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**NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC  
OF CHINA**

**中华人民共和国国家标准**

GB 15193.1-2003

Replace GB 15193.1-1994

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**Procedures for toxicological assessment of food**

**食品安全性毒理学评价程序**

**Issued on September 24, 2003**

**Implemented on May 01, 2004**

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**Issued by Ministry of Health of the People's Republic of China**

**Standardization Administration of the People's Republic of China**

## Foreword

### **This standard is compulsory in full text.**

This standard replaces GB15193.1-1994 *Procedures for toxicological assessment of food*.

There have been some significant changes in this standard over its previous edition

GB15193.1-1994 in the following aspects:

---Specific contents of test substance have been added in “Scope”: the safety of chemical, biological and physical factors that may cause harm to health concerned during food production, processing, storing, transport and selling process; assessment objects include food additives (including food enrichment), new resources of food and ingredients, novel foods, irradiated food, food container and packing materials, food tools, equipment, detergent, disinfectant, pesticide residue, veterinary drug residue, industrial microorganisms for food, etc;

---This has been added in the “Requirements for test substance”: “For formulated products, the formula of test substance shall be provided; when necessary, physical property, chemical property (including chemical name, structure, purity, stability, solubility, etc.) of all compositions of test substances, test report and relevant data shall be provided; source of raw materials, production technology, possible intake for human being and other relevant data shall be provided”;

---“TK gene mutation test” has been added in the second stage of “Genetic toxicity test” of “Four stages and contents of toxicological test”. V79/HGPRT gene mutation test has been changed from alternative test to required project of gene mutation test paralleled with Ames test. The primary alternative test has been changed to 3 from 4;

---“Food container and packing material, pesticide residue” has been added in “Principle of selecting toxicity test for different test substances”. For the selection principle to flavoring, “Acute toxicity test” (Article 3.2.4.2.1.1 in 1994 edition, Article 6.4.1.1.1 in this edition) has been deleted; for additives for other food, the “one mutagenicity test” has been changed to “two mutagenicity tests”; “Ames test or mouse bone marrow micronucleus test (MNT) preferred” has been changed to “Ames test and mouse bone marrow micronucleus test (MNT) preferred”(Article 3.2.4.2.2.1 in 1994 edition, Article 6.4.1.2.1 in this edition); “selection principle of toxicity test for food container and packing material” has been added;

---In “Result judgment of all toxicological tests”: result judgments of genetic toxicity have been completely adapted and the number has been changed from previous 4 to 3. “Result judgment principle for carcinogenicity test” has been added. The content in the bracket of novel food has been changed to “if it exceeds 5%, protein shall be supplemented to the content equivalent to control group and the added test substances shall not exceed 10% of feed at most in principle.” (Article 4.2.6 in 1994 edition, Article 7.2.6 in this edition).

---In “factors to be considered while conducting food safety assessment”: factors like “statistical significance and biological significance of test index”, “physiological effect and toxic effect”, “test substance that the intake is major for human being” and “time-toxicity effect relationship” have been added; in comprehensive assessment, “while conducting final assessment, the physicochemical property, toxicity, metabolism characteristic, accumulation effect, scope of contacted human being, usage amount and usage scope of food and possible intake for human being and other factors must be comprehensively considered” has been added.

---“Inspection organization” has been deleted.

GB15193.1-1994 shall be abolished since the implementation date of this standard.

This standard was proposed and under the jurisdiction of the Ministry of Health of the People's Republic of China.

This standard was drafted by: Institute of Nutrition and Food Safety, China Disease Prevention and Control Center.

Main drafters of this standard: Dai Yin, Chen Junshi, Xu Jinkang, Li Youhui.

This standard was initially issued in 1994 and revised for the first time.

# Procedures for toxicological assessment of food

## 1. Scope

This standard specifies the procedure for toxicological assessment of food.

This standard is applicable to the assessment of the safety of chemical, biological and physical factors that may cause harm to health concerned during food production, processing, storing, transport and selling process; assessment objects include food additives (including food enrichment), new resources of food and ingredients, novel foods, irradiated food, food container and packing materials, food tools, equipment, detergent, disinfectant, pesticide residue, veterinary drug residue, industrial microorganisms for food, etc;

## 2. Normative reference

The articles contained in the following documents have become this standard when they are quoted herein. For the dated documents so quoted, all the modifications or revisions made thereafter shall not be applicable to this Standard. For the undated documents so quoted, the latest editions shall be applicable to this Standard.

GB15670-1995 *The Toxicological Testing Method for Pesticides*

Hygiene control measures for irradiated food

Disinfection Management Measures

## 3. Terms and definitions

For the purpose of this Standard, following terms and definitions apply

### 3.1 Food additive

It refers to the synthetic chemicals or natural materials that are added in food to improve the food quality and color, aroma and taste and for the needs of preservation and processing.

### 3.2 Novel foods

It refers to food or raw materials of food that are newly discovered, developed (including new process and new technology) or introduced that have not been eaten yet or merely eaten in individual regions.

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