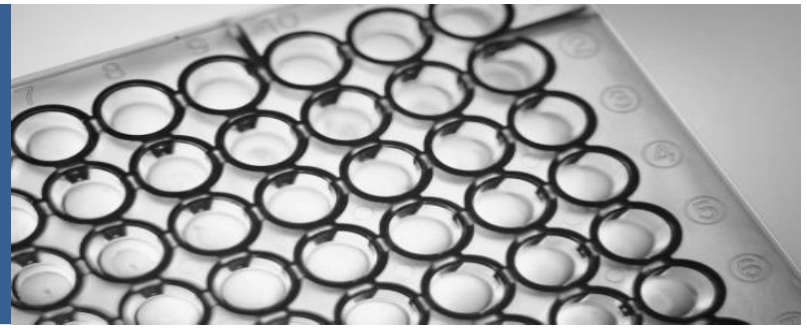
Latest updates of China REACH (MEE Order No.12)



Global Chemical Regulatory Compliance

www.cirs-group.com

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CIRS Europe
bryan.zhou@cirs-group.com

Who is CIRS?

- CIRS is an individual consulting firm founded in 2007 and headquartered in China;
- Has 300+ employees and annual revenue approximately 30 M USD;
- Has branch offices in Dublin(Ireland), London (UK), Arlington(US), Seoul (Korea), London (UK), Beijing(China), Hangzhou(China);
- CIRS provides regulatory compliance consulting, testing and training services.
- CIRS shares more than 70% Chinese consulting markets;
- Has 4000+ Clients including 300+ oversea companies

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CIRS Europe
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CIRS US
Add: #200-092, 3100 Clarendon Blvd., Arlington, VA 22201

CIRS Korea
Add: B-2310, 583, Yangcheon-ro, Gangseo-gu, Seoul, Republic of Korea

CIRS UK
Studio 310, Pill Box, 115 Coventry Road, London, E2 6GG

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Legislation History

2003.10.15
SEPA Order No.17 was implemented

2010.9.16
Guidelines on Notification of New Chemical Substances (2010 Edition) was published

2010.10.15
MEP Order No. 7 was implemented

2015.6.25
Draft Revised Guideline (For Consultations) was published

2016.3.8
Draft Revised Guideline was submitted to WTO for comments

2017.8.31
Data requirements in Guideline were adjusted

2019.7.9
Draft Revised Measures (For Consultations) was published. In Sep, the draft was submitted to WTO for comments.

2020.2.17
Approved during the Ministry internal meeting

2020.4.29
MEE Order No. 12 was published

2020.6.3
Consultation Document on Transition from MEP Order No.7 to MEE Order No.12 was published

2020.8.17
Guideline on New chemical Substance Registration (For Consultations) was published

(Deadline of submitting public comments: 06/09/2020)

2020.11.17
Official Guidelines on New chemical Substance Registration was published

2021.1.1
MEE Order No. 12 has been implemented

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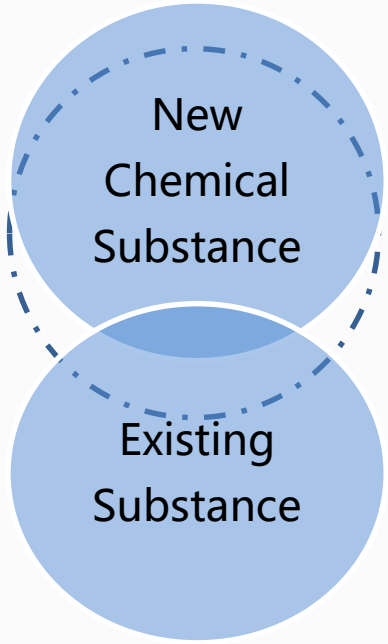
Registration Scopes

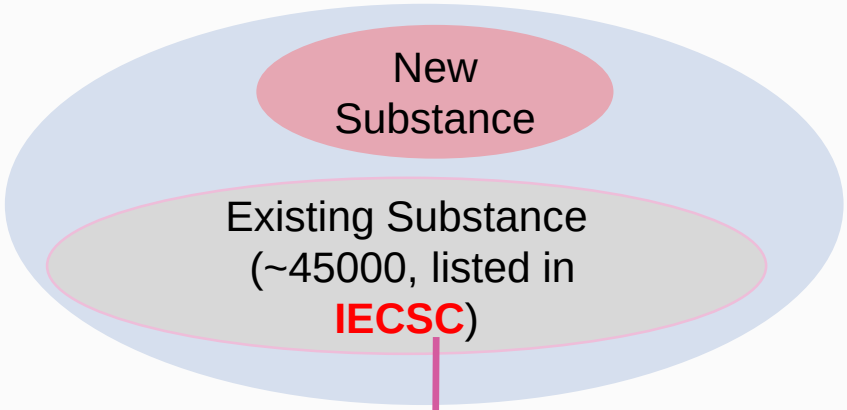


➢ **Scope of Applicable Substances：**

1. New chemical substances (except those not applicable or exempted): substances not listed in IECSC.
2. Existing substances : IECSC substance with new use management(i.e. use for other non-permitted industrial uses).

** IECSC: Inventory of Existing Chemical Substances in China*

Registration Scopes



Public part: https://apciss.cirs-group.com/?lang=en
Confidential part: submit an enquiry to MEE-SCC (3,000RMB per enquiry)

Updates

31 registered substances added

45 registered substances added

28 registered substances added

47 registered substances added

156 registered substances added

28 registered substances added

245 registered substances to be added 17/11/2020 (for public consultation)

新化学物质查新委托书

委托单位	杭州瑞旭科技集团有限公司
通信地址	中国浙江省杭州市滨江区秋溢路288号东冠高新科技园1号楼11层 （邮政编码:310052）
联 系 人	李建丹
电话	0571-89716578
电子邮件	lijd@cirs-group.com
传真	0571-87206533
CAS 号	[redacted]
结果通知方式	邮件回执
中文名称	[redacted]
英文名称	[redacted]
分 子 式	$C_{25}H_{25}N_2NaO_7S_2$
结 构 式	[redacted]

查新序号:CH18[redacted]

根据所提交的查新信息，国管中心确认该物质未收录进《中国现有化学物质名录》，属于新化学物质。

委托声明 Authorization statement:

本表签署人委托登记中心进行本项查新的真实意图是要生产或进口该化学物质，并当该化学物质未列入《中国现有化学物质名录》时进行新化学物质申报。本表签署人将查新结果用于任何其他用途或者将查新结果泄露给任何第三方时，本表签署人将承担全部责任。

申请人必须在下面空白处手工抄写下段中/英文字并签章，本表才生效：

"本签署人已阅读并接受本栏'委托声明'的全部内容。"

"The signer has read and accepts all of the contents of the 'authorization statement' in this column."

