

Environmental Management on Chemicals in China

Chemical Registration Center of SEPA

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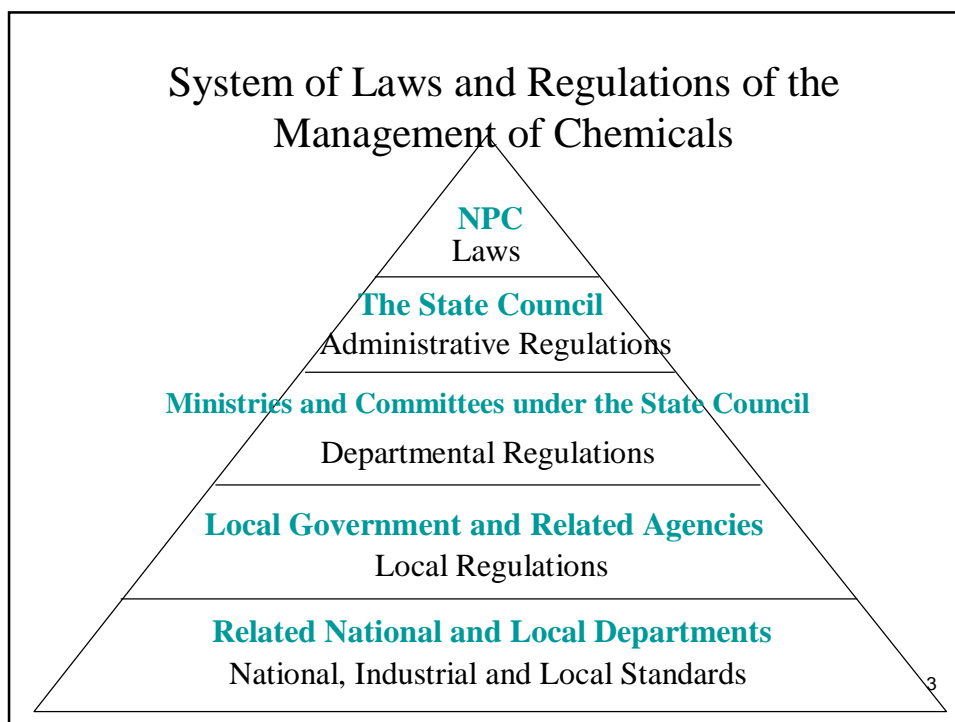
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Laws Concerning the Management of Chemicals

- Environmental Protection Law of the People's Republic of China (Amended in 1989)
- Law of the People's Republic of China on the Prevention and Control of Atmospheric Pollution (Amended in 2000)
- Law of the People's Republic of China on the Prevention and Control of Water Pollution (Amended in 1996)
- Law on Prevention and Control of Environmental Pollution Caused by Solid Waste (Amended in 2004)
- Law on Environmental Impact Assessment of the People's Republic of China (2002)
- Law of the People's Republic of China on the Prevention and Treatment of Occupational Diseases (2001)
- Production Safety Law of the People's Republic of China (2002)
- Law on the Promotion of Clean Production of the People's Republic of China (2002)
- Food Hygiene Law of the People's Republic of China (1995) <concerning food additives>
- Fire Control Law of the People's Republic of China (1998) <concerning flammable and explosive chemicals >

Administrative Regulations Concerning the Management of Chemicals

- Regulations on Safe Management of Hazardous Chemicals (revised in 2002) - List of Dangerous Goods (GB12268), Catalog of Hazardous Chemicals (2002 edition), List of Highly Toxic Chemicals (2002 edition), List of Highly Poisonous Chemicals (2003 edition).
- Administrative Regulations of the People's Republic of China on Pesticides (revised in 2001)
- Pharmaceutical Administration Law of the People's Republic of China (amended in 2001)
- Administrative Regulations of the People's Republic of China on Veterinary Medicine (revised in 2004)
- Regulations of the People's Republic of China on the Administration of Controlled Chemicals (1995) - Catalogue of Controlled Chemicals
- Regulation on Management of Drug-Making Chemicals (2002) - Catalogue of Drug-Making Chemicals
- Regulations on Industrial Product Manufacturing Permission License (2005)

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Departmental Regulations Concerning the Management of Chemicals

