New Chemical Substance Management in China

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We specialize in Product Stewardship

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New Chemical Management in China - History

'Provisions on Environmental Administration of New Chemical Substances' effective since **October 15th 2003 (Order No. 17)**

- New chemical is not allowed to be **imported** or to be **produced** in **mainland** China.


国家环境保护总局令

第 17 号

SEPA Order [2003] No. 17

《新化学物质环境管理办法》已经 2003 年 4 月 1 日国家环境保护总局第 4 次局务会议审议通过，现予发布，自 2003 年 10 月 15 日起施行。

China REACh

国家环境保护总局局长

二〇〇三年九月十二日

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New Chemical Management in China - History

The revised Provisions effective from **October 15th, 2010 (Order No. 7)**:

- New chemical is not allowed to be **imported** or to be **produced, or to be processed/used** in **mainland** China.

中华人民共和国环境保护部令

第 7 号

MEP Order [2010] No. 7

《新化学物质环境管理办法》已由环境保护部 2009 年第三次部务会议于 2009 年 12 月 30 日修订通过。现将修订后的《新化学物质环境管理办法》公布，自 2010 年 10 月 15 日起施行。

2003 年 9 月 12 日原国家环境保护总局发布的《新化学物质环境管理办法》同时废止。

China REACh

环境保护部部长 周生贤

二〇一〇年一月十九日

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New Chemical Management in China - History

The 2nd revision of the Provisions is effective from **Jan. 1st, 2021**

MEE Order [2020] No. 12

名　称	新化学物质环境管理登记办法		
索 引 号	000014672/2020-00609	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	2020-04-29
文　号	部令 第12号	主 题 词	

新化学物质环境管理登记办法

《新化学物质环境管理登记办法》已于2020年2月17日由生态环境部部务会议审议通过，现予公布，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》（环境保护部令第7号）同时废止。

生态环境部部长 黄润秋

2020年4月29日

New Chemical Management in China - History

- Original : SEPA Order [2003] No. 17: Oct. 15, 2003~Oct. 14, 2010
- 1st Rev.: MEP Order [2010] No. 7 : Oct. 15, 2010~Dec. 31, 2020
- 2nd Rev.: MEE Order [2020] No. 12: Jan. 1, 2021 ~
- Registrations made before year 2021 are still valid after implementation of 2nd Rev. in year 2021.

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生态环境部部长 黄润秋

2020年4月29日

New Chemical Substance Management

- New chemical substance refers to
  - Chemical substances not listed in IECSC.

IECSC: Inventory of Existing Chemical Substance of China.

Latest IECSC (Inventory of Existing Chemical Substance of China) download. www.randis.cn/html/ywb/Exwzx_266_296.asp

New chemical substance of Normal Registration under Order. No. 17 (original Rule) will be listed into IECSC first half of year 2021.

New chemical substance of Typical Registration under Order. No. 7 (1st Rev.) will be listed into IECSC around end of year 2025.

Some substances in IECSC will be managed for New Usages --- new rule of Order No. 12 (2nd Rev.)

