ICS 13.300
CCS A 80

NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

GB/T 21766-2025

Replacing GB/T 21766-2008

Chemicals - Test method of reproduction/developmental toxicity screening

化学品 生殖/发育毒性筛选试验方法

Issued on: August 29, 2025 **Implemented on: December 1, 2025**

Issued by: State Administration for Market Regulation;
Standardization Administration of the PRC

Table of Contents

Foreword

This document complies with the provisions of GB/T 1.1-2020 "Standardization Work Guidelines Part 1: Structure and Drafting Rules of Standardization Documents". Drafting.

This document supersedes GB/T 21766-2008 "Screening Tests for Reproductive/Developmental Toxicity of Chemicals" and is consistent with GB/T 21766-2008.

In comparison, aside from structural adjustments and editorial changes, the main technical changes are as follows.

- The time requirements for the trial period have been changed, including the number of days required for different stages. "mating period, pregnancy, and postpartum" (see 4.2.2).

4.2.3 (Chapter 3 of the 2008 edition);

- The requirements for ambient temperature in animal laboratories have been changed (see 5.2.1, 4.1.2 in the 2008 edition);

- The requirements for the number of experimental animals in the experimental process have been changed (see 5.5.1, 5.5.5.1, and 4.2.1 and 4.2.5.1 in the 2008 version);

- Added information on "litter size" (see 5.5.7), "estrous cycle" requirements for selecting female animals (see 5.6.3), and "clinical biochemistry".

The requirements for blood sample collection time and thyroid hormone level testing (see 5.6.5), and the requirements for vaginal smears during "gross anatomical examination" The requirements for X-ray examination and weighing of organs such as the prostate and seminal vesicles (see 5.6.6.1);

- The "Results Report" now includes sections on "Thyroid Hormone Levels" and "Number of Adult Female Animals with Normal or Abnormal Estrogenic Cycles and Their Weeks".

"Duration of period", "Puppy weight data", "AGD of all pups and weight on the AGD measurement date", "Nipple assessment of male pups" The record of the "situation" (see 6.3).

Please note that some content in this document may involve patents. The issuing organization of this document assumes no responsibility for identifying patents.

This document was proposed and is under the jurisdiction of the National Technical Committee on Standardization of Hazardous Chemicals Management (SAC/TC251).

This document was drafted by: Institute of Occupational Health and Poison Control, Chinese Center for Disease Control and Prevention; Hebei Medical University; and Fujian Ningjiajun Testing.

Technical Service Co., Ltd., Ningbo Sansheng Biotechnology Co., Ltd., Ningbo No. 2 Hormone Factory.

The main drafters of this document are: Zhang Rong, Pang Yaxian, Bao Lei, Liu Qingping, Li Bin, Chen Xiao, Zhang Hao, Qian Xingyu, and Liu Wei.

The release history of this document and the document it replaces is as follows.

- First published in 2008 as GB/T 21766-2008;

- This is the first revision.

Introduction

To address the growing need for endocrine disruptor screening in chemical risk assessments, this document is based on GB/T 21766-2008 "Chemicals".

This revision, based on the "Screening Methods for Reproductive/Developmental Toxicity of Drugs," adds endocrine-related endpoints, aiming to revise the existing testing guidelines.

New guidelines were developed to screen and test for potential endocrine disruptors. The revisions aim to incorporate endocrine-related indicators into the screening guidelines.

The exposure period covers certain sensitive periods in development (prenatal or early postnatal). The test substances provided in this document have effects on male and female reproductive processes.

Information on the effects of reproductive capacity (such as gonadal function, mating behavior, conception, embryonic development, and delivery) is limited.

This document is used in the early stages of chemical hazard assessment, or to provide information on the potential reproductive or developmental effects of chemicals of concern.

Preliminary information. For chemicals with almost no toxicological information, it can be used as part of a set of preliminary screening tests to determine bioavailability.

Dosage ranges for reproductive/development studies, or in other relevant circumstances. This document pertains to the use of clinical signs as a basis for safety assessment in laboratory animals. The humanitarian end.

This document does not provide complete information on all aspects of reproduction/development. It only provides limited means of detecting prenatal exposure.

Postpartum effects, or effects that may be induced during postpartum exposure. Due to (among other reasons) the relatively small number of animals in the dose group and the selection of the endpoint.

Due to factors such as the limited selection of subjects and the relatively short research period, this document cannot be used as conclusive evidence for determining the absence of reproductive/developmental toxicity. Furthermore, if other biological...

Reproductive/developmental toxicity test data, with positive results, can be used for preliminary risk assessment and help determine whether further testing is needed and what tests are required. Schedule.

This document provides data on adverse effects on endocrine-related endpoints, but is insufficient to determine whether a test chemical is an endocrine disruptor. Divide the evidence.

This document describes the oral route of exposure. If other routes of exposure are used, modifications are required.

1 Scope

This document establishes the basic principles for screening chemical reproductive/developmental toxicity, describes the test methods, and specifies the test data.

And the contents of the test report.

This document applies to tests for the teratogenicity, reproductive toxicity, and developmental toxicity of chemicals.

2 Normative references

GB 14925

3 Terms and Definitions

The following terms and definitions apply to this document.

3.1 androgenicity

A chemical substance has the ability to exhibit physiological effects similar to natural androgens (such as testosterone) in mammals.

3.2 Antiandrogenicity

The ability of a chemical substance to inhibit or interfere with the effects of natural androgens (such as testosterone) in mammals.

3.3 estrogenicity

A chemical substance has the ability to exhibit similar effects to natural estrogens (such as estradiol 17beta) in mammals.

3.4 Antiestrogenicity

The ability of a chemical substance to inhibit the effects of natural estrogens (such as estradiol 17beta) in mammals.

3.5 thyroid activity

A chemical substance has the ability to behave like a natural thyroid hormone (such as triiodothyronine, T3) in mammals.

3.6 Antithyroid activity

The ability of a chemical substance to inhibit the action of natural thyroid hormones (such