

Summary of Draft Revision of “Measures for the Environmental Management and Registration of New Chemical Substances

Dear precious client,

On June 11, 2026, China’s Ministry of Ecology and Environment (MEE) issued the “Measures for the Environmental Management and Registration of New Chemical Substances (Revised Exposure Draft)” to solicit public feedback. This revision was formulated in close alignment with the relevant requirements of the “Ecological and Environmental Code of the People’s Republic of China”, which was deliberated and adopted on March 12, 2026, and officially implemented on August 15, 2026. It represents a significant measure to align with the provisions of the Code and to advance China’s environmental management of new chemical substances into a new phase of codified governance.

名 称	关于公开征求《新化学物质环境管理登记办法（修订征求意见稿）》意见的函		
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关于公开征求《新化学物质环境管理登记办法（修订征求意见稿）》意见的函

为贯彻《中华人民共和国生态环境法典》有关规定，完善新化学物质环境管理登记制度，我部组织对《新化学物质环境管理登记办法》（生态环境部令12号）进行了修订，形成《新化学物质环境管理登记办法（修订征求意见稿）》及其编制说明，现公开征求意见。相关材料可登录我部网站（<http://www.mee.gov.cn>）“意见征集”栏目检索查阅。

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附件：1.征求意见单位名单
2.新化学物质环境管理登记办法（修订征求意见稿）
3.《新化学物质环境管理登记办法（修订征求意见稿）》编制说明

生态环境部办公厅
2026年6月10日

（此件社会公开）

Compared with the current “Measures for the Environmental Management and Registration of New Chemical Substances” (Decree No. 12 of the Ministry of Ecology and Environment, effective January 1, 2021), the scale of the changes and the breadth of the impact in this revision warrant close attention from every enterprise involved in the production, import, or processing and use of chemicals.

As a third-party service provider specializing in compliance with the registration of new chemical substances, Compliance Men has promptly conducted a systematic review of the exposure draft to help enterprises understand the changes, identify risks, and plan ahead.

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I. Overview of Key Changes: A Comprehensive Restructuring of Compliance Framework

II. Item-by-Item Comparison and Interpretation of the New and Old Regulations

III. Compliance Men's Recommendations

I. Overview of Key Changes: A Comprehensive Restructuring of Compliance Framework

- ✧ **Registration Types:** The environmental management filing requirement for new chemical substances has been abolished, and all such substances will now be subject to either simplified registration or regular registration. New chemical substances with an annual production or import volume of less than 1 ton will transition from filing to simplified registration; those with an annual production or import volume of 1 to 10 tons will transition from simplified registration to regular registration; and those with an annual production or import volume of 10 tons or more will remain subject to regular registration.
- ✧ **Applicant Eligibility:** Remove the provisions regarding foreign enterprises and agents; foreign enterprises must apply through an importer in China or a domestic subsidiary; remove the provision allowing processing users to act as applicants.
- ✧ **Scope of Registration Exemptions:** Exemptions for industries such as pharmaceuticals (including active pharmaceutical ingredients), pesticides (including active pesticide ingredients), and veterinary drugs (including active ingredients) have been removed; raw materials and intermediates must now be included in the registration process. New exemptions have been added for substances used in scientific research, inspection, testing, metrology, and monitoring.
- ✧ **Polymer Management:** Exemptions for materials such as monomers or reactants with a content not exceeding 2% and low-concern polymers remain largely unchanged; however, the process has shifted from automatic filing to substantive review, resulting in extended processing times.
- ✧ **Data Requirements for those with an annual production or import volume of 1 to 10 tons:** This category has been upgraded to regular registration; however, applicants are exempt from submitting risk assessment reports and socio-economic benefit analyses, thereby avoiding additional compliance costs.