本签署人已阅读并接受本栏"委托声明"的全部内容。

签署人:李建丹

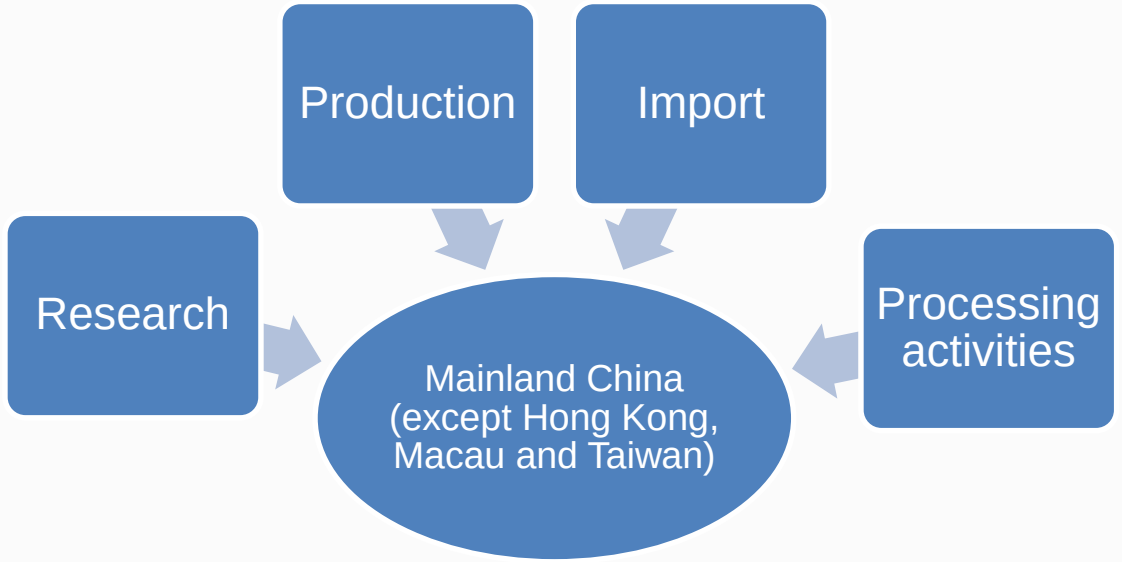
2018年 4月 16日

Exemption Scopes

Major Categories	Descriptions
1 Chemicals already under the management of other existing regulations	1) Pharmaceuticals (including API), pesticides (including active substances), veterinary drugs (API), cosmetics, food, food additives, feed, feed additives, fertilizers, etc. 2) Radioactive substances.
2 Substances existing in nature	1) Non-processed substance or processed by physical methods like gravity, water dissolution, etc. 2) Extracted from the atmosphere through various means; 3) Natural polymers; 4) Biomacromolecules; (Natural substances extracted or processed by **chemical methods can not be exempted**.)
3 Non commercial purpose or unintentionally produced	1) Impurities: total content of impurities shall not exceed 20%; 2) Products of random reactions; Products of unintentionally reactions in final use; 3) Waste water, waste gas, solid waste, and by-products.
4 Special Categories	1) Special materials: Glass; Frit; Pottery raw materials and ceramic ware; Steel and steel products; High-alumina cement; Portland cement; 2) Alloys; 3) Non-isolated intermediate substance ; 4) Articles; 5) New chemical substances produced by chemical reaction of products or preparations with specific functions, such as adhesion accelerator, chelating agent, surface treatment agent, etc.; 6) Physical mixtures that do not produce new substance; 7) Substance with or without hydrate are considered as same substances.

Registration Scopes

Applicable Geographical Scopes



- Not Include：
  - New chemical substances that are stored in a special customs supervision zone after importation and substances for exportation only without any processing or use
  - Trading, warehousing, transportation activities；
  - Use of articles containing new chemical substances.；

Registration Body

Applicant | Chinese manufacturer/importer | Overseas Enterprise ※ | Processing user

The processing users can act as the applicants if they meet one of the following conditions:

1. Use the exempted substance regulated by other regulations (e.g., medicine) for industrial purposes
2. Use the IECSC substance regulated by new use management for new uses

※Overseas Enterprise - the one who introduces directly the new chemicals into China

Agent

Overseas Enterprises shall appoint a Chinese local agent (OR)

The agent and the applicant shall carry out the registration obligations and post-registration obligations together, as well as bear the legal responsibilities.

The requirement for registered capital (> 3 million) is cancelled.

Registration Body

Overseas Enterprises

Chinese importer acts as applicant

Chinese agent (OR)

The certificate holder: Agent

The certificate holder: Applicant (overseas enterprise)

The following provisions shall be clarified in the Agency Agreement or Contract:

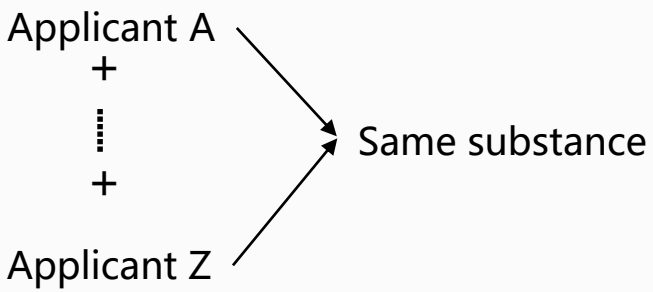
1. The agent and the applicant shall carry out the relevant obligations together, as well as bear the legal responsibilities.
2. The responsibilities and obligations when transferring the OR from A to B.
3. Validity period of agency relationship.

Registration Scopes

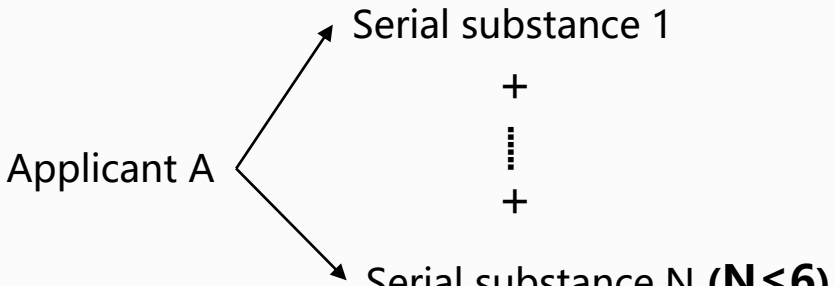
Registration Type	Requirements
Record Filing	• Tonnage level < 1t/y • Polymers with new monomers/reactants concentration less than 2% or PLC(polymer of low concern) and polymers that do not fall under the polymer record filing exclusion conditions
Simplified Registration	• Tonnage level 1<=Q<10 t/y
Regular Registration	• Tonnage level >=10 t/y

Joint Registration

For overseas applicants, they do not have to appoint the same agent.



