Interpretation on Guideline for Environmental Management registration of New Chemical Substances

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Revision background

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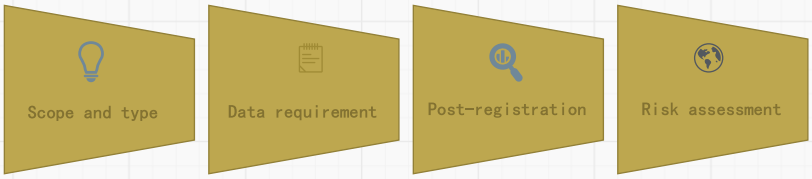
Major changes overview



- Registration scope refinement
- Registration type simplification

- Application materials requirement perfection
- Data requirements optimization
- Polymer
- Test

- Requirement refinement
- Post-registration management process standardization

- RA report standardization

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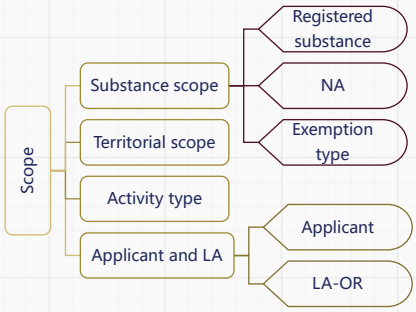
Registration Scope



- **Registered substance**

1. Chemical substances not included in the "*Inventory of Existing Chemical Substances in China* " (IECSC).
2. Chemicals subject to environmental management for new uses specified in the IECSC and those used for industrial purposes other than permitted uses.

- **NA**

1. Pharmaceuticals (including API), pesticides (including technic), veterinary drugs (including raw materials), cosmetics, food, food additives etc..
2. Radioactive material.

- **Territorial scope**

Research, production, import, processing and use of new chemicals within China, except for new chemicals that are stored in the special customs supervision area after import and are completely exported without any processing.

- **Applicant**

Domestic: Enterprises and institutions registered lawfully that can independently assume legal responsibilities and engage in the production or import of new chemicals.

Overseas: Production or trading companies that intend to export new chemicals to China.

- **LA-OR**

Enterprises and institutions that are legally registered in China and can independently bear legal responsibilities shall jointly perform environmental management registration for new chemicals with overseas applicants, and shall assume responsibilities in accordance with the law.

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Registration Type

MEP Order No. 7			MEE Order No. 12	
Notification type		Remark (Q: notification volume)	Remark (Q: notification volume)	Notification type
Regular notification	Level 4	≥1000t/a	Q≥10t/a	Regular registration
	Level 3	100≤Q＜1000t/a		
	Level 2	10≤Q＜100t/a		
	Level 1	1≤Q＜10t/a	1t/a≤Q＜10t/a	Simplified registration
Simplified notification	Special circumstances	Process product research and development, <10t/a, and no more than two years		
	Special circumstances	Intermediate or for export only, <1t/a	(1) New chemical substance monomer or polymer with reactant content not exceeding 2% (2) Low concern polymer (3) Other substances whose declared volume is less than 1t/a	Record
		Scientific research, 0.1t/a≤Q＜1t/a		
		(1) New chemicals monomer or polymer with reactant content not exceeding 2%		
		(2) Low concern polymer		
	General circumstances	＜1t/a		
Record	＜0.1t/a	R&D		
		test sample		

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Exclusion from Record of polymer

Cationic polymers

Polymers that can covalently bond with phosphonium ion, sulfonium ion, ammonium ion, and polymer containing amine group and isocyanate.

Degradable or unstable

Easily degraded, decomposed, and depolymerized polymers, and polymers that decomposes after production or use

Water-absorbent

Polymers that can absorb their own weight of water, with a number average molecular weight greater than or equal to 10,000 Daltons

Fluorine-containing polymer

In addition to impurities, those containing elements other than the following permitted elements*

*The polymer component must contain at least two elements of carbon, hydrogen, nitrogen, oxygen, sulfur or silicon.
Additional allowed elements: fluorine, chlorine, bromine and iodine covalently bonded to carbon, and chloride, bromide and iodide in the form of single ions.
Other allowed single ion elements are sodium, magnesium, aluminum, potassium and calcium, and lithium, boron, phosphorus, titanium, manganese, iron, nickel, copper, zinc, tin and zirconium with weight percentage less than 0.20% and other elements.