- ✧ **Technical Review Timeline:** Regular Processing Times: ≤ 45 working days & simplified registration: ≤ 20 working days. And the deadline for submitting supplementary materials has been shortened from 6 months to 20 working days.
- Items Specified on the Registration Certificate:** Remove agent information and refine pollution risk control measures.
- ✧ **Circumstances for Amendment:** Applications for amendment may be filed for reductions in registered quantities, changes to control measures (toward lower risk), and CAS numbers; changes in activity type require re-registration.
- ✧ **Inclusion in the Inventory:** Substances subject to implementing new-use management, those with a cumulative annual production and import volume nationwide of less than 10 tons, and those exempt from submitting test data (such as low-concern polymers, or those containing no more than 2% of monomers or reactants) are not included in “The Inventory of Existing Chemical Substances in China” (hereinafter referred to as IECSC) .
- ✧ **Method for Conveying the Information Stated on the Registration Certificate:** The requirement of conveying the information to downstream customers has been updated from “electronically or in writing” to “specified in the contract, such as sales contracts and agency contracts.”
- ✧ **Activity Records:** Records must be uploaded to the information system by March 31 of each year; the retention period requirement has been removed.
- ✧ **Protection of Commercial Information:** The five-year protection period limit has been removed.
- ✧ **Series Registration:** Abolished; each substance must be declared individually.
- ✧ **Letter of Commitment:** Abolished; pollution risk control measures are now directly included in the registration certificate.
- ✧ **Legal Liability:** The maximum fine for fraud/bribery and falsified test results has been raised to 100,000 yuan; Unlicensed production, import, or processing and use is subject to the "Ecological and Environmental Code of the People's Republic of China", with fines ranging from 200,000 to 2,000,000 yuan, and business operations may be suspended or shut down in serious cases.
- ✧ **Transition Period:** Substances that have been filed must be registered by December 31, 2026; registration certificates for already registered substances remain valid; applications that have been accepted but not yet processed may continue to be handled in accordance with Decree No. 12; the new regulations take effect on August 15, 2026.

II. Item-by-Item Comparison and Interpretation of the New and Old Regulations

Comparison Content	Source Regulation	Section Reference	Key Points of the Original Text
Registration Type	Current Decree No. 12	Article 4 Article 10	✧ Environmental management registration for new chemical substances is divided into regular registration, simplified registration, and filing.

			✧ New chemical substances with an annual production or import volume of 10 tons or more must undergo regular registration; those with a volume of 1 ton or more but less than 10 tons must undergo simplified registration; and those with a volume of less than 1 ton must undergo filing.
			◆ The State implements an environmental management registration system for new chemical substances. Enterprises and entities that produce or import new chemical substances shall apply to the competent department of the State Council responsible for ecological environment to obtain a registration certificate prior to production or import.
Revised Exposure Draft		Article 4 Article 10	◆ Environmental management registration for new chemical substances is divided into regular registration and simplified registration. For annual production or import volumes of 1 ton or more, an application must be filed to obtain a regular registration certificate; for volumes less than 1 ton, an application must be filed to obtain a simplified registration certificate. (The environmental management filing requirement for new chemical substances has been abolished)
	Key Interpretation and Impact Analysis		● Interpretation: The filing system has been completely abolished; substances with an annual production or import volume of 1 ton or more must undergo regular registration, while those with less than 1 ton must undergo simplified registration. ● Impact: Substances that previously required only filing (which took effect automatically) for annual production or import volumes of less than 1 ton are now subject to simplified registration (a substantive approval process). This extends the approval cycle, requiring enterprises to plan their application timelines in advance.
Applicant Eligibility	Current Decree No. 12	Article 11	✧ The applicant shall be an enterprise or public institution legally registered within the territory of the People's Republic of China that is capable of independently bearing legal liability and engaged in the production or import of new chemical substances. ✧ Production or trading enterprises intending to export new chemical substances to the territory of the People's Republic of China may also serve as applicants; however, they must designate an enterprise or public institution legally registered within the territory of the People's Republic of China that is capable of independently bearing legal liability to act as their agent, jointly fulfill the environmental management registration

and post-registration environmental management obligations for the new chemical substances, and bear liability in accordance with the law.

- ✧ For products such as pharmaceuticals, pesticides, veterinary drugs, cosmetics, food, food additives, feed, feed additives, and fertilizers—as defined in Article 2 of the Measures—that are classified as new chemical substances and are intended to be repurposed for other industrial uses, the manufacturer, importer, or processor of the relevant product may serve as the applicant.
- ✧ For chemical substances already listed in the “China Inventory of Existing Chemical Substances” and subject to environmental management for new uses, if such substances are intended for industrial uses other than those permitted, the producers, importers, or processors of the relevant chemical substances may all serve as applicants.