Series Registration



***Registration tonnage = tonnage of applicant A +…+tonnage of Applicant Z

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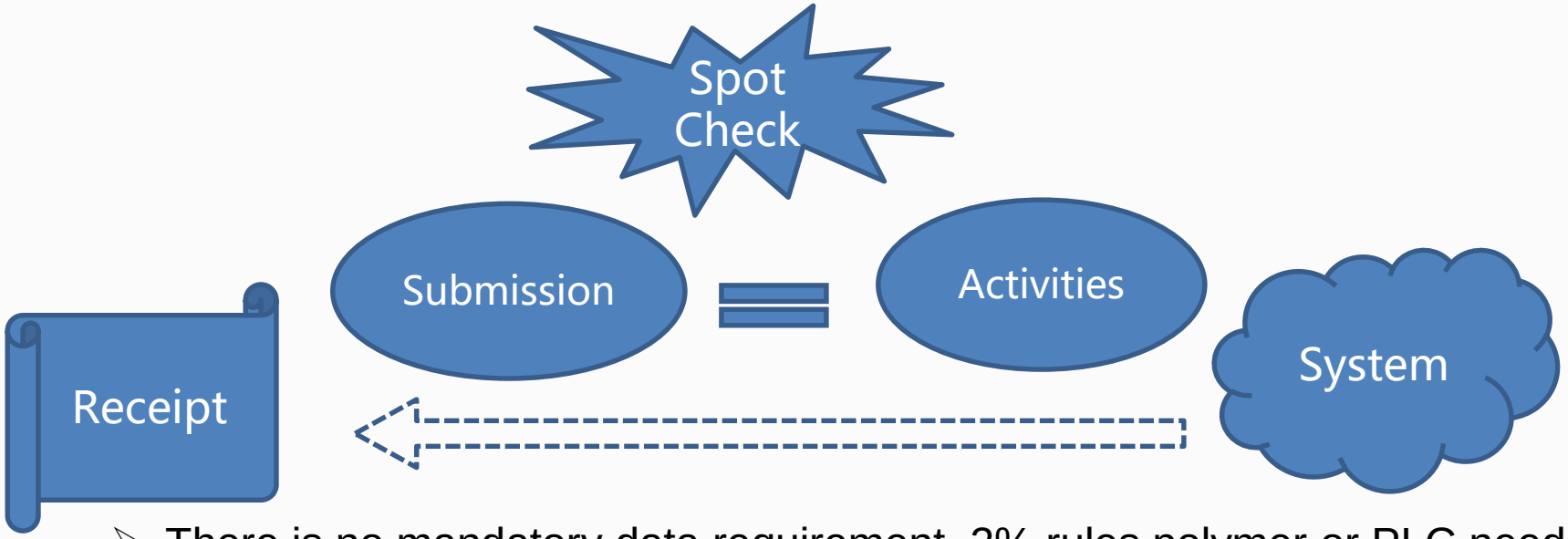
Record Filing



- There is no mandatory data requirement, 2% rules polymer or PLC needs to provide supporting documents, including:
  - List of monomers/reactants, molecular weight and distribution (GPC) and reaction mechanism;
  - Exclusion of polymer filing (a total of five, as follows) identification descriptions:
    1. Cationic (including polymers in natural water environment);
    2. Degraded or unstable;
    3. Water absorbent polymers with Mn≥10000Da;
    4. Certain types of fluoropolymers;
    5. Containing elements other than permitted elements.

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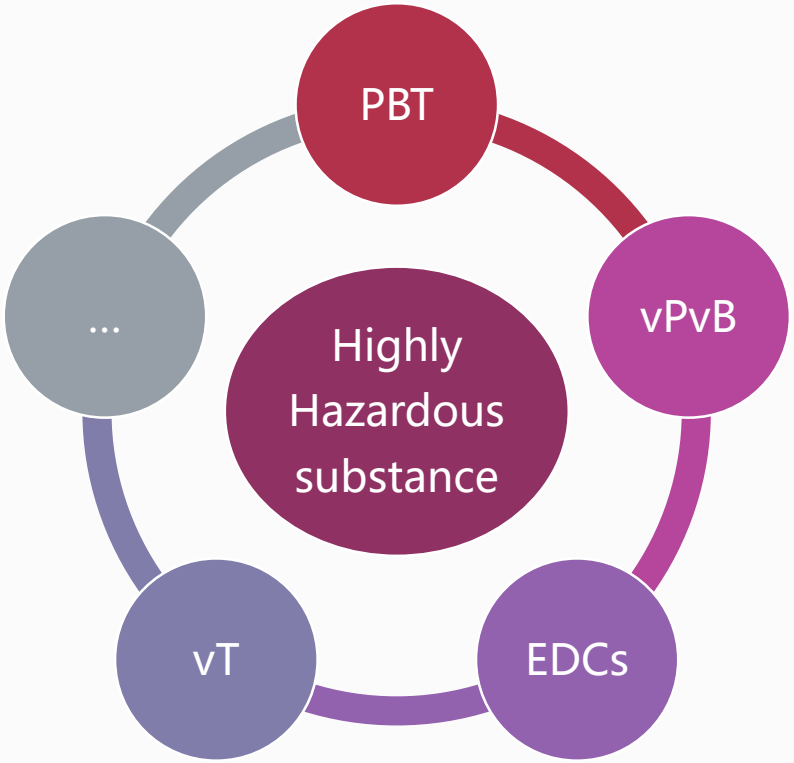
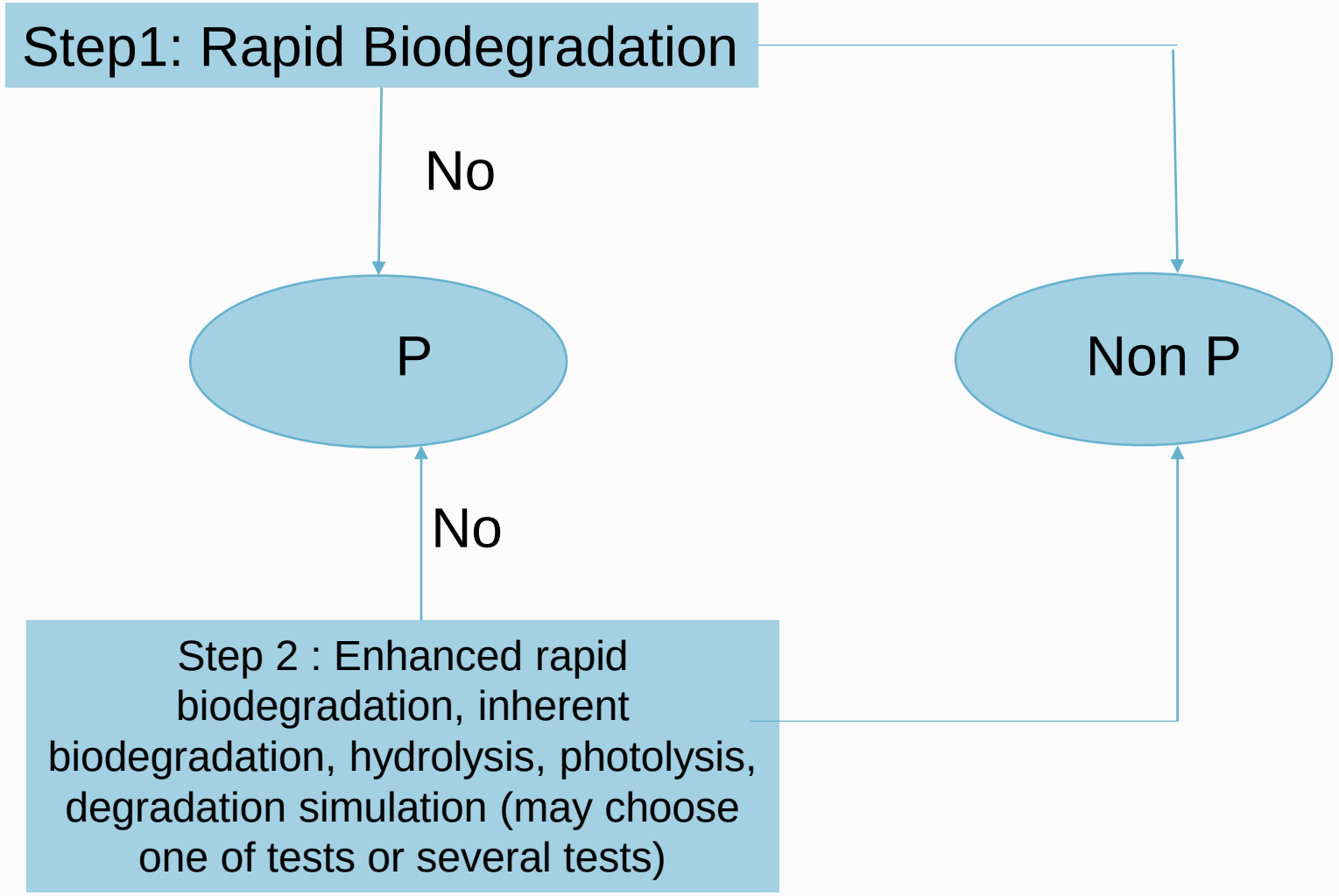
Highly Hazardous Substances

