

Provisions on Environmental Administration of New Chemical Substance Management of China

环境保护部办公厅函

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Chapter 1 General Provisions

Article 1 (Legislation Purpose)

The Provision is enacted by following relevant laws, in order to control environmental risks from new chemical substances (hereafter NCS), to protect human health, and to protect ecological environment.

Article 2 (Applicable Scope)

This Provision is applicable to activities in relation to the manufacture, import, process and usage of NCS and their environmental management undertaken within the tariff territory of the People's Republic of China. It is also applicable to relevant activities of NCS in areas of bonded area and of export processing area of China.

Management of medicine, pesticide, veterinary drug, cosmetic, food, food additive and feed additive is subjected to relevant laws and regulations. While new chemical substances used as raw materials and intermediates for above-mentioned products are subject to this Provision.

Chemical substances inside Articles, if they are intended to be released during their normal usage as designed, shall be managed by following this Provision.

Article 3 (Classifications)

NCS is classified as General New Chemical Substance, Hazardous New Chemical Substance, according to standards on chemical hazard identification and classification.

Hazardous New Chemical Substances having properties of persistency, bioaccumulation, environmental and human health risks are managed as Critical Environment-Risk NCS.

NCS as quoted in this Provision, are chemicals not listed in Inventory of Existing Chemical Substances of China (hereafter IECSC).

IECSC is established, adjusted and publicized by Ministry of Environmental Protection of China (hereafter MEP).

Article 4 (Basic Philosophy)

The State implements the policy of NCS management on risk classification, registration and tracking control.

Article 5 (Notification Certificate)

Manufacturer or importer of NCS, must make notification prior to the manufacture or import, apply for the NCS Environmental Management Notification Certificate (hereafter 'Certificate').

NCS having not obtained Certificate is forbidden to be manufactured, imported, or processed and used.

NCS having not obtained Certificate or without Scientific Research Record Notification, is not allowed to be used in scientific research.

Article 6 (Advanced Technology Support)

The State supports scientific research on assessment and control technology of NCS environmental risk and health risk, generalizes state-of-the-art environmental risk control technology, encourages to manufacture, import, process and use alternative chemicals that are environment-friendly, encourages registrants to share NCS registration data.

Article 7 (Secret Keeping)

Staff working for environmental management of NCS should keep the commercial and technical secrets for the registrants.

Article 8 (Public Surveillance)

Any company and individual have the right to reveal, impeach, accuse activities violating this Provision.

Chapter 2 Notification Procedure

Article 9 (Notification Types)

NCS notification is categorized as Typical Notification, Simplified Notification and Scientific Research Record Notification.

Article 10 (Typical Notification Requirements)

For manufacturing or importing quantity of NCS above 1 ton, registrant should submit NCS Notification Report to Chemical Registration Center of MEP (hereafter 'CRC') to make Typical Notification; while if the NCS meets criteria for Simplified Notification, registrant could apply for Simplified Notification.

The NCS Notification Report should contain following materials:

- (1) Typical Notification Form, and appendix of its classification, label and MSDS in accordance with national standards.
- (2) Risk Assessment Report, including the NCS' hazard assessment, exposure estimation assessment, risk control measures, as well as conclusion on its environmental risk and health risk assessment, etc..
- (3) test reports or data on physi-chemical properties, toxicology and eco-toxicology, and qualification proof of the test institutes; The eco-toxicology test reports must include those performed inside China by the application of China's test organisms according to relevant standards.

Article 11 (Typical Notification Quantity Level)

Typical Notification follows the principle of 'the higher the notification quantity, the higher requirement for test data'. Registrant should provide test reports or data according to NCS Notification Guidance compiled by MEP.

The notification quantity of NCS is divided into the following four levels from the low to high:

- (1) level 1 is for annual manufacturing quantity or annual importing quantity above 1 ton and less than 10 tons.
- (2) level 2 is for annual manufacturing quantity or annual importing quantity above 10 tons and less than 100 tons.
- (3) level 3 is for annual manufacturing quantity or annual importing quantity above 100 ton and less than 1000 tons.
- (4) level 4 is for annual manufacturing quantity or annual importing quantity above 1000 tons.

Article 12 (Simplified Notification – basic type)

For NCS with annual manufacturing quantity or importing quantity less than 1 ton, Registrant should make Simplified Notification to CRC in prior to the manufacturing or importing.

Following materials should be submitted:

- (1) NCS Simplified Notification Form;
- (2) eco-toxicology test reports performed inside China by the application of China's test organisms.

