



Solid Waste and Chemicals Management Center, MEE

Environmental Management Policy for New Chemical Substances in China

Division of Chemical Management

Solid Waste and Chemicals Management Center, MEE

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Overall policies on environmental management of new chemical substances

I. Overall policies

1. History

Measures for Environmental Management of New Chemical Substances
(SEPA **Order No.17**)

Measures on Environmental Management of New Chemical Substances
Order No. 17 of SEPA

Establish

2003

First Amendment

Measures for Environmental Management of New Chemical Substances
(MEP **Order No.7**)

Measures on Environmental Management of New Chemical Substances
Order No. 7 of MEP

Development

2010

Second Amendment

Measures for Environmental Management Registration of New Chemical Substances
(**MEE Order No.12**)

Measures on Environmental Management Registration of New Chemical Substances
Order No. 12 of MEE

Optimize

2020

I. Overall policies

2. Management System

policies

**Order
NO.12**

**Technical
Documents**

1. Inventory of Existing Chemical Substances in China
2. Guidance for Environmental Management Registration of New Chemical Substances and supporting forms and filling instructions (Announcement No. 51 [2020] of the MEE)
3. Announcement on Transition Matters Concerning Environmental Management Registration of New Chemical Substances(Announcement No. 46 [2020] of the MEE)
4. Announcement on Standardizing the Management of Chemical Testing Institutions (Announcement No. 85 [2016] of the MEP)
5. Guidelines for Approval of New Chemical Substances Environmental Management Registration Certificate (Published on the Ministry of Government Affairs Service platform)

I. Overall policies

2. Management System



- 1. Testing Guidelines of Chemicals, Testing Methods of Chemicals and relevant national standards for chemical testing**
- 2. Technical Requirements for Identification of substances for New Chemicals Notification and Registration;**
- 3. Framework Guideline on Environmental Risk Assessment Techniques for Chemical Substances (Trial)**
- 4. Technical Guideline for Environmental and Health Hazard Assessment of Chemical Substances (Trial);**
Technical Guideline for Environmental and Health Exposure Assessment of Chemical Substances (Trial)
Technical Guideline for Environmental and Health Risk Characterization of Chemical Substances (Trial)

I. Overall policies

3. Measures for Environmental Management Registration of New Chemical Substances (MEE Order 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7号）同时废止。

部长 黄润秋
2020年4月29日

General Provisions (Articles 1 to 9)

Chapter II Basic Requirements (Articles 10~14)

Registration, Simplified Registration (Articles 15~37)

Management (Articles 38~45)

Liability (Articles 46~51)

Supplementary Provisions (Articles 52~55)

I. Overall policies

4. Guidance for Environmental Management Registration of New Chemical Substances (Announcement No. 51 [2020], MEE)



名称	关于发布《新化学物质环境管理登记指南》及相关配套表格和填表说明的公告		
索引号	000014672/2020-01446	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	2020-11-17
文号	公告 2020年 第51号	主题词	

关于发布《新化学物质环境管理登记指南》及相关配套表格和填表说明的公告

为实施《新化学物质环境管理登记办法》（生态环境部令第12号），我部制定了《新化学物质环境管理登记指南》及相关配套表格和填表说明，现予公布。自2021年1月1日起施行。

《关于发布〈新化学物质申报登记指南〉等六项〈新化学物质环境管理办法〉配套文件的通知》（环办〔2010〕124号）和《关于调整〈新化学物质申报登记指南〉数据要求的公告》（环境保护部公告2017年第42号）同时废止。

附件：1.新化学物质环境管理登记指南

2.新化学物质环境管理登记配套表格及填表说明

生态环境部
2020年11月16日

Implementing guidance of Order No.12, which support to guide enterprises to apply for the environmental management registration of new chemical substances and fulfill their responsibilities and obligations under the Measures.

Clarify the specific requirements for notification dossiers, data requirements, quality of test data , environmental risk assessment reports, tracking management, etc..

