

Enacted on	August 25 th , 2018
Revised on	

Food Safety Standard for Black Garlic

Approved by	Prepared by
The president of Black Garlic International Conference	The chairman of Black Garlic Food Safety Dept.

Black Garlic International Conference
(Incorporated non-profit organization)

I Purpose

The purpose of this standard is to ensure internationally compatible food hygiene levels of black garlic under the policies of

- Working on HACCP (Safety)
- Being able to explain the products' safety scientifically with evidence (Evidence)
- Being able to clarify the product's food safety by presenting ingredients and manufacturing process (Traceability)

and show its management matters from the perspectives of

- Food safety management system
- GMPs (Good Manufacturing Practices)
- Controlling food hazards

II Administrative matters (☉ =required)

1. Food safety management system

(1) As an organization, there is a commitment for high standard food safety.

① Responsibilities of Managers

☉Managers prepare written documents regarding the safety of products and responsibilities to obey the law. In addition, managers communicate about these matters to employees.

- Managers provide resources necessary to carry out food safety programs.
- Have an up-to-date organization chart that describes an outline of the company.

② Training

- Offer effective training programs to educate new employees.
- ☉Have written documents on continuous trainings and provide employee training.

(2) There are rules on food safety and they are properly followed.

① Procedure

☉ Have detailed manual for processes and operations that may affect food safety quality, and perform them in effective ways.

- Communicate to employees involved in processes and operations that affect food safety regarding procedure.

② Requirements for general documents

- Have a written manual regarding procedure to manage documents.

③ Requirements for storing records

- Keep records to confirm observation of legal claims, customers' claims or food safety systems.
- Business operators set retention period of records necessary to meet legal requirements and

customer requirements.

(3) Have managing system on information related to quality of ingredients and products.

① Specification

- ◎ Have specification documents for ingredients, packing materials, products and contract manufacturing operations.
- The specification documents for ingredients, packing materials, products and contract manufacturing operations conform to legal and customers' claims.
- Specification documents for ingredients, packing materials, products and contract manufacturing operations are updated.
- Employees and dealing businesses are notified when specifications for ingredients, packing materials, products and contract manufacturing operations are revised.
- Have a manual for shipping procedure.
- Periodically check to confirm if contents of specifications match with actual products.
- Have a person in charge of managing specification documents for ingredients, packing materials, products and contract manufacturing operations.

② Approving suppliers and monitoring functions

- ◎ Exchange a contract and a specification document in advance with a supplier.
- Have a manual for procedure to confirm a supplier and comply with it.

③ Purchase

- When purchasing black garlic from new suppliers, it comprise with existing contracts and specification documents.

④ Traceability

- Traceability mechanism is in place and documented.
- ◎ Products can be identified in all manufacturing processes.
- ◎ There is a record from purchasing to production and delivery (for ingredients, packing materials and products).
- There are displays and printing procedure to identify an applicable product for all manufacturing processes and distribution processes.
- At least once a year, traceability system undergoes an assessment to see if it is actually functioning.
- Traceability systems are updated and records are maintained and managed as needed.

(4) Capacity to handle food safety troubles

① Handling complaints

- Have documented manual for handling complaints.
- Records of customers' and consumers' complaints, as well as following investigations and corrective actions are stored.

② Food safety trouble shooting management

- Have a capacity to withdraw and recall products when food safety problems arise.
- ◎ Records of food safety problems are kept.
- Have a food safety troubleshooting procedure document in which reports to institutions including municipal governments and removal and recall of products are summarized.
- Have a person in charge of making reports to business partners, consumers and government.
- Procedure to manage food safety problems is reviewed and verified at least once a year.
- Records of food safety problems are reviewed later.

③ Management of defective products

- Have a procedure document to manage defective ingredients, semi-finished products, products and packaging materials.
- Defective ingredients, semi-finished products, products and packing materials are managed by a person in charge.

④ Corrective actions

- Have a manual of corrective actions to analyze complaints and also to examine defective products.
- Properly perform corrective actions (including shipment, reprocessing, segregation, and disposal).
- Have a person responsible for determining the resumption of production and sales after corrective actions are made.

(5) Have scientific data to secure products' food sanitation.

① Products analysis

- Have a product analysis manual to check if a product satisfies legal and customers' requirements within its expiration date.
- ◎ Product sampling inspections are conducted at regular intervals to confirm that the pH is less than 4.6.
- ◎ Have test results using appropriate analytical procedure (such as ISO17025 provisions and methods certified by the industry).

② Management of measurement and monitoring equipment

- Measurement and monitoring equipment that has a significant impact on legal and customer requirements is reliable.
- Measurement and monitoring devices that are important for food safety are calibrated.
- Measures are taken and recorded if the measurement and monitoring equipment deviates from the established standards.

2. GMPs (Good Manufacturing Practices)

(1) Have Good Manufacturing Practices, GMPs: Man

① Personal hygiene

- ◎ There are rules of personal hygiene and they are applied to employees, agents and visitors.
- Personal hygiene rules comply with legal requirements, if they exist.
- Have procedure for notifying employees, vendors and visitors about what to do if an infection occurs.
- Have a person responsible to decide if a person with a suspicion of being infected can enter the manufacturing area.
- ◎ Manage people who may be sick.
- Employees, vendors and visitors strictly follow the personal hygiene rule.
- Employees, vendors and visitors are aware that they have to change their clothes in a particular work area.

