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NATIONAL STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA

GB 31647-2018

**National Food Safety Standard - General Hygienic
Regulation for Production of Food Additives**

食品安全国家标准 食品添加剂生产通用卫生规范

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National Food Safety Standard - General Hygienic Regulation for Production of Food Additives

1 Scope

This Standard specifies the basic requirements and management guidelines for the procurement, processing, packaging, labeling, storage and transportation of raw materials in the production process of food additives, as well as for the production sites, facilities and personnel.

This Standard is applicable to the food additives approved and published by the Administrative Department of Public Health under the State Council in the forms of standards, announcements, etc.; it includes nutrition enhancers, food flavors and compound food additives, etc.

2 Site Selection and Plant Environment

2.1 Site selection

2.1.1 The plant shall not choose the area that have significant contamination towards the product.

2.1.2 The plant shall not affect the living and safety of the surrounding residents.

2.1.3 The plant shall not choose the area that is prone to floods; there shall not be the potential sites where large number of insects breed around the plant; if it is difficult to avoid, then take necessary precautions.

2.2 Plant environment

2.2.1 The potential contamination risks associated with environment to the production of food additives shall be considered; and appropriate measures shall be taken to minimize such risks.

2.2.2 The production site shall be clean and dry.

2.2.3 The plant area shall be arranged reasonably; the functional zones such as living zone and production zone shall be clearly divided; and take appropriate separation and isolation measures to prevent the cross-contamination.

3.5 The signs for various zones and facilities in the plant shall be clear. The sites where using and storing hazardous chemicals shall have obvious warning signs.

3.6 The production sites that may generate pollution sources such as harmful gases, dust, sewage and waste slag shall be set separately; take corresponding protective measures; so that impose no impact on the surrounding environment and final products. The discharge of the waste gas, waste water and waste slag shall conform to the relevant state regulations.

3.7 The floors, walls, doors and windows, ceilings, etc. shall be easy to maintain, clean or disinfect. They shall be constructed with suitable durable materials. The cleaning operation area and accurate cleaning operation area shall meet the corresponding hygienic requirements according to the product characteristics. The requirements for the floor, wall, door and window, ceiling in the production workshop of the enzymic preparations, compound food additives, and food flavor shall meet the relevant hygienic requirements for the production site of the food processing enterprise.

4 Facilities and Equipment

4.1 Facilities

4.1.1 Water supply and drainage facilities

Appropriate water supply and drainage facilities shall be provided. The water quality of the production water shall conform to the provisions of GB 5749; if there are special requirements, it shall conform to the relevant provisions.

4.1.2 Cleaning and disinfection facilities

Adequate special cleaning facilities for the tools and equipment shall be provided; if necessary, provide appropriate disinfection facilities. Measures shall be taken to avoid cross-contamination from cleaning and disinfection tools.

4.1.3 Personal hygiene facilities

4.1.3.1 The locker room shall be set up at the production site; if necessary, the locker room can be set up at the entrance of the specific operation area; The size and facilities of the locker room shall be compatible with the number of the production personnel; the work clothes shall be isolated from the personal clothe and other articles.

4.1.3.2 If necessary, changing shoes (wearing shoes covers) facilities or work shoes and boots disinfection facilities shall be provided; the size of which shall meet the disinfection requirements.

4.1.3.3 The toilet shall not be directly connected to the areas where the products are

4.2.2 The equipment and utensils that come into contact with the raw materials, semi-finished products, finished products shall be made of non-toxic, odorless, anti-corrosive and non-shedding materials; shall be easy to clean and maintain.

4.2.3 The main fixed pipe connected to the equipment shall mark the flow direction of the materials in the pipe.

4.2.4 The equipment used for monitoring, controlling and recording, such as pressure gauges, thermometers, recorders, etc. shall be regularly calibrated and maintained.

4.2.5 Equipment maintenance and caring system shall be established; strengthen the daily maintenance and caring of the equipment; overhaul the equipment regularly; record immediately.