I. Overall policies

5. Supporting forms and filling instructions (Announcement No. 51 [2020], MEE)

Supporting Applications form for Registration and Management

- Application Forms for Regular Registration, Simplified Registration, and New Use Environmental Management Registration
- Record application form
- Certificate Change Application Form for Regular Registration and Simple Registration
- Notification Withdrawal Application Form
- Certificate Cancellation Application Form
- Application Form for Addition of Chemical Substances to the Inventory
- Application Form for Identification Information Disclosure Extension
- New Hazard Information Reporting Form
- First activity report form
- Annual report form
- List of Chemical Substance Use Code

I. Overall policies

6. Announcement on Transition Matters Concerning Environmental Management Registration of New Chemical Substances (Announcement No. 46 [2020] of the MEE)

Regular Registration

- ❖ Implementation of environmental risk control measures
- ❖ Information transfer, Information reporting and Record keeping
- ❖ Application for cancellation of registration certificate
- ❖ New use environmental management registration for Key environmental management hazardous new chemical substances, and specify permitted uses when listed in the Inventory.

Simplified Registration

- ❖ Information reporting and Record keeping
- ❖ Application for cancellation of registration certificate
- ❖ Validity period of R&D Simplified registration certificate: two years after the start of the first activity.

I. Overall policies

7. Inventory of Existing Chemical Substances in China

○ Adjusted and published by MEE

Inventory

Dynamic updates

● Chemical substances produced, sold, processed, used or imported in China **before October 15, 2003**, could be supplemented into the Inventory.

● Chemical substances registered under regulations on environmental management of new chemical substances (Order No. 17, No. 7, or No. 12) **after October 15, 2003**, would be included into the Inventory according to the regulations.



Requirements for registration of new chemical substances

II. Requirements for registration

1. Scope of registration

➤ **“new chemical substances”** as stated in the Measures refer to those chemical substances not listed in the Inventory of Existing Chemical Substances in China(IECSC).

➤ **Chemical substances that are subject to environmental management of new uses as stipulated in the Inventory(IECSC) and are used for industrial purposes other than the permissible use, they shall be subject to environmental management as new chemical substances.**

II. Requirements for registration

1. Scope of registration



Non-applicable categories

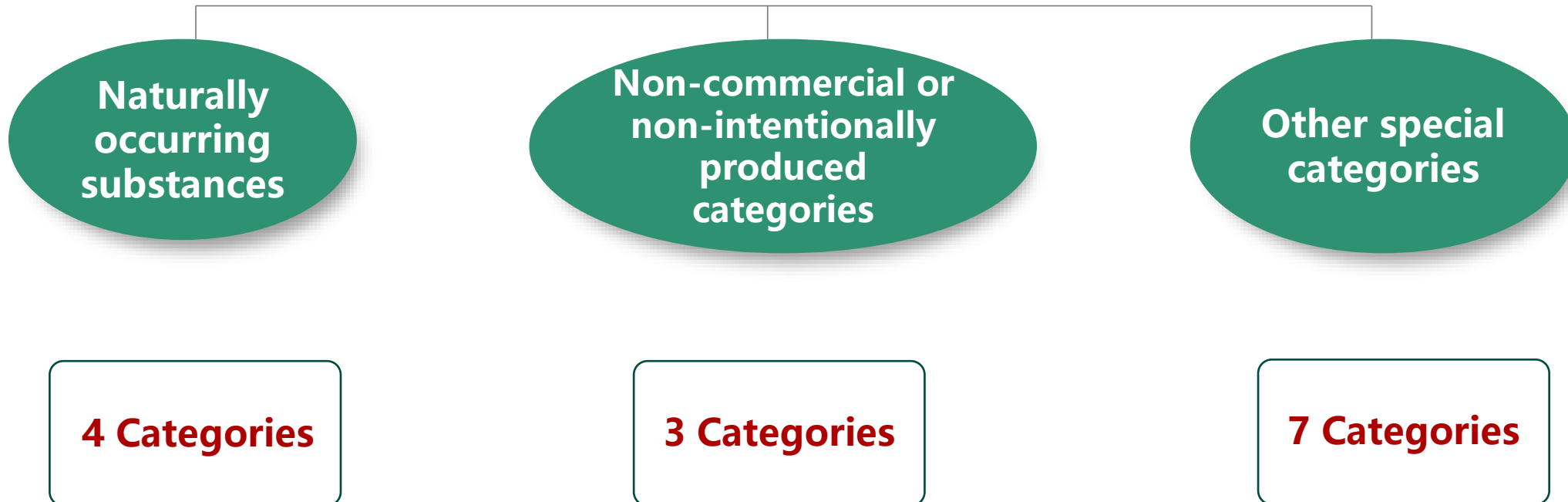
- Medicines (including active pharmaceutical ingredients), pesticides(including technical materials), veterinary drugs (including active pharmaceutical ingredients), cosmetics, food, food additives, feed, feed additives, fertilizers and other products;
- Radioactive material

