ASIA

REGULATORY BRIEFING

China

Chemical Regulatory Framework — Compliance Reference

Extracted from the Compendium of Global Chemical Regulations (2025–2026)
Regulation Ready Series, 11th Edition · Global Product Compliance (GPC) Europe AB
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China

1 Chemical Inventories

China maintains two main chemical inventories: the Inventory of Existing Chemical Substances Produced or Imported in China (IECSC) and the Inventory of Existing Cosmetic Ingredients in China (IECIC). The IECSC is published and managed by the Ministry of Ecology and Environment (MEE), while the IECIC is overseen by the National Medical Product Administration of China (NMPA) **[60]**.

1.1 Inventory of Existing Chemical Substances Produced or Imported in China

The Inventory of Existing Chemical Substances Produced or Imported in China (IECSC) was first published by the MEE in 2013. As of 2025, the public part of the Inventory includes over 47,100 chemical substances that are circulated, used, manufactured in China, including recent additions through the supplementation procedure **[61]**. The IECSC consists of two parts: a public part and a confidential part **[60]**. The public part is accessible through the MEE's published list, while access to the confidential part requires submitting a formal inquiry to the MEE **[62]**.

Substances listed in the IECSC, can be introduced into China directly, without any notification requirements. Substances not listed in the Inventory, are considered New Chemical Substance (NCS) and must undergo registration or record filing procedures based on their tonnage band and its intended use before it can be introduced to China **[63]**. Under the current system, only substances registered via regular registration can be added to the IECSC.

Depending on when the substance was first introduced into China, different procedures apply. Substances introduced before 2003 can be added to the IECSC through a nomination window, while substances introduced after 2003 become eligible for inclusion according to the timelines shown in Figure 4 **[64]**.

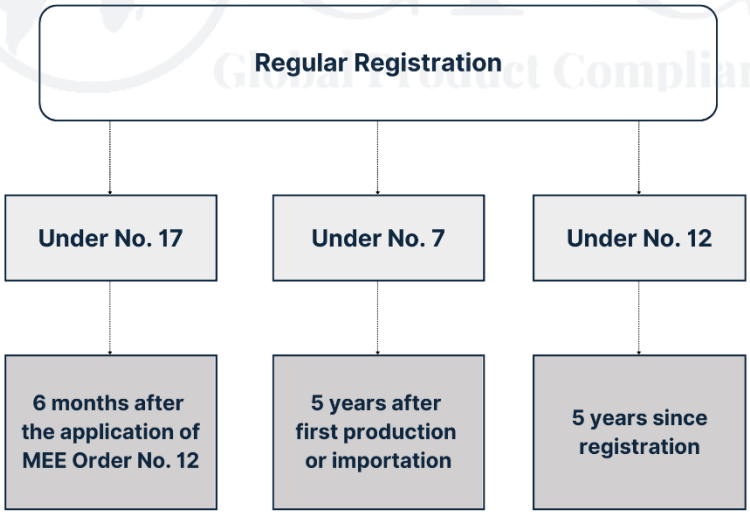

Figure 4 Inclusion timelines for substances in the IECSC under regular registration

1.2 Inventory of Existing Cosmetic Ingredients in China

The Existing Cosmetic Ingredients Inventory (IECIC) was first published by the NMPA in 2015 and updated in 2021 and 2024. The 2021 edition included 8,972 existing cosmetic ingredients **[65]**. A new version released in 2024 increased the number to 9,114 ingredients and incorporated restrictions and usage conditions in accordance with China's Cosmetic Supervision and Administration Regulations (CSAR) **[66]**.

Unlike the chemical inventory IECSC, the IECIC is fully publicly accessible through an excel file published by the NMPA **[67]**.