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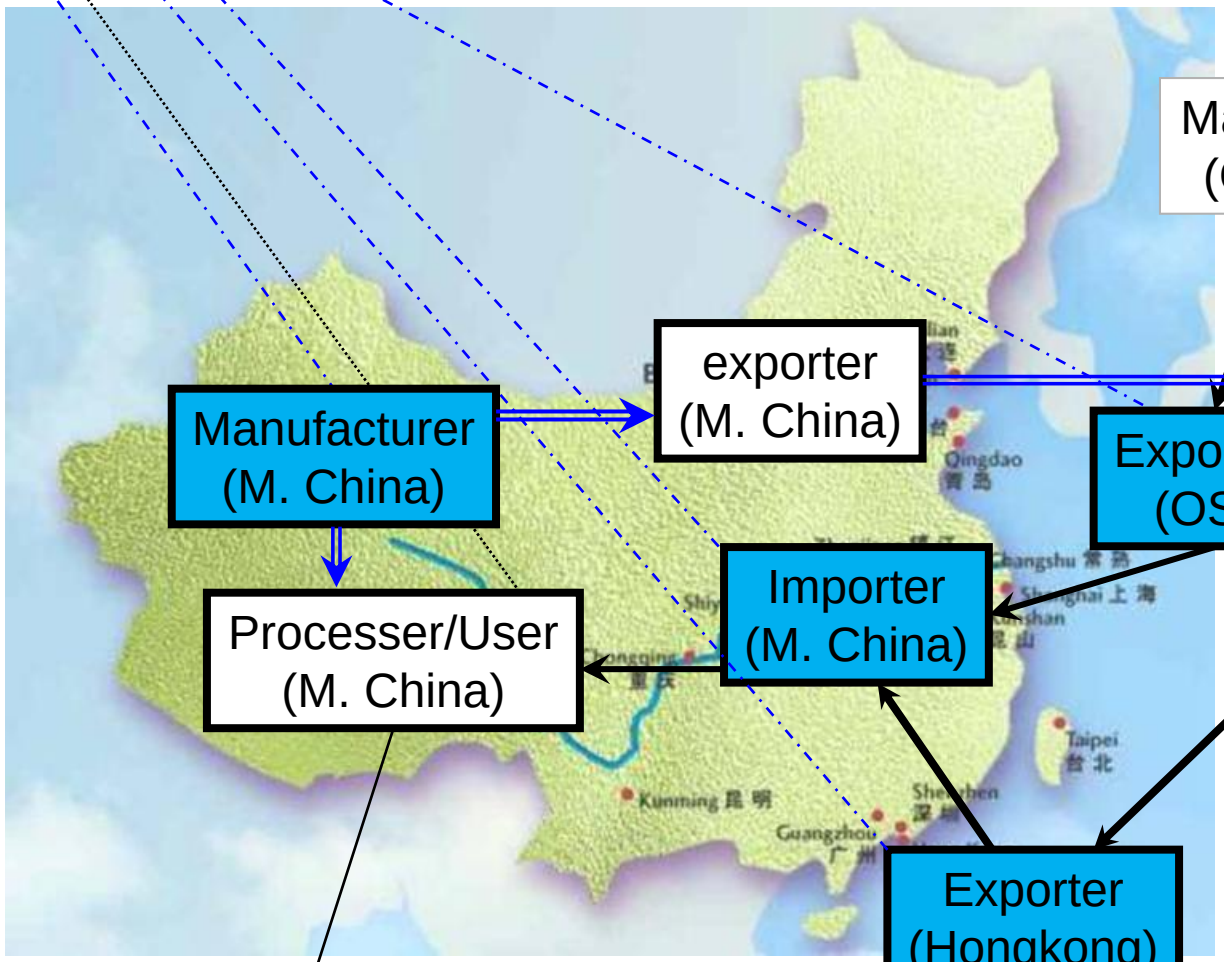
Registers



Can be registers for new usage of certain new chemical substances, new rule of Order No. 12 (2nd Rev.)

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Chinese Representative for Overseas Register

- Overseas Register needs Chinese Representative (Agent) to make registration to China.
- Similar to EU REACH 'OR'
  - Represents the register outside China for the legal responsibilities of the notified substance
  - One register can nominate several China Representatives
    - While for each notification, only one China Representative for each register.

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Registration Types – 3 types under Order No. 7 (1st Rev., before 2020 year end)

- Scientific Record Registration (No Certificate is issued)
- Simplified Registration (Certificate is issued)
  - Special Type
  - Basic Type
- Typical Registration

  (Certificate is issued. Registered substance will be listed into IECSC after 5 years)