➤ However, where the above products are altered to other industrial uses and the raw materials or intermediates used to produce the above products belong to new chemical substances, the Measures shall apply.

II. Requirements for registration



Exemption Category



II. Requirements for registration

2. Management principles and key points of control



key points of control

- new chemical substances that would cause persistent, bioaccumulative or severe harm to the environment or health
- new chemical substances that may stay in the environment for a long time, and may pose rather high risks to the environment and health

II. Requirements for registration

3. Registration Type

Regular Registration

Annual production or import of new chemical substances > 10 tons/year

Simplified Registration

Annual production or import volume of new chemical substances is 1 to 10 tons/year

Record

1. Annual production or import volume of new chemical substances is less than 1 ton per year;
2. The new chemical monomer or polymer contains no more than 2% of the reactants or polymerS of low concern

New Use Environmental Management Registration

Substances are used for industrial purposes other than the permitted uses, they shall be subject to environmental management as new chemical substances.

II. Requirements for registration

4. Applicant and Agent



Enterprises and institutions that are legally registered within China, able to independently bear legal responsibilities, and engaged in the production or import of new chemical substances.

- **Manufacture**
- **Import**
- **Processing and use**

Production or trading enterprises that intend to export new chemical substances to China may also serve as applicants. However, enterprises and institutions that are legally registered within the territory of China and able to independently bear legal responsibilities shall be designated as their agents



New chemical substances such as medicines, pesticides specified in Article 2 of the Measures, where intended for other industrial uses, the producer, importer or processor and user of relevant products may act as the Applicant.



For chemical substances that have been listed in the Inventory and been subject to environmental management for new uses, and are intended for industrial purposes other than permissible uses, the producer, importer or processor and user of relevant chemical substances may act as the Applicant.

II. Requirements for registration

4. Applicant and Agent

Enterprises and institutions that are legally registered within China and able to independently bear legal responsibilities shall be designated as their agents

The contents need to be clearly defined in the contract or agreement between applicant and agent

- The applicant and the agent perform the new chemical substance environmental management registration and post-registration obligations jointly, and bear the responsibilities

- Relevant responsibilities and obligations of changing agents;

- Validity period of the agency relationship.

II. Requirements for registration

5. Dossier requirements for registration

Simplified Registration Dossier requirements

- Regular Registration Application Forms
- Legal entity certificate or business license, agency contract or agreement, letter of attorney;
- Test reports or data on physical and chemical, and ecotoxicology properties
- Conclusion and basis for determination of persistence, bioaccumulation and toxicity
- Explanatory Materials on the necessity of information protection
- Commitment letters to implementing or transmitting environmental risk control measures;
- Qualification of testing agency
- Other available information on the environmental and health hazard characteristics and environmental risks

