

Guidelines on Hygiene Control of Import Processed Foods (Annex to Notice Shoku-an No. 0605001 of June 5th, 2008)

Section 1 Objectives

Under Article 8 paragraph 1 of the Food Safety Basic Law (Law No. 48 of 2003), food-related business operators including a person who intends to import foods that have been manufactured, processed, etc., in another country (hereinafter “importers”) are required to recognize that they themselves bear primary responsibility for ensuring food safety, and to appropriately take necessary measures to ensure food safety at each stage of the food supply process. Moreover, under Article 3 paragraph 1 of the Food Sanitation Law (Law No. 233 of 1947; hereinafter “Japanese Law”), they are also required to take responsibility for obtaining necessary knowledge and techniques, ensuring the safety of raw materials, practicing self-imposed examination and taking any other measures to ensure the safety of imported foods, etc.

The Imported Foods Monitoring and Guidance Plan sets out basic matters for guidance to importers based on these responsibilities, and promotes the practice of voluntary hygiene control. However, owing to recent cases of chemical food poisoning, etc., it has now become necessary to ensure and confirm the safety of imported processed foods in the exporting country to a level equivalent to that within Japan, at all stages of the food supply process including raw materials, manufacturing and processing, storage and transportation.

The purpose of these Guidelines is not only to prevent contamination by poisonous or harmful substances, etc., but also to emphasize basic matters for guidance on processed foods required of importers under the Imported Foods Monitoring and Guidance Plan, to promote voluntary hygiene control of import processed foods, and to take steps to improve safety.

After the completion of import procedures, all stages including storage, transportation, manufacturing, processing and sale within Japan are governed by the Law, and attention is also drawn to other laws, ordinances and notices designed to prevent the contamination of distributed foods by poisonous or harmful substances.

(Reference)

- Food Safety Basic Law, Article 8 (Responsibility of Food-Related Business Operators)
- Food Sanitation Law, Article 3 (Responsibility of Food-Related Business Operators)
- Special Measures Law Concerning the Prevention of Poisonous Substances from Contaminating Food in Distribution (Law No. 103 of 1987), Article 3 (Government Measures, etc.)

Section 2 Scope

These Guidelines are designed for importers who manufacture and import products to be exported to Japan under direct contract with overseas manufacturers, as well as importers of processed food in general. Moreover, even importers who are not in a direct contractual relationship with an overseas manufacturer should also, through the agency of an exporter or other such concern in the exporting country, strive to confirm the matters stated in these Guidelines with said manufacturer.

Section 3 Confirmation System

To confirm the matters stated in these Guidelines, importers should appoint responsible staff and contact personnel who have the necessary knowledge and skills.

Section 4 Matters to be Confirmed

Importers should confirm the matters set forth below, in writing, with the manufacturers of processed food that they intend to import. They should do so when signing contracts, upon the manufacture of products to be exported to Japan (including examination and certification), upon the renewal of contracts and whenever any problems arise, taking into account the establishment and enforcement of regulations on food hygiene in the exporting country, the level of hygiene control practiced by the manufacturer, and other factors. In addition, importers should also make necessary confirmation by conducting field surveys, posting local representatives, testing and inspecting products, etc. When confirming these matters, they should make use of manufacturers' records concerning raw materials, records of manufacturing controls, records related to products, records related to Hazard Analysis and Critical Control Point (HACCP) system, and so on.

1 Supervision by the Government of the Exporting Country, Etc.

Importers should confirm with manufacturers the following matters concerning supervision by the government of the exporting country, the standard of establishments, facilities and equipment of the manufactory, and hygiene control in the manufactory.

- (1) That the food is manufactured and processed in compliance with the laws and regulations of the exporting country. In particular, when there is a system of registration of manufactory, a system of permission for product exports, or other such system in the exporting country, that these are properly observed.

(Reference)

- Response Related to Imports (material used at the Emergency Inter-Sector Joint Conference on Safety Assurance of Imports, July 20th, 2007)

- (2) That the standard of establishments, facilities and equipment of the manufactory is at least equal to the standards concerning establishments, facilities and equipment stipulated in related Japanese laws and ordinances, etc.

