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China's General Hygiene Regulation for Food Production (GB14881)

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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 also serves as the basic foundation for Chinese inspections against overseas food manufacturing facilities seeking registration for export under China's Decree 145. This report provides an updated unofficial translation of the standard but also aims at providing further clarity on where to interpret these requirements as principles and not prescriptions.

Executive Summary:

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 also serves as the basic foundation for Chinese inspections against overseas food manufacturing facilities seeking registration for export under China's Decree 145. Food exporters should note that depending on the product, there may be additional commodity-specific GB standards that the Certification and Accreditation Administration of the People's Republic of China (CNCA) will consult and seek additional attestations of compliance. This report provides an updated unofficial translation of the standard but also aims at providing further clarity on where to interpret these requirements as principles and not prescriptions.

**NATIONAL STANDARD
OF THE PEOPLE'S REPUBLIC OF CHINA**
中华人民共和国国家标准

GB 14881-2013

**National Food Safety Standard
General Hygienic Regulation for Food Production**

食品安全国家标准
食品生产通用卫生规范

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National Food Safety Standard General Hygienic Regulation for Food Production

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*”.

1 Scope

This standard specifies basic requirements and management rules for locations, facilities and personnel of material purchasing, processing, packaging, storage and transportation in the process of food production.

This standard is applicable to production of various kinds of food; if it's necessary to develop a special hygienic regulation for a certain kind of food production, this standard shall be taken as a basis.

2 Terms and Definitions

2.1

Contamination

Process of biological, chemical and physical contamination factors transferred in the process of food production.

2.2

Insect pest

Adverse effect caused by creatures such as insect, bird or rodent including fly, cockroach, sparrow and rat.

2.3

Food processing personnel

Operation personnel directly contacting packaged or unpackaged food, food equipment and instrument and food contact surface.

2.4

Contact surface

Contactable surface of equipment, tools and instruments or human body.

2.5

Separation

Articles, facilities and areas are separated by leaving a certain space between one another instead of arranging physical blockage.

2.6

Partition

Articles, facilities and areas are separated by arranging physical blockage such as wall, hygienic barrier, shade or independent room.

2.7

Food processing location

Building and site for food processing and other buildings, sites and surrounding environment managed in the same way.

2.8

Monitoring

Observation or determination carried out according to the preset way and parameter to evaluate whether the controlling unit is under the controlled state.

2.9

Work clothes

Specialized clothes equipped to reduce the contamination risk of food processing personnel on food according to the requirements of different production areas.

3 Site Selection and Plant Surroundings

3.1 Site selection

3.1.1 For the plant, areas which have large contamination on food shall not be selected. If a place has obviously adverse effect which can't be improved by taking measures on food safety and food edibility, the plant shall not be built in the place.

3.1.2 For the plant, sites where hazardous waste, dust, harmful gas, radioactive substance and other diffusive contaminants can't be eliminated effectively shall not be selected.

3.1.3 For the plant, regions where flood disaster can easily occur should not be selected; if it's difficult to keep away, necessary precaution measures shall be designed.

3.1.4 There should not be potential locations with a large number of insect pest breeding around the plant; if it's difficult to keep away, necessary precaution measures shall be designed.

3.2 Plant surroundings

3.2.1 Potential contamination risk of the surroundings to food production shall be considered and appropriate measures shall be taken to reduce it to the minimum level.

3.2.2 The plant shall be arranged reasonably; each functional area shall be obviously divided with appropriate separation or partition measures to prevent cross contamination.

3.2.3 For the road in the plant, concrete, tar or other hard materials shall be paved; necessary measures shall be taken for vacant land, for example, cement, floor tile or lawn shall be paved to maintain clean surrounding and prevent raising dust and accumulating water under normal weather.

3.2.4 Plant greening shall be kept a proper distance from the production workshop, and vegetation shall be maintained periodically to prevent insect pest from breeding.

3.2.5 The plant shall be provided with proper drainage system.

3.2.6 Living area such as dormitory, canteen or recreation facilities of employees shall be kept a proper distance or partitioned from the production areas.

4 Plant and Workshop

4.1 Design and layout

4.1.1 Internal design and layout of plant and workshop shall meet the operation requirement of the food hygiene to avoid cross contamination during food production.

4.1.2 Design of plant and workshop shall be arranged reasonably according to production process to prevent and reduce the risk of contamination on products.

4.1.3 Operating areas in the plant and workshop shall be divided reasonably according to product characteristics, production process, production characteristics and the requirements of cleanliness in

production process and shall be effectively separated or partitioned. For example: operating areas are generally divided into clean operating area, quasi-clean operating area and general operating area; or clean operating area and general operating area, etc. General operating area shall be partitioned from other operating areas.

4.1.4 Inspection rooms¹ shall be partitioned from the production area.

4.1.5 Area and space of the plant shall be corresponding to the productivity to be convenient for equipment arrangement, cleaning and disinfection, material storage and personnel operation.

