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 Risk Assessment of Chemicals, 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.

For further clarification and questions, please contact us:
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Contents

Preface

These 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 risk assessment for chemical substances.

The Guidelines specify the principles, content, procedures, methods and technical requirements of chemical substance risk assessment. The hazard identification of new chemical substances shall be implemented according to the provisions of HJ 154-201□.

These Guidelines have been published for the first time.

The Guidelines were drawn up by the Division of Science and Technology 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 (DD/MM/201x).

The Guidelines will enter into force since (DD/MM/201x).

The Guidelines shall be interpreted and administered by the Ministry of Environmental Protection, P. R. China.

1. Applicable Scope

These Guidelines specify the technical methods and procedures of environmental risk assessment and health risk assessment for chemical substances.

The Guidelines apply to the experts of the review committee during China New Chemical Substance Notification (China NCSN) and China NCSN notifiers when completing risk assessment reports, as well as for the risk assessment of existing chemical substances.

2. Normative References

These 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 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 154 The guidelines for hazardous identification of new chemical substances

HJ/T155 The guidelines for chemical testing according to Good Laboratory Practices

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 Chemical Substances

Any organic or inorganic substance with a specific molecular identifier including substances produced completely, or in part, as a result of chemical reactions; any compound produced as a result of the reactions of naturally existing substances; any element or uncombined atomic group. Under the environmental management system, chemicals are divided into existing chemical substances and new chemical substances by the IECSC (Inventory of Existing Chemical Substances of China).

3.2 New Chemical Substances

Chemical substances that are not listed on the IECSC.

3.3 Existing Chemicals

Chemical substances that have been listed on the IECSC.

3.4 Risk

The probability of an adverse effect in an organism, a biological system or (sub-) population caused under specified circumstances by exposure to a chemical substance.

3.5 Risk Assessment

A process intended to calculate or estimate the risk to a given target organism, a biological system or (sub-)population, including the identification of attendant uncertainties, following exposure to a particular chemical substance, taking into account the inherent characterisation of the chemical substance of concern as well as the characterisation of the specific target system.

3.6 Hazard

An 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.

3.7 Effect

A change caused by exposure to a chemical substance, which affects the general state or dynamics of an organism, a biological system or (sub-) population.

3.8 Hazard Assessment

A process designed to determine the potential hazard caused by exposure to a chemical substance to an organism a biological system or (sub-) population. The process includes hazard identification and hazard characterization.

3.9 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,

3.10 Hazard Characterization

The qualitative and where possible, quantitative description of the inherent properties of a

chemical substance having the potential adverse effects. This includes a dose (concentration) - response (effect) assessment and its associated uncertainty.

3.11 Concentration-Effect Assessment

An assessment of the relationship between the quantities of exposure to a chemical substance (expressed as a concentration), in a specific manner over a certain time period, and the resulting effects, for an organism, a biological system or (sub-) population.

3.12 Assessment Factor

The correction factor is to extrapolate from the experimental dose (concentration) – response (effect) relationships to estimate the exposure concentration of a chemical substance at and above which adverse effects may occur.

3.13 Predicted No Effect Concentration (PNEC)

Based on existing knowledge, the concentration below which exposure to a chemical substance will not cause adverse effects.

3.14 Exposure

The total amount or concentration of a chemical substance that reaches a target organism, biological system or (sub-) population in a specific frequency for a defined duration.

3.15 Exposure assessment

Evaluation of the exposure of an organism, a biological system or (sub-) population to a chemical substance (and its derivatives).

3.16 Exposure Scenario

A group of conditions or assumptions about exposure pathways, sources, quantity or concentrations of a chemical substance and the exposed organism, system or (sub-) population (i.e. numbers, characteristics and habitat). It is used to aid in the evaluation and quantification of exposures in a given situation.

3.17 Risk Management Measures

The specific measures in the control strategy for a chemical substance that reduce the release and exposure of a chemical substance, thereby reducing the risk to human health and the environment. An appropriate risk control measure is the one that can ensure the effective control of risks.

3.18 Predicted Environmental Concentration (PEC)

The environmental concentration of a chemical substance is predicted based on the available information of the properties, functions and emission methods as well as the volume used of a chemical substance.

3.19 Risk Characterization

The qualitative and where possible, quantitative determination, including associated uncertainties, of the probability of occurrence of known and potential adverse effects of a

