

# Measures on the Environmental Management of New Chemical Substances

## Chapter 1 General Provisions

**Article 1** The Measures are formulated for the purposes of strengthening the environmental management of new chemical substances, preventing environmental pollution, protecting human health and securing the ecological environment.

**Article 2** The Measures are applicable to the environmental management activities regarding the production and import of new chemical substances within the territory of the People's Republic of China.

**Article 3** The State shall implement the declaration and registration systems for the environmental management of new chemical substances before the production and import of new chemical substances.

In accordance with the Measures, prior to the production or import of the new chemical substances, the producer or importer shall apply for the registration certificates regarding the environmental management of new chemical substances (hereinafter *the registration certificates*).

The Measures shall not apply to the chemical substances which have been produced and imported before the implementation of the Measures. They do not need to conduct any declaration of new chemical substances.

**Article 4** The term *new chemical substances* hereinafter in the Measures refer to any chemical substances which have not been produced or imported in the territory of the People's Republic of China before they are declared.

The State Environmental Protection Administration of the People's Republic of China is responsible for compiling and timely publishing the list of chemical substances being produced in or imported to China.

**Article 5** The State Environmental Protection Administration is responsible for the formulation of the environmental management standards and the technical requirements of new chemical substances.

**Article 6** The State Environmental Protection Administration has established a Professional Examination Committee on Environmental Management of New Chemical Substances (hereinafter *the Examination Committee*).

The Examination Committee shall be responsible for assessing the environmental impacts of the new chemical substances, and submit the evaluation and comments in writing to the State Environmental Protection Administration.

**Article 7** Any authorities and personnel involved in the environmental management of new chemical substances shall keep commercial and technical confidentiality for any information submitted by the applicant of the declaration of new chemical substances (hereinafter *the applicant*).

## Chapter 2 Declaration

**Article 8** The applicant, prior to the production or import of new chemical substances, shall submit such information as the Declaration Form of New Chemical Substances, reports with testing data, and quality certificates issued by the testing organizations, to the Chemical Registration Centre (hereinafter *the CRC*) of the State Environmental Protection Administration.

The contents of the Declaration Form shall include the names, molecular structure; testing methods, purposes, annual output or import volume; the physical-chemical properties, toxicological and eco-toxicological characteristics, preventive and emergency measures for accidents, and the preventive and elimination measures of pollution, waste disposal measures of the new chemical substances to be declared.

In the event that the testing data was acquired outside the territory of China, the organizations supplying the testing data shall be authorised by the supervisory authorities of the country in which the organizations are located.

The eco-toxicological data of the new chemical substances shall include the testing data acquired from the tests performed in the territory of China by using Chinese organisms.

**Article 9** The applicant who provides information containing commercial and technical confidentiality and requests for keeping their confidentiality shall indicate such request on the declaration information.

The applicant intending to publicise the contents of the aforementioned confidentiality shall inform the CRC in writing.

**Article 10** For the new chemical substances with similar molecular structure, the same or similar purposes, and similar testing data, the applicant may apply for serial declarations. A separate application for registration certificates shall be made according to each new chemical substance.

**Article 11** In the event that two or more applicants make a joint declaration for the same new chemical substance, each applicant shall apply for a registration certificate separately.

**Article 12** In the declaration of a new chemical substance which is included in the list of the existing chemical substances in more than four countries or in regional economic integration organizations, the applicant is only required to submit the Declaration Form and the report of eco-toxicological testing performed in the territory of China.

**Article 13** The applicant may apply for an exemption from declaration in one of the following conditions:

- (1) The annual production and import volume of the new chemical substances for scientific research purpose does not exceed 100 kilograms;
- (2) The polymer contained in the monomer of the new chemical substance is less than 2%;
- (3) The total production and import volume of the new chemical substance for technological research and development does not exceed 1,000 kilograms. For such a new chemical substance, the applicant may apply for one year's exemption from declaration, and no extension shall be granted;
- (4) The samples of new chemical substances are imported for the purpose of performing the eco-toxicological tests of new

chemical substances in the territory of China by using Chinese organisms.

Any declarer intending to apply for the exemption from declaration shall submit the Application Form for Exemption from Declaration to the CRC providing them with the certification information indicated in the first item of this Article. The applicant shall keep records of the scientific research, technological research and development, production or import volume of the substance and the customer particulars.

## Chapter 3 Registration

**Article 14** Within fifteen days of receipt of the declaration information submitted by the applicant, the CRC shall carry out a formal examination of the declaration information according to the requirements of the Measures. If the information conforms to the requirements, the declaration shall be provisionally accepted and the applicant shall be informed of the acceptance in writing; if the information does not conform to the requirements, the declaration shall be rejected and the applicant shall be informed of the rejection in writing.

If the declaration information submitted by the applicant is found to be incomplete or not conforming to the requirements of the Measures, the CRC shall inform the applicant of any additional information in writing.

For the preliminarily accepted declaration, the CRC shall submit the declaration information to the Examination Committee within five days of the acceptance.

**Article 15** Within 60 days of receipt of the declaration information, the Examination Committee shall evaluate the environmental impacts of the new chemical substances in accordance with the environmental management standards and the technical requirements for the new chemical substances formulated by the State Environmental Protection Administration, and then submit the evaluation and comments in writing to the State Environmental Protection Administration.

**Article 16** Within 30 days of receipt of the written evaluation and comments from the Examination Committee, the State Environmental Protection Administration shall make a decision on whether the declaration information shall be approved for registration. For the declaration to be approved, a registration certificate shall be issued; and for the declaration to be rejected, an explanation of the reasons shall be given.

