS Rev 8), SDS, etc.;
  - ❑ May have evaluation or restriction

### Classification and GHS

- ❑ Using the eighth revision of GHS (GHS Rev 8);
- ❑ SDS, labeling and packaging will be in accordance with the GHS;
- ❑ Transport of hazardous chemicals are under control

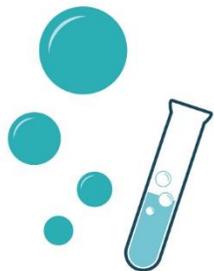


### Registration and Testing

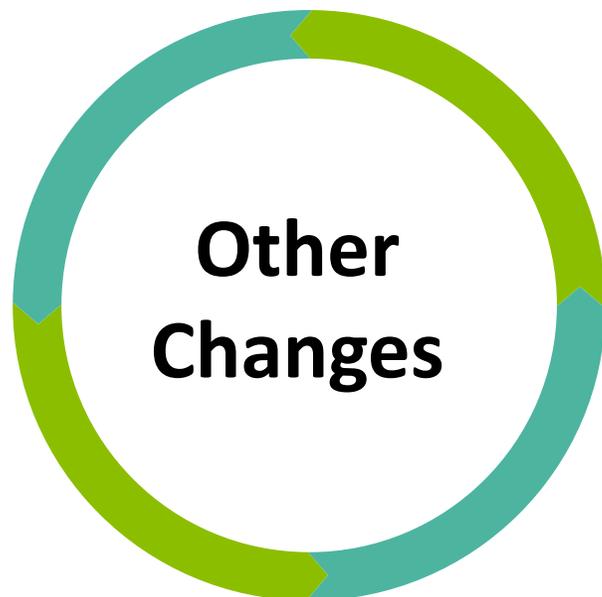
- ❑ Register all **“substances required to be registered”** in India (>1 t/a, **750 substances from Schedule II, 1.5 years time limit per registration**);
- ❑ Special rules for intermediates;
- ❑ Need to submit technical dossier;
- ❑ **Data for substances already registered with foreign regulator is acceptable.**
- ❑ **Testing strategy approved before conducting new testing; test must be carried out in NABL or GLP certified lab;**
- ❑ **CSR for >10t/a, exposure scenario for 1-10**
- ❑ May have risk evaluation or restriction

### Occupational Safety and Health

- ❑ Industry occupier should submit information relating to industrial activity and site safety report in which a hazardous chemical is handled;
- ❑ Safety audit report is required for the exceeding the threshold quantity of column 4 of Schedules XI or XII;
- ❑ Emergency Plan and notification of chemical accidents are regulated



## Other Changes for the Fifth Draft



### Authorised Representative (AR)

- Indian national or Indian entity, **but** with sufficient background in practical handling of substances and with minimum average net worth of ten times the average value of substances dealt during the last calendar/financial year.



### Changes to Schedules

- Schedule VI was changed to "Restricted or Prohibited Substances" and Schedule II changed from "List of Priority Substances" to "List of Priority Substances required to be Registered"

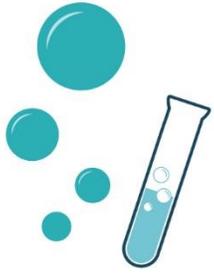


### Test Data

- Data for substances already registered with foreign regulator is acceptable.
- To avoid repeated testing, existing test data must be considered prior to requiring new testing. The Registrant must propose a testing strategy and get it approved by the Division before conducting any new test.

Thailand

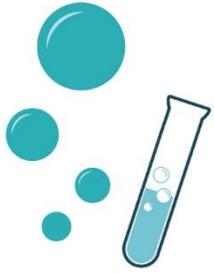




## Hazardous Substance Control Act B.E. 2535 (1992)

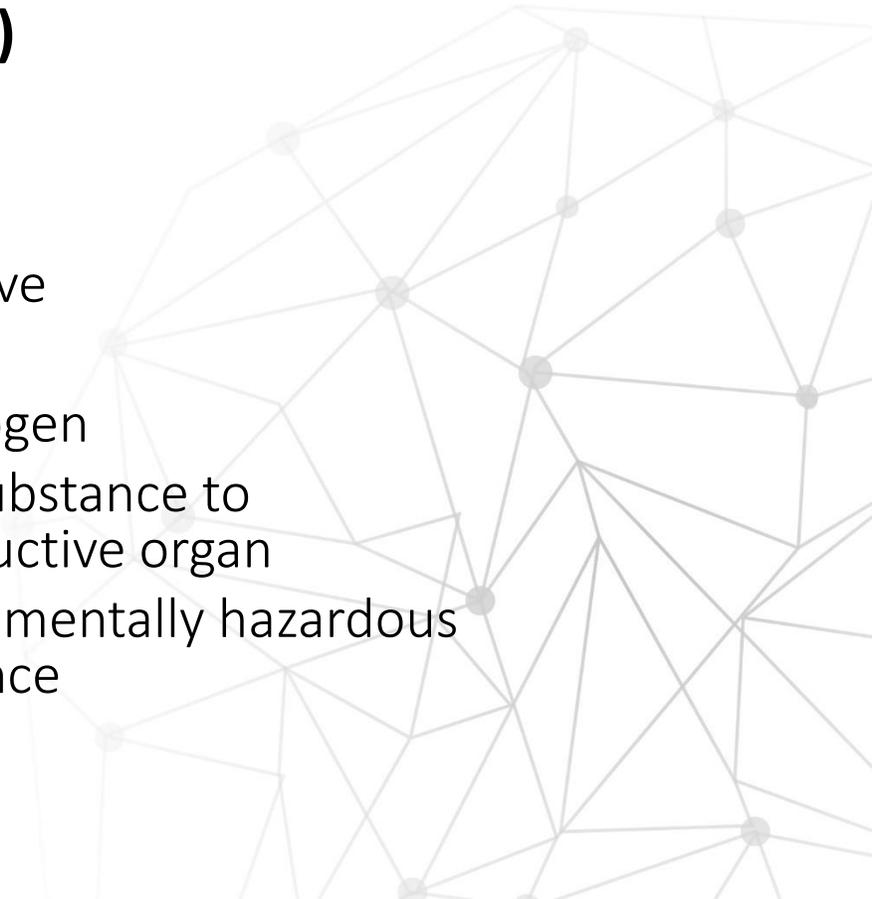
- Hazardous Substance Control Act B.E. 2535 (1992)
- Competent Authorities (6):
  - Department of Industrial Works (DIW)
  - Department of Agriculture (DOA)
  - Department of Fisheries (DOF)
  - Food and Drug Administration (FDA)
  - Department of Energy Business (DOEB)
  - Department of Livestock Development (DLD)
- B.E. 2556 (2013), List of Hazardous Substances
- B.E. 2558 (2015), Notification of Hazardous Chemicals

