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General Hygiene Regulation for Food Production

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Report Highlights:

On May 24, 2013, China released the National Food Safety Standard of General Hygiene Regulations for Food Production (GB14881-2013), which became effective on June 1, 2014.

This standard stipulates the basic requirements and management principles for venue, facilities and workers involved in food production; it covers raw material procurement, production, packaging, storage and transportation. This standard is final and applies to the production of foods of all kinds.

This standard can also serve as a reference for U.S. food manufacturers exporting to China in anticipation of China's registration process under Decree 145.

This report provides an unofficial translation of the standard.

General Information:

National Food Safety Standard for General Hygiene Regulations for Food Production

Foreword

This Standard replaces the General Hygiene Regulations for Food Enterprises (GB14881-1994).

This standard modifies the GB14881-1994 in the following aspects:

- Changes name of the standard;
- Modifies structure of the standard;
- Adds terms and definitions;
- Emphasizes food safety control requirements in the entire food production process, namely raw material purchase, processing, product storage and transportation; it also lists major control measures for biological, chemical and physical contaminations;
- Modifies sections related to production equipment; the standard sets requirements on layout, materials and design of the production equipment from the perspective of preventing biological, chemical and physical contaminations;
- Adds relevant requirements for the procurement, inspection and acceptance, transportation and storage of raw materials;
- Adds specific requirements on product traceability and recall;
- Adds requirements on record keeping and document management;
- Adds Appendix A: *Guide of Monitoring Procedure for Microorganism in the Food Production Environment*”.

National Food Safety Standard for General Hygiene Regulations for Food Production

1. Scope

This standard stipulates the basic requirements and the management principles for venue, facilities and workers with regard to food production from raw material procurement to production, packaging, storage and transportation.

This standard applies to the production of foods of all kinds; if a certain variety of food is subject to special hygienic requirements, the specific requirements shall be developed based on this standard.

2. Terminology and definition

2.1. Contamination

It refers to the introduction of various kinds of biological, chemical and physical pollutants into foods in the process of food production.

2.2. Insect pest

It refers to adverse effect caused by insects, birds and rodents (including fly, cockroach, bee, sparrow and rat, etc.)

2.3. Food processing workers

Persons directly or indirectly contact packaged or unpackaged foods, food producing equipment, containers, or food-contacting surface.

2.4. Contact surface

Surface of equipment, tools or human body that contact foods.

2.5. Separation

Separation by certain spaces between stuffs, equipment and areas; not separation by physical interdiction.

2.6. Segregation

Segregation made by physical interdiction such as walls, sanitary protective screens, shields or separate rooms.

2.7. Food processing establishment

Construction and venue used for food processing; or other construction, venue and the surrounding environment managed by the same methods.

2.8. Monitoring

Determine whether controlled link is function and under control by observation or measurement following pre-set methods and parameters.

2.9. Work clothes

The special clothes worn by food processing workers at different production areas to reduce contamination risks.

3. Site selection and factory environment

3.1. Site selection

3.1.1. A factory shall avoid the site in a region that may heavily pollute foods; it shall avoid a site in a region that compromise food safety or suitability, and it is impossible to take measures to improve the environment.

3.1.2. A factory shall avoid a site that cannot effectively clean diffuse pollutants, such as hazardous disposals, dust, harmful air, radiation materials, etc.

3.1.3. A factory shall avoid the region that is incidental to flooding disasters; if the factory must be built in the region, necessary preventative measures shall be taken;

3.1.4. The factory shall not be surrounded by areas that have abundant insect pests; if the factory must be built in the area, necessary preventative measures shall be taken.

3.2. Factory environment

3.2.1. Potential pollution risks by the environment to food production shall be considered; take appropriate measures to reduce the pollution risks to the lowest level;

- 3.2.2.** Layout of the factory shall be reasonably designed, with clear division of regions for different functions by separation or segregation measures to prevent cross contamination.
- 3.2.3.** Roads in the factory shall be paved with concrete, asphalt or other hardening materials; pave the vacant spaces with concrete, tiles, or grass to avoid floating dust and stagnant water.
- 3.2.4.** Keep a suitable space between the greening belt and the production workshops; manage the vegetation on a regular basis to prevent contamination caused by insect pests.
- 3.2.5.** Install appropriate drainage system.
- 3.2.6.** Separate or segregate the employee dormitory, cafeteria, entertainment facilities from the production area.