II. Requirements for registration

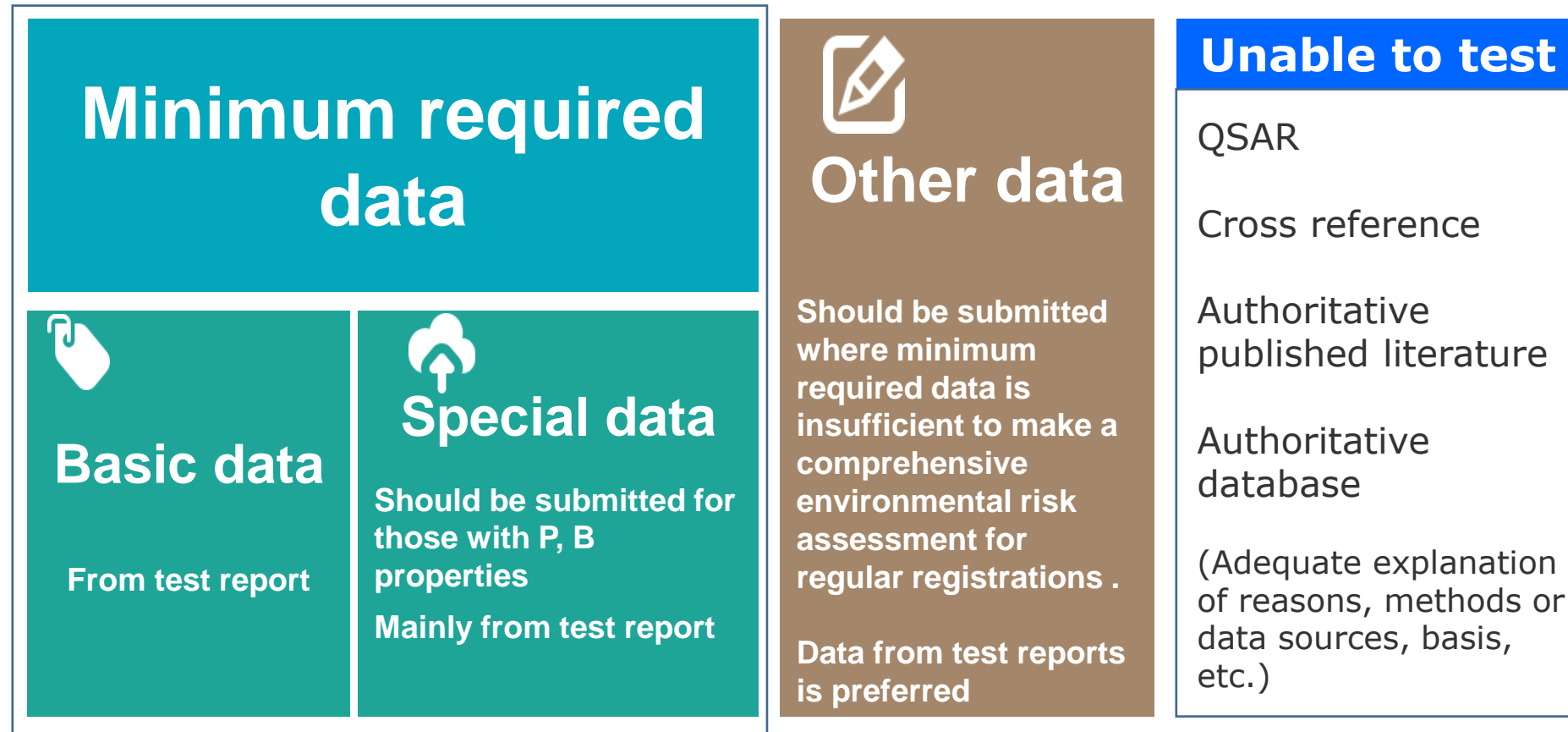
5. Dossier requirements for registration

Regular Registration Dossier requirements

- Regular Registration Application Forms
- Legal entity certificate or business license, agency contract or agreement, letter of attorney;
- Test reports or data on physical and chemical, toxicology and ecotoxicology properties
- Environmental risk assessment report
- Social and economic benefit analysis report (for highly-hazardous new chemical substances)
- Explanatory Materials on the necessity of information protection
- Commitment letters to implementing or transmitting environmental risk control measures and environmental management requirements;
- Qualification of testing agency
- Other available information on the environmental and health hazard characteristics and environmental risks

II. Requirements for registration

5. Dossier requirements for registration



II. Requirements for registration

5. Dossier requirements for registration

The ecotoxicology test report shall include test data completed in accordance with relevant standards by using organisms of China offered for test.

Gobiocypris rarus



Test Organisms in China refer to **native organisms** bred and propagated in China that meet the technical requirements of standard testing methods or test guidelines and are used for specific tests .