- Regulations for Environmental Management on the First Import of Chemicals and the Import and Export of Toxic Chemicals (1994) - List of Toxic Chemicals Banned or Severely Restricted in the People's Republic of China
- Provisions on the Environmental Administration of New Chemical Substances (2003) - Inventory of the Existing Chemical Substances in China
- Measures for the Prevention and Control of Environment Pollution by Discarded Dangerous Chemicals (2005)
- Measures for The Administration of Registration of Hazardous Chemicals (2002)
- Measures for the Administration of Operating Licenses for Hazardous Chemicals (2002)
- Measures for the Administration of Designated Production of the Package and Containers of Hazardous Chemicals (2002)
- Measures for the Administration of Licenses for the Purchase and Road Transportation of Highly Toxic Chemicals (2005)
- Regulations for Management of Road Dangerous Freight (2005)

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Standards Concerning the Management of Chemicals

- The Guidelines for the Hazard Evaluation of New Substances (HJ/T154-2004)
- The Guidelines for the Testing of Chemicals (HJ/T153-2004)
- The Guidelines of Chemical Testing Good Laboratory Practices (HJ/T155-2004)
- Classification and Labeling of Commonly Used Dangerous Chemicals (GB 13690-92)
- General Rules for the Preparation of Chemical Safety Data Sheet (GB16483-1996)
- Rule for Storage of Chemical Dangers (GB15603-1995)
- General Specifications for Transport Packages of Dangerous Goods (GB12463-90)
- Standard for Pollution Control on Hazardous Wastes Incineration (GB18484-2001)
- Standard for Pollution Control on Hazardous Wastes Storage (GB18597-2001)
- Standard for Pollution Control on the Security of Landfill Site for Hazardous Wastes (GB18598-2001)

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Industrial List Concerning the Management of Chemicals

- Catalogue for the Guidance of Industrial Structure Adjustment (2005)

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Management of New Chemical Substances

-- Provisions on the Environmental Administration of New Chemical substances

- The Provisions is the No. 17 Decree in 2003 of SEPA. It was enacted on September 12 of 2003 and took effect on October 15 of the same year. The promulgation of the Provisions serves as a milestone in the field of environmental management of chemicals in China.
- Background
 - Honoring the commitment China has made following its accession into the WTO
 - Getting compatible with international standards
 - Filling in the gap in the field of environmental management of chemicals in China

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Management of New Chemical Substances

-- Provisions on the Environmental Administration of New Chemical substances

- Inventory of Existing Chemical Substances in China (IECSC) was initiated in December of 1994 and was supplemented upon application five times in 1996, 1999, 2001, 2002 and 2003 respectively. Presently the IECSC covers around over 45,000 kinds of chemical substances.
- A range of guidelines were issued including the Guidelines for the Testing of Chemicals, the Guidelines for the Hazard Evaluation of New Substances and the Guidelines of Chemical Testing Good Laboratory Practices, all taking effect from June 1 of 2004.

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Management of New Chemical Substances

-- Provisions on the Environmental Administration
of New Chemical substances

- The New Chemical Substance Notification Guideline has been formulated.
- An Expert Committee on the Environmental Management on New Chemical Substances is established to take charge of the registration and review of new chemical substances. The Committee so far has a pool of 39 experts from related sectors.
- 7 qualified domestic eco-testing laboratories were publicized.

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Applicable Scope

- Territorial
 - Within the customs territory of P.R.C.
 - Excluding Hongkong, Macau, Taiwan
 - Excluding the confines of bonded areas and export manufacturing trade zones within P.R.C.
- Substances
 - New Chemical Substances, not listed in IECSC
 - Despite the concentration of new chemical substances inside the preparations

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Activities and Notifiers

- Activities
- Production within the customs territory of P.R.C.
 - Importation into the customs territory of P.R.C.
 - Exportation to the customs territory of P.R.C.
 - Transfer into the customs territory of P.R.C. from bonded areas and export manufacturing trade zones
- Notifiers
 - Domestic producer
 - Domestic importer
 - Foreigner exporter (Incl. those located in Hongkong, Macau, Taiwan, bonded areas and trade zones)

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Substance Scope--Exemptions

- Chemicals Under the Management of Other Existing Laws and Regulations
 - Radioactive substances
 - Military industry products
 - Pyrotechnics
 - Biological substances
 - Pesticides
 - Veterinary drugs
 - Pharmaceuticals
 - Cosmetics
 - Foods
 - Food additives
 - Feed
 - Feed additives
 - Tobacco and tobacco products

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Substance Scope—Exemptions Con't 1

- Substances That Exist in Nature
 - Substances that are unprocessed, or that are processed or treated only through the methods listed below:
 - Manual
 - Mechanical
 - Gravitational
 - Water soluble
 - Flootation
 - Heat dehydration
 - Extracted from the atmosphere through various means
 - Natural polymers, except for ones that are processed through physical or chemical processing

