



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

GB 15193.1-2014

**National Food Safety Standard -- Procedures for toxicological
assessment of food
(English Translation)**

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Table of Contents

Foreword...	3
1.Scope...	4
2.Requirements for test substances...	4
3.Contents of toxicological assessment for food safety...	4
4.Principle of selecting toxicity test for different test substances...	5
5.Objective of toxicological assessment of food and result judgment...	8
6.Factors that need to be considered during food safety assessment..	11

Foreword

This Standard replaces GB15193.1-2003 "Procedures for toxicological assessment of food".

Compared with GB15193.1-2003, the main changes in this Standard are as follows.

- The standard name is changed to be "Food safety national standard - Procedures for toxicological assessment of food";
- Modify "Scope";
- Delete "Terms and definitions";
- Modify "Requirements for test substances";
- Modify "contents of toxicological assessment for food safety";
- Modify "Principle of selecting toxicity test for different test substances";
- Modify "Objective of toxicity test";
- Modify "toxicological assessment result judgment";
- Modify "Factors that need to be considered during food safety assessment".

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 and its raw material, food additives, new food raw materials, irradiated food, food related products (used for food packaging materials, containers, detergent, disinfectant; and the tools and equipment used for food production and marketing), and food pollutants.

2.1 It shall provide the test substance's name, batch number, content, storage conditions, sources of raw materials, production processes, quality specifications, character, human recommended (possible) intake, and other relevant information.

2.2 For single-ingredient chemical substance, the physical, chemical property (including

chemical structure, purity, stability, etc.) of test substance (including impurities when necessary) shall be provided. For mixed substances (including formulated products), the composition 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 and relevant data shall be provided.

3.2.1 Genetic toxicity test contents. Bacterial reverse mutation test, mammalian erythrocyte micronucleus test, mammalian bone marrow chromosome aberration test, mouse spermatogonia or spermatocytes chromosome aberration test, in-vitro mammalian cell HGPRT gene mutation test, in-vitro mammalian cell TK gene mutation test, in-vitro mammalian chromosome aberration test, rodent dominant lethal test, in-vitro mammalian cell DNA damage repair (unscheduled DNA synthesis) test, Drosophila sex-linked recessive lethal test.

3.3 28-day oral toxicity test.

3.4 90-day oral toxicity test.

4.1 For all substances that are firstly-innovated by our country, especially that the

chemical structure suggests that there are potential chronic toxicity, genetic toxicity or carcinogenic properties;

4.2 For derivatives or analogs of which the chemical structure is basically same as that

of known substances (refer to those that have passed safety evaluation and are allowed for use), or the substances that have safe-use history in some countries and regions, then it may firstly conduct the acute oral toxicity studies, genetic toxicity test, 90-day oral toxicity test, and teratogenicity test.

4.4 Selection of the safety toxicology assessment test for food additives, new resources of food and ingredients, food related products, pesticide residue, veterinary drug residue

4.4.1.2.1 For enzyme preparations that have long history of safe consumption and that

are produced from edible parts of animals or plants, if the World Health Organization has announced the acceptable daily intake (ADI) or ADI is not required to be specified or several countries have approved the use, on the basis of providing relevant proving materials, generally it does not require to conduct toxicological test.

4.4.1.3.1 For the additives with comparatively complete toxicological data and the World

Health Organization has announced the ADI or that the ADI is not required to be specified, or several countries have approved the use, if the quality specifications are consistent with international quality specifications, then acute oral toxicity test and genetic toxicity tests are required; if the quality specifications are not consistent with international quality specifications, then it requires additional 28-day oral toxicity test; According to the test results, determine whether it needs to further conduct other related toxicity test.

4.4.1.3.3 For the additives with single component and high-purity extracted from animal,

plant or microorganism, if it is a new variety, then it needs to conduct oral toxicity test, genetic toxicity test, 28-day oral toxicity test, and teratogenicity test. After preliminary assessment, determine whether it needs to conduct further test. If it has been approved

for use by a foreign country or an international organization, then it shall conduct oral toxicity test, genetic toxicity test, and 28-day oral toxicity test. After preliminary assessment, determine whether it needs to conduct further test.

4.4.2 New food raw materials

It shall be evaluated in accordance with "New food raw material declaration and acceptance provisions" (State-Health-Food-Announcement [2013] 23).

4.4.3 Food related products

It shall be evaluated in accordance with "Food related product new varieties declaration and acceptance provisions" (Health-Supervision-Announcement [2011] 49).

5.1.1 Acute toxicity test

Understand the degree of toxicity, property and possible target organ of test substance; provide basis for selection of dose and toxicity observation index for further toxicity test; classify the acute toxicity dosage according to LD50.

5.1.5 Teratogenicity test

Understand whether the test substance has teratogenic effects and developmental toxicity; and obtain the not-observed adverse effect doses of teratogenic effects and developmental toxicity.

5.1.6 Reproductive toxicity test and reproductive-developmental toxicity test

Understand the test substance's reproductive-developmental toxicity to experimental animals' reproduction and their offspring, such as gonadal function, estrous cycle, mating behavior, gestation, childbirth, breast-feeding and weaning, and progeny growth and development. Obtain the not-observed adverse effect dose-level; provide a scientific basis for preliminarily formulating human-group safe contact limits.

5.2.1 Acute Toxicity Test

If LD50 is less than 100 times of recommended (possible) human-intake, then generally it shall give up that the test substance can be used in food; no further additional toxicology