Activated sludge in China



II. Requirements for registration

5. Dossier requirements for registration

1 Environmental risk assessment

- In a quantitative approach;
- Clarified specific requirements for hazard assessment, exposure assessment, and risk characterization;
- Build scenarios based on the life cycle stages and uses in China;
- Carried out based on technical guidelines.



2 Socio-economic benefit analysis

- Description of the activity scenarios of new chemical substance and chemical substances for application uses;
- Analyze and evaluate environmental, health, economic, and social impacts;
- Economic and social benefits outweigh the risks to human health and the environment, and have considerable or obvious advantages in both aspects.



II. Requirements for registration

5. Dossier requirements for registration

3 Application for identification information protection

- Chinese and English name, CAS number, molecular formula and structural formula, etc.;
- Information protection statement and other necessity explanatory materials.
- When the registered substance is included in the Inventory, postponement of disclosure of identification information can be applied for the chemical substance subject to information protection, necessity explanatory materials



Necessity explanatory materials include:

- Specific information column and corresponding protection period;
- A description of whether the information is known to the public;
- A description of whether the information has commercial value;
- Whether relevant measures have been and will be continuously taken to protect the information applied for protection from disclosure, and the specific measures.

II. Requirements for registration

5. Dossier requirements for registration

4

Chemical substances that cannot be tested

- If it is not possible to carry out toxicology or ecotoxicology tests, data derived from estimates, analogue cross-references or literature can be submitted.



5

Chemical substances used only as pesticide intermediates, pharmaceutical intermediates or veterinary intermediates

Only basic data could be submitted for the minimum required data for toxicology and ecotoxicology. Detailed information on the intermediates use of chemical substances should also be submitted.



II. Requirements for registration

5. Dossier requirements for registration

- **High-hazard chemical substances**

High-hazardous chemical substances are those with persistence, bioaccumulation and toxicity, and with very persistence and very bioaccumulation at the same time, or those with equivalent environmental or health hazard

High-hazardous chemical substances with equivalent environmental or health hazards include but are not limited to endocrine disruptors (EDCs) and highly toxic (acute or chronic) substances

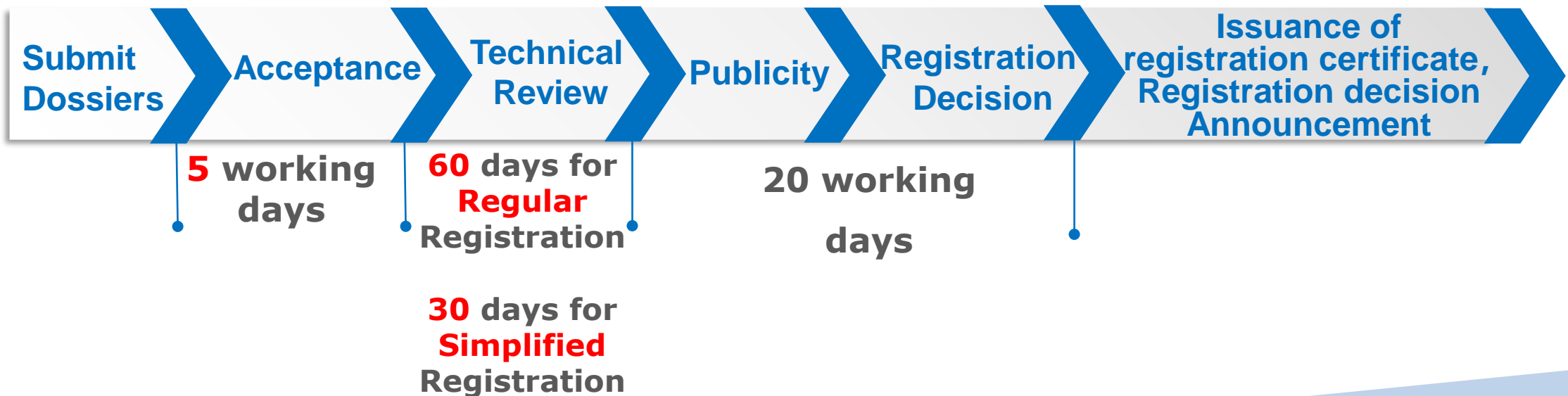
PBT/vPvB assessment:

Tiered Testing and Assessment
Judgment Criteria +
Screening methods and Criteria

II. Requirements for registration

6.Registration process and timeline

● Regular Registration/Simplified Registration



II. Requirements for registration

6.Registration process and timeline

Approval qualification

For Regular Registration

No unreasonable environmental risks are found, registration shall be approved.