Chemical Identification Protection is easy to apply

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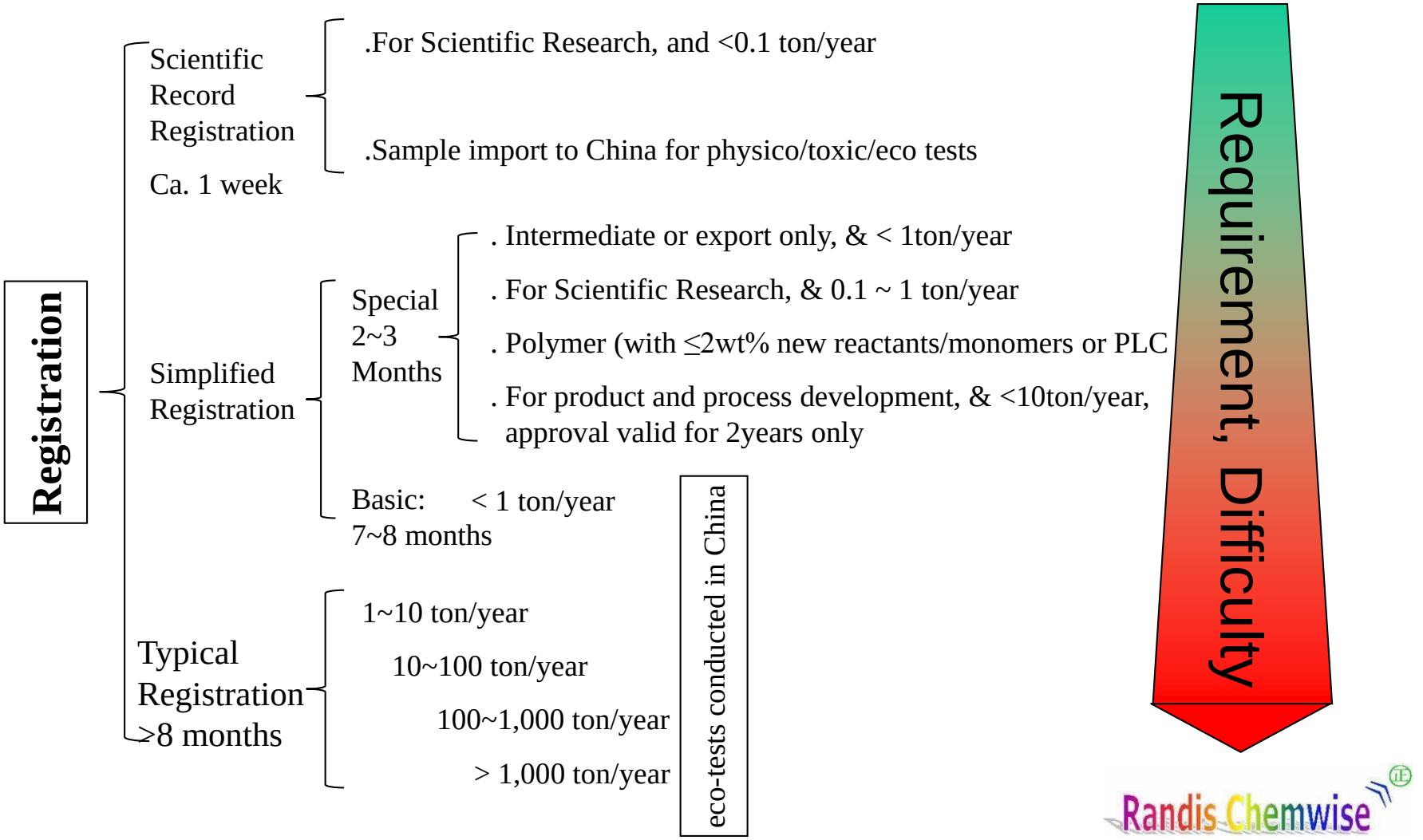
Registration Types --- 3 types under Order No. 7 (1st Rev., before 2020 year end)