Unlike existing chemicals listed in the IECSC, **existing cosmetic ingredients** are not automatically considered compliant**.** Instead, they must still be submitted to the NMPA via the NMPA submission platform. Currently, this platform is open for both Chinese and overseas companies. However, overseas companies without a Chinese business license must obtain a verification from a Chinese embassy to register an account on the platform. Additionally, the platform operates only in Chinese, so overseas companies may appoint an Only Representative (OR) to assist with submissions **[68]**.

New cosmetic ingredients are normally considered for inclusion in the IECIC after a three-year monitoring period following their registration. The evaluation process is shown in Figure 5 **[69]**.

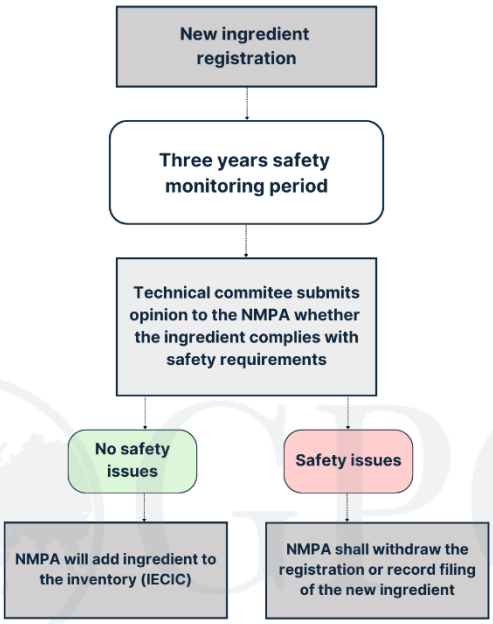

Figure 5 Procedure for including new cosmetic ingredients in the IECIC inventory

2 Status of GHS

China implements the **Globally Harmonized System of Classification and Labelling of Chemicals (GHS)** through a series of national regulations and standards. As of **August 1, 2025**, China's classification standards are aligned with the **eight revised edition (GHS 8)** following the publication of **GB 30000.1-2024**.

This update marks the first step in a broader revision of the **GB 30000 series**, which forms the core of China's chemical classification system. While **GB 30000.1-2024** entered into force on **August 1, 2025**, the **remaining 28 standards** (GB 30000.2 to GB 30000.29), each addressing specific hazard classes, are still under revision, and their enforcement dates have not yet been confirmed.

China first implemented the GHS through **State Council Decree No. 591: Regulations on Safe Management of Hazardous Chemicals**, which came into force on December 1. 2011, and remains the overarching legal framework for chemical management in China **[70]**. Under this regulation, manufacturers and importers are required to classify chemicals, provide compliant labels, and supply Safety Data Sheets (SDSs) in accordance with the applicable national standards.

2.1 GHS Classification

For GHS classification, China's governing standards are the **GB 30000 series**, consisting of 28 individual standards for each referring to a specific hazard class. The original GB 30000.2-2013 to GB 30000.29-2013 were based on **GHS 4** and have been in force since November 1, 2014.

The publication of **GB 30000.1-2024**, effective **August 1, 2025**, marks China's transition to **GHS 8 [71]**. This update introduces significant changes to hazard classification criteria, labeling, and safety data sheets. The final standard in the series, GB 30000.30-2025, covering desensitized explosives and aligned with GHS 10, was released on March 4, 2025. It details terminology, classification logic, and labeling requirements. This standard will take effect on July 1, 2026. Stakeholders should actively monitor updates to the remaining standards in the GB 30000 series to ensure continued compliance **[72]**. Table 18 lists the compulsory national standards for chemical classification.