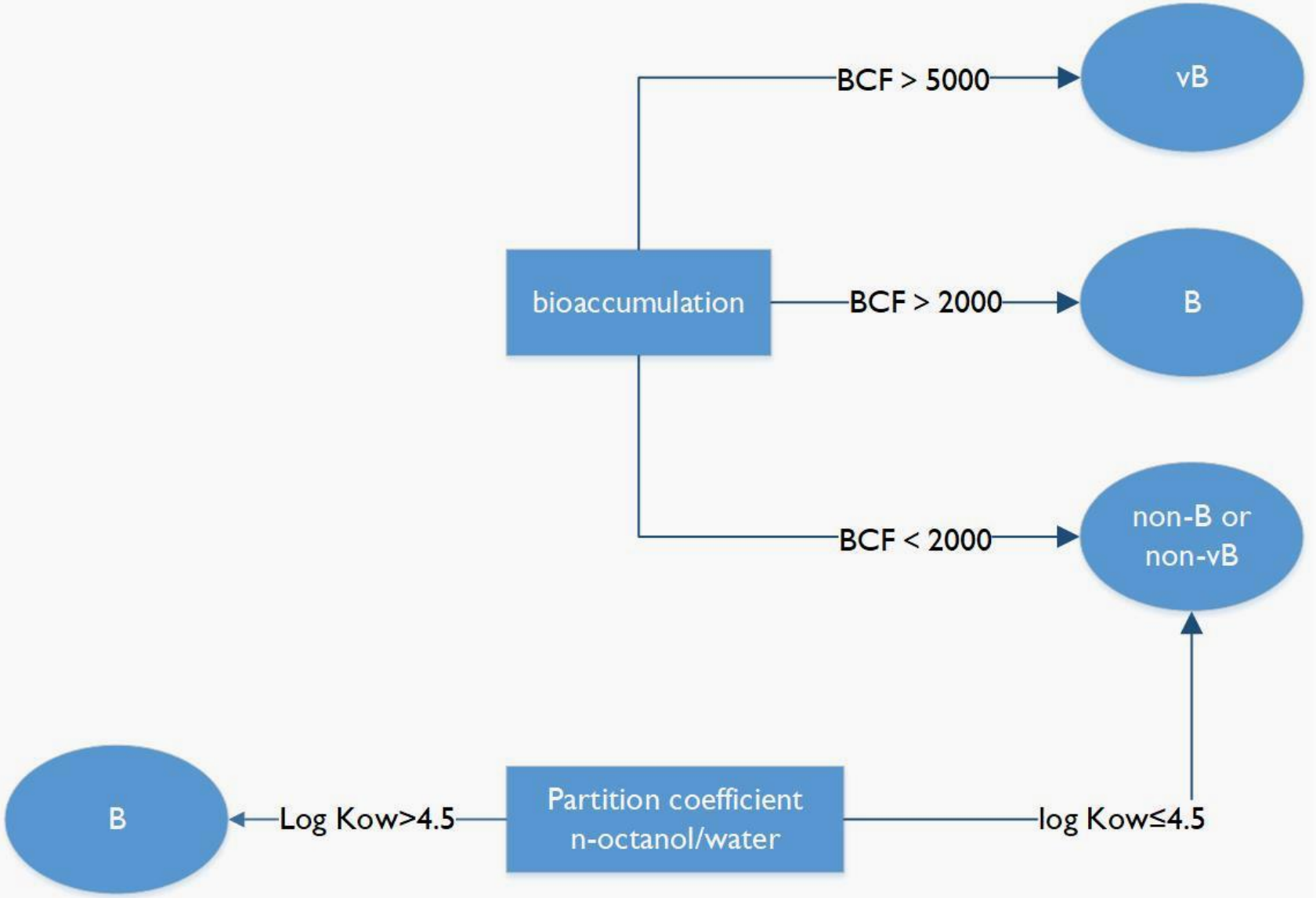


P: refers to persistence, indicating that it is not readily degradable in the environment and the determination of persistence does not apply to inorganic substances.
B: refers to bioaccumulation, indicating a tendency to accumulate in an organism.
T: refers to toxicity, indicating more severe acute or chronic toxicity.
EDCs: refers to endocrine disruptors.
v: A substance that indicates an enhancement of a property, such as very severe toxicity, is called a very toxic substance (vT substance).

