

Imported Foods Monitoring and Guidance Plan for FY 2025

1 Purpose

The purpose of the Plan is to promote the intensive, effective and efficient monitoring and guidance over imported foods, additives, apparatus, containers and packages and toys (hereinafter collectively referred to as “foods”) and thereby to further ensure the safety of imported foods.

2 Effective period of the Plan

The Plan shall be effective from April 1, 2025 till March 31, 2026.

3 Current circumstances of imported foods

(1) Current circumstances of imported foods

The total number of import notifications for foods imported into Japan for the purpose of marketing or any other commercial purposes during FY 2023 was about 2.35 million and their import weight reached 29.87 million tons. Meanwhile, according to the Food Balance Sheet by the Ministry of Agriculture, Forestry and Fisheries, the food self-sufficiency ratio (food self-sufficiency ratio based on the total calorific value supplied) of Japan stands at about 40%, and this means that, on calorie basis, we are almost 60% dependent on foods imported from other countries.

According to the interim report published in December 2024 on the results of the monitoring and guidance under the Imported Foods Monitoring and Guidance Plan for FY 2024, the number of import notifications during the period from April to September, 2024 was approximately 1.25 million [1.20 million] and the import weight reached some 11.70 million tons [11.10 million tons], and the number of inspections conducted during the said period amounted to approximately 105,000 [102,000], out of which 374 cases [379 cases] were found as violating the Food Sanitation Act (the Act No. 233 of 1947; hereinafter referred to as “the Act”) (Figures in bracket [] show the figures of the same period of last fiscal year. All these figures are preliminary figures).

(2) Review of monitoring and guidance results based on Imported Foods Monitoring and Guidance Plan for FY 2024

The Ministry of Health, Labour and Welfare (hereinafter referred to as “the MHLW”) and quarantine stations have improved the inspection system at the time of import, including the addition of inspection items and the installation and maintenance of sufficient testing apparatus for inspection. In the event that a violation of the Act is detected by monitoring inspections, etc. or information on recall of foods is obtained in the exporting country, the measure at importation has been enhanced by monitoring inspections^{*1} and inspection orders^{*2}, etc. In addition, in order to promote hygiene control measures in exporting countries, research on regulations of food

hygiene, discussions and investigations on specific issues were conducted with exporting countries. Furthermore, on-site inspections were conducted to verify the hygiene controls being implemented in exporting countries for imported beef, etc.

*1 Monitoring Inspection means inspections systematically implemented every fiscal year for the purposes of monitoring safety conditions of various foods in accordance with the provisions of Paragraph 1, Article 28 of the Act and of introducing necessary measures such as enhancing inspections on importation in the case of any violation of the Act is found.

*2 Inspection Order means a ministerial order that requires importers to have imported foods with a high risk of violating the Act inspected on each importation of the foods in accordance with the provisions of Paragraph 2 or 3, Article 26 of the Act.

4 System to implement Imported Foods Monitoring and Guidance Plan for FY 2025

(1) The implementation of monitoring and guidance over imported foods

It is stipulated in Article 4 of the Food Safety Basic Act (the Act No. 48 of 2003) that the food safety shall be ensured by taking necessary measures appropriately at each stage of the food supply chain both in Japan and in exporting countries. Based on this standpoint, in order to ensure the safety of imported foods, the following measures are to be taken at each stage from production in exporting countries up to distribution after importation into the domestic market in Japan.

(i) In order to promote hygiene control measures during the production, manufacturing, processing etc. (hereinafter referred to as “productions”) in exporting countries, the MHLW provides information on food hygiene regulations of Japan to embassies located in Tokyo, importers, and the relevant government officials and producers of exporting countries as well as to publish on the website of the MHLW (hereinafter referred to as “the website”). In addition, the MHLW holds bilateral discussions with exporting countries, conduct on-site inspections in exporting countries, and provide technical assistance to those countries.

(ii) If any violation of the Act is detected, the MHLW introduces necessary measures such as enhancing inspections on importation and publishes the detected violation cases in accordance with the provision of Article 69 of the Act.

(iii) The MHLW issues an order for comprehensive import ban on foods produced in a specific country or area or by a specific producer in accordance with the provisions of Paragraph 1, Article 9 or Paragraph 1, Article 17 of the Act if the MHLW considers such measures are inevitable to prevent possible food hygiene hazards in Japan.

- (iv) If an importer has repeatedly violated the Act, the MHLW provides necessary instructions to the importer in order to have the importer rectify the cause of the violation, and as necessary, the MHLW issues an order to prohibit or suspend the business of the importer in accordance with the provisions of Paragraph 2, Article 60 of the Act (hereinafter referred to as “the prohibition or suspension of the business of importers”).
- (v) Quarantine stations carry out checks, based on import notification made under Article 27 of the Act and inspections to verify the identity of the contents of the import notification and the actual goods, the compliance with the Act including compliance with specifications and standards for foods (hereinafter referred to as “the standards”) in accordance with the provisions of Paragraph 1, Article 13 or Paragraph 1, Article 18 of the Act.
- (vi) Quarantine stations systematically carry out monitoring inspections to monitor the safety of a wide variety of imported foods.
- (vii) In order to prevent possible food hygiene hazards, quarantine stations order inspections on imported foods with a high probability of violating the Act in accordance with the provisions of Paragraph 2 or 3, Article 26 of the Act.
- (viii) Quarantine stations hold seminars for and provide pre-import guidance to importers in order to encourage them to promote, as a part of their responsibilities for food business operator, voluntary hygiene management of imported foods.
- (ix) Upon detection of a violation of the Act, quarantine stations instruct the importer to take necessary measures such as disposal, reshipment or diversion for non-food use (hereinafter referred to as “disposal, etc.”). In addition, quarantine stations take measures such as instructing the importer to investigate the cause of the violation and to provide a report to prevent the recurrence.
- (x) After imported foods are distributed into the domestic market, local governments such as the governments of prefectures as well as cities and special wards with public health centers (hereinafter referred to as “local governments”) are in charge of monitoring and guidance over the imported foods. Upon detection of any violation of the Act, the MHLW, quarantine stations and local governments cooperate with each other to take measures to ensure the accurate and swift recall of the foods violating the Act by the importers, etc.

(2) Basic direction for monitoring and guidance over imported foods in FY 2025

In the Imported Foods Monitoring and Guidance Plan for FY 2025 (hereinafter referred to as “the Monitoring and Guidance Plan”), measures are continued, and based on recent situations around imported foods, systems are developed to thoroughly implement appropriate monitoring and guidance, such as improving the qualifications of food sanitation inspectors at quarantine stations and securing necessary number of personnel and inspection apparatus.

Monitoring inspections are conducted on a wide range of imported foods to ensure more effective implementation. In addition, monitoring inspections are conducted systematically based on the results of monitoring inspections, etc., and the review of inspection items and enhancing of inspections are considered based on the results of monitoring and guidance, etc. even in the middle of the fiscal year.

