



Guidance on Environmental Management Registration of New Chemical Substances

新化学物质环境管理登记指南

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Annex 1

Guidance on the Environmental Management Registration of New Chemical Substances

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

November 17, 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, the representative agents and the processors and users of new chemical substances. The applicants and the representative agents 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

New chemical substances refer to chemical substances that are not listed in the Inventory of Existing Chemical Substances of China (hereinafter referred to as the IECSC). For chemical substances that have been listed into the IECSC and subject to new usage environmental management, they are subject to environmental management as new chemical substances if they are used for industrial applications other than the permitted uses.

New chemical substances are subject to environmental management registration of new chemical substances prior to manufacture or import according to the Measures.

New chemical substances, whether in the form of pure substances or mixture components, fall under the scope of registration.

Chemical substances of variable composition and complex reaction products, etc. without unique and with uncertain molecular structure, and polymers, if identified as new chemical substances, fall under the scope of registration.

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 (including active pharmaceutical ingredients), cosmetics, food, food additives, feed, feed additives, fertilizers, etc.;

However, for aforementioned products that are intended to be used in other industrial applications, and those used as raw materials or intermediates for production of the aforementioned products, if identified as new chemical substances, the Measures shall apply.

(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

1) Impurities, which do not contribute to product functions, may come from raw materials or secondary or



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