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NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

GB/T 21035-2025

Replacing GB/T 21035-2007

Feed safety assessment - Teratogenicity test

饲料安全性评价 致畸试验

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Foreword

This document is in accordance with the provisions of GB/T 1.1-2020 "Guidelines for standardization work Part 1: Structure and drafting rules for standardization documents" Drafting.

This document replaces GB/T 21035-2007 "Feed Safety Evaluation - Feeding Teratogenicity Test" and is consistent with GB/T 21035-2007.

In addition to structural adjustments and editorial changes, the main technical changes are as follows.

a) Added some terms and definitions (see Chapter 3);

b) Added test principles (see Chapter 4);

c) Added solution preparation (see Chapter 5);

d) Added the types of instruments and equipment (see Chapter 6);

e) Added test substances (see Chapter 7)

f) Added requirements for the sex, number, and weight of experimental animals, as well as requirements for the selection of species and strains (see 8.1);

g) Added animal husbandry requirements (see 8.3);

h) Added specific details and requirements for dose grouping, such as the basis for dose selection and maternal mortality (see Chapter 9);

i) Added the test substance preparation method and administration volume (see 10.1.1);

j) The method of administering the test substance to rats in the traditional teratogenicity study has been changed (see 10.1.1, 8.1 of the 2007 edition);

k) Added maternal observation and weighing (see 10.3);

l) Added "Table 1 Live Fetus Appearance Examination Items", "Table 2 Common Abnormalities of Fetal Skeletons" and "Table 3 Common Abnormalities of Fetal Organs". (see 10.4);

m) The details of specimen preparation methods have been changed (see 10.4.3, 8.6 of the 2007 edition);

n) Added cross-sectional views of fetal rats at different positions (see 10.4.4);

o) Added test report (see Chapter 12).

Please note that some of the contents of this document may involve patents. The issuing organization of this document does not assume the responsibility for identifying patents.

This document is proposed and coordinated by the National Feed Industry Standardization Technical Committee (SAC/TC76).

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The previous versions of this document and the documents it replaces are as follows.

- First published in 2007 as GB/T 21035-2007;

- This is the first revision.

1 Scope

This document defines the terms related to the teratogenicity test for feed safety evaluation, and describes the test principles, reagents and solution preparation, instruments and equipment, The requirements for the content of the test report are specified, including the test substances, experimental animals and feeding management, dosage grouping, operating procedures, data processing and result evaluation.

This document applies to the teratogenicity evaluation of feed and feed additives.

2 Normative references

GB/T 6682

GB 14922

GB/T 14924.1

GB 14925

3 Terms and Definitions

The following terms and definitions apply to this document.

3.1 Harmful effects such as structural abnormalities, growth changes, functional defects, or death

The development of an organism that occurs before an individual is exposed to the test substance before development into an adult (including the embryonic, fetal, and postnatal stages)

3.2 Teratogenicity

The property of the test substance to cause permanent structural abnormalities in the offspring during the critical period of gestation, particularly during organogenesis.

3.3 Maternal toxicity

The test substance causes direct or indirect health damage to the parental pregnant animals, resulting in reduced weight gain, functional abnormalities, signs of poisoning, and even death. The toxicity of death.

3.4 Fertility rate parturition index

The number of animals that gave birth alive is the percentage of the number of pregnant animals.

3.5 fetal mortality

The percentage of stillbirths to the total number of litters.

3.6 Total number of teratocysts sumofterata

The number of all liveborn babies with malformations.