# GB

NATIONAL STANDARD OF THE

PEOPLE'S REPUBLIC OF CHINA

ICS 03.120.01

A 00

# GB/T 22760-2020

Replacing GB/T 22760-2008

# Consumer product safety - General principles for risk assessment

消费品安全 风险评估导则

**Issued on: July 21, 2020** **Implemented on: July 21, 2020**

**Issued by: State Administration for Market Regulation;**
**Standardization Administration of PRC.**

# Table of Contents

# Consumer product safety - General principles for risk assessment

## 1 Scope

This standard specifies the procedures, content and requirements of risk assessment for consumer product safety.

This standard applies to the risk assessment of consumer products during normal use and reasonably foreseeable misuse.

## 2 Terms and definitions

The following terms and definitions apply to this document.

**2.1**

**Consumer product**

Mainly but not limited to products designed and produced for personal use, including product components, parts, accessories, instructions for use and packaging.

[GB/T 35248-2017, definition 2.2]

**2.2**

**Injury**

Damage to human health or property.

Note: Rewrite GB/T 20002.4-2015, definition 3.1.

**2.3**

**Hazard**

The potential source which may cause injury.

[GB/T 28803-2012, definition 3.2]

**2.4**

[GB/T 28803-2012, definition 3.5]

**2.10**

**Intended use**

Use according to the information provided by the product and/or system. When there is no such information, use it in a generally understood mode.

[GB/T 20002.4-2015, definition 3.6]

**2.11**

**Reasonably foreseeable misuse**

The use of product and/or system in a manner not provided by the suppler which is caused by the behavior of a person that is easy to foresee.

[GB/T 20002.4-2015, definition 3.7]

**2.12**

**Tolerable risk**

According to the current social value orientation, the risk which is acceptable within a certain range.

Note: In this standard, "tolerable risk" and "allowable risk" are regarded as synonyms.

[GB/T 20002.4-2015, definition 3.15]

**2.13**

**Risk estimation**

The process of assigning values to the possibility of injury and the severity of its consequences.

[GB/T 28803-2012, definition 3.13]

**2.14**

**Risk analysis**

The process of systematically using existing information to determine hazards and estimate risks.

[GB/T 20002.4-2015, definition 3.10]

relevant information shall continue to be investigated and supplemented during the assessment process, to ensure that the information is true, reliable and timely.

### 3.2 Combining qualitative and quantitative methods

Scientific and effective risk assessment methods shall be selected for the types and characteristics of consumer product safety hazards (sources). When appropriate data are available, quantitative methods of risk assessment shall be given priority.

### 3.3 Throughout the life cycle of consumer products

According to the characteristics of each stage of the consumer product's life cycle, different risk assessment methods are used.

### 3.4 Comprehensive measurement

The level of development of science and technology, economy and knowledge shall be considered comprehensively, to determine the hazard (source), tolerable risk and risk level. As needed, the review shall be repeated to determine the tolerable risks.

## 4 Procedure and content of risk assessment

### 4.1 Procedure

The general procedures of risk assessment include pre-assessment preparation, hazard identification, risk estimation, risk evaluation and other steps.

The process of consumer product safety risk assessment is as shown in Figure 1. The risk assessment process of consumer product's physical hazards, chemical hazards and biological hazards can be refined on the basis of this process. See Appendix A and Appendix B.

general, the injury scenario includes but is not limited to the following:

a) The mode of operation that caused the injury;

b) The type and number of persons involved in the hazardous situation;

c) Time spent by consumers in the area where the injury occurred;

d) How often consumers operate consumer products;

e) The type of injury that may be caused by each injury situation;

f) Protective measures taken;

g) The service life of consumer products;

h) Accumulation effects of consumers exposed to hazardous situations, etc.

**A.3 Hazard identification**

**A.3.1 Methods of hazard identification**

The method of hazard identification is as shown in Table A.1.

**A.3.2 Contents of hazard identification**

In general, the content of hazard identification includes but is not limited to the following:

a) The possibility of causing product safety injury;

b) The severity of the product safety injury;

c) The mechanism that causes personal or property damage.

