GB

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National food safety standard - Hygienic specifications for the production of strain 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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National food safety standard - Hygienic specifications for the production of strain preparations for food processing

1 Scope

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 be elimination, collection, or control devices.

5.1.7 Lighting facilities

They shall comply with the relevant provisions of GB 14881.

5.1.8 Warehousing facilities

They shall comply with the relevant provisions of GB 14881.

5.1.9 Temperature control facilities

They shall comply with the relevant provisions of GB 14881.

5.2 Equipment

5.2.1 Production equipment

5.2.1.1 General requirements

They shall comply with the relevant provisions of GB 14881. Inoculation equipment, fermentation equipment, and enrichment equipment shall be equipped, and according to the characteristics of the product production process, drying equipment shall be equipped when necessary.

5.2.1.2 Materials

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

5.2.1.2.2 Equipment and utensils in contact with semi-finished products and finished products shall be made of materials with smooth and clean surfaces that comply with national regulations.

5.2.1.3 Design

It shall comply with the relevant provisions of GB 14881.

5.2.1.4 Inoculation equipment

Equipment related to strain inoculation such as ultra-clean workbench shall be equipped.

5.2.1.5 Fermentation equipment

5.2.1.5.1 Fermentation tanks, etc. that are suitable for the production scale shall be equipped, and batching tanks, seed tanks, auxiliary tanks, etc. can be equipped as needed. If necessary, equipment such as culture medium transportation, stirring, alkali liquid transportation, compressed air (or inert gas, carbon dioxide, etc.) transportation, automatic heating, dissolved oxygen control, steam sterilization, cleaning and disinfection, as well as instruments and apparatus, computer control systems, control cabinets, etc. can be equipped.

5.2.1.5.2 Compressed air or other gases used for fermentation production shall be filtered and purified to prevent indirect pollution.

5.2.1.6 Enrichment equipment

Enrichment equipment such as centrifuges or vacuum drum separators shall be equipped and facilitate cleaning and disinfection.

characteristics. The environment and equipment surfaces can be cleaned and disinfected by using hydrogen peroxide, ozone, UV, etc.; the surfaces in contact with strain can be cleaned and disinfected by using alkali, acid, steam, etc.

6.3.4 Equipment and utensils used for cleaning and disinfection shall be placed in a dedicated place and properly kept.

6.3.5 All production workshops shall develop a periodic schedule of cleaning and disinfection to ensure that the surfaces of all machines, pipes, and equipment in direct contact with strain are cleaned until the surfaces are smooth and free of bacterial residues.

6.3.6 The cleaning and disinfection process shall be recorded, such as the type, action time, concentration, and objects of detergents and disinfectants.

6.3.7 An effective monitoring process shall be developed to verify the effectiveness of cleaning and disinfection to ensure that disinfection operations meet relevant requirements.

6.4 Prevention and control of phage contamination

6.4.1 Measures to prevent and control phage contamination shall be established during the production process of bacterial strain preparations.

6.4.2 One or more of the following methods can be used to prevent and control phage contamination:

a) In the strain screening process, select strains that are resistant to phages, and regularly test strain resistance;

b) During the strain preservation process, the preserved strains are regularly separated and purified;

c) During the production process, different strains are regularly rotated;

d) During the cleaning and disinfection process, regularly conduct phage testing on facilities and equipment in the cleaning work area;

e) In the waste treatment process, strictly control the discharge of viable bacteria.

6.5 Personnel health management and hygiene requirements

They shall comply with the relevant provisions of GB 14881.

6.6 Pest control

It shall comply with the relevant provisions of GB 14881.

6.7 Waste disposal

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

6.7.2 Waste culture medium and bacterial cells shall be treated harmlessly.

6.7.3 Containers containing waste shall be specially marked and shall be reasonably constructed and impermeable. The containers can be closed when necessary to prevent product contamination.

6.8 Work clothes management

It shall comply with the relevant provisions of GB 14881.

