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**Consumer Product Safety – General Requirements on
Physical Hazard Assessment**

消费品安全 物理危害风险评估通则

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Consumer Product Safety – General Requirements on Physical Hazard Assessment

1 Scope

This Document describes general principles and general requirements for risk assessment of physical hazards for consumer product safety.

This Document applies to the risk assessment of physical hazards for consumer product safety.

2 Normative References

The provisions in following documents become the essential provisions of this Document through reference in this Document. For the dated documents, only the versions with the dates indicated are applicable to this Document; for the undated documents, only the latest version (including all the amendments) is applicable to this Document.

GB/T 22760-2020 Consumer Product Safety - General Principles for Risk Assessment

GB/T 39011-2020 Consumer Product Safety - General Principles for Hazard Identification

3 Terms and Definitions

For the purposes of this Document, the terms and definitions given in GB/T 22760-2020 and the following apply.

3.1 Consumer product

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

[SOURCE: GB/T 35248-2017, 2.2]

3.2 Safety

A state exempt from unacceptable risk.

[SOURCE: GB/T 20002.4-2015, 3.14]

3.11 Risk evaluation

The process of determining whether a tolerable risk has been achieved based on the results of a risk analysis.

[SOURCE: GB/T 22760-2020, 2.15]

3.12 Risk assessment

Including the whole process of risk identification, risk analysis and risk evaluation.

[SOURCE: GB/T 22760-2020, 2.16]

3.13 Intended use

Use according to the information provided by the product and/or system, and in the absence of such information, use it according to the commonly understood mode.

[SOURCE: GB/T 22760-2020, 2.10]

3.14 Reasonably foreseeable misuse

The use of the product and/or system not in the manner provided by the supplier as a result of easily foreseeable human behavior.

[SOURCE: GB/T 22760-2020, 2.11]

3.15 Tolerable risk

Risks that are acceptable within a certain range according to today's social value orientation.

NOTE: In this Document, "acceptable risk" and "tolerable risk" are considered synonyms.

[SOURCE: GB/T 22760-2020, 2.12]

4 Evaluation Procedures

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

The procedure for risk assessment of physical hazards for consumer product safety is shown in Figure 1.

Determine the use environment, service life, user population, and use behavior that may occur during the expected use or reasonably foreseeable misuse of the consumer product.

5.4 Determine tolerable risks

Considering that in the current certain period of time, under the current technical level and social and economic conditions, a certain consumer product shall not cause damage to consumers' human health or property during use; and the restricted requirements for the hazard (source) of this kind of consumer product can be determined as tolerable risk.

6 Harm Scene Construction

The combination of consumer product safety harm events under expected use or reasonably foreseeable misuse conditions that may cause harm shall be considered, and the hazard situation shall be recorded. In general, the harm scenarios include but are not limited to the following:

- a) The mode of operation that led to harm;
- b) The type and number of persons involved in the hazardous situation;
- c) The time the consumer spends in the area where harm occurred;
- d) The frequency with which the consumer operates the consumer product;
- e) The type of harm that may result from each harm scenario;
- f) The protective measures that have been taken;
- g) The service life of the consumer product;
- h) The cumulative effect of consumer exposure to hazardous situations, etc.

7 Hazard Identification

7.1 Overview

List information about the hazard (source), hazardous situation, and harm event, and describe the possible hazardous situation in terms of when and how the hazard (source) caused the harm.

7.2 Methods of hazard identification

The cause-result hazard identification work shall be carried out in accordance with the method in 5.2 of GB/T 39011-2020; or the result-cause hazard identification work shall be carried out in accordance with the method in 5.3 of GB/T 39011-2020.

7.3 Description of hazard identification

Hazards (sources) shall be recorded to ensure that the following information is clearly described:

- a) Characteristics of the hazard (source);
- b) Description of the hazardous situation;
- c) Description of the damage mechanism of each hazard (source) of the consumer product;
- d) Existing protective measures and their effectiveness;
- e) Other relevant information.

7.4 Hazard (source) list

According to the description in 7.3, and according to the requirements of Appendix C in GB/T 22760-2020, the hazards (sources) are classified and listed.

7.5 List of harm types

According to the provisions of Clause 6 and the requirements of Appendix D in GB/T 22760-2020, list the corresponding harm types in various harm scenarios.