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Substance Scope—Exemptions Con't 2

- Special Categories
 - Glass
 - Frit
 - Pottery raw materials and ceramic ware
 - Steel and steel products
 - High-alumina cement
 - Portland cement
 - Articles
 - Homogeneous and heterogeneous alloys, except for metal compounds and precisely defined intermetallic compounds

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Substance Scope—Exemptions Con't 3

- Categories that have noncommercial objectives or that are produced unintentionally, except when they are put directly onto the market as commodities
 - Impurities
 - Products of random reactions that occur when a certain chemical substance accidentally comes into contact with another substance or when an article comes into contact with an environmental factor (such as air, steam, a microorganism, or sunlight)
 - Products of random reactions that occur when a chemical substance, mixture, or article is in storage
 - Products of reactions that occur when a chemical substance, mixture, or article is in final use
 - Waste water, waste gas, solid waste, and by-products

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Types of Notification

- Typical Notification
- Serial Notification: similar molecular structure, same or similar usage, and similar test data
- Joint Notification: two or more notifiers
- Simplified Notification: already listed in four or more existing inventories in the world
- Notification Exemption
- Polymer Notification

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Notification Exemption

- manufactured or imported annually for scientific research purposes does not exceed 100 kg;
- polymer containing a new chemical substance monomer of less than 2 percent, and some special catalogs of polymers
- manufactured or imported for technological research and development does not exceed 1,000 kg, apply for a one-year notification exemption, but no extensions will be granted;
- imported for new chemical substance ecotoxicology testing in China

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Polymer Notification

- Not required: in IECSC already
- Notification Exemption
 - All of their monomers are already included in IECSC
 - Two or more monomers/reactants with the highest content in the polymer already exist in one or more other polymers in the Inventory, and other new chemical substance monomer of less than 2 percent
 - All of their blocks are already included in the block copolymerization in IECSC
 - Their precursors and branched chains are already included in the graft polymers in IECSC
 - of low concern
- Simplified Notification
- Typical Notification
- Serial Notification
- Joint Notification

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Data Requirements

- Notifier and substance identity
 - Notifier information
 - Substance identity
 - Determination method
 - Manufacture process
 - Usage and Exposure
- Environmental protection and Safety
 - Recommended safe usage
 - Emergency measures
 - Pollution prevention and abatement methods
 - Waste disposal measures
- Inherent Characteristics
 - Physiochemical properties
 - Toxicology
 - Ecotoxicology
- Non-compellent
 - MSDS
 - Commodity label

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Requirement on Materials

-Principle

- The **quality** and **quantity** of the information should be sufficient for the Expert Committee to make an objective assessment of the environmental and public health impact of the notified substance.
- The notifier may make an independent pre-assessment of the new chemical substance that is to be notified with reference to the *Guidance for the Hazard Assessment of New Chemical Substances* that was promulgated by SEPA

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Requirement on Materials

-Physicochemical property, at minimum

- Solid
 - relative density
 - flash point
 - self-ignition temperature
 - explosive limit
 - particle size
 - water solubility
 - Kow
- Gas
 - explosive limit
 - oxidizability
- Liquid
 - relative density
 - oxidizability/causticity
 - vapor pressure
 - Flammability
 - water solubility
 - Kow
 - pH

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Requirement on Materials

-Toxicological data, at minimum

- Basic level ($Q < 10^4 \text{kg}$)
 - Acute toxicity: acute peroral toxicity, acute inhalation toxicity, acute dermal toxicity, skin irritation, eye irritation, and skin sensitization
 - Short-term repeated dose toxicity: peroral toxicity, dermal toxicity, and inhalation toxicity
 - Mutagenicity: bacterial back mutation test and mammalian extracellular chromosome aberration test

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Requirement on Materials

-Toxicological data, at minimum

- **Level 1 ($10^4\text{kg} \leq Q < 10^6\text{kg}$), upon the basic level**
 - QSAR result
 - Mutagenicity
 - Reproduction/development toxicity
 - Repeated dose toxicity (90 days)
- **Level 2 ($Q \geq 10^6\text{kg}$), depend on the judgement of expertise**
 - Acute and/or repeated dose toxicity
 - Reproduction/development toxicity (second

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Requirement on Materials

-Ecotoxicological data, at minimum

- Basic level
 - algal growth inhibition test
 - daphnia 24h acute immobilization test
 - fish acute toxicity test
 - activated sludge respiration inhibition test
 - biodegradation test (or abiotic degradation test)
 - adsorption/desorption screening test
- Level 1 & 2: as basic level. Bioconcentration test is requested if non-biodegradable
- More test data might be requested when the Committee cannot make evaluation

