

# China New Chemical Substance Registration (MEE Order 12) & Hazardous Chemical Management



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**REACH24H**



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2. The Measures for the Environmental Administration Registration of New Chemical Substances

3. Hazardous Chemical Management

4. Preparation before entering to China market

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# Overview of Chemical regulations in China

## Regulations on the Control over Safety of Hazardous Chemicals (Decree 591)

### Business License

SAWS Order 41: Haz Chemicals Safe Production Permit  
**MANUFACTURE**

SAWS Order 55: Haz Chemicals Operation Permit  
**OPERATION / DISTRIBUTION**

SAWS Order 57: Haz Chemicals safe Use Permit  
**USE**

MOT Decree 36 & 2  
**TRANSPORTATION (by water and road)**

### China GHS

Inventory of Hazardous Chemicals (2915)

Hazardous Classification  
GB 30000.2 ~ 29

Safety Data Sheets  
GB/T 16483  
GB/T 17519

Labelling  
GB 15258  
GB/T 22234-2008

### Registrations

**MEE Order 12: The Measures for the Environmental Administration Registration of New Chemical Substances**  
**MANUFACTURE / IMPORT / RESEARCH / PROCESS FOR USE**

**SAWS Order 53: Registration of Hazardous Chemicals**  
**MANUFACTURE / IMPORT**

MPS Decree 77 (Highly Toxic Chemicals)  
**PURCHASE / TRANSPORT**

## Other Chemical Regulations

Regulations on the Administration of Precursor Chemicals (Decree 445)

SPSA Decree 5  
**PRODUCTION / OPERATION**

MPS Decree 87  
**PURCHASE / SALES / TRANSPORT**

MOC Decrees 7 and 8  
**IMPORT / EXPORT**

Regulations on Monitored and Controlled Chemicals (Decree 190)

MCI Decree 12

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# MEE Order 12 - Background

Oct 15, 2003

Measures for the Environmental Management of New Chemical Substances (SEPA Order 17)

Jan 1, 2020

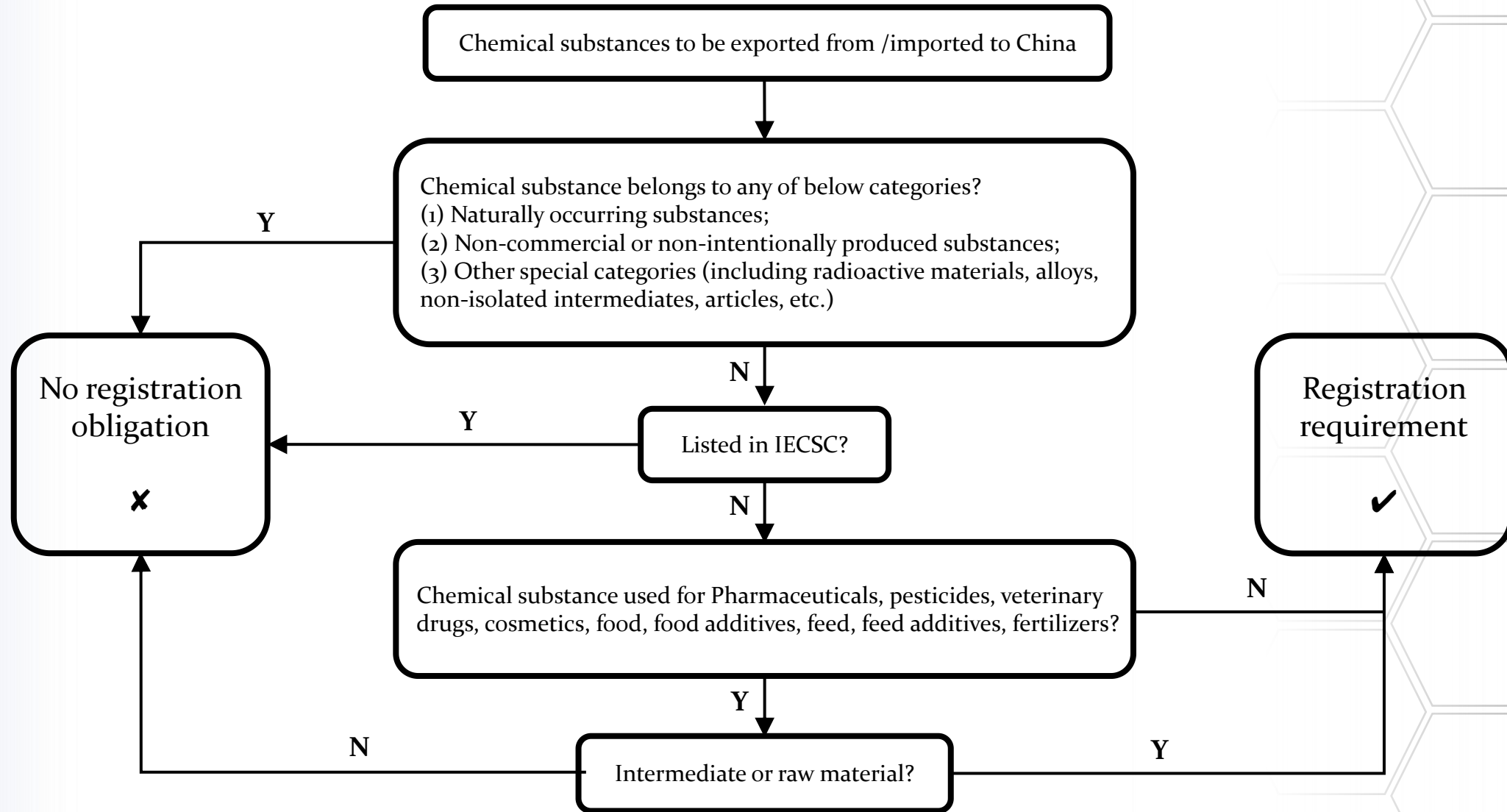
Measures for the Environmental Management Registration of New Chemical Substances (MEE Order 12)