4.2 Internal structure and materials of the building

4.2.1 Internal structure

The building's internal structure shall be easy for maintenance, cleaning or disinfection and shall be constructed with appropriate durable materials.

4.2.2 Ceiling

4.2.2.1 Ceiling shall be constructed with nontoxic, odorless materials corresponding to the production demand and easy for observing cleaning condition; if coatings are directly coated on the inner-layer of the roof as ceiling, nontoxic, odorless and mold-proof coatings difficult for shedding and easy for cleaning shall be used.

4.2.2.2 Ceiling shall be easy for cleaning and disinfection, and difficult for condensed water to vertically drip in the structure to prevent insect pest and mold from breeding.

4.2.2.3 Pipelines of accessories for steam, water and electricity shall not be arranged above the exposed food; if it's unavoidable, device or measure to prevent dust from scattering and water drop from dripping shall be provided.

4.2.3 Wall

4.2.3.1 Wall surface and partition shall be constructed with nontoxic, odorless and anti-seepage materials; wall surface within the range of operation height shall be smooth, difficult for accumulating dirt and easy for cleaning; if coatings are used, they shall be nontoxic, odorless, mold-proof, difficult for shedding and easy for cleaning.

4.2.3.2 Wall, partition and ground junctions shall be reasonable in structure, easy for cleaning and effectively avoid the accumulation of dirt such as the arrangement of smooth and accessible surfaces.

4.2.4 Doors and windows

4.2.4.1 Doors and windows shall be closed tightly. Door surface shall be smooth, adsorption-proof, anti-seepage and easy for cleaning and disinfection. They shall be made of water proof, solid, and non-deformable materials.

4.2.4.2 Doors of clean operating area, quasi-cleaning operation area and other areas shall be able to timely be shut down.

4.2.4.3 Window glass shall be made of shatter-resistant materials. If simple glass is used, necessary measures shall be taken to prevent contamination on materials, packaging materials and food after glass breakage.

4.2.4.4 If windows are arranged with sills, their structure shall be able to avoid dust accumulation and be easy for cleaning. Windows able to open shall be equipped with insect pest prevention window screen easy for cleaning.

4.2.5 Ground

4.2.5.1 Ground shall be made of nontoxic, odorless, anti-seepage and corrosion-resistant materials.

¹ Upon further consultations, "inspection rooms" is intended to mean an area where examination, sampling or taste test of the product can take place. It is not intended to mean a full accredited laboratory.

The ground structure shall be conducive to sewage discharge and cleaning.

4.2.5.2 Ground shall be flat, anti-skid, crack-free and easy for cleaning and disinfection and shall be provided with appropriate measures to prevent water accumulation.

5 Facilities and Equipment

5.1 Facilities

5.1.1 Water supply facilities

5.1.1.1 Water supply facilities shall ensure that the water quality, water pressure and water amount meet the production requirements.

5.1.1.2 The quality of food processing water shall meet the requirements of GB 5749. For food with special requirements of processing water quality, corresponding requirements shall be met. The quality of food production water such as indirect cooling water and boiler water shall meet the production requirements.

5.1.1.3 Food processing water and other water such as indirect cooling water, sewage or waste water without contacting with food shall be transported with completely separated pipelines to avoid cross contamination. Each pipeline system shall be marked explicitly for distinction.

5.1.1.4 Self-provided water source and water supply facilities shall meet the relevant requirements. Products used in water supply facilities involving hygienic security of drinking water shall also meet the relevant national requirements.

5.1.2 Drainage facilities

5.1.2.1 Drainage system shall be designed and constructed to ensure unblocked drainage and convenient cleaning and maintenance; it shall adapt to the need of food production and ensure that food, production and clean water be free from contamination.

5.1.2.2 The inlet of drainage system shall be installed with a device such as a floor drain with water seal to prevent solid waste from entering and discharged air from escaping.

5.1.2.3 Outlet of drainage system shall be provided with appropriate measures in order to reduce the risk of insect attack.

5.1.2.4 Indoor drainage shall flow from areas with high cleanliness to those with low cleanliness, and shall be designed to prevent backflow.

5.1.2.5 Sewage shall be disposed by proper ways before discharge to meet the relevant national requirements about sewage discharge.

5.1.3 Cleaning and disinfection facilities

Sufficient specialized cleaning facilities for food, tools and instruments and equipment shall be provided; where necessary, appropriate disinfection facilities shall be provided. Measures shall be taken to avoid cross contamination brought by tools and instruments for cleaning and disinfection.

5.1.4 Waste storage facilities

Specialized facilities for storing waste which are reasonably designed, anti-seepage and easy for cleaning shall be provided; facilities and containers for storing waste in the workshop shall be marked clearly. Where necessary, facilities for storing waste temporarily shall be arranged in proper site and waste shall be stored in classes according to characteristics.

5.1.5 Personal hygienic facilities

5.1.5.1 Changing room shall be arranged at the entrance of production location or production workshop; where necessary, changing room may be arranged at the entrance of the specific operating area as needed. The changing room shall be designed to ensure that work clothes, personal clothes and other articles be kept apart.

