DIÁLOGOS SETORIAIS UNIÃO EUROPEIA BRASIL

PROJETO APOIO AOS DIÁLOGOS SETORIAIS UNIÃO EUROPEIA - BRASIL

RELATÓRIO
CHEMICALS MANAGEMENT IN CHINA

APRIL 2013

www.dialogossetoriais.org

CONTATOS

Direção Nacional do Projeto

+ 55 61 2020.4906/4928/5082/4134

contato@dialogossetoriais.org

www.dialogossetoriais.org

This Final Report has been prepared by Milieu Ltd for the Ministry of Environment, Brazil, under Contract No.MD7401B/1 between Milieu Ltd and CESO CI Internacional SA. The primary authors were Dr Catherine Ganzleben and Ms Paola Banfi. Dr Catherine Ganzleben was responsible for overall editing of the report.

This report has been generated within the context of the Sectoral Dialogue on the control and regulation of chemicals between Brazil and EU, funded by the EU under the Sectoral Dialogue Programme. Further details are available at: http://www.dialogossetoriais.org/

Milieu Ltd. (Belgium), rue Blanche 15, B-1050 Brussels, tel: +32 2 506 1000; fax: +32 2 514 3603; Catherine.ganzleben@milieu.be; web address: www.milieu.be

Table of Content

Table of Tables

Table of Figures

Table of Boxes

Acronyms

AQSIQ	General Administration of Quality Supervision, Inspection and Quarantine
CCISS	Chinese Chemical Inventory Search System
CRC	Chemical Registration Centre
GB/	National standards
GB/T	Recommend national standards
GHS	Globally Harmonised System of Classification and Labelling of Chemicals
IECSC	Inventory of Existing Chemical Substances Produced or Imported in China
MEP	Ministry of Environmental Protection
MIIT	Ministry of Industry and Information Technology
NCSN	New Chemical Substance Notification
NRCC	National Registration Centre for Chemicals
REACH	Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals
SEPA	State Environmental Protection Administration
SAWS	State Administration for Work Safety

1. Introduction

This Draft Final Report has been prepared by Milieu Ltd for the Brazilian Ministry of Environment with the aim of describing the Chinese model for chemicals management. As such, the report provides detailed descriptions of Chinese chemicals legislation and focusses on the procedural aspects involved in administering the legislation.

We start by introducing the major legislative developments in the field of chemicals management in China over the past ten years in section 1.1, together with a roadmap to where each legislative act is discussed in the report. In section 1.2 we then introduce the 12th Five-Year Plan for Chemical Environmental Risk and Control, published in 2013. In section 1.3 we present the Inventory of Existing Chemical Substances Produced or Imported in China (IECSC), before introducing the key bodies involved in chemicals management in section 1.3. Finally, in section 1.5 we outline the legal framework in China as background to the discussion of chemicals legislation.

1.1. Chemicals Management in China and Roadmap to the Report

In the period 2010 to 2013, most legislative acts in China regarding chemical products have been revised by the Chinese government with the aim of overhauling the approach to chemicals management in China.

The most significant change came when, on 19 January 2010, the Ministry of Environmental Protection (MEP) of China released the revised version (Order No. 7) of the Provisions on Environmental Administration of New Chemical Substances, the regulation implementing the Chinese New Chemical Substance Notification system (China NCSN). The revision process has addressed the procedures for chemical risk assessment, the substance classification system, and the process by which chemical producers notify the placement of chemical substances on the market to authorities. Chemicals are considered "new" if they are NOT listed in the Inventory of Existing Chemical Substances Produced or Imported in China (IECSC) (see section 1.2). Companies wishing to place new chemical substances are now subject to a notification procedure, with information requirement tiered on the basis of tonnage. The notification requires the generation of (eco)toxicity data by industry, the completion of a risk assessment report, and the submission of this data to the regulatory authority, the Chemical Registration Centre (CRC) of the Ministry of Environmental Protection

(MEP). Reduced information requirements are available for substances on the market at <1 tonne, for substances intended for research and for polymers. CRC then issue Notification Certificates to authorise production or import. Order No. 7 also establishes post-notification obligations, including the requirement to report on production volumes and downstream users and to implement risk management measures. There are also requirements for passing information downstream. The requirements set under Order No. 7 and the procedures for its implementation are discussed under section 2 of this report.

Prior to the adoption of the NCSN, in 2009 Order No. 113 on the Registration of the Import and Export of Toxic Chemicals in China was issued. This Order sets requirements for importers and exporters of chemicals included in the List of Toxic Chemicals to register with the CRC and apply for an Import Registration Certificate in the case of foreign companies wishing to export to China, an Import Clearance Notification in the case of domestic importers or an Export Clearance Notification in the case of Chinese exporters. Order No. 113 and its administration by MEP are considered under section 3.

In 2011, Order 591 on the revised version of Regulations on Safe Management of Hazardous Chemicals was published, together with a range of implementing measures. The regulation is administered by the State Administration for Work Safety (SAWS) and addresses the production, storage, import, use, sales and transporting of chemicals listed in the Catalogue of Hazardous Chemicals. A list of Priority Hazardous Chemicals was also established, with the objective of setting stricter risk management requirements for these substances. The producers and importers of hazardous chemicals are required to register with the National Registration Centre for Chemicals (NRCC) of SAWS, and to prepare Safety Data Sheets and labels. NRCC is also responsible for ensuring that risk management measures are implemented by the holders of an Environment Administration Registration.

In addition, the producers and users of hazardous chemicals (and Priority Hazardous Chemicals) are required to submit an Environment Administration Registration to MEP, to allow local environmental protection agencies to track the production and use of hazardous chemicals. For Priority Hazardous Chemicals, an environmental impact assessment is required. SAWS also issues licenses for entities producing, distributing and using hazardous chemicals. Under their application for Safe Use Licenses, the users of hazardous chemicals are required to provide evidence of a range of risk management measures, including emergency procedures, occupational health and safety measures and the presence of relevant trained personnel. The various requirements and measures under Order 591 are discussed under section 4.

Certain toxic substances are subject to stricter control in China, with import and export strictly prohibited under Announcement No. 116 on the Catalogue of Commodities Prohibited from Import (The 6th Batch) and the Catalogue of Commodities Prohibited from Export (The 3rd Batch). This act serves to implement the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals Pesticides in International Trade and the Stockholm Convention on Persistent Organic Pollutants. It is discussed under section 5.

Finally, China has acted to implement the Globally Harmonized System of Classification and Labeling of Chemicals (GHS). Currently, Order No. 591 on the revised version of Regulations on Safe Management of Hazardous Chemicals is the basis for official GHS implementation, supported by a number of National Standards for labelling and packaging. The body responsible for the implementation of GHS is the Ministry of Industry and Information Technology (MIIT). The implementation of GHS in China is considered in section 6.

1.2. 12th Five-Year Plan for Chemical Environmental Risk Prevention and Control

Early in 2013, MEP published the 12th Five-Year Plan for Chemical Environmental Risk Prevention and Control (hereinafter refer to the Plan). The Plan outlines fundamental principles and approaches for the management of chemical risks in China. These include strengthening the chemical notification system (especially hazardous chemicals), establishing a list of restricted substances for phase-out, based on environmental risk assessment of chemicals, and promoting the use of more eco-friendly technologies to reduce or replace the use of hazardous chemicals or related technologies.

In addition, the plan identifies 58 chemical substances and seven industrial sectors for priority management. Those chemical substances are selected from groups of substances which are persistent, bioaccumulative and toxic (PBTs), very persistent and very bioaccumulative (vPvB), carcinogenic, mutagenic or reproductive-toxic (CMRs) or are endocrine disruptors. The list is divided into three categories of chemicals: 25 chemicals with accumulative risks; 15 chemicals associated with frequent environment accidents; and 30 chemicals defined as characteristic pollutants. An explanation of how chemicals were identified under the three categories and the proposed risk management measures are provided in box 1 below.

Box 1: Three categories of chemical prioritised for control under China's Five-Year Plan on Chemicals

1. **Chemicals with accumulative risks:** The selection of these 25 chemicals was based on the List of Priority Hazardous Chemicals for Environmental Management, with special consideration of the volume, usage, environmental hazards, bio-accumulative properties, etc. of each chemical. The risks are to be controlled by implementing prevention of pollution source, reduction in exposure, reporting of release and transfer, strengthening of registration system, etc.
2. **Chemicals associated with frequent environment accidents**: The selection of these 15 chemicals or chemical groups was based on the frequencies and impacts of environmental accidents in recent years. The high frequency of environmental accidents must be well controlled through strict management, strengthening the emergency response systems and reinforcing the efficiency of emergency response, etc.
3. **Characteristic pollutants:** According to the industrial release standards and environmental hazards, 30 chemicals or chemical groups, 12 of which are also included in category 2, are defined as characteristic pollutants. Releases to the environment shall be controlled and gradually reduced by reinforcing the environmental assessment, accomplishing the industrial standards, and intensifying monitoring and supervision, etc.

1.3. Inventory of Existing Chemical Substances Produced or Imported in China (IECSC)

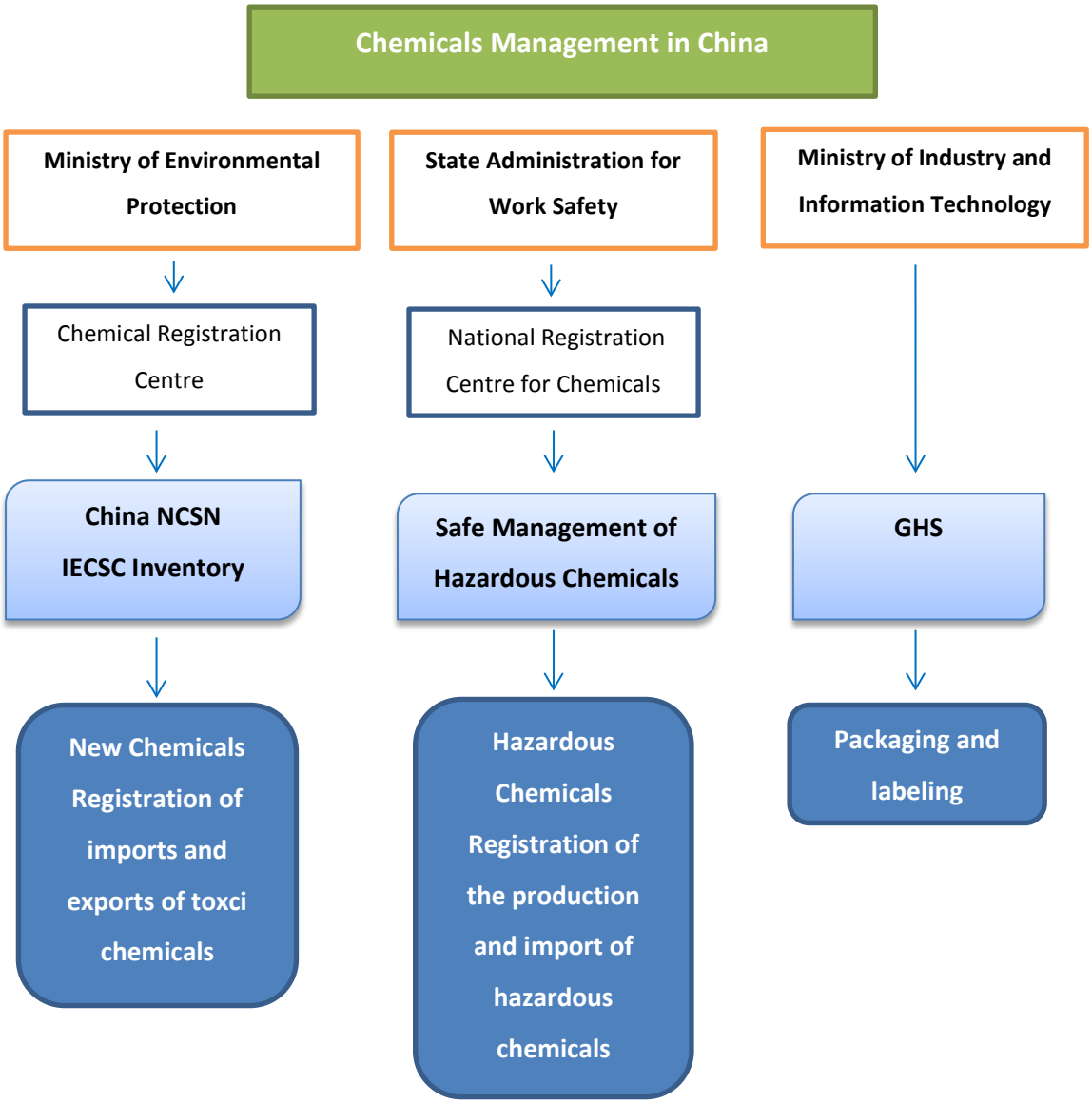
The Inventory of Existing Chemical Substances Produced or Imported in China (IECSC) was first compiled in 1995 and has been updated several times since then, most recently in 2010. IECSC lists substances already manufactured, used, sold/exported or importer in China, including elements, compounds (including one of the additives and impurities), byproducts, reaction intermediates and polymers, but excluding mixtures and articles. IECSC does NOT include substances managed by other departments, including: pesticides, tobacco and tobacco products, radioactive substances, military products, Food, food additives, pharmaceuticals and cosmetics.

INECSC includes 45,602 chemical substances. Of these, 37,427 are listed with a CAS Number, while for 8,175 substances, the CAS number is unknown. For substances without a CAS number, a unique serial number was given under IECSC. In addition, there are 3,166 confidential substances for which the Chinese and English substance names are not published.

1.4. Chemicals Management Infrastructures

The main bodies responsible for chemicals management is the Ministry of Environmental Protection (MEP) and the State Administration for Work Safety (SAWS). The Ministry of Industry and Information Technology (MIIT) has overall responsibility for the implementation of GHS, although a total of ten bodies are involved. In addition, the General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ) is responsible for the inspection of imports and exports of hazardous chemicals and their packages. The allocation of responsibility for chemicals management between MEP, SAWS and MIIT is presented in figure 2 below.

Figure 1: Key bodies responsible for chemicals management in China



In addition, various related ministries and commissions exercise powers over the production, use, distribution, transport, import and export of chemicals in accordance with State laws and regulations. Table 1 provides a summary of the relevant agencies and ministries and their respective competences. In the sections below we provide further details on the roles of MEP and SAWS in chemicals management in China.