4.2.6 All kinds of equipment and pipelines shall be intact, prevent damage and leakage.

5 Hygienic Management

5.1 Hygienic management system

5.1.1 Establish the product personnel and enterprise production hygienic management system and corresponding assessment criteria; confirm the job responsibilities. According to the characteristics of the product and hygienic requirements during the production and storage processes, establish monitoring system for key control links to ensure the product quality and safety.

5.1.2 Regularly check the implementation and effectiveness of the system; find problems in time for rectification.

5.1.3 The microbial monitoring during the production process of the products with microbial control requirements can refer to the requirements of Appendix A of GB 14881-2013.

5.2 Hygienic management of factory and facilities

5.2.1 When damage is occurred to the factory floor, wall, door and window, ceiling, etc.; repair them immediately.

5.2.2 All facilities in the factory shall be kept clean; promptly repair and update if problems occur.

5.2.3 Production, packaging, storage and other equipment and tools, production pipelines, exposed product contact surface, etc. shall be regularly cleaned and disinfected as needed. For the processes that are not suitable for disinfection, there shall be other appropriate measure to ensure the hygiene.

6.1.3 After the raw materials and relevant products are checked qualified for acceptance, they shall be classified, partitioned and stored separately; the rejected raw materials shall be placed separately from the qualified products in designated area; marked clearly; then they shall be returned or replaced in time.

6.1.4 The warehouse of the raw materials and relevant products shall be managed by special personnel; establish management system; regularly check the quality and hygiene conditions; timely deal with the raw materials and relevant products that have deteriorated or exceeded the shelf life. Warehouse shipment order shall follow the principle of first in, first out.

6.1.5 Before production and processing, sensory inspection shall be carried out on raw materials and relevant products; if necessary, laboratory inspection shall be implemented; ensure that they meet the specified requirements.

6.1.6 The materials for package or container containing food raw materials, food additives, and packaging materials directly in contact with the food additives shall be stable, non-toxic, harmless, hard to be polluted; conform to the relevant standards, safety and hygiene requirements.

6.1.7 The transportation tools and containers of raw materials shall be kept clean, well maintained; and disinfected if necessary. The food raw materials may not be shipped together with the toxic or harmful substances to avoid contamination. The food raw materials shall avoid direct sunlight during the transportation and storage processes; equip with rain and dust prevention facilities; if necessary, equip with facilities for heat preservation, cold storage and fresh preservation. The hazardous chemicals shall be stored in accordance with the relevant provisions of the state; and their use shall be operated in accordance with the prescribed methods to prevent cross-contamination or accidents.

6.1.8 Chemicals such as lubricants, cleaning agents, disinfectants shall be classified, labeled according to their use and stored safely; so as not cause pollution to the products. Use shall be carried out in accordance with the prescribed methods to prevent pollution or accidents.

6.2 Purchase requirements

6.2.1 The raw materials for food purchased shall be subject to the examination of the supplier's license and the product qualification certificate; the food raw materials that cannot provide the qualified certification documents shall be inspected in accordance with the food safety standards. When purchasing the raw materials of livestock and poultry, their quarantine and inspection certificate shall be checked. Prohibit to purchase the spoilage, recycling or hazardous waste after industrial processing as food raw materials.

6.2.2 When purchasing the food additives, the supplier's license and product certificate

7.5 Food additives produced by the extraction process shall strictly control the pressure, temperature, extraction time, flow rate of extraction solvent; and strictly control the residual amount of the solvent.

7.6 The production of compound food additives shall strictly control the formula; the mixing process shall control the corresponding process parameters to ensure the uniform mixing of materials.

7.7 If strains are used during the production process of the food additives, strict management and operation systems shall be in place. The preservation and expansion of the strains shall be carried out aseptically.

7.8 When raw materials and internal packaging materials enter into the production area, appropriate buffer areas and facilities shall be provided; if necessary, cleaning and disinfection shall be carried out; prevent foreign matters from entering the production line, and further cause the contamination of the products.