4. Factory building and workshop

4.1. Design and layout

- 4.1.1.** The interior design and layout of the factory buildings and workshops shall comply with requirements for hygienic operation to prevent cross contamination.
- 4.1.2.** Pursuant to the manufacturing techniques, the factory and the workshops shall be reasonably designed to prevent and reduce contamination risks;
- 4.1.3.** According to products, production techniques, and requirements on cleanliness, separate or segregate the factory and the workshops into different operation areas; for instance, the production area could be divided into the clean /the quasi-clean /the general operation areas, or be divided into the clean/the general operation areas. The general operation area shall be separated from other operation areas.
- 4.1.4.** The testing facilities within the factory building shall be separated from the production area.
- 4.1.5.** Size and space of the factory building shall be compatible to its production capacity; the factory shall have enough space for installation of equipment, cleaning and sterilization, material storage, and operation.

4.2. Interior framework and materials

4.2.1. Interior framework

The interior structure is easy to maintain, clean and sterilize; the interior framework shall be built with appropriate durable materials.

4.2.2. Roof

4.2.2.1. Build the roof with nontoxic, odorless materials; it shall be easy to observe cleanness of the roof. In the case of directly spraying paint to the roof in the factory building, use paints that are nontoxic, odorless, anti-mold, dropping-free, and easy to clean.

4.2.2.2. The roof shall be easy to clean and sterilize; in terms of structure, the roof shall prevent dropping of condensed water, invasion of insect pests, and occurrence of mold.

4.2.2.3. Avoid installing pipelines for steam, water and electricity above the exposed foods; if the installation is unavoidable, take measures to prevent dust or water from dropping.

4.2.3. Walls

4.2.3.1. Use nontoxic, odorless and anti-seepage materials for walls and segregations; wall surface within the operation height shall be smooth, easy to repel the accumulated dirt and clean; wall paint shall be nontoxic, odorless, anti-mold, dropping-free, and easy to clean.

4.2.3.2. The walls, the segregation and the wall/floor junctions shall be easy to clean; for instance, using the bending interfaces.

4.2.4. Doors and windows

4.2.4.1. Doors and windows shall be able to close tightly. Surface of the doors shall be flat and smooth, anti-absorbent and impermeable, easy to clean and sterilize. Doors shall be made from impervious, firm, solid materials.

4.2.4.2. Doors connecting the clean operation area, the quasi-clean operation area and other areas shall be able to close timely.

4.2.4.3. Use invulnerable materials for window glasses. If using common glass, necessary measures shall be taken to prevent contamination of broken glass to raw materials, packaging materials, and food.

4.2.4.4. If the windows are set up with windowsills, it shall be in the structure that could avoid accumulation of dust and is easy to clean. The retractable windows shall be provided with anti-insect window screening that is easy to clean.**Floor surface**

4.2.5.1. Use nontoxic, odorless, impermeable and anti-erosion materials as floor surface. Structure of the surface shall be easy to clean and drain the contaminants out.

4.2.5.2. The floor surface shall be flat and crack-free; it shall be easy to clean and sterilize; appropriate drainage measures shall be taken to prevent stagnant water.

5. Facilities and equipment

5.1. Facilities

5.1.1. Facilities for water supply

5.1.1.1. Water supply facilities must guarantee water quality, the water pressure, the water quantity and other requirements for production use.

5.1.1.2. Water for food production shall be in line with the quality provisions in GB 5749 (Drinking Water Sanitary Standard); water used for producing foods that have special requirements shall comply with relevant provisions. Quality of water for food production (such as indirect cooling water and boiler-use water) shall comply with the production requirements.

5.1.1.3. Separate the pipeline systems for transporting the water for food processing and the water that does not contact food (such as indirect cooling water, sewerage and waste water) to avoid cross contamination; the pipelines shall be clearly marked to distinguish their uses.

5.1.1.4. The self-supplied water resources and the water supply facilities shall comply with relevant provisions. Products used in the water supply facilities that involve hygiene and safety of drinking water shall comply with relevant national regulations.

5.1.2. Drainage system

5.1.2.1. The design and construction of the drainage system shall ensure smooth discharge and shall be easy to clean; the drainage system shall be compatible to the production needs, and shall protect water used for food production and cleansing from contamination.

5.1.2.2. Install water seals at the inlet of the drainage system so as to prevent the solid wastes from entering, and leaking of filthy air.

5.1.2.3. Take appropriate measures to reduce risks of insect pests.

5.1.2.4. The internal drainage shall allow water to flow from the areas with higher demand for cleanness to areas with lower demand for cleanness; install devices that prevents countercurrent flow of water.

5.1.2.5. The waste water, before discharge, shall be treated appropriated to comply with relevant sewage discharge regulations.