Table 1: Ministries and agencies involved in chemicals management in China

State Department	Responsibility
Ministry of Environmental Protection (MEP)	Environmental management of chemicals and hazardous wastes Administration of: • Order No. 7 on new chemicals notification (NCSN) • Order No. 113 on the Registration of the Import and Export of Toxic Chemicals • Order No. 22 on Environmental Administration Registration
State Administration for Work Safety	Occupational health, emergency response, GHS Administration of: • Order 591 on safe management of hazardous chemicals, including China GHS • Order No. 53 on the registration of the production and import of hazardous chemicals • Licensing the production, marketing and use of hazardous chemicals
Ministry of Industry and Information Technology (MIIT)	Administration of China GHS
General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ)	Inspection of imports and exports of hazardous chemicals and their packages, control of packaging and labeling
Ministry of Health	Occupational health, environmental hygiene, food hygiene and chemicals for daily use
State Bureau of Quality and Technical Supervision	Product quality and hazardous chemicals
State Administration of Petroleum and Chemical Industry	Petrochemical and chemical production
State Drug Administration	Medicines
Ministry of Agriculture	Pesticides, veterinary medicines and fertilizers
Ministry of Communications	Road and water transport
Ministry of Railways	Railway transport)
General Administration of Civil Aviation of China	Air transport
Ministry of Public Security	Fire control, explosion and highly toxic goods management
State Economic and Trade Commission	Industrial and occupational safety
Ministry of Foreign Trade and Economic Cooperation	Import and export
State Administration of Internal Trade	Domestic distribution of chemicals
General Administration of Customs	Entry and exit of imported and exported chemicals

1.4.1. Ministry of Environmental Protection

In March 2008, the Chinese National People's Congress reformed the State Environmental Protection Administration (SEPA) and renamed it as the Ministry of Environmental Protection (MEP). The reform strengthened administrative stability, political will and decision-making power for environmental protection and increased access to resources.

MEP is responsible for the administration of China's NCSN system under Order No. 7, including receiving and assessing notification dossiers and communicating outcomes to notifiers. MEP is also responsible for enforcing the post-notification obligations of Notification Certificate holders.

In accordance with Order No. 13 on the the Regulations on the Environmental Management of First Import of Chemicals and the Import and Export of Toxic Chemicals, MEP is responsible for the examination and approval of chemicals import and export, environmental supervision and management in chemical production and use, and emergency responding to and handling of chemical contamination accidents. MEP also leads inter-departmental coordination in carrying out environmental protection.

MEP also manages the Environmental Administration Registrations for the producers and users of hazardous chemicals under Order No. 22.

With regards to international activities, MEP coordinates with other relevant departments and represents China at international chemicals-related multi-lateral environmental agreements (MEAs), and is responsible for their implementation within China.

Chemical Registration Centre (CRC)

The Chemical Registration Centre of MEP (CRC) is a technical institute that is attached to Chinese Research Academy of Environmental Science. CRC receives notifications for producers and importers for new chemical substances under NCSN. CRC forwards dossiers to the Expert Committee for assessment and manages communication with the notifier.

In addition, CRC supports MEP in implementation of the Provisions on the Environmental Administration of New Chemical Substances and the Regulations for Environmental Management on the First Import of Chemicals and the Import and Export of Toxic Chemicals. Specifically CRC works to improve methods and techniques for sound chemicals management in China. A range of information and notices are available on the CRC website, with some material provided in English.

1.4.2. State Administration for Work Safety

The State Administration for Work Safety (SAWS) is the non-ministerial agency of the Government of the People's Republic of China responsible for the regulation of risks to occupational safety and health in China. With regards to chemicals, SAWS is responsible for Order No. 591 the Regulation on the Safe Management of Hazardous Chemicals. This includes registration of the production and import of hazardous chemicals and the licencing of the production, marketing and use of hazardous chemicals, and Priority Hazardous Chemicals. SAWS is supported in its work on chemicals by the National Registration Centre for Chemicals.

National Registration Centre for Chemicals

The National Registration Centre for Chemicals (NRCC) was established in 1997 as a public institution directly affiliated to the State Administration of Work Safety. NRCC is an agency providing technical support for the safe administration of dangerous chemicals in China.

Under Order 53 on Measures for the Administration of Registration of Hazardous Chemicals, the producers and importers of hazardous chemicals are required to register with NRCC prior to manufacturing or importation. In addition, NRCC is responsible for ensuring that the producers and users implement risk management measures.

In addition, NRCC performs tasks on a wide range of issues, summarised in box 1 below. With regards to chemical risk assessment, NRCC is involved in hazard identification, chemical classification and the registration of hazardous chemicals. The NRCC operates a chemical hazard identification laboratory equipped with advanced instruments and devices. NRCC provides emergency response to chemical accidents and works on occupational health and safety, including the standardization of safety procedures for enterprises using hazardous chemicals, the prevention and control of occupational hazards, risk assessment, training and consultancy. Furthermore, NRCC manages the national chemical emergency response hotline. In addition, NRCC is involved in the drafting and revision of regulations and standards on the safe management of chemicals.

Box 1: Summary of NRCC Responsibilities

- Registration & Administration of Hazardous Chemicals
- Chemical Accident Emergency Response
- Prevention and investigation of chemical accidents
- Identification and classification of chemicals hazards
- Work Safety Standardization of Hazardous Chemical Enterprises
- Prevention and control on occupational hazards
- Safety valuation and control of hazardous chemical processes
- International exchanges and cooperation
- Research results and technical services/products

1.5. The Chinese Legal Framework

In order to facilitate understanding, it is useful to provide a brief introduction into the Chinese legal framework. The Constitution of the People's Republic of China establishes the framework and principles of government and lists the fundamental rights and duties of Chinese citizens. Legislation in China can then be developed under four administrative levels, namely:

1) national laws issued by the National People's Congress;

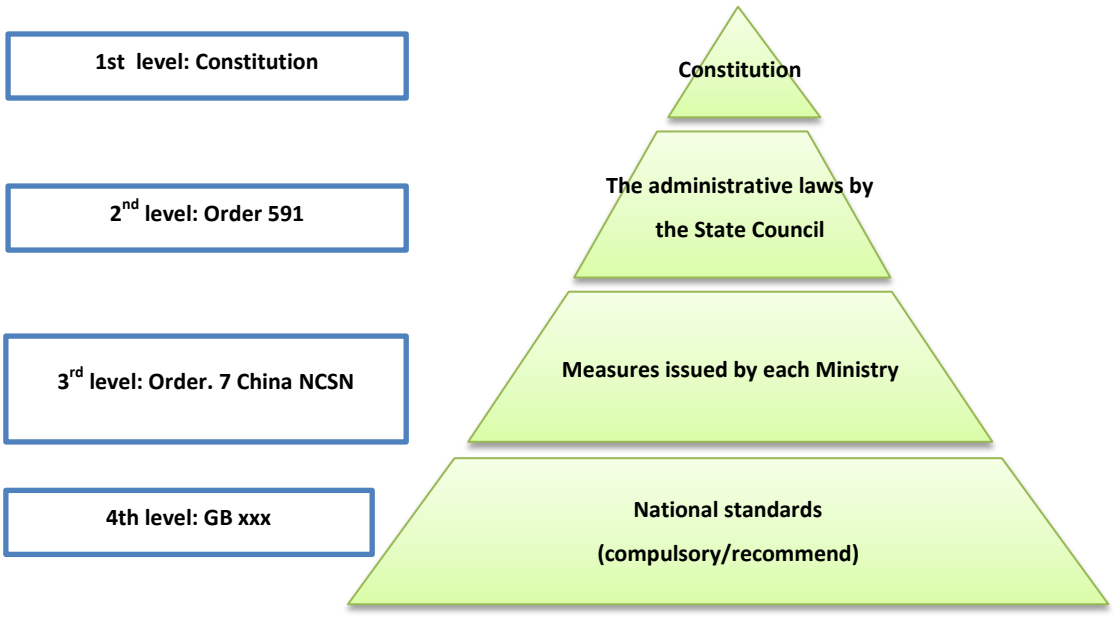
2) administrative regulations issued by the State Council and its departments;

3) regulations issued at the ministerial level; and

4) national standards, including compulsory national standard (GB) and recommend national standards (GB/T).

The National Standing Committee of the People's Republic of China formulates and promulgates national laws, including laws relating to chemicals. The State Council develops and issues national regulations and rules, including those relating to chemicals. The relevant ministries and commissions formulate and issue regulations and standards for chemicals under national or sectoral management. In addition, administrative agencies or the local People's Government issue local laws and regulation in the provinces, municipalities and autonomous regions (i.e. Hong Kong) formulate local legislation and standards. Together, these legislative acts form a general legal framework for chemicals management in China organized at the four administrative levels shown in figure 1 below.

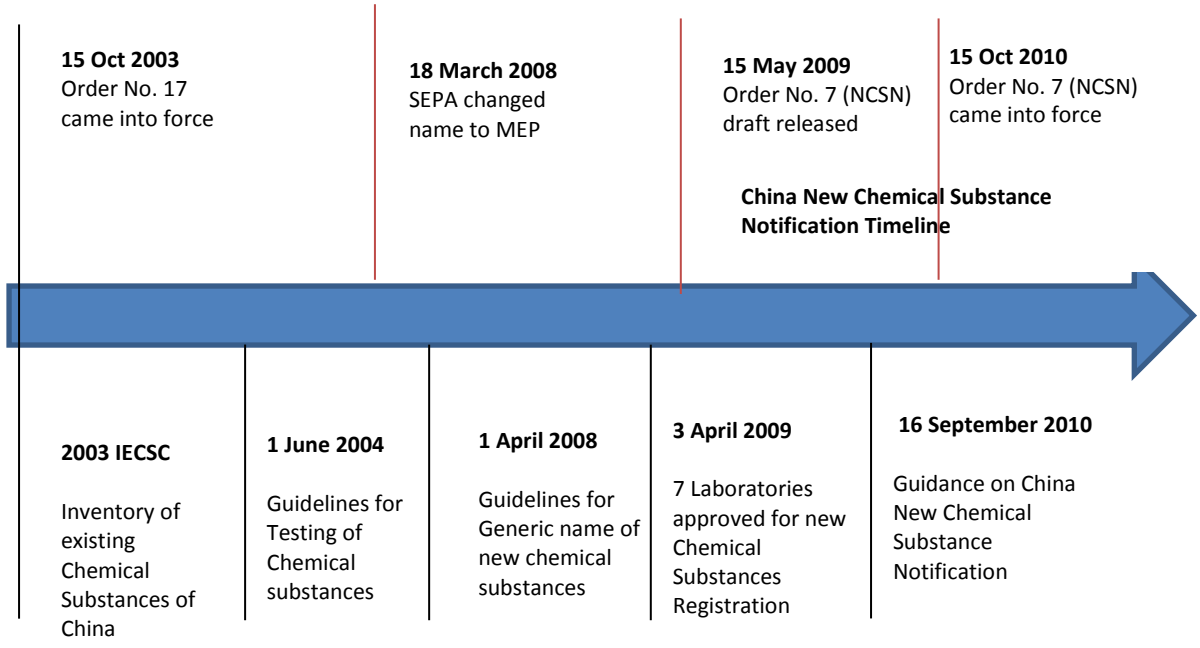
Figure 2: Legal framework for chemicals management in China



2. Order No 7 - CHINA NCSN

On 19 January 2010, MEP published the final version of "Regulation on the Environmental Management of New Chemical Substances" and announced the measures would be implemented from 15 October 2010. The revised procedures implement the New Chemical Substance Notification system (China NCSN), a more comprehensive management system for chemical substances through substances registration, evaluation and assessment and by tracking control. The revision was aimed at giving priority to environmental protection, scientific and technological innovation, and basic regulation of the market economy. The timeline from the 2003 measures up until the adoption of the new procedures in 2010 is shown in figure 3 below.

Figure 3: Timeline up to the adoption of Procedures for the Environmental Administration of New Chemical Substances, China NCSN



In terms of the historic development of the new Procedures, revision of the regulation on environmental management of new chemical substances was put the political agenda in 2009. In May 2009, the MEP launched a consultation on the proposed Regulations on the Environmental Management of New Chemical Substances with the ministries and committees under the State Council, academic groups, and some trade organisations. MEP and CRC received and summarised opinions and revised the "Opinion-soliciting Draft" accordingly. During a ministry affairs meeting in December 2009, the Regulations on Environmental Management of New Chemical Substances was deliberated and passed, in principle. The meeting decided that the draft shall be further revised and

issued for implementation. In January 2010, MEP officially issued the revised Regulation on Environmental Management of New Chemical Substances in form of Order No. 7, including 52 clauses in six chapters. It specifies that the Regulation shall be implemented as of October 15, 2010. The six chapters of Order No. 7, Regulation on the Environmental Management of New Chemical Substances, are:

- Chapter I General Principles (8 clauses)
- Chapter II notification Procedure (11 clauses)
- Chapter III notification Management (9 clauses)
- Chapter IV Tracking and Control (14 clauses)
- Chapter V Legal Responsibilities (7 clauses)
- Chapter VI Supplementary Provisions (3 clauses)

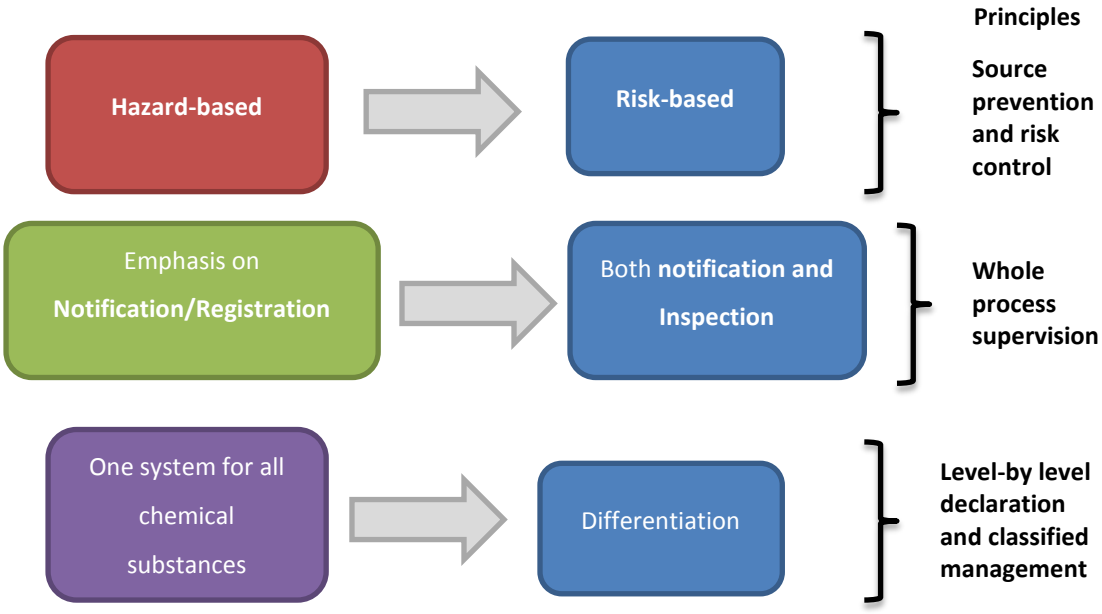
Order No. 7 expanded on the pre-existing regime for the registration of new chemical substances by increasing the volume and scope of chemicals concerned. The Order introduced the system of New Chemical Substance Notification (NCSN), which requires companies to submit a new chemical substance notification to CRC-MEP for new chemicals, irrespective of annual tonnage. “New chemical” means any chemical substance other than the approximately 45,000 substances that are currently listed on IECSC. In addition, NCSN involves a screening and notification mechanism for new chemical substances to allow for the rapidly identification of the potential risks of new chemical substances. China NCSN entered into force on October 15, 2010 with no transitional period. This means that new chemicals are not permitted on the Chinese market unless there has been a notification and a successful registration in China.