Article 13 (Simplified Notification – special type)

If manufactured or imported NCS meets one of the following criteria, Registrant should apply for Simplified Notification.

- (1) used as intermediate or only for export, annual manufacturing quantity or importing quantity is less than 1 ton;
- (2) for scientific research purpose, annual manufacturing quantity or importing quantity is above 0.1 ton and less than 1 ton;
- (3) A polymer containing a new chemical substance monomer below 2%, or the polymer belongs to low concern polymer;
- (4) for the purpose of process and product research & development, annual manufacturing quantity or importing quantity is below 10 ton, and within 2 years.

Registrant should submit Simplified Notification Form and relevant materials proving compliance of the criteria to make Simplified Notification.

Article 14 (Record Notification Requirement)

If either condition below is met, Registrant should make Scientific Research Record Notification by submitting Scientific Research Notification Form:

- (1) For the purpose of scientific research, annual manufacturing quantity or importing quantity is below 0.1 ton;
- (2) to import NCS sample for the purpose of eco-toxicology test performed inside China by the application of China's test organisms.

Article 15 (Serial Notification, Joint Notification, Repeative Notification)

For Typical Notification, following notification formalities can be applied for following cases:

- (1) The Registrant could make NCS Serial Notification for several NCSs that have similarities in formula structure, have similar or same application(s), and have similarities in testing data results;
- (2) Two or more Registrants could make NCS Joint Notification if they make Notification of same NCS at the same time and jointly submit the notification materials;

- (3) When two or more Registrants make Notification of same NCS one after another, if the latter Registrant gets permission from the previous Registrant to use the previous Registrant's test data, the latter Registrant could make Repeative Notification. The registrants should get agreement by their own on the test cost sharing.

Article 16 (Registrant Qualification)

NCS Registrant or its agent should be organization registered inside the territory of China.

Registrant for whom it is not the first time for it to make a NCS notification, shall not have black record of being ever punished due to violation of the Provision within the past 3 years.

Article 17 (Notification in Faith)

Registrant when making NCS notification, should submit all known information of the chemical's hazardous properties and environmental risks.

Article 18 (Publicity of Environmental Information)

In case that the registrant has confidential requirement for its commercial or technological secrets contained in the submitted notification materials, he shall mark them out in the notification materials.

Information involving risks to human health and environmental safety shall not be marked confidential.

Registrants who require to disclose the confidential information, shall inform CRC in written.

Article 19 (Test Institutes)

Test institutes inside China that are entrusted to provide test data for NCS notification purpose, should be those declared by MEP, and should receive inspections and supervision by MEP.

These institutes should perform the tests according to 'The Guidelines For The Testing of Chemicals' and relevant national standards, and according to 'The Guidelines of Chemical Testing Good Laboratory Practices' constituted by MEP.

Test institutes outside China that provide eco-toxicity test data, must pass the inspection by the administrative departments of the country or meet GLP criterion

Chapter 3 Registration Management

Article 20 (Typical Notification Procedure)

NCS Typical Notification follows the procedure below:

1. After accepting a Typical Notification, CRC should transfer the Notification Report to MEP's Chemical Substance Environmental Management Expert Evaluation Committee (hereafter 'Evaluation Committee'). The Evaluation Committee consists of experts from the fields of chemistry, chemical engineering, health, safety, environmental protection, etc..
2. The Evaluation Committee should conduct identification and technical evaluation on the NCS according to the standards and criterion for NCS hazard and risk assessment formulated by MEP, as well as relevant national standards on chemical hazard identification and classification:

- (1) the chemical's name and identification;
- (2) the chemical's hazardous properties on physic-chemical, on human health and on environment, etc.;
- (3) the chemical's exposure extent and its risks to human health and environment;
- (4) the suitability of the chemical's environmental and human health risk control measures

If the Evaluation Committee deem the materials are not enough to get comprehensive conclusion on the chemical's risks, CRC should inform the Registrant in written to supplement notification materials.

3. The Evaluation Committee should generate its technical evaluation opinions on the NCS, submit to MEP. The technical evaluation opinions should include:
 - (1) opinion on the NCS belongs to normal NCS, hazardous NCS or Critical Environment-Risk NCS;
 - (2) opinion on human health risk and on environmental risk;
 - (3) conclusion on the suitability of risk control measures;
 - (4) suggestion on whether to approve the registration.
4. MEP should examine the technical evaluation opinion, determine the NCS' classification, and make decision:

- (1) for NCS having suitable risk control measures, approve the registration, and issue the Certificate;
- (2) for NCS having no suitable risk control measures, refuse the registration, inform the Registrant in written and explain the reason.