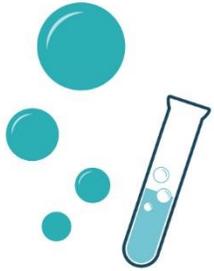




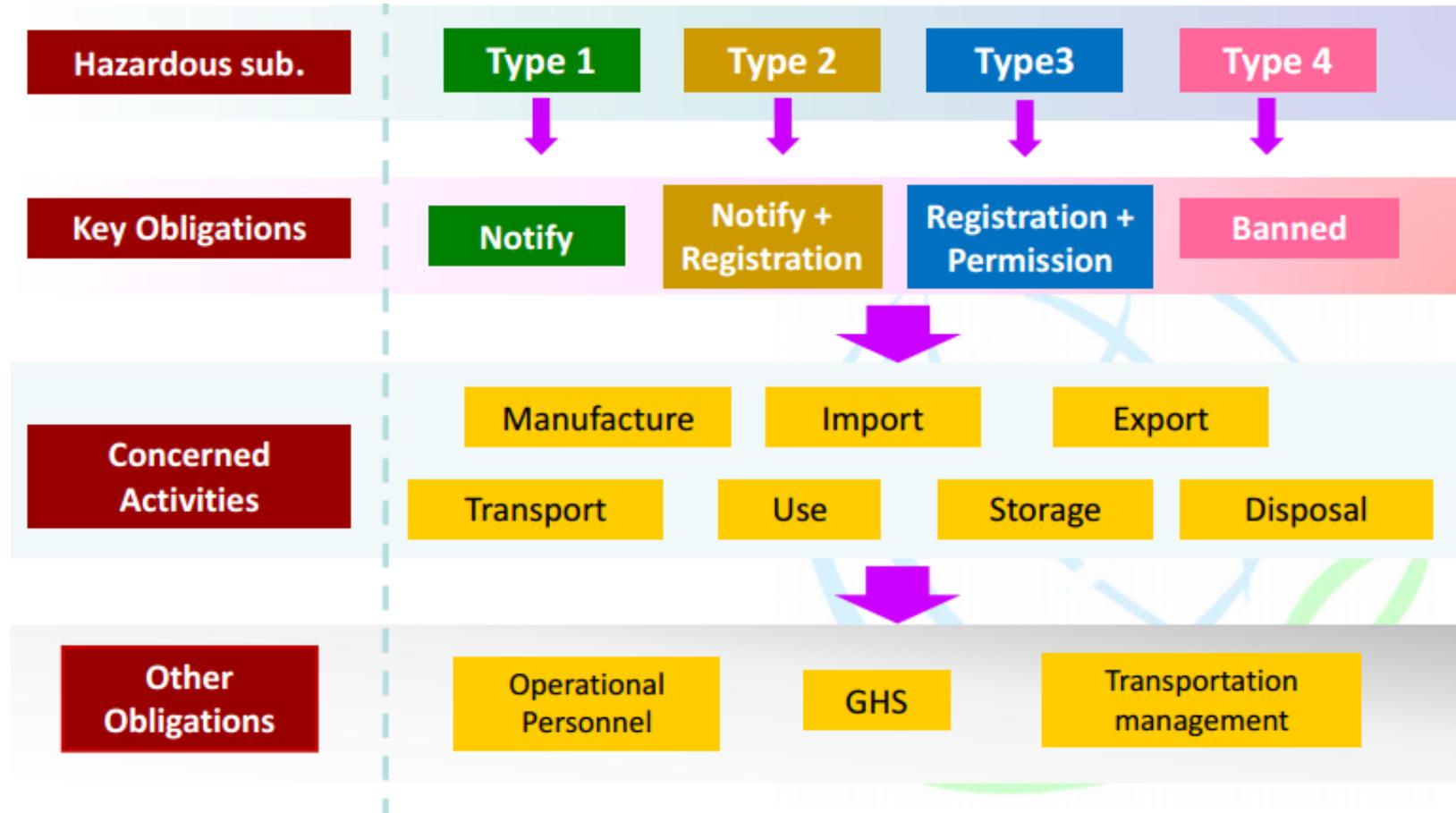
## Hazardous Substance List

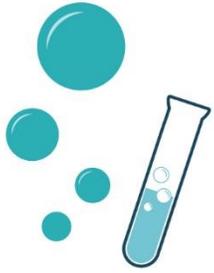
- **Annex 1, Annex 2, Annex 3, Annex 4, Annex 5 (5.6), Annex 6 (based on Responsible Authorities)**
- **Type 1, Type 2, Type 3, Type 4 (based on hazard)**
- Hazardous Substances List > 1,500 entries
- **Annex 5.6 (10 Properties):**
  - 1) Explosives
  - 2) Flammable substances
  - 3) Oxidizing agents and peroxides
  - 4) Toxic substances
  - 5) Mutagen
  - 6) Corrosive
  - 7) Irritant
  - 8) Carcinogen
  - 9) Toxic substance to reproductive organ
  - 10) Environmentally hazardous substance





