

The Guidelines for Hazard Identification of New Chemical Substances

Disclaimer

26 September 2011, The Ministry of Environmental Protection (MEP) of China published two drafts for the Guidelines for Risk Assessment of Chemicals and Guidelines for Hazard Identification of New Chemical Substances and consulted publically for comments.

These documents are essential standards that provide guidance to enable fulfillment of the regular notification requirements of China New Chemical Substance Notification (China NCSN) - Measures on Environmental Management of New Chemical Substances. In line with the guidance of China NCSN, the minimum requirements for regular notification include physicochemical, toxicological and eco-toxicological test reports and a risk assessment report.

This document is a translated copy of “The Guidelines for Hazard Identification of New Chemical Substances, *China*”. This document should be used as a reference only, in case of any discrepancy between the English and Chinese versions, the Chinese version shall prevail.

REACH24H Consulting Group has undertaken to translate the full Chinese legal text to help Non-Chinese companies understand and comply with obligations arising from this new chemical legislation.

REACH24H Consulting Group reserves the right of final explanation for this document. Industry should refer to the Ministry of Environmental Protection for any further legal explanation.

Nondisclosure: The document provided by Chemlinked is only accessible for the individual Standard Membership subscribers, while the Cooperate Members can grant the access to their colleagues in one organization (with the same corporate email address).

Note: The translated English texts of the China National/Industrial Standards contained in this publication are for scientific research purpose only. If any user intends to use the standards for commercial purposes, he/she should purchase the official version or contact REACH24H for help. The eBook does not include regulations and standards promulgated by Hong Kong, Macao and Taiwan.

For further clarification and questions, please contact us:

info@reach24h.com

Contents

Preface	4
1. Applicable Scope	5
2. Normative References	5
3. Terms and Definitions	6
4. General Principles.....	7
5. Methods of Hazard Identification	7
6. Environmental Management Categories	21

Preface

The Guidelines were compiled in order to implement the Environmental Protection Law of the People's Republic of China, to protect the environment, to protect human health and standardize the work of hazard identification for new chemical substances.

The Guidelines primarily specified the methods and procedures to identify the physical hazards, health hazards and environmental hazards of new chemical substances, as well as the regulatory requirements and classification methods of environmental management category.

The Guidelines were originally published in 2004 and have been revised for the first time. They were originally drawn up by the Chemical Registration Center of the Ministry of Environmental Protection, Chinese Research Academy of Environmental Sciences and Peking University Health Science Center.

Based mainly on the technical provisions in the *Safety rules for classification, precautionary labelling and precautionary statements of chemicals* (GB 20576 - GB 20599, GB 20601 and GB 20602), the regulatory requirements for new chemical substance notification and data evaluation provided in the supporting technical document of MEP Decree No. 7 *Measures on the Environmental Management of New Chemical Substances*, the *New Chemical Substance Notification Guidance Document*, these Guidelines have made several revisions and additions as follows:

- Revising and expanding the applicable scope;
- Incorporating some normative references;
- Adding and annulling several terminologies;
- Adjusting the general principles;
- Adjusting and partly revising the physico-chemical properties assessment, toxicology assessment and eco-toxicology assessment, which have been included in the hazard identification section of the Guidelines;
- Adding classification rules for the environmental management category of new chemical substances.

The former *Guidelines for Hazard Assessment of New Chemical Substances* (HJ/T 154-2004) will be annulled from the date of the implementation of the new Guidelines. The Guidelines were drawn up by the Department of Science, Technology and Standards under the Ministry of Environmental Protection. The Guidelines were mainly compiled by the Chinese Research Academy of Environmental Sciences. The Guidelines have been approved by the Ministry of Environmental Protection on _____(date/month/year). The Guidelines will enter into force on _____(date/month/year). The Guidelines shall be interpreted and administered by the Ministry of Environmental Protection, China.

1. Applicable Scope

The Guidelines specifies the methods and procedures to identify the physical-chemical, health and environmental hazards of new chemical substances, as well as the regulatory requirements and classification methods of environmental management category.

The Guidelines apply to the experts of the review committee during China New Chemical Substance Notification (China NCSN) and the self-assessments made by China NCSN notifiers.

2. Normative References

The Guidelines have referred to provisions in the following national standards (for undated references, only the most recent valid versions shall be applied to the Guidelines):

GB 20576	Safety rules for classification, precautionary labelling and precautionary statements of chemicals – Explosives
GB 20577	Safety rules for classification, precautionary labelling and precautionary statements of chemicals – Flammable gases
GB 20578	Safety rules for classification, precautionary labelling and precautionary statements of chemicals – Flammable aerosols
GB 20579	Safety rules for classification, precautionary labelling and precautionary statements of chemicals – Oxidizing Gases
GB 20580	Safety rules for classification, precautionary labelling and precautionary statements of chemicals – Gases under pressure
GB 20581	Safety rules for classification, precautionary labelling and precautionary statements of chemicals – Flammable liquids
GB 20582	Safety rules for classification, precautionary labelling and precautionary statements of chemicals – Flammable solids
GB 20583	Safety rules for classification, precautionary labelling and precautionary statements of chemicals – Self-reactive substances
GB 20584	Safety rules for classification, precautionary labelling and precautionary statements of chemicals – Self-heating substances
GB 20585	Safety rules for classification, precautionary labelling and precautionary statements of chemicals – Pyrophoric liquids
GB 20586	Safety rules for classification, precautionary labelling and precautionary statements of chemicals – Pyrophoric solids
GB 20587	Safety rules for classification, precautionary labelling and precautionary statements of chemicals – Substances which, when in contact with water, emit flammable gases
GB 20588	Safety rules for classification, precautionary labelling and precautionary statements of chemicals – Corrosive to metals
GB 20589	Safety rules for classification, precautionary labelling and precautionary statements of chemicals – Oxidizing liquids
GB 20590	Safety rules for classification, precautionary labelling and precautionary statements of chemicals – Oxidizing solids
GB 20591	Safety rules for classification, precautionary labelling and precautionary statements of chemicals – Organic peroxides