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China Test Organisms

- Definition: bred and cultivated in China, accord with technique criteria, used for designated test, including China domestic species and these commonly used internationally
- Species
 - *Gobiocypris rarus*
 - *Xiphophorus helleri*
 - Zebra fish
 - Active sludge

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Test Methods

- Toxicological & Ecotoxicological tests
 - Testing in China
 - Guidelines for Testing of Chemicals (HJ/T153-2004), and
 - Guidelines for the Testing of Chemicals (China Environ. Science Press, 2004)
 - Testing outside China
 - Guidelines for Testing of Chemicals (HJ/T153-2004)
 - OECD, ISO and other internationally universal test methods
- Physi-chemical property
 - Guidelines for Testing of Chemicals (HJ/T153-2004)
 - National or Industry Standards
 - OECD, ISO and other internationally universal test methods

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Test Institution Qualification

- China and other countries:
 - National Laboratory Accreditation; or
 - Recognition by MOH; or
 - GLP recognition by the State Food and Drug Administration
 - Measurement attestation at State level (limited to physical and chemical property tests)
- Other countries;
 - Certification or accreditation by its national authorities concerned with new chemical substance management; or
 - Authenticated or accredited by the authorities concerned with quality inspection, customs, public health, or agriculture of one's own country, when the national authorities concerned with new chemical substance management of one's home country to provide test data for new chemical substance notifications has not yet make authentication or accreditation
- If the test agency is not recognized by the national authorities concerned with environmental protection of one's own country, the CRC will not recognize it as test data provided for new chemical substance notifications either.

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Evaluation Method

- Guidance for the Hazard Assessment of New Chemical Substances (HJ/T 154-2004)
- Four health hazard levels according to complex toxicity evaluation and human exposure evaluation: extremely high(++++) , high(+++) , media(++), low(+).
- Five environment hazard levels according to complex toxicity evaluation and exposure to environment: extremely high(++++) , high(+++) , media(++), low(+), non(-).

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Evaluation Result

- Hazard classification
- Health and zoology evaluation
 - For extremely high hazard substances, recommend not to approve, and prohibit production, selling, usage
 - For high hazard substances, recommend to approve, with limitation on production, selling, usage and clear recommendations
 - For media hazard, recommend to approve, with clear requirements on proper protections for production, selling, usage
 - For low/non hazard substances, recommend to approve, without (special) requirements

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Environmental Management on the Import and Export of Toxic Chemicals

-- Regulations for Environmental Management on the First Import of Chemicals and the Import and Export of Toxic Chemicals

- The Regulations was issued by the former National Environmental Protection Agency, the former Ministry of Foreign Trade and Economic Cooperation and the General Administration of Customs and took effect from May 1 of 1994.
- Background
 - Implementing the voluntary prior informed consent procedure (PIC) contained in the London Guidelines for the Exchange of Information on Chemicals in International Trade
 - Practicing the Regulations on Safe Management of Hazardous Chemicals

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Environmental Management on the Import and Export of Toxic Chemicals

-- Regulations for Environmental Management on the First Import of Chemicals and the Import and Export of Toxic Chemicals

- List of Toxic Chemicals Banned or Severely Restricted in the People's Republic of China (the First Group) (including 27 types)
- In a bid to intensify the management over the import of mercury, SEPA and the General Administration of Customs jointly issued the Announcement on Mercuric Sulphide Being Listed in the List of Toxic Chemicals Banned or Severely Restricted in China (SEPA Document No. 166[2003]), and the Announcement was put into effect from October 15 of 2003.
- Regarding the implementation of the PIC Convention, SEPA and the General Administration of Customs jointly released the No. 29 Announcement in 2005 for the supplement of the List of Toxic Chemicals Banned or Severely Restricted in the People's Republic of China (the Second Group) (including 7 types), and the Announcement was put into effect from July 10 of 2005.

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Environmental Management on the Import and Export of Toxic Chemicals

-- Regulations for Environmental Management on the First Import of Chemicals and the Import and Export of Toxic Chemicals

- At the end of 2005, SEPA, together with the General Administration of Customs made some adjustment to the list of imported and exported chemicals under restriction by enacting the new edition of the Catalogue for Severe Restriction of Imported and Exported Toxic Chemicals of China, which was effective on January 1 of 2006.
- At the end of 2005, SEPA, the Ministry of Commerce and the General Administration of Customs jointly adjusted the list of banned chemicals for import and export by releasing the Catalogue of Commodities Forbidden to Import (the Sixth Batch) and the Catalogue of Commodities Forbidden to Export (the Third Batch), both taking effect from January 1 of 2006.
- SEPA and the General Administration of Customs jointly issued the No. 80 Announcement in 2006 for the revision of the Catalogue for Severe Restriction of Imported and Exported Toxic Chemicals of China, which took effect from January 1 of 2007. This revision is mainly for revising the custom code of the chemicals included in the said Catalogue based on the Harmonized Commodity Description and Coding System (HS) (2007 Edition) of the World Customs Organization (WCO) and further includes three new compounds in the Rotterdam Convention into the Catalogue.