In summary, the new order classifies chemicals into three categories, namely general chemicals, hazardous chemicals, and chemicals of environmental concern. The general requirement for the notification of new chemicals imported or produced in China includes information requirements that for the vary by tonnage bands (1-10 tonne, 10-100 tonnes, 100-1000 tonnes, +1000 tonnes) on the principle of the higher the volume, the higher the data requirements. Notification includes a risk assessment report, including information on hazard and exposure evaluation, as well as risk control conditions. If the imported or produced volume is less than 1 tonne per year in China, a simplified notification is provided for, while a separate research and development notification is required when producing or importing a new chemical substance less than 0.1 tonne per year. In the case of a producer or an importer who has registered hazardous chemicals or chemicals of environmental concern, they would have to prepare and submit an annual production or import report and an annual production or import plan to the Chemical Registration Centre (CRC). Thus the information requirements for notification depend on a combination of exposure (tonnage) and hazard. The notification of new chemicals can be processed by a Chinese entity only, and eco-toxicological data

will only be accepted from a small list of pre-approved labs in China. Furthermore, "joint notification" is only available for Chinese entities. CRC is responsible for evaluating the notification dossier and deciding whether to grant market access. In addition, CRC will determine the management type for the new chemical substance and implement specific risk management measures for new chemical substances under different the three categories.

The implementation of the 2010 Regulation has involved a conceptual shift in Chinese chemicals management. Firstly, the approach has shifted from a hazard based to a risk based approach that considers both hazard and exposure. Secondly, the requirement for notification is now to be coupled with inspections. Finally, the new system differentiates between chemical substances on the basis of hazard. This conceptual shift is presented in figure 5 below.

Figure 4: Conceptual shift in Chinese chemicals management



Order No. 7 has been called "China REACH", since it draws on many elements of the EU's Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), particularly those concerning risk assessment, risk management and data submission. Order 7 introduced a series of new concepts mirroring those in the EU's REACH. These include the use of:

- GHS-based criteria hazard communication;
- notification tonnage bands, (1tonne limitation for regular notification);
- post-notification tracking and acceptance of notifications only by legal-entities entities within the jurisdiction of the regulation;

- data sharing (not mandatory but recommendable); and
- chemical risk assessment similar to the chemicals safety assessment under EU REACH.

To explore how China could build on aspects of REACH to develop its laws on chemical risk management, the European Commission ran two sets of training courses in June and October 2008. Some 40 participants from the Chinese Ministry of Environmental Protection and affiliated institutes, as well as representatives from the State Administration of Work Safety, the Ministry of Health and Provincial Environmental Protection Bureaus, took part. The programme, supported by the EU-China Policy Dialogues Support Facility, explained EU standards, procedures and legislation and highlighted aspects of REACH that might be integrated into any reform of China's regulatory framework.

2.1. Notification Procedure

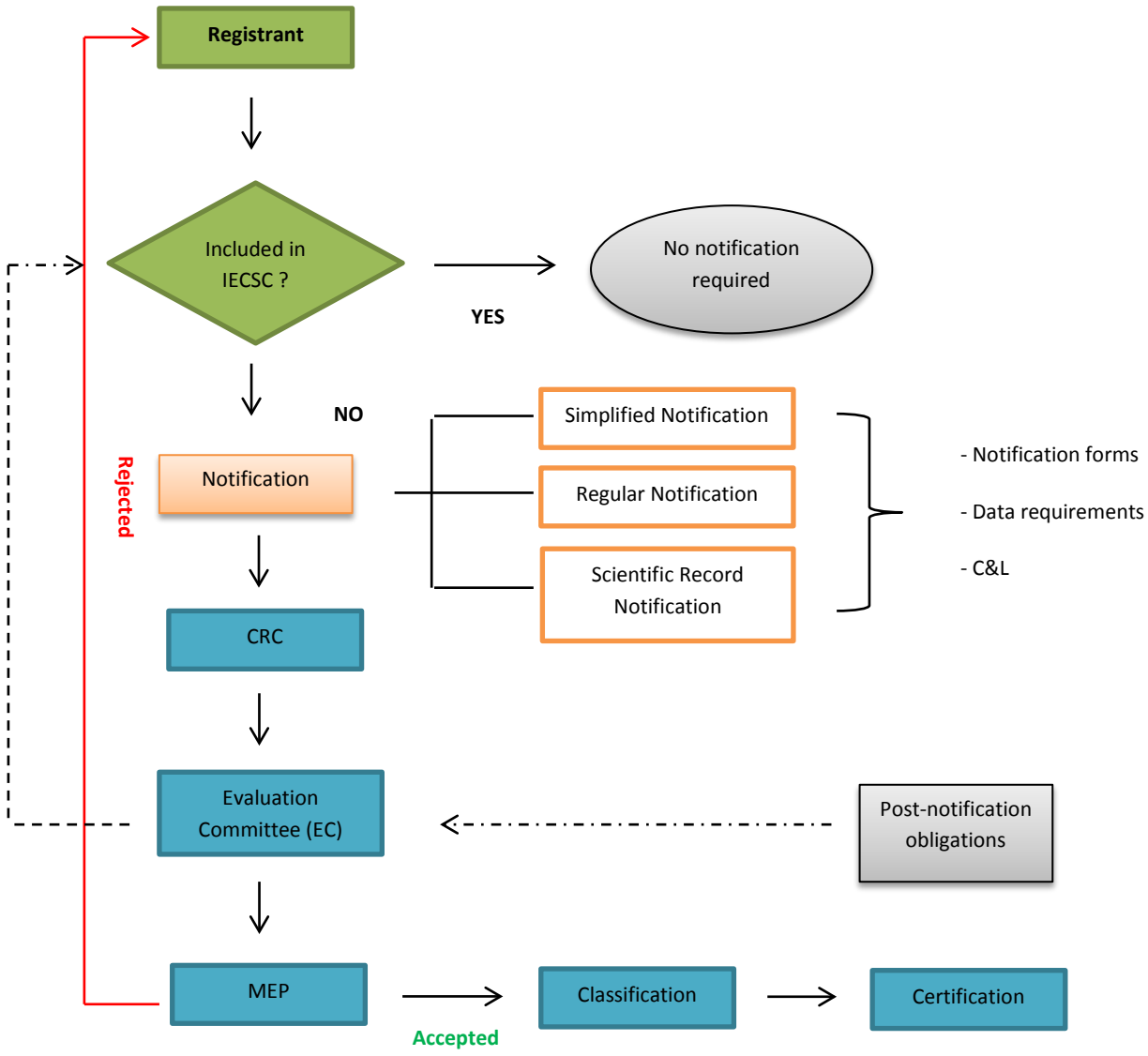
Following China NCSN, new chemicals not listed in IECSC shall be notified to CRC, irrespective of the tonnage volume produced ort placed on the market. Companies producing or placing a new substance on the market in China shall submit a new chemical substance notification to CRC-MEP, *irrespective of annual tonnage*. Any substance not currently listed on IECSC is to be considered a new substance. The requirement to notify applies not only to a new substance on its own, in preparation or articles intended to be released, but also to new substances used as ingredients or intermediates for pharmaceuticals, pesticides, veterinary drugs, cosmetics, food additives and feed additives.

More than 2,000 notification certificates have been issued by the Ministry of Environmental Protection in China since China NCSN entered into force.

Key steps in the notification procedure are presented in figure 4 below, with these steps described in greater detail in section 2.3 to 2.3.8 below.

The Chinese Chemical Inspection and Regulation Service (CRS), a consultancy service assisting chemical companies in making their notifications in China, provide on their website a non-official Guidance Document for New Chemical Substance Notification in China (China NCSN). In addition, data on notifications in provided on the website of CRS,

Figure 5: Key steps in the notification process



2.1.1. Checking Whether a Chemical is Listed in IECSC

To facilitate implementation of the Provisions of the Environmental Administration of New Chemical Substances, MEP has updated IECSC to allow for the identification of new chemical substances and to clarify the status of existing chemical substances in China. MEP will continue to include new substances which have been notified in accordance with the Provisions under IECSC. Under previous legislation, IECSC was updated annually via a process known as "IECSC supplementation". However, "IECSC supplementation" has now been abolished, meaning that only new substance approved via regular notification can be listed in the IECSC.

A company looking to produce and/or place a substance on the market in China should start by determining whether their substance is a new substance under Chinese law by checking whether the substance is listed in the IECSC. IECSC is updated by the CRC to include newly notified substances. Following the update of the IECSC in January 2013, there were 42,342 substances in IECSC. The full list can be downloaded in pdf format.

In addition, companies can search IECSC using the Chinese Chemical Inventory Search System (CCISS). CCISS provides for searches of IECSC by CAS, EC or by the English name of the chemical substance. CCISS will also provide initial assessment of Companies' obligations under relevant Chinese chemical laws.

There are 3,270 substances in the confidential section of IECSC for which no CAS number or molecular structure is given. Companies have to submit a formal enquiry to CRC in order to check whether a substance is listed in the confidential section of IECSC or not. CRC usually issues a letter of confirmation within 2 weeks and the enquiry costs 600 RMB (~100 USD).

2.1.2. Exemptions

There are four major categories of chemical substance that are exempt from this regulation:

1. **Chemicals subject to other existing laws and regulations**: radioactive substances, military industry products, pyrotechnics, biotic substances, pesticides, veterinary drugs, pharmaceuticals, cosmetics, foods, food additives, feed, feed additives, tobacco and tobacco products (intermediates and raw materials are not exempted);
2. **Substances existing in nature**:
    - Substances that are unprocessed, or that are manufactured or processed only through the following methods: manual, mechanical, gravitational, soluble in water, floatation in water, heat dehydration;
    - Extracted from the atmosphere through various means;
    - Natural polymers, except for ones that are chemically modified (Natural substances extracted or processed by chemical methods cannot be exempted);
3. **Substances on noncommercial purpose or unintentionally produced**: impurities, products of random reactions, 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. Single impurity less than 10% and total content of impurities shall not exceed 20%);

4. **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, non-isolated intermediates.

2.1.3. Notifier requirements

Companies that are allowed to submit new chemical notifications under China REACH include: manufacturers of new substance in China; importers of new substances into China; and foreign companies selling new substances on the Chinese market. The notifier requirements specify that only Chinese registered entities can notify, and that companies in Special Export Zones are now considered Chinese entities. Foreign companies are not allowed to notify chemicals, but rather must ask its Chinese subsidiary to notify the new substances on their behalf. The Chinese subsidiary must fulfill the criteria to be "the agent", presented in box 2 below. If the subsidiary does not qualify, a foreign entity must request that the importing company notify the new substance, or establish a representative.

Box 2: Agent requirements

- An "agent" is a Chinese registered organization which has already passed the annual inspection of the industrial and commercial bureau
- It shall already have permanent office and staff the professional person who is familiar with the notification flow of the new chemical substances
- Its registered capital is over 3000 thousands CNY
- An "agent "is required to have sufficient background in the practical handing of substances and the information related to them
- it should be always under the supervision and inspection of Ministry of Environmental Protection Agency of China and shows no records of punishment or violation the "measures" within the consecutive three years

2.1.4. Types of notification

There are three types of notifications under China REACH: general notification, simplified notification (under basic or specific condition) and scientific research record. As shown in figure 6 below, the data requirements are based on the principle of the greater the tonnage, the greater the data required.

Figure 6: Tonnage principle under Order 7

Tonnage principle: "The greater the tonnage, the greater the data required"(Art.11).

<1 metric tons per annum = simplified Notification

>1 metric tons per annum = Regular Notification

The new chemical substances to which each type of notification applies, together with anticipated timeframes, are presented in table 2 below. Activities requiring General Notification, Simple Notification and Simple Notification with conditions, can only be started after the applicant receives the relevant registration certificate issued by CRC.

Table 2: Types and applicable scope of notification

Type of notification	Applicable scope	Anticipated Timeframe
General notification	New chemical substances to be manufactured or imported ≥1 tonne. Based on tonnage band, there are four notification levels, the higher the tonnage band, more data required: - First level (1-10 tonnes) - Second level (10-100 tonnes) - Third level (100-1,000 tonnes) - Forth level (>1,000 tonnes)	4-18 months
Simple notification with basic condition	New chemical substance placed on the market or produced at <1 tonne per year;	3-4 months
Simple notification with specific conditions	New chemical substance - for export only with tonnage <1 tonne per year; - for scientific research with tonnage of 0.1-1 tonne per year; - for technological research with tonnage less than 10 ton per year - for polymer consisting of monomers already listed in IECSC(if the polymer itself is not listed in IECSC); - for polymers containing less than 2% new chemical substance weight by weight; and - for low concern polymers (if the polymer itself is not listed in IECSC).	2-3 months
Addition to the Scientific research record	New chemical substances used for scientific research with an annual quantity lower than 0.1 tonne or if the eco-tox testing sample is imported to be tested in laboratories in China. (no data is required, results published by MEP regularly)	3-5 working days

General Notification

The requirement for General Notification starts at 1 tonne and includes four tonnage based tiers, for which the data requirements increase with tonnage. Being based on tonnage, the notification requirements are tiered on the basis of potential exposure. The data requirements of the different notification types are considered below.

Simple Notification with Basic Conditions

Substances qualifying for Simple Notification with basic conditions include substances new substance produced or placed on the market at <1 tonne per year.

Simple Notification with Specific Conditions

A simple notification with specific conditions is required for an entity wishing to export a new chemical substance at a tonnage of under 1 ton per year, for new substances intended for scientific and technological research at relatively low tonnages, and for new polymers meeting one of the following three criteria: consisting of monomers already listed in IECSC; a polymers containing less than 2% new chemical substance weight by weight; and a low concern polymer. To qualify for being "low concern", a polymer must fall into one of three categories presented in box 2.

Box 2: Categories of new polymers that qualify for a simple notification with specific conditions

1. A polymer with an average molecular weight (MW) between 1,000~10,000 daltons. At the same time, the weight percentage of oligomer with MW<500 is <10%, and the weight percentage of oligomer with WW<1000 is <25%. Besides, the polymer shall not contain functional groups of high concern (for example, heavy metals) and highly active functional groups.
2. The average molecular weight (MW) of the polymer is >1,000 daltons. At the same time, the weight percentage of oligomer with MW<500 is < 2%, and the weight percentage of oligomer with WW<1000 <5%.
3. A polyester polymer.

Entities wishing to produce or import a new chemical substance in quantities <10 tonnes per year to be used for technological research shall apply for Simple Notification, with specific conditions. If approved, the effective period of the permit will be no more than 2 years and after this the entity cannot apply for this notification type again.

Addition to the Scientific Research Record

New substances intended for scientific research with a tonnage of <0.1 tonne are added to the Scientific Research Record, a public data base maintained online by MEP. Activities with these substances can be started once the notification form is submitted.

2.1.5. Data requirements for New Chemical Notification

Each type of notification requires different sets of data, presented in table 3 below and reviewed under the sub-sections below.