GB 20592	Safety rules for classification, precautionary labelling and precautionary statements of chemicals – Acute toxicity
GB 20593	Safety rules for classification, precautionary labelling and precautionary statements of chemicals – Skin corrosion/irritation
GB 20594	Safety rules for classification, precautionary labelling and precautionary statements of chemicals – Serious eye damage/eye irritation
GB 20595	Safety rules for classification, precautionary labelling and precautionary statements of chemicals – Respiratory or skin sensitization
GB 20596	Safety rules for classification, precautionary labelling and precautionary statements of chemicals – Germ cell mutagenicity
GB 20597	Safety rules for classification, precautionary labelling and precautionary statements of chemicals – Carcinogenicity
GB 20598	Safety rules for classification, precautionary labelling and precautionary statements of chemicals – Reproductive toxicity
GB 20599	Safety rules for classification, precautionary labelling and precautionary statements of chemicals – Specific target organ system toxicity- Single exposure
GB 20601	Safety rules for classification, precautionary labelling and precautionary statements of chemicals - Specific target organ system toxicity- Repeated exposure
GB 20602	Safety rules for classification, precautionary labelling and precautionary statements of chemicals – Hazardous to the aquatic environment
GB/T24782	Decision method of persistent, bioaccumulative and toxic substances, and very persistent and very bioaccumulative substances
HJ/T153	The guidelines for the testing of chemicals
HJ/T155	The guidelines of chemical testing according to Good Laboratory Practice
HJ □□□	The guidelines for risk assessment of chemicals (at drafting stage)
Decree No.7	Measures on the Environmental Management of New Chemical Substances

3. Terms and Definitions

The following terms and definitions apply to the Guidelines.

3.1 New Chemical Substances

Chemical substances not listed in the *Inventory of Existing Chemical Substances of China* (hereinafter referred to as IECSC).

3.2 Hazard

Inherent property of a chemical substance having the potential to cause adverse effects when an organism, a biological system or (sub-) population is exposed to that chemical substance.

3.3 Hazard Identification

The identification of the type and nature of adverse effects that a chemical substance has as inherent capacity to cause in an organism, a biological system or (sub-) population.

4. General Principles

4.1 Work Classification

As required in China NCSN,, regular notification is classified into four levels from the lowest to the highest, based on the notified tonnage bands in accordance with the provisions of *Measures on the Environmental Management of New Chemical Substances*.

- (i) Produced or imported in quantities of 1-10 (not including 10) tonnes per year
- (ii) Produced or imported in quantities of 10-100 (not including 100) tonnes per year
- (iii) Produced or imported in quantities of 100-1000 (not including 1000) tonnes per year
- (iv) Produced or imported in quantities of 1000 tonnes and above per year

For each different tonnage band, hazard identifications are conducted based on the required data by the relevant notification band.

4.2 Work Contents

The hazard identification of new chemical substances contains two technical sections: methods of hazard identification and classification into environmental management category.

The methods of hazard identification for new chemical substances consist of four technical sections: general requirements, data requirements, data evaluation and hazard classification.

The classification of environmental management category refers to regulatory requirements of classifying new chemical substances into general new chemical substances, hazardous new chemical substances and hazardous new chemical substance of priority environmental concern.

5. Methods of Hazard Identification

5.1 General Requirements

Hazard identification of new chemical substances consists of:

- (i) Submission of the required data according to the appropriate tonnage band;
- (ii) Evaluation of the data submitted and determination of hazardous effect;
- (iii) Determination of the hazard classification.

Hazard identification of new chemical substances consists of three sections: physical-chemical hazard identification, human health hazard identification and environmental hazard identification.

Free

Standard
for single user

Corporate
for unlimited users

Subscribe to CHEMLINKED Now

**Essential Information & Assistance with
China's Environmental & Regulatory Issues**

How to Purchase the Standard/Corporate Membership?

You can either click the "Sign up Now" button **Sign up Now** and pay it online securely through Paypal.com, or you can download the order form, fill up with your signature and return it to us by fax or email.

For more information please contact: orders@chemlinked.com

Subscribe Web: <http://chemlinked.com/en/subscribe>

• 7-DAY MONEY BACK GUARANTEE

Membership	Regulatory News	Events	Newsletter	e-Publication	Expert Articles	China Regulatory Database	China Inventory Toolbox	Full Access to Searchable Archive	Free access to all our webinars	Discount on all our seminars & workshops	Unlimited access permit for users in one organization
Free	√	√	√	√	x	x	Search Only	x	x	x	x
Standard	√	√	√	√	√	√	Search & Report Download	√	√	x	x
Corporate	√	√	√	√	√	√	Search & Report Download	√	√	√	√

REACH24H Europe

Suite 1E, Paramount Court, Corrig Road, Sandyford, Dublin 18, Dublin, Ireland
Tel: +353 1 8899 951 / Fax: +353 1 6865 683

REACH24H CHINA

6F, Building 2, HESHENG Trade Center, No 327 Tian Mu Shan Road, Hangzhou, China
Tel: +86 571 8700 7500 / Fax: +86 571 8700 7566

CHEMLINKED.COM / Free China REACH Helpdesk E-mail: info@chemlinked.com

Visit our website for more information about China Chemical News & Regulation updates