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NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

GB 15193.30-2025

National food safety standard - Test of developmental neurotoxicity

食品安全国家标准 神经发育毒性试验

Issued on: September 2, 2025 **Implemented on: March 2, 2026**

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

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Foreword

This document was issued on 2 September 2025 by the State Administration for Market Regulation; Standardization Administration of the PRC and takes effect on 2 March 2026.

It is a GB standard without the /T suffix: compliance is mandatory in China.

1 Scope

GB 15193.30-2025 is the Chinese national food safety standard for the developmental neurotoxicity test. It is one of the most demanding studies in the toxicology battery: the substance is given to the dam through gestation and lactation, and the offspring are then followed through development with behavioural, sensory, motor and learning assessments before their brains are examined morphometrically. The reason for the effort is that the developing nervous system can be damaged at doses that produce no effect in an adult animal and no visible malformation, so nothing else in the battery would detect it. The standard sets the purpose and principle of the test, the instruments and reagents, the test methods, the observation indicators, the pathological examination, the processing of the data and the evaluation of the result, and the test report. It takes effect on 2 March 2026.

This Standard specifies the basic test methods and technical requirements for developmental

neurotoxicity.

This Standard is applicable to the evaluation of the developmental neurotoxicity of test

substances.

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2 Terms and Definitions

2.1 Developmental neurotoxicity

Abnormal changes in the structure and function of the nervous system caused by exposure to

the test substance during development. These changes may occur at any stage of the life cycle.

2.2 Maternal Toxicity

Direct or indirect health damage caused by the test substance in pregnant female parent animals,

manifested as reduced weight gain, functional abnormalities, signs of poisoning, and even death,

etc.

2.3 No observed adverse effect level (NOAEL)

The maximum dose or concentration under specified test conditions, using existing techniques

or detection indicators, at which no adverse effects related to the exogenous chemical were

observed.

2.4 Lowest observed adverse effect level (LOAEL)

The lowest dose or concentration of an exogenous chemical that causes a certain effect in an

organism, compared to a suitable control, under specified test conditions.

3 Purpose and Principle of the Test

A test that exposes pregnant and lactating experimental animals to the test substance to evaluate

the neurotoxicity of their offspring. It typically observes changes in the structure and function

of the nervous system, as well as abnormalities in neurobehavior. This test can evaluate the

potential effects of the test substance on the functional and/or morphological development of

the nervous system in F1 generation animals; and determine whether the test substance has

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developmental neurotoxicity and its NOAEL and/or LOAEL.

4 Instruments and Reagents

4.1 Instruments/apparatus

Rat jumping box, rat dark-light box, rat shuttle box, rat Morris water maze, tuning fork,

forelimb suspension device, hot plate, rat treadmill, righting reflex tester, commonly used

laboratory dissection instruments, electronic balance, biological microscope, ophthalmoscope,

biochemistry analyzer, blood analyzer, coagulation analyzer, centrifuge, pathological slicer, etc.

4.2 Reagents

Formaldehyde, xylene, ethanol, hematoxylin, eosin, paraffin, blood cell analyzer diluent,

biochemistry analysis reagents, coagulation analysis reagents, etc.

5 Test Methods

5.1 Test substance

The test substance shall be the original sample whenever possible. If the original sample cannot

be used, the test substance shall be appropriately processed according to GB 15193.21.

5.2 Laboratory animals

5.2.1 Selection of animals

The selection of laboratory animals shall comply with the relevant provisions of GB14922.

Animals with proven sensitivity to the test substance shall be selected. Generally, rodents,

particularly rats, are preferred. Avoid using strains with low reproductive rates or high rates of

developmental defects. The gestation and lactation days mentioned in this Standard refer to

commonly used rat strains. If other species are used, the corresponding number of days shall

be selected, and their rationale shall be explained based on relevant toxicological, toxicokinetic,

and/or other data. The species, strain, source, microbiological grade, sex, weight, and age of

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the laboratory animals shall be clearly indicated.

5.2.2 Number and sex of animals

To obtain basic experimental data that meet statistical requirements and accurately evaluate the

toxic effects of the test substance on the neurodevelopmental process of animals, at least 20

litters of F1 generation animals shall be obtained for each dosage group and control group.

Within 4 days after birth (Postnatal Days, PND) (the birthday is PND 0), litter standardization

shall be performed; and excess F1 generation animals from each litter shall be randomly

removed to ensure that the number of F1 generation animals in each litter is as consistent as

possible and shall not exceed the average number of F1 generation animals per litter (8~12

animals) of the selected animal strain. The number of females and males in each litter of F1

generation shall be as consistent as possible. Selective removal of F1 generation animals is not

allowed, such as removing F1 generation animals based on body weight. Before the formal

experiment, it shall be determined which F1 generation animals shall be used for the pre-

weaning experiment and which for the post-weaning experiment.

5.2.3 Animal preparation

Use healthy, unused laboratory animals (except for consolidation experiments). Before the

experiment, animals shall undergo environmental acclimatization and quarantine observation

in the laboratory animal house for at least 3~5 days. At the start of the experiment, the difference

in animal weight shall not exceed +/-20% of the average weight; and the weight shall be within

the normal range for that animal strain. If pregnant animals are purchased, ensure they

acclimatize for 2~3 days. Pregnant rats mated with the same male shall be distributed as evenly

as possible among the groups, and each animal shall be uniquely identified.

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