

# Understanding the Obligations of China REACH and China Hazardous Chemical Management

Chris Ketchum, *Senior Regulatory Consultant*  
 Phone: 202-552-5523  
 E-mail: christopher@cirs-reach.com

Under China's MEE Order No. 12, issued in 2020, companies must submit new chemical substance registrations to the Solid Waste and Chemical Management Center (SCC) for substances not listed in the Inventory of Existing Chemical Substances in China (IECSC).

### What is Subject to Registration?

- Substance not listed in IECSC (2013)
- Substance subject to new use management



### What is EXEMPT from Registration?

- Naturally occurring substances
- Chemicals already under the management of other existing regulations
- Non-commercial or non-intentionally produced categories
- "Other special categories."

### Who is Responsible?

- Manufacturers of new substances in China;
- Importers of new substances in China;
- Companies who intend to apply for new uses registration or to change the registered uses managed by other laws and regulations to other industrial uses;

### OR Mechanism?

Companies in China can submit a new substance registration or appoint a local agent to do so. Foreign companies must appoint a local Chinese agent to submit new chemical registrations— or appoint their Chinese distributor/customer. The local agent should be knowledgeable and qualified to carry out the registration. The role of the agent is similar to the role of, "only representative," (OR) under EU REACH.

## Data Requirements – Record Filing

NO mandatory data requirement for non-polymers; however, polymers meeting the, "2% rule," or PLC, trigger the following requirements:

- List of monomers/reactants, molecular weight and distribution (GPC) and reaction mechanism;
- Exclusionary conditions declaration to describe if the polymer is:
  - Cationic (including polymers in natural water environment);
  - Degraded or unstable;
  - Water absorbent polymer with Mn≥10000Da;
  - Certain type of fluoropolymers;
  - Containing elements other than permitted elements

Have in mind:

- Record Filing is good for 5 years.
- Substances submitted for record filing will not be listed in IECSC
- Both the applicant and the OR will be listed in the public announcement. Only the number of substance(s) and recording filing number(s) will be listed in the announcement.

## Data Requirements - Simplified Registration

Physio-chemical Testing Data	Simplified Registration			Eco-toxicological Data	
	Gas	Liquid	Solid	Basic Data	Special Data (P and B)
IR/NMR/MS (at least 2)	✓	✓	✓	Algae growth inhibition toxicity (OECD 201)	Daphnia magna reproduction (OECD 211)
Melting Point/Freezing Point		✓	✓	Daphnia acute toxicity (OECD 202)	Fish Chronic Toxicity (Chinese, OECD 210/215)
Boiling Point		✓		Fish acute toxicity or short-term toxicity of fish embryo yolk sac absorption stage (Chinese, OECD 203/212)	
Density		✓	✓	Ready biodegradability (Chinese, OECD 301)	Mandatory
Vapor Pressure		✓		Inherent biodegradability (OECD 302), Hydrolysis (OECD 111)	
Water Solubility	✓	✓	✓	Bioaccumulation (Chinese, OECD 305)	Removed three eco-toxicological data tests: 1. Activated sludge respiration inhibition (Chinese, OECD 209) 2. Adsorption and desorption 3. Earthworm acute toxicity
Partition Coefficient n-octanol/water		✓	✓		
pH value		✓			
Particle Size					
Surface Tension					
Critical Point	✓				

## Data Requirements - Regular Registration

Physio-chemical Testing Data	Regular Registration			Toxicological Data		Eco-toxicological Data	
	Gas	Liquid	Solid	Basic Data	Special Data (P and/or B)	Basic Data	Basic Data
IR/NMR/MS (at least 2)	✓	✓	✓	Acute Toxicity (Oral, Dermal and inhalation) (OECD 401/420/423/425/402/403/436)	Carcinogenicity (OECD 451)	Algae growth inhibition toxicity (OECD 201)	
Melting Point/Freezing Point		✓	✓	Skin irritation (OECD 404/430/431/439)	Repeated dose 90-day toxicity (Oral, dermal and inhalation) (OECD 408/411/413)	Daphnia acute toxicity (OECD 202)	
Boiling Point		✓		Eye Irritation (OECD 405/437/438)	Two-generation or extended one-generation reproductive toxicity (OECD 416/443)	Fish acute toxicity or short-term toxicity of fish embryo yolk sac absorption stage (Chinese, OECD 203/212)	
Density		✓	✓	Skin sensitization (OECD 406/429/442)	Substances with broad uses	Activated sludge respiration inhibition (Chinese, OECD 209)	
Vapor Pressure		✓		Repeated dose 28-day toxicity (Oral, Dermal and inhalation) (OECD 407/410/412)	*Chronic Toxicity (OECD 452)	Adsorption and desorption (OECD 106/121)	
Water Solubility	✓	✓	✓	Screening for reproductive or development toxicity (OECD 421)	Carcinogenicity (OECD 451)	Earthworm acute toxicity (OECD 207)	
Partition Coefficient N-octanol/water		✓	✓	Gene mutation study in bacteria (OECD 471/472)	Prenatal developmental Toxicity (OECD 414)	Bioaccumulation (Chinese, OECD 305)	
pH value		✓		In vitro chromosome aberration test (OECD 473/487)	Repeated dose 90-dat toxicity (Oral, Dermal and Inhalation) (OECD 408/411/413)	Inherent biodegradability (OECD 302), Hydrolysis (OECD 111)	
Particle Size			✓	In vitro gene mutation test (OECD 476/490)	Two-generation or extended one-generation reproductive toxicity (OECD 416/443)	Ready biodegradability (Chinese, OECD 301)	
Surface Tension		✓		In vivo gene mutation test (OECD 486/488/489)	*Toxicokinetics	Daphnia magna reproduction (OECD 211)	
Critical Point	✓			In vivo chromosome aberration test (OECD 474/475)	• Required if: substances has health hazards (excluding local toxicity), or if tonnage/year > 1000— with broad uses.	Fish chronic toxicity (Chinese, OECD 210/215)	