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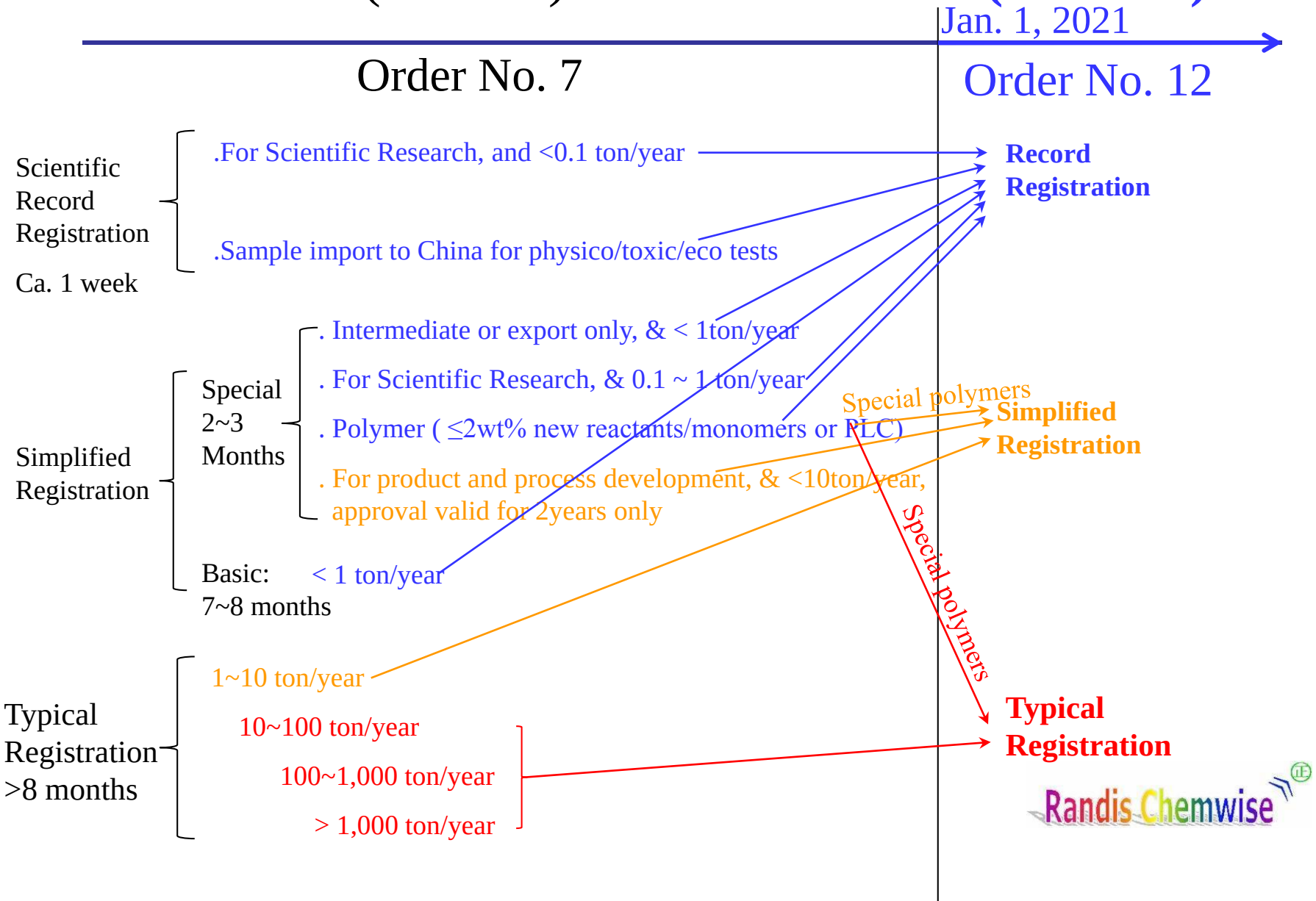
Registration Types

Order No. 7 (1st Rev.) → Order No. 12 (2nd Rev.)

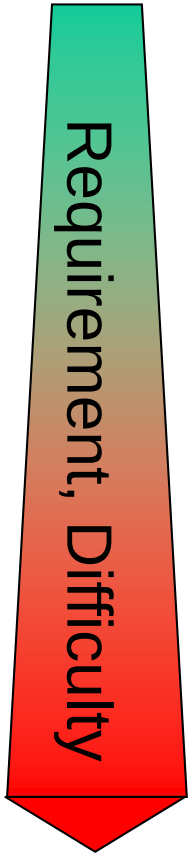


Registration Types --- 3 types (2nd Revision, from Jan. 2021)

Registration

- **Record Registration**
  - <1 ton/year (incl. special polymers)
  - *Polymers, no qty limit (polymers with ≤2wt% new reactants/monomers or PLC, excl. special polymers).
- **Simplified Registration**
  - 1 ~ 10 ton/year
  - Incl. special polymers.
- **Typical Registration**
  - ≥ 10 ton/year
  - Incl. special polymers.

eco-tests conducted with China organisms (fish, active sludge, etc.) is mandatory.



Special polymers: e.g., cationic polymers, degradable or unstable polymers, water-absorbing polymers, etc..