5.1.3. Cleaning and sterilizing equipment

Set up adequate facilities specially for cleaning foods, tools and equipment; if necessary, set up sterilizing facilities. Measures shall be taken to avoid cross contamination of the cleaning and sterilizing tools/facilities.

5.1.4. Facility for waste storage

Set up facilities with reasonable design for waste storage; the facilities shall be leaking-free and easy to clean; waste storage facilities and containers in workshops shall be clearly marked. If necessary, temporary wastes storage facilities can be set up at appropriate locations, and the wastes shall be sorted pursuant to their categories.

5.1.5. Personal sanitary facilities

5.1.5.1. A dressing room shall be set up at the entrance of the production area or the workshop; a dressing room can be set up at entrance of the special operation area when necessary. The dressing room shall allow separation of work clothes from personal wear and other articles.

5.1.5.2. When necessary, footwear (shoe cover) changing facilities or footwear sterilizing facilities shall be set up at the entrance of the workshop and inside the workshop. Size and specifications of the sterilization facilities shall fulfil needs for sterilization.

5.1.5.3. Toilets shall be set up if needed; structure, equipment and interior materials of the toilets shall be easy to keep clean; hand washing facilities shall be set up at suitable places in the toilet. Toilets shall not have direct connection to the areas for food production, packaging or storage.

5.1.5.4. Set up hand washing, drying and sterilizing facilities at the entrance of the clean operation area; if necessary, the facilities for hand washing and/or sterilizing shall be set up at the suitable locations in the operation area. The sterilizing facilities shall use non-manual switch taps.

5.1.5.5. The number of taps shall be compatible to the number of food processing workers in each working shift; set up the hot and cold water blending devices if necessary. The hand-washing sink shall be made from smooth, impermeable and easy to clean materials; its design and structure shall be easy to clean and sterilize. Hand washing instructions that are simple and easy to understand shall be placed at the prominent point near the hand washing facilities.

5.1.5.6. If necessary, facilities, such as an air shower or a showering room, shall be set up according to requirements on cleanness of food processing workers.

5.1.6. Ventilation facility

5.1.6.1. Make available the natural or the artificial ventilation. If necessary, control the temperature and humidity in the production area by natural ventilation or by mechanical equipment. The ventilation facility shall avoid air flow from the areas with lower demand for cleanness to areas with higher demand for cleanness.

5.1.6.2. The air inlet shall be reasonably laid out; keep appropriate distance and angles between the air inlet/outlet from the contamination sources (such as trash storage). Facilities, such as insects preventing net shall be installed in the air inlet/outlet; the ventilation and exhaust discharge facilities shall be easy to clean, maintain and replace.

5.1.6.3. If the air shall be filtered and cleaned in process of food production, air filters shall be installed and cleaned on a regular basis.

5.1.6.4. If necessary, the dust removal facility shall be installed according to the production needs.

5.1.7. Lighting facility

5.1.7.1. The workshops shall have enough natural lighting or artificial, where the luster and the brightness shall meet the needs for production and operation. The light source shall reflect real color of foods.

5.1.7.2. Use safe lighting facility or take protective measures if lights are installed over the foods and raw materials.

5.1.8. Storage facility

5.1.8.1. There shall be adequate storage facilities that meet requirements in terms of quantity and storage conditions.

5.1.8.2. The warehouses shall be built by nontoxic and solid materials, with flat floor surface and ventilation; it shall be easy to clean, and have insect prevention devices.

5.1.8.3. Raw materials, semi-finished products, finished products and the packaging materials shall be stored in different storage facilities or areas. The sections shall be clearly marked to avoid cross contamination. If necessary, the warehouses shall install the devices for temperature and humidity control.

5.1.8.4. The stored goods shall be kept a suitable distance away from the walls and the ground to allow air circulation and moving of the goods.

5.1.8.5. Detergents, disinfectant, pest control agents, lubricant and fuel shall be packaged safely with clear marks; they shall be stored separately from raw materials, semi-finished products, finished products and packaging materials.

5.1.9. Thermal control devices

5.1.9.1. Install heating, cooling or freezing devices pursuant to product production needs, as well as devices for temperature monitoring.

5.1.9.2. Install devices for room temperature control pursuant to production needs.

5.2. Equipment

5.2.1. Production equipment

5.2.1.1. General requirements

The production equipment shall be compatible to the production capacity; they shall be arranged according to the production process to avoid cross contamination.

5.2.1.2. Materials

5.2.1.2.1. The equipment and devices that contact raw materials, semi-finished products or finished products shall be made from nontoxic, odorless, anti-erosion, and dropping-free materials; the materials shall be easy to clean and maintain.