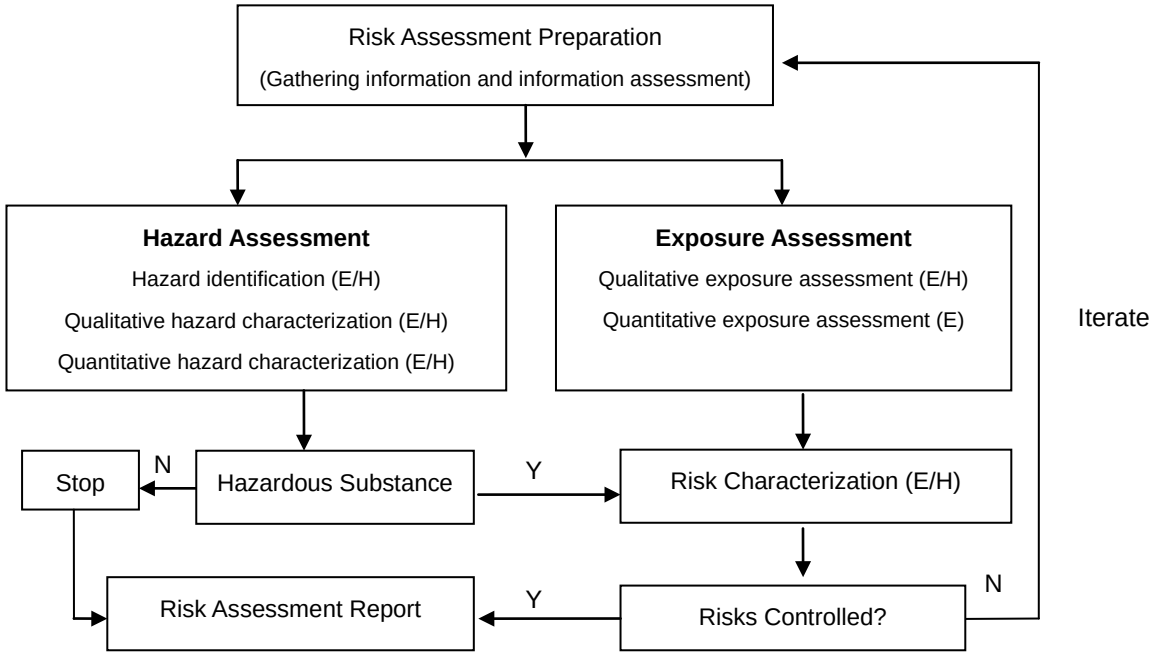
chemical substance in a given organism, biological system or (sub-) population, under defined exposure conditions.

4. Assessment Procedure

4.1 Assessment Process

The risk assessment of a chemical substance consists of four technical sections: hazard identification, hazard characterization, exposure assessment and risk characterization. Both hazard identification and hazard characterization fall into the category of hazard assessment. The risk assessment process of a chemical substance is shown in Figure 4.1. (E: Environmental, H: Health)

Figure 4.1 Risk Assessment Process for Chemical Substances



4.2 Others

4.2.1 Prior to carrying out a risk assessment, information about a chemical substance should be collected and its quality should be evaluated. The collected information includes substance identification, hazard and exposure information etc. The validity, reliability, relevance and adequacy of the collected information should also be assessed in accordance with the provisions of HJ 154.

4.2.2 If the data collected does not reflect several properties of the chemical substance, and the risk assessment of the chemical substance cannot be completed, further data should be collected until risks are controlled.

4.2.3 For the risk assessment methods of PBT (Persistent, Bioaccumulative and Toxic) and vPvB (very Persistent and very Bioaccumulative) substances, please refer to Appendix A.

4.2.4 For risk assessment of special chemical substances, a case-by-case assessment approach should be adopted.

5. Qualitative Environmental Risk Assessment

5.1 Qualitative Environmental Hazard Assessment

5.1.1 Overview of Tasks

A qualitative environmental hazard assessment consists of two sections: hazard identification and qualitative hazard characterization (hazard grading). The former identifies the environmental hazards caused by the intrinsic properties of a chemical substance; while the latter predicts qualitatively the hazard grades/levels of a substance in the environment.

5.1.2 Hazard Identification

(1) Gather the eco-toxicological data of a chemical substance and evaluate its data quality; determine the eco-toxicological effects and the relevant hazard dose.

(2) According to the provisions of GB 20602, provide the environmental hazard classification of a chemical substance based on its hazard dose. Environmental hazard identification of a new chemical substance should comply with the provisions of HJ 154.

5.1.3 Qualitative Hazard Characterization (Hazard Grading)

A grading and scoring system is adopted to qualitatively determine the environmental hazard level and its corresponding score according to the results obtained in the Section 5.1.2. An environmental hazard is divided into three grades: High Hazard, Medium Hazard, and Low Hazard. The hazard grades and assigned scores of each level can be found in Table 1.

Table 1: Aquatic Environmental Hazard Grading

Hazard Grades ($Hazard_{environment}$ Score)	**Environmental Hazard Classification**
High Hazard (3)	Acute Aquatic Toxicity Category 1 or Aquatic Chronic Toxicity Category 1 & 2
Medium Hazard (2)	Acute Aquatic Toxicity Category 2 or Aquatic Chronic Toxicity Category 3
Low Hazard (1)	Acute Aquatic Toxicity Category 3 or Aquatic Chronic Toxicity Category 4

5.2 Qualitative Environmental Exposure Assessment

5.2.1 Overview of Tasks

Qualitative environmental exposure assessment consists of three sections: identification of exposure assessment factors, exposure assessment factors scoring and environmental exposure grading.

5.2.2 Identification of Exposure Assessment Factors

Exposure assessment factors contain three sections: the volume of a chemical substance, the potential of release into the environment and residual time after release into the environment.

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Standard	√	√	√	√	√	√	Search & Report Download	√	√	x	x
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