Furthermore, to address the changes of the import situations due to the development of economic partnership agreements and globalization of food chain, it is continued to promote measures to effectively ensure safety at the productions stage in exporting countries through the bilateral discussions and on-site inspections and voluntary hygiene control measures by importers in addition to the inspection system focused at the time of import.

5 Specific Contents of Imported Foods Monitoring and Guidance Plan for FY 2025

(1) Matters to require intensive monitoring and guidance with confirmation of import notifications

(i) Checks based on import notifications in accordance with the provisions of Article 27 of the Act

With respect to foods for which an import notification is made in accordance with the provisions of Article 27 of the Act, the quarantine station confirms that the food does not fall under any one of those mentioned in each paragraph of Article 6 (Prohibited food and additives to sell), Paragraph 2 of Article 10 (Prohibition of sales of meat from unhealthy animals), or Article 16 (Prohibition of sales of toxic and harmful apparatus or containers and packaging) of the Act, that the food is not subjected to an import ban in accordance with the provisions of Paragraph 1, Article 9 or Paragraph 1, Article 17 of the Act; that additives contained in the food are approved as set forth in the provisions of Article 12 of the Act; and that the food is in compliance with the standards in accordance with the provisions of Article 13 or Article 18. These are confirmed with the import notification documents by the importer and, as necessary, by checking certificates issued by the government of the exporting country, by asking reports from the importer, and/or administrative inspections, etc.

(ii) Monitoring inspection in accordance with the provisions of Paragraph 1, Article 28 of the

Act

a. Development of the Monitoring Plan

In order to carry out monitoring inspections in an intensive, effective and efficient manner, the MHLW determines the number of inspections to be conducted for each inspection item stipulated for the monitoring inspection (hereinafter referred to as “the Monitoring Plan”) which is able to detect with a certain statistical confidence level as a basis, and taking into account the violation rate, the number of import notifications, the import weight and potential impacts on the public health. Monitoring inspections on those foods in which any violation was not found in previous inspections are also implemented at certain rate. In addition, development of a system necessary for efficient inspection implementation is considered.

For the Monitoring Plan for FY 2025, the number of inspections shall be about 100,000 cases as shown in Schedule 1. Continuously, inspections are conducted intensively on items with a high risk of health hazards, such as aflatoxins and pathogenic microbes. Additionally, the Monitoring Plan may be reviewed taking into consideration of import trends, inspection results, violation situations, survey results of food hygiene regulations of exporting countries, and information on occurrence of food-related health damages and recalls of unhygienic foods in exporting countries.

In addition, the MHLW ensures the steady implementation of inspections on agricultural chemicals in accordance with the Positive List System^{*3}, taking into account the regulations concerning agricultural chemicals in other countries, the status of their use, cases of detecting agricultural chemicals as well as violation cases of agricultural food products at the time of import.

^{*3} Positive List System for agricultural chemical residues means a system that prohibits, in principle, the sale, etc. of foods in which agricultural chemicals are resided in excess of the quantity specified as unlikely to cause harm to human health.

b. Systematic implementation of monitoring inspections

Each quarantine station prepares its own annual plan for carrying out the number of inspections the MHLW assigns and ensures its systematic implementation. Monitoring inspections should be conducted on a wide range of foods to ensure more effective implementation.

Meanwhile, monitoring inspections for foods subject to inspection order concerning agricultural chemical residues are carried out in order to verify the reliability on the control of agricultural chemical residues in exporting countries. These are to address concerns that

agricultural chemicals other than targeted by the inspection order may be contained in the foods in excess of the standard values since there are possibilities of insufficient control of agricultural chemical residues or of any change in agricultural chemicals used in exporting countries.

The MHLW checks the implementation of inspections based on the Monitoring Plan and provides instructions to quarantine stations as necessary. When the implementation of the planned inspections by a quarantine station or by a food group are deemed difficult due to changes in import situations or any other circumstances, the Monitoring Plan is reviewed and adjusted to the actual import situation to carry out effective inspections.

In case of emergency, the MHLW entrusts the testing affairs to registered laboratories in accordance with the provisions of Paragraph 4, Article 28 of the Act.

c. Enhancement of monitoring inspections

The MHLW instructs quarantine stations to enhance inspections of imported foods, as necessary, when information on the recall of foods or the occurrence of health hazards in exporting countries etc., is obtained, when violations of the Act are found through monitoring inspections, etc., when violations of the Act are found through monitoring and inspections by local governments, or when cases are confirmed in which health hazards are likely to occur.

As for the enhancement of inspections of agricultural chemical residues, in order to assess the situations of the agricultural chemicals use in the exporting country, the MHLW carries out monitoring inspections at a higher frequency for certain imported foods and inspection items concerned to enable detection of a violation with a certain statistical confidence level.

In addition, in order to prevent foods violating the Act to be consumed, the MHLW continues to carry out inspections that allow for a shorter period of time than in the past for results to be obtained.

d. Cancellation of enhanced monitoring inspections

When the MHLW determines that there is no longer a concern that foods violating the Act may be exported to Japan, the normal monitoring system is reinstated by canceling the enhanced monitoring inspections in accordance with either of the following procedures, i or ii:

- i) The exporting country has identified the cause of the violation, and based on the findings, preventive measures such as the formulation of a new regulation, the improvement of the control system and the enhanced inspection system have been introduced. Upon

confirmation of the effectiveness of such measures, the enhanced monitoring inspections may be cancelled; or

ii) When no violation of similar nature is found after one year from the date on which the monitoring inspections were enhanced or after more than 60 specimens were inspected, in principle, the enhanced monitoring inspections may be cancelled.

(iii) Administrative inspections other than the monitoring inspection in accordance with the provisions of Paragraph 1, Article 28 of the Act

In addition to inspections based on the Monitoring Plan, quarantine stations conduct inspections on imported foods based on the import notification documents in cases when they are imported into Japan for the first time (hereinafter referred to as “the initial import”) by the importer, when foods for which hygiene control in exporting countries is particularly significant are imported, when an accident has occurred during the transportation, or on any other occasions requiring inspections.

Furthermore, including the above, inspections to verify the identity of the contents of the import notification and the actual goods are carried out as necessary.

(iv) Inspection order in accordance with the provisions of Paragraph 2 or 3, Article 26 of the Act

a. Issuance of an inspection order

When the Minister of Health, Labour and Welfare deems it necessary in order to prevent any harm to the food hygiene, the MHLW initiates inspection orders for imported foods that were considered to have a high probability of violating the Act in accordance with either of the following procedures, i. or ii.