Oct 15, 2010

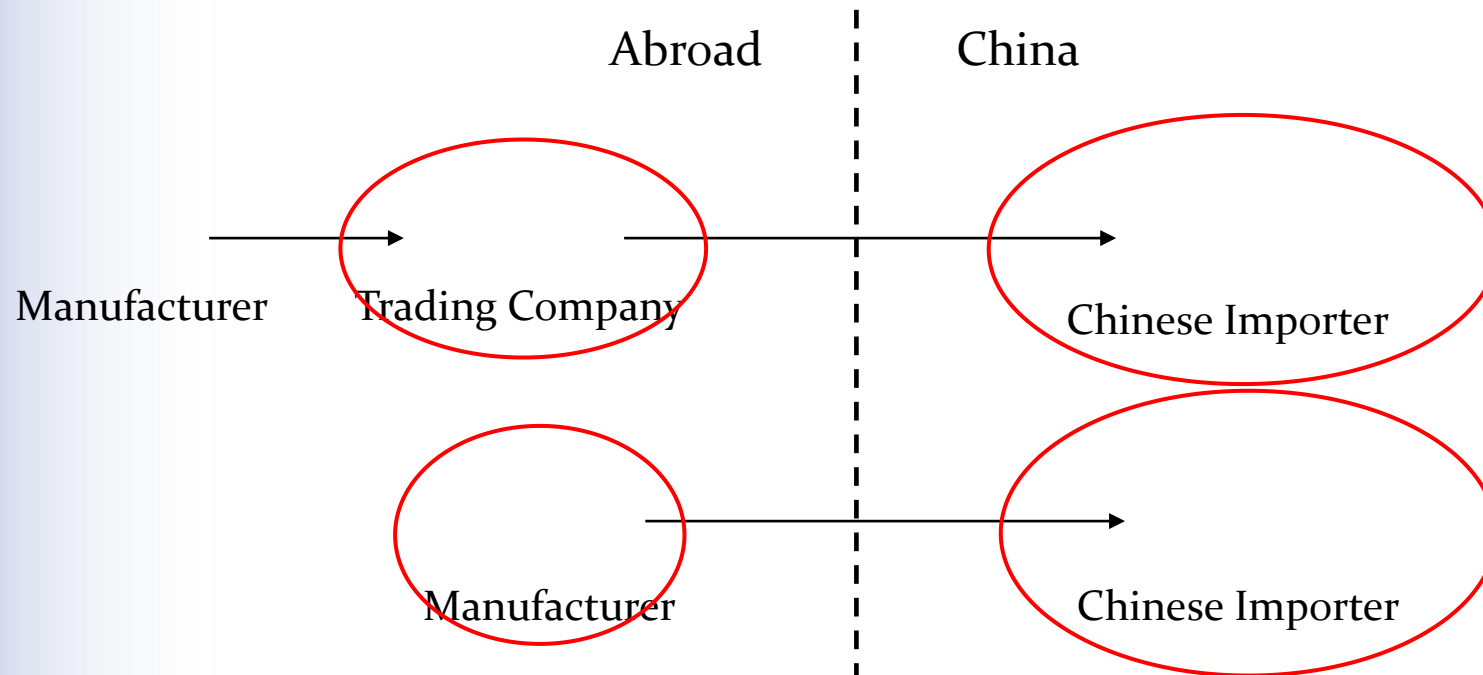
Measures for the Environmental Management of New Chemical Substances (MEP Order 7)



# MEE Order 12 – Chemical Substances to be registered



# MEE Order 12 – Registrants



## Overseas Registrant :

- Manufacturer or trading company who is the **direct exporter**
- Appoint a Chinese company as the representative