(Reference)

- Abattoir Law Enforcement Order (Cabinet Order No. 216 of 1953), Article 1 (Standards for Structure and Facilities of Ordinary Abattoirs)
- Enforcement Regulations of the Law Concerning Rules for Poultry Processing Business and Poultry Inspection (Ministry of Health & Welfare Ordinance No. 40 of 1990), Article 2 (Standards for Structure and Facilities)
- Rules for Food Business Establishment Standards Based on the Food Sanitation Law (Annex to Notice Ei-kan No. 43 of September 9th, 1957)

- (3) That the standard of hygiene control in manufactory is at least equal to the following standards concerning hygiene control stipulated in related Japanese laws and ordinances, etc. It should be noted that using methods of hygiene control based on HACCP system is also effective, and the active introduction of these is recommended.

- (a) Hygiene control in the harvesting of agricultural, forestry and fishery products
- (b) Hygiene control in food handling establishments, etc.
- (c) Hygiene control by food handlers and others in food handling establishments, etc.
- (d) Training for food handlers and others in food handling establishments, etc.

(Reference)

- Guidelines on Management and Operation Standards to be Observed by Food-Related Business Operators (Annex to Notice Shoku-an No. 0227012 of February 27th, 2004; hereinafter “Guidelines on Management and Operation Standards”)
- Procedure for Implementation of the Total Hygiene Controlled Manufacturing Process Approval System (Annex to Notice Sei-ei No. 1634 of November 6th, 2000)
- General Principles of Food Hygiene (CAC/RCP 1-1969, Rev. 4-2003)
- Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for its Application (Annex to CAC/RCP 1-1969, Rev. 4-2003)

2 Raw Material Acceptance Stages

Importers should confirm the following matters with manufacturers at the stage of accepting raw materials.

- (1) That quality criteria including Specification and Standards based on Japanese Law have been established for each raw material, and that it has been confirmed that each delivery lot complies with these. Specifically, importers should aim to procure raw materials for which the use of agricultural chemicals, veterinary drugs and other production materials, etc., is clear from contracts or other documentation shared with specific producers or vendors. Meanwhile, basic matters for

confirmation in accordance with the characteristics of raw materials are mainly those shown below.

(a) Foods in general (universal matters)

- That, when harvesting agricultural, livestock and fishery products to be used as raw materials, measures are taken to prevent contamination by dirt or wastewater, as well as measures to prevent contamination by agricultural chemicals, veterinary drugs, feedstuffs, fertilizers, faecal and others, by appropriately managing poisonous substances, wastes, etc.
- That, when harvesting, storing and transporting agricultural, livestock and fishery products to be used as raw materials, measures are taken to prevent contamination by rodents, insects, chemicals, foreign matter, micro-organisms, etc.
- That additives for which there is no designation based on Japanese Law have not been used.
- That additives that do not comply with Specification and Utilization Standards based on Japanese Law have not been used, and that the appropriate amount have been used.
- In the case of fresh vegetables, fish and shellfish, etc., that no colorants or other additives that may mislead consumers in the determination of quality or freshness are used.
- That compositional standards, manufacturing and processing standards, and other Specification and Standards based on Japanese Law have been met.
- That sterilization or other processes using irradiation not permitted in Specification and Standards based on Japanese Law have not been conducted.
- That the formal names, composition, and other details of raw materials and additives used are clearly notified.
- That drug substances specified in Pharmaceutical Affairs Law have not been included (Law No. 145 of 1960).
- That the history of food use, etc. in the exporting country is available.

(b) Agricultural products and products processed from them

- That, when products contain natural toxins, measures are taken to remove them by manufacturing, processing, etc.
- That the harvesting area is not polluted by radioactivity.
- That the use of agricultural chemicals and fertilizers has been confirmed.
- That maximum residue limits for agricultural chemicals based on Japanese Law have been met.
- That measures are taken to prevent contamination by genetically modified food that has not undergone safety assessment based on Japanese Law.
- That measures are taken to prevent the occurrence of mold when harvesting as well as during transportation and storage.