When MHLW publishes that the food is added to the list of foods subject to inspection order, the MHLW provides easy-to-understand information about the potential health hazards that may be caused by the foods.

i) When a health hazard has been occurred or is concerned to be caused by the imported food in the exporting country and/or Japan, or when a violation of the Act has been detected as a result of the monitoring inspection of aflatoxin, pathogenic microbes, etc., the imported foods manufactured by the same manufacturer, processed by the same processor, or imported from the same exporting country will be immediately subjected to inspection order.

ii) When more than one violation of the Act has been detected as a result of the monitoring inspection of the imported foods manufactured by the same manufacturer, processed by the same processor or exported from the same country, all or part of the imported foods

in question will be subjected to an inspection order, after taking into account the regulations and the hygiene controls being implemented in the exporting country as well as the historical compliance record of the imported foods and other factors.

b. Cancellation of an inspection order

When the MHLW determines that there is no longer a concern that the foods violating the Act will be exported to Japan, cancel the inspection order in accordance with either of the following procedures i or ii:

- i) The exporting country has identified the cause of the violation, and based on the findings, preventive measures such as the formulation of a new regulation, the improvement of the control system and the strengthening of the inspection system have been introduced. Upon confirmation of the effectiveness of such measures through bilateral discussions, on-site inspections, or inspections on importation of the foods, the inspection order may be cancelled; or
- ii) If no new violation is detected during two years from the date on which the most recent violation was found after the date of the notification of an inspection order (or from the date of notification of an inspection order if no violation has occurred since the date of such notification) or if there is no new violation during one year from the said date and at the same time, more than 300 specimens have been inspected based on the inspection order, in principle, the inspection order may be cancelled.

Thereafter, in case monitoring inspections on the concerned inspection items of the imported foods will be carried out at a higher frequency as necessary. Upon detection of any violation during the period of a higher frequency monitoring inspections, the food will be immediately subjected to inspection order.

(v) Comprehensive import ban in accordance with the provisions of Paragraph 1, Article 9 or Paragraph 1, Article 17 of the Act

As for imported foods produced in a specific country or area or by a specific business entity, if the violation rate stands above approximately 5% of the overall number of the said foods inspected, and if it is highly likely that the importation of the food violating the Act continues due to the level of the food hygiene control in the exporting country or area, the MHLW conducts review taking into consideration the extent of damage to human health caused by the foods. The Minister of Health, Labour and Welfare issues a ban on the importation of such food after consulting with the Health Science Council, to the extent that such a ban is deemed inevitable

in order to prevent potential food hygiene problems.

(vi) Emergency measures based on overseas information on food safety incidents

In order to ensure the safety of imported foods, the MHLW gathers information on food-safety problems occurring in other countries through relevant ministries and agencies, the National Institute of Health Sciences, the Japan Institute for Health Security, the governments of exporting countries and through the International Food Safety Authorities Network (INFOSAN) by the World Health Organization (WHO) and publishes major cases on the website.

If, as a result of the search that the violating food have already been imported into Japan, the MHLW instructs or requests the relevant quarantine stations or local governments to investigate the distribution and the stock status of the foods and to instruct the importers and other concerned parties to carry out inspections, the recall of the foods and/or any other appropriate measures. The MHLW also instructs quarantine stations to enhance their inspections over the foods and publishes the measures to address the issue.

(2) Promotion of hygiene control measures in exporting countries

The MHLW promotes hygiene control measures in exporting countries through the following efforts to prevent violation of the Act at the productions stage in exporting countries.

(i) Dissemination of information on food-hygiene regulations of Japan

The MHLW provides on the website the English translation of the food hygiene regulations of Japan, the lists of foods subject to inspection order or enhanced monitoring inspection, this Plan as well as the results of the monitoring and guidance conducted under the Plan.

In addition, the MHLW communicates such information widely among the government officials and producers of exporting countries by holding briefing sessions for the relevant staff of embassies located in Tokyo at the time of the revision of standards, through seminars on food hygiene regulations organized by the Japan International Cooperation Agency (JICA) as well as by holding meetings in exporting countries.

(ii) Bilateral discussions and on-site inspections

With regard to imported foods subject to inspection order as well as imported foods with a high probability of violating the Act, the MHLW asks the governments of the exporting countries through bilateral consultations, to investigate into the causes of the violations and to develop preventive measures based on the results, and thereby promotes the implementation of hygiene controls during the productions stage, the enhancement of monitoring systems and the introduction of pre-export inspections in the exporting countries.

Meanwhile, in order to effectively promote hygiene control measures for foods exported to Japan in exporting countries, the MHLW systematically collects information and conducts on-site inspections as appropriate, considering the countries exporting large amount of foods to Japan and the member countries of the economic partnership agreements. Exporting countries in which a large number of violations are reported in the results of interim report under the Plan for FY 2024 are also considered (violations of each paragraph of Article 6 of the Act related to toxic or hazardous substances such as mycotoxins and violations of Paragraph 2 or 3, Article 13 of the Act related to the standards concerning agricultural chemicals, veterinary drugs, microbes and additives).

When it is necessary to verify the hygiene control measures being implemented at the productions stage in the exporting countries in order to ensure the safety of imported beef, etc., the MHLW dispatches experts to carry out on-site investigations of the hygiene control measures in the exporting countries.

Furthermore, for exporting countries of livestock and poultry meat and offal for which hygiene control measures based on HACCP are required, as well as exporting countries of milk and dairy products, pufferfish, and oysters for raw consumption for which health certificates are required to be attached, the MHLW conducts on-site inspections to confirm hygiene control measures at the productions stage in the exporting country as appropriate. Bilateral consultations are held in the event of food hygiene problems.

(iii) Technical cooperation

The MHLW and quarantine stations promote technical cooperation that contributes to the enhancement of the monitoring systems of exporting countries including through information dissemination on the food hygiene control regulations of Japan, and through providing assistance for the improvement of testing techniques of agricultural chemical residues, mycotoxins and other substances.

(3) Promotion of voluntary safety management by importers

Paragraph 1, Article 8 of the Food Safety Basic Act stipulates that food business operators, including importers, shall be responsible for taking necessary measures to ensure food safety at each stage of the food supply chain based on the recognition that they bear the primary responsibility for ensuring food safety. Paragraph 1, Article 3 of the Act also stipulates that food business operators, including importers, are required to take necessary measures under their own responsibilities such as the acquisition of necessary knowledge and technology, ensuring the safety of raw materials and the implementation of voluntary inspections to ensure the safety of imported foods.

In light of these requirements, quarantine stations promote voluntary safety management among importers through the following guidance and measures to prevent violations of the Act and to ensure import notifications are made appropriately.

(i) Basic guidance for importers

Quarantine stations make sure that importers have a thorough understanding of the food hygiene regulations such as import procedures, inspection systems, the standards and requirements to attach health certificates as well as their responsibilities.

From the standpoint of the promotion of voluntary safety management by importers, quarantine stations provide importers in a timely manner with information on imported foods violating the Act and hygiene problems, newly established standards, and food hygiene regulations of exporting countries. Guidance to importers are provided through seminars or at the time of submitting import notification so that importers themselves ensure the safety of imported foods.