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Polymers of Low Concern (PLC) (2nd Revision, from Jan. 2021)

A polymer meeting any one of the following three conditions,

- One：
- ✓ Number-average Molecular Weight (Mn) is 1,000 ~ 10,000 daltons.
- ✓ Meets oligomer content criteria (<10% below 500 daltons and <25% below 1000 daltons).
- ✓ Does not contain high concern or high reactive groups, e.g. heavy metals, cyano groups (conjugated), acrylate, aziridines (excl. isocyanate-terminated), isocyanates, isothiocyanates, vinyl sulfones, alkoxysilanes (alkyl = methyl or ethyl), amines, spsiro-enamine, halosilanes, hydrazines, . α-lactones; β-lactones, methacrylate, etc.
- Two:
- ✓ 1. Number-average Molecular Weight (Mn) is > 10,000 daltons.
- ✓ 2. Meets oligomer content criteria (<2% below 500 daltons and <5% below 1000 daltons).
- Three: Polyester, the main chain of the polymer is formed by the ester bond of monomers, or the main chain is characterized by ester bonds.

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Special Polymers---New (2nd Revision, from Jan. 2021)

Special polymers refer to (close to US TSCA rule):

- Cationic polymers (e.g. containing phosphonium, sulfonium and ammonium cations etc. which are covalently linked to the polymer molecule) and potentially cationic polymers (e.g. polymers containing amine groups, isocyanates),
- Degradable or unstable polymers, and polymers that substantially decompose after manufacture or use.
- Water-absorbing polymers with Mn ≥ 10,000 daltons (capable of absorbing its weight of water. Water-soluble and water-dispersible polymers are not considered to be water-absorbing polymers),
- Fluoropolymers (structure of which contain perfluoroalkyl sulfonate, perfluoroalkyl carboxylic acid or fluorotelomere structural segments; and perfluoroalkyl structural segments that are covalently bonded to carbon or sulfur atoms in polymer molecules),
- Polylers containing non-permitted elements(e.g. monatomic counterions F-, >wt0.2% Li, B, P, Ti, Mn, Fe, Ni, Cu, Zn, Sn, and Zr).

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Registration Types --- 3 types (2nd revision, from Jan. 2021)

- Record Registration (No Certificate is issued)
- Simplified Registration (Certificate is issued):
  - First activity reported needed (same to Rev. 1)
  - No annual report needed (but required under Rev. 1).
  - PBT/vPvB substance maybe not approved.
- Typical Registration (Certificate is issued)
  - Re-registration for new usage of approved PB/PT/BT/PBT substance is needed.
  - Registered substance will be listed into IECSC after 5 years.
  - First activity reported needed (same to Rev. 1)
  - Annual report needed for high risk substances (same to Rev. 1).

Chemical Identification Protection is max. 5 years, maybe difficult to apply.

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Substance Hazard types--- (2nd revision, from Jan. 2021)

- Record: no hazard type classified.
- Simplified: PBT, Environmental accumulative risk, others → will not get approval
- Typical:
  - Hazardous substances: PB, PT, BT substance
  - High. Hazar. Sub.(Social/economic analysis is needed)
    - PBT substance,
    - vPvB substance,
    - Equivalently hazardous substance:
      - Endocrine disruptors(EDCs)
      - Extremely toxic substances:
        - ✓ Health hazard GHS category 1: acute toxicity, carcinogen, mutagen, reproductive toxicity, specific target organ toxicity (repeated exposure).
        - ✓ Aquatic chronic NOEC or EC_{10}<0.01mg/L, aquatic acute LC_{50}/EC_{50}<0.01mg/L(if <0.1mg/L, unless chronic NOEC/EC_{10}>=0.01mg/L, it is regarded as extremely toxic)
  - Other substances

Approval with ≥ one requirements below
1. Limit discharge concentration or amount
2. New use management
3. Annual reporting
4. Others

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Post Registration Management (2nd revision, from Jan. 2021)

- Manufacturer/importer/user of new substance shall provide following information to downstream users:
  - Registration Certificate No. or Record Registration Receipt number.
  - Registered usage.
  - Substance's hazards and risk control measures
  - Environmental administrative requirements.
- Researcher/manufacturer/importer/user shall maintain and archive activities of new substances (time, quantity, usage, implementation of risk control measures, etc.)
- Manufacturer/user of typical registration substance shall publicize implementation status of risk control measures etc. via its website, etc.