# HSCA Management Structure





# Thailand Chemical Inventory Notification - B.E. 2558 (2015)

- **Scope**

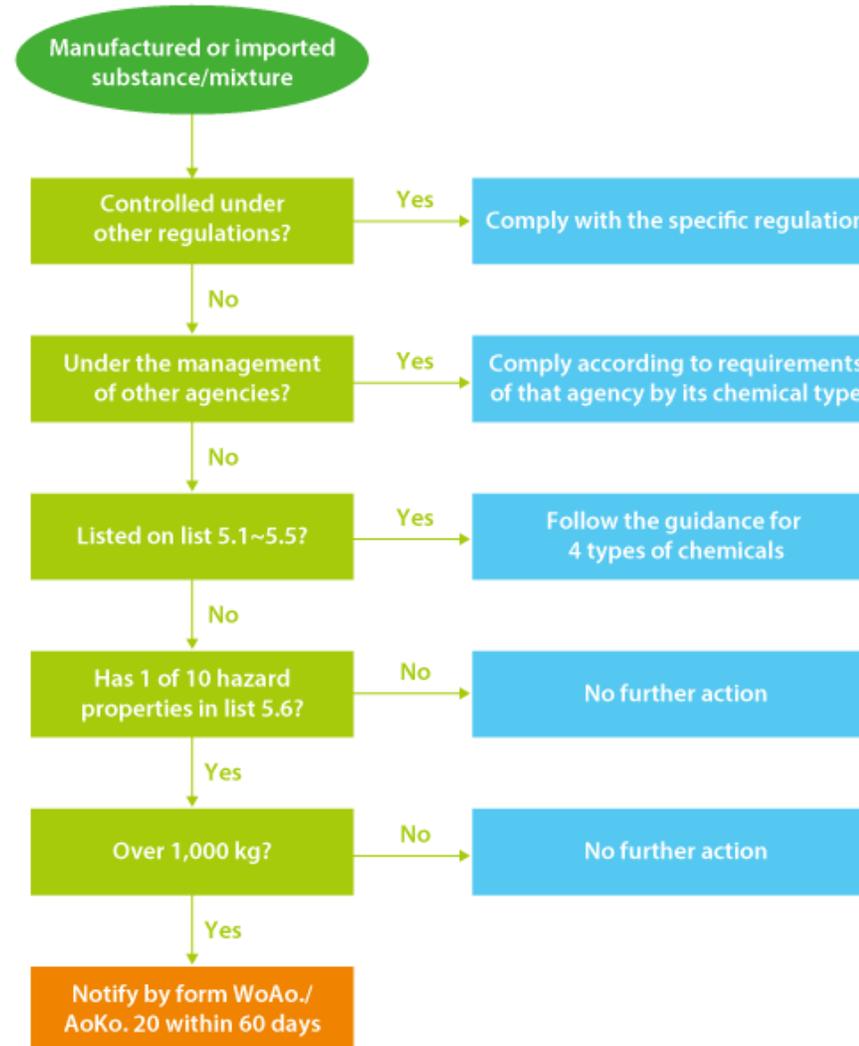
- Annex 5.6: 10 hazardous properties
- >1 t/y;
- Substances and mixtures
- **Manufactures and importers**

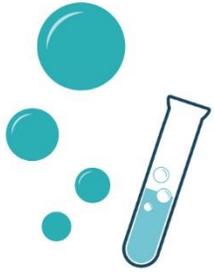
- **Exemption**

- Chemicals controlled under other regulation
- Chemicals controlled under other authorities

- **Main purpose:**

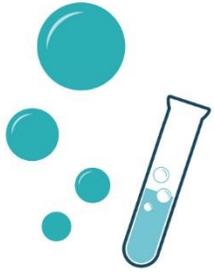
- Build a National Inventory of hazardous chemicals in Thailand and grasp their hazard properties
- Establish a new Annex 5.6





## Thailand Existing Chemicals Inventory

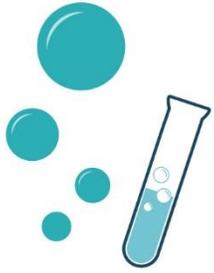
- DIW issued notice to release the **First Thailand Existing Chemicals Inventory** – includes 11,474 entries
- Substance information in the Inventory includes:
  - Chemical name, molecular formulas, hazardous substance type, chemical type, CAS number, chemical code, import quantity, production volume, and physical/health/environmental hazards
- Inventory sorts chemicals into three (3) hazardous substance types:
  - **List 1 – Low Risk** – Enterprises shall comply with standards regarding import/export, production, transportation, storage and disposal/recycling
  - **List 2 – High Risk** – Enterprises must obtain licensing from the Competent Authority before handling chemicals
  - **List 3 – Prohibited List** – All activities are prohibited, while substances used for R&D purpose or chemicals where contamination at use site is unavoidable with controlled risk management may be exempt



## Thailand Existing Chemicals Inventory (Cont'd)

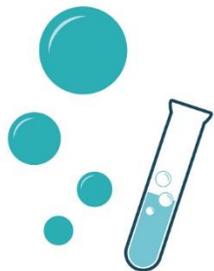
- Inventory also introduces chemical groups and codes:
  - Group LLC
  - Group GC (General Chemicals)
  - Group CoC (Chemicals of Concern)
  - Group CHC (Highly Careful Chemicals)
- Existing Chemical Inventory provides the basis for future management of existing chemical substances and new chemical substances
- Thailand Administration will release more information on the **Chemical Substance Act** (draft released last year)