Basic guidance for importers are listed in Schedule 2. Additional guidance may be given to importers depending on exporting countries and the types of foods. As for processed foods, in accordance with the Appendix1 “Guidelines on Voluntary Hygiene Control of Import Processed Foods” (hereinafter referred to as the “Processed Food Guidelines”) attached to the “Notification concerning the Guidelines on Voluntary Hygiene Control of Import Processed Foods”, Notice ShokuAn No. 0605001, dated June 5, 2008, issued by the Director General of the Department of Food Safety, Pharmaceutical and Food Safety Bureau, MHLW, importers are instructed to conduct necessary confirmation at the productions stage in exporting countries by taking into consideration the status of the development and implementation of food hygiene regulations in exporting countries and the level of hygiene controls implemented by the manufacturers.

Furthermore, quarantine stations urge importers to make sure that imported foods have not been illegally produced in exporting countries, and the raw materials, additives, manufacturing processes, testing data of the foods confirm to the Act by using the checklist based on the Processed Food Guidelines.

Regarding foods sold as “health foods”(the food which is widely sold or used as the food contributing to health maintenance and improvements), the guidance is provided to the importers to manufacture and sale raw materials of tablet and capsule type food products by ensuring the safety of food raw materials and product design, in accordance with the “Guidelines for Voluntary Inspections on Safety of Raw Ingredients and Product Design for the Tablet and Capsule Type Food Products”, and the “Guidelines for Good Manufacturing Practice (GMP) for Tablet and Capsule Form Food Products”, Notice KenSeiShokuKi No.

0311 Article 2, dated March 11, 2024, issued by the Director of Food Safety Standards and Evaluation Division, Public Health Bureau, MHLW” . Importers are instructed to take voluntary measure so that they ensure the safety of food by checking such as whether the materials are eligible as foods, enough eating habits in exporting countries, existence of the reported cases of adverse health events in Japan and other countries, cooperating with the pharmaceutical department as necessary. In the case of foods containing ingredients or substances that the MHLW has been calling for attention in response to the reported adverse health events in Japan and other countries, guidance is provided to implement appropriate management. In the case of foods containing specific ingredients or substances designated by the Minister of Health, Labour and Welfare and the Prime Minister in accordance with the provisions of Paragraph 1, Article 8 of the Act, guidance is provided to thoroughly confirm that the manufacturing method complies with “Standards for Manufacturing or Processing of the Foods Containing the Designated Ingredients, Etc.” (Notice of the Ministry of Health, Labour and Welfare No. 121, 2020).

Regarding the Positive List System for Food Apparatus and Containers and Packaging^{*4}, the new system is continued to be announced to importers and importers are instructed to ensure that food apparatus compliance with the Act, in preparation for full implementation by June 1, 2025.

^{*4} Positive List System for Food Apparatus and Containers and Packaging was introduced following the amendment of the Act in 2018. It means a system that evaluates the safety of the substances and prohibits, in principle, the use of substances, except for only those approved for use to food apparatus and containers and packaging.

Furthermore, importers are instructed to make appropriate import notifications based on accurate and latest information obtained from producers, etc., and to verify the identity of the contents of the import notification and the actual goods for foods imported for the first time and for foods for which hygiene control in exporting countries is particularly important such as meat and fishery products. When importers intend to import foods on a regular basis, they are instructed to make sure that there are no changes in raw materials and manufacturing process used for the foods as well as the verify the identity of the contents of the import notification and the actual goods, and the conformity of goods in the import notification with the items presented in the testing report of voluntary inspection.

In addition to these efforts, quarantine stations provide necessary information to importers whenever the standards are revised, inspection is enhanced, sales are prohibited, or other related changes in measures are made.

(ii) Implementation of pre-import guidance

Based on the guidance mentioned in (i) above, quarantine stations instruct importers to confirm in advance whether foods to be imported do not contain any of the pharmaceutical ingredients regulated under the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (the Act No. 145 of 1960), and confirm whether the ingredients are not narcotic regulated under the Narcotics and Psychotropics Control Act (the Act No. 14 of 1953). by obtaining necessary information from producers. importers are instructed to check their safety as foods for human consumption.

Quarantine stations promote pre-import guidance to prevent import of foods violating the Act by dispatching their staff members to international exhibitions held by their associated organizations for consultations and improving the system to implement pre-import guidance by cooperating with such organizations.

Regarding foods imported for the first time or foods that fall under the same category as those violated the Act or caused any hygiene problem in the past, quarantine stations encourage importers to consult with quarantine stations in advance. The website and/or seminars are used to further promote the pre-import guidance.

When the results of voluntary inspections are presented in the pre-import guidance, those testing results will be utilized when quarantine stations check the import notification documents to promote voluntary inspection before importation.

The results of pre-import guidance are shared among quarantine stations to promote effective monitoring and guidance.

(iii) When a violation is identified at the pre-import guidance

If, as a result of the safety check in advance at a pre-import guidance by an importer, the food being imported is found that it does not comply with the Act, the relevant quarantine station instructs the importer not to import unless appropriate measures to make the food comply with the Act are taken and the situation is rectified.

Even when the food is proved, through document check, etc., to be in compliance with the Act as a result of the rectification, the quarantine station, when necessary, instructs the importer to carry out a testing to verify that the food actually meets the standards.

(iv) Voluntary inspection

As for any food imported into Japan for the first time by the importer, quarantine stations thoroughly instruct the importer to carry out voluntary inspections with respect to inspection items necessary to verify that the food is in compliance with the Act such as standards, criteria

and additives used in the product.

Meanwhile, in cases where the food is to be imported on a regular basis, the importer are instructed to carry out voluntary inspections in accordance with the guidance mentioned in (i) above by regularly checking the standards and criteria and the usage of additives in the food and also taking into consideration of the violation cases in foods of the same category.

(v) Preparation and retention of records of imported foods

Based on the Appendix “Guidelines for Preparation and Retention of Records by Food Business Operators, based on Provisions in Paragraph 2, Article 1-3 of the Food Sanitation Act” attached to the “Notification of the Guidelines for Preparation and Retention of Records by Food Business Operators based on Provisions in Paragraph 2, Article 1-3 of the Food Sanitation Act,” Notice ShokuAn No. 0829001, dated August 29, 2003, issued by the Director General of the Department of Food Safety, Pharmaceutical and Food Safety Bureau, MHLW, importers are instructed to appropriately prepare and maintain records of the importation, sales and other details of the imported foods in order to check always the distribution status of the imported food. Importers are also instructed to maintain such information in a way that they are able to provide the information immediately to relevant quarantine stations and local governments should any violation of the Act be identified.

Further, in order to prevent any foods violating the Act to be consumed, quarantine stations instruct importers to provide such records as notified in the “Guidelines for the Implementation of “the Imported Foods Monitoring and Guidance Plan for FY 2016”” (Notice SeiShokuYu No. 1007 Article 1, dated October 7, 2016, issued by the Director of Imported Food Safety Office, Inspection and Safety Division, Department of Environmental Health and Food Safety, Pharmaceutical Safety and Environmental Health Bureau, MHLW) so that distribution surveys and the recall of foods violating the Act will be swiftly carried out upon detection of any violation through monitoring inspections.