Table 18 Overview of China's GB 30000 series standards for GHS classification

Standards	GHS Hazard
GB 30000.2-2013	Explosives
GB 30000.3-2013	Flammable gases
GB 30000.4-2013	Aerosols
GB 30000.5-2013	Oxidizing gases
GB 30000.6-2013	Gas under pressure
GB 30000.7-2013	Flammable liquids
GB 30000.8-2013	Flammable solids
GB 30000.9-2013	Self-reactive substances and mixtures.
GB 30000.10-2013	Pyrophoric liquids
GB 30000.11-2013	Pyrophoric solids
GB 30000.12-2013	Self-heating substances and mixtures
GB 30000.13-2013	Substances and mixtures which in contact with water emit flammable gases
GB 30000.14-2013	Oxidizing liquids
GB 30000.15-2013	Oxidizing solids
GB 30000.16-2013	Organic peroxides
GB 30000.17-2013	Corrosive to metals
GB 30000.18-2013	Acute toxicity
GB 30000.19-2013	Skin corrosion/irritation
GB 30000.20-2013	Serious eye damage/irritation
GB 30000.21-2013	Respiratory or skin sensitization
GB 30000.22-2013	Germ cell mutagenicity
GB 30000.23-2013	Carcinogenicity
GB 30000.24-2013	Reproductive toxicity
GB 30000.25-2013	Specific target organ toxicity- single exposure
GB 30000.26-2013	Specific target organ toxicity-repeated exposure
GB 30000.27-2013	Aspiration Hazard
GB 30000.28-2013	Hazardous to the aquatic environment
GB 30000.29-2013	Hazardous to the ozone layer
GB 30000.30-2025	Desensitized explosives

2.2 Local Adaptation of GHS

The following building blocks for the GHS have not yet been adopted in China (GHS 8):

- Flammable gases, 1A and 1B, Category 1A (pyrophoric gas)
- Chemicals under pressure, all categories

2.3 GHS Labeling Requirements

China has its own national standards for the labeling of hazardous chemicals in the workplace. As of **July 1, 2025**, the requirements are set out in:

- GB 15258-2023: General Rules for the Preparation of Precautionary Labels for Chemicals **[73]**.
- GB 190-2009: Packaging Labels for Dangerous Goods, based on the 15th revised edition of the UN Model Regulations **[74]**.

The newly enforced **GB 15258-2023** aligns China's labeling requirements with **GHS 8** and introduces several important updates, including:

- Clearer rules for label layout and small packaging.
- Retention of the simplified label option for volumes below 100 ml, with improved clarity.

China's labeling requirements continue to differ in several respects from those of the **EU CLP Regulation**. While both systems are based on the GHS framework, China maintains specific national approaches that reflect local regulatory preferences and practical considerations. Key differences include:

- The use of black-framed pictograms for hazardous chemicals, which is acceptable for domestic use in China.
- The absence of a limit on the number of precautionary statements (P-statements) required on the label.
- No specified minimum size for pictograms under Chinese standards.
- The requirement for labels to include a 24-hour domestic emergency contact number.

The transport labeling requirements continue to be governed by **GB 190-2009: Packaging Labels for Dangerous Goods**, which came into force on May 1, 2010 **[74]**. This standard specifies the requirements for pictograms, label size, color, and packaging of hazardous chemicals.

2.4 Safety Data Sheets

The format and content of Safety Data Sheets (SDS) in China are set by the standard GB/T 16483-2008, Safety Data Sheet for Chemical Products: Content and Order of Sections, and the standard GB/T 17519-2013, Guidance on the Compilation of Safety Data Sheet for Chemical Products **[75, 76]**.

GB/T 16483-2008 is the primary standard for checking SDS compliance. It came into force in 2009 and specifies the requirements for the structure, content, and format of Safety Data Sheets in line with China GHS **[75]**. GB/T 17519-2013 came into force in 2014 and provides additional guidance for SDS authoring in China.

As with labeling requirements, a 24-hour emergency phone number is also mandatory for SDSs **[77]**. This must be a domestic landline number in China that can provide Chinese-language support and technical advice in case of emergency.

With the release of GB 30000.1-2024, which entered into force on August 1, 2025, updates to classification rules now indirectly impact SDS-related requirements **[78]**. These include:

- Lowered cut-off values for classifying respiratory and skin sensitizers (from ≥ 1.0 % to ≥ 0.1 %).
- Introduction of cut-off values for aspiration hazards (≥ 1.0 %).
- Revisions to hazard communication and labeling that may also affect the content and structure of SDSs.