(2) Have Good Manufacturing Practices, GMPs: Facility, equipment

① Institutional setting

- Facilities are located, designed, constructed and maintained to ensure product safety.
- ◎ The facilities are effectively maintained, cleaned and disinfected to prevent biological, chemical and physical contamination.
- The lighting has appropriate illumination and design, and the work is done effectively.
- Areas that have contacts with food are kept clean and disinfected if necessary.
- The drainage is designed to be food safe.
- ◎ The site and the area around the building are cleaned and there is no waste.

② Employee facility

- Have a changing room for employees.
- Have appropriate restrooms that are isolated from manufacturing area.
- Have appropriate hand-wash stations.
- Eating areas are set avoiding manufacturing, packing and storage areas.

③ Maintenance and management of facilities and equipment

- Have a procedure to maintain and manage facilities and equipment.
- Maintenance of facilities and equipment are conducted effectively.
- Have a documented manual to clean facilities and equipment.
- Cleaning of facilities and equipment are conducted effectively.
- Materials used to maintain and repair are suitable for the purpose of use.

(3) Have Good Manufacturing Practices, GMPs: Method

① Cleaning and sterilization

- In order to keep facilities, equipment, and devices clean, cleaning and disinfection procedure are in place, and confirmation after cleaning and washing is conducted.
- Equipment, tools and chemicals for cleaning and sterilization are clearly labeled.
- Equipment, tools and chemicals for cleaning and disinfection are stored at the place

where they are separated from products, equipment and packaging materials.

- Cleaning and sterilization are conducted by trained staff.

② Pollution management of products

- ◎ Have zoning or other effective procedure to reduce or avoid the possibility of contamination of biological, chemical and physical hazards.

③ Insect control, mouse control and pest control

- ◎ Have effective insect, mouse and pest control methods.

- Insect, mouse and pest control measures are appropriate for products, ingredients and facilities.

- Insect, mouse and pest controls are conducted by an appropriate person and measures are taken to deal with examination results.

④ Water quality control

- Have management procedure for water, ice and steam so as not to compromise product safety.

- Have procedure to prevent cross contamination of non-drinking water and drinking water.

⑤ Waste control

- Have rules regarding disposal and storage of waste.

- ◎ Waste containers are clearly distinguished by application.

⑥ Shipment and storage

- Have enough space to store products and ingredients.

- ◎ Storage facilities are designed to prevent contamination of ingredients and products during storage.

- Product transport minimizes degradation (ex, due to temperature and humidity control).

- Have proper shipping procedure and it is performed effectively.

- Have proper vehicle procedure and it is performed effectively.

- Maintenance and sanitation procedure is documented for loading vehicles and equipment.

- Maintenance and sanitation procedure documented for loading vehicles is conducted effectively.

3. Food hazard control

(1) Work on HACCP

① Pre-procedure

- Business operators comply with legal and product requirements.

- Procedure 1: Have a food safety team consisting of members with different job responsibilities (food safety, manufacturing, engineering, procurement, logistics etc.).

- Procedure 2: All the members of food safety team members are properly qualified and

they can demonstrate evidences for specialized trainings that they received.

- Procedure 3: Maintain product specifications stating materials, packaging materials, storage conditions, etc.
- Procedure 5: Have a manufacturing flow chart.
- Procedure 6: The created flow chart is verified on site.

② HACCP

- ◎ Procedure 7: Conduct hazard analysis at each process stage.
- Conduct hazard factor analysis by the appropriate personnel (team).
- ◎ Procedure 8: Establish critical control points (CCPs) when hazards cannot be reduced or eliminated by Good Manufacturing Practice (GMP) as a result of hazard analysis.
- ◎ Procedure 9: Establish tolerance limits for each CCP
- ◎ Procedure 10: Establish monitoring procedure for each CCP.
- Conduct CCPs effectively.
- ◎ Procedure 11: For each CCP, set corrective action for when the allowable limit exceeds.
- ◎ Procedure 12: Establish verification method.
- Conduct verification method effectively.
- ◎ Procedure 13: Record and manage documents for HACCP.
- All HACCP related records and documentation procedure have been effectively implemented.
- The operator has a clear control over all steps considered to be influential, including for those not CCP.

(2) Have measures to deal with intentional forgery and contamination of products

③ Food defense

- Analyze the possibility of intentional forgery and contamination of products.
- ◎ Weak defense points in the manufacturing procedure are identified, and additional measures for access control are taken to deal with intentional forgery and contamination of products.
- Have a procedure to take measures on spoiled products when intentional forgery and contamination are found.

(3) Managing allergen under control (when applicable)

④ Allergen control

- ◎ Have a document referring to managing allergen materials to prevent cross-contamination in the manufacturing processes.
- Both legal and customers' claims are considered in the process of allergen managing.
- There is procedure for handling ingredients and products to identify and prevent possibility of cross-contamination of allergens.
- Have a manual to clean surfaces that touch products.
- Remove allergens with possibilities to cause cross-contamination of allergens from surfaces those come into contact with products.

•Throughout the manufacturing process including production and sales, there is a system to separate each step.

Concluded