5.2.1.2.2. Surface of the equipment and devices that have contact with foods shall be made of smooth and anti-absorbent materials that are easy to clean, maintain and sterilize. The materials shall not react with foods, detergent and disinfectants under normal conditions, and shall be kept in the wholesome status.

5.2.1.3. Design

5.2.1.3.1. Design and structure of the production equipment shall prevent falling of parts, metal chips, lubricant, or other pollutants into the produced foods; they shall be easy to clean, sterilize, check and maintain.

5.2.1.3.2. The equipment shall be fixed on the wall or the floor, or leave enough gap between the equipment and the wall/floor for maintenance and cleaning.

5.2.2. Monitoring device

The devices used for monitoring, controlling and recording, such as the pressure gauge, thermometers, and recorders; such devices shall be calibrated and maintained regularly.

5.2.3. Maintenance and repair of the equipment

Establish the system for maintenance and repair of the equipment; follow the daily maintenance and repair schedule, timely record the repair and maintenance.

6. Hygiene management

6.1. Hygiene management system

6.1.1. Establish the management systems and evaluation standards to regulate food processing workers and food production; clearly identify responsibilities of each position and adopt the “post responsibility mechanism”.

6.1.2. Based on characters of foods and hygiene requirements on production and storage, establish the HACCP system, which bears great significance in food safety; implement the system well, and conduct inspection regularly; problems detected shall be corrected timely.

6.1.3. Establish hygiene monitoring system on production environment, food processing workers, equipment and facilities; define scope, objects and frequency of internal monitoring. Record and file the monitoring results; regularly inspect implementation and effects of the monitoring system; problems detected shall be corrected timely.

6.1.4. Establish the protocol of cleaning and sterilization, and the protocol of the cleaning/sterilization tool management. The equipment and tools before and after cleaning/sterilization shall be kept separately to avoid cross contamination.

6.2. Hygiene management for factory buildings and the facilities

6.2.1. The facilities in the factory buildings shall be kept clean, and shall be repaired timely once problems occur; the floor, roof, ceiling and walls, if broken, shall be repaired timely.

6.2.2. Equipment and tools for processing/packaging/storage, pipelines for production, and surface that have contact with foods shall be cleaned and sterilized regularly.

6.3. Health management and hygienic requirements for food processing workers

6.3.1. Health management for food processing workers

6.3.1.1. Establish and implement the health management system for food processing workers.

6.3.1.2. The food processing workers shall have a health check each year, and obtain a health certificate. They shall receive health training before taking up a job.

6.3.1.3. Food processing workers with the following diseases shall be transferred to positions at which their diseases do not affect food safety: infectious disease of digestive tract (such as diarrhea, typhoid, viral hepatitis type A and viral hepatitis type E), active pulmonary tuberculosis, suppurative skin diseases and exudative dermatitis; prominent unclosed wounds on the skin.

6.3.2. Hygienic requirements for food processing workers

6.3.2.1. Before entering the food production facility, the food processing workers shall clean themselves to avoid polluting foods.

6.3.2.2. The food processing workers shall properly wear clean work clothes before entering the production areas; they shall wash and sterilize their hands as required; their hair shall be kept in the working caps, or restricted by hair nets;

6.3.2.3. In the production areas, the food processing workers shall not wear accoutrement or watches; they are not allowed to wear make ups, nail polish or scented sprays; nor are they allowed bringing into the production areas personal belongings that are irrelevant to food production.

6.3.2.4. After using the toilet or contacting stuffs that may pollute foods, or engage in activities that are irrelevant to food production, the food processing workers shall wash and sterilize hands before resuming food production.

6.3.3. Visitors

Persons other than food processing workers are not allowed to enter the food production areas. If they need to enter the areas in special circumstances, they are subject to the same hygienic requirements on food processing workers.

6.4. Pest control

6.4.1. Keep the workshop in good and complete condition and keep the environment clean to prevent pest invasion and breeding.

6.4.2. Establish and implement measures for pest control, with regular inspections. Take effective measures (such as installing gauze curtain, gauze net, mouse sticking plate, lamp against flies and air curtain) in the workshops and the warehouses to prevent mice and insects from entering. If detecting traces of mouse or pest in the facilities, the source shall be investigated to eliminate the hazard.

6.4.3. Develop a complete and accurate factory floor plan for pest control; the floor plan shall indicate locations of mousetraps, mouse sticking plate, fly-killing lamps, outdoor baits, the biochemical catching and killing devices, etc.