5.1.5.2 Facilities for changing shoes (putting on shoe covers) or disinfection facilities for work shoes or boots shall be arranged as needed at the entrance and necessary place of the production workshop. If disinfection facilities for work shoes or boots are arranged, their specification and size shall meet the requirements of disinfection.

5.1.5.3 Restroom shall be arranged as needed; its structure, facilities and internal materials shall be easy to keep clean; facilities for washing hand shall be arranged at proper place in the rest room. The restroom shall not be directly open to areas for food production, packaging or storage.

5.1.5.4 Facilities for washing and drying hand and disinfection shall be arranged at the entrance of clean operating area; if necessary, facilities for washing hand and (or) disinfection shall be added in the operating area; for the faucets matched with disinfection facilities, their switches shall be non-manual.

5.1.5.5 Quantity of the faucets for hand washing facilities shall be proportionate to the quantity of food processing personnel of the same shift; where necessary, mixer of cold and hot water shall be arranged. Wash basins shall be made of smooth, water-proof and easy-to-clean materials and shall be designed and constructed to be easy for cleaning and disinfection. Simple and clear hand washing method shall be marked at visible position adjacent to hand washing facilities.

5.1.5.6 According to the cleanliness of food processing personnel, where necessary, facilities such as air shower and shower room may be arranged.

5.1.6 Ventilation facilities

5.1.6.1 Appropriate natural ventilation or artificial ventilation measures shall be taken; where necessary, natural ventilation or mechanical facilities shall be used to effectively control temperature and humidity of production environment. For ventilation facilities, air shall not flow from operating areas with low requirements on cleanliness to those with high requirements on cleanliness.

5.1.6.2 Air inlet position shall be arranged reasonably, and contamination source such as air inlet, air outlet and device for storing outdoor garbage shall be kept an appropriate distance and angle. Air inlet and outlet shall be equipped with facilities such as mesh enclosure to prevent insect pest from intruding. Ventilation facilities shall be easy for cleaning, maintenance or replacement.

5.1.6.3 If filtration and purification treatment for air is needed in the production process, air filtration device shall be added and cleaned periodically.

5.1.6.4 According to production requirements, where necessary, de-dusting facilities shall be installed.

5.1.7 Lighting facilities

5.1.7.1 Sufficient natural lighting or artificial lighting shall be provided in the plant; luster and luminance shall meet production and operation requirements; light source shall make it possible that food takes on actual color.

5.1.7.2 If lighting facilities are needed to be installed above the exposed food and materials, safe lighting facilities shall be adopted or protection measures shall be taken.

5.1.8 Storage facilities

5.1.8.1 Storage facilities corresponding to quantity, storage requirements of products shall be provided.

5.1.8.2 Warehouse shall be made of nontoxic and solid materials; warehouse ground shall be flat and convenient for ventilation. Warehouse shall be designed to be easy for maintenance and cleaning to prevent insect pest from hiding and shall be provided with device for preventing insect pest from intruding.

5.1.8.3 Materials, semi-finished products, finished products and packaging materials shall be arranged with different storage sites or placed in different areas according to different properties and

shall be marked explicitly to prevent cross contamination. Where necessary, warehouse shall be equipped with control facilities of temperature and humidity.

5.1.8.4 Storing articles shall be kept a proper distance from wall and ground in order to be conducive to ventilation and articles handling.

5.1.8.5 Detergent, disinfectant, pesticide, lubricant or fuel shall be packaged safely and marked explicitly and shall be kept apart from materials, semi-finished products, finished products and packaging materials.

5.1.9 Temperature control facilities

5.1.9.1 Appropriate heating, cooling and freezing facilities and facilities for monitoring temperature shall be equipped according to the characteristics of food production.

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

Production equipment corresponding to productivity shall be provided and arranged in order according to process flow to avoid cross contamination.

5.2.1.2 Materials

5.2.1.2.1 Equipment and instruments contacting with materials, semi-finished products and finished products shall be made of nontoxic, odorless, corrosion-resistant materials difficult for shedding and shall be easy for cleaning and maintenance.

5.2.1.2.2 Surface of equipment and tools and instruments contacting with food shall be made of smooth, nonabsorbent materials easy for cleaning, care, and disinfection, and will not react with food, detergent and disinfectant under normal production and shall be kept in wholesome condition.

5.2.1.3 Design

5.2.1.3.1 All production equipment shall make it possible in design and structure to avoid parts, metal chip, lubricating oil or other contamination factors being mixed into food and shall be easy for cleaning, disinfection, inspection and maintenance.

5.2.1.3.2 Equipment shall be fixed on the wall or floor without any gap or sufficient space shall remain between it and ground or wall during the installation to be convenient for cleaning and maintenance.

5.2.2 Monitoring equipment

The equipment used for monitoring, controlling and recording such as pressure gauge, thermometer or recorder and shall be calibrated and maintained periodically.