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Post Registration Management (2nd revision, from Jan. 2021)

- Researcher/manufacturer/importer/user of new substance shall report to authority about newly discovered hazards of registered new substances.
- Authority may based on need ask to provide further information for already-approved new chemical substances.
- MEE will provide information on registrations, first activity and annual reports etc. to local EPAs, local EPAs will make spot checks.
- Companies with violation to Order No. 12 (2nd Rev.) will be fined and be rejected for new chemical substance registration for 1 or 3 years.

Post Registration Management Matrix (2nd revision, from 2021)

Post-Registration Management	Registrations under Order 7			Registrations under Order 12		
	Record	Simpl.	Typical	Record	Simpl.	Typical
First Import Report	x	x	√	x	√	√
Annual Report	x	x	Critical substances	x	x	(highly) haz. substances
Registration information (e.g. certificate No.) to downstream users	x	x	√	√	√	√
Activity record; management requirement to downstream users	x	√	√	√	√	√
Publication at company website	x	x	x	x	x	√

Registrations made under Order 7 and Order 12 should both follow this matrix.

Test Data Requirement under Order 12 (2nd revision, from 2021)

Data	Simplified Regis.			Typical Regis.		
Physico/Chemical	Gas	Liquid	Solid	Gas	Liquid	Solid
Spectrum	√	√	√	√	√	√
Melting Point		√	√		√	√
Boiling Point		√			√	
Density		√	√		√	√
Vapor Pressure		√			√	
Water solubility	√	√	√	√	√	√
LogKow		√	√		√	√
pH		√			√	
Particle size						√
Surface Tension					√	
Critical Point	√			√		
Dissociation cons. pKa					√	√
Henry's constant(from test or calculation)				√	√	√

Test Data Requirement under Order 12 (2nd revision, from 2021)

Data	Typical Registration		
Toxicity	Basic Substance	Persistent or Bioaccumulative	P&B
Acute toxicity (Oral +dermal + inhalation)	√	√	√
Skin Irritation	√	√	√
Eye Irritation	√	√	√
Skin Sensitization	√	√	√
Mutagenic (471+473+476, if any positive then relatively 475/474/486/488)	√	√	√
Repeated Toxicity (one route)	28d	90d or QSAR	90d
Reproduction/ Develop toxicity	TG 421 (or 424, 416, 443)	TG 414 + 2 QSAR	TG 414 + 416/443
Toxicokinetics (report or QSAR etc.)			√
Chronic Toxicity (when it has a widespread dispersive use or frequent or long-term human exposure)			√
Carcinogenicity (assessment or report)		√	√
Others (e.g. Organophosphorus substances should provide neurotoxicity data)			

Test Data Requirement under Order 12 (2nd revision, from 2021)

Data	Simplified		Typical	
Eco-toxic	Basic	P&B	Basic	P or B, P&B
201 Acute Algae toxicity	√	√	√	√
202 Acute Daphnia toxicity	√	√	√	√
203 or 212 acute fish toxi. (test with China organism)	√	√	√	√
209 Activated sludge Res.(test with China sludge)			√	√
106/121 Adsorption/Desorption (Logkoc)			√	√
Degradation(test with China organism)	√	√	√	√
207 Acute earthworm toxicity			√	√
211 Daphnia reproduction		√	√	√
BioConcentration(test with China organism)	√	√	√	√
210 or 215 Chronic fish(test with China organism)		√	√	√
208 plant Growth, 220/222 Earthworm reprod., 218/225 Sediment				or/and
Others e.g. 229/234 fish test for Endocrine disruptors				