Revised
Exposure Article 10
Draft

- ◆ Applicants for environmental management registration of new chemical substances shall be enterprises or institutions within the territory of the People’s Republic of China that are legally registered, capable of independently bearing legal liability, and engaged in the production or import of new chemical substances. **(Delete the provisions regarding overseas enterprises and agents; delete the provisions regarding processing users)**

Key Interpretation and
Impact Analysis

- **Interpretation:** The provisions regarding “foreign enterprises + domestic agents” and “processing users” have been removed; processing users and foreign enterprises are no longer eligible to apply independently.
- **Impact:** Foreign manufacturers must complete registration through an importer in China or by establishing a domestic subsidiary; compliance processes for cross-border trade and processing must be restructured.

Scope of
Registration
Exemptions Current
Decree No. Article 2
12

- ✧ The Measures do not apply to the following products or substances: (1) pharmaceuticals, pesticides, veterinary drugs, cosmetics, food, food additives, animal feed, feed additives, fertilizers, and similar products—except for those repurposed for other industrial uses, as well as new chemical substances used as raw materials or intermediates for the aforementioned products; (2) radioactive substances.
- ✧ Guidance Clarification: Pharmaceuticals → Pharmaceuticals

(including active pharmaceutical ingredients); Pesticides → Pesticides (including active pesticide ingredients); Veterinary Drugs → Veterinary Drugs (including active pharmaceutical ingredients)

Revised Exposure Draft	Article 2 Article 42	◆ The Measures apply to activities such as the application for, acceptance, review, and decision-making regarding Environmental Management Registration Certificates for New Chemical Substances, as well as the follow-up management of such certificates. (Exemptions for pharmaceuticals, pesticides, etc., have been deleted.)	◆ The Measures do not apply to chemical substances used for scientific research and technical services such as testing, inspection, metrology, and monitoring, nor to radioactive chemical substances. (New exemptions for scientific research, etc., have been added.)
Key Interpretation and Impact Analysis		● Interpretation: ① Remove exemptions for industries such as pharmaceuticals, pesticides, and veterinary drugs; ② Add new exemptions for scientific research, testing, inspection, metrology, and monitoring.	● Impact: All upstream raw materials for industries such as pharmaceuticals, agrochemicals, and personal care products must be included in the registration process , ensuring full regulatory coverage.
Current Decree No. 12	Article 10	✧ Registration is required if any of the following conditions are met: (2) The polymer contains no more than 2% of a new chemical substance as a monomer or reactant, or is classified as a low-concern polymer.	
Polymer Management	Article 11	◆ If a new chemical substance submitted for registration is a low-concern polymer or a polymer in which the content of new chemical substance monomers or reactants does not exceed 2%, the submitter is exempt from submitting the materials specified in subparagraphs (2) through (4) of paragraph (1) of this Article; however, supporting documentation demonstrating compliance with the relevant circumstances must be submitted. (Framework carried over)	

Data Requirements for those with an annual production or import volume of 1 to 10 tons	Key Interpretation and Impact Analysis		● Interpretation: The simplified management framework for polymers remains largely unchanged. Polymers of low concern and those with low reactant content continue to qualify for material exemptions, requiring only the submission of supporting documentation; data requirements remain largely consistent with the previous regulations. ● Impact: Compliance costs for companies will remain largely unchanged; however, the approval process will shift from automatic approval to substantive review, resulting in longer registration cycles. Companies should plan accordingly well in advance.
	Current Decree No. 12	Article 16	✧ To apply for simplified registration, the following must be submitted: (1) a simplified registration application form; (2) reports or data on physical and chemical properties, as well as ecotoxicological test results regarding persistence, bioaccumulation, and aquatic toxicity; (3) a written commitment to implement environmental risk control measures.
Data Requirements for those with an annual production or import volume of 1 to 10 tons	Revised Exposure Draft	Article 11	◆ Applicants for regular registration shall submit the following: (1) a regular registration application form; (2) test reports or data on physicochemical properties, health toxicology, and ecotoxicology; (3) a pollution risk assessment report and corresponding pollution risk control measures; (4) for high-hazard substances, a socio-economic benefit analysis. ◆ If the cumulative annual production and import volume of a new chemical substance for which registration is sought is less than 10 tons nationwide, the applicant is exempt from submitting the materials specified in subparagraphs (3) and (4) of the first paragraph of this Article.
	Key Interpretation and Impact Analysis		● Interpretation: Although the 1–10 tons category has been upgraded to “regular registration,” companies are exempt from submitting risk assessment reports and socio-economic benefit analysis materials, and the data requirements are essentially the same as those for the original simplified registration. However, regulatory requirements will be further refined, explicitly requiring companies to specify concrete, implementable, and verifiable pollution risk control measures. ● Impact: A smooth transition between the old and new systems, without imposing additional testing burdens on companies.

