

Imported Foods Monitoring and Guidance Plan for FY 2020

1 Purpose

The purpose of the Plan is to promote the intensive, effective and efficient monitoring and guidance over imported 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, 2020 till March 31, 2021.

3 Current circumstances of imported foods etc.

(1) Current circumstances of imported foods

The total number of import notifications filed for foods, additives, equipment, containers and packages and toys (hereinafter collectively referred to as “foods”) imported into Japan for the purpose of marketing or any other commercial purposes during FY 2018 are about 2.48 million and their import weight reached 34.17 million tons. Meanwhile, in accordance with 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 our country 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 2019 about the results of the inspections and guidance under the Imported Foods Monitoring and Guidance Plan for FY 2019, the number of import notifications filed during the period from April to September, 2019 is approximately 1.30 million [1.23 million] and the import weight reached some 12.49 million tons [12.20 million tons], and the number of inspections conducted during said period amounted to 112,000 [103,000], out of which 407 cases [385 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 last year. All of these figures are preliminary figures).

(2) Review of monitoring and guidance results based on Imported Foods Monitoring and Guidance Plan for FY 2019

The Ministry of Health, Labour and Welfare (hereinafter referred to as “the MHLW”) and quarantine stations have expanded and enhanced their systems for inspection on importation of foods by adding inspection items and upgrading the testing and other equipment, and thereby have reinforced the inspection and guidance upon importation including monitoring inspection^{*1} and inspection order^{*2}. In addition, with an aim to prompt exporting countries to take appropriate sanitary control measures for foods to be imported to Japan, the MHLW conducted consultations

and investigations with exporting countries related to individual issues, including investigations on regulations related to food hygiene at the stage of exporting countries. In addition to these efforts, the MHLW carried out on-site inspections about the sanitary controls being implemented at the stage of exporting countries with relation to bovine spongiform encephalopathy (hereinafter referred to as “BSE”), 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 strengthened inspections on importation in the case of any violation of the Act.

*2 Inspection Order means an 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 Imported Foods Monitoring and Guidance Plan for FY 2020

(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 processes both in Japan and in other countries. Based on this standpoint, in order to secure the safety of imported foods, the following measures are to be taken from the stage of the production processes in exporting countries up to the stage of their distribution after importation into the domestic market.

(i) In order to promote sanitary control measures during the production, manufacturing, processing etc. in exporting countries (hereinafter referred to as “production etc.”), the MHLW will provide information on our food-sanitary regulations to embassies located in Tokyo, importers, and the relevant government staffs and producers of exporting countries and will publish such information on the website of the MHLW (hereinafter simply referred to as “the website”). In addition to these efforts, the MHLW will hold bilateral discussions with exporting countries, conduct on-site inspections in exporting countries, and provide technical support to those countries.

(ii) If any violation of the Act is detected, the MHLW will introduce necessary measures such as strengthening of inspections on importation, and at the same time, will publish the detected violation in accordance with Article 63 of the Act.

- (iii) The MHLW will issue 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 8 or Paragraph 1, Article 17 of the Act if the MHLW considers such measures are inevitable to prevent possible harm to the food sanitation in our country.
- (iv) If an importer has repeatedly violated the Act, the MHLW will provide necessary instructions to the importer in order to have the importer rectify the cause of the violation, and should the occasion demand, the MHLW will issue an order to prohibit or suspend the business of the importer in accordance with the provisions of Paragraph 2, Article 55 of the Act (hereinafter referred to as “the prohibition or suspension of the business of importers”).
- (v) Quarantine stations will carry out a check, based on import notification documents filed under Article 27 of the Act and inspections on the identity of actual goods referring to the contents of import notification documents, and as to compliance with the Act including compliance with specifications and standards relevant to foods (hereinafter referred as “the standards”) in accordance with the provisions of Paragraph 1, Article 11 and Paragraph 1, Article 18 of the Act.
- (vi) Quarantine stations will carry out monitoring inspections in a systematic manner to ensure the extensive monitoring of various imported foods for the purpose of food safety.
- (vii) In order to prevent possible harm to the public health in terms of food sanitation, quarantine stations will order inspections of imported foods with a high risk of violation of the Act in accordance with the provisions of Paragraph 2 or 3, Article 26 of the Act.
- (viii) Quarantine stations will hold seminars for and provide pre-import guidance to importers in order to encourage them to promote, as one of their duties as food business operator, voluntary sanitary controls.
- (ix) Upon detection of a violation of the Act, quarantine stations will take necessary measures such as ordering the importer to discard, reship or use for any other purpose than human consumption (hereinafter referred to as “discard, etc.”) such violating foods and will direct the importer to provide a report on measures taken by the importer to prevent the recurrence.
- (x) After imported foods are released 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”) will be placed 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 will cooperate with each other in taking measures to ensure the accurate and swift recall of the violating foods by the importer.