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Application doc.

Record form

- Business license, LA agreement, POA
- Illustrative materials conforming to the corresponding circumstances (polymer)
- Other acquired information

Simplified registration form

- Business license, LA agreement, POA
- Testing reports
- PBT judgement conclusion and basis
- Materials on the necessity of information protection
- Letter of commitment to implement/transmit risk control measures
- Test organization qualification
- Other acquired information

Regular registration form

- Business license, LA agreement, POA
- Testing reports
- Environmental risk assessment report
- Analysis report on social and economic benefits (high-hazard)
- Materials on the necessity of information protection Letter of commitment to implement/transmit risk control measures
- Test organization qualification
- Other acquired information

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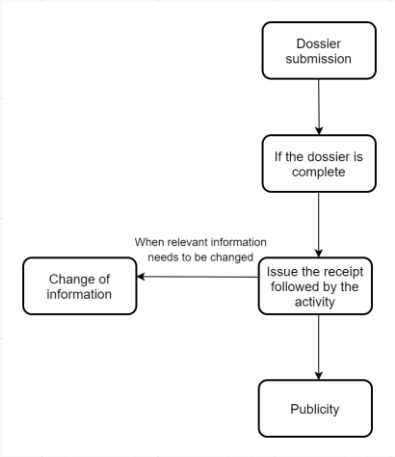
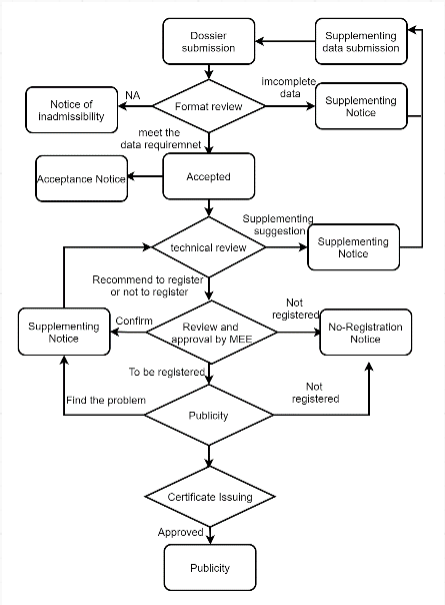
Registration Process





Approval process for the record and registration

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Fail to pass the technical review

Regular registration

- Concealment or fraud;
- Fail to supplement within 6 months
- After supplementing the materials, the application materials still have serious quality problems;
- Unreasonable environmental risks;
- Fail to meet the requirements for the necessity of application activities for highly hazardous chemical substances;

Simplified registration

- Concealment or fraud;
- Fail to supplement within 6 months;
- After supplementing the materials, the application materials still have serious quality problems;
- The applied substances have the characteristics of PBT;
- Accumulated environmental risks exist;

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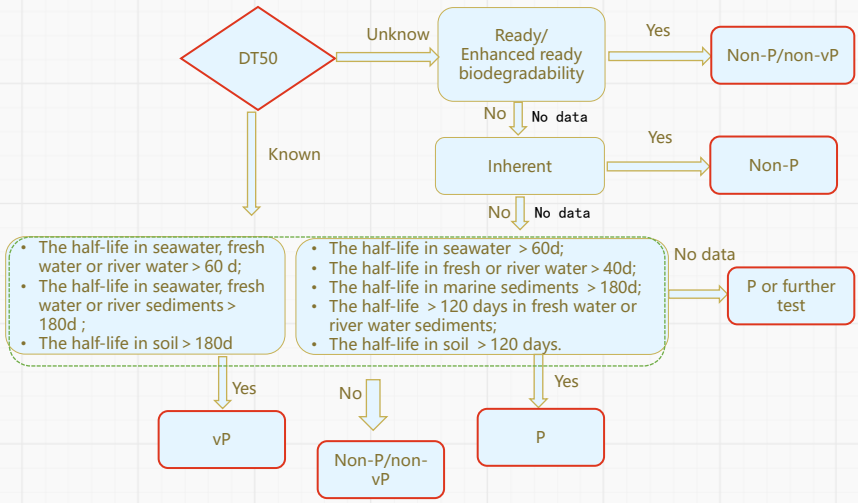
PBT determination-Persistence