Technical Review Timeline

Items Specified on the Registration Certificate

Current Decree No. Article 25
12

Revised Exposure Draft Article 23
Article 17/18

Key Interpretation and Impact Analysis

Current Decree No. Article 26
12

Revised Exposure Draft Article 24

✧ The technical review period for regular registration shall not exceed sixty days, and the technical review period for simplified registration shall not exceed 60 days.

◆ The technical review period for regular registration shall not exceed forty-five working days, and the technical review period for simplified registration shall not exceed twenty working days. **(The time limit is specified as working days)**

◆ Applicants shall have no more than twenty working days to submit supplementary materials. **(Previously 6 months → 20 working days)**

● **Interpretation:** ① The timeframe for technical reviews has changed, with public holidays excluded (regular: 60 days → 45 working days; simplified: 30 days → 20 working days); ② The deadline for submitting supplementary materials has been significantly reduced from a maximum of 6 months to 20 working days.

● **Impact:** Technical review management has become stricter, placing higher demands on the quality of companies' registration materials. Since technical review timelines are calculated in working days and are subject to statutory holidays, the actual review period may exceed 60 days. At the same time, the deadline for submitting supplementary materials has been further tightened, compelling companies to strictly ensure the completeness and compliance of their registration materials, submit high-quality materials on the first attempt, and improve the registration approval rate.

✧ The registration certificate shall specify: (1) the type of registration certificate; (2) the names of the applicant and its agent; (3) identification information for the new chemical substance, such as its Chinese and English names or class names; (4) the intended use; (5) the quantity applied for registration; (6) the type of activity; and (7) environmental risk control measures.

◆ The registration certificate shall specify: (1) the type of registration certificate; (2) the name of the registration certificate holder **(deleting "agent")**; (3) identification information for the new chemical substance, such as its Chinese and English names or class names; (4) pollution risk control

measures, including intended uses, registration quantities, activity types, and other pollution risk control measures; and (5) environmental management requirements.

Key Interpretation and Impact Analysis	● Interpretation: ① Delete the "Agent" information; ② Refine the "Pollution Risk Control Measures." ● Impact: The control measures specified on the registration certificate must be strictly implemented and may not be arbitrarily altered during information verification.
Current Decree No. Article 29 12	✧ For new chemical substances that have already obtained a regular registration certificate, if any of the following circumstances arise before the substance is included in the "China Inventory of Existing Chemical Substances", the registration certificate holder shall reapply for registration: (1) The intended volume of production or import is expected to exceed the volume specified in the original registration application; (2) The intended activity type is expected to change from import to production; (3) The intended use of the new chemical substance is expected to change; (4) The environmental risk control measures are expected to change; (5) Other circumstances that result in an increased environmental risk.
Circumstances for Amendment Revised Exposure Draft Article 27	◆ For new chemical substances that have already obtained a regular registration certificate, if any of the following circumstances apply prior to their inclusion in the "China Inventory of Existing Chemical Substances", the registration certificate holder shall apply to amend the registration certificate: (1) a change in the name of the registration certificate holder; (2) a proposed reduction in the registration volume or a change in other pollution risk control measures to further reduce pollution risks; (3) A change in the CAS number of the new chemical substance. Except for the circumstances specified in the first paragraph, if any other information specified in the regular registration certificate changes, the registration certificate holder shall reapply for a regular registration certificate.

Key Interpretation and
Impact Analysis

- **Interpretation:** ① Reduction in registration volume, changes to control measures (toward lower risk), and CAS numbers → amendment registration; ② Changes in activity type (e.g., from production to import) → re-registration; ③ Other changes → re-registration.
- **Impact:** The path for making changes is clearer, but changes in activity type require a new application, so companies need to plan ahead.

Current
Decree No. Article 44
12

- ✧ New chemical substances that have obtained a regular registration certificate shall be included in the "China Inventory of Existing Chemical Substances" five years after the date of their initial registration.
- ✧ For high-hazard chemical substances and new chemical substances that are persistent and bioaccumulative, or persistent and toxic, or bioaccumulative and toxic, environmental management requirements other than annual reporting shall be specified upon their inclusion in the "China Inventory of Existing Chemical Substances" (hereinafter referred to as IECSC).
- ✧ New chemical substances subject to simplified registration or filing, as well as new chemical substances with regular registrations that have been withdrawn or revoked, shall not be included in IECSC.

