



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

GB 31612-2023

**National food safety standard - Hygienic practice for bacterial
preparations for food processing**

食品安全国家标准 食品加工用菌种制剂生产卫生规范

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Foreword

This document was issued on 6 September 2023 by the State Administration for Market Regulation; Standardization Administration of the PRC and takes effect on 6 September 2024.

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

1 Scope

GB 31612-2023 covers hygienic practice in the production of bacterial preparations for food processing - the strain preparations and starter cultures that go into food as living organisms. It runs from site selection and the factory environment through factory buildings and workshops, facilities and equipment, health management, raw materials, food additives and food-related products, food safety control during production, inspection, storage and transport of products, product recall management, training, the management system and its personnel, to records and document management; Appendix A deals with microbiological control of processing. Much of it builds on the general hygienic practice standard GB 14881 and on GB 31639, adding what is particular to growing microorganisms on purpose: terms

such as the original seed lot, and siting rules that keep such a plant away from the production sites of biological products. The hazard here is the reverse of the usual one. The product is a culture, so the plant cannot sterilise its way to safety; it has to keep one organism alive and every other one out, from the seed lot onward through every transfer. A mandatory national food safety standard for culture producers, the food manufacturers who buy from them, and inspectors.

This standard specifies the basic requirements and management guidelines for sites, facilities, and personnel in the production process of strain preparations for food processing, such as raw material procurement, strain use and management, processing, packaging, storage, and transportation.

This standard is applicable to the production of strain preparations for food processing, and is not applicable to products for direct consumption and distiller's yeast, red yeast rice, etc. produced by solid-state fermentation technology.

2 Terms and definitions

The terms and definitions defined in GB 14881 and GB 31639 and the following apply to this standard.

2.1 Original seed lot

Viable bacteria for preparing the main seed lot.

2.2 Main seed lot

A sufficient number of uniform composed viable bacteria formed after passage and propagation of the original seed lot, which are used for preparing the working seed lot.

2.3 Working seed lot

Viable bacteria obtained from the activation and passage of the main seed lot on a suitable culture medium, which are used for production.

3 Site selection and factory environment

3.1 Site selection

3.1.1 It shall comply with the relevant provisions of GB 14881.

3.1.2 No factory shall be built near the production sites of biological products, chemicals, and other products that are produced by using microorganisms.

3.2 Factory environment

It shall comply with the relevant provisions of GB 14881.

4 Factory buildings and workshops

4.1 Design and layout

4.1.1 It shall comply with the relevant provisions of GB 14881.

4.1.2 The factory buildings, equipment layout, and process flow shall be reasonably connected, the building structure shall be complete, and it shall be able to meet the requirements of production process and hygiene. The following shall be considered in the design.

- a) Avoid cross-contamination between raw materials, semi-finished products and finished products;
- b) Requirements for temperature, humidity, and other process parameters of the production process to prevent interference in adjacent workshops;
- c) Facilitate the cleaning of the inside and outside of raw material storage tanks, fermentation tanks, semi-finished product storage tanks, etc.;
- d) The air inlet for fermentation, drying, and other processes shall be set in a dry and clean location, and it shall be easy to clean and replace filter facilities;
- e) Prevent strains, contact surfaces, or packaging materials from being contaminated by microorganisms, chemicals, etc. through reasonable layout, separation, and other measures.

4.1.3 The production area for bacterial strain preparations shall meet the following requirements.

4.1.3.1 The operation area shall be divided into general work area, quasi-cleaning work area, and cleaning work area according to the production process and hygiene requirements.

4.1.3.2 Effective separation shall be set up between work areas with different cleanliness classes. An independent air purification system with a filter device shall be installed in the cleaning work area and positive pressure shall be maintained to prevent

air from non-cleaning work areas from entering the cleaning work area and causing cross-contamination.

4.1.3.3 The enrichment, emulsification, drying, mixing, and inner packaging of bacterial cells shall be a cleaning work area (except when the enrichment and They shall comply with the relevant provisions of GB 14881.

5.1.3 Cleaning and disinfection facilities

They shall comply with the relevant provisions of GB 14881.

5.1.4 Waste storage facilities

They shall comply with the relevant provisions of GB 14881.

5.1.5 Personal hygiene facilities

5.1.5.1 They shall comply with the relevant provisions of GB 14881.

5.1.5.2 Disinfection facilities shall be set up at the entrance to the cleaning work area, and secondary changing rooms and special work clothes, gloves, etc. for the cleaning work area shall be equipped as needed.

5.1.6 Ventilation facilities

5.1.6.1 They shall comply with the relevant provisions of GB 14881.

5.1.6.2 Air filtering and regulating facilities shall be installed in the cleaning work area, and the air filtering device shall be cleaned and replaced regularly. The air in the factory building shall flow from the cleaning work area with high cleanliness requirements to the quasi-cleaning work area and general work area with low cleanliness requirements. Ventilation facilities shall be installed in general work areas to remove moist and dirty air in a timely manner.

5.1.6.3 The air inlet shall be more than 2 m away from the ground or roof, away from pollution sources and exhaust outlets, and air filtering equipment shall be installed according to the requirements of the cleanliness class. The exhaust outlet shall be equipped with an easy-to-clean, corrosion-resistant mesh cover to prevent animal intrusion; the ventilation device shall be easy to disassemble, clean, repair, or replace.

5.1.6.4 In areas where odors, toxic and harmful gases, or dust is generated, there shall