(2) Basic direction for monitoring and guidance over imported foods in FY 2020

In the Imported Foods Monitoring and Guidance Plan for FY 2020 (hereinafter referred to as “Monitoring and Guidance Plan”), while seeking to further promote the above measures, the MHLW will continue to improve qualities of food sanitation inspectors of quarantine stations, arrange personnel properly, and upgrade the testing equipment in order to consolidate the system to implement appropriate monitoring and guidance.

The MHLW will upgrade the plan for monitoring inspections taking into consideration the results of the monitoring inspections conducted and at the same time, will review the inspection items and other requirements taking into consideration the results of monitoring and guidance as well as other relevant factors even at the middle of the fiscal year.

In addition, it is expected that the number of imported foods will increase with the promotion of the Economic Partnership Agreement, including the entry into force of the Comprehensive and Advanced Agreement on the Trans-Pacific Partnership (TPP11 Agreement), the Japan-EU Economic Partnership Agreement and the Japan-US Trade Agreement. It is expected that food chains will become more complicated due to globalization. Therefore, in addition to the monitoring system centered on the inspection at the time of import, we will further promote efforts to effectively ensure the safety of the production stage in the exporting countries.

Furthermore, with the aim of enacting a law that partially amends the Food Sanitation Law, etc. (Law No. 46, 2018; hereinafter referred to as the “Revised Food Sanitation Law”) on June 1, 2020, Promote inter-national consultation and disseminate information.

5 Specific Contents of Imported Foods Monitoring and Guidance Plan for FY 2020

(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 a food for which an import notification is filed in accordance with the provisions of Article 27 of the Act, the quarantine station will confirm; that the food does not fall under any one of those mentioned in each item of Article 6 (Prohibited food and additives to sell), Paragraph 2 of Article 9 (Prohibition of sales of meat having diseases), 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 8 or Paragraph 1, Article

17 of the Act; that additives contained in the food fall under those as set forth in the provisions of Article 10 of the Act; and that the food is in compliance with the standards, by checking the import notification document filed by the importer of the food and, as necessary, by checking any certificate document 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 a Monitoring Plan

In order to ensure that monitoring inspections will be carried out in an intensive, effective and efficient manner, in principle, the MHLW will determine for each food group the number of inspections to be conducted for each inspection item stipulated for the monitoring inspection (hereinafter referred to as “the monitoring plan”) so that a violation will be detected with a certain level of reliability from statistical viewpoint, after taking into account the violation rate, the number of import notifications filed, the import weight and potential impacts on the public health that may be caused by the violation.

In addition, even for inspections having no violation detected from the inspections conducted so far, the MHLW will ensure that appropriate number of inspections will be conducted. For the monitoring plan for FY 2020, the number of inspections shall be about 99,700 cases (increased 700 cases compared to FY 2019) as shown in Schedule 1, and the monitoring plan may be reviewed taking into consideration import trends, survey results of food sanitation regulations at the stage of exporting countries, and information about food-related health damages and recalls of unsanitary foods occurring in exporting countries.

In addition, the MHLW will ensure the steady implementation of inspections of residual agricultural chemicals in accordance with the Positive List System^{*3}, taking into account the regulations concerning agricultural chemicals, the status of their use, cases of detection of agricultural chemicals as well as violation cases of agricultural food products (such as banana and coffee beans) at the time of import in other countries.

*3 Positive List System for residual agricultural chemicals means a system that prohibits, in principle, the sale, etc. of foods in which agricultural chemicals remain in excess of a predetermined level that may not harm human health.