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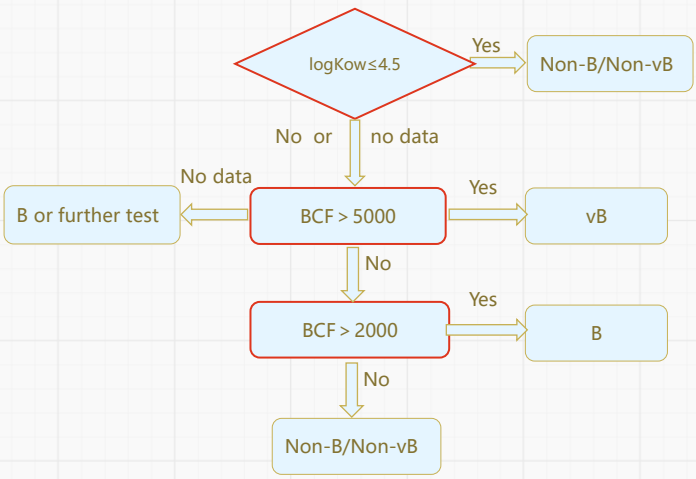
PBT determination-Bioconcentration



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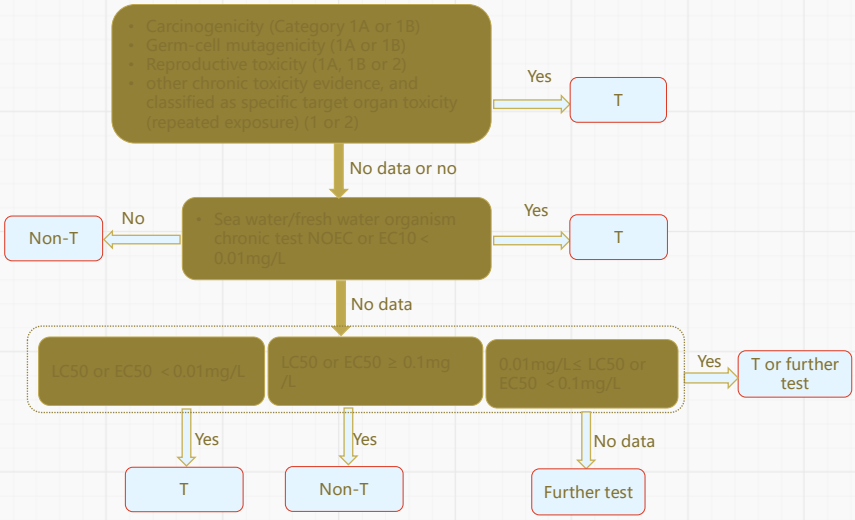
PBT determination-Toxicity



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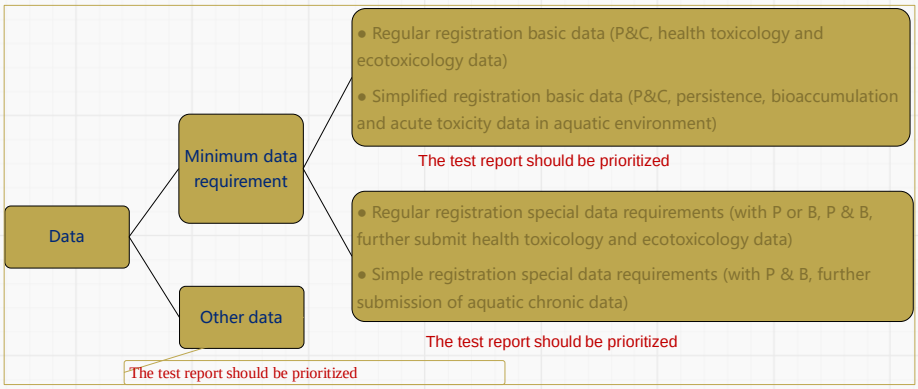
Overall Data Requirement