MEP should make publicize the NCS registration content before approving the registration.

Article 21 (Simplified Notification Procedure)

Simplified Notification follows the procedure below:

- (1) CRC should report to MEP with written proposals, after accepting the Simplified Notification.

If eco-toxicology test reports are required according to requirement, the Evaluation Committee should conduct technical evaluation on the Notification materials, bring forward technical evaluation opinion, and report to MEP.

- (2) MEP will approve the registration and issue Notification Certificate for notifications meeting requirements; MEP will disapprove the registration and will inform the Registrant about the reason in written for notifications that do not meet requirements.

Article 22 (Record Notification Procedure)

NCS Scientific Research Record Notification follows the procedure below:

- (1) CRC should submit on monthly basis to MEP after receiving Scientific Research Record Notifications;
- (2) MEP will publicize at government's website periodically.

Article 23 (Registration Publicity)

MEP should publicize chemical name, registrant, notification type and NCS management classification, etc. of the registered NCS at government website.

Article 24 (Registration Timetable)

CRC should submit the notification materials to Evaluation Committee within 5 working days after accepting Typical Notification materials; CRC should submit proposals in written to MEP within 5 working days after accepting Simplified Notification materials.

Expert Evaluation should not exceed 60 days for Typical Notification; Expert Evaluation should not exceed 30 days for Simplified Notification. If CRC inform the Registrant to supplement materials, the time waiting for the supplemented materials is not counted.

MEP should decide whether to approve the registration within 15 working days after receiving the materials from Evaluation Committee or CRC. If the decision could not be made within 15 working days, another 10 working days can be taken after approval by responsible person of MEP.

Article 25 (Certificate Content)

Notification Certificate should show the following items:

- (I) Name of the registrant or the agent.
- (II) Name of the NCS.
- (III) Application of the NCS
- (IV) Registration quantity level and the quantity.
- (V) Management Classification of NCS.

Notification Certificate of Typical Notification should also show the risk control measures and administrative management requirements.

Article 26 (New Property Updating and Processing)

When finding new hazardous properties of NCS, Notification Certificate Holder should report immediately to CRC.

CRC should submit the new property information to Evaluation Committee for technical evaluation.

MEP will take following measures according to technical evaluation opinion from Evaluation Committee:

- (I) to supplement relevant risk control measures into the Notification Certificate if the risks can be controlled by increasing risk control measures, and to urge the Holder to carry out these measures;
- (II) to withdraw the Certificate if no appropriate risk control measures, and to publicize it.

Article 27 (Re-Notification)

If registration of a NCS has been approved but not listed in IECSC yet, the Notification Certificate Holder should re-notify it if either of cases below is met:

- (I) to increase the amount level
- (II) to change the application of Critical Environment-Risk NCS

If to change application of Critical Environment-Risk NCS registration of which has been approved and listed in IECSC, the Re-notification can also be made by its processor.

Article 28 (Information Communication)

MEP should communicate related information of Hazardous NCS (incl. Critical Environment-Risk NCS), to relative administrative ministries.

Chapter 4 Tracing Control

Article 29 (Pre-condition for Environmental Impact Assessment Approval)

Environmental Protection Administrative departments should take new chemical substance registration as pre-condition of proving Environmental Impact Assessment of constructing projects that manufactures or processes/uses the NCS.

Article 30 (Information Passing)

Notification Certificate Holder of Typical Notification, should describe clearly the hazard of the NCS in MSDS, and pass the following information to processor:

- (I) risk control measures as ruled in Notification Certificate;
- (II) MSDS;
- (III) classification results of the NCS according to 'Safety Rules For Classification, Precautionary labeling and Precautionary Statements of Chemicals'.;
- (IV) other relevant information.

Article 31 (Normal Risk Control Measures)

Notification Certificate Holder of Typical Registration and related processor, should take one or more risk control measures as listed below according to the requirements on the Certificate:

- (I) conducting training on NCS risks and protection knowledge;

- (II) enforcing personal protection of the work staff contacting the NCS;
- (III) setting safe protection e.g. confinement, isolation, etc., placarding warning signs;
- (IV) improving NCS' manufacture and usage method to decrease release and environment exposure;
- (V) improving pollution prevention and control techniques to decrease discharge to environment;
- (VI) establishing emergency preparedness plan and emergency handling measures;
- (VII) taking other risk control measures.