The MHLW will continue to carry out inspections based on the status of violations, etc., and will also carry out inspections on pathogenic microorganisms based on cases of food poisoning in Japan related to imported food products and detection status overseas.

b. Systematic implementation of monitoring inspections

Each quarantine station will prepare its own annual plan for carrying out such number of inspections as the MHLW will assign to each of them in accordance with the number of inspections planned in the monitoring plan in order to ensure the systematic implementation of inspections.

Meanwhile, as for foods subject to inspection order concerning residual agricultural chemicals, monitoring inspections will be carried out in order to verify the reliability of the control of residual agricultural chemicals, etc., being implemented in export countries, since there are possibilities that the control of residual agricultural chemicals being conducted in exporting countries may be insufficient and that any change in agricultural chemicals used in exporting countries may occur and there is also a fear that agricultural chemicals other than those covered by the inspection order may be contained in the foods in excess of standard values.

The MHLW will check the implementation of inspections based on the monitoring plan and provide instructions to quarantine stations as necessary. Should it be found difficult to carry out station by station or food group by food group inspections as planned due to any change in import trends or any other circumstances, the monitoring plan will be reviewed to ensure that inspections will be carried out in accordance with the actual import situation.

In the case of an emergency, the MHLW will entrust affairs relevant to inspections to registered conformity assessment bodies in accordance with the provisions of Paragraph 4, Article 28 of the Act.

c. Strengthening of monitoring inspections

When the MHLW receives information on the recall of a food or the emergence of a food-related health damage in exporting countries and other countries, or when any food is found to violate the Act during a monitoring inspection or otherwise, or when a violation of the Act is identified through the monitoring and guidance by a local government, the MHLW will instruct quarantine stations to reinforce their inspections of the relevant import food as necessary.

As for the reinforcement of inspections of residual agricultural chemicals, in order to grasp the level of the use of the control over agricultural chemicals, etc. by the exporting country, the MHLW will carry out monitoring inspections on a higher proportion of imported foods concerned and for more inspection items so that violations may be detected with a certain level of reliability from statistical viewpoint.

In addition, in order to prevent any food violating the Act from human consumption, the MHLW will continue to carry out inspections whose results can be obtained in a shorter period of time.

d. Cancellation of strengthening of monitoring inspections

When the MHLW determines that there is no longer a fear that foods violating the Act may be exported to our country, the normal monitoring system will be reinstated by canceling the strengthening of 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 have been introduced such as the formulation of a new regulation, the improvement of the control system of agricultural chemicals and the strengthening of the inspection system. Then upon confirmation of the effectiveness of such measures, the strengthening of 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 strengthened or after more than 60 specimens were inspected, in principle, the strengthening of 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 will conduct inspections on imported foods based on the import notification documents when they are imported into Japan for the first time (hereinafter referred to as “the initial import”), when they especially need sanitary control in exporting countries, when an accident has occurred during the transportation, or on any other occasions requiring inspections.

In order to promote voluntary controls by importers, inspections on the identity of actual goods referring to the contents of import notification documents will to be carried out.

(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 sanitation of the country that may arise out of an imported food with a high risk of violation of the Act, the MHLW will order importers to have the imported food inspected in accordance with either of the following procedures, i. or ii.

Meanwhile, when the food is added to the list of foods subject to inspection order, the MHLW will provide easy-to-understand information about the potential health hazards that may be caused by the food.

- i When a harm to health has been caused or is feared to be caused by the imported food in the exporting country and/or our country, or when a violation of the Act has been detected as a

result of the monitoring inspection of aflatoxin, pathogenic microorganisms, etc., the imported food manufactured by the same manufacturer, processed by the same processor, or imported from the same exporting country will be immediately subjected to an inspection order.

- ii When more than one violation of the Act has been detected with regard to residual agricultural chemicals as a result of the monitoring inspection of the imported food manufactured by the same manufacturer, processed by the same processor or exported from the same country, all or part of the imported food in question will be subjected to an inspection order, after taking into account the regulations and the sanitary controls being implemented in the exporting country, the historical compliance record of the imported food and other factors.

b. Cancellation of an inspection order

When the MHLW determines that there is no longer a fear that the food violating the Act will be exported into our country, the normal monitoring system will be reinstated by canceling 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 have been introduced such as the formulation of a new regulation, the improvement of the control system of agricultural chemicals and the strengthening of the inspection system. Then upon confirmation of the effectiveness of such measures through bilateral discussions, on-site inspections, or inspections on importation of the food, the inspection order may be cancelled; or
- ii As for foods subject to inspection order with respect to residual agricultural chemicals, etc., 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, the inspection order may be cancelled.