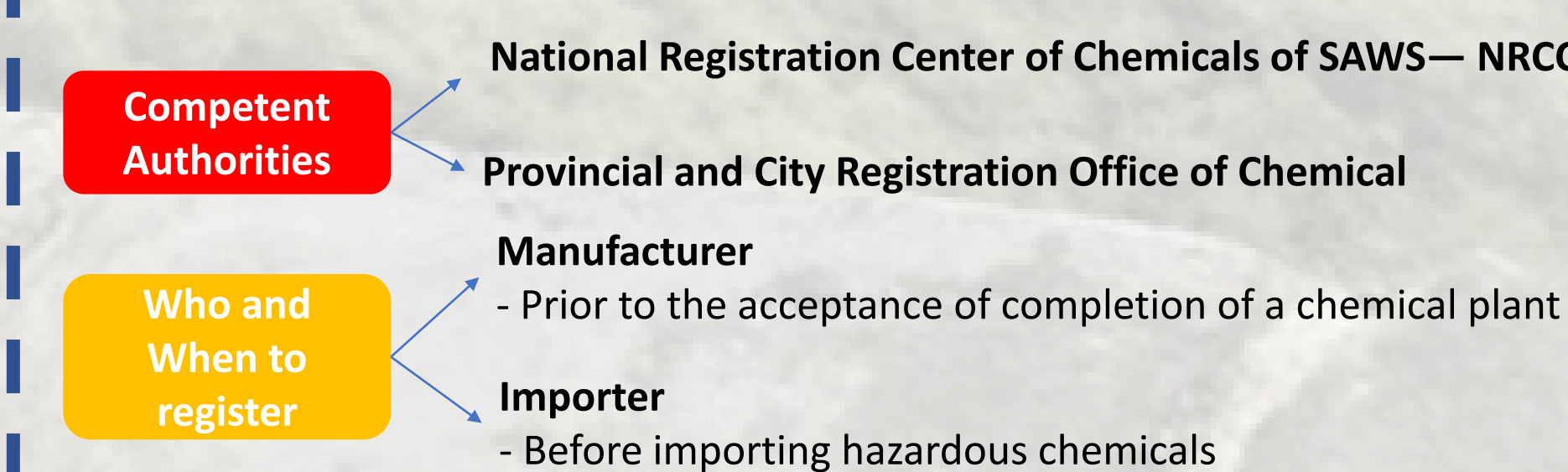
## Non-Testing Data Requirements

Information	Regular	Simplified	Record Filing
Application	✓	✓	✓
Business License	✓	✓	✓
Basic data	✓	✓	×
Environment Risk Report	✓	×	×
CBI Protection Necessity Explanation	✓	✓	×
Affidavit of Executing Environmental Risk mitigating Measures	✓	✓	×
Socio-economic value Analysis	✓	×	×
Qualification of labs	✓	✓	×
Evidence and conclusion of P, B, T	×	✓	×
Explanatory Documents for Polymer Record Filing	×	×	✓