Additionally, a draft revision of GB/T 16483 was released in 2023 to further align SDS format and content with GHS Revisions 7 and 8. This revised standard is expected to be formally enforced by late 2025. In the meantime, companies are encouraged to begin voluntary alignment with the draft to ensure a smooth transition and future regulatory compliance.

2.5 GHS in Transport

The labeling requirements for the transport of hazardous chemicals in China continue to be governed by the national standard **GB 190-2009: Packaging Labels for Dangerous Goods**, which came into force on May 1, 2010 **[74]**. This standard was adopted based on the 15th revised edition of the UN Recommendations on the Transport of Dangerous Goods – Model Regulations. It specifies the requirements for pictograms, label size, color, and packaging of hazardous goods.

While GB 190-2009 remains valid as of September 2025, an update to the standard is anticipated in the near future to align China's transport labeling requirements with the latest versions of the UN Model Regulations.

For comprehensive classification and labeling in the transport context, **GB 190-2009** is used alongside the following standards:

- **GB 12268**: List of Dangerous Goods.
- **GB 6944:** Classification and Code of Dangerous Goods, which provide essential guidance on the classification and hazard coding of dangerous goods in China.

3 Chemical Regulation

The main legislation governing the chemical market in China is the **Measures for the Environmental Management Registration of New Chemical Substances**, also known as **MEE Order No. 12**, issued by the Ministry of Ecology and Environment (MEE). This regulation came into force on January 1, 2021, simultaneously repealing the previous regulation (MEP Order No. 7).

China's regulation of new chemical substances dates back to 2003, when the former State Environmental Protection Administration (SEPA) published the country's first national-level regulation dedicated to new chemical management: SEPA Order No. 17, Measures on Environmental Management of New Chemical Substances. In 2010, this regulation was revised and reissued as MEP Order No. 7 by the former Ministry of Environmental Protection (MEP). The Inventory of Existing Chemical Substances in China (IECSC) was first introduced under MEP Order No. 7. Finally, in 2020, MEP Order No. 7 was replaced by the current regulation, MEE Order No. 12.

MEE Order No. 12 imposes registration obligations on new chemical substances that are not listed in the Inventory of Existing Chemical Substances in China (IECSC) or are subject to new-use environmental management controls. Substances already regulated under other existing laws are exempted from the scope of MEE Order No. 12. These include:

- Radioactive substances
- Pharmaceuticals (including active pharmaceutical ingredients (APIs))
- Pesticides (including technical materials)
- Veterinary drugs
- Cosmetics
- Food and food additives
- Feed and feed additives
- Fertilizers

Also exempted are substances occurring in nature, such as natural polymers and biomacromolecules, as well as substances used for non-commercial purposes and unintentionally produced substances.

Recent updates under MEE Order No. 12 have clarified criteria for PBT/PT/BT substances and reinforced registrants' obligations to communicate environmental risk control measures downstream. The online

registration system is now integrated into MEE's National Integrated Online Government Services Platform (zwfw.mee.gov.cn) **[79]**.

3.1 Authority

The **Ministry of Ecology and Environment of China (MEE)** is the competent authority responsible for regulating the **manufacture** and **importation** of chemicals in China. The MEE oversees the registration of new chemical substances under MEE Order No. 12.

All manufacturers, importers, or processing users introducing new chemical substances into the Chinese market are required to submit registration applications to the MEE. Upon The Solid Waste and Chemicals Management Center (SCC) of the MEE, or an expert panel appointed under the MEE-SCC, then conducts the technical review of the dossier in accordance with the provisions and guidance of MEE Order No. 12.

Following registration, municipal and local Departments of Ecology and Environment are responsible for post-registration supervision. These authorities are empowered to conduct inspections and impose enforcement measures or penalties on companies found to be in breach of regulatory obligations.