Table 3: Data required per each type of notification

Notification Type	Required Documentation	Testing requirements
Application for the scientific research record	Application form for the Scientific Research Record, including: -Substance name & structure -Research/Testing plans	No testing required
Simple Notification with basic conditions	Simplified notification form, including info on: -Substance name & structure -Basic physicochemical info - supporting documents -available hazard data	Acute toxicity tests, including: -acute toxicity study with Brachydanio rerio -acute toxicity test with earthworms depending on substance properties Data on physico-chemical properties, including: -ready biodegradability; melting point; partition coefficient n-octanol/water; and water solubility. *Tests must be carried out in Chinese labs approved by MEP*
Simple Notification with specific conditions	Simplified notification form, including info on: -Substance name & structure -Basic physicochemical info - supporting documents -available data on physicochemical properties and hazards -for polymers only: composition data about monomer, GPC data, and polymerization mechanism shall be given.	No testing requirements
General Notification	Notification form, including info on: -Substance name & structure -Spectral Data -Physicochemical and toxicology -Risk assessment report	Data requirements increase with tonnage bands: 1-10t, 10-100t, 100-1000t/y, 1000t/y+; Many high-level tests can be waived based on the results of low-level tests *Tests must be carried out in Chinese labs approved by MEP*

Key aspects of data include the data source, data sharing, test agencies and test methods for the notification of new chemical substance, and these are considered after the review of data requirement by notification type.

Scientific Research Record

Scientific research record applies to new chemical substances used for scientific research purpose with an annual quantity lower than 0.1 ton and samples to be introduced to China for testing purpose. Testing data is not required, with entities are only required to submit a Scientific Research Record form.

Simple Notification with Basic Conditions

Simple notification with basic conditions applies to the new chemical substances manufactured in/imported to China at a tonnage < 1 tonne per year. For simplified notification with basic conditions applicants shall submit:

- The simplified notification form; and
- A test report of mandatory eco-toxicological testing in China, with the data requirements presented in table 4 below.

Table 4: Minimum data requirements for organic and inorganic new substances under simply notification with basic conditions

Test Name	Test scheme	Organic substance	Inorganic substance
Ready biodegradability	The test must be conducted as a first step.	Yes	No
Acute toxicity study with Brachydanio rerio	The test must be carried out if the substance is not readily biodegradable.	Yes	Yes
Earthworm, acute toxicity test	The test must be conducted if the LC50 of fish cannot be obtained due to the fact that the solubility of the substances in water is <100mg/L and the substance is not shown to be toxic to aquatic life at its saturated concentration.	Yes	Yes

Simple Notification with Specific Conditions

The difference between Simple Notification with specific conditions and Simple Notification with basic conditions is that there is no mandatory testing requirement for simplified notification under specific conditions. For simplified notification with specific conditions, the applicant shall submit:

- The Simple Notification form;
- Supporting documents;
- For polymers only: composition data about monomer, GPC data, and polymerization mechanism shall be given.

In addition, the applicant shall include any available physicochemical, toxicological or other information in the notification form that could describe the properties of the substance. Additionally, the applicant shall provide evidence to prove that the substances qualify for Simple Notification with specific conditions.

General Notification

The minimum requirements for General Notification include physicochemical, toxicological and eco-toxicological test reports and a risk assessment report (further discussed under section 2.3.7). The data requirements from testing under a General Notification vary according to the tonnage bands 1-10t/y, 10-100t/y, 100-1000t/y and 1000t+/y in which the new chemical is imported or produced. The test data requirements for each tonnage band are provided in CIRS's non-official Guidance Document for China NSCN. Many of the high-level tests can be waived on the basis of the results of low-level tests.

Test Agencies and Test Methods

According to the regulation, test reports must provide minimum data in either Chinese or English. Test reports shall indicate clear methods used and be accompanied by the accreditation materials provided by competent authorities.

Some of the eco-toxicology tests must be carried out in MEP-approved eco-toxicity laboratories in China. Other tests can be carried out in domestic laboratories with certain qualifications and/or overseas testing agencies (GLP laboratories are preferred). The laboratories based outside of China must be certified by the local country and the copy of certificate of the laboratory must be provided. They may complete the test as per Chemical Test Guidelines (HJ/T153－2004) of China or follow OECD methods or ISO standards.

Data sources

Data generated from the following sources is accepted for the notification of new chemical substances:

- test reports;
- published authoritative literature;
- authoritative database; and
- other non-testing methods such as QSAR, read-across; and
- expert opinion.

Reports of studies involving tests are given greater importance than other data sources. Data generated by non-testing methods is usually not accepted at initial stage of review, unless the testing could not be conducted scientifically.

For different data sources, requirements for supporting documents are different. For data generated by testing, the certificate of the test agency must be provided. For data generated from published literature, the original text of the literature must be provided (a summary or a quotation is not enough). For data generated from authoritative database, the name of the database, the issuing agency, and the version number shall be given. For data generated by QSAR, the QSAR model, parameters, the recommending agency or research agency, the version, a robust illustration of results and other useful information shall be provided. For expert opinions, general information about the expert, such as the title/duty, company/organization, field of research, and main research achievements shall be provided.

Data sharing

Data sharing is not mandatory but is nevertheless encouraged under the regulation. If several companies notify the same substance, there are two procedures by which they can share data under a general notification, either joint notification or repeated notification. In both cases, the notification tonnage band shall be the sum of the annual tonnage of all applicants.

A joint notification refers to the case in which a notification dossier is jointly submitted by two or more applicants. When a joint notification is approved, an independent Registration Certificate will be issued for each applicant.

Repeated notification allows a late applicant to refer to the dossier and data prepared by the previous applicant. Written authorization is required from the previous applicant.

If a company wishes to register several new substances with similar physicochemical structures and toxicological properties, the company can submit one **serial notification** for the group of chemicals**.** Likewise, several companies notifying similar new chemicals can work together to submit a **joint serial notification** dossier.

2.1.6. Filling Data Gaps by Testing

After collecting all the available substance information and analyzing the data gaps based on the tonnage band, the registrant shall carry out testing in qualified testing institutions in order to fill the data gaps. Where data requirements include the need to have test results from laboratories based in China, the entity will have to start by applying for a scientific research record before producing or importing a sample of the new substance to China for testing. Once results are available from the basic tests, requirements for high level tests can be adjusted. The entity will then have to analyze the testing results, collate testing report and translate testing report.

2.1.7. Risk Assessment Report

The major development in the 2012 China NCSN as compared with its 2003 version lies in the shift from a hazard-oriented to a risk-oriented assessment. Accordingly, the minimum requirements for General Notification include a risk assessment report, as well as test reports on physicochemical, toxicological and eco-toxicological properties.

Reflecting this shift, the 2004 Guidelines for the Hazard Evaluation of New Chemical Substances (HJ/T 154-2004) have been revised by MEP into two separate documents, the Guidelines for Risk Assessment of Chemicals and the Guidelines for Hazard Identification of New Chemical Substances. Unofficial translations of the Guidelines on Chemical Risk Assessment and of the Guidance on the Hazard Identification of New Chemical Substances are available online. The guidelines are under consultation and are yet to be finalised. The Guidelines apply both to notifiers when assessing risks

from new chemicals substances and completing risk assessment reports and to the experts of the CRC review committee when reviewing notifications.

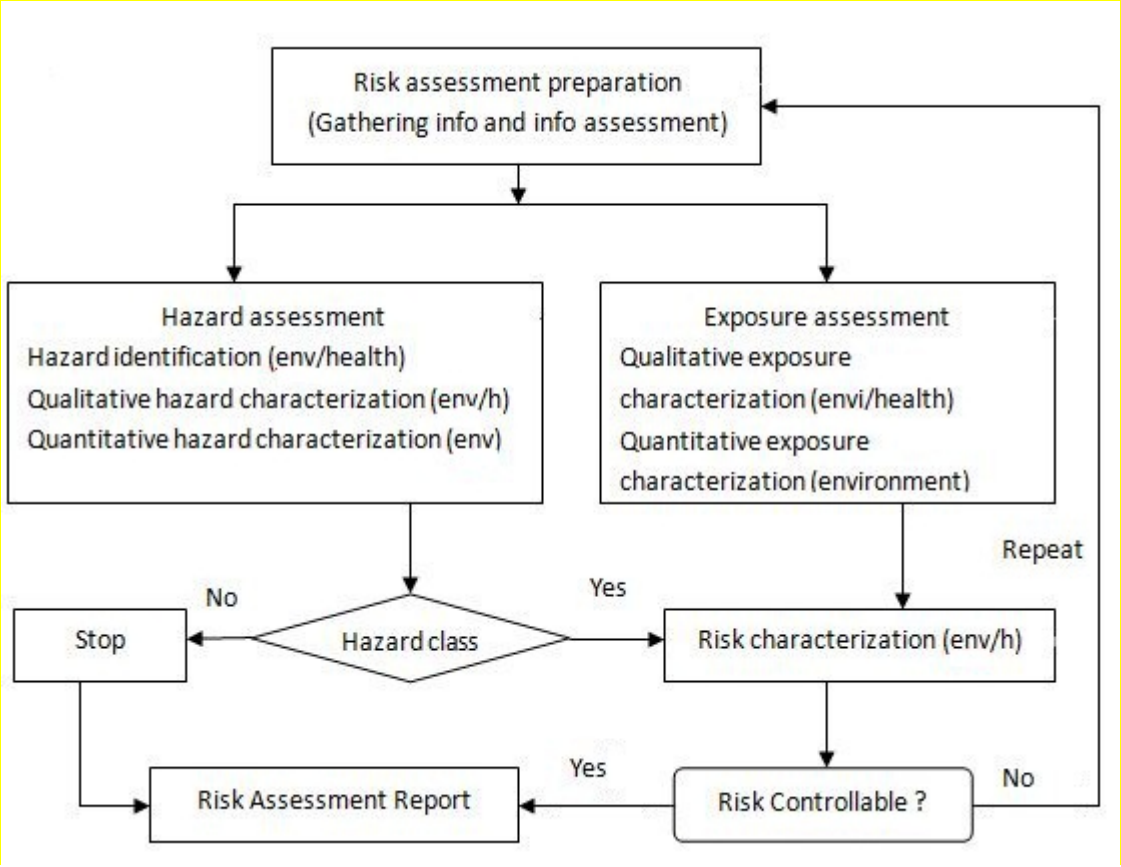
Risk Assessment Procedure

The risk assessment of a chemical substance includes the following steps:

- Hazard assessment, including both hazard identification and hazard characterization;
- exposure assessment; and
- risk characterization.

The risk assessment process of a chemical substance is shown in Figure 7 below.

Figure 7: Risk assessment process



Source: Guidelines on Chemical Risk Assessment

Hazard Assessment and Categorisation into Risk Categories

The new draft Guidance on the Hazard Identification of New Chemical Substances specifies the methods and procedures to identify hazards of new chemical substances and to classify them into

"risk management categories". The guidance also specifies the regulatory requirements for each category. The contents of the guidance are provided in box 3 below.

Box 3: Contents of the Guidelines for Hazard Assessment of Chemicals

Contents

Regarding methods for hazard identification for new chemical substances, the guidance outlines general requirements, data requirements, data evaluation and hazard classification. Hazard identification requires a separate analysis of the physico-chemical, health and environmental hazards. Following hazard identification, new chemicals are then classified into three risk management categories, namely:

- General new chemical substances;
- hazardous new chemical substances; and
- priority hazardous new chemical substances (substances with PBT properties).

This categorisation determines the post-notification obligations and the risk management measure to be applied to the new substance, discussed in sections 2.5 and 2.6 respectively.

Risk Assessment

The Guidelines on Chemical Risk Assessment provide guidance to chemical manufacturers and importers of new chemicals by specifying the principles, content, procedures, methods and technical requirements of the chemical substance risk assessment required under a General Notification. Risk assessment involves the combined consideration of hazard (as identified under the hazard assessment) and exposure in order to characterise risks. Risks to the environment and to human health are characterised separately and reply upon the development of exposure scenarios. The current risk assessment strategy proposed in the draft guidelines remains at a basic level, reflecting the fact that China is still gaining experience with chemical risk assessment. For example, the health risk assessment uses a qualitative grading system, rather than a quantitative approach. The proposed approach for the environmental risk assessment takes a quantitative approach. The content of the guidelines for risk assessment are shown in box 3 below.

Box 4: Contents of the Guidelines for Risk Assessment of Chemicals

- Preface
- Chapter 1: Applicable Scope
- Chapter 2: Normative References
- Chapter 3: Terms and Definitions
- Chapter 4: Assessment Procedure
- Chapter 5: Qualitative Environmental Risk Assessment
- Chapter 6: Quantitative Environmental Risk Assessment
- Chapter 7: Qualitative Health Risk Assessment
- Appendix A
- A.1 Identification of PBT or vPvB Substances
- A.2 Hazard Characterization of PBT or vPvB Substances
- A.3 Exposure Assessment of PBT or vPvB Substances
- A.4 Risk Characterization & Risk Management Measures of PBT/vPvB Substances
- Appendix B: Chemical Risk Assessment Models, Formulae, Parameters and Calculating Methods
- Appendix C: Qualitative Uncertainty Analysis

2.1.8. Notification Dossier

The notification dossier for the NCSN must be submitted in Chinese to the CRC and must include the documents set out in table 5 below.

Table 5: Documents to include in a NCSC notification dossier

Notification form	Test report detailing the substance's physiochemical properties and its toxicity and eco-toxicity properties and relevant certificates from testing laboratories
Risk assessment report	Recommended classification and labelling
Chinese Safety Data Sheets	Other supporting documents, as required

If the notification is incomplete, CRC will inform the applicant in written form and request a complete notification.

2.2. Evaluation of Notifications and the Registration of New Chemicals

The following section considers the procedures through which CRC evaluates applications for notifications and takes decisions regarding the registration of new chemicals. The different types of notification are considered in turn.

2.2.1. Evaluation of a General Notification

CRC receives the dossier for a General Notification and forwards them to MEP's Expert Committee within 5 working days. In accordance with the guidance on hazard identification and risk assessment and relevant national standards for chemical hazard identification and classification, the expert committee reviews the following information:

- Name and identifier;
- Physio-chemical, human health and environmental hazards
- The degree of exposure and the risks to human health and environment; and
- the appropriateness and adequacy of risk management measures;

Within 60 days of receipt of the dossier, the expert committee submits an evaluation report to the MEP, containing opinions on:

- whether the new chemical substance is categorized as general new chemical substance, a hazardous new chemical substance or a priority hazardous new chemical substance;
- the human health and environmental risks of the new chemical substance;
- the appropriateness and adequacy of risk management measures;
- whether the new chemical substance is approved for registration.

Should CRC request supplementary materials from the applicant, the time required to prepare and submit materials shall not be included in the 60 day time limit for the duration of expert committee review.

Before making a decision, MEP shall publicize relevant information related to the new chemical substance. Based on the opinions of the expert committee, the MEP determines the environmental management category of the new chemical substances and decides whether to:

(a) Issue a Registration Certificate if there are appropriate and adequate risk management measures in place; or
(b) Reject the application on the basis of inappropriate and inadequate risk management measures, and inform the applicant of the decision in writing.

MEP shall make a decision within 15 working days of receiving the notification documents from CRC or the expert committee. This can be extended by 10 working days in specific cases. The total time from application to issuing the certification is expected to take 80-90 days for a General Notification.

2.2.2. Evaluation of a Simple Notification

After accepting application materials for a simple notification, CRC prepares an evaluation report and submit it to MEP within 5 working days of receiving the Simple Notification request. If eco-toxicology test reports are required, the expert committee perform technical review and submit an evaluation report to MEP, within 30 days. A Registration Certificate is issued if the application meets the requirements. If not, MEP rejects the application and informs the applicant in writing of the decision and reasons for rejection. The total time from application to issuing the certification is expected to take 50-60 days for a General Notification.

