



Guidance on Environmental Management Registration of New Chemical Substances (Draft)

新化学物质环境管理登记指南（征求意见稿）

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Annex 1

Guidance on the Environmental Management Registration of New Chemical Substances

(Consultation Draft)

**Ministry of Ecology and Environment of the
People's Republic of China**

XX XX, 2020

Preface

The Guidance is compiled according to Article 6 of the *Measures for the Environmental Management Registration of New Chemical Substances* (Order No. 12 of the Ministry of Ecology and Environment of the P. R. China, hereinafter referred to as the *Measures*) in order to standardize the environmental management registration of new chemical substances, guide the applicants and the presentative agents in completing the environmental management registration of new chemical substances and fulfil responsibilities and obligations as specified in the *Measures*.

The Guidance is a supporting normative document for the implementation of the *Measures*, which details the relevant provisions of the *Measures* and specifies the implementation requirements. The Guidance mainly includes the scope of registration, registration types, registration procedure, requirements for registration application materials, special provisions for polymers, and new usage registration for environmental management, re-registration, change, withdrawal and revocation of registration certificate, and tracking management after registration.

The Guidance shall primarily be applicable to the applicants and the representative agents of new chemical substances, who shall according to the requirements of the *Measures* and the Guidance carry out environmental management registration of new chemical substances, implement tracking management requirements and take effective measures to prevent and control the environmental risks of new chemical substances. Processors and users of new chemical substances shall implement environmental risk control measures and environmental management requirements.

The Guidance will be revised in due course according to the actual management needs.

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Guidance on the Environmental Management Registration of New Chemical Substances

I. Environmental Management Registration Scope of New Chemical Substances

(I) Scope of substances subject to registration

1. Substances subject to registration

Chemical substances or products that conform to the following provisions shall be subject to environmental management registration of new chemical substances:

- (1) New chemical substances, which are not listed in the *Inventory of Existing Chemical Substances of China* (hereinafter referred to as the *IECSC*);
- (2) Chemical substances subject to new usage registration for environmental management, which have been listed into the *IECSC* and subject to new usage environmental management, and are used for industrial applications other than the permitted uses;
- (3) New chemical substances contained in surfactants, plasticizers, preservatives, dispersants, flame retardants and other products with specific functions, or their preparations;
- (4) New chemical substances contained in articles and intended to release under normal conditions of use;
- (5) Chemical substances of variable composition and complex reaction products, etc. without unique and with uncertain molecular structure, intermetallic compounds and polymers, which belong to new chemical substances;
- (6) New chemical substances that are intermediates other than non-isolated intermediates;
- (7) New chemical substances that are pharmaceuticals (including active pharmaceutical ingredients), pesticides (including pesticide technical), veterinary drugs, cosmetics, food, food additives, feed, feed additives, fertilizers and other products that are to be used in other industrial applications, and those used as raw materials or intermediates for production of the aforementioned products.

2. Inapplicable categories

The *Measures* does not apply to the following chemical substances or products, for which the environmental management registration of new chemical substances is not required:

- (1) Pharmaceuticals (including active pharmaceutical ingredients), pesticides (including pesticide technical), veterinary drugs, cosmetics, food, food additives, feed, feed additives, fertilizers and other products;
- (2) Radioactive materials.

3. Categories of exemption

Chemical substances or products that conform to the following requirements are exempt from the environmental management registration of new chemical substances.

(1) Naturally occurring substances

- 1) Unprocessed substances or substances physically processed only by manual, mechanical or gravitational means, or by dissolution in water, by flotation or by heating solely to remove water, *etc.*;
- 2) Substances extracted from air by any means;
- 3) Natural polymers that have not been chemically processed;
- 4) Living substances that have not been chemically processed to change their chemical structures, such as ribonucleic acid, deoxyribonucleic acid, proteins and other biomacromolecules.

(2) Non-commercial or non-intentional produced substances



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Free trial



Standard



Corporate



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