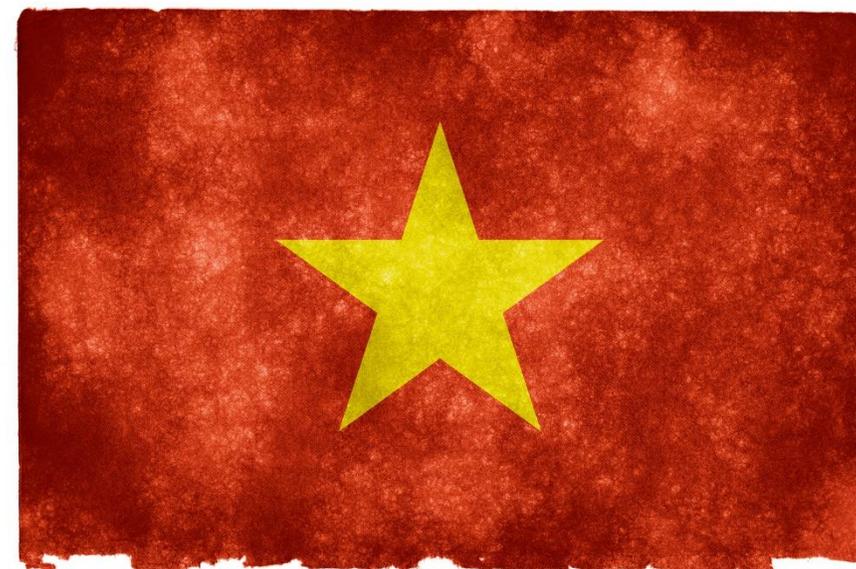
**Vietnam**

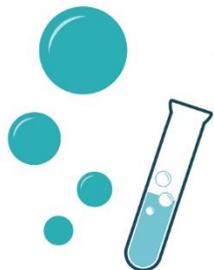




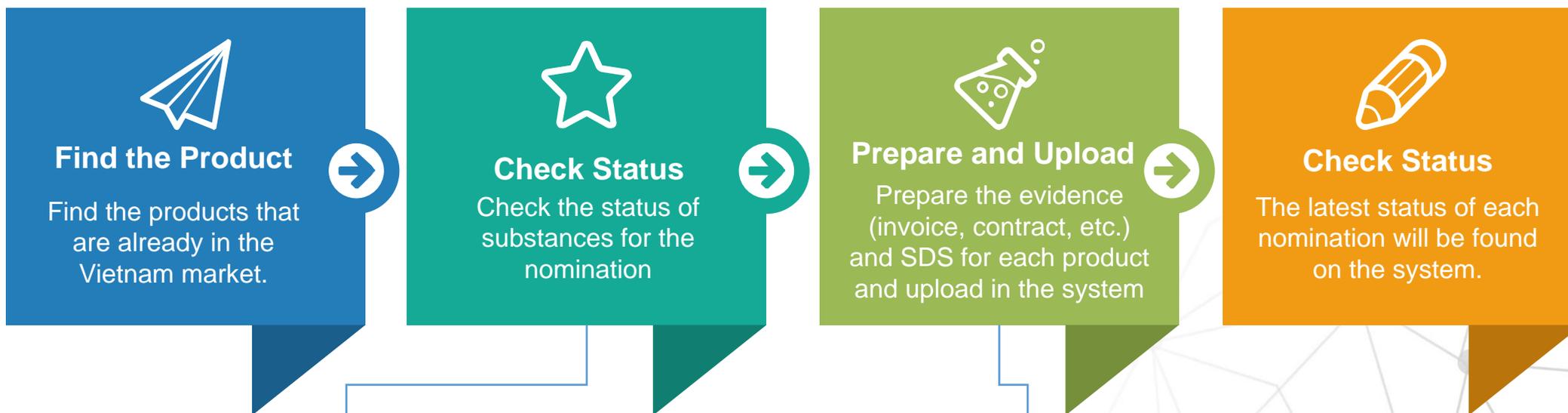
## Vietnam—Supplementation of National Chemical Inventory (NCI)

- Window was closed 30 May 2020;
- After the 5<sup>th</sup> Supplementation, **41,307 substances** were in the draft NCI with 4530 chemicals added in the previous round;
- Four (4) statuses - approved, wait for approval, lack of evidence, and not nominated;
- **Only Vietnamese entities** in the chemical industry can have an account for the NCI nomination;
- Nomination system is based on the Vietnam National Chemical Database System.
- **Latest Update - The 6<sup>th</sup> Supplementation Window re-opened on 16 Oct 2020 thru 15 Apr 2021.**