For high-hazardous chemical substances, the requirements for the necessity of application activity shall also be met

Approval qualification

For Special Registration

substances those not found to be persistent, bioaccumulative and toxic, and not found to have any accumulated environmental risks, registration shall be approved

II. Requirements for registration

7. Information change of Registration certificate

Re-registration

- 01 Activity type: import change to production**
- 02 The production or import volume exceed the registration volume**
- 03 Change the uses of chemical substances**
- 04 Change the environmental risk control measures**
- 05 Other situations leading to increased environmental risk**

Dossier requirements

- Resubmission of the registration application form and a statement of reasons for the change;
- New environmental risk assessment reports;
- New environmental risk control measures to be taken and description of suitability ;
- New test report or data;
- Socio-economic benefit analysis report (if required);
- New commitment letters

II. Requirements for registration

7. Information change of Registration certificate

Change of
Regular
Registration
Certificates

1

- Chang of Applicant/Agent name
- Change of registered agent
- Activity type: change from production to import, or increase imports activity
- Change of identification information such as chemical names, CAS NO., molecular formulas and structural formulas

2

- Registration volume
- Activity type
- Application use
- Environmental Risk Control Measures
- Change of Applicant/agent name
- Change of registered agent
- Change of chemical names, CAS NO., molecular formula and structural formula and other identification information

Change of
Simplified
Registration
Certificates

II. Requirements for registration

8. Dossier requirements for Record Notification

Record Notification

I. The annual production or import volume of new chemical substances is less than 1 Ton/a

II. The polymer contains no more than 2% of new monomers or reactants, or belongs to a polymer of low concern

Record Notification for Polymers

- Meets the definition of polymer in the guideline
- Meets one of the two polymer Record conditions
- Doesn't meet any polymer record exclusions

II. Requirements for registration

Polymer Record Exclusions

- 1 **Cationic polymers, or those polymers that are anticipated to become cationic polymer in natural aquatic environment (such as polymer containing amine group and isocyanate).**
- 2 **Degradable or unstable polymers, including those that are easy to degrade, decompose and depolymerize, and those that decompose after production or use.**
- 3 **Water absorbing polymers with a number-average molecular weight of 10,000 or more.**
- 4 **Fluorine-containing polymers that contain the structure fragment of perfluoroalkyl sulfonate group and perfluoroalkyl carboxylic acid group or fluorine telomeres, or; that contain the structure fragment of perfluoroalkyl groups covalently bonded with carbon or sulfur atoms in polymer molecules.**
- 5 **Elemental Composition Restrictions**

II. Requirements for registration

8. Dossier requirements for Record Notification

Dossier requirements for Polymer Record



List of monomers/reactants: Including the chemical name, CAS NO., content of the monomers/reactants, whether listed in the IECSC or not



Molecular weight distribution data: including Gel Permeation Chromatography (GPC) of polymers, or other results of characterization of polymer molecular weight and its distribution



The mechanism and process of polymerization



The explanation which indicates the applicated polymer does not meets any polymer record exclusions

II. Requirements for registration

9. Record process

After the Applicant submits complete Record materials, the online registration system automatically sends a Record receipt. The new chemical substance related activities may be carried out by the Applicant base on the Record content.

A

MEE shall organize its affiliated technical agency to conduct random inspections of compliance of the filed materials.