8 Risk Estimation

8.1 Overview

The goal of risk estimation in this Clause is the process of assigning a value to the severity of the harm and the probability of its occurrence for the harm that may result from a physical hazard (source) for consumer product safety.

8.2 Severity of harm

The same consumer product may cause multiple harm events; and each harm event shall result in different degrees of harm. The value assignment of the severity of damage can be determined by subjective judgment; and the relevant professional experts can make judgments in the form of experimental testing or simulation, expert or consumer questionnaires and interviews. The judgment basis can refer to Table 1 in GB/T 22760-2020.

8.3 Possibility of harm occurrence

8.3.1 Overview

The possibility of harm can be judged according to b) of 4.2.3.2 in GB/T 22760-2020 and the method of A.4.2 in Appendix A of this Document. The data from experimental simulation, experimental testing, consumers, expert judgment and other channels can be given

corresponding weights for calculation to obtain the possibility of harm occurrence.

8.3.2 Experimental simulation

Through virtual simulation, real scene observation and other methods, it can obtain the harm events caused by the interaction between human, product and environment when consumers use a certain product, and then infer the possibility of harm occurrence.

8.3.3 Experimental testing

For some hazards (sources), experimental testing methods can be used to determine whether they meet the relevant standards or specifications, so as to obtain the possibility of harm occurrence of the product in a specific harm scenario.

8.3.4 Consumer interview

If consumer goods have been put into circulation and use, the possibility of harm events can be judged by collecting relevant information from consumer questionnaires.

8.3.5 Expert judgment

When the statistical data of harm events are insufficient, the subjective judgment of experts (such as Delphi method and fishbone diagram method) can be used to supplement; but the results of expert judgment are only used as a reference for the possibility of harm occurrence.

8.3.6 Other methods

Through the information from literature, consumer complaints, public opinion, recall notification and other channels, it provides a reference for judging the possibility of harm occurrence.

9 Risk Assessment

For a certain hazard (source), the risk level of the hazard of the consumer product can be estimated according to the possibility of the harm occurrence caused by it and the severity of the harm occurrence. For the classification of consumer product safety risk levels, please refer to Appendix E in GB/T 22760-2020.

If a consumer product has two or more hazards, risk assessment shall be carried out for each hazard separately, and the highest risk level of each hazard shall be taken as the safety risk level of the consumer product.

10 Risk Assessment Report

A risk assessment report shall be prepared and all written records in the assessment process

F - Children with disabilities

G – Magnetic flux;

H – Small parts;

I – Foods exists in the use environment;

J - Insufficient environment lighting;

K - Caregiver negligence

L – Caregiver lacks of ability;

M - Inappropriate use of age;

N – Lack of use education.

Figure A.1 -- Schematic Diagram of Product A Hazard Identification Based on Failure Tree Method

From the failure tree method and related harm cases, it can be seen that due to the reasons of the product itself (such as magnetic flux and small parts), it is easy for children to accidentally swallow Product A and cause harm. Through in-depth analysis, it can be seen that if only one is swallowed, most of them shall be excreted in the stool, but as long as children swallow two or more tablets, these Product A shall be adsorbed together. If Product A are present in different segments of the intestines, the intestines shall be twisted together, causing intestinal obstruction. At the same time, due to an intestinal tube is fixed and compressed by Product A, it shall cause ischemic necrosis and lead to intestinal perforation, resulting in peritonitis. If compression of the mesenteric blood vessels may lead to blood vessel wall necrosis and hemorrhage, resulting in suffocation and even death, and other harms.

A.3.3 Determine hazards (sources)

Based on the above analysis, it is known that the hazards (sources) of Product A are small parts and magnetic flux.

A.3.4 Determine the type of harm

According to the harm cases that have occurred and the judgment of relevant experts, the accidental swallowing of Product A by children can easily lead to intestinal obstruction, intestinal perforation and suffocation, and the like harmful results.

A.4 Risk estimation

A.4.1 Severity of harm

The classification of harm severity can be based on Table 1 in GB/T 22760-2020. For the convenience of statistics, this Document assigns a value to the harm severity at all levels, see Table A.2.

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Linkin: <https://www.linkedin.com/in/waynezhengwenrui/>

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