2.2.3. Additions to the Scientific Research Record

CRC reports applications to be added to the Scientific Research Record monthly to MEP, which makes the data publically available on their website. No Registration Certificate is issued for an addition to the Scientific Research Record.

2.2.4. Notification Certificate

The Notification Certificate includes the following information:

- The name of registrant or agent;
- The name of new chemical substance;
- Notified uses;
- Notification level and volume;
- The category of management;

In addition, a Notification Certificate for a General Notification details risk management measures and administrative requirements. Once a Certificate has been issued, import or manufacture can proceed. The period for which the certificate is valid depends on the type of notification.

Regarding confidentiality, the Notification Certificate can show a generic product name rather than the substance name, if the entity applies for confidentiality. If a representative notifies on behalf of a foreign entity, both names will be shown on certificate.

2.2.5. Requirement to Report New Hazard Information

Should new hazard data come to light for a new chemical substance for which a Notification Certificate has been issued, the holder of Notification Certificate (hereafter cited as "certificate holder") is required submit that new hazard data to CRC. CRC then submits the new hazard information to the expert committee for technical review. Based on the opinions of the expert committee, MEP may decide to take the following measures:

(a) Include more risk management measures in the Notification Certificate and require the applicant to implement those measures; or

(b) If there are no appropriate and adequate risk management measures, withdraw the Notification Certificate.

2.2.6. Re-notifications

For substances not listed on IECSC and for which as Notification Certificate has been issued, the certificate holder shall re-notify the new substance if: there is an increase in the volume produced or imported that shifts the substance into the next tonnage band; or if the registered uses of a priority hazardous new chemical substance change.

For Priority Hazardous New Chemicals which are already listed on IECSC, the downstream users of the new chemical substances may also re-notify the new substance if they would like to change the registered uses.

2.3. Post-notification Obligations

Depending on the type of notification, and for General Notifications on the risk management category of the substance, certificate holders need to fulfill different post-notification obligations, summarized in table 6 below

Table 6: Post-notification obligations for different risk categories of new chemicals

Type	Category	Risk Management Measures Required	Post-notification Obligations
General notification	**General new substances**	Basic management (6 Requirements)	1. Communicate Safety Data Sheet to downstream users 2. Implement risk management measures 3. Submit first-activity report 4. Keep documents on file for over 10 years 5. Do not sell chemicals to downstream users who are not capable of implementing risk management measures 6. Submit updates if new hazard arises
	Hazardous new substances	General management (8 Requirements)	*Basic management plus* 7. Submit annual report (for previous year) 8. Comply with The Measures for The Administration of Registration of Hazardous Chemicals
	Priority hazardous new substance	Key management (11 Requirements)	*Basic management plus general management plus* 9. Submit report on disposal information 10. Submit Circulation Report 11. Submit annual plan (for next year)
Simple notification		Annual management (2 Requirements)	1. Submit annual production/import volumes for the previous year 2. Keep documents on file for over 10 years
Scientific Research Record		Specified management (2 Requirements)	1.Requirements of professionals and facilities 2. Can only be used for scientific research purpose

2.3.1. First Activity report

Certificate holders of a General Notification shall submit first-activity report to CRC within 30 days of starting production of a new chemical substance for the first time or within 30 days of transferring the new chemical substances to downstream users after the first import.

2.3.2. Annual Report

Certificate holders of a Simple Notification are required to submit the total tonnage volume of a new chemical substance that was manufactured or imported in the previous year before 1 February of each calendar year.

Certificate holder of a General Notification for a hazardous new chemical substance or a priority hazardous new chemical substance must submit an Annual Report including the information in box 3 for the previous year before 1 Feb of each calendar year.

Box 3: Information to include in the Annual Report

- The total tonnage of the new chemical substance manufactured or imported
- Whether risk management measures have been implemented
- Environmental exposure and release information
- Data on the impact of the new substance on environment and human health
- Other information related to environmental risks

In 2013, CRC published a new form and a guidance document on completing the annual activity report for new chemical substances. The report is to be submitted by the certificate holders via an online reporting system.

2.3.3. Annual Plan and Circulation Report

In addition to the First Activity Report and the Annual Report, Certificate holders of a General Notification for a priority hazardous new chemical substance shall submit an Annual Plan for the manufacture or import for the current year to CRC, along with a report on disposal. They must also report the downstream sale of the substance to CRC within 30 days in a Circulation Report, each time since they transfer the substance to a different downstream user.

2.3.4. Record Keeping

Certificate holders shall keep new chemical notification application materials and other information related to manufacture or import activities for 10 years and above.

2.4. Risk Management Measures

The certificate holder and downstream user must implement the risk management measures specified in the Notification Certificate. These may include general risk management measure, or specific measures for substances classified as Priority Hazardous New Chemicals.

2.4.1. General Risk Management Measures

General risk management measures may include:

- Providing education on the risks of new chemical substances and preventative measures;
- Strengthening person protection of personnel in contact with new chemical substances;
- Establishing closed systems, quarantine zones, and placing visual warnings;

- Process improvements for the manufactured or use of new chemicals to lower release and environmental exposure;
- Improving waste management and disposal to reduce environmental discharge;
- Preparing emergency plans and emergency response measures;
- Taking other appropriate risk management measures;

For Priority Hazardous New Chemicals, certificate holder and downstream users shall comply with other existing laws or administrative measures such as the Regulations on the Safe Management of Hazardous Chemicals.

2.4.2. Risk Management Measures for Priority Hazardous New Chemical Substances

For Priority Hazardous New Chemicals, certificate holder and downstream user must implement the following risk management measures:

- Monitor or estimate the environmental release of the priority hazardous substances during production or use. If certificate holder and downstream users do not have the capacity for monitoring, they shall appoint a MEP monitoring agency or hire a technical consultancy recognized by MEP.
- Adopt technical measures to control releases and take appropriate measures to prevent accidental release to the environment during transport,
- Dispose of the priority hazardous new chemical substance in accordance with relevant laws.

2.5. Information in the Supply Chain

2.5.1. Public Disclosure

MEP publishes the names of new chemical substances, the applicants, the category of notification and the risk management category on their website. In addition, MEP reports relevant information on hazardous new chemical substances and priority hazardous new chemical substances, to other authorities.

2.5.2. Downstream Communication

The certificate holder of a General Notification is required to list the hazard properties of the new chemical substance in a Safety Data Sheet. The certificate holder must then communicate the following information to downstream users:

- Risk management measures listed in the Registration Certificate;
- Safety Data Sheet;
- Chemical classification, precautionary label and statements;
- Other relevant information.

2.6. Enforcement

Procedures for enforcement of the notification of new chemical substances and the implementation of risk management measures include supervision and inspection by the local environmental protection agency. Relevant procedures are discussed below.

2.6.1. Supervision Notice

Within 30 days of receiving the First Activity Report or a Circulation Report of the substance submitted to CRC from the certificate holder, MEP issues a supervision notice to the local environment protection authorities in the province where the manufacturers or downstream users of hazardous new chemical substances are located. The environmental protection authorities at provincial level are responsible for sending the supervision notice to the environmental protection authorities at city level or county level where the manufacturers or downstream users are based. The supervision notice shall include:

- the name of the new substance;
- the risk management category of management;
- risk management measures on registration certificate; and
- administrative requirements and key points for inspection and supervision.

2.6.2. Supervision and Inspection

Local environmental protection authorities supervise the production and/or use of new chemical substances in accordance with the requirements of supervision notice and administrative supervision and inspection guidelines issued by MEP. If the production or use of new chemical substances have

caused or might cause immediate or future environment pollution, local environmental protection authorities are empowered to order the producer or downstream user to take immediate action to eliminate this hazard. The local authorities will also report the situation to MEP. Based on the report, MEP may request additional hazard information from the certificate holder.

2.6.3. **Regular Inspection**

MEP will organize a comprehensive inspection of installations producing or using new chemical substances every 5 years. For new chemical substances manufactured or imported or used without registration certificate, environmental protection authorities will take legal actions in accordance with relevant laws.

2.7. Advantages, Challenges and Disadvantages of China NCSN

2.7.1. Advantages

Implementation of the 2010 NCSN system in China represents a considerable improvement on the former situation, since entities placing new substances on the market or producing them in China are required to submit a notification to the CRC. For >1 tonne new substances, the Chinese authorities will gain access to data on the physico-chemical properties of the substances, as well as the results of toxicity and eco-toxicity testing, with data yields increasing with tonnage and therefore likely exposure. For substances that qualify for Simple Notification with basic conditions, data is limited to the physico-chemical properties and acute toxicity testing.

For substance that quality for Simple Notification with specific conditions, data is limited to data that is already available to the notifier, with no additional testing requirements. However, since the criteria that allow qualification for Simple Notification with specific conditions imply that these substances are of relatively low tonnage and intended for either research or export, or are polymers, the exposure is likely to be low. The decision to allow new substances at up to <10 tonnes intended for technological research (i.e. product research) to be produced or imported clearly represents a balance between risk management and economic interests in maintaining and strengthening China's position in product innovation.

2.7.2. Challenges and Disadvantages

Challenges with Implementation

The implementation of China NSCN remains in the early stages, with just over 2,000 notifications having been processed by CRC. As such it remains premature to make an assessment of the effectiveness of implementation, and MEP and CRC and likely to be gaining experience with procedures and mechanisms. MEP continues to publish guidance and to improve the online tools and forms, and the Registration Certificate.

Scope Limited to New Chemical Substances

Given that China NSCN applies only to new chemical substances, they are obvious questions regarding the availability and quality of data on substances that are already listed under IECSCS and hence produced or on the market in China. MEP has stated that it aims to substantially strengthen management of chemicals in China, with the longer-term objective of moving from the current

Chinese regulatory focus on "new" substances to cover also "existing" substances. This would be more in line with the dual phase-in and non-phase-in substance scope of REACH.

Costs to Companies

The total cost consists of three major parts: the administration fee, the testing fee and the consulting fee. The administration fee is fixed and it is charged by CRC. It is a small proportion of the total costs, typically around 200 RMB.

The testing fee accounts for a large proportion of the total costs and it is charged by certified laboratories. The testing fee is tonnage based. It typically costs several hundred thousand RMB to carry out testing to obtain a full set of data. Some ecotoxicological tests must be carried out in Chinese laboratories, certified by MEP. This means that companies wishing to import a new substance to China will first have to seek to have their substance added to the Scientific Research Record, import <0.1 tonne for testing and receive test results from the Chinese laboratory for applying for a General Notification. Some high level testing items could be waived by analysing the results of the basic testing items and thus the corresponding testing fee would be lower.

Should a foreign company seek to make a notification, they will need to work either with their local suppliers, or through a local consultancy, the latter involving a fee.

3. Order No 113 - Registration of the Import and Export of Toxic Chemicals

In 1994, the Chinese government released the Provisions on the First Import of Chemicals and the Import and Export of Toxic Chemicals, amended in 2009 by Order No. 113 on the Registration of the Import and Export of Toxic Chemicals in China. Pursuant to the 2009 Notice, the import and export of toxic chemicals within the scope are subject to the requirement to register in China. The List of toxic chemicals severely restricted to be imported into or exported from People Republic of China is available online and currently including 158 substances. Specifically, companies which deal with import and/or export of listed toxic chemicals need to register with the Chemical Registration Centre (CRC) of MEP and apply for relevant registration certificates or custom clearance notification. Given the toxicity of listed substances, it is likely that companies dealing with these chemicals will face additional obligations under the Regulations on the Safe Management of Hazardous Chemicals, considered under section 4 below.

The Notice of Registration of the Import and Export of Toxic Chemicals in China places obligations on foreign exporters, domestic importers and domestic exporters. Different actors in the supply chain are defined in table 7 below and their obligations summarized. Procedures for the application for the relevant documents are described below.

Table 7: Roles and obligations of different actors in the supply chain

Roles	Definitions	Obligations
Foreign exporter	Foreign companies exporting toxic chemicals to China	Apply for Registration Certificate for the Environmental Management on the Import of Toxic Chemicals
Domestic importer	Domestic companies importing toxic chemicals to China	Apply for Import Clearance Notification
Domestic exporter	Domestic companies exporting toxic chemicals from China	Apply for Export Clearance Notification

3.1. Application for a Registration Certificate

Foreign companies that export listed toxic chemicals to China will need to apply for an **Import Registration Certificate**. A Registration Certificate is issued to each foreign exporter for each chemical substance, allowing trade with one domestic importer. Each Registration Certificate is valid period for two years. The foreign exporter shall prepare materials in box 4 and submit them to CRC.

Box 4: Documents to be submitted when applying for an Import Registration Certificate

- Application form;
- Business contract or agreement (reflecting two years' trade information); and
- Duplicate copy of Verification of Import/Export Right.

There is a registration fee of US$10,000 per certificate, or the equivalent in RMB. CRC conducts a completeness and correctness check within 5 days from the receipt of all documents and the application fee. A reference number is allocated to each application and preliminary feedback is given on CRC's website. CRC reviews each application and reports to MEP. Once the application is approved by MEP, a Registration Certificate is issued by MEP and distributed by CRC. If the application is denied, the applicants will be duly notified by CRC. The whole processing period is 30 working days from the arrival of the completed application materials.

3.2. Application for Import Clearance Notification

For every batch of listed chemicals imported into China, the domestic importer shall apply for an **Import Clearance Notification** by providing a copy of the Registration Certificate obtained from the foreign exporter. In applying for an Import Clearance Notification, the domestic importers submit the materials in box 5 to CRC.

Box 5: Documents to be submitted when applying for and Import Clearance Notification

- Application form
- Copy of the Registration certificate obtained from the foreign business partner
- Original contract for every batch of goods
- Documents communicating information to downstream users (safety data sheet)
- Verification of Import/Export Right

CRC conducts a completeness and correctness check within 5 days of the receipt of all documents. A reference number is allocated and preliminary feedback given on the CRC website. CRC reviews each application and communicates the outcome to MEP. Once the application is approved by MEP, an Import Clearance Notification is issued by MEP and distributed by CRC. If the application is denied, the applicants will be duly notified by CRC. The whole processing period lasts no more than 20 working days from the arrival of the completed application materials.

3.3. Application for an Export Clearance Notification

Domestic companies must apply for **Export Clearance Notification** for every batch of listed chemicals, before exporting those goods to other countries. The domestic exporters must supply the materials in box 6 when applying for Export Clearance Notification.

Box 6: Documents to be submitted when applying for and Export Clearance Notification

- Application form
- Original contract for every batch of goods
- Document to communicate information to downstream users (safety data sheet)
- Verification of Import/Export Right

CRC checks completeness and correctness within 5 days, allocates a reference number and provides preliminary feedback online. CRC reviews the application and reports to the MEP. Once the application is approved by MEP, it issues the Export Clearance Notification which is sent to the applicant by CRC. Applicants will be duly notified by CRC if the application is denied. The whole processing period lasts no more than 20 work days from the arrival of the completed application materials.

In addition, there are Special Rules that apply to specific toxic chemicals, for example arsenic and its compound products, sodium cyanide, mercury and it compound products, etc. In particular, rule 2 and 3 serve to implement the PIC procedure for specific substances.