Highly Hazardous Substances : Determination of Persistence

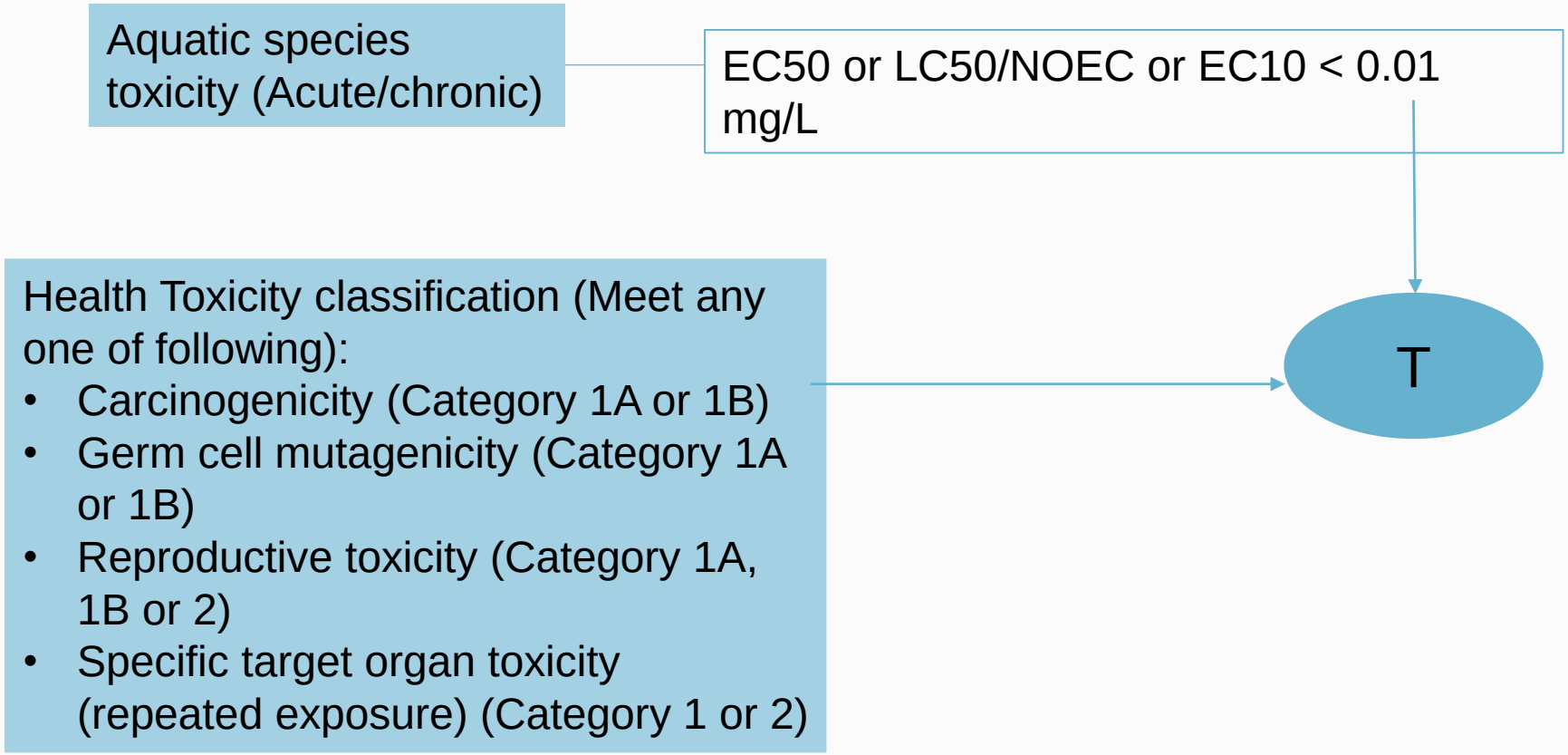


Highly Hazardous Substances : Determination of Bioaccumulation



- If log Kow>4.5, it is considered as bioaccumulation, but if BCF is less than 2000, it is considered as non-B substance.

Highly Hazardous Substances : Determination of Toxicity



- For simplified registration, if aquatic acute toxicity EC50 or LC50 =0.01~0.1mg/L, substance will be considered as Toxic substance; if aquatic chronic toxicity NOEC or EC10> 0.01mg/L, substance will be considered as Non-T substance.

Highly Hazardous Substances

Including but not limited to:
1. EDCs
2. vT substances (meet any of the following):

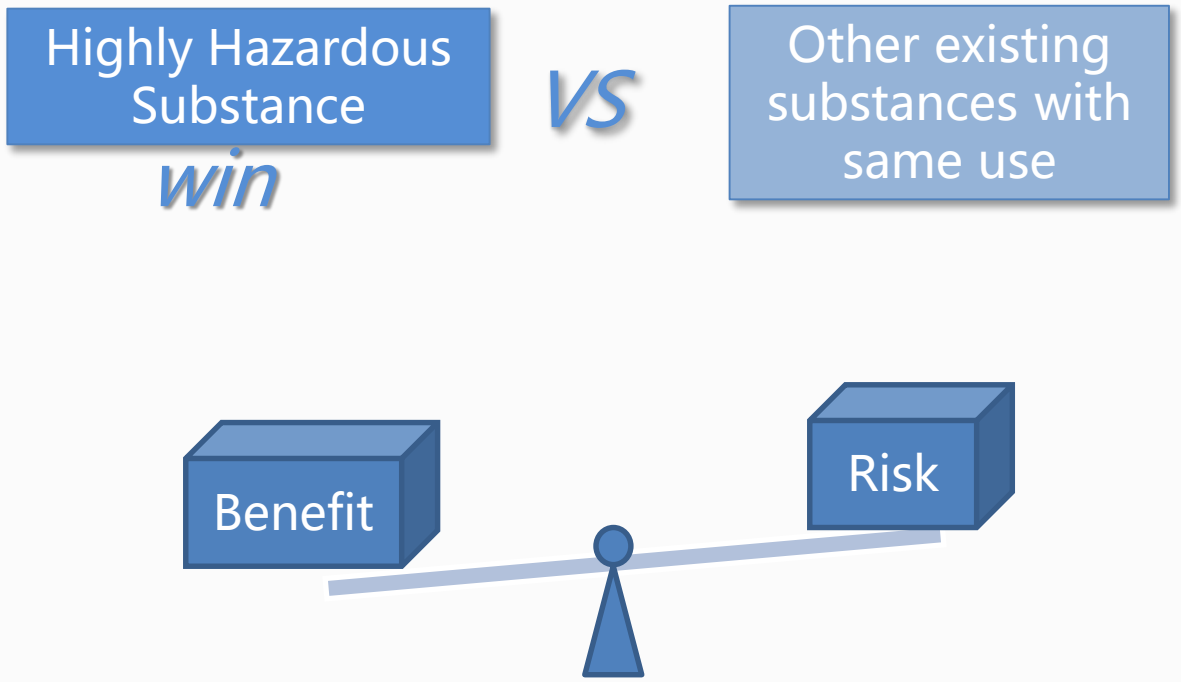
- Acute toxicity (oral, dermal, inhalation) category 1
- Carcinogenicity (1A or 1B category)
- Germ cell mutagenicity (1A or 1B category)
- Reproductive toxicity (1A or 1B category)
- Specific target organ toxicity (repeated exposure) (category 1)
- Aquatic chronic toxicity NOEC or EC10<0.01mg/L
- Acute aquatic toxicity EC50 or LC50<0.1mg/L (in the absence of aquatic chronic toxicity data)