**A.4 Risk estimation and risk evaluation**

The methods that can be used for risk estimation and risk evaluation include but are not limited to the methods as shown in Table A.1.

comprehensive analysis is carried out to determine the possible exposure pathways and exposure chemicals.

Evaluate the quality of the data by collecting data from epidemiological studies, animal experiments, short-term tests, in vitro tests of chemical substances; integrate all valid information, use the weight of evidence method to determine the causal relationship between the exposure and adverse reactions of chemical substances under specific conditions, to make a qualitative evaluation and description of the possibility of adverse effects of the exposed population under a specific exposure route. When necessary, it is also necessary to understand the mode of action (MOA) of chemical substances. This information can help understand whether the data obtained from experimental animals can be extrapolated to humans.

### B.3 Hazard characterization

The characterization of chemical hazards is mainly based on the analysis of the dose-effect relationship of chemical substances, to deduce the safety threshold of human exposure to chemical substances or the acceptable dose of risk under specific exposure routes. Specifically, it can be carried out in two ways: threshold effect measurement-effect evaluation and derivative no-effect degree (DNEL) derivation, non-threshold effect measurement-effect evaluation and DNEL derivation.

### B.4 Exposure assessment

#### B.4.1 Inhalation exposure

The amount of inhalation exposure represents the concentration of chemical substances in the air in the breathing area, usually expressed as the average concentration in a reference time period (for example, every day); exposure may be intermittent, short-term or long-term; assess and establish relevant exposure scenarios and conditions; exposed substances may exist in different time periods, in different forms (such as aerosols) and different exposures.

#### B.4.2 Skin exposure

The main ways of skin exposure are: particles or aerosols containing airborne substances deposited on the skin, or substances that may remain on the skin after using the product (such as residues on clothes after washing or dry cleaning). The amount and concentration of the substance, the area, duration and frequency of skin exposure will affect the actual skin exposure risk results of the substance.

#### B.4.3 Oral exposure

The main ways of oral exposure are, for example, by sucking, chewing or licking

consumer products; food swallowing; substances present in books, textiles, etc., can cause oral exposure through hand-to-mouth behavior; some accidental chemical substances, such as oral cavity cleaning agents, glues, plastic softeners and polyvinyl chloride products may cause oral exposure, which needs to be considered. Generally, there is no need to consider the exposure caused by products or chemicals that the human body hardly touches. Oral exposure substances are often related to the use of consumer products, especially the main characteristic parameters such as the release, migration, solubility and dosage of target substances in consumer products, which can be used to quantify various exposure processes.

#### B.4.4 Other routes of exposure

In addition to the main exposure pathways mentioned in B.4.1 to B.4.3, in special circumstances, other exposure pathways shall also be considered, such as eye splash exposure, or in a few cases, exposure within the cortex (such as wearing earrings or piercing, etc.). These exposure routes can be expressed as the total amount of the target substance contacting the human body, usually expressed as the average daily dose.

### B.5 Risk characterization

#### B.5.1 Quantitative risk characterization

Quantitative risk characterization can be carried out by comparing the estimated exposure amount of the target chemical hazard in the relevant exposure scenario with the safety threshold of the human exposure chemical substance or the acceptable dose of the risk. For non-genotoxic carcinogens and non-carcinogens, if the estimated exposure is less than or equal to the safety threshold, or for genotoxic carcinogens, if the estimated exposure is less than or equal to the risk acceptable dose, the risk is considered to be tolerable.

In addition, it is necessary to identify the source of uncertainty in the whole process of risk assessment, qualitatively describe or quantitatively analyze the uncertainty in the process of hazard identification, hazard characterization, exposure assessment and risk characterization.

#### B.5.2 Qualitative risk characterization

When there is no data on the health effects of exposure to a specific population, or although there are data, it is not enough to derive the safety threshold or risk acceptable dose; however, when there are qualitative toxicity data or partial toxicological prediction results can be obtained through models or cross-reference methods, qualitative risk characterization can be performed. The endpoints of qualitative risk characterization mainly include irritation, corrosion, sensitization, certain acute toxicity, carcinogenicity and mutagenicity.

**This is an excerpt of the PDF (Some pages are marked off intentionally)**



**------ The End ------**