6.4.4. Measures for killing pests shall be conducted regularly within the factory area.

6.4.5. The physical, chemical or biological agents used to control pests shall not affect safety and quality of the foods; nor shall the agents contaminate the food-contact surfaces, equipment, tools or the packaging material. The factory shall keep records of the pest insect control measures.

6.4.6. Before using insecticides or other medicaments, take preventive measures to avoid harm to human health, foods, equipment and tools; in case of accidental contamination, the contaminated equipment and tools shall be cleaned thoroughly.

6.5. Waste Disposal

6.5.1. Establish the system for storage and disposal of wastes. Relevant requirements shall be followed in disposing wastes that need special treatment. Dispose wastes on a regular basis; the perishable wastes shall be removed as fast as possible, while other wastes shall be removed and cleaned timely.

6.5.2. The wastes storage areas shall be isolated from the food processing areas to prevent contamination; take measures to prevent release of aversive, harmful or toxic gas; take measures to prevent breeding of insects and rats in the area.

6.6. Management of work clothes

6.6.1. Persons entering the production area shall wear work clothes.

6.6.2. Food processing workers shall wear work clothes (such as jacket, pants, cap, footwear and hair net etc.) that suit categories and production techniques of foods. When necessary, food processing workers shall be provided respirator, apron, raglan sleeve and gloves.

6.6.3. Establish the system for cleaning of the work clothes; timely change the work clothes when necessary; in production, the work clothes shall be kept clean and complete.

6.6.4. Design, fabric and tailoring of the work clothes shall meet requirements of different operation areas to reduce risks of cross contamination. Pocket position and fasteners shall be considered to prevent dropping of pocketed stuffs and losing of the fasteners that would cause food contamination.

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

7.1. General requirements

The enterprise shall establish the management system for procurement, acceptance, transportation and storage of food materials, food additives and food-related products that comply with relevant national requirements; it is prohibited to add substances that are detrimental to human health or safety.

7.2. Raw Materials

7.2.1. In procurement, check food material supplier's license and product quality certificates; food materials without such documents shall be tested pursuant to food safety standards.

7.2.2. Raw materials can only be accepted and used after inspection; otherwise, they shall be stored in an isolated and designated area with clear marks; the unqualified products shall be timely returned or changed.

7.2.3. Appearance (or sensory) inspection, and lab testing if necessary, shall be conducted before the materials are put into processing; materials that present abnormal testing results in items involving food safety shall not be used. Only suitable food materials can be used.

7.2.4. In transportation and storage, food materials shall avoid direct sun exposure, and shall be covered by rain and dust proof devices. According to the characters and the hygienic requirements of the food materials, the device for thermal insulation, cold storage and fresh-keeping shall be equipped.

7.2.5. The vehicles and the containers to transport food materials shall be kept clean and in good conditions, and shall be sterilized when necessary. Food materials shall not be shipped together with toxic and harmful substances to avoid contamination.

7.2.6. Storage for food materials shall be managed by designated persons; establish the system for regular quality and hygiene inspection; food materials that have deteriorated or passed the warranty period shall be cleared off timely. The principle of first-in first-out shall be adopted; characters of the food materials shall be considered in shipping the materials out of the warehouse.

7.3. Food Additives

7.3.1. In procurement, check food additive supplier's license and product quality certificates; food additives can only be used after passing inspection.

7.3.2. The vehicles and the containers to transport food additives shall be kept clean and in good conditions; they shall protect the food additives from contamination.

7.3.3. Storage for food additive shall be managed by designated persons; establish the system for regular quality and the hygiene inspection; food additives that have deteriorated or passed the warranty period shall be cleared off timely. The principle of first-in first-out shall be adopted; characters of the food additives shall be considered in shipping the materials out of the warehouse.

7.4. Food-related products

7.4.1. In procurement, check food-related product (such as packaging materials, containers, detergents and disinfectors) supplier's license and product quality certificates; suppliers of food-related products that are subject to licensing shall provide their licenses as well. Food-related products can only be used after passing inspection.

7.4.2. The vehicles and the containers to transport food-related products shall be kept clean and in good conditions; they shall properly protect the food-related products from cross contamination.

7.4.3. Storage for food-related products shall be managed by designated persons; establish the system for regular quality and hygiene inspection; food-related products that have deteriorated or passed the warranty period shall be cleared off timely. The principle of first-in first-out shall be adopted.

7.5. Other issues

Packaging materials and containers that contain food materials, food additives or have direct contact to foods shall be produced from materials that are stable, non-toxic, harmless, contamination-free, and meet relevant hygienic requirements.

