

**New Policies on
Chemical Environmental Management
in China**

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Overview of Order No.7

- Issued by: MEP
- Issuance date: January 19, 2010
- Effective as of: October 15, 2010
- Form: Ministerial Order No. 7
- Title: Measures on Environmental Management of New Chemical Substances
- Structure: 52 clauses in 6 chapters

Chapter II
notification
Procedure
(11 clauses)

Chapter III
notification
Management
(9 clauses)

Chapter I
General
Principles
(8 clauses)

Chapter VI
Supplementary
Provisions
(3 clauses)

Chapter V
Legal
Responsibilities
(7 clauses)

Chapter IV
Tracking and
Control
(14 clauses)



**Ministerial
Regulation
No.7**

Notification Scope

Red ones are different from the current Order No.17

- Activities
 - Research
 - Manufacturing
 - Import
 - **Used as process materials**
- Territories
 - Chinese territory
 - Excluding HK, Macao & Taiwan
 - **Including bonded areas and export-oriented processing areas**
- Substances
 - Chemical substances not listed in the “Inventory of Existing Chemical Substances in China”
 - Raw materials and intermediates for producing medicines, etc.
 - **Articles designed to intentionally release the contained new chemical substances during their regular utilization**
- Exclusion and exemption categories
 - Finished products restricted by other regulations: medicines, pesticides, veterinary drugs, cosmetics, foods, food additives, feed additives, radioactive substances, military engineering products, fire engineering products and tobaccos
 - Natural substances: natural substances from physical process and air extraction, natural polymers and life matters
 - Non-commercial or unintentional products: impurities, accidental reaction products, wastes and byproducts
 - Other special substances: materials, alloys, non-isolated intermediates and other articles

Notification Types

Higher requirements for testing data corresponding to higher level of notification

- Normal notification

Four levels

- Level I: $1t \leq \text{notified quantity} < 10t$
- Level II: $10t \leq \text{notified quantity} < 100t$
- Level III: $100t \leq \text{notified quantity} < 1000t$
- Level IV: $\text{notified quantity} \geq 1000t$

Three forms: serial notification, joint notification and repeated notification

- Simplified notification

- Basic circumstance: $\text{notified quantity} < 1t$
- Specific circumstances
 - Intermediates or exportation only, $\text{notified quantity} < 1t$
 - For scientific research, $0.1t \leq \text{notified quantity} < 1t$
 - Polymers containing new chemical monomers of 2% or lower, or polymers of low concerns
 - Process and product R&D, $\text{notified quantity} < 10t$ (within 2 years)

- Record notification

- Scientific research, $\text{notified quantity} < 0.1t$
- Imported for conducting eco-toxicity tests of new chemicals within Chinese territory by using Chinese target organism

Document Requirements for Normal Notification

- New Chemical Substance Normal Notification Form
- Risk Assessment Report
- Physical-chemical, toxicological and eco-toxicological properties test report and qualification certificate of the testing agency
- Classifications and labels made according to “Safety Rules for Classification, Precautionary Labeling and Precautionary Statements of Chemicals” (GB20576~20602-2006)
- Material Safety Data Sheet (MSDS) of Chemicals

The Eco-toxicological Properties Test Report should contain the data conducted within Chinese territory by using Chinese target organism.

Document Requirements for Simplified & Record Notification

- Simplified Notification
 - New Chemical Substances Simplified Notification Form
 - Basic circumstance: Eco-toxicological properties test report conducted within Chinese territory by using Chinese target organism
 - Specific circumstances: certification documents corresponding to the circumstance
- Record Notification
 - New Chemical Substances Scientific Research Record Form

Technical Assessment—Normal Notification

- Contents
 - Name and identification
 - Hazard properties of physical-chemical, and related to human health and environment
 - Exposure degree and risks to human health and environment
 - Appropriateness of the control measures of risks to human health and environment
- Conclusions
 - Opinions on the management classifications of new chemical substances into general and hazardous categories, including the hazardous category under priority environmental management
 - Evaluation opinions on human health and environment risks
 - Evaluation conclusions on the appropriateness of risk control measures
 - Suggestion on the registration approval

MEP Examination and Approval

- For chemical substances with appropriate risk control measures, registrations shall be approved, certificates shall be issued.
- For chemical substances without appropriate risk control measures, notification application shall be rejected with the written notice of the rejection reasons.

The notification contents of new chemical substances should be announced before the decision is made on approving or rejecting the notification application.

Time Limit for Notification Procedure

- Normal notification
 - Format check: 5 working days
 - Expert evaluation: 60 days
 - MEP approval: 15 working days
- Simplified notification
 - Format check: 5 working days
 - Expert evaluation (basic circumstance only): 30 days
 - MEP approval: 15 working days
- Record notification
 - Format check: 5 working days
 - Expert evaluation or MEP approval: None

The time for submitting supplemental documents shall not be included into the days for expert evaluation.