B

The information on Record and cancellation of Record of new chemical substances shall be published on the government website of MEE

C

II. Requirements for registration

10. Dossier Submission

Application on New Chemical Substance Online Registration System



Online Application path: log in to the Ministry of Ecology and Environment “National Integrated Online Government Affairs Service Platform” > select “New Chemical Substances” >select “Item Notification” in the column of “13002 New Chemical Substance Environmental Management Registration Certificate Issue and Approval Items”

地址: http://zwfw.mee.gov.cn/ecdomain/#/commonPage_1



Requirements for post-registration tracking management

III. Tracking Management

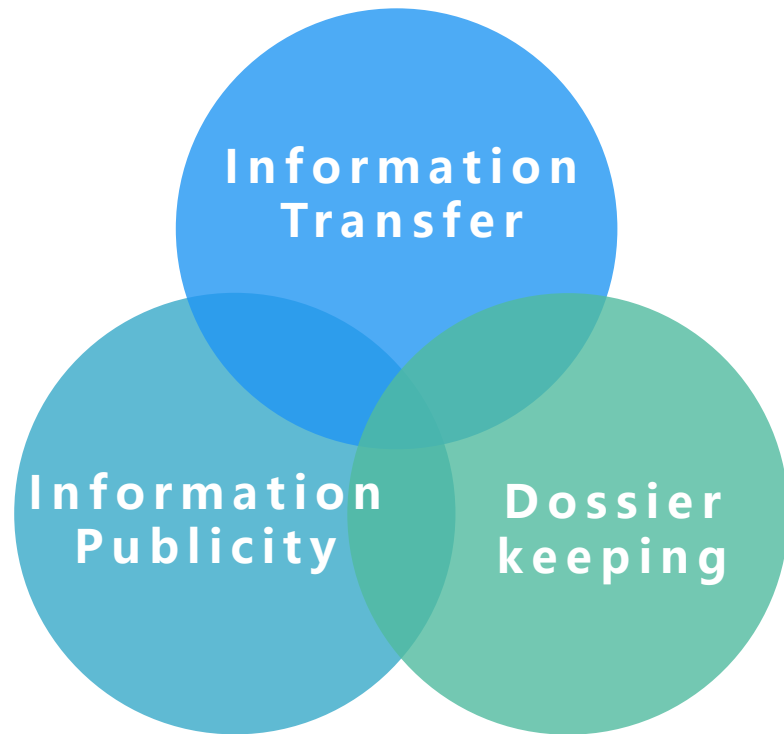
1. Post-registration Information Report



Application on New Chemical Substance Online Registration System

III. Tracking Management

2. Management requirements



- **For Regular Registration, Simplified Registration, Record**
- Information to be transferred: certificate number or record receipt number, uses, environmental and health hazard characteristics and environmental risk control measures, environmental management requirements

- **For Regular Registration:** Producers and processing users should disclose the implementation of environmental risk control measures and environmental management requirements after the first activity

- Establish a new chemical activity recording system;
- Regular and simplified registration dossiers and activity records shall be kept for at least 10 years
- Record Notification dossiers and activity records shall be kept for at least 3 years

III. Tracking Management

3. New Hazard Information and Environmental Risk Tracking

New Hazard Information

- Report new environmental or health hazard characteristics or environmental risks timely;
- Take measures to eliminate or reduce environmental risks timely

For new chemical substances whose environmental risks may continue to increase, relevant researchers, producers, importers and processing users may be required to further submit relevant environmental or health hazards and environmental exposure data information