Before entering into the production areas, the food materials, food additives and food packaging materials shall go through a buffer zone, or take measures to clean the exterior package to reduce risk of contamination.

8. Food safety control in food production

8.1. Control the risk of product contamination

8.1.1. Identify the key links of food safety in production through hazard analysis, and establish hazard control measures in the links. Make available relevant documents in the area of the key links to implement the control measures, such as the ingredients (feed intake) forms, the post operation procedures, etc.

8.1.2. Encouraging the adoption of HACCP to control food safety in production.

8.2. Control of biological contamination

8.2.1. Cleaning and sterilization

8.2.1.1. Establish effective cleaning and sterilization mechanisms for production equipment and the environment pursuant to characters of the materials, products and the production techniques, aiming to reduce the risk of microorganism contamination.

8.2.1.2. The cleaning and sterilization plans shall include the following contents: areas and names of the equipment/devices to be cleaned and sterilized; the responsibility of cleaning and sterilization workers; the detergent and disinfectant to be used; the methods and frequency of cleaning and sterilization; verification of the sterilization effect and correction of non-compliances; records of the cleaning, sterilization and the monitoring work.

8.2.1.3. The cleaning and sterilization mechanism shall be implemented and faithfully recorded; timely verify the sterilization results, and take corrective measures once problems were detected.

8.2.2. Microorganism Surveillance in food production

8.2.2.1. Conduct Microorganism surveillance in key control links pursuant to characters of products. If necessary, establish the Microorganism surveillance plan, covering monitoring within the production environment and the in-process product.

8.2.2.2. The Microorganism surveillance plan for food processing procedure shall be composed of Microorganism surveillance indicators, sample point, monitoring frequency, sampling and testing method, principles for assessment and rectification measures, etc. The plan shall be established pursuant to the Appendix A, and take the production techniques and product characteristics into consideration.

8.2.2.3. The Microorganism surveillance shall include monitoring over the pathogen and the indicator bacterium. The Microorganism surveillance results shall reflect control of microorganism pollution in the food processing procedure.

8.3. Control of chemical pollution

8.3.1. Establish the management system to prevent chemical pollution by analyzing the possible pollution sources and paths; develop appropriate control plans and control procedures.

8.3.2. Establish the using protocols of food additives and food processing aids. Food additives use shall follow provisions in the National Food Safety Standard GB2760 (Standards for Uses of Food Additives).

8.3.3. Other than food additives in food processing, it is prohibited to add not-for-food-use chemical substances and other substances that may harm human health.

8.3.4. Lubricants applied to the movable parts of food processing equipment that may directly or indirectly contact food shall be edible oil, or other oil that comply with food safety requirements.

8.3.5. Establish the using protocols of chemicals, such as detergent and disinfectants. Chemicals that might pollute the food shall not be used or stored in the production locations unless for cleaning/sterilization and for production use.

8.3.6. The food additives, detergents, and disinfectants shall be appropriately stored in suitable containers with clear labels; they shall be stored according to purposes of use; such substance shall be accurately measured before use; keep records of the use.

8.3.7. Monitor potential harmful substances generated in food processing and take effective measures to reduce risks caused by such substances.

8.4. Control of physical pollution

8.4.1. Establish the management system to prevent pollution by foreign substances; analyze the possible pollution sources and paths, formulate the control plans and the control procedure.

8.4.2. Maximally prevent the risk of food pollution by foreign substances, such as glass, metal and/or plastics by taking the measures of equipment maintenance, hygienic management, on-site management, visitor management and supervision over food processing.

8.4.3. Take effective measures, such as the screening net, traps, magnetic iron and electronic metal detector, to reduce risk of pollution by metal and/or other foreign substances.

8.4.4. In facility repair, maintenance or construction, take appropriate measures take to prevent food pollution by foreign substances, odor or scraps.

8.5. Package

8.5.1. Under normal conditions of storage, transport, and distribution, the food package shall give the maximum protection to the food from contamination.

8.5.2. Verify label of the packaging materials before use to avoid misuse; faithfully record use of the packaging materials.

9. Inspection

9.1. An enterprise can inspect the raw materials and the products by itself, or entrust a qualified institution to conduct the inspection; the enterprise shall establish the record keeping system of the pre-delivery inspections.

9.2. Enterprises conducting self-inspection shall have compatible laboratories and inspection capacity for the inspections; the inspection shall be conducted by qualified inspectors following the required methods; the inspection instruments and devices shall be checked regularly.

9.3. The laboratories shall have complete management system where original inspection records and reports shall be kept in proper custody. Establish the sample retention system, which enables timely sample retention.