Notification Certificate Holder of Hazardous NCS (incl. Critical Environment-Risk NCS) and related processor, should obey relevant requirements as set by valid laws and regulations e.g. Decree on Dangerous Chemical Management.

Article 32 (Critical Risk Control Measures)

Notification Certificate Holder of Critical Environment-Risk NCS and related processor, should also take following risk control measures:

- (I) during manufacturing or processing/using, should monitor or estimate its release to environment. Such monitor can be entrusted to institutes affiliated to EPB or to other institutes, recognized by EPB of above city level;
- (II) During transfer, should be equipped with relevant facilities and take measures according to related rules, to prevent Critical Environment-Risk NCSs from entering environment in case of accident, and prompting emergency measures;
- (III) should treat the Critical Environment-Risk NCS according to rules for Hazardous Wastes when the NCS is disposed.

Article 33 (Transferring Forbidden)

Notification Certificate Holder of Typical Notification, shall not transfer NCS to processor having no capability in taking risk control measures.

Article 34 (Research & Development Management Requirement)

Scientific research, technology and product research & development activities of NCS should be conducted in designated facilities under direction of professionals, by strictly following relevant management rules.

NCS manufactured and imported for the purpose of scientific research, of technology and product research & development, should be preserved properly, and shall not be used for other purpose; if it needs to be destroyed, it should be disposed according to rules for hazardous wastes.

Article 35 (Activity reporting)

Notification Certificate Holder of Typical Notification, should submit the First-time Activity Reporting Form to CRC about the activity within 30 days of the first manufacturing, or the first transfer of the imported NCS to processor.

Notification Certificate Holder of Critical Environment-Risk NCS, should also report to CRC within 30 days for transfer of the NCS to each different processor.

Article 36 (Annual Reporting)

Certificate Holder of Simplified Notification should report to CRC the actual manufacturing or importing status of the NCS for the previous year before each February 1st.

Notification Certificate Holder of Hazardous Chemical Substance (incl. Critical Environment-Risk NCS), should report information below to CRC of the NCS for the previous year before each Feb. 1st:

- (I) actual manufacturing or importing status;
- (II) implementation status of risk control measures;
- (III) environmental exposure and release status;
- (IV) actual impact to environment and to human health;
- (V) other information related to environment risks.

Notification Certificate Holder of Critical Environment-Risk NCS, should also report to CRC the NCS manufacturing or importing plan for the year, and the preparation on risk control measures.

Article 37 (Material Keeping)

Notification Certificate Holder should keep the NCS notification materials, as well as NCS' manufacturing/importing status etc. for more than 10 years.

Article 38 (Surveillance Notice)

MEP should issue Surveillance Notice to Provincial Environmental Protection Department of the place where the manufacturer, processor of Hazardous Chemical Substance (incl. Critical Environment-Risk NCS) is located within 30 days after receiving the First-time Activity Reporting Form or report of the transfer.

The Provincial Environmental Protection Department should send the Surveillance Notice to county/city level EPB of the place where the manufacturer or processor is located.

The Surveillance Notice contents include: name of the NCS, management classification, risk control measures and administrative requirements as well as surveillance/inspection factors as indicated on Notification Certificate.

Article 39 (Surveillance and Inspection)

The local Environmental Protection Agencies having the responsibility of supervision and management, should surveil and inspect the NCS manufacturing, reprocessing/usage activities according to the Notice and according to Guidance of NCS Surveillance/Management/Inspection formulated by MEP.

If finding manufacturing or processing/using NCS activities cause or probably will cause acute or cumulative environmental pollution problems, (local EPA) should order the manufacturer/processor to immediately take measures to eliminate the hazards or risks, and report level by level till to MEP.

MEP may ask the Notification Certificate Holder to provide possible new hazardous of the NCS based on the reported case, and handle the case by following New Property Update and Processing as defined by this Provision.

Article 40 (Notification Certificate Withdrawal)

If the Notification Certificate Holder has not manufactured or imported, or stops the manufacturing and importing activities, could apply for Notification Certificate Withdrawal with explanation, hand back the Notification Certificate.

MEP will approve the Withdrawal, and publicize the information of the cancelled NCS, after confirming the manufacturing or importing activities have not occurred, or after confirming there is no hazardous environmental impacts.

Article 41 (IECSC Listing Procedure)

MEP publicizes and lists the registered Normal NCS into IECSC after 5 years of its first manufacturing or importing.

Notification Certificate Holder of Hazardous NCS (incl. Critical Environment-Risk NCS) should submit to CRC the Actual Activity Report at 6 months before 5 years' period is reached since the first-time actual manufacturing or importing activity.