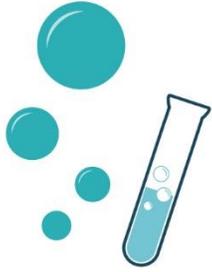


# The NCI Nomination Process

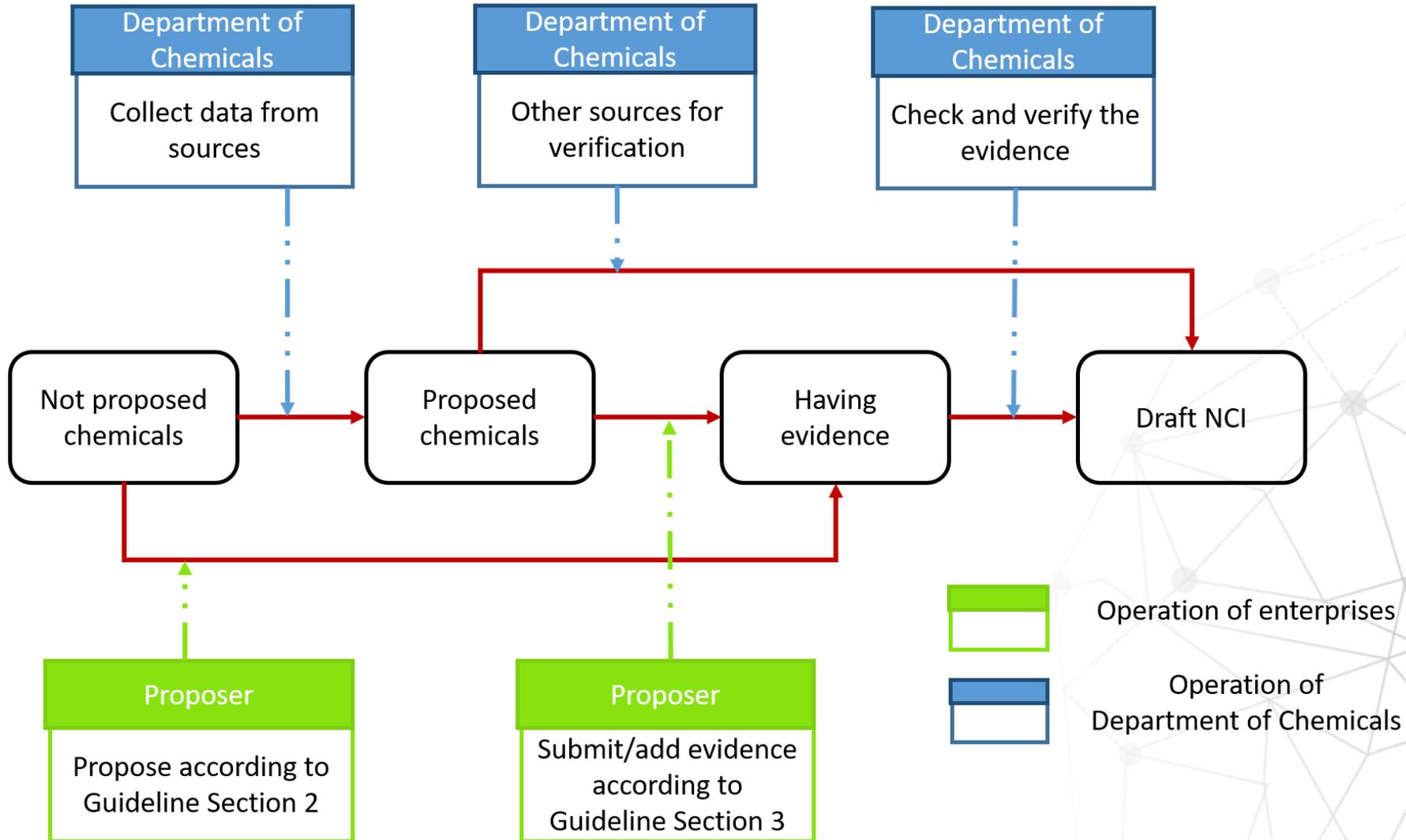


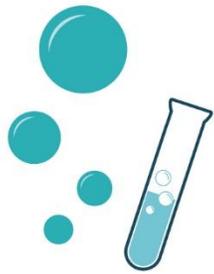
- **Approved** → Will be listed
- **Wait for approval** → No action required, can submit additional evidence
- **Lack of evidence** → Need more evidence
- **Not nominated** → Need to nominate with substances identification and evidence

- Nominated substances appear on the SDS;
- Evidence need to prove the existence of the products/substances in Vietnam market;
- Identification of substances (chemical name, CAS No.) is required.

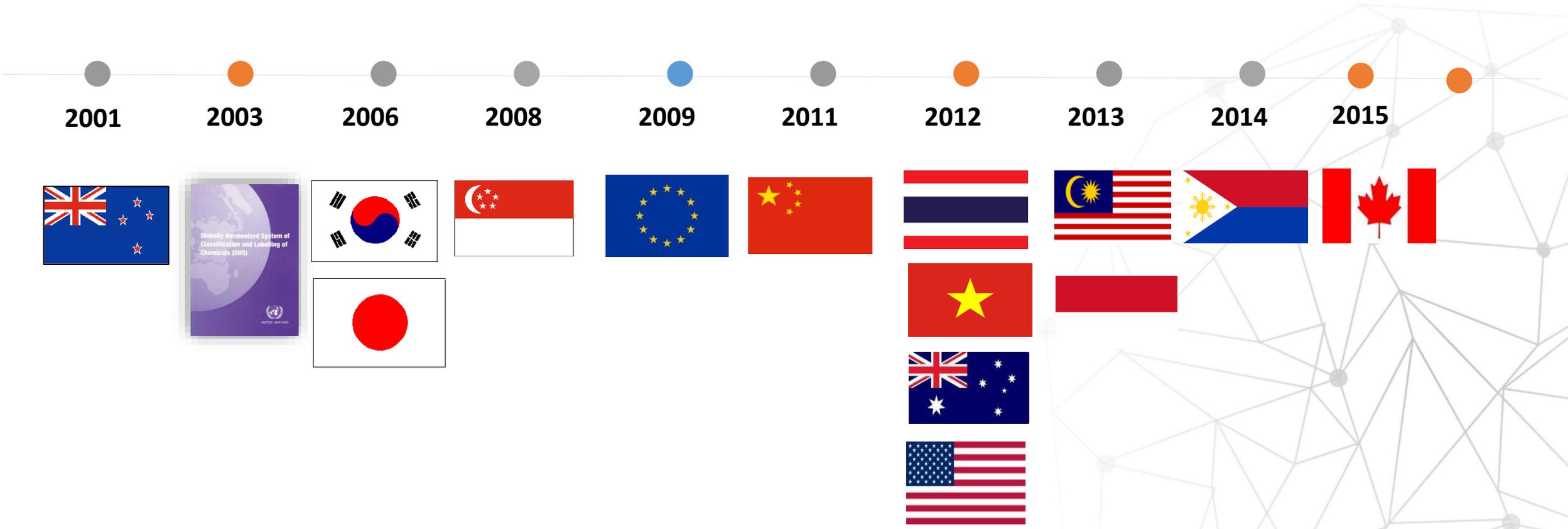


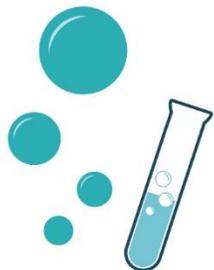
# Process of Adding Chemicals to the Draft NCI