★ **Focal Point：**

1. Graded data submission
2. Pharmaceutical intermediates, pesticide intermediates, veterinary drug intermediates

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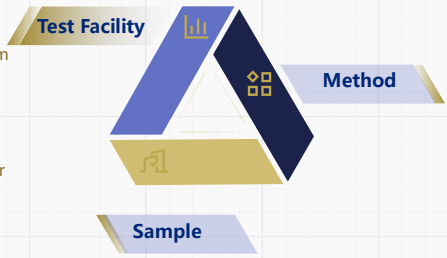
Requirement on test facility and report

Domestic:
- Obtain qualification certification of inspection;
- Toxicology and eco-tox test institutions shall also conform to GLP standard.

Abroad:
- Conforming to the national management requirement or GLP for P&C;
- GLP for toxicology and ecotoxicology test facility.



When the OECD chemical testing guidelines are updated and the domestic chemical testing methods or relevant national standards are not updated in time, refer to the latest OECD chemical testing guidelines

The test data for physicochemical properties, health toxicology and ecotoxicology characteristics should come from pure substances (total impurities <total impurities < 20%, single impurity content does not exceed 10%)

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Special Registration Type

- **Joint registration**: If two or more applicants apply for the environmental management registration of the same new chemical substances at the same time, they may submit application materials together for the joint registration of environmental management of new chemical substances.。
- **Series registration**: If the same applicant applies for multiple new chemical substances with similar molecular structure, same or similar usage and similar testing data, the applicant can apply for environmental management series registration of new chemical substances.
- **Registration for Polymer**:
  - Polymers don’ t meet the record requirement
  - Polymers intended to be listed into IECSC

★ **Focal point**
- Joint registration and series registration
- Regular registration for polymer.

- **Withdrawal**: After the application for registration of environmental management of new chemical substances, application for environmental management of new use, application for registration certificate change and other applications submitted by the applicant are accepted, the applicant may submit a written application for withdrawal of registration, stating the reason for the withdrawal, before it is approved.
- **Cancellation**: After obtaining the registration certificate, the applicant submits an application for cancellation on the data page, explains the reason for the cancellation, and returns the registration certificate.

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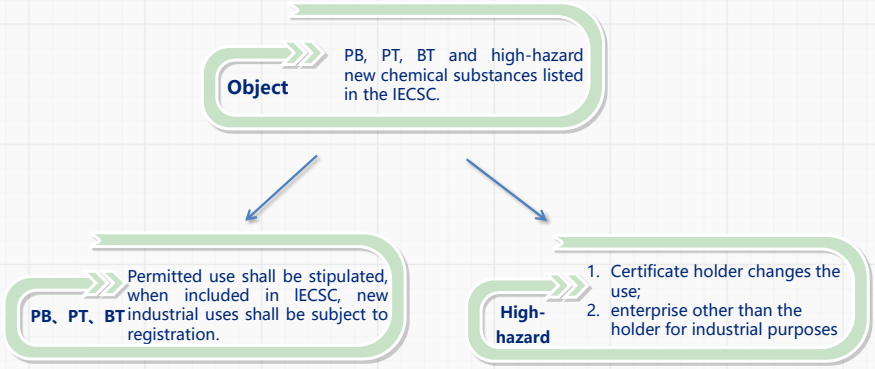
New Usage Management



Document Requirement :

1. New use environmental management registration form;
2. Environmental exposure assessment report, risk control measures, etc.

Approval decision:

1. Non-high-hazard substances: the new permitted use would be added in the "Inventory";
2. High-hazard substances: the scope of environmental management for new uses remains unchanged

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Post registration management

Regular registration:

- Increasing the volume produced or imported;
- The type of activity changes from import to production;
- Changing of the usage;
- Changing of the risk control measures;
- Other circumstances that increase environment and health risk.

Regular registration:

- Applicant/ agent name change;
- Agent change;
- The type of activity changes from production to import;
- Change of identification information

Simplified registration:

- Applicant/agent name;
- Agent;
- Identification information;
- Registration volume;
- The type of activity;
- The usage;
- Risk control measures

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Post registration management

	MEP Order No. 7	MEE Order No. 12
Information transfer	• The risk control measures specified in the registration certificate; • MSDS; • Classification result; • Other related information	• The registration certificate number or record notification receipt number; • The applied uses; • The characteristics of environmental and health hazards and environmental risk control measures; • The requirements for environmental management
Data Archive	10 years above	• Regular and simplified registration: at least 10 years; • Record notification: at least 3 years
Risk control measures publicity	No relevant requirement	Disclose the implementation of environmental risk control measures and requirements for environmental management through their official websites or other ways accessible to the public.