## Domestic Registrant :

- **Direct importer**

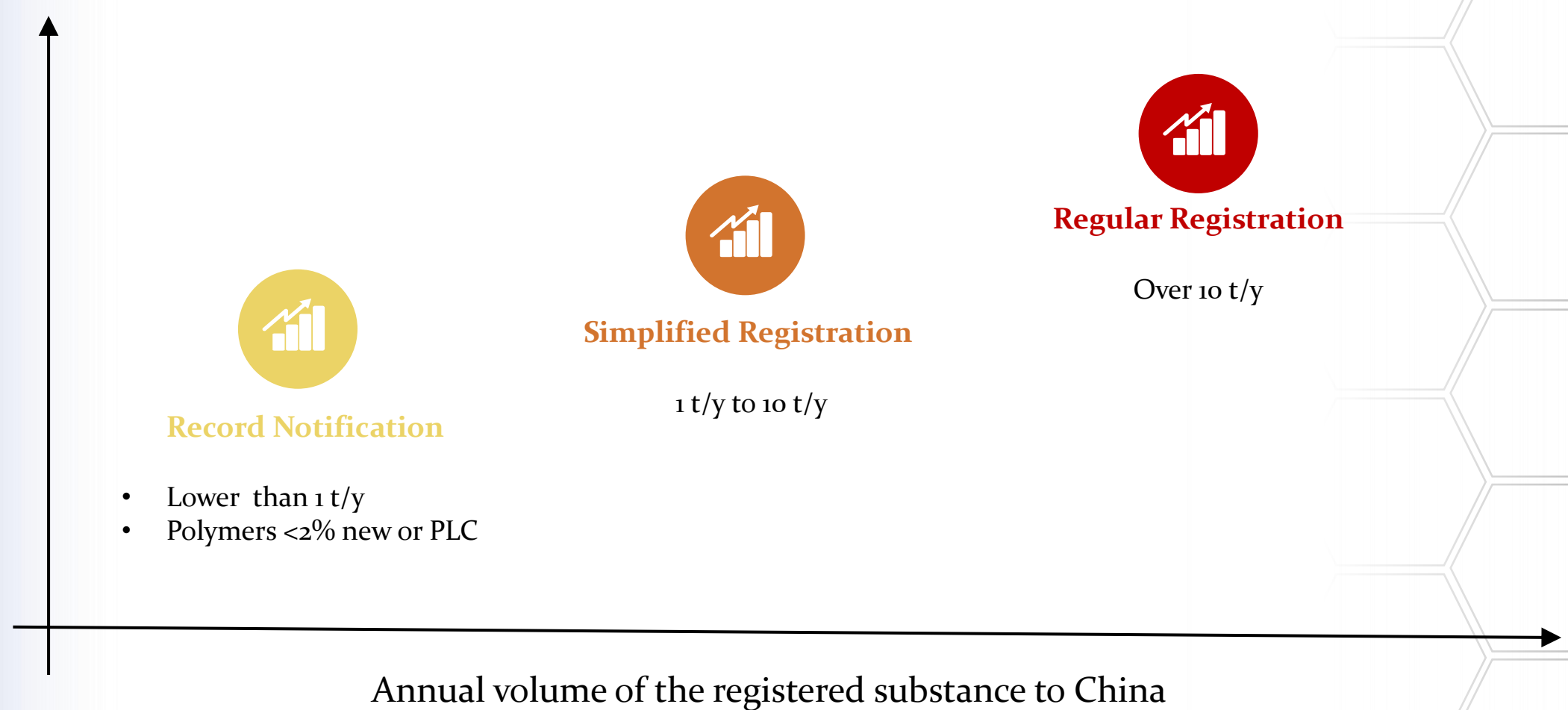
## Domestic Registrant :