5.2.3 Equipment maintenance and repair

Equipment maintenance and repair system shall be established to strengthen the regular maintenance and care of equipment; the equipment shall be inspected periodically and the result shall be recorded timely.

6 Hygiene Management

6.1 Hygiene management system

6.1.1 Hygiene management system for food processing personnel, food production and corresponding assessment standard shall be established; post responsibilities shall be determined to carry out post responsibility system.

6.1.2 Monitoring system for critical control points to guarantee food safety shall be established

according to the characteristics of the food and hygienic requirements in the production and storage process to be implemented well and inspected periodically. If any problem is found, it shall be timely corrected.

6.1.3 Hygienic monitoring system for production environment, food processing personnel, equipment and facilities shall be established to determine the range, object and frequency of internal monitoring. The monitoring results shall be recorded and filed, and executive condition and effect shall be inspected periodically so that any problem can be rectified if it's found.

6.1.4 Cleaning and disinfection system and management system for cleaning and disinfection instruments shall be established. Equipment and tools and instruments before and after cleaning and disinfection shall be kept apart and safely kept to avoid cross-contamination.

6.2 Hygiene management of plant and facilities

6.2.1 Facilities in the plant shall be kept clean and repaired or renewed timely in case of any problem; in case of any damage of plant ground, roof, ceiling and wall, it shall be repaired timely.

6.2.2 Equipment and tools and instruments for production, packaging and storage, pipeline for production and contact surface of exposed food shall be cleaned and disinfected periodically.

6.3 Health management and hygienic requirement for food processing personnel

6.3.1 Health management for food processing personnel

6.3.1.1 Health management system for food processing personnel shall be established and carried out.

6.3.1.2 Personnel involved in food processing shall undergo an annual physical examination check and obtain a health certificate; they shall accept hygienic training before taking posts.²

6.3.1.3 Food processing personnel who suffer from infectious disease of digestive tract such as dysentery, typhoid, viral hepatitis A and viral hepatitis E, diseases affecting food safety such as active pulmonary tuberculosis and suppurative or exudative dermatosis, or the personnel whose skin injury has not been healed shall be transferred to other posts without affecting food safety.

6.3.2 Hygiene requirements of food processing personnel

6.3.2.1 The personnel shall handle personal hygiene before entering food production site to avoid contaminating food.

6.3.2.2 The personnel shall wear clean work clothes when entering the operating area, wash hand and disinfect as needed; hair shall be hidden in work cap or restraint by hairnet.

6.3.2.3 The personnel shall not wear jewelry and watch and shall not make up, dye fingernails and spray perfume; they shall not carry or store personal articles irrelevant to food production.

6.3.2.4 After going to the rest room, contacting articles which may contaminate food or engaging in other activities irrelevant to food production, they shall wash hand and disinfect before engaging in activities relevant to food production contacting food, tools and instruments or food equipment again.

6.3.3 Visitors

Those who are not food processing personnel shall not enter food production site; if they enter the food production site under special circumstances, they shall abide by the same hygienic requirements with food processing personnel.

6.4 Insect pest control

² After further consultations with Chinese authorities, 6.3.1.2 is a Chinese facility-specific requirement. U.S. GMP on disease control in personnel (21 CFR 110.10(a)) has been confirmed to already meet this requirement.

6.4.1 The building shall be kept in wholesome condition and tidy to prevent insect attack from intruding and breeding.

6.4.2 Insect pest control measures shall be prepared and carried out for periodical inspection. Effective measures such as yarn curtain, gauze, rat guard, fly prevention lamp or wind screen shall be taken in production workshop and warehouse to prevent rodent or insects from intruding. If trail of insects or rodent is found, its source shall be traced to eliminate hidden danger.

6.4.3 A map of insect pest control shall be exactly drawn to mark the positions of mousetrap, glue board, fly-killing lamp, outdoor bait and killing device of biochemical pheromone.

6.4.4 Pest control shall be carried out periodically in the plant.

6.4.5 During the treatment by physical, chemical or biological agent, food safety and the proper food quality shall not be affected and food contact surface, equipment, tools and instruments and packaging material shall not be contaminated. Pest control shall be recorded correspondingly.

6.4.6 Before using various kinds of pesticides or other drugs, preventive measures shall be taken to avoid contamination on persons, food, equipment and tools; in case of contamination carelessly, contaminated equipment or tools shall be cleaned thoroughly in time to eliminate contamination.

6.5 Waste disposal

6.5.1 System for waste storage and elimination shall be prepared; for waste with special requirements, its disposal shall meet the relevant requirements. Waste shall be eliminated periodically; corruptible waste shall be eliminated as soon as possible; where necessary, waste shall be eliminated timely.

6.5.2 Waste location outside the workshop shall be isolated from food processing site to prevent contamination; smelly or harmful, toxic gas shall be prevented from escaping; insect pest shall be prevented from breeding.

6.6 Work clothes management

6.6.1 The personnel shall wear work clothes while entering the operating areas.

6.6.2 Specialized clothes such as coats, pants, shoes, caps and hairnet shall be equipped according to the food characteristics and the requirements of production process; where necessary, mask, apron, sleeve or glove may be equipped.