3.2 Concerned Bodies

Anyone who intends to **research, manufacture, import, or process new chemical substances in China** must complete the required registration before carrying out these activities. The registration obligation applies to:

- Chinese manufacturers and importers.
- Chinese processors (users of new chemical substances).
- Foreign companies that wish to place new chemical substances on the Chinese market.

Chinese manufacturers and importers can submit registration applications themselves. However, foreign companies must appoint a **Chinese agent**, known as an **Only Representative (OR)**, to fulfil registration and post-registration obligations. The OR shares legal responsibility with the foreign enterprise and must be sufficiently knowledgeable and qualified to carry out the registration process in compliance with MEE Order No. 12.

3.3 Comparison between MEE Order No. 12 and EU REACH

MEE Order No. 12 is sometimes referred to as **China REACH** due to its similarities with the European Union's **REACH Regulation**. Both MEE Order No. 12 and EU REACH aim to protect human health and the environment through the identification, assessment, and management of chemical substances.

Both regulations apply a tonnage-based registration system, with requirements and information obligations increasing according to the annual tonnage of the substance placed on the market. In addition, both frameworks provide mechanisms for the restriction or control of highly hazardous substances. Table 19 provides a comparison of key aspects of MEE Order No. 12 and EU REACH.

Table 19 Comparison between MEE Order No. 12 and EU REACH

	MEE Order No. 12	**EU REACH**
Substances to be registered	Substances not listed in IECSC; applies to substances manufactured or imported in China in specified quantities.	Substances manufactured or imported in the EU/EAA
Polymer	Registration required for polymers as well, as long as they are defined as new substance.	Polymer themselves are exempt from registration.
Only Representative (OR)	Non-Chinese companies (incl. distributors) exporting new substances to China may appoint an OR.	Only non-EU/EEA manufacturers, formulators, or article producers can appoint an OR.
Registration type/form	Record Filing, Simplified Registration, Regular Registration / Individual	Standard (Full) Registration and reduced Registration (intermediate);

	MEE Order No. 12	EU REACH
	Registration, Series Registration, and Joint Registration	Joint Submission and Individual Submission
Data sharing	No Substance Information Exchange Forum (SIEF); data sharing is not mandatory.	SIEF. Testing on vertebrate animals as last resort. Data sharing is mandatory to avoid duplicate testing.
Data requirements for registration	Physicochemical properties, toxicological, and ecotoxilogical data requirements depend on tonnage bands (1-10 TPA and > 10 TPA). No test data required for Record Filing (<1 TPA, polymer with NM<2% PLC) Additional data required for highly hazardous substances (e.g. PBT/vPvB) and PB/PT/BT substances. Some ecotoxicological tests must be performed using local test organisms (e.g. Gobiocypris rarus, activated sludge); testing must be done in China.	Physiochemical properties, toxicity and ecotoxicity data requirements depend on tonnage bands (1-10 TPA, 10-100 TPA, 100-1000 TPA, > 1000 TPA).
GLP qualification	Due to not being OECD member, China GLP test data is not accepted as international GLP data under EU REACH and other chemical regulations.	Toxicity and ecotoxicity must follow internationally accepted GLP standards.
Language	Predominantly Chinese. Test reports in English are possible, but a Chinese translation of the summary must be provided.	English
Software	No specific software. Submission by using SCC's online registration system.	IUCLID submission to ECHA through REACH-IT
Registration Fee to Authority	No registration fee required by SCC. Enquiry for full IESCS check by SCC currently RMB 3,000 per substance.	Registration fees apply

4 Compliance Procedure

The compliance dossier requirements and assessment procedures under **MEE Order No. 12** differ depending on the **registration type**. The higher the **annual tonnage band**, the more complex the dossier and assessment procedures become.