7.9 It shall be avoided producing and processing the products used different raw materials on the same production line or production equipment; prevent the cross-contamination. If it is necessary to share the production line, establish the cleaning and disinfection systems; clean the production line and production equipment when the products are switched; if necessary, disinfect them; check the cleaning and disinfection effects; ensure the food additives are not contaminated.

7.10 Management systems shall be established to prevent the biological, chemical and physical contamination of the product; analyze the possible contamination source and ways; develop appropriate control plans and procedures.

7.11 Attention shall be paid to the possible generation of hazardous substances during the production process; take effective measures to reduce the risks to the safe range.

7.12 The site producing and using the corrosive chemicals such as strong acid and alkali shall be marked with obvious warnings; the emergency handling facilities shall be provided.

7.13 Encourage the use of more advanced quality management systems for quality and safety control of the production process.

8 Package Mark

8.1 Food additives shall take shaped package.

8.2 The packaging materials and forms of food additives shall be able to ensure the product safety and quality maximumly on the conditions of normal storage, transportation and sales.

11 Product Traceability and Recall Management

It is necessary to establish an effective traceability and product recall system from raw material procurement to product sales; which shall meet the requirements of relevant national laws and regulations.

12 Training

12.1 A training system related to the positions of food additive production shall be established; develop and implement the training plans; record the training activities.

12.2 Personnel engaged in production, inspection and other related work shall be employed after post training and passing the examination.

12.3 Personnel involved in the operation of hazardous chemicals shall be trained with relevant knowledge of hazardous chemicals.

12.4 Personnel involved in the preservation, expansion of culture of strains, and related operations shall be trained with strains related knowledge, and have corresponding skills.

12.5 When food safety related laws and regulations are updated, corresponding training shall be carried out timely.

13 Management Systems and Personnel

13.1 Management systems

13.1.1 Enterprises shall develop a management system to guarantee the food safety.

13.1.2 Food safety management system shall be compatible with production scale, process technology level and product type and characteristics; additionally, it shall also be continuously improved according to the production practice and implementation experience.

13.1.3 Enterprises involved in the production of hazardous chemicals shall also have the corresponding protection and disposal systems.

13.2 Personnel requirements

13.2.1 Enterprises shall have food safety management personnel, professional and technical personnel, operators and inspectors compatible to the produced food additives.

Appendix A

(Informative)

Guidelines for Food Safety Control Requirements of Different Food Additive Production Forms

Food additives come from a wide range of sources, including food ingredients, non-food ingredients, even hazardous chemicals. Meanwhile, the production forms and production processes of food additives are very complicated and diverse; which mainly include chemical reaction methods, natural raw materials extraction methods from animals and plants, biological fermentation methods, physical mixing methods, and the like basic methods, as well as the cross-over and mixed use of the above methods.

Appendix takes examples to propose corresponding control requirements for different forms of food additive production; so that provide guidelines and assistance for the site selection, plant and production process layout, cleaning area determination of food additive enterprises; in actual production, it can be implemented by referring to the product characteristics, production process, and the like factors; see Table A.1 in details.

A.1 According to the different forms of food additive production, equipment and facilities characteristics, set up the corresponding factory; establish corresponding food safety control system; ensure its implementation and improvement.

A.2 Regardless the forms of production, the package, storage, transportation of final food additive products can ensure the quality of food additives and prevent the cross-contamination; be able to ultimately ensure the hygiene and food safety of the final food products.

Table A.1 -- Guidelines for Food Safety Control Requirements of Different Food Additive Production Forms

Production form	Process characteristics	Factory, equipment and facilities characteristics	Cleaning area division	Personnel and hygiene management system
Chemical reaction method (chemical synthesis, chemical separation, etc.), gas production	Refer to chemical production management	Most of them are pipeline continuous production lines; according to the product	In addition to packaging link, other production area shall be required as general operation	In addition to packaging link, the management control level for personnel and hygiene in other

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