

ICS 07.100
CCS C 53



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

GB 15193.21-2014

Replacing GB 15193.21-2003

**National Food Safety Standard -- Principle for preparing test
materials**

食品安全国家标准 受试物试验前处理方法
(English Translation)

Issued on: December 24, 2014

Implemented on: May 1, 2015

**Issued by: National Health and Family Planning Commission of the
People's Republic of China**

Table of Contents

Foreword

1 Scope

2 Terms and definitions

2.1 Test substance

2.2 Vehicle

2.4 No observed adverse effect level

3 Vehicle selection

4 Test, test substance pre-treatment methods

4.2 Higher expansion ratio test water disposal

4.3 Processing liquid test substance

4.4 Pulverized solid test substance is not easy to handle

4.5 Test substances containing alcohol treatment

4.7 Test substance containing the probiotic microorganisms or other processing

4.8 Recommended human large amount of test substance treatment

4.9 Human recommended a smaller amount of test substance treatment

4.10 Test substance incorporated feed processing

4.11 Handling food-related products category test substance

Foreword

This standard replaces GB 15193.21-2003 "test substance treatment." this standard compared with GB 15193.21-2003, the main changes are as follows.

- Standard name was changed to "national food safety standards of the test before the test substance approach";
- Increasing the terms and definitions;
- Increasing the solid test substance treated easily crushed;
- To increase the body recommended a smaller amount of processing the test substance;
- Increasing the incorporation of the test substance feed processing;
- Modify the selection medium;
- Modify the recommended human handling a large amount of test substance;
- Modify the teabag handling test substance;

- Revised higher expansion ratio test disposal;
- Modify the treatment liquid test substance;
- Modify the test substance containing toxic treatment of essential nutrients and other substances.

National Food Safety Standard Before the test, the test substance treatment

1 Scope

This standard specifies the test method for pre-treatment was subjected to safety evaluation when.

This standard applies to the evaluation of the test before the test substance was tested safety when handling.

2.1 Test substance

Single ingredient or mixture being tested.

2.2 Vehicle

Make the test substance into the test system, and make it a medium homogeneous mixture.

2.3 of wine group

Production of raw materials containing ethanol alcohol test was used.

2.4 No observed adverse effect level

Through animal experiments, the existing technical means and detection index was not observed any of the test substance-related toxic effects maximum dose.

3 Vehicle selection

Vehicle to help test substance into the test system or an important medium for animals. The test should be based on the physical and chemical characteristics and the nature of the test substance Choose a suitable solvent (solvent, suspending agent or emulsifier), the test substance is dissolved or suspended in a vehicle, and generally use distilled water, vegetable oil, Starch, gelatin, carboxymethyl cellulose, sucrose fatty acid esters, such as the use of other solvents shall state the reasons. Chosen vehicle itself should not produce Toxicity; and between the various components of the test substance is not a chemical reaction, and maintain its stability; no special or irritating odor.

4 Test, test substance pre-treatment methods

Note: According to the requirements of toxicology tests and the need for pre-treatment (such as concentration, removal of known security component, etc.) of the test substance should be provided treatment, consisting of a Points and proportion, and provide the appropriate information.

Processing of test substance shall be consistent with the main steps of the production process of the original product. The test was not carried out when the same test should be the appropriate treatment for physical and chemical properties of the test characteristics and the test substance.

Processing 4.1 teabag class test substance Extraction should be products recommended drinking the same way, available water extract of the test article was tested. If the product is no special push Recommended to drink, the water extract can be used to extract the following conditions. atmospheric pressure, temperature of 80 °C ~ 90 °C, soaking time 30min, by the amount of water 10 times or more the mass was again extracted twice, and the extracts were combined and concentrated to the desired concentration, and marked with the concentrate feed off ratio system. If the product has a special way of taking the recommendation (such as the recommended consumption after soaking products), it is considered in the test.

4.2 Higher expansion ratio test water disposal

Should be considered water-swelling test was administered dose and the impact of the test substance in experimental animals, in order to choose the right side of the test is administered Formula (orally or incorporated into feed). Such as the use of orally administered, should choose water as solvent.

4.3 Processing liquid test substance

Liquid test substances need to be concentrated treatment, which method should be used without destroying the active ingredient. You can use a temperature of 60 °C ~ 70 °C Concentrated by evaporation under reduced pressure or atmospheric freeze-drying methods. After concentrating the liquid test substance meets the test requirements of human recommended amount, but not by Orally administered, in order to allow the incorporation of animal feed administered.

4.4 Pulverized solid test substance is not easy to handle

Easily pulverized solid test substance (such as those containing gum, candied fruit) available lyophilized crushing manner, and described in detail in the test report.

4.5 Test substances containing alcohol treatment

Recommended test substance containing a large amount of ethanol, in the amount of its recommended dosage design test, if more than the maximum oral animal capacity, you can

enter Line concentrated. Ethanol concentration of less than 15% volume fraction of the test substance, the concentrated ethanol should be restored to the original styling products test substance concentration degree. Ethanol concentration higher than 15% of the test substance, the ethanol concentration should be adjusted to 15% was concentrated, and adjust a concentration of ethanol each dose group Cause. Do not need to concentrate the test substance, the ethanol concentration > 15% ethanol concentration in each dose group should be adjusted to 15%. When bacterial Reply mutation test should test and flies will remove ethanol. When adjusting the ethanol concentration of the test substance, in principle, should be used for producing the test substance Wine group.

4.6 containing the test substance or treatment of essential nutrients and other substances are known to exist in security issues Essential nutrients and other substances, such as product formulations containing excessive intake is easy to produce a safety problem (such as vitamin A, selenium, etc.) or known security issues substances (such as caffeine, etc.), in an amount designed to test their recommended doses, such as the dose of the toxic substance known to reach Effect dose, based on the original design of the dose should be considered additional to remove the substance or the substance reduced dose (eg dropped unobserved harmful Effect level) of the test substance dose, so that the combined toxic effects of the toxic effects of the test substance and the other ingredients of the substance with other components Evaluated.

4.7 Test substance containing the probiotic microorganisms or other processing

Containing probiotics or other microorganisms when the test substance during the bacterial reverse mutation assay or in vitro cell assay, should inactivate microorganisms, and Explain how.

4.8 Recommended human large amount of test substance treatment

For larger body recommended amount of test substance, when their test dose recommended amount of design, such as more than animals fed the maximum capacity or over-doped the feed limit (10% mass fraction), then it can allow the removal of non-security issues part of the test materials and test report Described in detail.

4.9 Human recommended a smaller amount of test substance treatment

Human recommended a smaller amount of test substance should be tested by oral administration ways.

4.10 Test substance incorporated feed processing

Such as the incorporation of the test substance in feed mass fraction of more than 5%, according to the nutritional needs of the animal feed formulation after the test, such as proteins You can adjust the quality casein, vegetable oil and other fats can be used to