9.4. Based on characters of the product, production techniques, and the material control, determine the items and frequency of inspection to verify effectiveness of the control measures in production. Items, such as net content and appearance that are affected by the production procedure shall be inspected more frequently than other items.

9.5. Same kind of product in different packages, regardless of specification and form of package, can be inspected together.

10. Storage and transport of food products

10.1. Select appropriate storage and transportation means according to the products and hygiene requirements; if necessary, the device for thermal insulation, cold storage and fresh-keeping shall be provided. It is prohibited to store or transport foods with toxic, harmful or odor stuff.

10.2. Establish and implement appropriate storage system; timely respond to abnormalities.

10.3. The container, tools and equipment for storage, transportation and loading/unloading foods shall be safe, harmless, and kept clean to reduce the risk of food contamination.

10.4. Food in storage and transportation shall avoid direct exposure to sun, rain, strong changes of temperature/humidity, or violent collision to prevent adverse impact on the food.

11. Product recall

11.1. Establish food recall system pursuant to relevant laws and regulations.

11.2. Upon detection of foods that fail to comply with food safety standards or are not suitable for consumption, (the food producer) shall immediately terminate production of such foods, recall foods already sold, notify both sellers and consumers, and keep record of the recall and notification.

11.3. Take measures, such as harmless disposal or destroy, to the recalled products to avoid its entering into the market again. In case of the food being recalled because its labelling, identification or the instructions fail to comply with the food safety standards, the food producer shall take remedial measures to assure the food safety and to clearly explain the situation to consumers when the product is put into market again.

11.4. The food producer shall keep records of the product batches; the producer shall label the product batches for traceability.

12. Training

12.1. Establish the training system for the food production-related positions; provide food safety trainings to employees engage in food production and in relevant positions.

12.2. The trainings will build employees' awareness and responsibility to comply with food safety-related laws, regulations and requirements, and will improve their professional knowledge.

12.3. Pursuant to specific requirements of different positions, the food producer shall formulate and implement annual training programs and evaluate effectiveness of the trainings; the producer shall keep good records of the training.

12.4. Timely conducts training when there are updates of the food safety laws and regulations.

12.5. The training program shall be reviewed and revised regularly to assess effectiveness of the trainings. The producer shall conduct regular inspections so as to ensure the program is carried out effectively.

13. Management structure and personnel

13.1. Assign professionals and management persons for food safety work; establish the management system to guarantee food safety.

13.2. The food safety management system shall be compatible with the production capacity, techniques and products; it is necessary to improve the food safety management system according to the production and experiences accumulated in food safety management.

13.3. The food safety management persons shall understand the basic principles and the operation rules of food safety; they shall be able to sense potential risks, and take appropriate preventive and corrective measures to ensure effective management.

14. Management of records and files

14.1. Management of records

14.1.1 A system of records keeping shall be established to record with details the various stages in food production, namely procurement, processing, storage, inspection and sales. The records shall be complete and faithful, so as to enable effective traceability of food products from material procurement to product distribution.

14.1.1.1 Faithfully record the name, specifications, quantity, suppliers (name and contact), the purchase date, as well as the date of procurements of the food materials, the food additives, and the food packaging materials, etc.

14.1.1.2 Faithfully record processing procedure (including the technological parameters, and the environment monitoring), inventory and the inspection batch number, inspection date, inspectors, testing methods and the inspection results.

14.1.1.3 Faithfully record the name, batch number, specifications, quantity, reasons of recall and residual plans, etc.

14.1.1.4 The records of inspection of the purchased raw materials, food additives and the food-related products (such as the packaging materials) shall be signed by record keeper and reviewers; the records shall be complete and kept for at least 2 years.

14.1.2 A mechanism for customer complaints shall be established. Relevant department shall keep records of customer complaints (writing or oral), find out the causes and solve the problem properly.

14.2 Establish the system for effective document management; ensure the documents used in all areas are the valid versions.

14.3 Encourage the use of advanced technologies, i.e. computer information system, to record and manage files.

Appendix A

Guide for Microorganism Surveillance Plan in the Food Production Process

This Appendix specifies the key points that shall be considered when formulating the “Microorganism Surveillance Plan of the Food Production Environment”; in production, the Plan could be implemented according to product characteristics and production techniques.

A1. The microorganism surveillance in food processing is an important means to safeguard foods safety; it is a tool to verify/evaluate effectiveness of the surveillance on target microorganism, and to ensure continuous improvement of the overall food quality and safety system.

A2. This Appendix proposed the key points to be considered in developing the Microorganism Surveillance Plan in food production.