MEP will organize experts of Evaluation Committee to conduct Review evaluation on the actual activity, publicize and list the Hazardous NCS (incl. Critical Environment-Risk NCS) into IECSC based on the evaluation result.

NCS by Simplified Notification and Scientific Research Record Notification will not be listed into IECSC.

Article 42 (Periodic Survey)

MEP organizes NCS survey every 5 years.

For chemicals that have been legally manufactured or imported within territory of the People's Republic of China before October 15, 2003, MEP is to list them into IECSC.

Manufacturing, importing or processing/using NCS without Notification Certificate, will be punished by MEP in accordance with laws.

Chapter 5 Legal Liabilities

Article 43 (False Notification)

In violation of this Provision, Registrant hides relevant information or provides false notification materials when making notification, MEP will order it to correct, publicize its violation, make the records, and to issue it a fine from 10,000 to 30,000 Yuan; if the NCS has been registered, the Notification Certificate will be withdrawn.

Article 44 (Punishment by MEP)

In violation of this Provision, any of following will be ordered to correct and be fined by MEP upto 10,000 RMB:

- (I) Failing to submit the updated environmental risks of the registered NCS;
- (II) Failing to submit the First-time Activity Reporting Form or the transfer information according to the requirement;
- (III) Failing to submit the NCS manufacturing or importing activities of the previous year;
- (IV) Failing to submit the actual activity report.

Article 45 (Punishment 1 by local EPB)

In violation of this Provision, a company conducts one of the following acts, local EPB having the administrative responsibilities orders the company to correct, issues a fine from 10,000 to 30,000 Yuan, reports to MEP, publicizes the violations, takes the records:

- (I) Refusing or baffling inspections by environmental protection bureau, or conducting falsifications when inspected;
- (II) manufacturing/importing NCS without Notification Certificate, or without following the requirements of the Certificate;
- (III) processing/using NCS which has not obtained Notification Certificate;
- (IV) not taking risk control measures according to requirements of the Certificate;
- (V) transferring the NCS to processors/users that do not have the capability of taking risk control measures.

Article 46 (Punishment 2 by local EPB)

In violation of this Provision, a company conducts one of the following acts, local EPB having the administrative responsibilities orders it to correct, issues it a fine from 10,000 to 30,000 Yuan:

- (I) not passing risk control information to processor according to rules;
- (II) not keeping the NCS notification materials, as well as NCS' actual manufacturing/importing activities etc.. according to rules;
- (III) for the manufactured/imported NCS that are registered for the purpose of Scientific Research and technology/product research & development, using it for other purpose, or not managing it according to requirements.

Article 47 (Punishment to Violation by Evaluation Experts)

Experts of Evaluation Committee, causing the evaluation result in severe inconsistent with the fact due to falsification or duty breaching during the evaluation, will be eliminated the qualification as Evaluation Committee member, and be noticed to public by MEP.

Article 48 (Punishment to Violation by Testing Institutes)

China domestic testing institutes providing test data for NCS registration purpose, will be eliminated from the Declared Institute List, and noticed to public by MEP, if

they fabricate or juggle the data, or they have other falsification behaviors during the test.

Article 49 (Punishment to Misuse of Authority)

In violation of this Provision, working staff involved in NCS administration misuse their authorities or neglect their duties, will be punished according to law; criminal penalty will be accused in case of crime.

Chapter 6 Supplementary Provisions

Article 50 (Terminology Definition) Terminologies in this Provision are defined as below,

- (I) Normal New Chemical Substance refers to new chemical substance without hazardous properties discovered yet, or its hazards are below relevant hazard identification and classification thresholds according to relevant standards;
- (II) Hazardous New Chemical Substance refers to new chemical substance possessing physicochemical/human health/environment hazards, and reaching or exceeding relevant hazard identification and classification thresholds according to relevant standards.

Article 51 (Relevant Forms) The format of Forms as quoted in this Provision is constituted by MEP:

- (I) NCS Typical Notification Form
- (II) NCS Simplified Notification Form
- (III) NCS Scientific Research Record Form
- (IV) NCS Environmental Management Notification Certificate
- (V) NCS First-Time Activity Reporting Form
- (VI) NCS Supervision Notice

Article 52 (Effectiveness Timetable)

This Provision takes effectiveness from October 15, 2010.

The 'Provisions on the Environmental Administration of New Chemical substances' issued by SEPA on September 12, 2003 is abolished at the same time.