6.6.3 Cleaning system for work clothes shall be prepared, where necessary, work clothes shall be replaced timely; during the production, work clothes shall be kept clean and in wholesome condition.³

6.6.4 Work clothes shall be designed and made to adapt to the requirements of different operating areas to reduce the risk of cross contamination; position of work clothes pocket and connection fastening shall be reasonably selected to reduce the contamination risk caused by content or fastening dropping.

7 Food Material, Food Additives and Products Relevant to Food

7.1 General requirements

Purchasing, acceptance, transportation and storage management system for food material, food additives and products relevant to food shall be established to ensure that the food materials, food additives and products relevant to food meet the relevant national requirements. Any substance

³ “Cleaning System” does not necessarily need to be on site. Laundering may take place offsite. This requirement is intended to ensure facility personnel clothing is clean.

which may damage human health and life safety shall not be added to food.

7.2 Food material⁴

7.2.1 License and certificate of the Supplier for the purchased food materials shall be checked; food materials without certificate shall be inspected according to food safety standard.

7.2.2 Food materials can't be used until they pass the acceptance. Food materials without passing the acceptance shall be kept apart from the materials in designated areas and marked obviously and shall be returned and replaced timely.

7.2.3 Sensory inspection should be conducted before processing and where necessary, laboratory inspection shall be conducted; once the item indexes involving food safety are found to be abnormal, the food materials shall not be used and only the verified applicable ones shall be used.

7.2.4 During transportation and storage, the food materials shall be kept away from direct sunlight and shall be equipped with rainproof and dustproof facilities; according to the characteristics and hygiene requirements of food materials, they shall also be provided with facilities for insulation, cold storage and fresh keeping.

7.2.5 Transportation tools and vessels of food materials shall be kept clean and be maintained in good condition and be disinfected where necessary. The food materials shall not be shipped together with toxic and harmful substance to avoid contamination on food materials.

7.2.6 For warehouse of food materials, management system shall be established and it shall be managed by specific personnel who are responsible for periodically inspecting the quality and hygienic condition and timely cleaning bad food materials or those exceeding quality guarantee period. The distribution order of warehouse shall comply with the principle of "first in first out"; where necessary, it shall be determined according to the characteristic of different food materials.

7.3 Food additives⁵

7.3.1 License of the Supplier and certificate of products shall be inspected where food additives are purchased. The food additives can't be used until they pass the acceptance.

7.3.2 The transportation tools and containers of food additives shall be kept clean and be maintained in good condition and shall be provided with necessary protection to avoid contamination on the food additives.

7.3.3 Storage of food additives shall be managed by specific personnel who are responsible for periodically inspecting the quality and hygienic condition and timely cleaning the bad food materials or those exceeding quality guarantee period. The distribution order of warehouse shall comply with the principle of "first in first out"; where necessary, it shall be determined according to the characteristic of food additives.

7.4 Products relevant to food⁶

7.4.1 Products relevant to food such as purchased food packaging materials, containers, detergent and disinfectant shall be inspected for certificate; those which are carried out with license management shall also be inspected for the license of the Supplier and those such as food packaging materials can't be used until they pass the acceptance.

⁴ "License and Certificate" do not necessarily refer to government-issued documentation. A "license" may be a form of permission for a supplier to serve in that capacity (e.g. contract). A "certificate" may be documentation that the products being supplied are quality products and meet specifications.

⁵ See footnote 4 above.

⁶ See footnote 4 above.

7.4.2 The transportation means and vessels of products relevant to food shall be kept clean and be maintained in good condition and shall be provided with necessary protection to avoid contamination on food materials and cross contamination.

7.4.3 Storage of relevant products relevant to food shall be managed by specific personnel who are responsible for periodically inspecting the quality and hygienic condition and timely cleaning the bad food materials or those exceeding quality guarantee period. The distribution order of warehouse shall comply with the principle of "first in first out".

7.5 Other

For packaging or containers of food materials, food additives and packaging materials directly contacting food, their materials shall be stable, nontoxic, harmless, and difficult to be contaminated and meet hygienic requirements.

Food materials, food additives and food packaging materials shall be provided with a certain buffer or cleaning measures for external packaging to reduce the contamination risk.

8 Food Safety Control in Production Process

8.1 Contamination risk control of product

8.1.1 Hazard analysis method shall be used to define the key link of food safety during production process and control measures for the key link of food safety shall be taken. In the area of the key link, relevant documents such as list of ingredients (feeding) and post specifications shall be prepared to implement control measures.

8.1.2 Hazard Analysis and Critical Control Point system is encouraged to be adopted for the food safety control during production process.

8.2 Control of biological contamination

8.2.1 Cleaning and disinfection

8.2.1.1 According to the characteristics of material, product, and process, it is required that an effective cleaning and disinfection system is developed for production equipment and environment to reduce the risk of microbial contamination.