A3. Microorganism surveillance in food processing mainly includes the environmental microorganism surveillance and the Microorganism surveillance over in-process product. The environmental microorganism surveillance is conducted to evaluate hygiene control in processing, and to find out potential contamination sources. Targets of the environmental surveillance are food-contact surfaces, contact surfaces adjacent to foods or food-contact surfaces, and air. The microorganism surveillance on the in-process product is mainly implemented to evaluate hygiene control capability in food processing and hygiene of products.

A4. Microorganism surveillance in food processing covers microorganism evaluation of each link in food processing, effect of cleaning/sterilization, and effect of microorganism control.

The following elements shall be considered in developing the control plan:

- a) Microorganism surveillance in food processing is composed of microorganism surveillance indicators, sampling point, surveillance frequency, sampling and testing methods, principles of evaluation, and handling of detected non-compliance.
- b) Microorganism surveillance indicators: indicator microorganism that could evaluate hygiene of the processing environment and capability of microorganism control (such as aerobic plate count, coliform bacteria, yeast mold, or other indicator bacterium) in food processing. If necessary, pathogen can also be used as the surveillance indicator.
- c) Sampling spot for microorganism surveillance in food processing: the sampling spot for environment surveillance are the spots where microorganism may exist or cause contamination. The sampling spot could be determined by relevant documents/materials, and could be determined by experiences or accumulated historical data. The sampling spot for surveillance of the in-process product shall cover the in-process products that may experience changes of the microorganism level, which will in consequence affect product safety/food quality; for example, the in-process products produced after the critical control point of the microorganism surveillance. For details, please refer to table A.1.
- d) Frequency of the microorganism surveillance in food processing: the frequency is determined by likelihood of occurrence of contamination. The frequency shall be determined by relevant documents/materials, and could be determined by experiences, professional knowledge, or accumulated historical data. For details, please refer to table A.1. The surveillance shall be dynamic; it is adjusted and regularly evaluated based on changed data and risks of contamination in food processing. For instance, sampling spots and surveillance frequency shall be increased when surveillance shows high level of the indicator microorganism, or detecting pathogen in final products, or after critical facility construction/maintenance, or the hygiene situation deteriorates; if the surveillance result always meets requirements, the sampling spots and the frequency could be reduced.
- e) Sampling and testing methods: environment surveillance usually uses the smearing sampling method, while the in-process product surveillance mainly adopts the direct sampling method. Selection of the testing methods is determined by the surveillance indicators.
- f) Principles of evaluation: use certain surveillance indicators for evaluation. The indicators' limits are determined by effect of microorganism surveillance and effect on product quality/food safety;
- g) Measures to handle non-compliances detected in microorganism surveillance: the monitoring results at all surveillance spots shall comply with the limits and maintain steady; when minor non-compliance occurs, strengthen surveillance by increasing sampling frequency. When severe non-compliance occurs, it shall be corrected immediately; meanwhile, find out reasons of the non-compliance, so as to decide whether correction measures are necessary.

Table 1 Sample of the Microorganism surveillance plan in food production

Surveillance Item	Suggested sampling spots ^a	Suggested microorganisms to be surveillance ^b	Suggested frequency of surveillance ^c	Suggested limits of the surveillance indicators
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Environmental Microorganism Surveillance	Food contact surface	Hands/working clothes/gloves of the food processing workers, and surface of equipment (such as the conveyer belt, tools) that directly contact foods	Aerobic plate count, coliform bacteria, etc.	Verify effect of cleaning after cleaning/sterilization; frequency of other surveillances shall be conducted every week, every other week, or every month	Determine limit of the surveillance indicators pursuant to reality in production
	Surface that is adjacent to food or food contact surface	Surface of equipment, surface of racks, control panels, parts, etc.	Indicator microorganisms for hygienic condition, such as the aerobic plate count, coliform bacteria; if necessary, monitor pathogen	Every other week or every month	Determine limit of the surveillance indicators pursuant to reality in production
	Air in the processing area	Spots close to the exposed products	Aerobic plate count, yeast-like molds, etc.	Every week, every other week or every month	Determine limit of the surveillance indicators pursuant to reality in production
	Microorganism surveillance in the process	The in-process product whose microorganism level in the processing link may change, which in consequence may affect food safety and/or quality	Indicator microorganism for hygiene condition (such as the aerobic plate count, coliform bacteria, yeast-like molds or other indicator microorganisms)	Products produced after the shift starts, and every week (or every other week, or every month) in continuous production	Determine limit of the surveillance indicators pursuant to reality in production