(vi) Enhancement of food safety knowledge among importers, customs brokers and bonded warehouse operators

Quarantine stations hold seminars not only for importers but also for customs brokers and bonded warehouse operators to provide information about guidance listed (i) to (v) above and dispatch their staff members to seminars held by their associated organizations, with the aim of improving the business operators’ knowledge on food safety and thereby to ensure the safety of imported foods.

As necessary, quarantine stations encourage importers to consult in advance with local governments having jurisdiction over the area where their places of business are located to seek

advice on labelling requirements such as appropriate expiration dates.

(4) Responses upon detection of a violation

The quarantine station, the MHLW and relevant local governments cooperate with each other to ensure the safety of imported foods and instruct the importer to promptly dispose of or recall the food violating the Act and to investigate into the cause of the violation and to take appropriate preventive measures. In addition, other necessary measures including the enhancement of inspection on importation are introduced as follows:

(i) When a violation is detected through the inspection on importation or any other procedures:

a. In the case where the food violating the Act has not yet cleared customs:

The relevant quarantine station instructs the importer to dispose of the food violating the Act and to report on the progress of such disposal.

Meanwhile, the MHLW introduces necessary measures including the enhancement of inspection on importation.

b. In the case where the food violating the Act has already cleared customs:

The relevant local government having jurisdiction over the area where the place of business of the importer is located orders the importer to recall or otherwise dispose of the food violating the Act, where necessary, and instructs to report on the progress of such action taken.

In order to ensure the efficient implementation of the recall or any other disposal by the importer, the relevant quarantine station reports to the MHLW in a timely manner the lot numbers of the food violating the Act products, the name and address of the importer and other relevant information (hereinafter referred to as the “information on food violating the Act”).

Meanwhile, the MHLW provides the information on food violating the Act to the relevant local government that has jurisdiction over the area where the place of business of the importer is located, and takes other necessary measures including the enhancement of inspection on importation.

The quarantine station instructs the importer, while directing disposal of the food violating the Act as temporary measures, to follow as directed by the local government having jurisdiction over the area where the place of business of the importer is located.

In addition to these response measures, the MHLW share the relevant information with the Consumer Affairs Agency, in accordance with the provisions of Paragraph 1 and 2, Article 12 of the Consumer Safety Act (the Act No. 50 of 2009).

- (ii) When a violation is detected through any inspection during the domestic distribution process:

Upon notification from any local government of any violation of import food detected in the domestic distribution process as a result of sampling inspections (sampling or inspection based on the provision of Article 28, Paragraph 1 of the Act) and/or voluntary inspections by the distributor, etc., the MHLW provides the information on food violating the Act to quarantine stations. Based on the information, the MHLW takes necessary measures including the enhancement of inspection on importation where necessary.

Should there be any reported health hazard caused by the imported food, the MHLW makes prompt notification to prevent further expansion of the damage, to quarantine stations regarding foods subsequently imported and to local governments regarding foods already distributed into the domestic market, and takes necessary measures.

- (iii) Instructions to importers for the prevention of the recurrence

To prevent the recurrence of violations, quarantine stations require the importer who has violated the Act to report on the following:

- a. Investigation and report of the cause of the violation

Quarantine stations require the importer to investigate and report into the cause of the violation and give instructions to the importer to prevent recurrence of violations. If the cause is not identified after three months from the detection of the violation, quarantine stations require the importer to report on the progress of its investigation.

- b. Report of the results of the rectification of the cause before resumption of importation

Before allowing the resumption of the importation of the food in question, quarantine stations confirm the rectification of the cause of the violation through the investigation as mentioned in a. above. If necessary, quarantine stations verify the rectification of the cause by referring to a report of investigations in the exporting country conducted by the importer and/or other inspections carried out by the exporting country and request for a report on the results of the rectification.

- (iv) Prohibition or suspension of the business of importers based on the provisions of Paragraph 2, Article 60 of the Act

From the standpoint of ensuring food safety, the MHLW may order the prohibition or suspension of the business of importers who have repeatedly committed violations, or importers whose imported foods caused or may cause damage to the public health, in order to have them rectify the cause of the violation and take preventive and other necessary food hygiene control measures.

In addition, as for importers whose violation rate is 5 % or more and who may be subjected

to the disposition for prohibition or suspension of business, the MHLW requires them to submit explanations about their preventive measures and provides guidance so that no more violations be committed by them, in accordance with the Appendix “Guidelines for the Prohibition or Suspension of Business of Importers under Paragraph 2, Article 55 (current Article 60) of the Act” attached to the “Notification concerning the Prohibition or Suspension of Business of Importers under Paragraph 2, Article 55 (current Article 60) of the Act”, Notice ShokuAn No. 0110003 dated January 10, 2006 issued by the Director General of the Department of Food Safety, Pharmaceutical and Food Safety Bureau, MHLW. If hygiene control measures are still deemed insufficient, the importers are subjected to the disposition for prohibition or suspension of business until necessary measures are taken.

Quarantine stations enhance monitoring inspections over food products imported by such importers in accordance with the seriousness of the violations and conduct the verification of the preventive measures introduced by the importers.

(v) Indictment of malicious cases

Quarantine stations indict cases deemed as amounting to criminal offences such as the submission of a false import notification and illegal importation of foods violating or highly likely to violate the Act, and release the information about such indictment in a timely manner.

(vi) Publication of violations

In order to alert the public against food hygiene hazards, the MHLW promptly publishes on the website the name of the importer who has violated the Act or violated any action taken under the Act (except for importers whose violation is of minor nature and who have rectified the violation immediately) and the details of the food violating the Act imported by the importer (as for the names of violating importers, the publication period is limited to one year) in accordance with the provisions of Article 69 of the Act. In addition to the publishing information on the names of violating importers, the progress of the response measures including the disposal, recall, etc., of food products violating the Act, the details of corrective actions and the causes of the violations is also published as soon as such information becomes available.

(5) Promotion to exchange information and opinions between involved parties (risk communication)

By utilizing the website, MHLW official SNS accounts (e.g., Food Safety Information X, formerly Twitter, etc.) and any other means, the MHLW and quarantine stations actively provide the public with easy-to-understand information about efforts for ensuring safety of imported foods

and hold sessions for information exchange and facilitate risk communication.

(i) Provision of information about the Monitoring Plan, etc.

Quarantine stations communicate the notices concerning the Monitoring Plan, the Inspection Order, the enhancement of inspections and other measures widely among importers, customs brokers and bonded warehouse operators to facilitate the smooth implementation of the monitoring and guidance under the Plan. The MHLW also makes public, information concerning the Monitoring Plan, the issuance of inspection orders, the enhancement of inspections and other measures.

(ii) Provision of information concerning bilateral discussions and on-site inspections

The MHLW publishes information concerning bilateral discussions and on-site inspections that have been held or conducted in order to promote hygiene control measures in exporting countries.