- **Chinese Manufacturer**



# MEE Order 12 – Registration Type

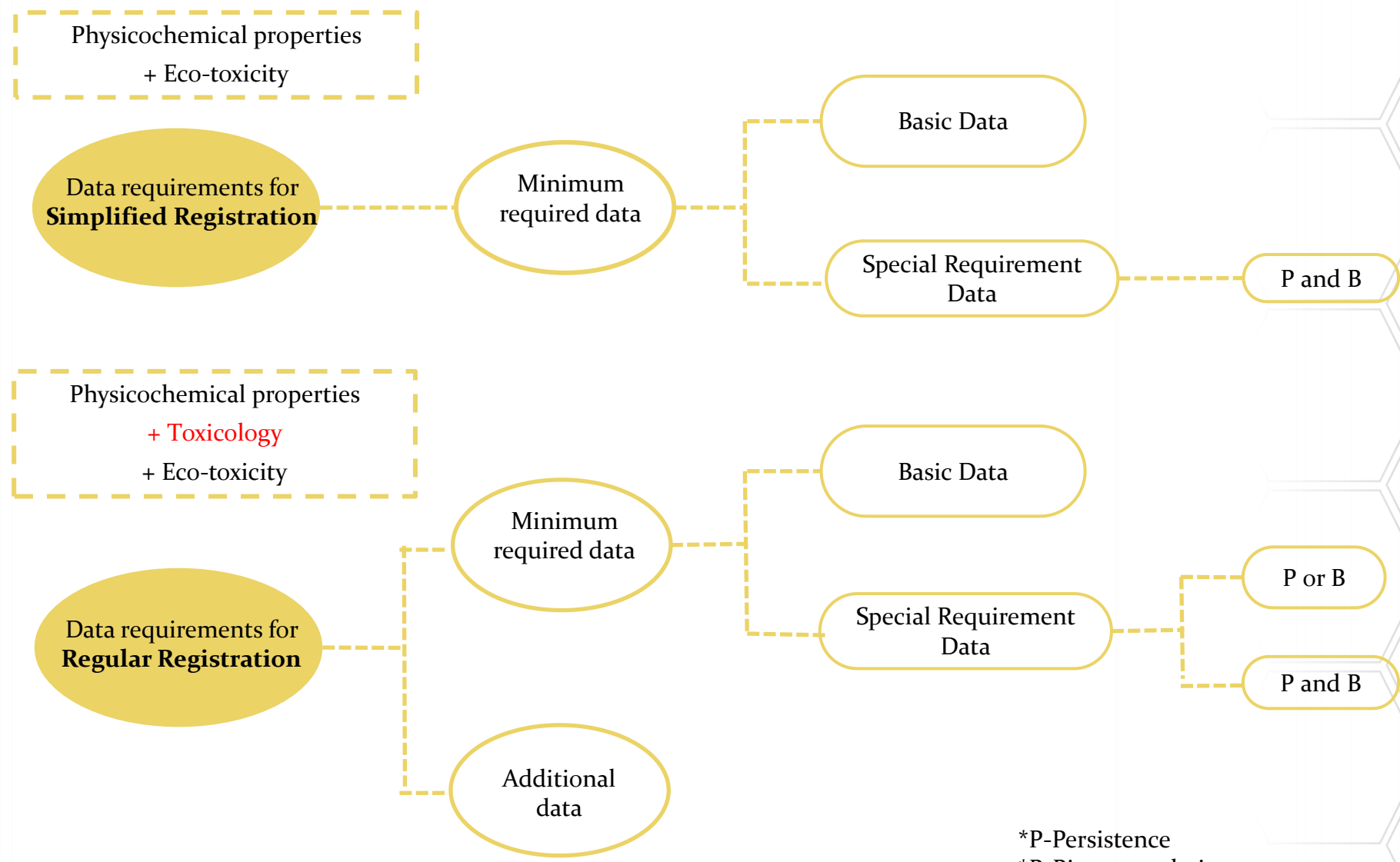
Complexity



# MEE Order 12 – Documents Required and Review Period

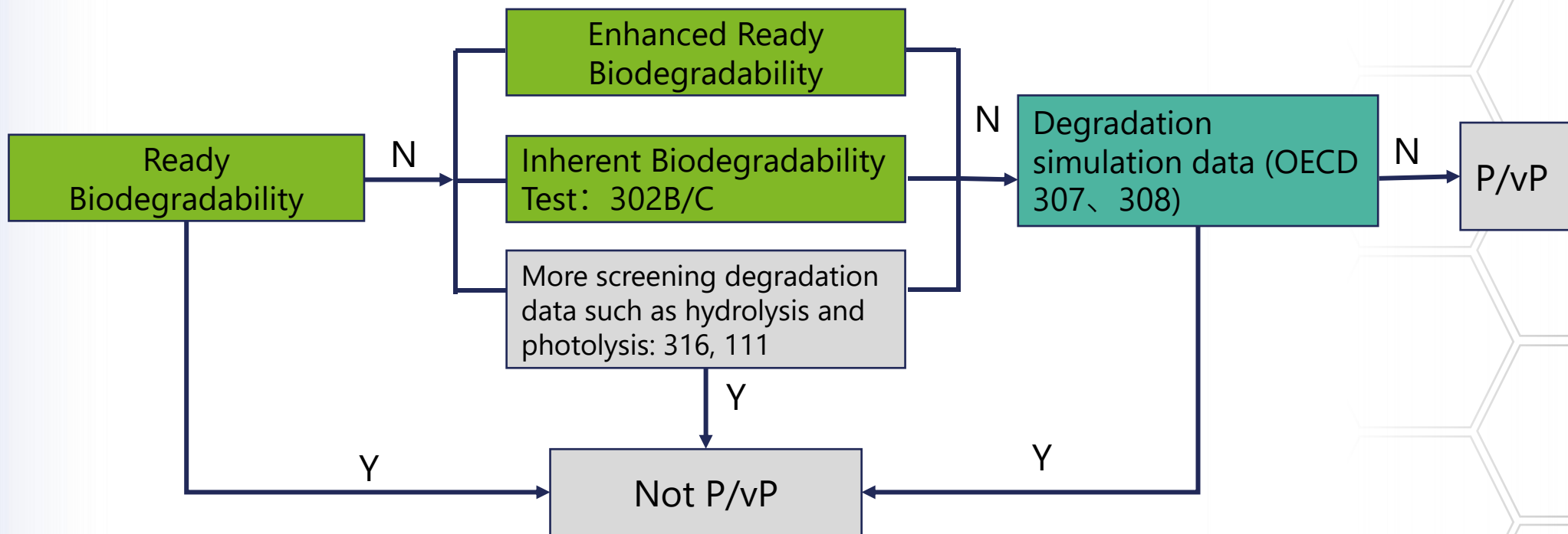
Registration Type	Documents required	Review Period
Record Notification	Application form (with attachments), business certification (domestic company), PoA (overseas registrant), other existing information regarding to risk and safety (GPC report and other documents to prove the polymer meets the criteria)	Receipt immediately received after submission
Simplified Registration	Same required information for Record Notification, test reports or study reports for required data, the basis and conclusions on the persistence, bioaccumulation and toxicity, CBI information, Letter of commitment about environmental risk control, Qualification of testing institutes	Registration certificate received after review and approval by the authorities (3 months on average)
Regular Registration	Same required information for Record Notification, test reports or study reports for required data, the basis and conclusions on the persistence, bioaccumulation and toxicity, CBI information, Letter of commitment about environmental risk control, Qualification of testing institutes, Environmental risk assessment report, Socio-economic benefit analysis report (for highly hazardous new chemicals)	Registration certificate received after review and approval by the authorities (6 months on average)

