

New Chemical Substance Notification Guidance (Draft)

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

China MEP notified the Committee on Technical Barriers to Trade under World Trade Organization (WTO) this draft guidance ([G/TBT/N/CHN/1170](#)) on 8 Mar 2016.

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.

Chemical substances subject to the relevant management of the above mentioned laws and regulations (such as TCs and APIs, etc.), except those used for other industrial use.

(2) Naturally occurring substances

(i) Unprocessed substances or substances processed only by manual, mechanical or gravitational

The 2% principle refers to the polymer nomenclature guidelines for which the naming of the polymer is based on its starting monomers and reactants, namely:

- (1) The name of the polymer should indicate all the monomers or reactants in the name present in the polymer over a concentration of 2% (w/w).
- (2) Monomers or reactants present in a concentration of less than or equal to 2% (w/w) are not required to be indicated in the polymer name.

For example, for the monomers (w/w) which polymerize as: M1 (35%), M2 (28%), M3 (15%), M4 (12%), M5 (5%), M6 (1.5%); with reaction initiators or end-capping agents (w/w): R1 (2.2%), R2 (1.3%); and with additives: A1 and A2. The polymer name may thus have the following three names:

- (i) Polymer name 1: Polymer of M1 with M2, M3, M4, M5 and M6, initiated or terminated by R1 and R2
- (ii) Polymer name 2: Polymer of M1 with M2, M3, M4 and M5, initiated or terminated by R1 and R2
- (iii) Polymer name 3: polymer of M1 with M2, M3, M4 and M5, initiated or terminated by R1.

Explanation:

- The percentage molecular weight concentration of M6 and R2 are both less than 2% and therefore may be omitted from the name of the polymer;
- All three names shown above are acceptable as the polymer name, however notifiers can only notify using one of the names. Other names shall be regarded as other new chemical substances;
- Additives that are not incorporated in the polymer structure should not appear in the name of polymer, but should be included in the list of monomers/reactants;
- The change of monomer or reactant concentration of the monomers or reactants included in the name of already notified polymers is permitted;
- The monomers or reactants included in the name of previously notified polymers may not be altered, appended or deleted.

B. Requirements for Simplified Notification of Polymers

1. Polymers Containing Monomers as New Substances with Concentration <2%

If a polymer itself is not included in the IECSC but contains one or more new chemical substance monomers/reactants present in $\leq 2\%$ (w/w) concentration, then this polymer can be notified by simplified notification.

If a polymer itself is not included in the IECSC but all monomers or reactants are included, or the new chemical monomers/reactants of which the concentration $> 2\%$ (w/w) have acquired regular notification certificate, then this polymer can be notified by simplified notification.

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