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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 standardise the notification of new chemical substances and guide the notifier in completing the notification of new chemical substances.

The focus of this guidance document is on the notification procedures and categories. The guidance specifically addresses the six aspects of the Measures which are: the scope of application, notification types and submissions, notification procedure for registration, application material requirements, special provisions for polymers and the supervision and management of the registration following notification. It also describes the notification application report content, notification submission and data requirements as well as the post-registration requirements.

The main parties the guidance document is addressed to are the new chemical substance notifiers or representative agents. The notifiers or representative agents should adhere to the requirements of the guidance in order to complete new chemical substance notifications, to implement the post-registration risk control measures and to assist in the supervision and management of the new chemical substances.

The guidance document can also be consulted by the test institutes which provide the new chemical substance notification testing data and the evaluation committee who technically review the new chemical substance notification. It can also be consulted by local environmental protection branches of all levels that supervise new chemical substance management.

If required, the guidance shall be amended for practical administration purposes in a timely manner.

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New Chemical Substance Notification Guidance Document

1. Applicable Scope of New Chemical Substance Notification

(1) 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 and intermediates in the production of pharmaceuticals, pesticides, veterinary medicine, cosmetics, 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, complex reaction products without unique structural formulae and polymers.

2. Categories of Exemption

The Measures do not apply to the following categories of chemicals, preparations 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, 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 displacement or thermal dehydration etc.;
- (ii) Substances extracted from air by all methods;
- (iii) Naturally occurring polymers that have not been chemically modified;
- (iv) Living matter, such as DNA, RNA, proteins etc. and other biological macromolecules;

(3) Categories of non-commercial or non-intentional production

- (i) Impurities: Produced as an unintended constituent in a substance during manufacturing, likely originating from the starting raw material or the result of secondary or incomplete reactions during the manufacturing process. If the impurity or impurities are unintentionally present in the final substance, single impurities are acceptable below 10% (w/w) concentration but the total impurities shall not exceed 20% (w/w) concentration of the chemical substance.
- (ii) Chemical substances produced by chemical reaction, in particular:
 - a) Chemical substances which result from a chemical reaction that occurs due to incidental exposure to a chemical or other substance, or due to environmental factors (such as air, moisture, micro-organism, sunlight or other exposure);
 - b) Chemical substances which result from incidental chemical reactions with other chemical substances, preparations or articles during storage;
 - c) Chemical substances which are produced from uninitiated chemical reactions during the final usage of other substances, preparations or articles.
- (iii) Waste products and by-products produced from chemical reactions of water, gas, and solid waste.

The above categories exclude commodities placed on the market or produced intentionally which are produced by the above means.

(4) Other Special Categories

- (i) Materials: Glass materials, glass frit, ceramic materials and wares, steel and its products, high alumina cement, Portland cement etc.
- (ii) Alloys: Alloys are defined as homogeneous and heterogeneous solids or liquids consisting of a mixture of two or more kinds of metals, or a mixture of one kind of metal and other non-metallic compounds. This category excludes intermetallic compounds.
- (iii) Non-isolated intermediates: An intermediate is a substance, produced in one reaction step which is then consumed in the next reaction step, which is thus transformed into another substance or product during the complete reaction process. Therefore, intermediates should not be present in the final chemical substance or product, except as impurities.

A non-isolated intermediate is an intermediate which is not intentionally removed from the reaction vessel or device. This also includes the temporary transfer of it into another reaction vessel after a reaction step, and the subsequent use in the next reaction step in the same work area.

The Measures apply to intermediates but do not apply to non-isolated intermediates.

(iv) Articles

For products to be classified as articles, they should meet all of the following three requirements:

- a) Possess a specific shape or design formed during manufacture.

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