

# 国家环境保护总局令

第 17 号

《新化学物质环境管理办法》已经 2003 年 4 月 1 日国家环境保护总局第 4 次局务会议审议通过,现予发布,自 2003 年 10 月 15 日起施行。

国家环境保护总局局长

解振荣

二〇〇三年九月十二日

# **Provisions on the Environmental Administration of New Chemical substances (reference translation)**

Issued by: The State Environmental Protection Administration of P. R. China; Issued on: 12 September 2003; Effective as of: 15 October 2003

## **Chapter 1 General Provisions**

### Article 1

This Provisions is formulated for the purpose of enhancing the environmental management on new chemical substances, preventing environmental pollution, and protecting human health and safeguarding the ecological environment.

### Article 2

This Provisions is applicable to activities in relation to the manufacture or import of new chemical substances and their environmental management undertaken within the territory of the People's Republic of China.

### Article 3

The State shall, for the purpose of the environmental management of new chemical substances, establish the systems of notification and registration applied to any of the manufacture or import of new chemical substances.

Any manufacturer or importer of new chemical substances shall, prior to the manufacture or import of new chemical substances, make notifications and applications for the registration certificates for the environmental management on new chemical substances (hereinafter cited as 'the registration certificates') in accordance with relevant provisions of this Provisions.

The aforesaid provision shall not be applied to the chemical substances which have been manufactured or imported before the effective date of this Provisions.

### Article 4

The term 'new chemical substance', as used in this Provisions, means any chemical substance which has not yet been manufactured or imported in China before the date on which it is notified.

The State Environmental Protection Administration of the People's Republic of China (hereinafter cited as 'the SEPA') is responsible for compiling and timely publicizing the inventory of chemical substances manufactured or imported in China.

#### Article 5

The SEPA is empowered to formulate and promulgate relevant standards and technical requirements for the environmental management of new chemical substances.

#### Article 6

The SEPA shall establish a Expert Committee on the Environmental Management on New Chemical Substances (hereinafter cited as 'The Expert Committee').

The main responsibility of the Expert Committee is to evaluate the environmental impacts on new chemical substances and, after evaluation, submit reports in written form on the evaluation results to the SEPA.

#### Article 7

Any administrative department or person involved in the environmental management of new chemical substances shall keep the commercial and technical secrets for the notifiers of new chemical substances (hereinafter cited as 'the notifiers').

## **Chapter 2 Notification**

#### Article 8

The notifiers shall, prior to the manufacture or import of new chemical substances, complete and submit the notification forms and the testing reports of new chemical substances, together with a copy of the document on the qualification of the testing entity(ies), to the Chemical Registration Center of SEPA (hereinafter cited as 'CRC-SEPA').

The contents of the notification form shall include information of the new chemical substance notified: the name(s) and the molecular structure; the method(s) applied in measuring; the use(s) of the new chemical substance; the scheduled annual amount of manufacture or import; the physi-chemical properties, toxicological and eco-toxicological characteristics; the measures for accident prevention and emergency responses; and the measures for pollution prevention and elimination and for waste disposal, etc..

In case that the testing data were completed out of China, the testing entity(ies) involved shall have been accredited by qualifications the competent authorities of the country in which the entity(ies) is(are) located.

The eco-toxicological data of new chemical substances shall include those obtained through biological tests performed in China by the application of China's test organisms.

#### Article 9

The notifiers who provide information materials containing commercial and technical secrets shall give confidential indications at the relevant items in the materials.

The notifiers who will uncover the secrets which is mentioned in aforesaid item shall inform CRC-SEPA in written form.

#### Article 10

The notifiers may make a serial notification on the new chemical substances with similarities in molecular constitutions, similarities or sameness in use(s) and testing data, whereas the registration certificate shall be applied for each new chemical substance.

#### Article 11

In case that two or more notifiers make a joint notification on the same new chemical substance, each notifier shall apply for a registration certificate separately.

#### Article 12

In notifying a new chemical substance which has been included in the inventories of existing chemical substances in at least four countries or regional economic integration organizations, the notifier is only required to complete and submit the notification form and the report of eco-toxicological testing performed in China.

#### Article 13

In one of the following cases, the notifier may apply for exemption from the notification:

- (a) The annual amount of manufacture or import of the new chemical substance does not exceed 100 kilograms and they are only used for scientific research purpose;

(b) A polymer containing a new chemical substance monomer less than 2% (w/w);

(c) The total amount of the manufacture or import of a new chemical substance does not exceed 1,000 kilograms and they are specifically used for technologies research and development. In this case, the manufacturer or importer may apply for one-year exemption from notification and no extension will be granted;

(d) Samples of new chemical substances imported for the purpose of performing the eco-toxicological tests in China as required by this Provisions.

Any notifier intending to apply for the exemption from notification shall submit the application form for exemption from notification to CRC-SEPA and provide the necessary documents demonstrating the conformities to the aforesaid provision and s/he is obliged to keep a record of the information on the scientific research of the substance, the research and development of relevant technologies, the quantities of the substance manufactured or imported, the names of the customers, and others.

### **Chapter 3 Registration**

#### Article 14

CRC-SEPA shall, within 15 days after receiving notification materials, complete the format check on the notification materials in accordance with relevant provisions of this Provisions, inform the notifiers in written form that their notification materials are in conformity with the format requirements provided for in this Provisions and thus accepted; or inform the notifiers in written form that their notification materials are not in conformity with the format requirements provided for in this Provisions and thus rejected.