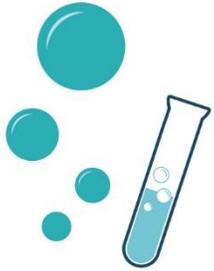
# GHS Implementation History





# Overview of GHS Standards in Countries and Regions

Country or Region	Classification	Label	SDS	UNGHS
China Mainland	GB 30000.2~29-2013	GB 15258-2009	GB/T16483-2008 GB/T17519-2013	Rev. 4
China Taiwan	CNS15030-1~28	《危害性化學品標示及通識規則》	《危害性化學品標示及通識規則》	Rev.4
South Korea	MOEL Public Notice 2016-19 NIER Notice No. 2019-45	MOEL Public Notice 2016-19 NIER Notice No. 2019-45	MOEL Public Notice 2016-19	Rev. 4 Rev. 3
Japan	JIS Z 7252-2019	JIS Z 7253-2019	JIS Z 7253-2019	Rev. 6
Thailand	B.E. 2555 (2012)	B.E. 2555 (2012)	B.E. 2555 (2012)	Rev. 3
Vietnam	Circular No. 32/2017/TT-BCT	Circular 32/2017/TT-BCT Decree 43/2017/ND-CP	Circular No. 32/2017/TT-BCT	Rev. 3 onwards
Philippines	DENR: EMB MC 2015-011	EMB MC 2015-011	EMB MC 2015-011	Rev. 4
Singapore	SS 586 : Part 2 : 2014	SS 586 : Part 2 : 2014	SS 586 : Part 3 : 2014	Rev. 4
Malaysia	CLASS ICOP 2019	Industry Code of Practice 2014	Industry Code of Practice 2014	Rev. 3
Indonesia	Order No.04/BIM/PER/1/2014	Order No. 04/BIM/PER/1/2014	Order No. 04/BIM/PER/1/2014	Rev. 4
Australia	Classifying Hazardous Chemicals National Guide 2018	Labelling of Workplace Hazardous Chemicals - Code of Practice 2018	Preparation of Safety Data Sheets for Hazardous Chemicals - Code of Practice 2018	Rev. 3 [Rev. 7]
New Zealand	Hazardous Substances (Classification) Notice 2017	Hazardous Substances (Labelling) Notice 2017	Hazardous Substances (Safety Data Sheets) Notice 2017	Rev. 5 [Rev. 7]



# GHS Latest News

## ● Australia to Adopt GHS Revision 7 from January 2021

- On Jan 10, 2020, Safe Work Australia (SWA) announced that GHS Rev. 7 would be officially employed starting Jul 1, 2020 for management of workplace hazardous chemicals.
- However, on Jun 5, 2020, in view of the impact of the COVID-19 pandemic on Australian businesses, the SWA announced to delay the start date of the full two-year transitional period to [Jan 1, 2021](#).
- Businesses will be allowed to classify and label their chemicals in accordance with GHS Rev. 7 starting on Jul, 1, 2020. Suppliers and end users will also be able to supply and use GHS Rev. 7 labelled chemicals under these arrangements.
- Dedicated GHS 7 webpage - <https://www.safeworkaustralia.gov.au/ghs-7-transition>

## ● New Zealand Mulling Adoption of GHS Revision 7

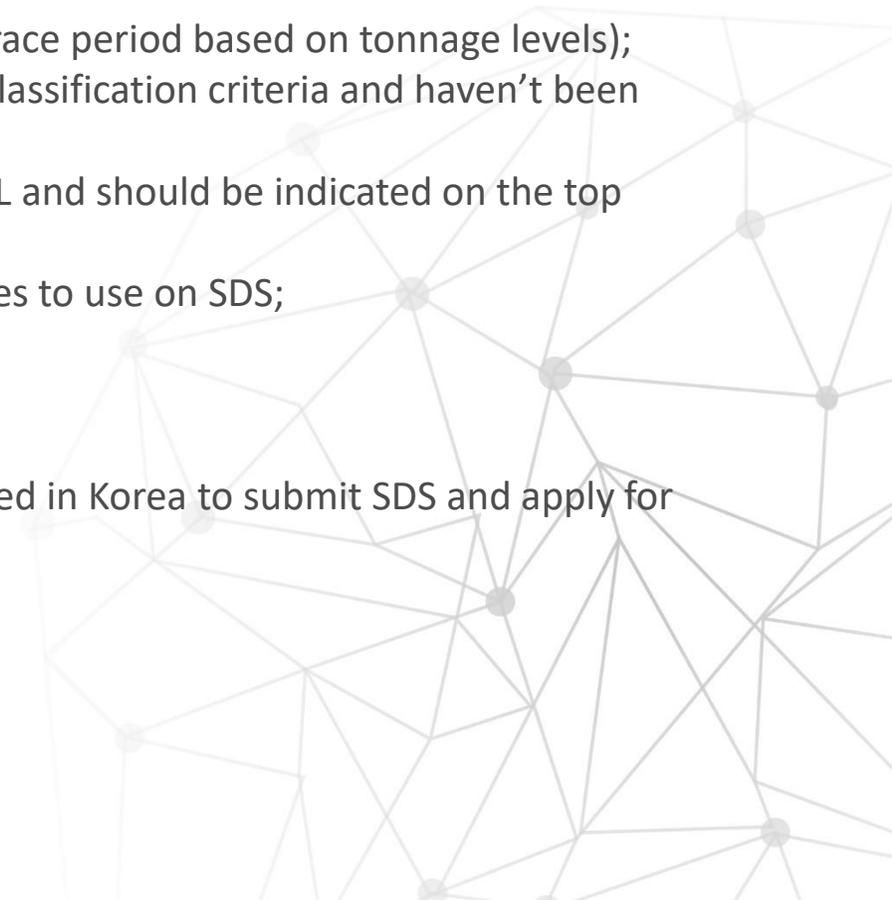
- In Oct 2019, New Zealand Environmental Protection Authority (EPA) consulted on its intent to update the current classification framework for hazardous substances to GHS Rev. 7 (2017) with a two-year transitional period.
- In June 2020, NZ EPA requested feedback on the next stage of the project, which involves updating existing hazardous substance individual approvals and group standards to convert their current HSNO classifications to GHS classifications.
- On 19 Oct 2020, HSNO approved the issue of 207 new group standards that are based on GHS Rev. 7 classifications. The new 2020 group standards come into force on 30 Apr 2021.