Inclusion in
the Inventory

Revised
Exposure Article 37
Draft

- ◆ New chemical substances that have obtained a routine registration certificate shall be included in the "China Inventory of Existing Chemical Substances" five years after the date of initial registration.
- ◆ **Substances shall not be included in IECSC under the following circumstances:** (1) where the cumulative annual production and import volume nationwide is less than 10 tons; (2) where environmental management for new uses is implemented; (3) where the submission of materials specified in subparagraphs (2) through (4) of paragraph 1 of Article 11 is exempted; (4) where the regular registration certificate has been withdrawn or revoked in accordance with the Measures.

Key Interpretation and
Impact Analysis

- **Interpretation:** High-hazard chemical substances that exhibit any two of the following properties—persistence (P), bioaccumulation (B), and toxicity (T)—and are subject to environmental management for new uses; substances with a cumulative national production or import volume of less than 10 tons; and substances for which no test data needs to be

submitted—such as low-concern polymers, monomers, or reactants with a content not exceeding 2%—are all excluded from the IECSC.

- **Impact:** Even if registered, high-hazard substances will not be considered “existing substances,” and controls on their uses will be stricter. Substances already subject to new-use management must be re-registered if used for purposes other than those permitted.

- ✧ Producers, importers, and users of new chemical substances shall provide the following information to downstream users: (1) the registration certificate number or filing receipt number; (2) the intended uses of the new chemical substance; (3) the environmental and health hazard characteristics, measures to control environmental risks of the new chemical substance; (4) environmental management requirements for the new chemical substance.

- ✧ Guidance Details: Information may be provided electronically or in writing, and the content and supporting documentation shall be properly archived for future reference.

- ◆ Enterprises and institutions that produce or import new chemical substances **shall clearly stipulate in contracts for sales, consignment, and other arrangements** that the following information specified on the registration certificate be communicated to downstream users: (1) the registration certificate number; (2) pollution risk control measures, including the registered uses of the new chemical substance; and (3) environmental management requirements for the new chemical substance.

- **Interpretation:** The requirement for information disclosure has been upgraded from “electronic or written” to “explicitly stipulated in the contract.”

- **Impact:** Information disclosure has shifted from a soft requirement to a hard contractual obligation, providing a verifiable basis for enforcement and retroactive review.

- ✧ A system for recording activities related to new chemical substances shall be established, and such records shall be kept accurately. Materials and activity records for regular and simplified registrations shall be retained for at least 10 years, while materials and activity records for filing shall be retained for

Current
Decree No. Article 38
12

**Method for
Conveying
the
Information
Stated on the
Registration
Certificate**

Revised
Exposure Article 31
Draft

Key Interpretation and
Impact Analysis

**Activity
Records**

Current
Decree No. Article 39
12 Article 41

at least 3 years.

- ✧ Where the submission of an annual report is required, the registration certificate holder shall report on the previous year's activities by April 30 of each year.

Revised
Exposure Article 32
Draft

- ◆ A system for recording activities related to new chemical substances should be established to ensure accurate documentation, and **activity records for the previous year should be uploaded to the Environmental Management Information System by March 31 of each year.**

Key Interpretation and
Impact Analysis

- **Interpretation:** ① Enterprises and institutions that produce or import new chemical substances must uniformly upload their activity records to the information system by March 31 of each year; ② The specific provision regarding retention periods has been removed (replaced with a requirement to retain records in the information system).
- **Impact:** Reporting frequency is standardized, enabling the centralization of regulatory data nationwide and facilitating dynamic risk assessment.

Current
Decree No. Article 13
12

- ✧ The protection period for identification information such as the names of new chemical substances **shall not exceed 5 years** from the date of initial registration or filing.

**Protection of
Commercial
Information:**

Revised
Exposure Article 13
Draft

- ◆ **The five-year protection period limit has been removed;** only the general principle regarding the necessity of confidentiality remains.

Key Interpretation and
Impact Analysis

- **Interpretation:** The five-year cap on the protection period has been removed.
- **Impact:** Protection of corporate business information is now more flexible; however, applicants must provide a more thorough justification of the need for protection and supporting materials (such as database screenshots and links). It is not recommended to file applications casually.