4.1 Registration Types

There are three main registration types under **MEE Order No. 12**: **Record Filing**, **Simplified Registration**, and **Regular Registration** (see Figure 6). These types are primarily distinguished by the annual tonnage band, with exceptions for polymers and substances subject to **New Use Environmental Management**.

- **Record Filing** applies to substances with an annual tonnage below 1 tonne per annum (TPA), as well as to polymers containing less than 2% of a new chemical substance and to Polymers of Low Concern (PLC).
- **Simplified Registration** applies to substances manufactured or imported in quantities between 1 and 10 TPA.
- **Regular Registration** is required for substances exceeding 10 TPA and for substances subject to New Use Environmental Management, regardless of tonnage.

In addition, **Joint Registration** allows multiple applicants to submit a registration for the same substance simultaneously, while **Series Registration** enables a single applicant to register up to six similar new

chemical substances at the same time. **Repeat registration** has been abolished under **MEE Order No. 12**. For joint registrations, overseas enterprises must appoint the same **Only Representative (OR)**.

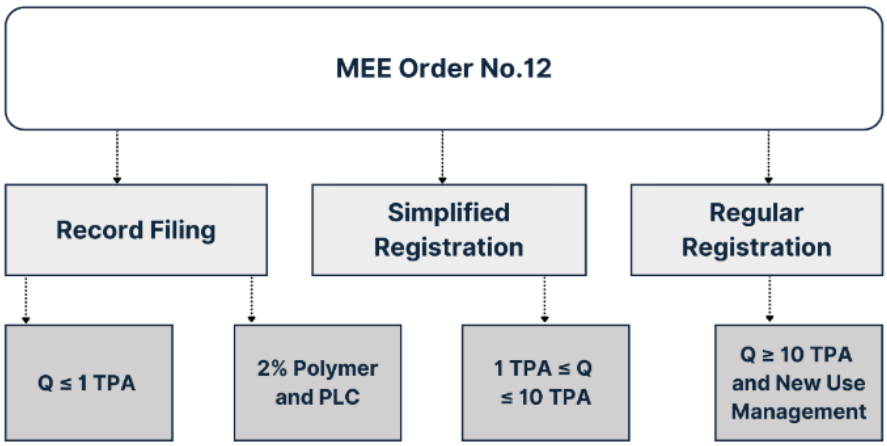

Figure 6 Registration types under MEE Order No. 12

4.2 Registration Documents

The required documents increase in number and complexity from Record Filing to Simplified Registration to Regular Registration.

4.2.1 Record Filing

For Record Filing, applicants must prepare the following documents:

- Application form.
- Business license, Power of Attorney (POA) for overseas applicants, authorization letter.
- Documents justifying Confidential Business Information (CBI) protection.
- Any existing supporting information (test data, literature, known risks, etc.).
- For polymers: documentation proving eligibility for Record Filing.

There is no pre-assessment for Record Filing substances. Once submitted online, the Record Filing receipt is generated automatically. However, the MEE may conduct random checks after registration.

4.2.2 Simplified Registration

For Simplified Registration the required documents are:

- Application form.
- Business license, POA for overseas applicants, authorization letter.
- CBI protection documents.
- Supporting information (test data, literature, known risks).
- Commitment letter.
- Supporting documents for testing institutions.
- Physical and chemical data.
- Ecotoxicological data.
- PBT (persistent, bioaccumulative and toxic) assessment (conclusion and basis).
- Applicants must demonstrate that the substance is not a PBT substance and poses no cumulative environmental risk.

4.2.3 Regular Registration

For Regular Registration, the applicant needs to prepare the following documents:

- Application form.

- Business license, POA for overseas applicants, authorization letter.
- CBI protection documents.
- Supporting information.
- Commitment letter.
- Supporting documents for testing institutions.
- Physical and chemical data.
- Ecotoxicological data,
- PBT assessment (conclusion and basis).
- Toxicological data.
- Environmental risk assessment report (Chemical Safety Report (CSR)).
- Socio-economic benefits analysis (for highly hazardous substances).