# MEE Order 12 – Data Requirement



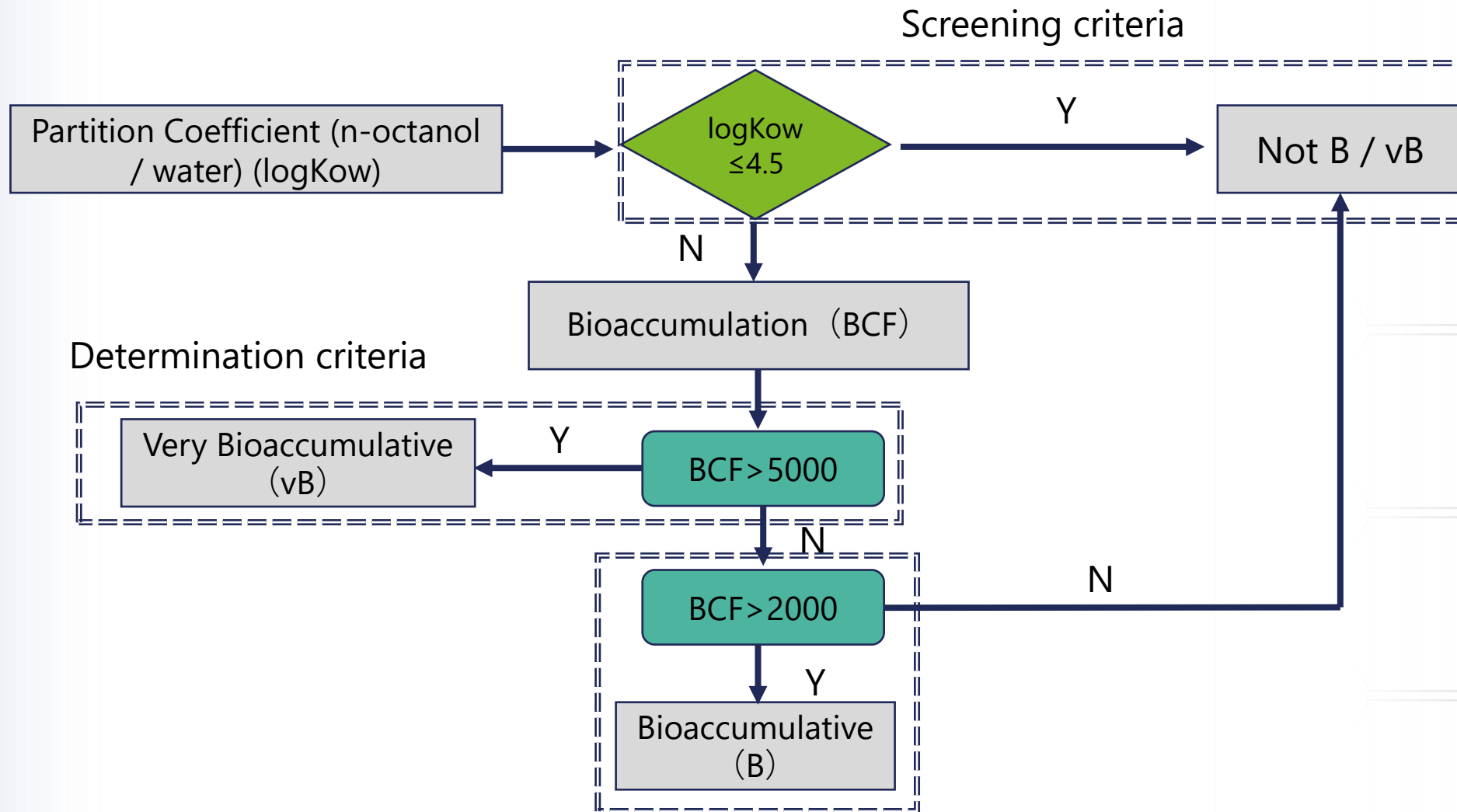
\*P-Persistence  
\*B-Bioaccumulation

# MEE Order 12 – Persistence Property



P.S. The criteria is not applicable for inorganic substances.

# MEE Order 12 – Bioaccumulation Property



P. S. Bioaccumulation test can be waived conditionally.

# MEE Order 12 –Physicochemical Tests

Data item	Simplified Registration			Regular Registration		
	Gas	Liquid	Solid	Gas	Liquid	Solid
Spectrum	√	√	√	√	√	√
Melting/freezing point		√	√		√	√
Boiling point		√			√	
Density		√	√		√	√
Vapor pressure		√			√	
Water Solubility	√	√	√	√	√	√
N-octanol/water partition coefficient		√	√		√	√
pH		√			√	
Particle size						√
Surface tension					√	
Critical point	√			√		
Dissociation constant					√	√
Henry's constant				√	√	√
Others						

# MEE Order 12 – Toxicological Tests (only for Regular Registration)

Data Item	Basic data	P or B	P and B
Acute toxicity	√	√	√
Skin irritation	√	√	√
Eye irritation	√	√	√
S k i n sensitization	√	√	√
Mutagenicity	√	√	√
Repeated dose toxicity	√	√	√
Reproductive/developmental toxicity	√	√	√
Toxicokinetics			√
Chronic toxicity			√
Carcinogenicity		√	√
Others			√

# MEE Order 12 – Eco-toxicological Tests

Data item	Simplified Registration		Regular Registration		
	Basic data	P and B	Basic data	P or B	P and B
Inhibitory toxicity on alga growth	√	√	√	√	√
Acute toxicity on daphnia	√	√	√	√	√
Acute toxicity on fish or short-term toxicity testing on fish embryo-yolk sac at absorption stage	√	√	√	√	√
Respiratory inhibitory toxicity on activated sludge			√	√	√
Adsorption/desorption			√	√	√
Degradation	√	√	√	√	√
Acute toxicity testing on earthworm			√	√	√
Reproduction testing on large daphnia		√	√	√	√
Bioaccumulation	√	√	√	√	√
Chronic toxicity testing on fish		√	√	√	√
Seed germination and root elongation test or terrestrial plant growth test				√	√
Enchytraeid reproduction testing or earthworm reproduction testing				√	√
Chronic toxicity on benthos				√	√
Others					



# MEE Order 12 – Qualifications of Overseas Testing Institutes

Testing type	Qualification of the Overseas laboratory	Testing Methods
Physicochemical tests	Meet the management requirements of the competent authority in the country where they are located or the internationally recognized OECD GLP requirements	OECD Guidelines or other internationally recognized testing methods
Toxicological tests	OECD GLP	
Eco-toxicological tests	OECD GLP	

# MEE Order 12 – Other registrations

Special form of registration	Definition	Requirements
Serial registration	Registration of multiple new chemical substances of similar molecular structure, identical or similar uses, and similar testing data, which are submitted as a series by the same applicant	<ol style="list-style-type: none"> <li>1. The quantity registered shall be the sum of quantities of each substance in a series</li> <li>2. Number of new chemicals in each series <math>\leq 6</math></li> </ol>
Joint registration	Registration of the same new chemical substance by two or more applicants at the same time	<ol style="list-style-type: none"> <li>1. The quantity registered shall be the sum of quantities submitted by each applicant</li> <li>2. The withdrawal of a joint registration certificate requires the submission of withdrawal application by all joint applicants</li> </ol>