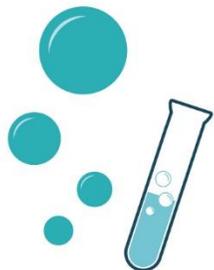


# GHS Latest News

## ● South Korea's New GHS Policy

- On 8 Jun 2020, MoEL released a draft revision to the “Standards for Classification and Labelling of Chemical Substances and SDS (MoEL Notice No. 2020-247)
- The most important changes made include the following provisions:
  - Requires submission of SDS to MoEL within 5 years from **16 Jan 2021** (grace period based on tonnage levels); Note - for mixtures with components that do not fall under the hazard classification criteria and haven't been listed on the SDS need to submit a confirmation letter to MoEL.
  - SDS number will be assigned via SDS IT system upon submission to MoEL and should be indicated on the top right corner of the SDS;
  - Use Categories – draft Standards provide 48 use categories for companies to use on SDS;
  - CBI Non-Disclosure Application with CBI protection valid for five years;
  - Cut-Off Limits;
  - GHS Classifications and H&P Statements have been revised;
  - Overseas manufacturers can appoint an “Only Representative” (OR) based in Korea to submit SDS and apply for CBI protection.





# China GHS

Fully implemented from 1 Dec 2011  
(Based on GHS Rev. 4)

- Ministry of Industry and Information Technology (MIIT)
- Ministry of Foreign Affairs (MFA)
- Development and Reform Commission (DRC)
- Ministry of Finance (MOF)
- Ministry of Ecology and Environment (MEE, formerly MEP)
- Ministry of Transportation (MOT)
- Ministry of Agriculture and Rural Affairs (formerly MOA)
- National Health Commission (formerly NHFPC)
- General Administration of Customs (GAC)
- State Administration for Market Review (SAMR, formerly CFDA, AQSIQ and SAIC)
- **Ministry of Emergency Management (MEM, formerly SAWS)**

**Regulations on Safety Administration of Hazardous Chemicals  
(Decree No. 591)**

Replaces Decree No. 344 (2012), Published 2.2011, Officially Implemented 12.1.2011

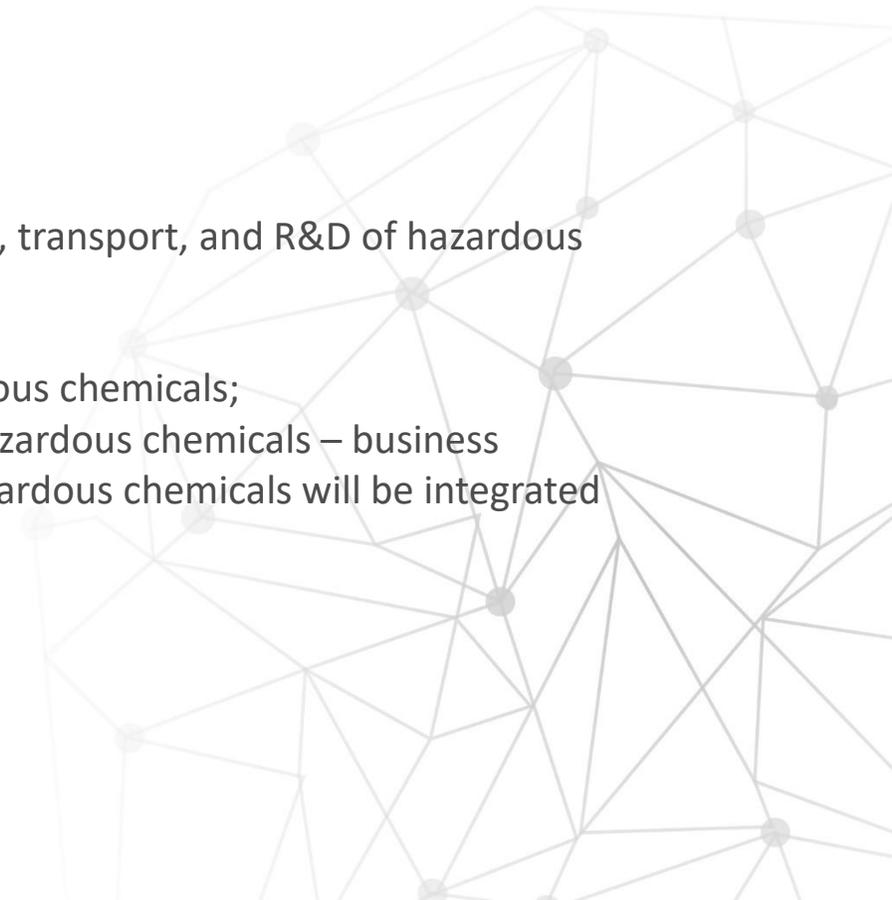




# GHS Latest News

## ● China Draft Law on Safety of Hazardous Chemicals

- On 2 Oct 2020, MEM published the new draft “Law on Safety of Hazardous Chemicals to replace Decree 591. Public comment until 1 Nov 2020.
- **Major highlights include:**
  - Clarify the responsibilities of different authorities concerned;
  - Enhance the planning and safety management of chemical parks;
  - Employ strict safety management measures on manufacture, storage, transport, and R&D of hazardous chemicals;
  - Strengthen the management of use safety of hazardous chemicals;
  - Clarify the regulatory responsibility (MEE) for safe disposal of hazardous chemicals;
  - Appropriate adjustments to the administrative approval system of hazardous chemicals – business licenses for production safety, use safety, and operation safety of hazardous chemicals will be integrated into one;
  - IT-enabled approaches to regulation of hazardous chemical safety;
  - Exercise harsher punishments against violations.