Rule 1: A supplier of arsenic and its compound products must have approval from the local Environmental Protection Bureau to produce these products.

Rule 2: For DDT, Hexachlorobenzene, Sodium cyanide, Tetramethyllead, Tetraethyllead, Pentachlorophenol, Chlordane, Oxirane, and Hexachlorocycloh (BHC), a supplier must have approval from the local Environmental Protection Bureau to produce these products. In addition, pursuant to the "Prior Informed Consent (PIC) procedure", a "Response Letter" from the import country's designed national authority (DNA) must be included in the application for a Registration Certificate.

Rule 3: Rules 1 and 2 are also applied to Mercury and its compound products. In addition, the applicant should provide an "Opinion Letter" issued by the local Environmental Protection Bureau.

4. Order No 591 - Regulation on Safe Management of Hazardous Chemicals

Order No. 591 on the revised version of Regulations on Safe Management of Hazardous Chemicals was published in China on 11 March 2011, and replaced the version issued in 2002. The regulation addresses the production, storage, import, use, sales and transporting of hazardous chemicals. In particular, it expanded the scope to include downstream users. This regulation is the main law regulating existing chemicals in China and implements GHS. More than 8 government bodies are involved in the implementation of this law, with SAWS having overall responsibility. The Order is supported by a number of measures, listed in box 5 below.

Box 5: List of Laws for Hazardous Chemicals

- Measures for the Administration of Production Licenses for Hazardous Chemicals
- Measures for the Administration of Operating Licenses for Hazardous Chemicals (revised in 2011)
- Measures for the Administration of Safe Use Permit for Hazardous Chemicals(new in 2012)
- Measures for the Administration of Registration of Hazardous Chemicals(revised in 2011)
- Measures for the Administration of Standardization of Management of Hazardous Chemicals(released in Aug 2011)
- Catalogue of Hazardous Chemicals(to be released in 2012)
- Measures for the Administration of Safety Clearance on Construction Projects for Hazardous Chemicals
- Measures for the Administration of Safety Supervision of Major Sources of Hazard;
- Measures for the Administration of Safety Management of Transmission Pipeline for Hazardous Chemicals
- Measures for the Administration of Physical Hazard Identification and Classification for Hazardous Chemicals
- Measures for the Registration of Environmental Administration of Hazardous chemicals for public consultations (issued by MEP in 2012)

4.1. Scope of the Regulation

The Regulation covers hazardous chemicals, defined as highly toxic chemicals and other chemicals which are toxic, corrosive, explosive, flammable and do harm to human body, facilities and environment. All chemicals meeting GHS classification criteria will be regulated as hazardous chemicals. Exemptions include: explosives for civil use, fire crackers, radio-active substance, and chemicals used for national defense.

Hazardous chemicals are listed in the 2002 Catalogue of Hazardous Chemicals, which consists of three parts, including the:

- List of dangerous goods (GB12268-2005);
- Catalogue of Highly Toxic Chemicals (approx. 150 chemicals); and
- Other chemicals identified by authorities.

There are more than 3,700 chemicals in the 2002 Catalogue. An updated Catalogue is expected to be released by SAWS during the first half of 2013. The hazardous chemicals in the Catalogue are further classified into categories, with the classification into different categories setting requirements for the implementation of different risk management measures by producers and users. Categories are presented in table 8 below.

Table 8: Categories of hazardous chemicals

Catalogue of Highly Toxic Chemicals	List of 60 Hazardous Chemicals for Priority Management
Catalogue of Hazardous Waste	List of Priority Hazardous Chemicals for Environment Management
Catalogue of Precursors for Explosives	List of Toxic Chemicals Restricted to Be Imported/Exported (considered under section 3)
Prohibited Chemicals (2005)	Catalogue of Industrial Products
List of highly toxic chemicals and other hazardous chemicals for which transportation is prohibited on inland waterways	

Companies who produce, store, use, sell or transport hazardous chemicals in China are subject to different obligations, for example, safety evaluation report, production license, safe use permit, operating license, registration of hazardous chemicals, SDS and chemical labels. Foreign companies importing into China are obliged to package and label their products in accordance with Chinese GHS, and to provide Safety Data Sheets.

4.2. Priority Hazardous Chemicals

29 June 2011, SAWS published Order No. 95 including the first List of 60 Hazardous Chemicals for Priority Management (Priority Hazardous Chemicals). Priority Hazardous Chemicals were selected from the 2002 Catalogue of Hazardous Chemicals based on the hazard properties of the chemicals and their propensity to cause accidents. The list of Priority Hazardous Chemicals also includes some substances or mixtures with the classifications under basic conditions (20℃ and 101.3kPa) shown in table 9.

Table 9: Substance classification included in the list of hazardous chemicals for priority management

Flammable gases category 1	Pyrophoric solids category 1
Flammable liquids category 1	Substances and mixtures which are in contact with water emit flammable gases category 1
Pyrophoric liquids category 1	Phosgene such as bis(trichloromethyl)carbonate

SWAS aims to prioritize and strengthen inspections of companies who manufacture, store, sell or use Priority Hazardous Chemicals. Facilities for the production and storage of chemicals on the list shall be equipped with automated monitoring instruments to monitor parameters such as temperature and pressure. Manufacturers shall also prepare sound emergency response plan to deal with possible chemical accidents. Companies who use Priority Hazardous Chemicals to manufacture products shall obtain a Safe Use Permit, as described above.

4.3. Registration of the Production and Import of Hazardous Chemicals

Order 53 on Measures for the Administration of Registration of Hazardous Chemicals entered into force on 1 Aug 2012. It requires that the producers and importers of hazardous chemicals in China to register hazardous chemicals with NRCC prior to manufacturing or importation, and sets obligations on producers and user to implement risk management measures.

Companies based outside of China are not obliged to register their exports of hazardous chemicals to China, rather the domestic importer has the responsibility to register. Importers are divided into trade importers and downstream users. Domestic entities approved to proceed with production and imports are issued with a Registration Certificate. The validity of the Registration Certificate is 3 years and the Certificate must be renewed 3 months prior to the certificates expiry date.

In terms of the scope, the production or import of chemicals listed in the Catalogue of Hazardous Chemicals and chemicals that have been identified as hazardous by designed institutions must be registered. In 2012, SAWS published draft measures for the administration of physical hazard identification and classification of chemicals, clarifying how to determine whether registration is required for a chemical product (substance or mixture) that is not listed in the Catalogue of Hazardous Chemicals.

In addition to registering hazardous chemicals with NRCC, producers and importers of hazardous chemicals are also required to prepare safety data sheets and labels for chemicals and maintain a chemical safety management file, including hazardous properties of chemicals with known physical hazards, identification and classification reports and the name and quantity of chemicals that have not been assessed.

The measures also require producers and importers to identify physical hazards and classify chemicals with unknown hazard properties at SAWS-approved institutions and submit identification and

classification report to NRCC. The following categories of chemicals are defined as chemicals with unknown hazard properties:

- Chemicals listed in the Catalogue of Hazardous Chemicals, for which new physical hazard properties have been discovered;
- Mixtures containing more than one physical hazardous component listed in the Catalogue;
- A chemical that is not listed in the Catalogue but with unknown physical hazard properties; and
- A newly developed chemical product that lacks physical hazard information.

4.3.1. Documents Required for the Registration of Hazardous Chemicals

In applying for the registration of the production of import of a hazard chemical, a domestic entity must provide a range of information to NRCC, including information on themselves as the legal entity, information on the chemical substance, including physico-chemical properties and (eco)toxicology data, processes in which the substance is to be uses and major sources of risk. The details information requirements under each part of the application form are provided in table 10 below. The registration relies on existing data and does not require the producer or importer to conduct additional testing. In addition, the legal entity must supply a domestic 24h emergency telephone number.

Table 10: Information required by the registration form for registering the production or import of hazardous chemicals

Form section	Information Required
Legal entity information	Name, date of formation, address, legal representative, sales revenue, business license, qualifications of import, manufacturer's information, no. of products, storage facilities, EHS professionals, etc. Importers are divided into trading importer and downstream user importer.
List of chemicals	Index, Chinese name, trade name, HS code, whether a chemical is listed in the Catalogue/List of Highly Toxic Chemicals/List of Hazardous Chemicals for Priority Management/List of Precursor Chemicals for Drugs & Explosives, country of origin, annual volume. Country of origin is only required for imported hazardous chemicals.
Information on each hazardous chemical	Product identifier, manufacturer's information, composition, classification & labeling, physiochemical properties, toxicological properties, eco-toxicological properties, main uses and uses advised against, hazard properties, storage conditions, occupational exposure limits (for producers), transportation information and emergency response measures. The source of toxicological and eco-toxicological data shall also be given unless certain exemption criteria are met.
Identification of major source of risk	Name of source of major hazards, address, main facilities, and accidents in the past 3 years. Not required for trading importer without storage facilities.
Identification of chemical process for key priority management	Description of chemical process, facilities. This is not required for a trading importer.

4.3.2. Transitional Period for Importers

The requirement to register the production and import of hazardous chemicals under Order 53 came into force on 1 Aug 2012. However, the implementation of the requirement to register by importers has been delayed as some documents and IT system are not ready yet. Once the procedures are in place, companies will be given a certain period to complete their registrations. NRCC plans to initiate registration of hazardous chemicals in a few selected cities before launching nationwide registrations. NRCC plans to complete the registration of all production and imports of hazardous chemicals within 3 years. During the transition period, companies can continue their production and supply. For chemicals that are newly added to the Catalogue of highly toxic chemicals, a transitional period is foreseen.

4.4. Enforcement of Requirements for the Import and Export of Hazardous Chemicals

The General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ) is responsible for the inspection of imports and exports of hazardous chemicals and their packages. Chinese companies who export hazardous chemicals abroad by sea or air need to obtain hazard identification and classification report from designated testing lab in China to determine if the chemicals are dangerous goods. If so, producers of the dangerous goods and packages need to be inspected by local inspection and quarantine authorities and receive a certification from AQSIQ. Otherwise, the goods cannot be exported. If foreign companies export hazardous chemicals to China, the Chinese importer shall apply for an inspection by the local Inspection and Quarantine authority at the port of entry. Documents to be provided when applying for an inspection are presented in box 7 below.

Box 7: Documents to be provided to support an inspection of hazardous chemical imports and exports

- Declaration of conformity
- Licenses: Registration certificate for hazardous chemicals, operating license, safe-use license and business license
- SDS in Chinese; sample of hazard communication label
- Report on hazard identification and classification

In their inspection, AQSIQ will:

- Identify whether the composition/constituent information of goods, physical and chemical properties, hazard class, packaging category meet the requirements of relevant standards, and whether they are consistent with the hazard identification and classification report, SDS and chemical safety label provided when applying for an inspection;

- Identify whether a Chinese SDS has been provided along with the goods, whether a Chinese label has been affixed on the packaging of goods; whether the contents in SDS and label meet the requirements of relevant standards and are consistent with the goods.
- Identify whether the models, category, specification, unit quantity and mark of packaging meet the standard requirements and whether the packaging has been adapted to the properties and uses of the inspected goods.
- Identify whether the packing method meets standard requirement and whether the use of package is appropriate, whether the packaging is sealed tightly and whether the goods inside the package have leaked.

If hazardous chemicals and packaging materials pass inspection, CIQ will issue a Certificate of Inspection and Quarantine of Imported Commodities and the chemical products can then be sold and used in China.

4.5. Licensing Production and Marketing of Hazardous Chemicals

Under the Measures for The Administration of Operating Licenses for Hazardous Chemicals, all domestic entities producing and marketing hazardous chemicals in China must obtain a license from the SAWS. There are three types of licenses in China, including:

- The production license for manufacturers;
- The operating license for companies importing/distributing/selling hazardous chemicals in China; and
- The Safe Use License for companies who use certain hazardous chemicals to manufacture products.

Regarding the use of hazardous chemicals, from May 2013 companies using hazardous chemicals to manufacture products (excluding the producers of hazardous chemicals) must apply for a Safe Use License from the administrative department of work safety at city level when the following conditions apply:

- The industrial sector is listed in the Catalogue of Applicable Industry Sector for the Safe Use Permit of Hazardous Chemicals (for example, production of fertilizer); and
- The quantity used exceeds the threshold volume stipulated by the standard usage quantity of hazardous chemicals (for example, for chlorine, the threshold value is 180t/y). So far, a threshold value has been set for 62 hazardous chemicals (60 hazardous chemicals for priority management and two other chemicals).

A safe use permit is valid for 3 years. Under their application for Safe Use Licenses, the users of hazardous chemicals are required to provide evidence of a range of risk management measures, including emergency procedures, occupational health and safety measures and the presence of relevant trained personnel. The documents required when applying for a safe use permit are listed in box 8 below.

Box 8: Documents required when applying for a Safe Use Permit

- application form for safe use permit
- safety management system and safety operation procedure
- details of full-time environmental and health and safety staff
- qualifications of safety responsible person and environmental and health and safety staff
- emergency response plan in case of accident
- safety data sheet provided by suppliers
- copy of business license
- safety evaluation report by third party
- copy of evaluation report of a new chemical plant
- list of emergency response personnel, equipment and facilities

4.6. Registration of the Production and Use of Hazardous Chemicals with MEP

In Oct 2012, MEP released Order No. 22 containing trial Measures for the Environmental Administration Registration of Hazardous Chemicals, which entered into force on 1st March 2013. The Order restates the obligation for the registration with CRC of the import and export of toxic chemicals, as discussed under section 3. In addition it requires the producers of and companies using hazardous chemicals listed in the Catalogue of Hazardous Chemicals to manufacture products to submit an environmental administration registration to the environmental protection authorities. Those hazardous chemicals are further classified into two categories: general hazardous chemicals and Priority Hazardous Chemicals (following Order No. 95 establishing the List of Hazardous Chemicals for Priority Management).

For general hazardous chemicals, manufacturers and companies must submit an Environmental Administration Registration to local environmental protection authorities at county level and obtain a Certificate, which is then valid for 3 years. Documents required for registration are presented in box 9 below.

Box 9: Documents required when applying for and Environmental Administration Registration

- Environment administration registration form including legal entity information, the names of hazardous chemicals, volume, uses, operational method, safety data sheet, environmental risk management measures, transfer of waste and disposal of hazardous waste
- Result of environmental impact assessment
- Environment emergency response plans
- Environment monitoring report

In addition to the above requirement, there are more stringent requirements for the registration of Priority Hazardous Chemicals. Companies must prepare an environmental risk assessment report and submit this report to authorities. Companies must pass on-site inspection before a registration certificate is granted and must report data on the release and migration of the hazardous chemicals to environmental protection authorities before 31st Jan of each calendar year. The Registration Certificate for Priority Hazardous Chemicals will be issued by environmental protection authorities at provincial level.

Companies that produced or used hazardous chemicals before the new measures enter into force must submit an Environmental Administration Registration within 3 years of entry into force.

A number of supporting documents for the Environmental Administration Registration are published on the MEP website, including:

- Registration form;
- Change of registration certificate;
- Sample registration certificate; and
- Guidance on preparation of risk assessment report for Priority Hazardous Chemicals for Environmental Management.