→ Highly hazardous chemical substances with equivalent environmental or health hazards

➢ For regular registration, vT substances should be determined based on a combination of health and ecotoxicological data.

Highly Hazardous Substances : Social-economic Benefit Analysis Report

- **For Highly Hazardous Substance Registration or New Use Registration:**



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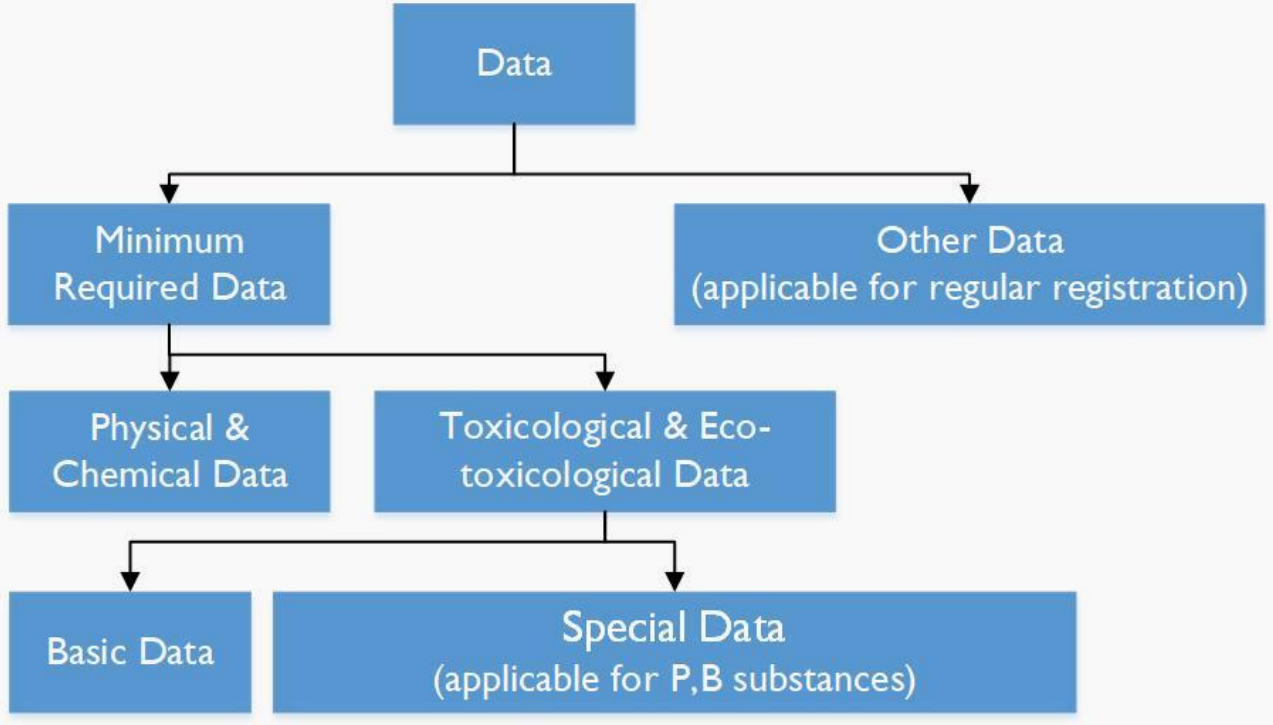
Minimum Data Requirement



1. **For the minimum required data, testing reports are mandatory**; for other data, testing reports are preferable to other sources (QSAR, READ-ACROSS, Systematic literature review, etc.).
2. Non-testing data can only be accepted if the testing is unable to be conducted. Required info: explanations on infeasibility of testing, methods or data sources, basis, etc.
3. Determination of P/B is based on the basic data, further conduct the testing to meet the special data requirements.

Minimum Data Requirement

Physico-chemical Testing Data	Simplified Registration			Regular Registration		
	Gas	Liquid	Solid	Gas	Liquid	Solid
IR/NMR/MS (at least 2)	√	√	√	√	√	√
Melting Point/Freezing Point		√	√		√	√
Boiling Point		√			√	
Density		√	√		√	√
Vapor Pressure		√			√	
Water Solubility	√	√	√	√	√	√
Octanol-Water Partition Coefficient		√	√		√	√
pH value		√			√	
Particle Size						√
Surface Tention					√	
Critical Point	√			√		
Dissociation constant					√	√
Henry’ s Law Constant				√	√	√

Minimum Data Requirement - Toxicological Data (Regular Registration)

Basic Data

- Acute Toxicity (Oral, Dermal and inhalation) (OECD 401/420/423/425/402/403/436)
- Skin irritation (OECD 404/430/431/439)
- Eye Irritation (OECD 405/437/438)
- Skin sensitization (OECD 406/429/442)
- Repeated dose 28-day toxicity (Oral, Dermal and inhalation) (OECD 407/410/412)
- Screening for reproductive or development toxicity (OECD 421)
- Gene mutation study in bacteria (OECD 471/472)
- In vitro chromosome aberration test (OECD 473/487)
- In vitro gene mutation test (OECD 476/490)
- In vivo gene mutation test (OECD 486/488/489)
- In vivo chromosome aberration test (OECD 474/475)

1. If any in vitro tests are positive, additional in vivo endpoints shall be provided.

2. If any three of vitro tests result in positive, then it will be considered as mutagenic, additional two In vivo experiments on genotoxic endpoints shall be provided.

Special Data (P or B)

- Carcinogenicity (OECD 451)
- Repeated dose 90-day toxicity (Oral, dermal and inhalation) (OECD 408/411/413)
- Two-generation or extended one-generation reproductive toxicity (OECD 416/443)

Required when substances with broad uses

Special Data (P and B)

*Toxicokinetics

- Required if the substances has health hazards (excluding local toxicity)
- Required comprehensive toxicokinetic test report if tonnage level over 1000 t/y and with broad uses.

