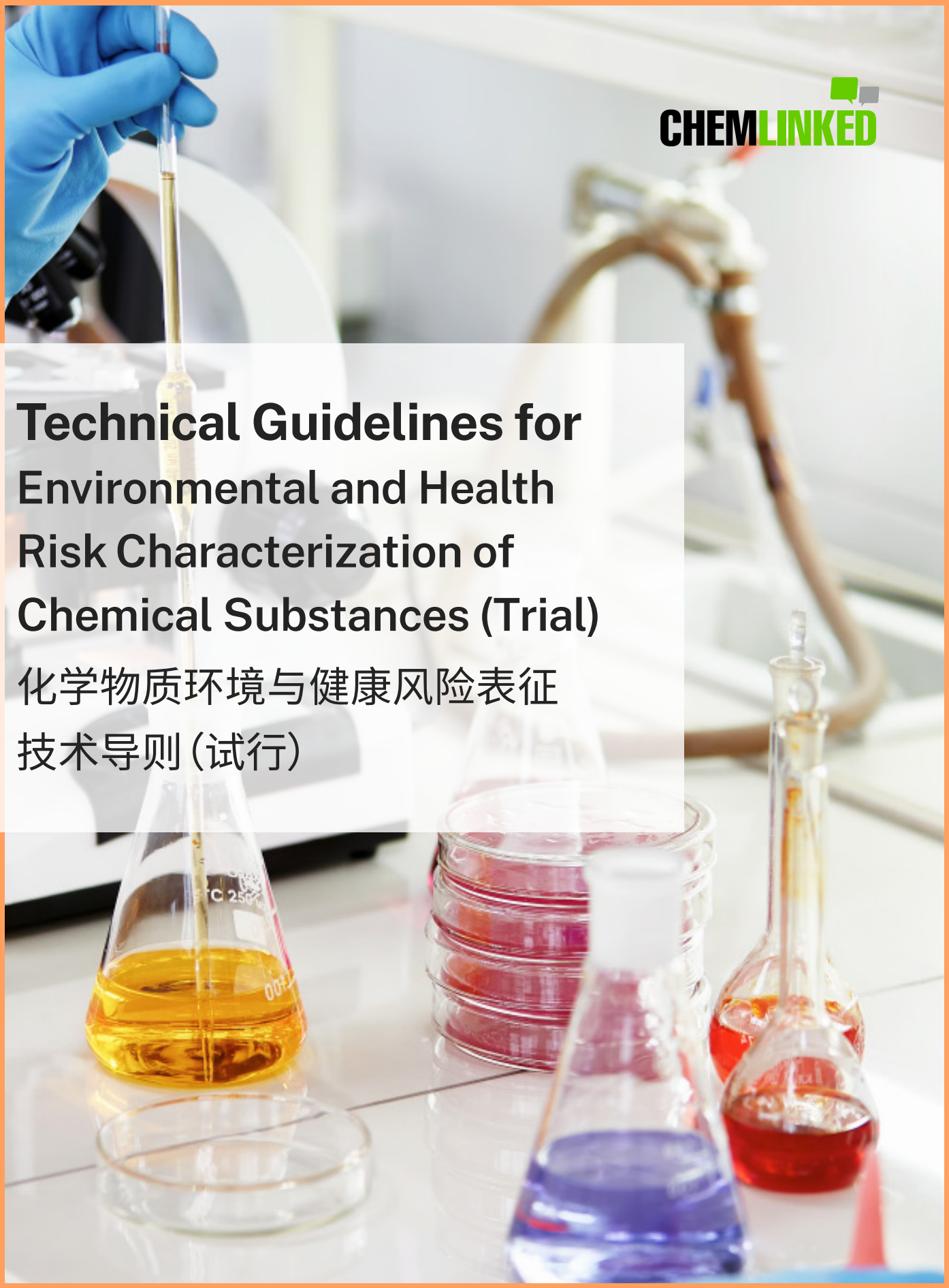

Technical Guidelines for Environmental and Health Risk Characterization of Chemical Substances (Trial)

化学物质环境与健康风险表征技术导则(试行)

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Contents

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This Guidelines aims to provide guidance on environmental and health risk characterization of chemical substances.

1. Scope of Application

This Guidelines stipulates the principles, processes and technical points for the environmental risk characterization of chemical substances and the characterization of health risks caused by indirect exposure via the environment.

This Guidelines is applicable to environmental and health risk characterization of chemical substances.

2. Normative References

This Guidelines refers to the following documents or their terms. For undated reference documents, the effective version is applicable to this technical guideline.

Framework Guidelines for Environmental Risk Assessment Techniques and Methods of Chemical Substances (Trial) (Huan Ban Gu Ti No.54 of 2019)

Measures for the Environmental Management Registration of New Chemical Substances (MEE Order No.12)

Guidance on Environmental Management Registration of New Chemical Substances (MEE Announcement No. 51 of 2020)

3. Terms and Definitions

3.1 Environmental risk characterization

The analysis and judgment of the degree of risk to the ecological environment caused by chemical substances, based on the environmental hazard assessment and exposure assessment of chemical substances.

3.2 Health risk characterization

The analysis and judgment of the degree of risk to human health caused by chemical substances via environment exposure, based on the health hazard assessment and exposure assessment of chemical substances.

3.3 Environmental risk characterization ratio

The ratio of the environmental exposure concentration of chemical substance to the predicted no-effect concentration, which is used to characterize the environmental risk level of chemical substances.

3.4 Health risk characterization ratio

The ratio of the dose of indirect exposure of human body via the environment to the safe dose/virtually safe dose, which is used to characterize the health risk level of chemical substances.

3.5 Uncertainty

The degree of deviation of the environmental and health risk assessment results of chemical substances from the actual situation, caused by the insufficient scientific knowledge, limitations of assessment methods, and lack of basic data.

4. Principles

4.1 Transparency

Characterization methods, assumptions, uncertainties and the validity of characterization results should be clarified in environmental and health risk characterization.

4.2 Clarity

The environmental and health risk characterization process should be concise and easy to understand, and the figures and formulas should be self-explanatory to ensure that both professional and non-professionals can fully understand.

4.3 Consistency

The environmental and health risk characterization should be consistent with the environmental management requirements for chemical substances.

4.4 Rationality

The environmental and health risk characterization should be based on reasonable judgments, scientific methods and assumptions.

5. Processes

The environmental and health risk characterization procedures of chemical substances mainly include the following four steps (as shown in Figure 1).

5.1 Integrate hazard exposure information

Integrate the environmental and health hazard assessment and exposure assessment results of chemical substances, and clarify the Predicted No-Effect Concentration (PNEC) and predicted Environmental Concentration (PEC) of each environmental assessment target, as well as the information of Tolerable Daily Intake (TDI)/Virtually Safe Dose (VSD), Average Daily Exposure Dose (ADD) of the human body through different exposure routes such as inhalation, drinking water, ingestion (of fish) and intake of soil.

5.2 Calculate the risk characterization ratios

Calculate the environmental and health risk characterization ratios (RCRs) of chemical substances based on the aforementioned environmental and health hazard data and exposure data of chemical substances.

5.3 Conduct uncertainty analysis

Identify the main sources of uncertainties in the environmental and health risk assessment process and conduct uncertainty analysis.

5.4 Reach risk assessment conclusion

According to the calculation result of environmental and health RCRs of chemical substances, combined with the uncertainty analysis result, an assessment conclusion of whether the chemical substance has any unreasonable environmental and health risks is drawn.

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