(iii) Announcement of monitoring results under the Plan

The MHLW publishes annually the summary report of the progresses and the results of monitoring inspections and inspection orders, the yearly trends of the result of monitoring and guidance, the summary of instruction and guidance over importers, etc., carried out under the Plan around August of the following fiscal year. The interim report of the first half of the fiscal year (from April to September) is published around December.

(iv) Efforts to facilitate risk communication on food safety

The MHLW introduces a public comment process to invite opinions on the draft Monitoring and Guidance Plan for the next fiscal year. In addition, for better mutual understanding on efforts and knowledge related to food safety, as risk communication, the MHLW hold sessions for information exchange in cooperation with local governments and other concerned ministries and agencies, and concerned bodies, to provide consumers, business operators, etc. with the details of the Monitoring and Guidance Plan and its progress by utilizing the website and official SNS of the MHLW (e.g., Food Safety Information X, formerly Twitter, etc.).

(v) Others

Quarantine stations endeavor to gain public understanding of the actual conditions of monitoring and guidance on imported foods through activities such as visit tours at quarantine stations for general consumers.

(6) Other activities necessary for the implementation of monitoring and guidance

(i) Development and skill enhancement of human resources in charge of food safety

The MHLW hold seminars and training sessions to improve the knowledge and skills on food safety for food sanitation inspectors engaging in monitoring and guidance and laboratory testing of imported foods at quarantine stations.

(ii) Evaluation of tests and inspections of foods carried out by quarantine stations

With technical advice from the MHLW's regional offices that supervise the Registered Laboratories, the MHLW will systematically carries out the evaluation of the GLP (Good Laboratory Practices) at quarantine stations and provide instructions in order to ensure the proper implementation of monitoring inspections and other related operations by quarantine stations.

Schedule 1

Food Groups	Inspected Substances*1	Number of inspection specimens*2	Total number of Inspection specimens*2
Livestock Foods Beef, pork, chicken, horse meat, other poultry meat, etc.	Antibacterial substances, etc.	2,100	5,850
	Residual agricultural chemicals	2,100	
	Additives	240	
	Pathogenic microbes	690	
	Standards, etc.	690	
	Radiation irradiation	30	
Processed Livestock Foods Natural cheese, meat products, ice cream, frozen food (meat), etc.	Antibacterial substances, etc.	1,800	10,200
	Residual agricultural chemicals	1,500	
	Additives	1,100	
	Pathogenic microbes	3,700	
	Standards, etc.	2,100	
	Radiation irradiation	60	
Fishery Foods Bivalves, fish, crustacea (shrimps, crabs), etc.	Antibacterial substances, etc.	2,200	5,630
	Residual agricultural chemicals	1,400	
	Additives	300	
	Pathogenic microbes	1,200	
	Standards, etc.	410	
	Genetically modified food	60	
Processed Aquatic Foods Processed fish products (fillet, dried or minced fish, etc.), frozen food (marine animals, fish), processed fish egg products, etc.	Antibacterial substances, etc.	3,600	16,930
	Residual agricultural chemicals	3,100	
	Additives	1,510	
	Pathogenic microbes	4,720	
	Standards, etc.	4,000	
	Radiation irradiation	60	
Agricultural Foods Vegetables, fruit, wheat, corn, beans, peanuts, nuts, seeds, etc.	Antibacterial substances, etc.	2,900	19,050
	Residual agricultural chemicals	10,400	
	Additives	950	
	Pathogenic microbes	2,000	
	Standards, etc.	200	
	Mycotoxins	2,100	
	Genetically modified food	380	
	Radiation irradiation	120	
Processed Agricultural Foods Frozen food (processed vegetables), processed vegetable products, processed fruit products, spices, instant noodles, etc.	Antibacterial substances, etc.	720	21,590
	Residual agricultural chemicals	5,800	
	Additives	3,500	
	Pathogenic microbes	3,000	
	Standards, etc.	3,400	
	Mycotoxins	4,200	
	Genetically modified food	510	
	Radiation irradiation	460	
Other Foods Health foods, soups, seasoning, confectionary, cooking oil and fat, frozen food, etc.	Residual agricultural chemicals	800	7,200
	Additives	4,000	
	Standards, etc.	1,200	
	Mycotoxins	1,200	
Beverages Mineral waters, soft drinks, alcoholic beverages, etc.	Residual agricultural chemicals	430	2,050
	Additives	1,000	
	Standards, etc.	500	
	Mycotoxins	120	
Additives Apparatus, containers and packaging Toys for infants	Standards, etc.	1,500	1,500
Foods subject to enhanced inspection*3	Antibacterial substances, etc., Residual agricultural chemicals, Additives, Pathogenic microbes, Standards, etc., Mycotoxins, Genetically modified food, Radiation irradiation, Removal of SRMs	10,000	10,000
Grand total (gross) *2			100,000

*1: Examples of inspection substances

- Antibacterial substances, etc. : Antibiotics, synthetic antimicrobials, hormone agents, etc.
- Residual agricultural chemicals : Organophosphorus, organochlorine, carbamates, pyrethroid agricultural chemical, etc.
- Additives : Preservatives, coloring agents, sweeteners, antioxidants, fungicides, etc.
- Pathogenic microbes : Enterohemorrhagic *Escherichia coli* (*E.coli*) O26, O103, O104, O111, O121, O145, and O157, *Listeria monocytogenes*, etc.
- Standards, etc. : Items stipulated in the standards (bacterial count, coliform bacteria, radioactive substances, etc. (excluding pathogenic microbes)), shellfish poisons (diarrhetic shellfish and paralytic shellfish poisons), etc.
- Mycotoxins : Aflatoxin, deoxynivalenol, patulin, etc.
- Genetically modified food : Genetically modified food etc. that have not been assessed for safety.
- Radiation irradiation : Whether irradiation is applied

*2: The total numbers of specimens are approximate aggregations of the numbers of inspections in the relevant food groups or inspected substances.

*3: Additional inspections conducted during the implementation of the plan, based on the occurrence of violations and overseas information at the time of importation.

