



New Chemical Substance Notification Guidance (Draft)

新化学物质申报登记指南（征求意见稿）

China Ministry of Environmental Protection (MEP)

Translated by ChemLinked

2015/06

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Ministry of Environmental Protection of the People's Republic of China

June 2015

Preface

This guidance document has been compiled according to Article 11 of the ‘Measures on the Environmental Management of New Chemical Substances’ (Decree No. 7 of the Ministry of Environmental Protection of the P. R. China, hereinafter referred to as the ‘Measures’) in order to standardize the notification of new chemical substances and guide the notifier in completing the notification of new chemical substances.

The guidance document is focused on the notification procedures and categories. The guidance specifically addresses the management scope, contents of notification materials, notification format, data requirements as well as the post-notification requirements, etc. from six aspects of the Measures, including the applicable scope, notification types and submission format, notification procedures, application material requirements, special provisions for polymers and the supervision and management after notification.

The notifiers should according to the requirements of the guidance complete new chemical substance notifications, implement risk control measures and assist in the supervision and management of the new chemical substances. The test institutes which provide testing data for new chemical substance notification, the evaluation committee who technically review the new chemical substance notification, and the local environmental protection departments of all levels responsible for the supervision and management of new chemical substances should according to the requirements of the guidance carry out related tasks. The Solid Waste and Chemicals Management Center, MEP (SCC-MEP) are responsible for the technical review of the relevant notification materials, regulating and guiding the technical quality, etc.

This version is the first revision of the “New Chemical Substance Notification Guidance” released by the Ministry of Environmental Protection of the P. R. China in 2010 ([2010]124).

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I Applicable Scope of New Chemical Substance Notification

A. Applicable Chemical Substances

1. Substances Requiring Notification

Any chemical substance that is not included in the 'Inventory of Existing Chemical Substances in China' (hereinafter referred to as the 'IECSC'), is considered to be a new chemical substance.

A new chemical substance notification shall be performed in accordance with the 'Measures on the Environmental Management of New Chemical Substances' (Decree No. 7 of the Ministry of Environmental Protection of the P. R. China, hereinafter referred to as the 'Measures') prior to the manufacture or import of the new chemical substance.

New chemical substances used as raw materials or intermediates in the production of pharmaceuticals, pesticides, veterinary medicine, cosmetics, foodstuffs, food additives, feed additives etc., shall comply with the Measures.

The Measures apply to all new chemical substances contained in surfactants, plasticizers, preservatives, dispersing agents, flame retardants and other intermediate products or products with specific functions, irrespective of their concentration.

The Measures also apply to new chemical substances of variable composition and complex reaction products, etc. without unique structural formulae and new polymers.

2. Categories of Exemption

The Measures do not apply to the following categories of chemicals, finished products or chemical substances:

(1) Finished products covered by other laws and regulations

For example: pharmaceuticals, pesticides, veterinary medicines, cosmetics, foodstuffs, food additives, feed and feed additives, fertilizers, radioactive materials, military products, explosives, tobacco etc.

(2) Naturally occurring substances

- (i) Unprocessed substances or substances processed only by manual, mechanical or gravitational methods, or by water dissolution, water flotation or thermal dehydration, etc;
- (ii) Substances extracted from air by all methods;
- (iii) Naturally occurring polymers that have not been chemically modified;

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