Series Registration	Current Decree No. 12	Article 17	✧ A single applicant may file a single application for environmental management registration of multiple new chemical substances that have similar molecular structures, the same or similar uses, and similar test data. The registered quantity is determined by the sum of the registered quantities for each substance. ✧ If two or more applicants simultaneously apply for environmental management registration of the same new chemical substance, they may jointly submit application materials to apply for joint environmental management registration of the new chemical substance. The registered quantity is determined by the sum of the registered quantities for each applicant.
	Revised Exposure Draft	Article 14	◆ If two or more applicants simultaneously apply to register the same new chemical substance, they may jointly submit application materials to apply for a joint registration. The registered volume is determined by the sum of the volumes applied for by each applicant. ◆ The state encourages applicants to share registration test data.
	Key Interpretation and Impact Analysis		● Interpretation: Because substances with similar structures and isomers often exhibit differences in their physicochemical and toxicological properties, the original series registration required strict matching of test data and was relatively difficult to submit. The new regulations retain only joint registration and remove the provisions for series registration. ● Impact: Following the cancellation of serious registration, companies will no longer be able to register multiple new chemical substances with similar structures and intended uses as a group. Instead, they will need to conduct testing, compile documentation, and submit separate registrations for each substance individually. This change will directly increase companies' submission costs and significantly raise compliance expenses. At the same time, the submission process has become more detailed and cumbersome, requiring companies to plan their new substance registration strategies well in advance to avoid compliance delays and late filings.
Letter of Commitment	Current Decree No. 12	Article 15 Article 16	✧ When applying for simplified registration or regular registration, a written commitment to implement or communicate environmental risk control measures and environmental management requirements must be submitted. This commitment must be signed by the legal representative of the

enterprise or institution, or by a person authorized by the legal representative, and bear the official seal.

Revised
Exposure
Draft

Article 11
Article 12

◆ **Requirement for written commitment removed**

Key Interpretation and
Impact Analysis

- **Interpretation:** The requirement for a written commitment has been removed, and pollution risk control measures are now directly specified on the registration certificate.
- **Impact:** This reduces the number of required application documents by one; however, the control measures specified on the registration certificate must be strictly implemented and cannot be arbitrarily altered during information verification.

Current
Decree No.
12

Article
46-51

- ✧ Obtaining a registration certificate through fraud or bribery: A fine of not less than 10,000 yuan but not more than 30,000 yuan; registration applications from the entity will not be accepted for 3 years.
- ✧ Testing agencies engaging in fraud: A fine of not less than 10,000 yuan but not more than 30,000 yuan (both the agency and the responsible person shall be penalized); test reports issued by the agency will not be accepted for 3 years.
- ✧ Unlicensed production, import, or processing and use: A fine of not less than 10,000 yuan but not more than 30,000 yuan; in serious cases, registration applications from the entity will not be accepted for 1 year.

Legal Liability

Revised
Exposure
Draft

Article
38-41+
"Ecological
and
Environmen
tal Code of
the People's
Republic of
China"

- ◆ Obtaining a registration certificate through fraud or bribery: A fine of not less than 10,000 yuan and not more than 100,000 yuan; registration applications from the entity will not be accepted for 3 years. **(The maximum fine has been increased.)**
- ◆ Testing agencies engaging in fraud: A fine of not less than 10,000 yuan and not more than 100,000 yuan (both the agency and the responsible individuals shall be penalized); test reports issued by such agencies shall not be accepted for 3 years. **(The maximum fine has been increased.)**
- ◆ production, import, or processing and use without a registration

certificate: Penalties shall be imposed in accordance with the relevant provisions of the "Ecological and Environmental Code of the People's Republic of China".

