

Provisions on the Environmental Administration of New Chemical Substances in China (2010)

Provisions on the Environmental Administration of New Chemical Substances in China (2010)

Order No.7 of the Ministry of Environmental Protection (MEP)

Issued on: 30 December 2009 Date of entry into force: 15 October 2010

Table of Contents

Chapter 1 General Provisions	- 2 -
Chapter 2 Notification Procedure	- 3 -
Chapter 3 Registration Administration.....	- 6 -
Chapter 4 Tracking and Supervision	- 9 -
Chapter 5 Legal Liabilities	- 13 -
Chapter 6 Supplementary Provisions	- 14 -

Chapter 1 General Provisions

Article 1 Purpose

This Provision is formulated for the purpose of controlling the environmental risks of new chemical substance, protecting human health and safeguarding the ecological environment.

Article 2 Applicable Scope

This Provision is applicable to activities in relation to the research, manufacture, import and use of new chemical substances and their environmental management undertaken within the territory of the People's Republic of China including the low-tax zone and export-zone.

Pharmaceuticals, pesticides, veterinary drugs, cosmetics, food, food additives and feed additives are subject to other laws or regulations. However, the raw materials or intermediates of above products are subject to the Provision if they are new chemical substances. Articles containing new substances that are intended to be released are also subject to the Provision.

Article 3 Category of Management

A new chemical substance is categorized as general new chemical substance or hazardous new chemical substance based on the hazard information and classification of the new substance.

Hazardous new chemical substances possessing persistent, bio-accumulative properties or are harmful to ecological environment and human health will be further classified as priority hazardous new chemical substances for environmental management (hereafter cited as "priority hazardous new chemical substances").

New chemical substance is defined as a chemical substance other than those currently listed on the Inventory of Existing Chemical Substances Produced or Imported in China (IECSC).

IECSC is promulgated, updated and published by the MEP.

Article 4 Basic Principle

The State will manage the risks of new chemical substances in accordance with categories of management and implement a notification and a tracking system;

Article 5 Registration Certificate

Prior to the manufacture or importation of a new chemical substance, manufacturer and importer (hereinafter cited as '*registrant*') shall notify the new chemical substances and obtain

a new chemical substance environmental administration certificate (hereafter cited as '*registration certificate*').

The manufacture, import or use of new chemical substance is forbidden if a registration certificate has not been issued for the new chemical substance. A new chemical substance shall not be used in research and development unless a registration certificate or a scientific research record certificate has been issued.

Article 6 Encouragement of Advanced Technology

The State supports research on environment and human health risk assessment for new chemical substances, promotes the application of advanced new substance environmental risk management measures, encourages the research, manufacture, import and use of environment-friendly substitute substance, and encourages registrants to share data.

Article 7 Confidentiality

Any administrative department or person involved in the environmental management of new chemical substances shall keep the commercial and technical secrets for the registrants of new chemical substances;

Article 8 Public Supervision

Any entity or individual has a right to report, disclose or sue any non-compliant acts against the Provision.

[Go to top](#)

Chapter 2 Notification Procedure

Article 9 Types of Notification

There are three types of notification: typical notification, simplified notification and scientific research record.

Article 10 Requirement of Typical Notification

Registrant shall submit typical notification to the Chemical Registration Center (hereinafter cited as '*CRC*') for the new chemical substances to be manufactured or imported at or above the annual volume of 1 ton. For new substances meeting the conditions of simplified notification, simplified notification shall be submitted;

For typical notification, the following data shall be submitted:

- a) Typical notification form accompanied by recommended classification, precautionary labeling, chemical label and Chinese safety data sheet that have been classified and prepared in accordance with relevant national standards.
- b) Risk assessment report containing hazard assessment, exposure assessment, risk management measures, and conclusions of environmental risk assessment and human health assessment;
- c) Test report detailing the substance's physiochemical, toxicological and eco-toxicological properties as well as the qualifications of laboratories. Eco-toxicological data must include test data on Chinese creatures in accordance with relevant guidelines.

Article 11 Notification Level

Typical notification follows the principle of 'the higher the volume, more data required'. Registrant shall provide corresponding test data or materials in accordance with guidance documents prepared by the MEP.