(c) Livestock products and products processed from them

- That measures are taken to prevent contamination by Enterohemorrhagic *Escherichia coli* O157, *Listeria monocytogenes* and other pathogenic micro-organisms.
 - That the breeding area is not polluted by radioactivity.
 - That the breeding area is not a country or region from which import is prohibited in connection with bovine spongiform encephalopathy (BSE).
 - That the products contain no specified risk material connected with BSE.
 - That the products do not use (and are not contaminated by) beef, etc., derived from countries or regions from which imports are prohibited in connection with BSE.
 - That the use of veterinary drugs and feed additives has been confirmed.
 - That maximum residue limits for agricultural chemicals, veterinary drugs and feed additives based on Japanese Law have been met.
- (d) Fishery products and products processed from them
- That measures are taken to prevent contamination by *Vibrio parahaemolyticus* and other pathogenic micro-organisms.
 - That shellfish are caught in seas in which shellfish poisoning is appropriately monitored.
 - That species of blowfish are those whose import is permitted.
 - That measures are taken, through identification of fish species, to prevent contamination by other species of blowfish.
 - That measures are taken to confirm the sea area subject to catches and, through proper identification of fish species, to prevent contamination by poisonous fish.
 - That the use of veterinary drugs and feed additives has been confirmed.
 - That maximum residue limits for veterinary drugs and feed additives based on Japanese Law have been met.
- (2) That the matters listed in (1) above have been confirmed by regular tests, inspections, etc. Tests for residual agricultural chemicals, etc., should take into account the type of chemicals used for the agricultural products in question, records of their application, and other details on the state of use, as well as the results of soil and water quality surveys, etc.
- (3) No raw materials should be accepted if it is known to contain parasites, pathogenic micro-organisms, poisonous substances, decomposed matter, deteriorated matter or foreign matter which would not be eradicated or removed to an acceptable level by normal processing, cooking, etc.
- (4) When the monitoring results carried out by an administrative organ or other body in the exporting country are available, importers should confirm the results, but

should also import samples and confirm said results by means of tests and inspections inside Japan whenever necessary.

- (5) That each raw material has been subjected to appropriate lot management.

(Reference)

- Guidelines on Management and Operation Standards
- Basic Matters for Guidance to Importers (Annex Table 2, Notice Shoku-an No. 0331001 of March 31st, 2008)

3 Product Manufacturing and Processing Stages

Importers should confirm the following matters with manufacturers at the stages of manufacturing and processing products.

- (1) That a system of control has been arranged to ensure that food can be manufactured and processed under a hygienic condition. As measures for preventing contamination by poisonous or harmful substances, in particular, that the following matters are thoroughly observed.
- (a) Hygiene control of establishments, facilities and equipment, etc.
- That windows and entrances are not left open. If they have to be left open of necessity, that measures are taken to prevent dirt, rodents, insects, etc., from entering establishments.
 - That equipment, utensils and dismantled parts of them are properly cleaned, sterilized and disinfected to prevent the food from contaminating by metal fragments, foreign matter, chemical substances, etc., and that they are stored hygienically in appropriate places by means of preventing contamination.
 - That chopping boards, kitchen knives, protective clothing and others that come into direct contact with food are fully cleaned and disinfected each time they are contaminated or after the end of the work.
 - That containers for detergents, sterilizers, disinfectants and other chemicals are clearly identified, and that measures are taken to prevent them from contaminating food (for example, by preparing utilization management records and storage facility).
 - That establishments are managed so that outsiders cannot access them without permission.
- (b) Measures against rodents and insects
- That establishments and surrounding areas are appropriately managed and maintained, breeding sites of rodents and insects are eliminated, and measures are taken to prevent rodents and insects from entering establishments (for example, by installing wire mesh screens, traps, etc.).
 - That, when rodenticides or insecticides are used, these are handled appropriately to prevent them from contaminating food.