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Environmental Management on the Import and Export of Toxic Chemicals

-- Regulations for Environmental Management on the First Import of Chemicals and the Import and Export of Toxic Chemicals

- The competent department for dealing with the examination and approval of the import and export of toxic chemicals under SEPA has formally networked with the electronic port system of related custom department from October 1 of 2005.
- A new edition of the Delivery Note for the Environmental Management on the Imported or Exported Toxic Chemicals and registration application form were publicized to support the electronic networking.

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Registration Application

- Applicant: Foreign companies
- Documents: Application Form, Contract
- Registration fee: US\$10,000/certification
- Payment: Guidance
- Evaluation period: 30 days
- Valid period of certification: 2 years
- Amount per certification: no limit but reasonable

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Declaration Notification Application

- Domestic Importer
- Documents: Application form, Copy of registration certificate, Qualification document, Contract, Downstream buyer
- Registration fee: None
- Evaluation period: 10 days
- Valid period: 6 months

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Special Catalogue

- Chemicals listed in PIC convention
- Chemicals listed in POPs convention
- Export of Arsenic compounds
- Export of Sodium Cyanide
- Mercury
 - Import: Quota control, designated users and usages
 - Export: Comments from provincial EPB

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Relevant Materials

- Detailed Rules on Implementing the Regulations
- Directions for the Registrations
- Document requirements
- Application flow chart
- Application form
- Form sample, Instruction to fill in

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Other information

- All materials are available from CRC-SEPA's website
- Application process is available from the website
- CRC-SEPA website: <http://www.crc-sepa.org.cn>
- Phone: (+86-10) 84915286
- Fax: (+86-10) 84913897
- E-mail: weihua@crc-sepa.org.cn
- Mail address: Chemical Registration Center of SEPA
Beiyuan, Anwai, Beijing 100012, PRC
- Visiting: Room 801, Building 1, CRAES
8# Dayangfang, Anwai, Chaoyang District,
Beijing
- Application on Internet will be accessible soon
 - Both paper documents and electronic data are required in test-run
 - Only electronic data when formally running

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Contact

Post address: Division of New Chemical Substance Management
Chemical Registration Center of SEPA
No. 8, Dayangfang, Beiyuan, Andingmenwai
Chaoyang District, Beijing, P. R. China

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E-Mail

Notification of New Chemical Substance: ncn@crc-sepa.org.cn

Service of New Chemical Substance Affirmance: ncncheck@crc-sepa.org.cn

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Management of Discarded Dangerous Chemicals

- Measures for the Prevention and Control of Environment Pollution Caused by Discarded Dangerous Chemicals (2005)
- Measures for the Administration of Registration of Hazardous Waste (2004)
- Measures for the Administration of Duplicate Form for the Transfer of Hazardous Waste (1999)
- The National Catalogue of Hazardous Wastes (1998)

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Management of Discarded Dangerous Chemicals

- Operation of discarded dangerous chemicals
 - The environmental protection bureaus above the provincial level taking charge of issuing the operational license of discarded dangerous chemicals
 - Encouraging the units producing dangerous chemicals to recycle and dispose the discarded chemicals of the same kind as their products
- Disposal requirements to enterprises being closed down, suspended of operation, merging with other enterprises or switching to other products
 - Properly handling the discarded, warehoused dangerous chemicals and equipment
 - Checking the soil and groundwater of the premise and compiling the environmental risk assessment report
 - Compiling and performing the environmental restoration plan if any pollution of the premise has been made and entrusting professional checkup organs to do the checkup after the environmental restoration
- Collecting or paying the fees for the disposal of discarded dangerous chemicals and bearing the responsibility for the disposal
 - Submitting the discarded dangerous chemicals taken over to professional organs for disposal
 - The department responsible for taking over the chemicals shall take charge of collecting the disposal fees. In case there is no clearly identified person for the chemical or the chemical is submitted by the public, the receiving department of the chemical should apply for the disposal fee to the financial department at the same level.