There are 4 levels for typical notification depending on the volume of a substance:

1. First level: 1~10t/y;
2. Second level: 10~100t/y;
3. Third level: 100~1000t/y;
4. Fourth level: 1000t/y+;

Article 12 Simplified Notification under Basic Conditions

Registrant shall submit simplified notification under basic conditions to CRC for the new substances with the volume less than 1t/y. The following data shall be submitted:

1. Simplified notification form;
2. Report of Chinese mandatory eco-toxicological testing

Article 13 Simplified Notification under Special Conditions

Registrant shall submit simplified notification under special conditions if the new chemical substance meets one of the following conditions:

1. for export only with tonnage under 1 ton per year;
2. for scientific research with tonnage between 0.1 to 1 ton per year;
3. for technological and product research with tonnage less than 10 ton per year (up to 2 years);
4. for polymers containing less than 2%w/w new substances and low concern polymers.

For simplified notification, registrant shall submit simplified notification form and corresponding document of evidence.

Article 15 Serial Notification, Joint Notification and Repeated Notification

For typical notification, registrant can choose the following notification type when certain conditions are met.

1. One applicant may make a serial notification for the new chemical substances with similarities in molecular constitutions, similarities or sameness in use(s) and testing data;
2. Two applicants or above may make a joint notification if they intend to notify the same new chemical substance;
3. Repeated notification allows a late applicant to refer to the test data prepared by the previous applicant. Furthermore, the written authorization from the previous applicant is required. Cost sharing mechanism is negotiated and determined by applicants themselves

Article 16 Qualification of Registrant

Registrant or its agent shall be a legal entity registered within the territory of China. Non-first-time Registrant or agent shall not have any records of violating the Provision within past three years.

Article 17 Full Disclosure

Registrant shall disclose all known hazard properties and environmental risk information of a new chemical substance when submitting new substance notification.

Article 18 Environment Information Dissemination

For the information involving commercial or technological secrets that need to be kept confidential, registrant shall indicate it clearly in the application materials submitted.

The information that may endanger human health or environment safety cannot be kept confidential.

The applicant shall notify CRC in written form if they wish to make relevant information public.

Article 19 Testing Agencies

Domestic testing agencies that provide test data for new chemical substance notification must be those announced by MEP by public notice and accepting the supervision and inspection of CRC;

Domestic testing agencies shall follow chemical test lab operation guidelines published by MEP and carry out relevant tests in accordance with Chemical Test Guidelines or relevant national standards.

Overseas testing organizations that provide data for new chemical notification must be inspected and certified by relevant authorities or follow Good Laboratory Practice.

[Go to top](#)

Chapter 3 Registration Administration

Article 20 Registration Procedure for Typical Notification

After accepting typical notification, CRC shall submit application materials to the expert committee of the MEP for review. The expert committee consists of member experts in chemistry, chemical engineering, health, safety and environment.

The expert committee shall perform technical review from the following aspects in accordance with new chemical substance hazard and risk assessment guidelines issued by MEP and relevant national standards for chemical hazard identification and classification:

1. Name and identifier;
2. Physio-chemical, human health and environmental hazards
3. The degree of exposure and the risks to human health and environment;
4. Appropriateness and adequacy of risk management measures;

If the expert committee cannot perform comprehensive evaluation due to incomplete notification materials, CRC will inform the applicant in written form and request more materials.

The expert committee shall submit the evaluation report to the MEP. The evaluation report shall include the following contents:

1. Opinion on whether the new chemical substance is categorized as general new chemical substance, hazardous new chemical substance or priority hazardous new chemical substance for environmental management;
2. Opinion on the human health and environmental risks of the new chemical substance;
3. Opinion on the appropriateness and adequacy of risk management measures;
4. Opinion on whether the new chemical substance is allowed to be registered;

The MEP shall determine the category of management for new chemical substances and make the following decisions based on the opinions of the expert committee:

1. Issue registration certificate if there are appropriate and adequate risk management measures in place;
2. Reject application and inform the applicant of the decision and reasons for rejection in written form if there are not appropriate and adequate risk management measures in place.

Before making a decision, MEP shall publicize relevant information related to the new chemical substance.