8.2.1.2 Cleaning and disinfection system shall include: cleaning and disinfection area and name of equipment or instruments; responsibilities of cleaning and disinfection work; detergent and disinfectant; cleaning and disinfection method and frequency; verification of cleaning and disinfection effect and treatment for those failing to meet the requirements; cleaning and disinfection work and monitoring record.

8.2.1.3 The cleaning and disinfection system shall be guaranteed to be implemented and recorded faithfully; the disinfection effect shall be timely verified and it shall be corrected timely in case of any problem.

8.2.2 Microbial monitoring of food processing

8.2.2.1 The critical control point is determined according to the product characteristics to carry out microbial monitoring; where necessary, the microbial monitoring procedure of food processing shall be established, including microbial monitoring of production environment and process product.

8.2.2.2 The microbial monitoring procedure of food processing shall include: microbial monitoring indexes, sampling points, monitoring frequency, sampling and inspection method, evaluation principles and rectification measures. The specific items may be developed by reference to the requirements of Appendix A in combination with production process and product characteristics.

8.2.2.3 The microbial monitoring shall include pathogenic bacteria monitoring and indicator bacteria

monitoring, and the microbial monitoring result of food processing shall be able to reflect the control level of microbial contamination during food processing.

8.3 Control of chemical contamination

8.3.1 The management system to avoid chemical contamination shall be established; the possible contamination source and contamination way shall be analyzed and the proper control plan and control procedure shall be developed.

8.3.2 Use system of food additives and processing aids for food industry shall be established and the food additives shall be used according to the requirements of GB 2760.

8.3.3 Any non-edible chemical composition except food additives and other substances which may hazard human health shall not be added during food processing.

8.3.4 On the production equipment, if the movable components which may directly or indirectly contact food need lubrication, the edible oil or other oil meeting requirements of food safety shall be adopted.

8.3.5 The use system of chemicals such as detergent and disinfectant is established. Except for the cleaning and disinfection requirement and process demand, the chemicals which may contaminate food shall not be used and stored in the production site.

8.3.6 All food additives, detergents and disinfectants shall be preserved in proper container and shall be stored with obvious mark and in classes; during the receiving, they shall be exactly measured and recorded.

8.3.7 Hazardous substances resulting from food production must be monitored and effective measures must be encouraged and taken to reduce risk.

8.4 Control of physical contamination

8.4.1 The management system to avoid contamination of foreign matters shall be established; the possible contamination source and contamination way shall be analyzed and the corresponding control plan and control procedure shall be developed.

8.4.2 The measures such as equipment maintenance, hygiene management, site management, outsider management and processing supervision shall be taken to reduce the contamination risk of foreign matters such as glass, metal and plastic cement in maximum extent.

8.4.3 Effective measures such as arrangement of screen mesh, collector, magnet and metal checker shall be taken to reduce the risk of metal or other foreign matters to contaminate food.

8.4.4 During site repair, maintenance and construction, the proper measures shall be taken to avoid foreign matters, unpleasant smell and chips to contaminate food.

8.5 Packaging

8.5.1 The food packaging shall be able to protect the food safety and quality in maximum extent under normal storage, transportation and marketing (wholesale and retail) conditions.

8.5.2 Identification shall be checked to avoid misuse where the packaging material is used; and the use condition of packaging material shall be recorded truthfully.

9 Inspection

9.1 The inspection shall be carried out for material and product through self-inspection or by the consignable food inspection institution with corresponding qualification and the recording system for delivery inspection of food is established.

9.2 For self-inspection, the corresponding inspection room⁷ and inspection capability to inspection items shall be provided with; the inspection is carried out by the inspection personnel with corresponding qualification according to required inspection method; the inspection instruments and equipment shall be inspected periodically.

9.3 The inspection room shall be provided with sound management system to properly preserve the original record and inspection report of each inspection. Products sampling system shall be established to timely keep sample.

9.4 Comprehensive consideration shall be taken for factors such as product characteristics, process characteristics, and material control condition to reasonably determine inspection items and frequency so as to effectively verify control measures during production process. The inspection frequency of net content, sensory requirements and other inspection items easy to change due to effect of production process shall be greater than that of other inspection items.

9.5 For the same variety of product with different packaging, inspection items free from effect of packaging specification and packaging type may be inspected together.

10 Storage and Transportation of Food

10.1 Proper storage and transportation conditions are selected according to requirements of food characteristics and hygiene; where necessary, the facilities shall be equipped for insulation, cold storage and fresh keeping. The food shall not be stored and transported together with toxic, harmful or smelly articles.

10.2 Suitable storage system shall be established and carried out and in case of any abnormality, it shall be timely treated.

10.3 The containers, tools and instruments and equipment to store, transport and load and unload the food shall be safe, harmless and clean to reduce the risk of food contamination.

10.4 During the storage and transportation, the direct sunlight, rain, notable temperature and humidity change and violent impact shall be avoided to prevent the adverse effect on food.