Key Interpretation and Impact Analysis

- **Interpretation:** ① Obtaining a registration certificate through fraud or bribery: The maximum fine has been increased from 30,000 yuan to 100,000 yuan, while the "refusal to accept applications" period remains unchanged at 3 years; ② Fraud by testing institutions: The maximum fine has been increased from 30,000 yuan to 100,000 yuan, and the dual-penalty system and the provision that "test reports will not be accepted for 3 years" remain in effect; ③ Unlicensed production, import, or processing and use: The legal basis for penalties has shifted from Decree No. 12 to the "Ecological and Environmental Code of the People's Republic of China", and the range of fines has been significantly increased.
- **Impact:** Pursuant to **Article 1206** of the "Ecological and Environmental Code of the People's Republic of China" (**Production or Importation in Violation of Registration Certificate Requirements**): For a first-time violation, the entity shall be ordered to rectify the violation and shall be fined not less than 200,000 yuan but not more than 1,000,000 yuan; if the entity refuses to rectify the violation, it shall be fined not less than 1,000,000 yuan but not more than 2,000,000 yuan, and ordered to restrict production or suspend production for rectification; in serious cases, the registration certificate shall be revoked, and the entity shall be ordered to suspend operations or close down. **Article 1207 (Production without a license, importation without a license, or use of unlicensed new chemical substances to produce products)**: For a first-time violation, the entity shall be ordered to rectify the violation and shall be fined between 200,000 yuan and 1,000,000 yuan; if the entity refuses to rectify the violation, it shall be fined between 1,000,000 yuan and 2,000,000 yuan and ordered to restrict production or suspend operations for rectification; in serious cases, the entity shall be ordered to suspend business or close down. **The cost of noncompliance has jumped from a previous maximum of 30,000 yuan to a maximum of 2 million yuan, creating a powerful legal deterrent.**

	Current Decree No. 12	Article 53 Article 55	✧ Any environmental management registrations for new chemical substances that have already been filed shall remain valid after the Measures take effect. ✧ The Measures shall take effect on January 1, 2021, and Decree No. 7 is hereby repealed.
	Revised Exposure Draft	Article 44 Article 45 Article 47	◆ For cases that have already been filed in accordance with the current Decree No. 12, the filing applicant shall apply for a registration certificate in accordance with the relevant provisions of the Measures by December 31, 2026. ◆ For registration applications that were accepted pursuant to Decree No. 12 prior to the effective date of the Measures, the processing may continue in accordance with the provisions of Decree No. 12 after the Measures take effect. ◆ Where a registration certificate has already been obtained, it shall remain valid after the implementation of these Measures; however, if there are changes to the information specified therein, a new application must be filed. ◆ The Measures shall take effect on August 15, 2026, and Decree No. 12 shall be repealed simultaneously.
Transition Period	Key Interpretation and Impact Analysis		● Interpretation: ① Substances that have been filed must be registered by December 31, 2026; ② Registration certificates for substances that have already been registered remain valid; ③ Applications that have been accepted but not yet processed may continue to be processed in accordance with Decree No. 12. ● Impact: Under the new regulations, the filing requirement will be eliminated, and approval will no longer be automatic. Companies required to apply for registration should plan accordingly; given the tight timeline, they should prepare in advance.

III. Compliance Men's Recommendations

In light of such significant regulatory changes, Compliance Men recommends that companies take the following actions immediately:

- ✧ **Conduct a comprehensive review of existing substance lists:** Compile a list of all chemical substances currently in production, under development, or planned for import; identify new chemical substances; and determine the registration type and required materials in accordance with the new regulations.

- ✧ **Prioritize Substances Subject to Filing:** Existing substances subject to filing must complete simplified registration applications by December 31, 2026. Given the limited timeframe, we recommend immediately beginning data preparation.
- ✧ **Restructure the Cross-Border Trade Compliance Workflow:** Overseas companies must promptly identify their importers in China, redesign trade terms, and clarify registration responsibilities and cost allocation.
- ✧ **Improve the quality of submission materials:** Since the time allowed for corrections has been significantly reduced to 20 business days, it is crucial to submit high-quality materials on the first attempt. We recommend having your materials pre-reviewed by a professional third-party organization.
- ✧ **Strengthen information communication and record management:** Clearly specify registration certificate information and control measures in sales and agency contracts, establish an activity record system, and ensure that records are uploaded by March 31 of each year.
- ✧ **Re-evaluate strategies for high-hazard substances:** Even after registration, high-hazard substances will not be included in IECSC; if new uses are involved, a new registration application must be filed. Therefore, it is advisable to plan the scope of uses in advance.

Compliance is not a cost—it is a competitive advantage. For further information on these revisions, please contact Compliance Men—making complex compliance simple.

Our services

- ◆ IECSC comprehensive search
- ◆ New chemical substance registration
- ◆ New usage environmental management registration
- ◆ Data-gap analysis/test monitoring
- ◆ PBT Properties Identification
- ◆ Environmental risk assessment report preparation
- ◆ Social and economic benefit analysis report preparation
- ◆ IECSC supplementation (add existing chemical substances into IECSC list)
- ◆ Customized China REACH training

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