Article 21 Registration Procedure for Simplified Notification

After accepting simplified notification application materials, CRC shall prepare an evaluation report with its opinions in written form and submit it to MEP;

If eco-toxicology test reports are required, the expert committee shall perform technical review and submit an evaluation report to MEP; Registration certificate will be issued if the application meets the requirements of the Provision; If the application does not meet the requirements of the Provision, MEP shall reject the application of registration certificate and inform the applicant of the decision and reasons for rejection in written form;

Article 22 Procedure for Application of Scientific Research Record

After accepting application materials of scientific research record, CRC shall report them to MEP monthly; MEP will publicize them regularly on government website;

Article 23 Public Disclosure

MEP shall publish the names of new chemical substances, the applicants, the category of notification and the category of management for the new chemical substances on government website.

Article 24 Processing Time

CRC shall submit a new chemical substance notification report to the expert committee within 5 working days since they have accepted typical notification application materials; CRC shall submit a written report to MEP within 5 working days since they have accepted simplified notification application materials;

The maximum duration of expert committee review is 60 days for typical notification; for simplified notification, the duration of review shall not exceed 30 days. In the event that CRC request supplemental application materials, the time of preparing and submitting those materials shall not be included in the duration of expert committee review.

MEP shall make a decision within 15 working days since they have received new chemical notification documents from CRC or the expert committee. The duration can be extended by 10 working days if approved by the responsible person of MEP.

Article 25 Registration Certificate

Registration certificate shall list the following information:

1. The name of registrant or agent;
2. The name of new chemical substance;
3. Registered uses;
4. Notification level and volume;
5. The category of management;

Registration certificate for typical notification shall detail risk management measures and administrative requirements.

Article 26 Report New Hazard Information

The holder of registration certificate (hereafter cited as “certificate holder”) shall submit new hazard information to CRC should a new hazard has been discovered for the new chemical substance that a registration certificate has been issued.

CRC shall submit new hazard information to the expert committee for technical review.

The MEP shall take the following measures based on the opinions of the expert committee:

1. Include more risk management measures in registration certificate and require the applicant to implement those measures if the new risks could be controlled by increasing risk management measures;
2. Withdraw registration certificate and issue a public notice if there are no appropriate and adequate risk management measures in place;

Article 27 Re-notifications

For substances which are not listed on IECSC and for which registration certificate have been issued, registrant shall re-notify the new substance if the following conditions are met:

1. Increase the volume band of registration certificate;
2. Change registered uses of priority hazardous new chemical substances;

For priority hazardous new chemical substances which are already listed on IECSC, the downstream users of the new chemical substances may also re-notify the new substance if they would like to change the registered uses.

Article 28 Information Sharing

MEP shall report relevant information related to hazardous new chemical substances (including priority hazardous new chemical substances) to other authorities.

[Go to top](#)

Chapter 4 Tracking and Supervision

Article 29 Factor of Environmental Impact Assessment

MEP shall, in reviewing documents of environmental impact assessment of any project of new construction, renovation or expansion in relation to the manufacture or use of new chemical substances, check the registration certificates and take them as one of the important factors for decisions.

Article 30 Information Communication

The certificate holder of typical notification shall list the hazard properties of the new chemical substance in chemical safety data sheet and communicate the following information to downstream users:

1. Risk management measures listed in registration certificate;
2. Chemical safety data sheet;
3. Chemical classification, precautionary label and statements;
4. Other relevant information.

Article 31 General Risk Management Measures

The certificate holder and downstream user shall implement one or many of the following risk management measures:

1. Provide education on the risks of new chemical substances and preventative measures;
2. Strengthen person protection of personnel in contact with new chemical substances;
3. Set separate room, quarantine zones, and place warning signal;
4. Improve the technological process of how new chemical substances are manufactured or used to lower release and environmental exposure;
5. Improve the technological process of waste disposal to reduce environmental discharge;
6. Prepare emergency plans and emergency response measures;
7. Take other appropriate risk management measures;

For priority hazardous new chemical substances, certificate holder and downstream users shall comply with other existing laws or administrative measures such as the <regulations on the safe management of hazardous chemicals>.