The approval criteria for Regular Registration are stricter because it applies to substances of high tonnage or high environmental risk. For highly hazardous substances, authorities must approve the intended use.

4.3 Registration Procedure

The registration procedure for **New Chemical Substances (NCS)** under **MEE Order No. 12** follows the process illustrated in Figure 7.

4.4 Post-Registration Obligations

After receiving the registration certificate, certificate holders and their Chinese ORs must comply with the following post-registration obligations as set out in Articles 38 to 42 of MEE Order No. 12. Failure to comply may lead to legal liabilities.

4.4.1 Communication of Information (Article 38)

Producers, importers, and processors must communicate key information to downstream users. This includes the registration certificate number, the intended purpose of use, the environmental and health hazard characteristics, environmental risk control measures, and any environmental management requirements for the new chemical substance. The information may be provided in either electronic or written form.

4.4.2 Data Preservation (Article 39)

Researchers, producers, importers, and processors are required to document all activities related to the new chemical substances. For foreign registrants, their Chinese agent must assist in fulfilling this obligation. Documentation must be retained for at least ten years for substances registered under Regular and Simplified Registration, and for at least three years for substances registered under Record Filing.

4.4.3 Information Disclosure (Article 40)

After the first manufacture or import, producers and processors holding a Regular Registration must publish their environmental risk control measures and update them as necessary.

4.4.4 Activity Report and Annual Report (Article 41)

The **First Activity Report** applies to **all registration types**, while the **Annual Report** applies only to **Regular Registration**. The First Activity Report must be submitted within 60 days of first manufacturing or importing the substance. An Annual Report must be submitted by April 30 each year, starting from the calendar year following registration. The First Activity Report applies to all registration types, while the Annual Report obligation applies only to Regular Registration.

4.4.5 New Hazardous Information and Environmental Risk (Article 42)

Researchers, producers, importers, and processors must immediately report any new hazardous information related to the substance. If the new information indicates an increased environmental risk, appropriate measures must be taken to reduce that risk.