Items of the registration certificate

- Title of the applicant or application agent
- Name of the new chemical substance
- Notified uses
- Notified level and quantity
- Management category of the new chemical substance
- Risk control measures and administrative requirements should also be included in the Certificate of Normal Notification

Initial Activity Report

- Holder of the Normal registration certificate should submit the New Chemical Substance Initial Activity Report to CRC-MEP within 30 days after the initial production activity, or within 30 days after the initial import and transfer of the new chemical substances to the user.
- Holder of the registration certificate of hazardous new chemical substances under priority environmental management should also submit the information on the flow of the new chemical substances to CRC-MEP within 30 days after each transfer of the hazardous new chemical substances under priority environmental management to different users.

Annual Report

- Holder of a simplified registration certificate should submit a report on the actual production or import of the new chemical substance approved in the previous year to CRC-MEP before February 1st each year.
- Holder of a registration certificate of hazardous new chemical substances (including the hazardous new chemical substances under priority environmental management) should submit to CRC-MEP before February 1st each year the information on:
 - Actual production or import;
 - Implementation of risk control measures;
 - Environmental exposure and release;
 - Actual impact on the environment and human health;
 - Other information related to environmental risks.
- Holder of a registration certificate of hazardous new chemical substances under priority environmental management should also submit to CRC-MEP the production or import plan of the new chemical substances notified in the current year as well as the preparation situation for the implementation of risk control measures.

Applicant Qualification Requirements

- Applicant or application agent for notification of new chemical substances must be the entity registered in Chinese territory.
- For applying for notification of new chemical substances that have been notified before, the applicant must not bear records of administrative punishment for breaking the Measures on Environmental Management of New Chemical Substances.

Testing Agencies

- The testing agencies in Chinese territory providing data on the test of new chemical substances for notification should be the testing agencies of chemical substances announced by MEP, at the same time under its supervision and inspection.
- The testing agencies in Chinese territory should abide by the guidelines for chemical test laboratory issued by MEP and conduct eco-toxicity tests on the new chemical substances according to guidelines for the testing of chemicals or relevant national standards.
- The testing agencies not located in Chinese territory providing data based on the eco-toxicity test of the new chemical substances conducted outside of Chinese territory must pass the inspection of the authority in charge in the country or meet GLP guidelines.

Listing in the “Inventory”

- Holder of a registration certificate of the general new chemical substances shall be announced listing into the “Inventory” by MEP as of five years after the initial production or import activity.
- Hazardous new chemical substances (including hazardous new chemical substances under priority environmental management)
 - Holder of a registration certificate should submit to CRC-MEP the report on the actual activities six months previous to the end of the fifth year after the initial production or import activity.
 - MEP shall organize the experts of the Evaluation Committee to conduct retrospective evaluation on the actual activity report, and the new chemical substances shall be listed into the “Inventory” based on the evaluation results.

Strengthened Management of the Registration of Import/Export of Toxic Chemical Substances

- In September 2009, MEP promulgated the “Notification on Strengthening the Work of Environmental Management and notification of Toxic Chemical Substances” (HuanBan [2009]113).
- In order to facilitate the implementation of the Notification, on January 7, 2010, MEP released the “Notice on Adjusting the registration certificate for Environmental Management of the Import/Export of Toxic Chemical Substances and the Application Forms” (HuanBanHan [2010]15).

Application Scope

- Chemical enterprises listed in the “2010 List of the Import/Export of Toxic Chemical Substances Under Strict Restriction by China” (No. 76 Announcement released by MEP & the Customs), as well as the relevant manufacturers, users and traders of such substances.

Variations Compared to Former Registration Requirements

- Additional requirements for pre-examination and post supervision to be conducted by Provincial Environmental Protection Departments;
- Administration is extended to the relevant manufactures and users in upper and lower streams of the import/export;
- Adjustment of requirements for application documents to be submitted by different types of enterprises as well as the procedures;
- Additional requirement for industry social responsibility.

Time Limit for Registration Approval and Effective Period

- ◆ Time limit for registration:
 - Import registration certificate: within 30 days after the acceptance of the application
 - Import/Export Pass: within 20 days after the acceptance of the application
- ◆ Effective period:
 - Import registration certificate: 2 years of validity
 - Import Clearance Notification: 6 months of validity, not exceeding the effective date of the registration certificate
 - Export Clearance Notification: 6 months of validity
- ◆ Quantity limit for notification
 - Import Clearance Notification: Not exceeding the quantity limit registered in the registration certificate, cumulative annual import not exceeding the quantity limit ratified by Provincial Environmental Protection Department
 - Export Clearance Notification: Cumulative annual export not exceeding the quantity limit ratified by Provincial Environmental Protection Department

**Thank you for
your attention!**