7 Raw materials, food additives, and food-related products

7.1 General requirements

They shall comply with the relevant provisions of GB 14881.

7.2 Raw materials

7.2.1 Strains

7.2.1.1 The strains allowed to be used according to the regulations, announcements and relevant regulations issued by the health administration department of the State Council shall be used, and there shall be supporting materials or reports on strain identification, genetic stability, safety, etc.

7.2.1.2 After identification, the strains shall be freeze-dried or stored in liquid nitrogen in a timely manner. At least 2 portions shall be preserved, one for long-term preservation and the other for seed lot preparation.

7.2.1.3 Strain archival information shall be established, including complete records of source, history, screening, identification, number of passages, preservation methods, quantity, start using, etc.

7.2.1.4 The genetic stability of strains shall be ensured and mutations shall be prevented during the passage process.

7.2.2 Other raw materials

The raw materials added during the fermentation and preparation process of strains shall comply with corresponding standards and relevant regulations.

7.3 Food additives

be used to sterilize the culture medium, and the temperature and time shall be continuously monitored.

8.2.4 Fermentation

8.2.4.1 Operating procedures for strain fermentation shall be formulated.

8.2.4.2 During the fermentation process, the positive pressure of the fermentation tank shall be maintained, and technical parameters such as temperature and pH value of the fermentation broth shall be monitored.

8.2.4.3 The specification requirements for fermentation broth at the end of fermentation shall be formulated and effectively controlled.

8.2.4.4 The maximum storage time and temperature for fermentation broth from reaching the end of fermentation to enrichment shall be limited to prevent contamination.

8.2.5 Enrichment and emulsification

8.2.5.1 Operating procedures for bacterial cell enrichment and emulsification shall be formulated, and storage requirements shall be specified.

8.2.5.2 Before bacterial cell enrichment, pipes, enrichment equipment, and related tools that are in direct contact with the fermentation broth shall be cleaned, disinfected, or sterilized.

8.2.5.3 Before emulsification, the emulsifier, related equipment, containers, and related tools in direct contact shall be sterilized.

8.2.5.4 The centrifugal separation and emulsification of different strains must not be carried out at the same time in the bacterial cell enrichment and emulsification workshop to prevent cross-contamination (except for mixed strain preparation products).

8.2.6 Drying

8.2.6.1 Operating procedures for bacterial cell drying shall be formulated and preservation requirements shall be specified.

8.2.6.2 Parts of drying equipment that come into direct contact with materials shall be disinfected or sterilized regularly.

8.2.6.3 Specification requirements for dried strain preparations shall be formulated and effectively controlled.

8.2.7 Compounding or standardization

8.2.7.1 The compounding or standardization of strain preparations shall be carried out in the cleaning work area.

8.2.7.2 Containers for compounding or standardization shall be sterilized or disinfected.

8.2.7.3 The process formula and specification requirements for the compounding or standardization of strain preparations shall be formulated.

8.2.8 Packaging

8.2.8.1 The inner packaging of strain preparations shall be carried out in a cleaning work area.

8.2.8.2 Packaging materials and packaging methods that help ensure the safety and stability of strain preparations during the shelf life shall be used.

8.2.9 Clearance

8.2.9.1 After each production stage of each batch of products is completed, it will be decided whether to clear the site based on the characteristics and requirements of the next batch of products, as well as the quality status of the products in the batch.

8.2.9.2 During site clearance, all tools, instruments, parts, etc. that come into direct contact with the product shall be cleaned and disinfected, and site clearance records shall be filled in.

8.2.9.3 Clearance records shall be included in batch production records.

8.3 Control of chemical pollution

It shall comply with the relevant provisions of GB 14881.

8.4 Control of physical contamination

It shall comply with the relevant provisions of GB 14881.

9 Inspection

It shall comply with the relevant regulations of GB 14881.

10 Storage and transportation of products

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

10.2 Products in the warehouse shall be checked regularly, and any abnormalities shall be dealt with promptly.

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