- That raw materials, products, packaging materials, etc., are placed in containers, and stored away from floors or walls.
- (c) Handling of wastes and waste water
- That procedures are specified for the methods of storing and disposing wastes.
 - That waste containers are clearly distinguished from other containers and are kept clean to prevent leakage of waste fluids or foul odors.
 - That areas for storing wastes are separated from food handling and storage areas (including areas adjacent to these) and are appropriately managed so that they can have no adverse impact on the surrounding environment.
 - That appropriate methods are used to dispose wastes and waste water.
- (d) Handling of foods, etc.
- That pathogenic micro-organisms, etc., and their toxins are eradicated or removed to a safe level in the processes of manufacturing, processing or cooking food.
 - That measures are taken to prevent contamination of raw materials and products by metals, glass, dirt, detergents, machine oil and other foreign matter, and that inspections are carried out whenever necessary.
 - That cut or sliced meat, etc., is checked for foreign matter, and that, if any foreign matter is found, the part suspected of contamination should be removed.
 - That containers and packaging are hygienic and protect products from contamination or damage, and that they can be appropriately labeled.
 - That packaging materials and sealant gas are non-poisonous, and that they cannot impact the safety or quality of food during storage or under specific conditions of use.
- (e) Management of water used, etc.
- That water used in processes that have a direct impact on food manufacturing and processing (hereinafter “water used”) should be potable water. Also, that steps are taken to prevent water used from being contaminated by other water used inside establishments for purposes not directly related to food manufacturing, or water used in processes such as cooling that do not have a direct impact on food safety.
 - That the quality of water used is regularly tested. Also, when there is a risk that water sources have been contaminated as a result of an unforeseen disaster, etc., that they are not used until their safety has been confirmed.
 - That, when water tanks are used, said tanks are regularly cleaned and are kept clean.
 - That, when well water, an independent water supply, or other water is used, it is regularly confirmed and recorded that sterilizing or water purifying devices are working properly.
 - That ice is made from potable water supplied by appropriately managed water supply equipment.

- That, when water is re-used, it is appropriately treated as necessary to prevent an adverse impact on food safety.
- (f) Hygiene control of food handlers
- That food handlers are provided with a hygienic uniform, cap, mask and shoes for exclusive use, etc., that they are prohibited from bringing foreign matter inside food handling establishments, and that access to and from establishments is controlled.
 - That unnecessary personnel are prohibited from entering food handling areas, and that, when persons other than food handlers enter food handling areas, they are required to change into clean uniform for exclusive use, etc., in an appropriate location and to observe hygiene control provisions in the establishments.
- (2) That persons responsible for food hygiene have been appointed to each food handling establishments or each division.
- (3) That it has been confirmed, through regular tests and inspections, that final products comply with Specification and Standards based on the Japanese Law. Importers should also confirm this, whenever necessary, via tests and inspections by a official laboratory in the exporting country, or inside Japan. Basic matters for confirmation in accordance with the characteristics of products shall be as shown in 2 (1).
- (4) That each product has been subjected to appropriate lot management.

(Reference)

- Guidelines on Management and Operation Standards
- Basic Matters for Guidance to Importers

4 Product Storage, Transportation and Distribution Stages

Importers should confirm the following matters with manufacturers at the stages of storage, transportation and distribution of products.

- (1) That products are handled hygienically during storage, transportation and distribution, and that the following matters are thoroughly applied as measures to prevent contamination by poisonous or harmful substances.
- (a) That measures are taken to prevent contamination of food through appropriate handling of insecticides, etc.
- (b) That vehicles, haulage containers and others used for transporting foods are not those which could contaminate the foods, containers or packaging. Also, that their structure makes them easy to wash and disinfect, and that they are always kept in a clean condition.

- (c) That, when foods and loads other than foods are mixed, if necessary, the food is put in appropriate containers and separated from the other loads to prevent contamination.
 - (d) That foods are controlled during transportation in such a way as to avoid contamination by dirt, toxic gases.
 - (e) That, when vehicle or haulage container once used for transporting different commodities of food or loads other than foods is re-used, the vehicle or container is washed effectively and disinfected as needed.
 - (f) That appropriate lot management has been carried out, and that any abnormalities in volume and packaging condition, etc., are confirmed as the situation demands.
- (2) Besides the matters listed in (1) above, that the following matters have been confirmed.
- (a) That appropriate temperature control is carried out to prevent the occurrence of safety hazards owing to the reproduction of micro-organisms.
 - (b) That there is no decomposition or deterioration caused by accidents or inappropriate temperature control, etc.
 - (c) That, when preservation standards based on the Japanese Law have been stipulated for foods, these have been observed.
 - (d) That salt-cured and other foods, etc., have not been stored outdoors for long periods.
 - (e) That establishments are managed so that outsiders cannot access them without permission.

