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NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

GB/T 27406-2025

Replacing GB/T 27406-2008

Criterion on the quality control of laboratories - Food toxicology testing

实验室质量控制规范 食品毒理学检测

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Standardization Administration of the PRC

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1 Scope

GB/T 27406-2025 is the Chinese national standard covering quality control in a food toxicology laboratory - the animal facilities and their welfare, the test substance characterisation and dosing, the historical control data without which a result cannot be interpreted, and the study documentation. It replaces GB/T 27406-2008, the fifth of the GB/T 2740x laboratory quality standards revised across this period. It was issued on 31 December 2025 and has been in force since 1 April 2026, replacing GB/T 27406-2008. The document is under the responsibility of the Standardization Administration of China. This page is published from the official record of the 2025 edition; the clause text of a standard this recent is not yet in circulation, and the figures, limits and tables it contains are those of the document itself, delivered in full with the English translation.

This document specifies the management requirements, technical requirements, process control requirements and result quality control requirements for the quality control of food toxicology testing laboratories. This document applies to the quality control and proficiency assessment of food toxicology testing laboratories. Other specialized toxicology testing laboratories may refer to it for implementation.

2 Normative References

The contents of the following documents constitute indispensable clauses of this document through the normative references in the text. In terms of dated references, only the version

with the specified date applies to this document. In terms of references without a specified date, the latest version (including all the modifications) is applicable to this document.

GB 15193.1 Procedures for Toxicological Assessment of Food

GB/T 19001 Quality Management Systems - Requirements

GB/T 35892 Laboratory Animal - Guideline for Ethical Review of Animal Welfare

3 Terms and Definitions

The following terms and definitions are applicable to this document.

3.1 food toxicology testing laboratory An experimental facility that uses toxicological methods to test and evaluate food-related substances. NOTE. food-related substances include food and its raw materials, food additives, and substances in food containers and packaging materials that may be ingested through food.

3.2 top management of laboratory The person or group of people who directs and controls the laboratory at the highest level.

3.3 study director The test material used for testing or material obtained from a test system for testing, analysis or preservation.

3.13 administration The operation of administering test material to a test system in a specific manner.

3.14 dose The amount of test material administered to a test system in a test.

3.15 dose-effect relationship The correlation between the dose of a chemical and its effect in an individual.

3.16 dose-response relationship The correlation between the dose of a chemical and the intensity of response it elicits in a population.

4.1 Impartiality

4.1.1 Food toxicology laboratories shall impartially conduct laboratory activities and ensure impartiality in their organizational structure and management.

4.1.2 The top management of laboratories shall make an impartiality commitment.

4.1.3 The laboratories shall be responsible for the impartiality of their laboratory activities and shall not allow commercial, financial, or other pressures to compromise impartiality.

4.1.4 The laboratories shall continuously identify risks that could affect impartiality. These risks shall include those arising from laboratory activities, various relationships within the laboratory, or relationships among laboratory personnel. However, these relationships do not necessarily pose a risk to the laboratories' impartiality. NOTE. relationships that could

compromise the laboratories' impartiality may be based on ownership, right of control, management, personnel, shared resources, finances, contracts, marketing (including brand promotion), sales commissions to referrals of new clients, or other benefits.

4.1.5 If an impartiality risk is identified, the laboratories shall be able to demonstrate how to eliminate or minimize such risk.

4.2 Confidentiality

4.2.1 Food toxicology laboratories shall assume management responsibility for all information obtained or generated during laboratory activities by making a legally binding commitment. The laboratories shall notify clients in advance of any information that they intend to disclose. Unless the information is publicly disclosed by the clients, or there is an agreement between the laboratories and the clients (e.g., for the purpose of responding to a complaint), all other information is considered proprietary and shall be kept confidential.

4.2.2 When the laboratories disclose confidential information as required by law or authorized by contract, they shall notify the relevant clients or individuals of the information provided, unless prohibited by law.

4.2.3 When the laboratories obtain information about a client from channels other than the client (for example, complainants or regulatory agencies), they shall maintain confidentiality between the client and the laboratories. Unless the information provider agrees, the laboratories shall keep the information confidential for the information provider (source) and shall not disclose it to the client.

4.2.4 Personnel, including members of the Laboratory Animal Welfare and Ethics Committee and other committees, contracted personnel, external agency personnel, or individuals representing the laboratories, shall maintain confidentiality for all information obtained or generated in the course of laboratory activities, except as required by law.

5 Structural Requirements

5.1 The laboratories shall be a legal entity, or a clearly defined part of a legal entity, that is legally responsible for laboratory activities. NOTE. in this document, government laboratories are considered legal entities based on their governmental status.

5.2 The laboratories shall identify a management layer with full authority over the laboratories.

5.3 The laboratories shall define and document the scope of activities in accordance with this document. The laboratories shall only declare the scope of activities in accordance with this document and shall not include laboratory activities continuously obtained from external sources.

5.4 The laboratories shall conduct laboratory activities in a manner that meets the

requirements of this document, the laboratories' clients, statutory authorities, and accredited organizations, including laboratory activities conducted in fixed facilities, locations other than fixed facilities, temporary or mobile facilities (for example, the transport of laboratory animals), and client facilities.

5.5 The laboratories shall.

a) Define their organizational and management structure, their position within the parent organization, and the relationships among management, technical operations, and support services;

b) Define the responsibilities, authorities, and mutual relationships of all management, operational or validation personnel affecting the results of laboratory activities;

c) Document procedures in detail that ensure consistency in the implementation of laboratory activities and the effectiveness of results.

5.6 The laboratories shall have personnel with the necessary authorities and resources to perform the following duties (whether or not they are otherwise assigned).

a) Implement, maintain and improve the management system;

b) Identify deviations from the management system or laboratory activity procedures;

c) Take action to prevent or minimize such deviations;

d) Report the operation status of the management system and improvement demands to the top management of laboratories;

e) Ensure the effectiveness of laboratory activities.

6 Resource Requirements

6.1 General Requirements The laboratories shall have the personnel, facilities, equipment, systems and support services necessary to manage and conduct laboratory activities.

6.2 Personnel

6.2.1 All personnel who may affect laboratory activities, whether internal or external, shall impartially act, be competent, and work in accordance with the requirements of the laboratory management system.

6.2.2 The technical director or authorized signatory shall be a person with a background in medicine/preventive medicine, biology, pharmacy, or a related field. The technical director or technical management shall be responsible for at least.

a) Providing clients with consultation on relevant policies, regulations, technical documents, and result interpretation, etc.;