### What's Considered "Hazardous Chemical" in China?

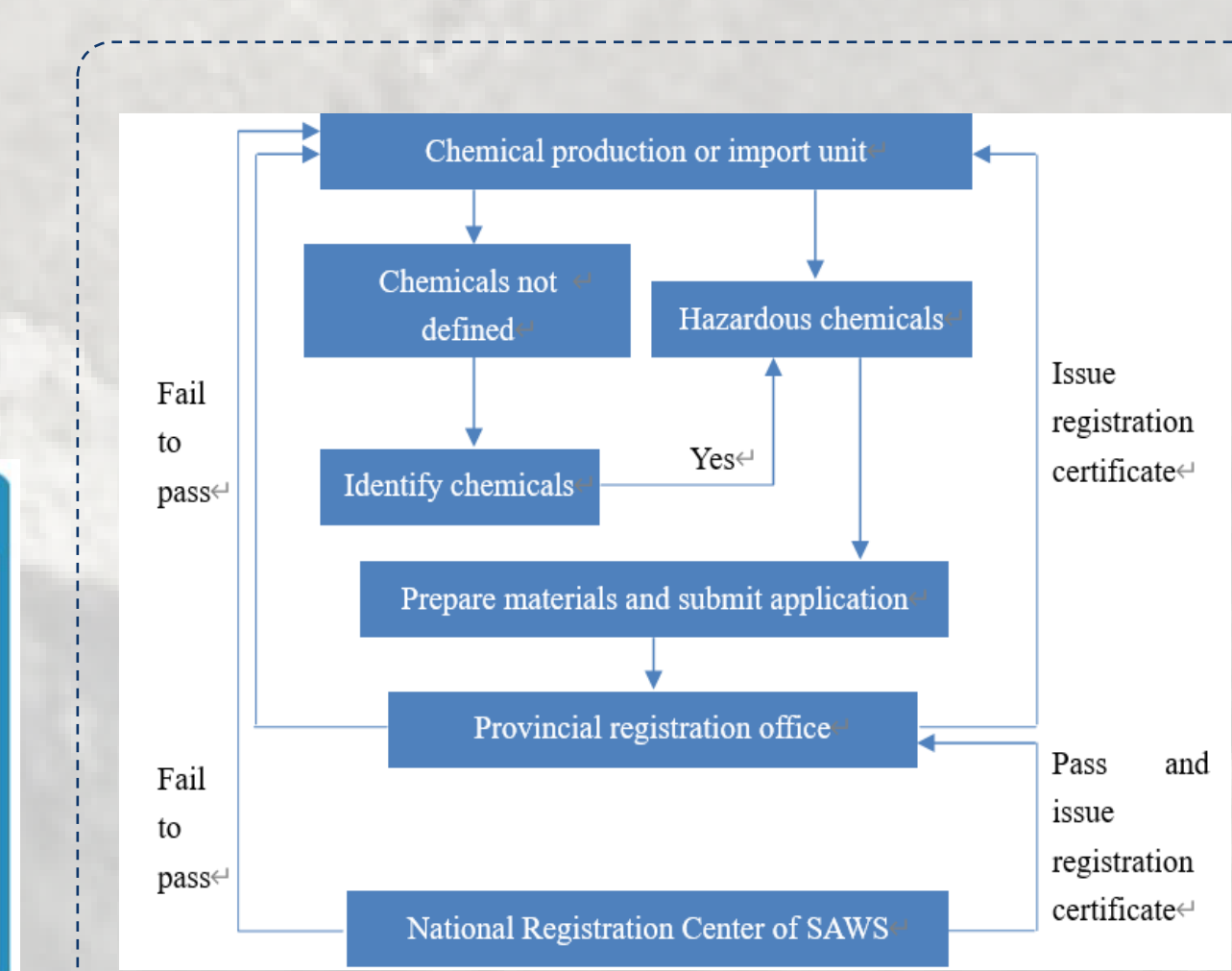
Substances and mixtures, listed in the Catalog of Hazardous Chemicals (2015) in China, which are: toxic, corrosive, explosive and flammable, and can cause harm/damage to humans, infrastructure, and environment. Hazardous chemicals can also be identified by using the, "confirmation rule," provided in SAWS Order 60. Hazardous mixtures should be identified using the, "70% rule."

### Hazardous Chemical Registration under SAWS Order 53



- Requirements
1. Hazardous chemical identity and properties
  2. Registrant identity (business license and import qualification)
  3. SDS and label
  4. Domestic 24hr Emergency Response Phone (a service provided by NRCC)

Timeline: 2-3 months (may be reduced due to the digitalized registration process)



Registration Type	Requirements
Record Filing	<ul style="list-style-type: none"> <li>• Tonnage level &lt; 1t/y</li> <li>• Polymers with new monomers/reactants concentration less than 2%; or PLC (polymer of low concern), and polymers that do not fall under the exclusionary conditions</li> </ul>
Simplified Registration	<ul style="list-style-type: none"> <li>• Tonnage level 1-10 t/yr</li> </ul>
Regular Registration	<ul style="list-style-type: none"> <li>• Tonnage level ≥10 t/yr</li> </ul>



**CIRS Group USA Inc.**  
 Address: Suite 600, 4250 N. Fairfax Dr, Arlington, VA 22203  
 Website: www.cirs-reach.com  
 Phone: +1 (703)520-1420