The State Environmental Protection Administration shall inform the CRC of its decisions, and then the CRC shall inform the applicant of the decision in writing.

**Article 17** Within fifteen days after the receipt of the Application Form for Exemption from Declaration, the CRC shall offer suggestions for handling such cases and submit the suggestions to the State Environmental Protection Administration for examination.

Within fifteen days of the receipt of the application information as well as the suggestions for handling the case, the State Environmental Protection Administration shall make a decision on whether the application for exemption from declaration shall be approved, and then inform the CRC of its decision. The CRC shall inform the applicant of the decision in writing.

**Article 18** For the decision on the approval for registration or for exemption from declaration made in accordance with Article 16 and Article 17 of the Measures, the State Environmental Protection Administration shall submit the decision and the advice note of surveillance regarding the environmental impacts of the new chemical substances to the environmental protection department of the province where the producer or importer of the new chemical substances is located.

The provincial environmental protection department shall submit such information as the decision and the advice note of surveillance regarding the environmental impacts of the new chemical substances to the regional environmental protection department of the municipality or county where the producer or importer of the new chemical substances is located.

## Chapter 4 Surveillance

**Article 19** Within five days of the production, import or transfer date of the new chemical substances, the holder of the registration certificate shall complete a data form recording the production, import and circulation of the new chemical substances. The form shall be submitted to the environmental protection department of the county where the producer or importer is located.

Within five days of the receipt of the data form, the environmental protection department at the county where the producer or importer is located shall report to the regional municipal environmental protection department, which shall then report to the provincial environmental protection department within five days of receipt of the data form. Within five days of receipt of the data form, the provincial environmental protection department shall report to the State Environmental Protection Administration.

**Article 20** For the new chemical substances to be transferred from the place of production or the place of import, the environmental protection department of the county where the producer or importer is located, shall within five days of receipt of the data form, submit such information as the circulation and the decision of the new chemical substances, as well as the advice note of the surveillance of the environmental impacts of the new chemical substances, to the environmental protection department of the county where the user is located at.

Within five days of receipt of the circulation and the decision of the new chemical substances and the advice note of the surveillance of the environmental impacts of the new chemical substances, the environmental protection department of the county where the user is located shall report to the regional municipal environmental protection department, which shall report to the provincial environmental protection department within five days of receipt of the aforementioned information.

**Article 21** The holder of the registration certificates shall keep the declaration, production or import, and the impacts of the new chemical substances until the date that the chemical substances are announced.

**Article 22** During the examination of the documents regarding the production of the new chemical substances, or the assessment on the environmental impacts of any new construction, renovation or expansion projects relating to the production of the imported new chemical substances, the environmental protection department shall assess whether these items have obtained the registration certificates as an important factor in the decision-making process.

**Article 23** The environmental protection department at the county level or above should carry out the surveillance and inspection of the new chemical substances within the administrative district, and shall, in case the new chemical substances are found to cause harm to the environment, order the producer, the importer or the user to take emergency measures to eliminate the harm and report the situation to the State Environmental Protection Administration and the environmental protection department of the senior level.

Upon receipt of the report, the State Environmental Protection Administration shall check and investigate the facts, and may withdraw the registration certificates of the new chemical substances originally held by the producer or importer.

## Chapter 5 Legal Responsibilities

**Article 24** Any applicant who is in breach of the requirements of the Measures and makes false claims in the application procedures for the registration certificate shall be ordered by the State Environmental Protection Administration to make rectification and fined RMB10,000 to RMB30,000. In addition, the infringement shall be publicised and recorded by the State Environmental Protection Administration. Any application for the declaration of new chemical substances submitted by the same applicant shall not be accepted in the following three years.

**Article 25** Any applicant who is in breach of the requirements of the Measures and has conducted one of the following acts shall be ordered to make rectification, fined not more than RMB30,000, and reported to the State Environmental Protection Administration by the local environmental protection department at the county level or above. In addition, the breach shall be publicised and recorded by the State Environmental Protection Administration. Any application for declaration of new chemical substances submitted by the same applicant shall not be accepted in the following three years.

- (1) Refusing on-the-spot inspection made by the environmental protection department or conducting falsifications during inspection;
- (2) Having not completed the data form that contains such information as the production, import and circulation of the new chemical substances as required by the Measures;
- (3) Having not retained such information as the declaration, production, import and environmental impacts of the new chemical substances as required by the Measures;
- (4) Producing or importing the new chemical substances which have not applied for declaration or acquired the registration certificates.

**Article 26** Should any of the requirements stipulated in the Measures be subject to breach with respect to the abuse of power, dereliction of duties or disclosure of the applicant's commercial and technical confidentiality, the environmental management organizations of the new chemical substances and their personnel shall be subject to administrative penalty. Furthermore, the parties shall be subject to investigation for criminal responsibilities in the event that a crime has been committed.

## Chapter 6 Supplementary Provisions

**Article 27** The formats and contents of the following documents shall be standardised by the State Environmental Protection Administration:

- (1) Declaration Form of New Chemical Substances;
- (2) Application Form for Exemption from Declaration of New Chemical Substances;
- (3) Registration Certificate of New Chemical Substance;
- (4) Advice note of surveillance regarding the environmental impacts of the new chemical substances;
- (5) Data form of the production, import and circulation of the new chemical substances.

**Article 28** The charges for the declaration and registration of the new chemical substances shall comply with the related stipulations of the State.

**Article 29** The Measures shall come into force on 15 October 2003.