The publication these documents initiates implementation of the Environmental Administration Registration in China. According to MEP's 12-year plan, the first round of Environmental Administration Registrations will be completed before 2015.

5. Announcement No. 116 (2005) on Commodities Prohibited from Import and Export

Certain toxic substances are subject to stricter control in China, with import and export strictly prohibited. Announcement No. 116 on the Catalogue of Commodities Prohibited from Import (The 6th Batch) and the Catalogue of Commodities Prohibited from Export (The 3rd Batch) was published by the Ministry of Commerce, the General Administration of Customs, and the State Environmental Protection Administration (now MEP) on December 31, 2005. This act serves to protect human health, safeguard environmental safety, phase out outdated products and implement the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals Pesticides in International Trade and the Stockholm Convention on Persistent Organic Pollutants.

6. The Classification, Labeling, Packaging of Chemicals in China – China GHS

6.1. Implementation of GHS in China

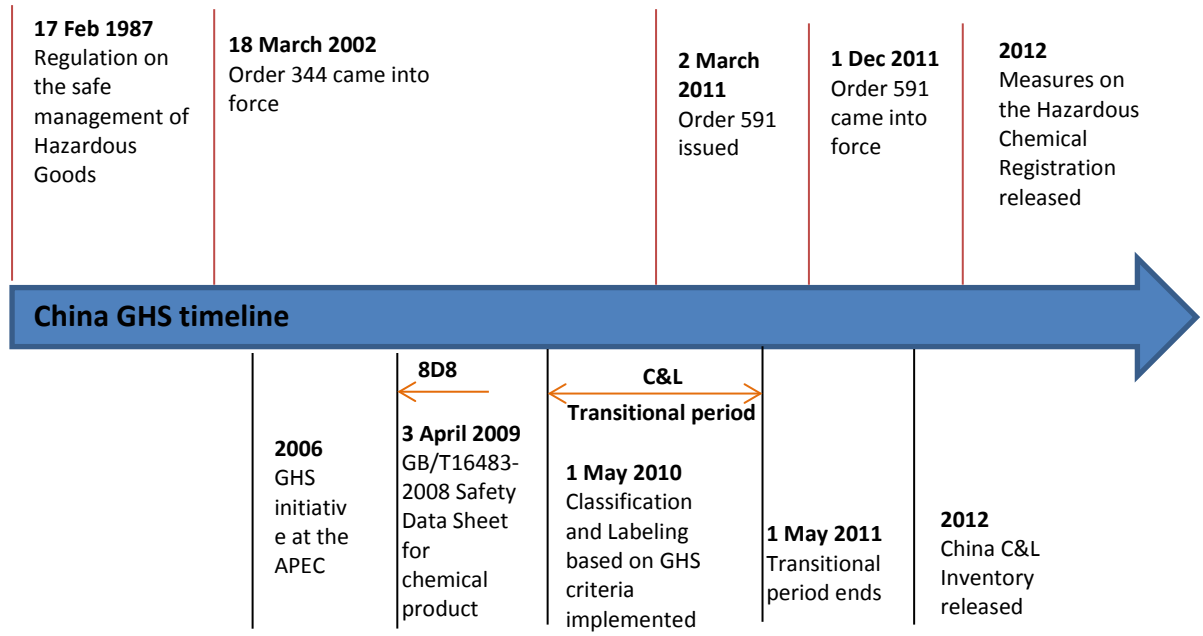
The Globally Harmonized System of Classification and Labeling of Chemicals (GHS) is an internationally agreed-upon system, created by the United Nations, aimed at establishing consistent criteria for the classification and labeling of chemicals on a global level.

At present, Order No. 591 on the revised version of Regulations on Safe Management of Hazardous Chemicals is the basis for official GHS implementation by enforcing labelling and packaging requirements for industry in China. In addition, Order No. 591 refers to the safe management of production, storage, use, operation and transportation of hazardous chemicals, as well as the registration/notification of hazardous chemicals (discussed above). Order No. 591 is supported by a number of National Standards.

In 2006, 26 compulsory National Standards (e.g. GB 20576 - GB 20602-2006) on Safety rules for the classification, precautionary labeling and precautionary statements of chemicals were published. 2008 then saw the publication of two recommended Standards, GB/T 16483-2008 on Safety Data Sheets and GB/T 22234-2008 on the labeling of chemicals according to the GHS. In 2009, three compulsory Standards were published, on packaging (GB 190-2009), classification and hazard communication (GB 13690-2009) and on precautionary labelling (GB 15258-2009). These entered into force on 1 May 2010, with a 1 year transitional period for implementation. Companies selling chemicals to China and chemical companies in China were required to adopt these Standards to classify, label and package chemicals as well as prepare safety data sheets in accordance with the requirements of GHS as from 1 May 2011. Order 591 includes enforcement procedures for China GHS National Standards, in the form of penalties. Companies who fail to classify, label and package hazardous chemicals in accordance with those standards would face a maximum penalty of 50,000 yuan, or a ban on production or import.

A timeline for the implementation of GHS in China is provided in figure 8 below.

Figure 8: China GHS Timeline



6.2. Competent Authorities for China GHS

A total of ten ministerial departments in China are involved in GHS implementation. The primary department is the Ministry of Industry and Information Technology (MIIT), established in March 2008. This Ministry integrates the functions of several (technical) commissions from different Ministries and is heading the implementation of GHS in China. Other ministries involved include MEP, Ministry of Transport, Ministry of Railway, Ministry of Agriculture, Ministry of Health, General Administration of Customs, State Administration for Industry and Commerce, Ministry of Public Security, AQSIQ and SAWS.

6.3. Classification Standards

The mandatory national classification standard in China is General rules for classification and hazard communication of chemicals **(GB 13690-2009)**, which came into force on 1 May 2010. It refers to the 26 National Standards that were issued in 2006. The Standard specifies the classification and hazard communication of chemicals in consistence with the GHS. The Standard applies to the classification and hazard communication of chemicals. In addition, the Standard governs the labels of chemical workplaces and of chemical consumer goods. The transition period is between 1 May 2010 and 1 May 2011.

6.4. Labeling and Packaging Standards

China has three National Standards related to the labeling and packaging of chemical products in line with GHS. The first mandatory National Labeling Standard (GB 15258-2009), the General rules for preparation of precautionary label for chemicals came into force on 1 May 2010 and specifies the relevant definitions, content, preparation requirements and application methods of precautionary labels for chemicals. Where the precautionary label of a product is specified by a special standard, i.e. for pesticides, gas cylinders, etc., these shall be conducted in accordance with said special standard. Examples of precautionary labels, transport symbols, and precautionary statements for different categories of chemicals are given in this standard.

The second mandatory Standard (GB 190-2009) Packaging Labels for Dangerous goods is based the 15th revised edition of the UN recommendations on the *Transport of Dangerous Goods*, and specifies the requirements for pictograms, label size, colour and packaging of hazardous goods.

The third labeling Standard is Labeling of Chemicals Based on GHS (GB/T 22234-2008). The Chinese government firstly published this as a recommended standard in 2008, based on the Japanese version. In 2009, the Chinese government updated this with a mandatory labeling standard, GB 15258-2009, which has added more features that work better for Chinese companies and which states that China's GHS national standards apply to both workplace chemicals and consumer products.

6.5. Safety Data Sheets

The most important National Standard related to Safety Data Sheet in China is Safety data sheet for chemical products: Content and order of sections (GB/T 16483 -2008). This Standard, which entered into force in February 2009, sets the structure, content and generic forms of the Safety Data Sheet for Chemical Products. According China's mandatory national labeling standard for chemicals (GB 15258-2009), a domestic 24-hour emergency phone number must be provided on the precautionary label of any imported chemical.

6.6. Labeling and Safety Data Sheets for Hazardous Chemicals

Following the Regulations on Safe Management of Hazardous Chemicals, the producers of hazardous chemicals shall provide Safety Data Sheets and affix chemical safety labels on packages. The SDS and labels shall be prepared in accordance with national standards (in Chinese). Companies cannot

sell hazardous chemicals that do not have SDS and chemical safety labels. Penalties for non-compliance are presented in table 11 below.

Table 11: Penalties for non-compliance with requirement for labelling hazardous chemicals

Offences	Penalties
No proper operating license	RMB 100,000 to 200,000
No SDS or label, SDS and labels do not comply with national standards	RMB up to 50,000 Repeated infringement up to RMB 100,000
Manufacturers and importers fail to register hazardous chemicals	RMB up to 50,000 Repeated infringement up to RMB 100,000

6.7. GHS Labelling for Consumer Products in China

Most consumer products containing chemicals (excluding cosmetics) are subject to Chinese chemical control laws and GHS requirements, as well as product specific national standards and additional labeling requirements. Examples include detergents, paints, fuel additives, lubricants, air fresheners, adhesives, aerosol products, disinfectants and pesticides for households, etc, with product specific national standards presented in box 10 below.

Box 10: National Standards for specific products

- GB/T 25322-2010 Safety Label of Consumer Product
- QB/T 2952-2008 Requirements for detergent marks and packaging
- GB 5296.3-2008 Instruction for use of consumer products-General labeling for cosmetics
- SH 0164-1992 Rules for the Packing, Storage, Transportation and Inspection upon Delivery of Petroleum products (applicable to Lubricants, industrial oils and related products)
- BB/T 0005-2010 Labelling, classification and terms of aerosol products
- GBT 18419-2009 Domestic sanitary insecticidal-Aerosols

In China, GB 13690-2009 General Rule for Classification and Hazard Communication of Chemicals clearly says that the standard applies to both workplace chemicals and consumer products. However, it is not clear whether China will adopt a risk-based labelling approach for consumer products in accordance with Annex V of GHS.

6.8. Challenges with China GHS

Challenges with GHS implementation in China include the lack of expertise amongst both the regulatory bodies and the regulated industry, as well as a lack of data to set against the classification criteria. In addition, the Chinese GHA does not differentiate between substances and mixtures.

In addition the large number of government bodies involves creates coordination problems and dilutes responsibilities. Finally, thus far, enforcement remains weak.

7. Conclusion

In the past ten years, chemicals legislation in China has been revised to provide for a more comprehensive regulation of chemicals, including a notification system for new chemicals, as well as legislation on the safe management of chemical identified as being hazardous. Legislation from 1994 requiring the registration of the import and export of toxic chemicals was updated in 2009.

In terms of increasing the availability of data on chemicals, the recent implementation of NCSN in China will serve to generate physio-chemical and (eco)toxicity data on new chemicals through the testing requirements, tiered by tonnage for substances produced and on the market at >1 tonne to reflect risk of exposure. Notification is required under the system for all new substances imported or placed on the market, although substances <1 tonne only require a Simple Notification with basic conditions, involving limited requirements for testing. Companies wishing to import or produce new chemicals for export only with tonnage <1 tonne per year, for scientific research with tonnage of 0.1-1 tonne per year and for technological research with tonnage <10 ton per year can apply for a Simple Notification with special conditions, under which no testing is required. The threshold for new substances for technological research qualifying for a Simple Notification with specific conditions is relatively high at up to 10 tonnes, given that there are then no requirements for testing.

New chemical substances used for scientific research with an annual quantity lower than 0.1 tonne must apply for addition to the Scientific Research Record, with no testing requirements. Notably, certain ecotoxicity tests have to be conducted in China by laboratories certified by MEP, which means that companies wishing to import the new substance to China will first have to seek to have their substance added to the Scientific Research Record, import <0.1 tonne for testing and receive test results from the Chinese laboratory for applying for a General Notification.

For new substances subject to a General Notification, a risk assessment report is required. Under the hazard assessment, substances are categorized into general New Chemical Substances, Hazardous New Chemical Substances; and Priority Hazardous New Chemical Substances (substances with PBT properties). The post-notification requirements are then tiered according to the hazard classification of the new substance, with more stringent reporting and risk management requirements in place as hazard increases. Though reporting, MEP will gain a picture of the volumes of hazardous new chemicals produced in the previous year, and for priority hazardous new chemicals, the production volumes planned for the current year, as well as information on the downstream users of these substances. In addition, the legislation sets the requirement for the transfer of information downstream

using safety data sheets and labelling. Enforcement is undertaken by the local environmental protection authorities, including inspections. This remains in the planning stage.

However, it must be emphasized that new data is only being generated and provided to MEP on new chemicals, representing a small fraction of the chemicals produced and on the market in China. Regarding information on existing toxic chemicals being imported into and used in, there are procedures in place for the Registration of import and export of toxic chemicals with MEP under Order No. 113, covering 158 toxic chemicals. The data requirement to register imports and exports are limited, although a Safety Data Sheet is required. Although MEP will have a picture of the toxic chemicals moving in and out of China, no new data is generated.

Order No. 591 on the Regulations on Safe Management of Hazardous Chemicals regulation addresses the production, storage, import, use, sales and transporting of chemicals listed in the Catalogue of Hazardous Chemicals (approx. 3,700 chemicals) is managed by SAWS. SAWS is responsible for issuing licenses to entities wishing to produce, market general chemicals and use hazardous chemicals. Under their application for Safe Use Licenses, the users of hazardous chemicals are required to provide evidence of a range of risk management measures, including emergency procedures, occupational health and safety measures and the presence of relevant trained personnel. There is no specific mention of environmental protection measures; rather the focus is on occupational health and safety. It is not known whether these documents are made public by SAWS.

Order 53 on Measures for the Administration of Registration of Hazardous Chemicals requires that the producers and importers of hazardous chemicals to register with NRCC prior to manufacturing or importation, and sets obligations on producers and user to implement risk management measures. In applying for, a domestic entity must provide a range of information to NRCC, including information on the legal entity, information on the chemical substance, including physico-chemical properties and (eco)toxicology data, processes in which the substance is to be uses and major sources of risk. The registration relies on existing data and does not require the producer or importer to conduct additional testing. The requirements for the registration of imports of hazardous chemicals are enforced by AQSIQ.

In addition, there is a requirement that producers and users of hazardous chemicals obtain an Environment Administrative Registration from MEP. In applying for this, the operators must provide information on hazardous chemicals, including volumes, uses, process methods, as well as environmental risk management measures and measure for the transport and disposal of hazardous waste. In addition, they must provide the results of an environmental impact assessment, an

emergency response and an environmental monitoring report. It is not known whether these documents are made public by MEP.

It is not clear to what extent the different bodies, in particular SWAS and MEP, do or do not share information. In particular, it would be useful for MEP to have access to the data on the intrinsic properties and hazards of hazardous chemicals supplied to SAWS in the registrations under Order No. 53. In terms of gaps in data availability, for existing chemicals that are not currently classified as either toxic (158 chemicals) or hazardous (approx. 3,700 chemicals), there are no requirement to notify to either MEP or SAWS and provide data. With regards to existing chemicals, the onus falls on MEP and SAWS to recognize the hazard classification of substances and add them to the Catalogue of Hazardous Substances. The Catalogue is to be updated in the near future.

In addition, the requirements to register the production of hazardous chemicals to both SAWS and MEP could be streamlined to reduce the administrative burden on the producers of hazardous chemicals. It is possible that the Safe Use License and the Environment Administrative Registration could be integrated, both in the application process and resulting inspections, with data shared between MEP and SAWS.