Environmental Risk Tracking

III. Tracking Management

4. Supervision Management

Supervision mode

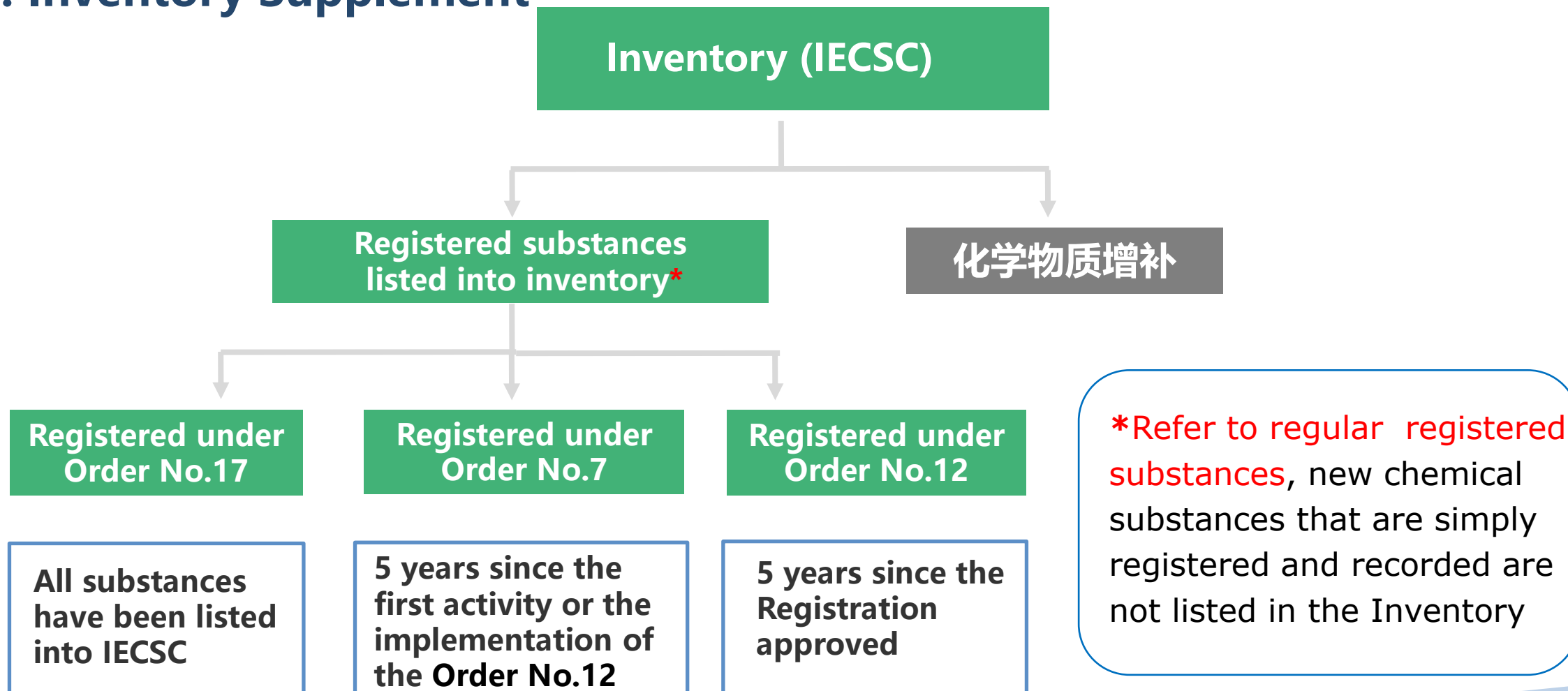
- Environmental supervision and spot check;
- Random selection of both inspectors and inspection entities and the prompt release of results;
- Included in the annual environmental enforcement work plan;

Supervision content

- Whether to apply for environmental management registration of new chemical substances as required;
- The authenticity of the registration, whether to implement the requirements stated in the registration certificate and other relevant requirements of the Measure.

III. Tracking Management

5. Inventory Supplement



III. Tracking Management

5. Inventory Supplement

For chemical substances produced, sold, processed, used or imported in China **before October 15, 2003**, the applicant may submit a **supplement application** form and relevant evidence materials to apply for adding them to the *Inventory*.

Supplement conditions

1. The applied substance is not listed in the Inventory;
2. Meet the Scope of registration in the Measure.

Applicant

1. Enterprises producing, importing, processing and using related chemical substances;
2. Relevant industry associations;
3. Other related entities.

III. Tracking Management

5. Requirements for Inventory Supplement

 **Supplement application form**

Accurate and standardized identification information of chemical substances:

Chinese and English chemical name, alias, CAS number, molecular formula, structural formula and other information

 **Annex to application**

Substantiation materials that can prove that the chemical substance has been produced, sold, processed or imported in China before October 15, 2003, including but not limited to Distribution invoice, Customs export declaration, Industry statistics, Chemical industry yearbook, Documents issued by management departments, Publications.



Thanks

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