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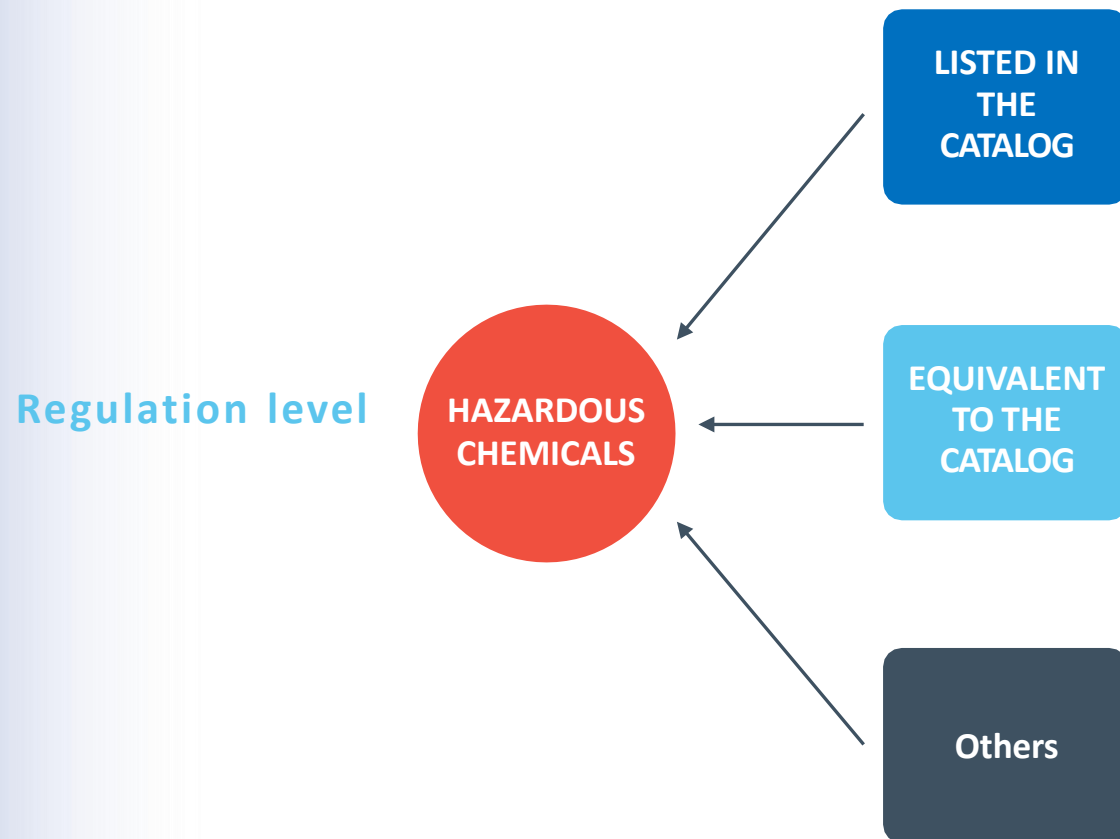
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# Hazardous Chemical Management – Hazardous Chemicals Determination



## Catalog of Hazardous Chemicals 2015

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- ✓ Entries 1-2827
- ✓ Entry 2828: 88 sub-items
- ✓ Conforming to the 70% principle, constituents listed in the Catalog  $\geq 70\%$

## Conforming to the Determination Principle

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- ✓ Conforming to the determination principle: 81 items of GHS classification

## Not confirming to catalog or determination principle

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- ✓ Chemicals of low hazard according to GHS classification
- ✓ Non-hazardous chemicals