Article 32 Key Risk Management Measures

For priority hazardous new chemical substances, certificate holder and downstream user shall adopt the following risk management measures:

1. Monitor or estimate the environmental release of the priority hazardous substances during the period of manufacturing or using. If certificate holder and downstream users do not have the capacity of monitoring, they shall appoint monitoring agency of MEP above city-level or third party testing agency recognized by MEP.
2. Get equipped with relevant apparatus and take appropriate measures to prevent accidental release to the environment in accordance relevant rules during the process of transferring the substances,
3. Dispose the priority hazardous new chemical substance in accordance with relevant laws;

Article 33 Transfer of New Chemical Substances

Certificate holder of typical notification shall not transfer new chemical substances to downstream users who do have the capability of implementing risk management measures;

Article 34 Requirements on Research and Development

Scientific research or technological and product research and envelopment activities must be carried out in special facilities and under the guidance of professionals.

New chemical substances used for scientific research or technological and product research and envelopment shall not be used for other purposes. If disposal is needed, they shall be disposed in accordance with relevant waste disposal regulations.

Article 35 Activity Report

Certificate holder of typical notification shall submit first-activity report to CRC within 30 days since the date of manufacturing for the first time or within 30 days since the date of transferring the new chemical substances to downstream users after import for the first time.

Certificate holder of priority hazardous new chemical substance shall report the circulation of the substance within 30 days every time since they transfer the substance to a different downstream user.

Article 36 Annual Report

Certificate holder of simplified notification shall submit the actual volume of manufacture or import of the new chemical substance for the previous year before 1 Feb of each calendar year. Certificate holder of hazardous new chemical substances shall report the following information for the previous year before 1 Feb of each calendar year.

1. The actual volume of manufacture or import;
2. Whether risk management measures have been implemented;
3. Environmental exposure and release information;
4. The actual impact of the new substance on environment and human health;
5. Other information related to environmental risks;

Besides that, certificate holder of priority hazardous new chemical substances shall submit annual plan of the manufacture or import for the current year to CRC along with the status of implementation of risk management measures.

Article 37 Record Keeping

Certificate holder shall keep new chemical notification application materials and other information related to manufacture or import activities for 10 years and above.

Article 38 Supervision Notice

MEP shall issue a supervision notice to local environment protection authorities at provincial level where the manufacturers or downstream users of hazardous new chemical substances are located within 30 days after receiving first activity report or the circulation report of the substance submitted by CRC.

The environmental protection authorities at provincial level are responsible for sending the supervision notice to the environmental protection authorities at city level or county level where the manufacturers or downstream users are based.

The supervision notice shall include the name of the new substance, the category of management, risk management measures on registration certificate, administrative requirements and key points for inspection and supervision.

Article 39 Supervision and Inspection

Local environmental protection authorities shall supervise the manufacturing or processing activities of new chemical substances in accordance with the requirements of supervision notice and administrative supervision and inspection guidelines issued by MEP.

If the manufacturing or processing activities of new chemical substances have caused or might cause immediate or accumulative environment pollution, local environmental protection authorities are empowered to order the manufacturer or downstream user to take actions immediately to eliminate this hazard and report it to MEP.

MEP may request the certificate holder to provide new hazard information based on the report received. This shall be dealt with in accordance with article 26.

Article 40 Withdraw Registration

Certificate holder that has not engaged in manufacturing or importation activities or has stopped manufacturing and importation may withdraw their application of registration certificate, explain it and hand back the registration certificate.

MEP shall permit the withdrawal and issue a public notice if the above case is confirmed or there is no environmental hazard caused by the new chemical substance.

Article 41 Procedure for Adding a New Chemical Substance onto IECSC

General new chemical substances will be added onto IECSC by the public notice of MEP after 5 years since the date of the first manufacturing or importation by the certificate holder.

The certificate holder of hazardous new chemical substances shall submit a report about actual activities to CRC 6 months prior to the date on which the limit of 5 years is reached since the date of the first manufacturing or importation.

MEP will organize an expert committee to conduct the evaluation of the actual activities and add hazardous new chemical substances onto IECSC based on the result of evaluation.