11 Product Recall Management

11.1 The product recall system shall be developed according to the relevant national regulations.

11.2 Where the produced food is uncomformable with the food safety standard or other inedible conditions are found, the production shall be stopped immediately and the food already sold in market shall be recalled; the relevant production operators and consumers shall be notified and the recall and notification condition shall be recorded.

11.3 The recalled food shall be safely disposed or be destroyed to avoid them flowing into the market again. For food that is recalled due erroneous labeling, identification, or directions for use that is not in conformity with food safety standards, corrective measures shall be taken to guarantee the safety of the product, and explain the situation to consumers once the product is re-launched for sale.

11.4 Production batch shall be reasonably divided and recorded and identification shall be carried out such as product batch No. to be convenient for product traceability.

12 Training

⁷ Upon further consultations, “inspection room” is intended to mean an area where examination, sampling or taste test of the product can take place. It is not intended to mean a full accredited laboratory.

12.1 Training system for relevant post of food production shall be established and the corresponding training about food safety knowledge shall be carried out for food processing personnel and practitioners of relevant post.

12.2 The awareness and responsibility of the practitioner to comply with relevant laws, regulations and standards of food safety and implement management system of food safety shall be promoted and the corresponding knowledge level shall be improved through the training.

12.3 The annual training plan of food safety shall be developed and implemented according to the actual demand of different posts of food production and the assessment is carried out; the training record is made.

12.4 Where the relevant laws, regulations and standards of food safety is updated, the training shall be timely developed.

12.5 The training plan shall be examined and revised periodically and the training effect is evaluated; and the routine inspection is carried out to ensure the effective implementation of training plan.

13 Management System and Personnel

13.1 The professional technical personnel and management personnel of food safety shall be allocated and the management system to guarantee food safety shall be established.

13.2 The management system of food safety shall be corresponding to the production scale, process level and variety characteristics of food and shall be continuously improved according to actual production and implementation experience.

13.3 The management personnel shall know about the basic principles and operation specifications of food safety and shall be able to judge the potential risks and take suitable preventive and corrective measures to ensure the effective management.

14 Record and Document Management

14.1 Record management.

14.1.1 The recording system shall be established to record links of food production such as purchasing, processing, storage, inspection and marketing (sales) in detail. The record contents shall be complete and true to ensure that all links from material purchasing to production, to marketing of the product may be traced effectively.

14.1.1.1 The contents such as name, specification, quantity, Supplier's name and contact and purchase date of products relevant to food such as food materials, food additives and food packaging materials shall be recorded truthfully.

14.1.1.2 The contents such as food processing (including process parameter and environmental monitoring), storage condition of food and inspection batch No., inspection date, inspection personnel, inspection method and inspection result of the product shall be recorded truthfully.

14.1.1.3 The contents such as name, specification, quantity, production date, production batch No., Purchaser's name and contact, quality certificate and marketing (sales) date of delivery product shall be recorded truthfully.

14.1.1.4 The contents such as name, batch, specification, quantity, recall reason and subsequent rectification program of recalled food shall be recorded truthfully.

14.1.2 The purchasing inspection record of products relevant to food such as food materials, food

additives and food packaging materials and delivery inspection record of food shall be rechecked and signed by the record personnel and examiner; the record contents shall be complete. The preservation period shall not be less than 2 years.

14.1.3 The customer complaint handling mechanism shall be established. As for the written or verbal advice and complaint proposed by customers, the related management departments of the enterprise shall make records, find out the reasons and handle them carefully.

14.2 The management system of document shall be established to effectively manage documents so as to ensure that documents at each relevant location are valid.

14.3 The advanced technology and means (such as information system of electronic computer) are encouraged to be adopted to carry out record and document management.

Appendix A⁸

Microbial Monitoring Procedure Guide of Food Processing

Note: this appendix gives key points which shall be considered where the environmental microbial monitoring procedure in food processing is developed, and they may be referred to in actual production according to factors such as product characteristics and technical level of production process.

A.1 The microbial monitoring during food processing is important means to ensure the food safety and the tool to verify or evaluate effectiveness of target microorganism control procedure and to ensure the continuous improvement of whole food quality and safety system.

A.2 This appendix proposes the key points which shall be considered where the microbial monitoring procedure of food processing is developed.

A.3 The microbial monitoring of food processing mainly includes the environmental microbial monitoring and microbial monitoring of process product. The environmental microbial monitoring is mainly used to judge the hygiene control condition of processing and find out the potential contamination source. Generally, the environmental monitoring objects include food contact surface, adjacent contact surface to food or food contact surface and environmental air. The microbial monitoring of process product is mainly used to evaluate the hygiene control capacity of processing and hygienic condition of product.

A.4 The microbial monitoring of food processing covers microbiology evaluation and evaluation of cleaning and disinfection effect and microorganism control effect of each link during processing.