(Reference)

- Guidelines on Management and Operation Standards
- Basic Matters for Guidance to Importers
- Ensuring Food Safety and Proper Control of Poisonous and Deleterious Substances Pertaining to Case No. 114 (Notice Ei-shoku No. 102, Yaku No. 999 of December 20th, 1984)

Section 5 Recall and Disposal

1 Establishment of Recall Procedures

If a food hygiene problem caused by food imported occurs, with a view to preventing health hazards to consumers in advance, importers should establish a system of responsibility for recall, specific measures of recall, and procedures of reporting to the relevant administrative organs, which allow importers to recall the products in question promptly and appropriately.

- (1) Establishment of recall plans
 - (a) Creation of a lot code system
 - (b) Filing of product shipment and sale records

- (c) Preparation of a sick consumer complaint records
 - (d) Organization of recall teams
 - (e) Provision on recall procedures
 - (f) Provision on measures of informing consumers
 - (g) Provision on measures of managing recalled products
 - (h) Provision on measures of assessing the progress of recall and the recall results
- (2) Start of recall (matters to be reported to relevant administrative organs)
- (a) Cause of recall
 - (b) Scope of recalled food
 - (c) Distribution area of recalled food
 - (d) Quantity of recalled food
- (3) Measures after recall
- (a) Evaluation of recall plan
 - (b) Implementation of necessary compensation measures
- (4) Preparation and filing of recall records
- (a) Names and lot numbers of recalled items
 - (b) Reason for recall
 - (c) Monitoring records at the time of manufacturing
 - (d) Final product inspection records
 - (e) Records related to storage, shipment and distribution
 - (f) Scope of products subject to recall
 - (g) Measures and route of recall and notices to consumers
 - (h) Communication with administrative organs
 - (i) Quantities recalled
 - (j) Test Result of recalled items
 - (k) Measures of disposing of recalled items
 - (l) Evaluation of recall effects and whether necessary to make associated changes to recall plans, etc.
 - (m) Records concerning details of compensation following recall

(Reference)

- Guidelines on Management and Operation Standards

2 Product Disposition Measures

Importers should accurately and promptly take measures such as disposing recalled products. Moreover, recalled products should be stored in clear distinction from normal products, and product disposition and other measures should be implemented appropriately under instructions from the relevant administrative organ.

(Reference)

- Guidelines on Management and Operation Standards

3 Public Notification

Whenever necessary when recalling products, etc., importers should consider making public notification of information related to said recall, etc., with a view to creating cautionary awareness among consumers, etc.

Section 6 Other Matters

1 Education, Etc., on Japanese Food Hygiene Regulations

Importers should give education and guidance on Japanese food hygiene regulations to manufacturers that intend to export food to Japan, as well as occasionally providing information whenever there are violations, etc., in food both in Japan and abroad, and taking steps for improvement whenever necessary.

Importers should also dispatch technicians or other personnel to local establishments whenever necessary to give guidance on food hygiene, etc., and should take steps to harmonize levels of technology, knowledge and awareness.

2 Proper Labeling

Importers should ensure that the labeling of food imported by themselves complies with standards under related laws and ordinances in Japan, while also confirming these whenever necessary, for example by advance consulting the relevant administrative organ.

3 Preparing and Keeping Records

Importers should make efforts to properly prepare and file records at the time of import, sale, and other processes in the supply of food imported by themselves, to ensure that the state of distribution of said food can be confirmed at all times.

(Reference)

- Guidelines on the Creation and Filing of Records by Food-Related Business Operators under the Provisions of Article 1-3 Paragraph 2 of the Food Sanitation Law (Annex to Notice Shoku-an No. 0829001 of August 29th, 2003)

4 Tests and Inspections

When implementing tests and inspections, and handling the results thereof, importers should confirm that reliability is assured in terms of their accuracy and precision, etc.