- *Chronic Toxicity (OECD 452)
- Carcinogenicity (OECD 451)
- Prenatal developmental Toxicity (OECD 414)
- Repeated dose 90-dat toxicity (Oral, Dermal and Inhalation) (OECD 408/411/413)
- Two-generation or extended one-generation reproductive toxicity (OECD 416/443)

*Additional required tests

Minimum Data Requirement - Eco-toxicological Data (Regular Registration)

Basic Data

- Algae growth inhibition toxicity (OECD 201)
- Daphnia acute toxicity (OECD 202)
- Fish acute toxicity or short-term toxicity of fish embryo yolk sac absorption stage (Chinese, OECD 203/212)
- Activated sludge respiration inhibition (Chinese, OECD 209)
- Adsorption and desorption (OECD 106/121)
- Earthworm acute toxicity (OECD 207)
- Bio-accumulation (Chinese, OECD 305)
- Inherent biodegradation （OECD 302), Hydrolysis (OECD 111)
- Rapid biodegradation (Chinese, OECD 301)
- Daphnia magna reproduction (OECD 211)
- Fish chronic toxicity (Chinese, OECD 210/215)

Special Data (P or B)

- Fish chronic toxicity (Chinese, OECD 210/215)
- Seed germination and root elongation test or long-term tests for terrestrial plants; Worms reproduction or earthworms reporduction; Benthic organism chronic toxicity (US EPA OPPTS 850.4200/OECD 208, 220/222, 218/225
- Choose one of tests from three tests listed above (exclude exempted tests)

Tests are not mandatory, you may choose one of tests

Meet any one of following requirements, Fish chronic toxicity data is required to be submitted:

1. Registration level is over 100t/y
2. Fish acute/short-term test and daphnia magna test result in toxic effects (EC50 or LC50<0.01mg/L)

Special Data (P and B)

- Fish chronic Toxicity (Chinese, OECD 210/215)
- Seed germination and root elongation test or long-term tests for terrestrial plants (US EPA OPPTS 850.4200/OECD 208)
- Worms reproduction or earthworms reporduction (OECD 220/222)
- Benthic organism chronic toxicity (OECD 218/225)

Minimum Data Requirement - Eco-toxicological Data (Simplified Registration)

Basic Data

- Algae growth inhibition toxicity (OECD 201)
- Daphnia acute toxicity (OECD 202)
- Fish acute toxicity or short-term toxicity of fish embryo yolk sac absorption stage (Chinese, OECD 203/212)
- Bio-accumulation (Chinese, OECD 305)
- Inherent biodegradation （OECD 302), Hydrolysis (OECD 111)
- Rapid biodegradation (Chinese, OECD 301)

Special Data (P and B)

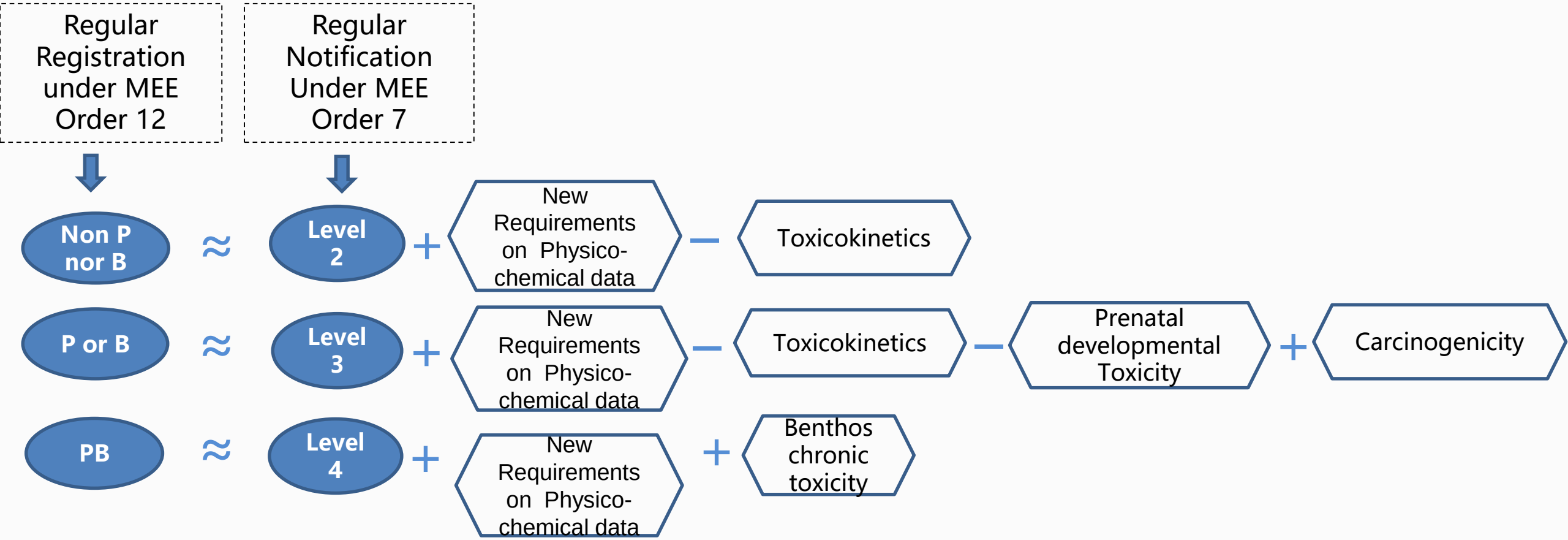
- Daphnia magna reproduction (OECD 211)
- Fish Chronic Toxicity (Chinese, OECD 210/215)

⇐ Tests are not mandatory, you may choose one of tests

⇐ Removed three eco-toxicological data tests:

1. Activated sludge respiration inhibition (Chinese, OECD 209)
2. Adsorption and desorption
3. Earthworm acute toxicity

Minimum Data Requirement- Data Requirement Comparison



Minimum Data Requirement-Special Category Substance's Requirement

- **Chemical substances that cannot be tested** (submit non-test data and explain the reason)
- Inorganic compounds and metals (same as Order 7)
- Decomposes or reacts with water/light (except for substances that emit flammable gas in contact with water) (same as Order 7)
- **Chemical substances used only as pesticide intermediates, pharmaceutical intermediates or veterinary drug intermediates**

  ☑ **Basic data + detailed description of intermediate use**

  ☒ **Special request data**

- **Special type polymer (meet the following three conditions at the same time)**

  1. The metals contained are limited to sodium, magnesium, potassium, and calcium;
  2. Insoluble in water, n-octanol, n-heptane, tetrahydrofuran and dimethylformamide;
  3. Stable under acid-base conditions (pH values of 4.0, 7.0, 9.0, respectively);

  ☑ **Description of special types of polymers**
  ☒ **Health and ecotoxicology data + risk assessment report**

Minimum Required Data Information – Testing Agency and Test Method Requirements

- Qualification of testing agency and testing method requirements remain largely unchanged, with a few points worth noting:
  - If the test method used in the report has been revised over 5 years, the validity of the report must be stated.
  - Ecotoxicology laboratories in China territory are subject to spot checks by the competent authorities on their testing and conditions.
  - Chinese test organisms deleted swordtail and zebrafish.