During development, the following contents shall be considered:

a) The microbial monitoring of processing shall include the microbial monitoring indexes, sampling points, monitoring frequency, sampling and inspection method, evaluation principles and treatment for non-conformance condition.

b) The microbial monitoring indexes of processing shall take the indicator microorganism (such as aerobic bacteria count, coliform bacteria, yeast or other indicator bacteria) which is able to evaluate the hygienic condition of processing environment and process control capacity as priority. Where necessary, the pathogenic bacteria may also be adopted as the monitor index.

c) The microbial monitoring sampling points of processing: sampling points of environmental

⁸ After thorough review, Appendix A is considered non-binding on all products as it is cross-referenced in Section 8.2.2 as “where necessary.”

monitoring shall be places which are contaminated due to the possible existence or entrance of microorganism. The sampling points may be determined according to the relevant literature information, experience or accumulated historical data. The sampling points of process product monitoring plan shall cover all process products whose microorganism level may change and may affect the product safety and (or) food quality in the whole processing link, for example, the one behind the key control point controlled by microorganism. The specific contents may refer to examples detailed in Table A.1.

d) The microbial monitoring frequency of processing: monitoring frequency shall be developed based on the possible risk of contamination. The reasonable monitoring frequency may be determined according to the relevant literature information, relevant experience and professional knowledge or accumulated historical data. The specific contents may refer to examples detailed in Table A.1. The microbial monitoring of processing shall be dynamic, adjusted according to the data change and contamination risk of processing and periodically evaluated. For example, where the indicator microorganism monitoring result is on the high side, the pathogenic bacteria is found in final product, after the significant maintenance construction activities are completed, or downtrend appears for hygienic condition, the sampling points and monitoring frequency are needed to be increased; where the monitoring result meets the requirements all the time, the sampling points or the monitoring frequency may be properly reduced.

e) The sampling and inspection method: generally, coating sampling is the primary of environmental monitoring and the direct sampling is adopted for process product monitoring. The selection of inspection method shall be based on the monitor index.

f) The evaluation principles: the judgment shall be carried out according to the certain monitor index limit and the limit may be determined based on the microorganism control effect and its influence on the product quality and food safety.

g) The treatment requirements for inconformity condition of microbial monitoring: the monitoring result of each monitoring point shall meet the monitor index limit and remain stable; where the slight inconformity appears, measures such as increasing sampling frequency may be adopted to strengthen monitoring; where the severe inconformity appears, correction shall be carried out immediately and the reason leading to problem shall be found out at the same time to determine whether the corresponding corrective measures are taken for microorganism control procedure.

Table A.1 Microbial Monitoring Example of Food Processing

Monitoring items		Suggested sampling points ^a	Suggested monitoring microorganism ^b	Suggested monitoring frequency ^c	Suggested monitor index limit
Environmental microbial monitoring	Food contact surface	Hands and work clothes of food processing personnel, surfaces of glove conveyors, tools and instruments and other equipment directly contacting food	Bacterial colony, coliform etc.	The verification of cleaning effect shall be carried out after the cleaning and disinfection and others may be carried out every week, every two weeks or every month	Determined in combination with actual situation of production
	Adjacent contact surface to food or food contact surface	External surface of equipment, support surface, control panel and contact surface of part car	Indicator microorganism for hygienic condition of bacteria colony and coliform; where necessary, the pathogenic bacteria is monitored	Every two weeks or every month	Determined in combination with actual situation of production

Monitoring items		Suggested sampling points ^a	Suggested monitoring microorganism ^b	Suggested monitoring frequency ^c	Suggested monitor index limit
	Environmental air of processing area	Position close to exposed product	Bacteria colony, yeast etc.	Every week, every two weeks or every month	Determined in combination with actual situation of production
Microbial monitoring of process product		Process product whose microorganism level may change and may affect the food safety and (or) food quality during processing link	Indicator microorganism for hygienic condition such as bacteria colony, coliform, yeast or other indicator bacteria	Every week (every two weeks or every month) for the product produced in the first time of shift beginning and subsequent continuous production process	Determined in combination with actual situation of production
^a Sampling points may be selected according to the food characteristics and actual situation of processing. ^b One or more hygiene indicator microorganism may be selected to implement monitoring according to the requirements. ^c Monitoring frequency may be determined according to the risk of specific sampling points.					

Monitoring items		Suggested sampling points ^a	Suggested monitoring microorganism ^b	Suggested monitoring frequency ^c	Suggested monitor index limit
	Environmental air of processing area	Position close to exposed product	Bacteria colony, yeast etc.	Every week, every two weeks or every month	Determined in combination with actual situation of production
Microbial monitoring of process product		Process product whose microorganism level may change and may affect the food safety and (or) food quality during processing link	Indicator microorganism for hygienic condition such as bacteria colony, coliform, yeast or other indicator bacteria	Every week (every two weeks or every month) for the product produced in the first time of shift beginning and subsequent continuous production process	Determined in combination with actual situation of production
^a Sampling points may be selected according to the food characteristics and actual situation of processing. ^b One or more hygiene indicator microorganism may be selected to implement monitoring according to the requirements. ^c Monitoring frequency may be determined according to the risk of specific sampling points.					