Schedule 2

	Risk factors at the time of importation (typical examples)	Items to be checked in advance	Items to be checked regularly (including at the time of first importation)	Items to be checked during the transportation and storage processes
Foods in general (Items in common)	<ul style="list-style-type: none"> Containing hazardous or toxic materials in the food Mixing with rotten or deteriorated matter, or unclean Mixing with foreign matter 	<ul style="list-style-type: none"> Taking measures to prevent contamination of hazardous or toxic materials at the point of receiving raw material and manufacturing and processing process 	<ul style="list-style-type: none"> Ensuring that no hazardous or toxic materials are contained, by regular checking and testing 	<ul style="list-style-type: none"> Whether any rot or deterioration occurred due to accidents or improper temperature control Whether the food processed by salting or other methods is stored outdoors for a long time Whether the any contamination occurred with pesticides, etc. used in the warehouse
	<ul style="list-style-type: none"> Contamination by pathogenic microbes 	<ul style="list-style-type: none"> Taking measures to prevent contamination by pathogenic microbes 	<ul style="list-style-type: none"> Ensuring that no pathogenic microbes are present through regular checking and testing 	<ul style="list-style-type: none"> Whether proper temperature control is implemented to prevent harm due to the growth of microbes
	<ul style="list-style-type: none"> Use of undesignated additives Use of additives for undesignated purposes, or the use of additives that does not conform with the standards for their use, such as overuse 	<ul style="list-style-type: none"> Ensuring that no undesignated additives are used, including those used for raw material Ensuring that additives do not comply with the standards are not used, and that the appropriate amount is used 	<ul style="list-style-type: none"> Ensuring that no undesignated additives are used, and that the proper amount of additives is used by regular checking and testing 	
	<ul style="list-style-type: none"> Non-conformity with standards (soft drinks, meat products, frozen foods, and other products) 	<ul style="list-style-type: none"> Ensuring that standards for constituents, manufacturing and processing standards, and other standards are met Ensuring that no sterilization by irradiation, etc. is conducted (excluding those for controlling germination of potatoes) Asking manufacturers and producers to provide the formal names and percentages of raw materials and additives used in the manufacturing process and the final products Ensuring that the final product conforms with the Food Sanitation Act by checking and testing, as necessary 	<ul style="list-style-type: none"> Confirming that no change has been made in the manufacturing process and the raw materials Ensuring conformity with the standards for constituents, by regular checking and testing Ensuring compliance with the Food Sanitation Act, by testing the final products 	<ul style="list-style-type: none"> Compliance with storage standards Checking whether any accident has occurred
	<ul style="list-style-type: none"> GM foods whose safety has not been assessed 	<ul style="list-style-type: none"> Checking whether GM food has been approved Whether or not there is a need for safety review among food derived from genome editing technology 	<ul style="list-style-type: none"> Ensuring that no GM food whose safety has not been assessed is mixed through regular checking and testing Periodic confirmation of the existence of food derived from genome editing technology Confirmation by prior consultation if it is a food derived from genome editing technology 	<ul style="list-style-type: none"> Whether proper control is carried out

Agricultural products and related processed foods	<ul style="list-style-type: none"> • Mycotoxins such as aflatoxin and patulin (cereals, beans, spices, apple juice, etc.) 	<ul style="list-style-type: none"> • Taking measures to prevent mold from growing at the time of ingathering and transportation/storage 	<ul style="list-style-type: none"> • Ensuring that no mycotoxins are present by regular checking and testing 	<ul style="list-style-type: none"> • Whether proper control of temperature and humidity is carried out to prevent the growth of mold
	<ul style="list-style-type: none"> • Natural poisons such as cyanogenic glycosides 	<ul style="list-style-type: none"> • Checking whether any natural poisons are present in food • Measures should be taken to remove any natural poisons during the manufacturing, processing and other processes • Taking measures to prevent contamination of any hazardous or toxic plants 	<ul style="list-style-type: none"> • Ensuring that no natural poisons are present by regular checking and testing 	
	<ul style="list-style-type: none"> • Radioactive contamination (mushrooms, processed concentrated berries, herbs, etc.) 	<ul style="list-style-type: none"> • Ensuring that the harvesting area is not contaminated by radioactive substance 	<ul style="list-style-type: none"> • Checking the level of radioactivity by regular checking and testing 	
	<ul style="list-style-type: none"> • Pathogenic microbes such as Enterohemorrhagic <i>Escherichia coli</i> O157 (fresh vegetables) 	<ul style="list-style-type: none"> • Taking measures to prevent contamination by pathogenic microbes 	<ul style="list-style-type: none"> • Ensuring that no pathogenic microbes are present by regular checking and testing 	<ul style="list-style-type: none"> • Whether proper temperature control is carried out to prevent harm due to the growth of any microbes
	<ul style="list-style-type: none"> • Residual agricultural chemicals 	<ul style="list-style-type: none"> • Checking how agricultural chemicals are used • Ensuring raw materials of processed foods conform with residue standards 	<ul style="list-style-type: none"> • Ensuring compliance with proper usage and dosage of agricultural chemicals, before and after ingathering • Ensuring that residual agricultural chemicals are below proper levels, by regular checking and testing 	<ul style="list-style-type: none"> • Checking whether any agricultural chemicals were used after ingathering
	<ul style="list-style-type: none"> • GM foods whose safety has not been assessed (corn, papaya, etc.) 	<ul style="list-style-type: none"> • Checking whether GM food has been approved • Taking measures to prevent any unassessed GM food from being mixed 	<ul style="list-style-type: none"> • Ensuring that no GMO food whose safety has not been assessed is mixed through regular checking and testing 	<ul style="list-style-type: none"> • Whether proper control is carried out
	<ul style="list-style-type: none"> • Use of additives that may mislead consumers in the recognition of quality and freshness (fresh vegetables) 	<ul style="list-style-type: none"> • Ensuring that no colorant, bleach, or other additives that may mislead consumers in the recognition of quality or freshness have been used 	<ul style="list-style-type: none"> • Checking the types of additives used through regular checking and testing 	

Livestock products and related processed foods	<ul style="list-style-type: none"> Contamination by pathogenic microbes such as Enterohemorrhagic <i>Escherichia coli</i> O157 and <i>Listeria monocytogenes</i> (meat, natural cheeses, etc.) 	<ul style="list-style-type: none"> Taking measures to prevent contamination by pathogenic microbes 	<ul style="list-style-type: none"> Ensuring that no pathogenic microbes are present through regular checking and testing 	<ul style="list-style-type: none"> Whether proper temperature control is implemented to prevent harm due to the growth of microbes
	<ul style="list-style-type: none"> Radioactive contamination (reindeer meat, beef extracts, etc.) 	<ul style="list-style-type: none"> Ensuring producing area is not contaminated by radioactive substance 	<ul style="list-style-type: none"> Checking the level of radioactive substance by regular checking and testing 	
	<ul style="list-style-type: none"> Errors concerning health certificates (meat, meat products, milk and dairy products) 	<ul style="list-style-type: none"> Checking each item on the health certificate issued by the governmental agency of the producing or exporting country 		<ul style="list-style-type: none"> Ensuring that a complete health certificate is attached
	<ul style="list-style-type: none"> Bovine spongiform encephalopathy (BSE) (beef and beef-derived products) 	<ul style="list-style-type: none"> The producing area is not a country or region from which import is prohibited No specified risk material (SRM) is contained in the product No beef, etc. originated from countries or regions from which import is prohibited is contained or used 		
	<ul style="list-style-type: none"> BSE (sheep, goat meat, etc.) 	<ul style="list-style-type: none"> No BSE animal has been found in the producing country or region No SRM is contained in the product No sheep, goat meat, etc. originated from countries or regions from which import is prohibited is contained or used 		
	<ul style="list-style-type: none"> Residual agricultural chemicals, veterinary drugs, and feed additives 	<ul style="list-style-type: none"> Checking how agricultural chemicals, veterinary drugs and/or feeds additives were used Ensuring raw materials of processed foods must conform with residue standards 	<ul style="list-style-type: none"> Checking compliance with proper usage and dose of agricultural chemicals Checking compliance with proper usage, dose, and drug withdrawal period of veterinary drugs and feed additives Checking levels of residual agricultural chemicals, veterinary drugs, and feed additives, by regular checking and testing 	
	<ul style="list-style-type: none"> Use of additives that may mislead consumers in the recognition of quality and freshness (meat) 	<ul style="list-style-type: none"> Ensuring that no colorant or other additives that may mislead consumers in the recognition of quality or freshness has been used 	<ul style="list-style-type: none"> Checking the types of additives used by regular checking and testing 	