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Comparison and analysis –Post Registration

	MEP Order No. 7	MEE Order No. 12
Initial activity report	General notification: Within **30** days from the date of the first production, or within **30** days from the date of the first import and transfer to the processing user;	Within **60** days from the date of the first production, or within **60** days from the date of the first import and transfer to the processing user;
Every-time activity report	Certificate holder of key environmental management new chemicals submit within 30 days of each transfer to different processing users	**Cancel the submission** Establish a record system for the activities, which shall truthfully record the time, quantity and use of the activities, the implementation of environmental risk control measures and requirements for environmental management and other information.
Annual report	Simplified notification, regular notification: submit annual report before 1st, Feb.	Registration certificate requires the submission of annual reports, starting from the next year of registration, the certificate holder shall submit annual report before April 30 each year

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Comparison and analysis – IECSC listing

	MEP Order No. 7	MEE Order No. 12
IECSC	• General：automatic inclusion by MEE 5 years from the date of the first production or import activity • Hazardous（Key environment management）：submit the application 6 months before five years from the date of first production or import	• Chemicals produced, sold, processed, used or imported within China before 15th October 2003, enterprises could apply for inclusion ; • Regular registration certificate: five years from the date of first registration; • Order No. 7: included at the end of five years from the date of first activity, or at the end of five years from the date of implementation of Order No. 12; • Order No. 17: included within six months from the date of implementation of Order No. 12. • Apply to regular registration certificate that have been cancelled by notifier.

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Supervision and Suggestions

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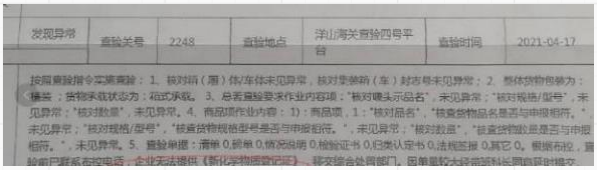
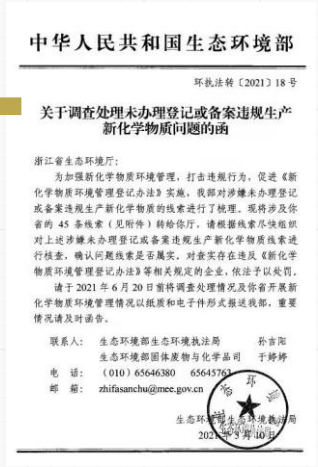
Supervision and Suggestions

- **Customs inspection:** Shanghai, Qingdao, Dalian, Tianjin, Shenzhen
- **Ministry of Ecology and Environment:** Drafting relevant supervision and management documents; successively sending "Letters on the investigation and handling of unregistered or registered illegal production of new chemical substances" to local environmental protection bureaus (Zhejiang, Jiangxi, Sichuan, Jiangsu, Shandong, Liaoning, etc.)





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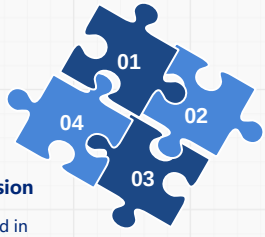
Suggestions

Polymer registration

The supporting materials for the exclusion from Record for polymer don’ t have to be from test data.

Data sharing

There is no volume accumulation for submitting the same test report.



Information protection extension

When registered substances are listed in the "IECSC", the identification information that have not been protected or has expired will be disclosed. Applicants can apply for the extension of disclosure of substance identification information, the maximum extension shall not exceed 5 years.

Simplify requirements for intermediates

Chemicals that are only used as intermediates of pesticide, pharmaceutical or veterinary drug. The minimum required data for health toxicology and ecotoxicology can only submit basic data, but detailed information demonstrating that the chemical is used for intermediate purposes should be submitted.

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Thank You.

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