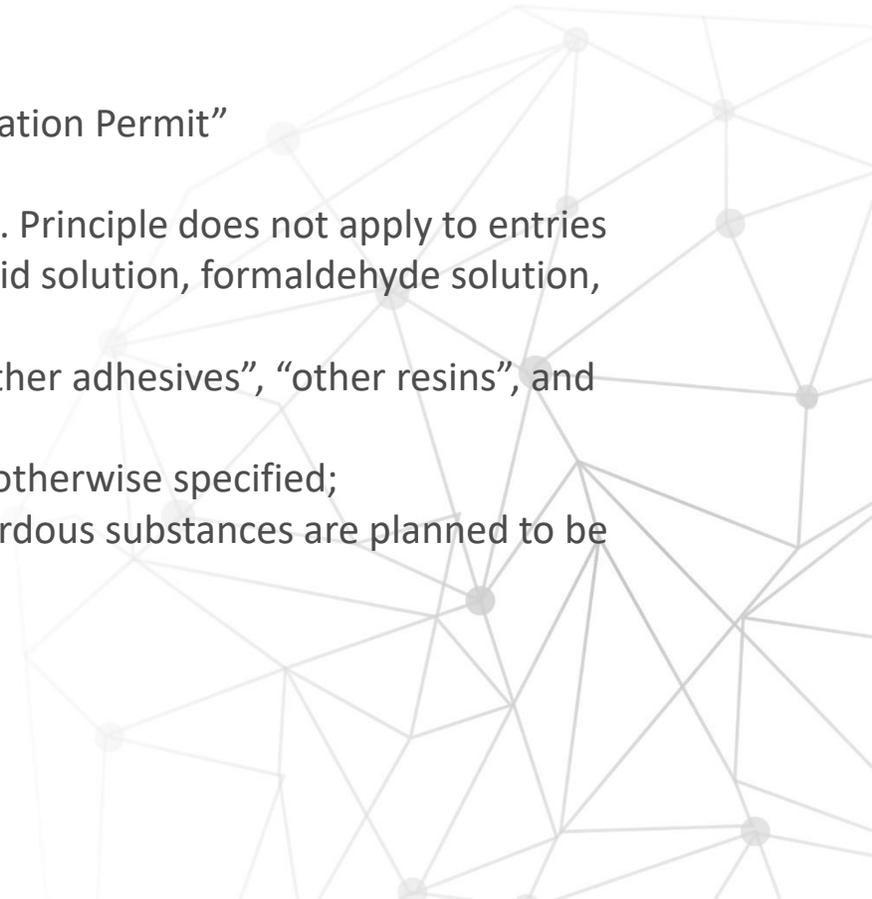


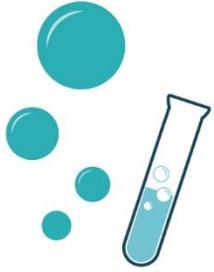


# GHS Latest News

## ● China Revision of Implementation Guidance of the 2015 Inventory of Hazardous Chemicals

- In Aug 2020, MEM solicited comments on the draft revision to the Guidance for the Implementation of China 2015 Inventory of Hazardous Chemicals
- **Main content revisions include:**
  - Sale of dry ice (solid carbon dioxide) does not require a “HazCom Operation Permit”
  - Exempts automobile diesel fuels with a grade of -10# or above
  - Management of mixtures meeting the 70% principle is further clarified. Principle does not apply to entries with a standard concentration of less than 70% such as hydrochloric acid solution, formaldehyde solution, and Entry No. 2828
  - Improve Entry No. 2828 – added four more items: “other coatings”, “other adhesives”, “other resins”, and “other products with flash points  $\leq$  60C.
  - Make clear the solution in the Inventory are aqueous solutions unless otherwise specified;
  - Improve the Classification Information Sheet – classification of 88 hazardous substances are planned to be adjusted





# Regulatory Calendar



# Regulatory Calendar



2020

**Jan 1 - South Korea:** Risk assessment of chemicals at or above 10 tons per year

**Jan 1 - Taiwan:** Phase II existing chemical registration for 106 PECs

**Jul 1 - South Korea:** Notification of products containing priority management substances under K-REACH

**By Feb 1 China:** New chemical annual reporting (deadline will be changed to Apr 30 next year)

**Jan 1 – Jan 31 Thailand:** Hazardous chemical substances activities declaration for the second half year of 2019

**Jul 1 Australia:** Implementation of AICIS

**Feb 1 - Feb 29 Thailand:** Annual reporting for the possession of type 4 hazardous substances

**Apr 1 - Sep 30 Taiwan:** Annual reporting of registered new and existing chemical substances

**Apr 4 - May 30 Vietnam:** 5<sup>th</sup> Supplementation of draft National Chemical Inventory (NCI)

**Jul 1 - Jul 31 Thailand:** Hazardous chemical substances activities declaration for the first half year of 2020

**Jan 1 – Australia:** Adoption of GHS Rev. 7 for workplace hazardous chemicals

**Jan 1 China:** Measures for the Environmental Management Registration of New Chemical Substances (MEE Order 12 of 2020) to be implemented

**Apr 15 Vietnam:** 6<sup>th</sup> Supplementation of draft National Chemical Inventory (NCI)

**By Nov 30 Australia:** First annual declaration under AICIS to cover 14 months from Jul 1, 2020 - Aug 31, 2021

**By Sep 1 Australia:** Online registration renewal as part of transition to AICIS (Further instructions to be released)

**Jan 1 South Korea:** New SDS rules to be implemented requiring SDS to be submitted to MoEL

2022

**South Korea:** Phase-in existing substances registration

- >1000 t/y or CMRs (364 substances) above 1 t/y by **2021**
- 100-1000 t/y by **2024**
- 10-100 t/y by **2027**
- 1-10 t/y by **2030**



# Thank You!

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