# Hazardous Chemical Management – China GHS Classification

		Unst. Expl.	Div. 1.1	Div. 1.2	Div. 1.3	Div. 1.4	Div. 1.5	Div. 1.6
Physical Hazards	1. Explosive							
	2. Flammable gases	Cat. 1	Cat. 2	Unst. Gas A	Unst. Gas B			
	3. Aerosols	Cat. 1	Cat. 2	Cat. 3				
	4. Oxidizing gases	Cat. 1						
	5. Gases under pressure	compressed gas	liquefied gas	Refrigerated liquefied gas	Dissolved gas			
	6. Flammable liquid	Cat. 1	Cat. 2	Cat. 3	Cat. 4			
	7. Flammable solid	Cat. 1	Cat. 2					
	8. Self-reactive substance/mixture	Type A	Type B	Type C	Type D	Type E	Type F	Type G
	9. Pyrophoric liquid	Cat. 1						
	10. Pyrophoric solid	Cat. 1						
	11. Self-heating substance/mixture	Cat. 1	Cat. 2					
	12. Substance/mixture which in contact with water, emit flammable gases	Cat. 1	Cat. 2	Cat. 3				
	13. Oxidizing liquid	Cat. 1	Cat. 2	Cat. 3				
	14. Oxidizing solid	Cat. 1	Cat. 2	Cat. 3				
	15. Organic peroxides	Type A	Type B	Type C	Type D	Type E	Type F	Type G
	16. Corrosive to metal	Cat. 1						
Health Hazards	1. Acute toxic - oral/inhalation/dermal	Cat. 1	Cat. 2	Cat. 3	Cat. 4	Cat. 5		
	2. Skin corrosion/irritation	Cat. 1	Cat. 1A	Cat. 1B	Cat. 1C	Cat. 2	Cat. 3	
	3. Serious eye damage/irritation	Cat. 1	Cat. 2	Cat. 2A	Cat. 2B			
	4. Respiratory/Skin Sensitization	Cat. 1	Cat. 1A	Cat. 1B				
	5. Germ cell mutagenicity	Cat. 1A	Cat. 1B	Cat. 2				
	6. Carcinogenicity	Cat. 1A	Cat. 1B	Cat. 2				
	7. Reproductive toxicity	Cat. 1A	Cat. 1B	Cat. 2	Lactation			
	8. STOT - single exposure	Cat. 1	Cat. 2	Cat. 3				
	9. STOT - repeated exposure	Cat. 1	Cat. 2					
	10. Aspiration hazard	Cat. 1	Cat. 2					
Environmental Hazards	1.1 Hazardous to the aquatic environment - Acute	Cat. 1	Cat. 2	Cat. 3				
	1.2 Hazardous to the aquatic environment - Chronic	Cat. 1	Cat. 2	Cat. 3	Cat. 4			
	2. Hazardous to the ozone layer	Cat. 1						

## 14 GHS classifications not adopted

- Explosive Cat. 1.5
- Explosive Cat. 1.6
- Aerosols Cat. 2
- Aerosols Cat. 3
- Flammable liquid Cat. 4
- Self-reactive Type F
- Self-reactive Type G
- Organic peroxides Type G
- Desensitized explosives
- Acute Toxic Cat. 4
- Acute Toxic Cat. 5
- Skin Corr./Irrit. Cat. 3
- Aspiration hazard Cat. 2
- Aquatic hazard - Acute Cat. 3
- Aquatic hazard - Chronic Cat. 4

# Hazardous Chemical Management – Supervision Measure

	Over 70% listed in the catalog	At least one of the 81 GHS classification	Others
One book one label (SDS & Label)	Required	Required	Required
Hazardous chemical registration	Required	Required	Not Required

Safety Data Sheets  
 GB/T 16483  
 GB/T 17519

Labelling  
 GB 15258  
 GB/T 22234-2008

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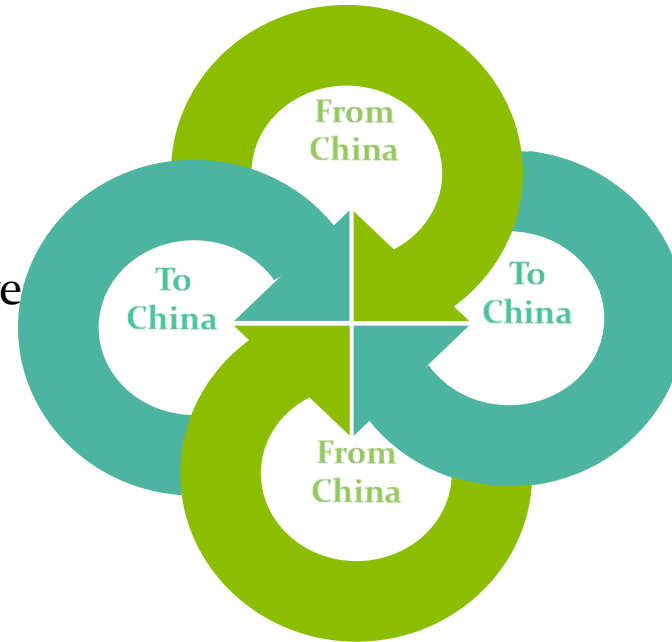
# Preparation before entering to China market

## Domestic Manufacturer

- Obligated to do registration as the applicant
- Deliver registration information to downstream customer
- SDS, Label, hazardous chemical registration

## Overseas Supplier

- Can do registration as the applicant
- Domestic company as the representative
- Deliver registration information to downstream customer
- SDS, Label, hazardous chemical registration (China standards)



## Overseas Buyer

- Reduce risks of non-compliance to regulations
- Ask for registration information from the supplier

## Domestic Importer

- Can do registration as the applicant
- Deliver registration information to downstream customer



# Preparation before entering to China market

Registration Type		Timeline	Certificate
Record Notification	General Type	10wks	Record Notification Receipt (no official seal)
	PLC or <2% polymer	15wks	
Simplified Registration		8 to 12 months	Registration Certificate with official seal
Regular Registration		Over 12 months	Registration Certificate with official seal

# Thank You.

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