New chemical substance for which simplified notification registration certificate or scientific research record certificate has been issued will not be added on to IECSC.

Article 42 Regular Inspection

MEP will organize a comprehensive inspection on new chemical substances every 5 years.

Substances manufactured or imported within the territory of China before 15 Oct 2003 will be added onto IECSC by MEP.

For new chemical substances manufactured or imported or used without registration certificate, environmental protection authorities will take legal actions in accordance with relevant laws.

[Go to top](#)

Chapter 5 Legal Liabilities

Article 43 False Notification

Any registrant who, in violation of this Provision, hides relevant information or provides false application materials in the application for the registration certificates shall be subject to a fine of RMB10,000 at least and RMB30,000 at most, by the MEP. In this case, the MEP is empowered to order the violator to rectify the wrongful acts, record and publicize the fact of violations, and rescind registration certificate if a certificate has been issued.

Article 44 Punishment Items by MEP

Any registrant who, in violation of this Provision, has one of the following wrong-doings shall be subject to a maximum fine of RMB 10,000 by MEP and rectify the wrongful acts under the order of MEP.

1. Having not reported the update about the hazard information of the new chemical substance timely;
2. Having not submitted first-activity report or the circulation of new chemical substance as required;
3. Having not submitted annual plan as required;
4. Having not submitted a report about actual activities as required;

Article 45 Punishment Items by Local Authorities Part 1

Any registrant who, in violation of this Provision, has one of the following wrongful acts shall be subject to a fine of RMB10,000 at least and RMB30,000 by the local environmental protection authorities. In this case, the local authorities shall report the wrongful acts to MEP which will then record and publicize the fact of violations.

1. Refusing field inspections by the competent environmental protection authorities or conducting falsifications when inspected;
2. Manufacturing or importing new chemical substances without registration certificate or without meeting the requirements of registration certificates;
3. Processing or using new chemical substances that do not have registration certificates;
4. Having not implemented risk management measures in accordance with requirements of registration certificates;
5. Transferring new chemical substances to downstream users that do not have the capability of implementing risk management measures;

Article 45 Punishment Items by Local Authorities Part 2

Any registrant who, in violation of this Provision, has one of the following wrongful acts shall be subject to a fine of RMB10,000 at least and RMB30,000 by the local environmental protection

authorities. In this case, the local authorities are empowered to order the violator to rectify the wrongful acts.

1. Having not communicated risk management information to downstream users;
2. Having not kept the application materials for registration certificate, and information related to actual manufacture and import activities;
3. Using new chemical substances for scientific research and technological and product research for other purposes

Article 47 Punishment on Wrongful Act of Expert in Expert Committee

In the event that an expert in expert committee makes falsifications or has negligent actions during the process of review of new chemical notification, which has led to false evaluation result, MEP will rescind the qualification of expert and publicize it.

Article 48 Punishment of the Wrongful Act of Testing Agency

In the event that a domestic testing agency falsifies test data or has other wrongful acts during the process of generating data for new chemical notification, MEP will remove the testing agency from the list of approved testing agencies and publicize it.

Article 49 Punishment of Abusing Power

In case of abusing power or neglecting duties, the relevant department and the responsible person(s) involved in the environmental management on new chemical substances shall be subject to administrative punishments in accordance with relevant laws and regulations; in cases of a crime committed, criminal penalties shall be imposed in accordance with relevant laws and regulations.

Chapter 6 Supplementary Provisions

Article 50 Definitions

1. General new chemical substances are defined as new chemical substances whose hazards have not been found or whose hazards are below relevant classification criteria;
2. Hazardous new chemical substances are defined as new chemical substances having physio-chemical, human health or environmental hazard properties which have reached or exceeded relevant classification criteria.

Article 51 Format of Forms and Texts

The following forms and texts are prepared by the MEP:

1. Typical notification form;
2. Simplified notification form;
3. Scientific research record form;
4. Registration certificate;
5. First-activity report form;
6. Supervision notice;

Article 52 Date of Entry into Force

The Provision shall enter into force on 15 Oct 2010. The < Provisions on the Environmental Administration of New Chemical Substances> issued on 12 Sep 2003 by SEPA will become invalid.

[Go to top](#)