New Chemical Registration in China

MEE Order 12

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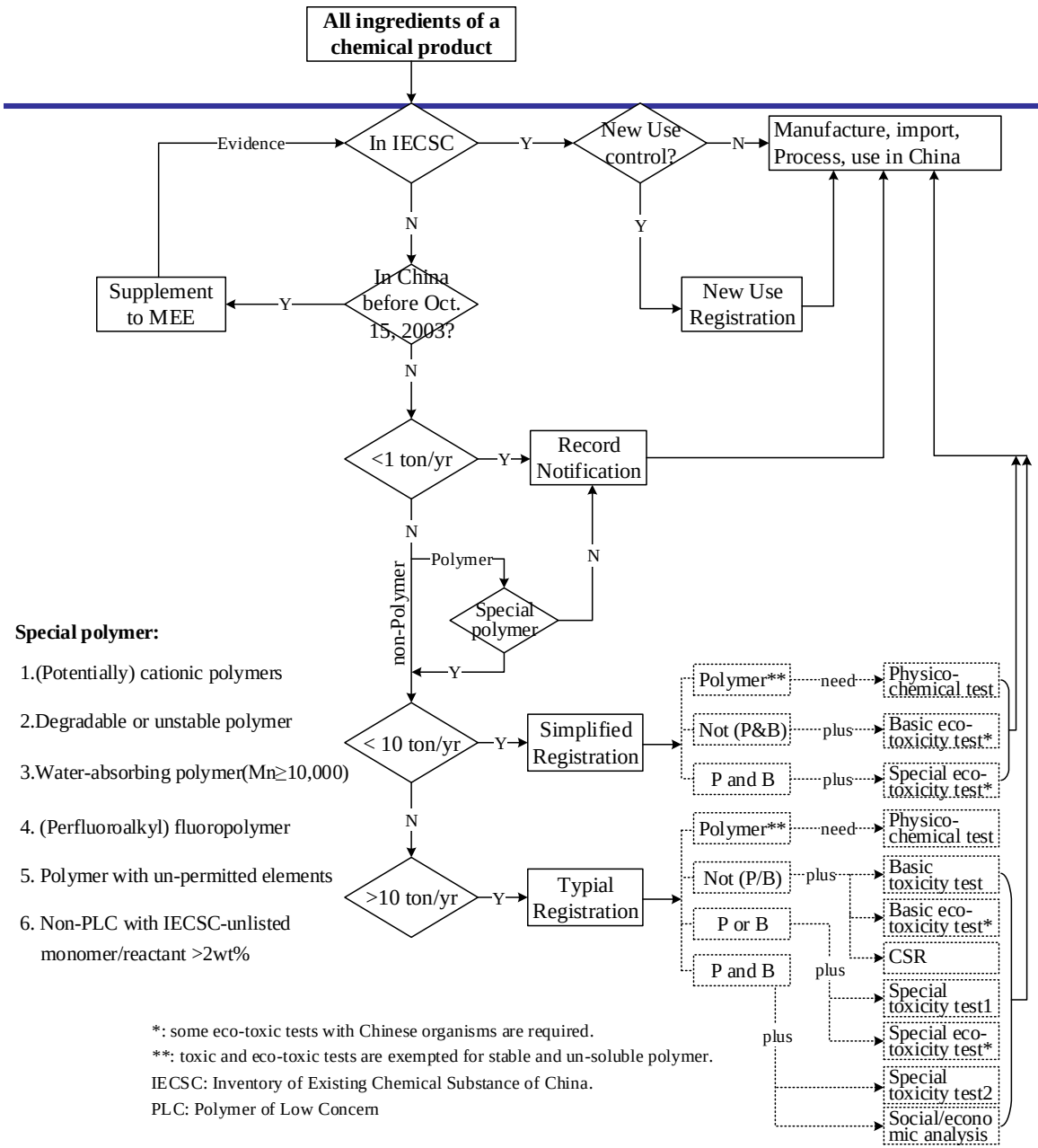

Special polymer:

1.(Potentially) cationic polymers

2.Degradable or unstable polymer

3.Water-absorbing polymer(Mn≥10,000)

4. (Perfluoroalkyl) fluoropolymer

5. Polymer with un-permitted elements

6. Non-PLC with IECSC-unlisted monomer/reactant >2wt%

*: some eco-toxic tests with Chinese organisms are required.

**: toxic and eco-toxic tests are exempted for stable and un-soluble polymer.

IECSC: Inventory of Existing Chemical Substance of China.

PLC: Polymer of Low Concern

New chemical registration under Order 12 (from 2021)

Randis Chemwise

Contact Randis

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