With regards to GHS in China, the legislation is now in place and the challenges lie with full implementation. Training is required to support compliance and allow industry to gain experience with the system. There is a need for better coordination between the multiple responsible bodies and for enforcement.

Most recently, MEP published the 12th Five-Year Plan for Chemical Environmental Risk Prevention and Control, outlining principles and approaches for the management of chemical risks in China. These include strengthening the chemical notification system, establishing a list of restricted substances for phase-out, based on environmental risk assessment of chemicals, and promoting the use of more eco-friendly technologies to reduce or replace the use of hazardous chemicals or related technologies. In addition, the plan identifies 58 chemical substances and seven industrial sectors for priority management.

In conclusion, China has recently published a range of legislation that has served to significantly tighten and extend its chemicals legislation. The current challenge now lies with implementation and enforcing that legislation. Future challenges are reflected in the goals of the Five-Year Plan, and involve in particular strengthening the notification system to include existing chemicals.

Annex I: Chemicals Management Legislation in China

Category	Regulations
New Chemicals Management	Order No. 7 - The Provisions on Environmental Administration of New Chemical Substances (15 Oct 2010) Inventory of Existing Chemical Substances Produced or Imported in China (IECSC) (updated in 2010)
Existing Chemicals Management - Import and Export of Toxic Chemicals	Provisions on the First Import of Chemicals and the Import and Export of Toxic Chemicals (1994) MEP Notice of Registration of the Import and Export of Toxic Chemicals in China (MEP [2009] 113) List of toxic chemicals severely restricted to be imported into or exported from China (revised in 2011)
Existing Chemicals Management - Hazardous Chemicals	Order 591 – The Regulations on Safe Management of Hazardous Chemicals in China (1 Dec 2011) (Main Law) Measures for The Administration of Registration of Hazardous Chemicals (revised in 2011) Measures for The Administration of Operating Licenses for Hazardous Chemicals (revised in 2011) The Measures for the Administration of Safe Use Permit for Hazardous Chemicals(new in 2011) The Measures for the Administration of Standardization of Management of Hazardous Chemicals(released in Aug 2011) The Catalogueue of Hazardous Chemicals(to be revised in 2011)
Classification, Labelling and SDS	GB 20576 ~ GB 20602-2006 – Safety rules for classification, precautionary labeling and precautionary statements of chemicals GB 13690-2009 - General rules for classification and hazard communication of chemicals GB 15258-2009 – General rules for preparation of precautionary label for chemicals GB 190-2009 - Packaging Labels for Dangerous goods GB/T 16483-2008 - Safety data sheet for chemical products: Content and order of sections
Narcotic Drugs and Drug Precursors	Regulations for Administration of Precursors and Chemicals used in Production of Narcotic Drugs and Psychotropic Substances(2005); Catalogueue of Classification and Types of Precursor Chemicals(2005);
Prohibited Chemicals	The Catalogueue of Commodities Prohibited from Import (The 6th Batch) and the Catalogueue of Commodities Prohibited from Export (The 3rd Batch);
Food Additives	Food Safety Law; The Regulations for Implementation of Food Safety Law. The Measures for The Administration of New Food Additives(revised in 2010) - Order No. 73 of MoH; Administrative Measures for the Manufacture of Food Additivies - Order No. 123 of AQSIQ GB 2760-2011 Food Safety National Standards for the Usage of Food Additives GB 14880-2009 Food Safety National Standards for the Usage of Nutrition Enrichment GB xxxx-xxxx Food Safety National Standards - General Rules for the Labeling of Food Additives(Draft) GB 7718-2011 Food Safety National Standards - General Rules for the Labeling of Prepackaged Foods
Pesticides, Biocides & Disinfectants	Regulation on Pesticide Administration (revised in 2012); Enforcement Measures of the Regulation on Pesticide Administration (Order 9, 2007); Data Requirement on Pesticide Registration (Order 010, 2007); Measures for the Administration of Pesticide Labels and Manuals. Measures on Disinfectant Administration issued by the Ministry of Health (MOH) in 2002; Guidance on Application of Administrative Approval License of Disinfectants and Disinfecting Apparatuses (2006); Administrative licensing procedure for health-related products(2006);
Cosmetics and Cosmetic Ingredients	Regulations concerning the hygiene supervision over cosmetics(1990); Detailed Rules for the Implementation of the Regulation on the Hygiene Supervision over Cosmetics(2005); Hygienic Standard for Cosmetics(2007) The Measures for the Administration of Hygiene License for Cosmetics (revised in 2010); Guideline for Risk Evaluation of Substances with Possibility of Safety Risk in Cosmetics(2010); Standard Chinese Names of International Cosmetics Ingredients Inventory (2010); Cosmetics Technical Requirement Standard(2011); Guidelines for the Registration and Evaluation of New Cosmetic Ingredient(2011);
Occupational Exposure Limits & Protection	GBZ 2.1-2007 - Occupational exposure limits for hazardous agents in the workplace. Regulation on the Labor Protection in Workplaces Handling Toxic Materials;
Transportation of Dangerous Goods	GB 6944-2012 - Classification and code of dangerous goods Gb 12268-2012 -List of dangerous goods

Annex II: Notification Data Requirements by Tonnage Band

Data requirements for substances produced or on the market at 1-10 tonnes		
Qualitative and quantitative identification of the notified substance		
IR	GC	
UV	GPC	
NMR	ICP-AES	
MS	XRD	
HPLC	AAS	
Physico-chemical Properties Testing		
1	Melting Point (solid)	
2	Boiling Point (liquid)	
3	Density (solid, liquid)	
4	Vapor Pressure (liquid)	
5	Partition coefficient n-octanol/water (solid, liquid)	
6	Water solubility (solid, liquid)	
7	Surface tension (liquid)	
8	PH value (liquid)	
9	Flash point (liquid)	
10	Granulometry / Particle size (solid)	
11	Oxidizing properties (solid, liquid, gas)	
12	Self-ignition temperature (solid, liquid, gas)	
13	Flammability (solid, liquid, gas)	
14	Explosive properties (solid, liquid)	
15	Explosive limit (gas)	
16	Critical point (gas)	
Toxicology Properties Testing		
10	Acute toxicity by oral	
11	Acute toxicity by dermal	
12	Acute toxicity by inhalation	
13	Skin irritation or skin corrosion	
14	Eye irritation	
15	Skin sensitization	
16	Repeated dose 28-day toxicity study (At least one study of the three exposure routes must be provided according to the use of the substance)	by oral
		by dermal
		by inhalation
17	Mutagenicity	Bacterial reverse mutation test (Ames)
18	In vitro mammalian chromosome aberration test	
Eco-toxicology Properties Testing		
19	Algae growth inhibition study	
20	Acute toxicity study with Daphnia magna	
21	Acute toxicity study with Brachydanio rerio (The study should be conducted in China)	
22	Activated sludge respiration inhibition testing	
23	Adsorption/desorption properties	
24	Ready biodegradability (The study should be conducted in China)	
25	Earthworm, acute toxicity test	

Data requirements for substances produced or on the market at 10-100 tonnes	
Qualitative and quantitative identification of the notified substance	
IR	GC
UV	GPC
NMR	ICP-AES
MS	XRD

HPLC	AAS	
Physico-chemical Properties Testing		
1	Melting Point (solid)	
2	Boiling Point (liquid)	
3	Density (solid, liquid)	
4	Vapor Pressure (liquid)	
5	Partition coefficient n-octanol/water (solid, liquid)	
6	Water solubility (solid, liquid)	
7	Surface tension (liquid)	
8	PH value (liquid)	
9	Flash point (liquid)	
10	Granulometry / Particle size (solid)	
11	Oxidizing properties (solid, liquid, gas)	
12	Self-ignition temperature (solid, liquid, gas)	
13	Flammability (solid, liquid, gas)	
14	Explosive properties (solid, liquid)	
15	Explosive limit (gas)	
16	Critical point (gas)	
Toxicology Properties Testing		
10	Acute toxicity by oral	
11	Acute toxicity by dermal	
12	Acute toxicity by inhalation	
13	Skin irritation or skin corrosion	
14	Eye irritation	
15	Skin sensitization	
16	Repeated dose 28-day toxicity study (At least one study of the three exposure routes must be provided according to the use of the substance)	by oral
		by dermal
		by inhalation
17	Repeated dose 90-day toxicity study (At least one study of the three exposure routes must be provided according to the use of the substance)	by oral
		by oral
		by dermal
18	Mutagenicity	Bacterial reverse mutation test (Ames)
19	Mutagenicity	In vitro mammalian chromosome aberration test
20	Mutagenicity	Rodent Bone marrow chromosome aberration test or micronucleus test
21	Screening for reproductive/developmental toxicity	
22	Toxicokinetics (Absorption)	
Eco-toxicology Properties Testing		
23	Algae growth inhibition study	
24	Acute toxicity study with Daphnia magna	
25	Acute toxicity study with Brachydanio rerio (The study should be conducted in China)	
26	Activated sludge respiration inhibition testing	
27	Adsorption/desorption properties	
28	Degradation	Ready biodegradability (The study should be conducted in China)
29	Degradation	Inherent Biodegradability (The study should be conducted in China)
30	Degradation	Hydrolysis test with PH function
31	Earthworm, acute toxicity test	
32	14 days extended toxicity study in fish, (The study should be conducted in China)	
33	Daphnia magna Reproduction study	
34	Bioaccumulation in aquatic species, preferably fish	

Data requirements for substances produced or on the market at 100-1000 tonnes

Qualitative and quantitative identification of the notified substance		
IR	GC	
UV	GPC	
NMR	ICP-AES	
MS	XRD	
HPLC	AAS	
Physico-chemical Properties Testing		
1	Melting Point (solid)	
2	Boiling Point (liquid)	
3	Density (solid, liquid)	
4	Vapor Pressure (liquid)	
5	Partition coefficient n-octanol/water (solid, liquid)	
6	Water solubility (solid, liquid)	
7	Surface tension (liquid)	
8	PH value (liquid)	
9	Flash point (liquid)	
10	Granulometry / Particle size (solid)	
11	Oxidizing properties (solid, liquid, gas)	
12	Self-ignition temperature (solid, liquid, gas)	
13	Flammability (solid, liquid, gas)	
14	Explosive properties (solid, liquid)	
15	Explosive limit (gas)	
16	Critical point (gas)	
Toxicology Properties Testing		
10	Acute toxicity by oral	
11	Acute toxicity by dermal	
12	Acute toxicity by inhalation	
13	Skin irritation or skin corrosion	
14	Eye irritation	
15	Skin sensitization	
16	Repeated dose 28-day toxicity study (At least one study of the three exposure routes must be provided according to the use of the substance)	by oral
		by dermal
		by inhalation
17	Repeated dose 90-day toxicity study (At least one study of the three exposure routes must be provided according to the use of the substance)	by oral
		by oral
		by dermal
18	Mutagenicity	Bacterial reverse mutation test (Ames)
19	Mutagenicity	In vitro mammalian chromosome aberration test
20	Mutagenicity	Rodent Bone marrow chromosome aberration test or micronucleus test
21	Reproductive/developmental toxicity	Aberration Test
		Two-generation reproductive toxicity study
22	Toxicokinetics (Whole)	
Eco-toxicology Properties Testing		
23	Algae growth inhibition study	
24	Acute toxicity study with Daphnia magna	
25	Acute toxicity study with Brachydanio rerio (The study should be conducted in China)	
26	Activated sludge respiration inhibition testing	
27	Adsorption/desorption properties	
28	Degradation	Ready biodegradability (The study should be conducted in China)
29	Degradation	Inherent Biodegradability (The study should be conducted in China)
30	Degradation	Hydrolysis test with PH function
31	Earthworm, acute toxicity test	

32	14 days extended toxicity study in fish, (The study should be conducted in China)	
33	Daphnia magna Reproduction study	
34	Bioaccumulation in aquatic species, preferably fish	
35	Chronic toxicity test in fish (in China), at least one of the three)	Fish Early life-stages Toxicity Test
		Fish short-term toxicity test on embryo and sac-fry stages
		Fish larvae growth tests
36	Seed Germination/Root Elongation Toxicity Test	

Data requirements for substances produced or on the market at 1000+ tonnes

Qualitative and quantitative identification of the notified substance		
IR	GC	
UV	GPC	
NMR	ICP-AES	
MS	XRD	
HPLC	AAS	
Physico-chemical Properties Testing		
1	Melting Point (solid)	
2	Boiling Point (liquid)	
3	Density (solid, liquid)	
4	Vapor Pressure (liquid)	
5	Partition coefficient n-octanol/water (solid, liquid)	
6	Water solubility (solid, liquid)	
7	Surface tension (liquid)	
8	PH value (liquid)	
9	Flash point (liquid)	
10	Granulometry / Particle size (solid)	
11	Oxidizing properties (solid, liquid, gas)	
12	Self-ignition temperature (solid, liquid, gas)	
13	Flammability (solid, liquid, gas)	
14	Explosive properties (solid, liquid)	
15	Explosive limit (gas)	
16	Critical point (gas)	
Toxicology Properties Testing		
10	Acute toxicity by oral	
11	Acute toxicity by dermal	
12	Acute toxicity by inhalation	
13	Skin irritation or skin corrosion	
14	Eye irritation	
15	Skin sensitization	
16	Repeated dose 28-day toxicity study (At least one study of the three exposure routes must be provided according to the use of the substance)	by oral
		by dermal
		by inhalation
17	Repeated dose 90-day toxicity study (At least one study of the three exposure routes must be provided according to the use of the substance)	by oral
		by oral
		by dermal
18	Mutagenicity	Bacterial reverse mutation test (Ames)
19	Mutagenicity	In vitro mammalian chromosome aberration test
20	Mutagenicity	Rodent Bone marrow chromosome aberration test or micronucleus test
21	Reproductive/developmental toxicity	Aberration Test
22	Reproductive/developmental toxicity	Two-generation reproductive toxicity study
23	Toxicokinetics (Whole)	
24	Chronic toxicity study (At least one study of the three exposure routes	By oral
		By dermal

	must be provided according to the use of the substance	By inhalation
25	Carcinogenicity study	
Eco-toxicology Properties Testing		
26	Algae growth inhibition study	
27	Acute toxicity study with Daphnia magna	
28	Acute toxicity study with Brachydanio rerio (The study should be conducted in China)	
29	Activated sludge respiration inhibition testing	
30	Adsorption/desorption properties	
31	Degradation	Ready biodegradability (The study should be conducted in China)
32	Degradation	Inherent Biodegradability (The study should be conducted in China)
33	Degradation	Hydrolysis test with PH function
34	Earthworm, acute toxicity test	
35	14 days extended toxicity study in fish, (The study should be conducted in China)	
36	Daphnia magna Reproduction study	
37	Bioaccumulation in aquatic species, preferably fish	
38	Chronic toxicity test in fish - at least one of the three (conducted in China)	Fish Early life-stages Toxicity Test
		Fish short-term toxicity test on embryo and sac-fry stages
		Fish larvae growth tests
39	Seed Germination/Root Elongation Toxicity Test	


União Europeia


DIÁLOGOS SETORIAIS
UNIÃO EUROPEIA BRASIL


Ministério do
Planejamento


GOVERNO FEDERAL
BRASIL
PAÍS RICO É PAÍS SEM POBREZA