CRC-SEPA shall, if finding the notification materials incomplete or not in conformity with the format requirements provided for in this Provisions, inform the notifier in written form, in one time, all components which shall be supplemented or corrected.

CRC-SEPA shall submit the accepted notification materials, within 5 days after they were accepted, to the Expert Committee.

#### Article 15

The Expert Committee shall, within 60 days after received the notification materials, proceed the evaluation on the environmental

impacts of the new chemical substances in accordance with relevant standards and technical requirements for the environmental management on new chemical substances adopted or issued by the SEPA and then submit the evaluation reports in written form to the SEPA.

#### Article 16

The SEPA shall, within 30 days after received the evaluation reports from the Expert Committee, make the decisions on whether to approve the application for notification. Those whose applications for notification have been approved will be awarded the Registration Certificates and those whose applications for notification were rejected will be given explanations.

The SEPA shall inform CRC-SEPA its decisions and CRC-SEPA is responsible for forwarding the decisions in written form to notifiers.

#### Article 17

CRC-SEPA shall, within 15 days after received the application for the exemption from notification, make suggestions on decisions and submit them to the SEPA for review and audit.

The SEPA shall, within 15 days after received the application materials and the suggestions on decisions, make decisions on whether to approve the application for exemption from notification and inform CRC-SEPA its decisions. CRC-SEPA is responsible for forwarding the decisions to the notifiers in written form.

#### Article 18

The SPEA shall, after having made decisions on the registration or the exemption from notification in accordance with Article 16 and Article 17 respectively, inform its decisions and transmit the notice on the supervision and inspection over environmental impacts of new chemical substances to the environmental protection administrative departments at the provincial level where the manufacturers or importers concerned are located.

The provincial environmental protection administrative departments shall transmit the decisions and the notices aforesaid to the environmental protection administrative departments of the counties or municipalities where the manufacturers or importers of the new chemical substances are located.

## **Chapter 4 Supervision and Management**

### Article 19

Any holder of the registration certificates shall, within 5 days after each batch actually manufactured, imported or transferred new chemical substances to users, fill in and submit a record form on manufacture, import or circulation of new chemical substances to the environmental protection administrative department of the county where the manufacturer or importer is located.

The environmental protection administrative department at county level shall, within 5 days after received the record form, report to the municipal environmental protection administrative department; the latter shall, within 5 days after received the record form, report to the environmental protection administrative department at the province level; the provincial environmental protection administrative department shall, within 5 days after receiving the record form, report to the SEPA.

### Article 20

The environmental protection administrative department at the county level shall, within 5 days after received the record forms from manufacturers or importers who transferred new chemical substances out of the county, inform environmental protection administrative department another county where the users are located and transmit the information on the circulation of new chemical substances, relevant decisions and the notices on the supervision and inspection over environmental impact of new chemical substances .

The environmental protection administrative department of the county where the users are located shall, within 5 days after they received the information on the circulation of new chemical substances, relevant decisions and the notices on the supervision and inspection over environmental impact of new chemical substances, report to the municipal environmental protection administrative departments at the next upper level; the latter shall, within 5 days after received the reports, report to the environmental protection administrative departments at the provincial level.

### Article 21

The holders of the registration certificates shall keep the materials for notification, record of the manufacture or import and the environmental impacts of new chemical substances until the date when the chemical substances are publicized.

## Article 22

Environmental protection administrative departments 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 for decisions.

## Article 23

The environmental protection administrative department at the county level or above is empowered to exercise supervision and inspection over activities in relation to new chemical substances under its jurisdiction and, in finding the facts that the environment is endangered by new chemical substances, shall order the manufacturers or importers or users to take emergent measures to eliminate harms and report directly to the SEPA and the environmental protection administrative department at its next higher level simultaneously.

The SEPA shall check and investigate the facts after received the reports and may withdraw the registration certificates of new chemical substances from relevant manufacturers or importers.

## **Chapter 5 Legal Liabilities**

### Article 24

Any notifier who, in violation of this Provisions, made falsifications 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 SEPA. In this case, the SEPA is empowered to order the violator to rectify the wrongful acts, record and publicize the fact of violations and refuse any notification submitted by the aforesaid violator in the following 3 years.

### Article 25

Any organization or person who, in violation of this Provisions, conducted one of the following acts shall be subject to a fine not exceeding RMB30,000, by the local environmental protection administrative department at the county level or above, and the department is empowered to order the violator to rectify the wrongful acts and submit a report on the violation to the SEPA. The SEPA will record and publicize the facts of violations and refuse any notification of new chemical substances made by the violator in the following 3 years.

- (a) Refusing field inspections by the competent environmental protection administrative department or conducting falsifications when inspected;
- (b) Having not filled in and/or submitted the record form providing information on the manufacture, import and circulation of new chemical substances as required;
- (c) Having not kept the materials for the notification, manufacture, import and environmental impacts of new chemical substances as required;
- (d) Manufacturing or importing new chemical substances without application for or being awarded the registration certificates.

#### Article 26

In case of misusing authorities, neglecting duties or disclosing the commercial and technical secrets of notifiers, 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 27

The standardized formats and contents of the following documents shall be stipulated by the SEPA:

- (a) Notification form of new chemical substances;
- (b) Application form for exemption from notification of new chemical substances;
- (c) Registration certificate on new chemical substance;
- (d) Notice on the supervision and inspection over environmental impact of new chemical substances;
- (e) Record form of the manufacture, import and circulation of new chemical substances.

#### Article 28

Charges for notification and registration of new chemical substances shall comply with the relevant state stipulations.

#### Article 29

This Provisions shall come into force on 15<sup>th</sup> of October, 2003.