Minimum Data Requirement-Time Cost

Registration Type	Time Cost	Note
Record Filing	Once application is submitted, activity can be started	It will take 1-2 weeks for supporting documents preparation.
Simplified Registration	8-14 months (Testing period and authority review period included)	PB substances will take longer time on testing.
Regular Registration	14-30 months (Testing period and authority review period included)	PB substances will take longer time on testing.

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Information Protection-General Requirements

- Basic Information Protection Requirements
  1. Protection requirements should be submitted with application together, after the submission, no additional protection request can be added.
  2. Columns that can request information reports are provided with check boxes, and those without check boxes shall not be protected

Columns that can request information protection

- Chemical substance identification information
- Information on domestic processing users
- Existence form of the applied substance
- Substance's processing information
- Substance use information
- List of monomers/reactants
- Polymerization mechanism
- Description of Exclusions from Record Filing
- Impurities

Need to submit a description of the necessity of information protection (except for Record filing)

1. Data Protection Statement.
2. Describe the confidentiality column and the expected period.
3. Indicate whether the public is informed, e.g.
   - Public access, including competitors.
   - Whether domestic and foreign authorities have made it public.
4. Indicate if there is a business value, for example:
   - There is a causal relationship between leaks and impairment of competitive market position.
   - Leaks can speculate on commercial technical information.
   - Describe the measures that have been taken to prevent leaks.

New

Information Protection-Validity and extension of substance identification information

≤5 years from the date of registration or record filing

Six months before the expiration date

Extension ≤5 years

- ✓ The registration certificate holders jointly apply;;
- ✓ The necessity of the extension is sufficiently justified.;
- ✓ Not a highly hazardous or highly risky substance;

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Post Registration Management-Activity Report

Report	Order No.12
First Activity Report	√
Each Activity Report (New substance of high environmental concern)	×
Annual Activity Report	√
5-year Activity Report	×
New Hazard Information Report	√
√ required； × cancelled	

- Simplified Registration & Regular Registration
- Within 60 days from the date of activity
- The implementation of management requirements must be made public and archived for future reference (regular registration, producers and processing users)

- Regular registration (submitted as required on the certificate);
- Change from before February 1st to April 30th each year;
- Processing users should provide assistance.

Post Registration Management-Information to Downstream User

Information Contents

- ✓ Registration certificate number or filing receipt number;
- ✓ Application use;
- ✓ Substance hazard characteristics and risk control measures;
- ✓ Environmental management requirements on the registration certificate;

At the same time,

1. The information should continue to be transmitted level by level until the final processing user;
2. Do not process and use new substances that have not been registered or filed;
3. Deliver and archive in electronic or written form for future reference;

Post Registration Management-Information Change and Re-registration

Registration Information Change		Regular Registration	Simplified Registration	Record Filling
Applicant/Agent Name (1)		Apply for registration certificate change	Apply for registration certificate change	Apply for change through the online registration system, obtain a new receipt No.
Agent Transfer (2)				
Substance Identity Information (3)				
Activity Type	Manufacture -> Import			
	Manufacture -> Manufacture & Import			
	Import -> Manufacture	Re-registration		
Quantity Increase				
Registration Use				
Environmental Risk Control Measures				
Other circumstances leading to increased environmental risks (changes in process conditions, production site or environmental management requirements, etc.)				

Post Registration Management-Information Preservation Obligations

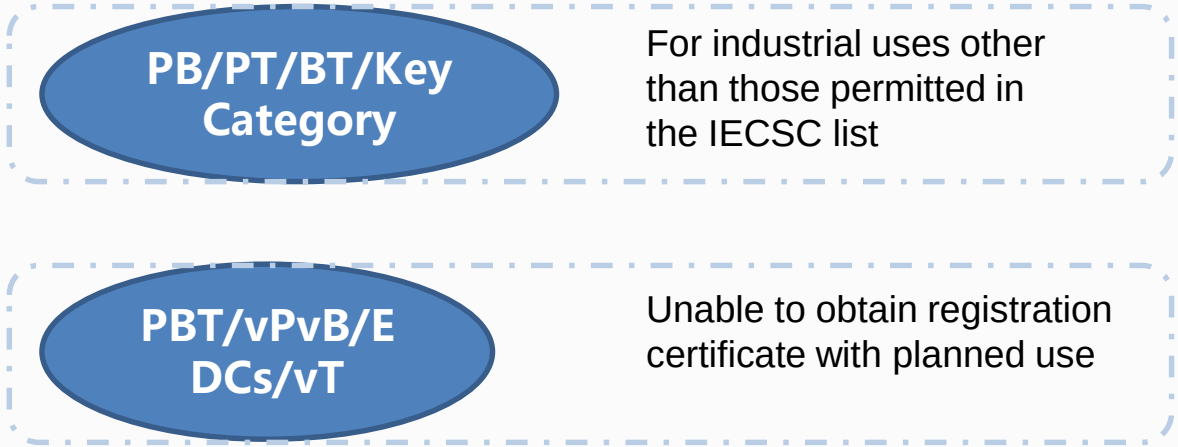
Registration Type	Information Contents	Time Limit
Regular Registration	1. Registration application information or filing information; 2. First and annual activity reports (if any); 3. Information transmission documents; 4. Activity records, including activity time, quantity, actual use purpose, implementation of environmental risk control measures and environmental management requirements, information transmission to downstream processing users, etc.	At least 10 years
Simplified Registration		
Record Filing		At least 3 years

Post Registration Management-Requirement for joining the IECSC

- Substances have been placed in China before October 15, 2003
- Completion of regular registration is changed from the date of the first activity to five years from the date of the first registration announcement for joining the IECSC

MEE Order.12

Post Registration Management-New Use Environment Management



Follow regular registration procedures

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Latest Supervision

- Different customs in China
- National and Provincial Environmental authorities

Thank You

If you have any questions about chemical regulation compliance, please contact your *compliance expert*:

bryan.zhou@cirs-group.com

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Phone: +353 1 477 3708 Web: www.cirs-reach.com