Seafood and processed seafood	<ul style="list-style-type: none"> • Pathogenic microbes such as <i>Vibrio parahaemolyticus</i> (fillet, shelled and/or peeled fresh fish and shellfish to be eaten raw) 	<ul style="list-style-type: none"> • Taking measures to prevent contamination by pathogenic microbes in cleaning water used at processing plants, etc. • Compliance with processing standards 	<ul style="list-style-type: none"> • Ensuring that no pathogenic microbes are present through regular checking and testing 	<ul style="list-style-type: none"> • Compliance with storage standards • Whether proper temperature control is carried out to prevent harm due to the growth of any microbes
	<ul style="list-style-type: none"> • Non-conformity with standards for constituents, standards for processing, and standards for storage for oysters for raw consumption 	<ul style="list-style-type: none"> • Checking whether the standards for processing in the exporting country are at the same level as in Japan 	<ul style="list-style-type: none"> • Ensuring conformity with the standards for constituents through regular checking and testing 	<ul style="list-style-type: none"> • Checking the certificates issued by the governmental agency of the exporting country • Compliance with storage standards
	<ul style="list-style-type: none"> • Diarrheic shellfish poisons or paralytic shellfish poisons (shellfish) 	<ul style="list-style-type: none"> • Checking that shellfish is gathered in sea areas where proper monitoring of shellfish poisoning is implemented 	<ul style="list-style-type: none"> • Ensuring that no shellfish poisons are present through regular checking and testing 	
	<ul style="list-style-type: none"> • Mixing with poisonous pufferfish 	<ul style="list-style-type: none"> • Ensuring that only fish of the approved type(s) are imported • Taking measures to prevent different types of pufferfish from being mixed in, through proper identification of fish types 		<ul style="list-style-type: none"> • Checking the certificates issued by the governmental agency of the exporting country • Ensuring that no different types of pufferfish are mixed, through proper identification of fish types
	<ul style="list-style-type: none"> • Errors concerning health certificates (oysters for raw consumption and pufferfish) 	<ul style="list-style-type: none"> • Checking each item on the health certificate issued by the governmental agency of the exporting country 		<ul style="list-style-type: none"> • Ensuring that a complete health certificate is attached
	<ul style="list-style-type: none"> • Mixing with poisonous fish such as fish with ciguatera (southern groupers, parrot fish, barracudas, etc.) 	<ul style="list-style-type: none"> • Checking the seas where the fish are caught • Taking measures to prevent poisonous fish from being mixed in, through proper identification of fish types 		<ul style="list-style-type: none"> • Ensuring that no poisonous fish are mixed, through proper identification of fish types
	<ul style="list-style-type: none"> • Residual veterinary drugs and feed additives 	<ul style="list-style-type: none"> • Checking on the use of veterinary drugs and feed additives • Raw materials of processed foods must conform with the residue standards 	<ul style="list-style-type: none"> • Checking compliance with proper usage, dose, and drug withdrawal period of veterinary drugs and feed additives • Checking the levels of residual veterinary drugs and feed additives, by regular checking and testing 	
	<ul style="list-style-type: none"> • Use of additives that may mislead consumers in the recognition of quality and freshness (fresh fish and shellfish) 	<ul style="list-style-type: none"> • Ensuring that no colorant, carbon monoxide or other additives that may mislead consumers in the recognition of quality or freshness has been used 	<ul style="list-style-type: none"> • Checking the types of additives used by regular checking and testing 	<ul style="list-style-type: none"> • Checking the color of the product (e.g., scarlet)
	<ul style="list-style-type: none"> • Histamine 	<ul style="list-style-type: none"> • Checking at the point of receiving raw material • Proper temperature control during the manufacturing, processing and other processes. 	<ul style="list-style-type: none"> • Checking the level of histamine by regular checking and testing 	<ul style="list-style-type: none"> • Whether proper temperature control is carried out to prevent harm due to the histamine formation

Health foods in general	<ul style="list-style-type: none"> Containing pharmaceutical ingredients regulated under the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices 	<ul style="list-style-type: none"> Ensuring that no pharmaceutical ingredients are contained 	<ul style="list-style-type: none"> Ensuring that no drug substance is contained by checking and testing 	
	<ul style="list-style-type: none"> Containing hazardous or toxic substance 	<ul style="list-style-type: none"> Whether or not there is any history of food use in the exporting country Whether or not there is any adverse health events Foods containing designated ingredients must comply with “Standards for Manufacturing or Processing of the Foods Containing the Designated Ingredients, Etc.” Ensuring the safety of raw materials and product design for tablet and capsule type food products 	<ul style="list-style-type: none"> Checking the history of food use in the exporting country There are no adverse health events in the exporting country Compliance with “Standards for Manufacturing or Processing of the Foods Containing the Designated Ingredients, Etc.” 	
Additives and their preparation	<ul style="list-style-type: none"> Use of undesignated additive Non-conformity with the specification 	<ul style="list-style-type: none"> Checking the formal names of the additives and their types of sources materials and extractants Checking the formal names and content rates if additive preparation is used Ensuring that no undesignated additives are used Ensuring that the product conforms to the related standards, such as specification and manufacturing standards GMO technology whose safety has not been assessed shall not be used. 	<ul style="list-style-type: none"> Ensuring conformity with the specification through regular checking and testing 	<ul style="list-style-type: none"> Checking compliance with storage standards
Apparatus, containers and packages, and toys for infants	<ul style="list-style-type: none"> Non-conformity with standards 	<ul style="list-style-type: none"> Checking the materials, shape, colors, targeted ages, and the purpose of use Ensuring that the product conforms with related standards, such as general standards for raw materials, standards for each material, standards for each purpose of use, and manufacturing standards 	<ul style="list-style-type: none"> Ensuring that the materials conform with general standards for raw materials and specifications for each material through regular checking and testing 	
	<ul style="list-style-type: none"> Inclusion of substances other than the positive list (Apparatus and containers and packaging made of synthetic resin) 	<ul style="list-style-type: none"> Ensuring that the substance is listed on the positive list 	<ul style="list-style-type: none"> Ensuring to check positive list regularly 	