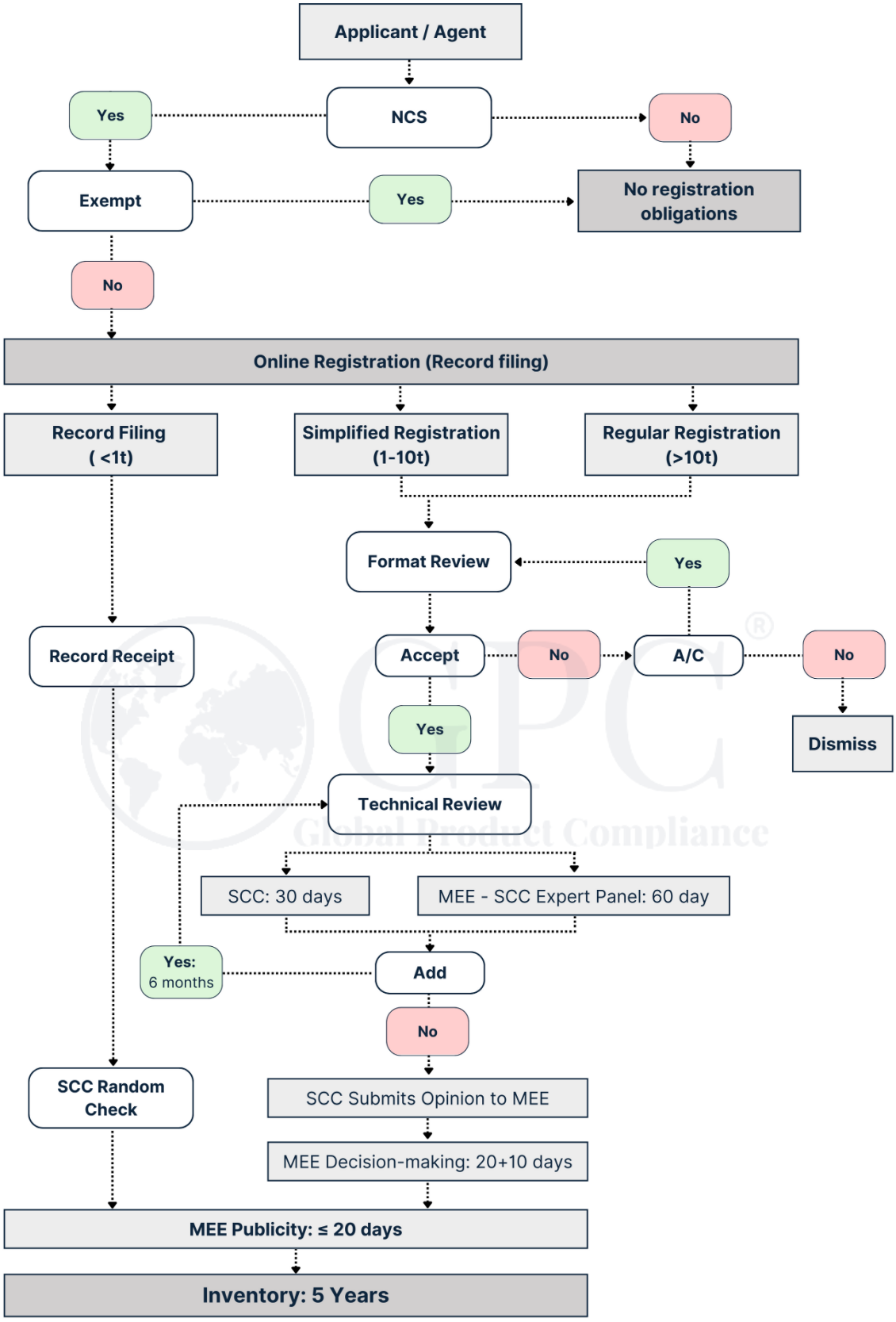

Figure 7 Compliance procedure for New Chemical Substance in China

4.5 Fees

According to the current regulations, the application and evaluation of New Chemical Substances (NCS) in China do not involve an official administrative fee. However, the MEE Solid Waste and Chemicals Management Center (MEE-SCC) currently charges a service fee of RMB 3,000 (approximately USD 420) per substance for verification of whether a substance is identified as a New Chemical Substance.

4.6 Penalties for Non-Compliance

Failure to comply with the obligations described above may result in various penalties imposed by the Ministry of Ecology and Environment (MEE) or the local Departments of Ecology and Environment. Non-compliance with post-registration obligations, submission of false information, or violation of registration requirements may trigger one or more of the following types of punishment:

Monetary Penalties

The most common penalty is a monetary fine. Breaches of the post-registration obligations may result in fines of up to RMB 30,000 (approximately USD 4,200) imposed by the MEE or the local competent authorities.

Behavioral Sanctions

In addition to monetary penalties, companies may also face behavioral sanctions. Non-compliant behavior may lead to negative entries in China's social credit system, potentially affecting the company's business standing. The MEE or local authorities may also decide to suspend acceptance of the company's registration applications for up to three years.

Penalties for Testing Institutions

Testing institutions that provide false reports or conduct tests illegally may face sanctions. The MEE or local authorities may refuse to accept test reports from such institutions for up to three years. In severe cases, the MEE may revoke the institution's qualification entirely.

4.7 Annual Report

The Annual Report requirement applies only to new chemical substances that meet the criteria for persistent, bioaccumulative, and toxic (PBT) substances or are classified as highly hazardous. This obligation is specified in the registration decision issued by the MEE.

As of January 2025, the Annual Report requirement also extends to substances registered under Simplified Registration if the substance is identified as high-risk by the MEE Solid Waste and Chemicals Management Center (MEE-SCC).