

DISCLAIMER

Measures on the Environmental Management of New Chemical Substances, China or 'China REACH' is a new piece of chemical legislation that regulates new chemicals in China. The new regulation was published on January 19th 2010 and it was enacted into Law on the 15th of October 2010 and is currently being enforced.

Published by the Ministry of Environmental Protection of the People's Republic of China, this new chemical regulation affects all chemical companies manufacturing in China or exporting new chemicals into China.

This document is a translated copy of the *Measures on the Environmental Management of New Chemical Substances, China*, (hereinafter 'Measures'). This document should be used as a reference only, in case of any discrepancy between the English and Chinese versions, the Chinese version shall prevail.

RCS has undertaken to translate the full Chinese legal text to help Non-Chinese companies understand and comply with obligations arising from this new chemical legislation.

RCS reserves the right of final explanation for this document. Industry should refer to the Ministry of Environmental Protection for any further legal explanation.

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Measures on the Environmental Management of New Chemical Substances, China

1. General Provisions

Article (1) Aim

The purpose of the Measures outlined below is to control the risk that new chemical substances pose to the environment, to ensure public health and safety and to protect the environment. These Measures are established according to the 'Decision of the State Council on Establishing Administrative License for the Administrative Examination and Approval Items Really Necessary To Be Retained' and other relevant legislations and administrative regulations.

Article (2) Scope

The Measures are applicable to environmental management of the activities regarding research, manufacture, import, process and use of new chemical substances within the territory of the People's Republic of China. The Measures are also applicable to environmental management of the new chemical substances activities within the Bonded Zones and Export Processing Zones.

The management of pharmaceuticals, pesticides, veterinary medicine, cosmetics, food additives, feed additives etc. shall comply with other relevant laws and regulations. However, environmental risk management for the new chemical substances used as raw materials and intermediates for the production of the aforementioned products shall comply with the Measures.

The new chemical substances contained in articles which are intended to be released under normal or reasonably foreseeable conditions of use, shall also comply with the Measures.

Article (3) Classification

In accordance with the chemicals hazardous properties identification and classification standards, new chemical substances are classified into general new chemical substances and hazardous new chemical substances.

Hazardous new chemical substances which are present with persistent, bioaccumulative, environmental and human health hazard properties are determined as hazardous new chemicals of priority environmental concern.

'New chemical substances' mentioned in the Measures refer to chemical substances that are not listed in the Chinese Inventory of Existing Chemical Substances (IECSC).

The Chinese Inventory of Existing Chemical Substances is established, adjusted and published by the Ministry of Environmental Protection (hereinafter MEP).

Article (4) Main Systems

The State shall implement the risk control management system, notification and registration system, and follow-up control system for new chemical substances.

Article (5) Registration Certificate

In accordance with the Measures, prior to production or import of the new chemical substances, the producer or importer shall apply for the registration certificates for environmental management of new chemical substances (hereinafter 'registration certificates').

New chemical substances shall not be produced, imported and processed unless the registration certificates have already been obtained.

New chemical substances shall not be used for scientific research unless registration certificates are obtained or record notification is applied.

Article (6) Promotion of Advanced Technology

The State supports environment and human health risk assessment and risk management of new chemical substances, promotes advanced environmental risk control technology of new chemical substances, encourages environment-friendly alternative technology for chemical research, production, import and processing, and encourages applicants to share registration data of new chemical substances.

Article (7) Confidentiality

Any authorities and personnel involved in the environmental management of new chemical substances shall always maintain confidentiality and keep confidential the commercial and technical information submitted by the applicants.

Article (8) Public Supervision

All companies and individuals have the right to expose, report and allege any violation of the Measures.

2. Notification Procedure

Article (9) Type of Notification

Notification of new chemical substances can be classified into regular notification, simplified notification and scientific research record notification.

Article (10) Regular Notification

The applicant, prior to the production or import of new chemical substances in quantities of 1 tonne or more per year, shall submit new chemical substance regular notification to the Chemical Registration Centre (hereinafter 'CRC') of the MEP. The applicant may apply for simplified notification in cases fulfilling the requirements of simplified notification.

The contents of notification report shall include:

- (1) Regular notification form of the new chemical substances, attached with classification, labelling and material safety data sheet which are in accordance with relevant national standards for chemicals classification, precautionary labeling and precautionary statements;
- (2) Risk assessment report, including the hazard assessment, exposure assessment, the risk management measures and the conclusion of environmental hazard and human health hazard assessment.
- (3) The testing report or documents of the physical-chemical properties, toxicological and eco-toxicological characteristics, and quality certificates issued by the testing organizations. The eco-toxicological data of the new chemical substances shall include the testing data acquired from the tests performed in the territory of China, using Chinese organisms in accordance with provisions of relevant standards.

Article (11) Tonnage Rank of Regular Notification

The regular notification shall comply with the principles of 'the higher volume rank, the more testing data required'. The applicant shall submit relevant test data or information according to the guidelines on the notification and registration of the new chemical substances developed by the MEP.

With regard to the notification volume of the new chemical substances, regular notification can be divided into four ranks:

- (1) First rank: production or import reaching 1 tonne or more and less than 10 tonnes per year.
- (2) Second rank: production or import reaching 10 tonnes or more and less than 100 tonnes per year.
- (3) Third rank: production or import reaching 100 tonnes or more and less than 1000 tonnes per year.
- (4) Fourth rank: production or import reaching 1000 tonnes or more per year.

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