Thereafter, monitoring inspections will be carried out on a higher proportion of the imported food and for more inspection items so that violations will be detected with a certain level of reliability from statistical viewpoint with respect to inspection items applicable to the imported food and upon detection of any violation, the food will be immediately subjected to inspection order.

- (v) Comprehensive import ban in accordance with the provisions of Paragraph 1, Article 8 or Paragraph 1, Article 17 of the Act

As for an imported food 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 food inspected and if it is highly likely that the importation of the violating food will continue taking into consideration the level of the food sanitary control in the exporting country, the MHLW will conduct review taking into consideration the extent of damage to human health that may be caused by the food, and the Minister of Health, Labour and Welfare will issue a ban on the importation of such food after consulting the Pharmaceutical Affairs and Food Sanitation Council, to the extent that such a ban is deemed inevitable in order to prevent potential food sanitation problems.

(vi) Emergency measures in response to alert information, etc. from other countries

In order to ensure the safety of imported foods, the MHLW will gather information on food-safety problems occurring in other countries through relevant ministries and agencies, the National Institute of Health Sciences, the National Institute of Infectious Diseases and the governments of exporting countries and through the International Food Safety Authorities Network (INFOSAN) run by the World Health Organization (WHO) and will publish major cases on the website. And if it is found through the search that the violating food have already been imported into our country, the MHLW will instruct the relevant quarantine stations or local governments to investigate into the level of the distribution and the stock status of the food in Japan and also instruct them to direct the importers and other concerned parties to carry out inspections, the recall of the food and/or any other appropriate measures. The MHLW will also instruct quarantine stations to reinforce their inspections over the food and will publish the progress of countermeasures being implemented.

(2) Promotion of sanitary control measures at the stage of exporting countries

The MHLW will promote sanitary control measures in exporting countries through the following efforts so that any violation of the Act may be prevented at the stage of the production processes in exporting countries.

(i) Dissemination of information about the food-sanitary regulations of our country and other relevant information. The MHLW will provide on the website the English translation of the food sanitary regulations of our country, the lists of foods subject to inspection order or to enhanced monitoring inspection, this Plan as well as the results of the monitoring and guidance conducted under the Plan with an aim to promote information dissemination.

In addition, the MHLW will strive to communicate such information widely among the government staff 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 relevant standards, through seminars on food sanitary regulations organized by the Japan International Cooperation Agency (JICA) as well as by holding explanatory meetings in exporting countries.

(ii) Bilateral discussions and on-site inspections

Not only with respect to import foods subject to inspection order but also with respect to import foods with a high risk of violation of the Act, the MHLW will ask, through bilateral consultations and other opportunities, the governments of the exporting countries to investigate into the causes of the violations and to develop preventive measures based on the results, and thereby will strive to promote the implementation of sanitary controls during the stage of the production processes, the enhancement of monitoring systems and the introduction of pre-export inspections in the exporting countries.

Meanwhile, in order to encourage exporting countries to promote the sanitary control measures for foods exported to Japan, the MHLW will gather information and conduct on-site inspections in a systematic manner by placing particular emphasis on countries in which a large number of violations have been detected, according to the interim report about the results of the inspections and guidance under the Imported Foods Monitoring and Guidance Plan for FY 2019, in addition to countries exporting large amount of foods to our country as well as the member countries of the economic partnership agreements, considering that the majority of violations reported so far consist of violations of each items of Article 6 of the Act that relates to toxic or hazardous substances such as mycotoxins and violations of Paragraph 2 or 3, Article 11 of the Act that relates to the standards concerning agricultural chemicals, veterinary drugs, microorganisms and additives.

Further, in order to ensure the safety of imported beef, etc., if it is necessary to verify the sanitary control measures being implemented at the production process in the exporting countries, the MHLW will dispatch experts to the exporting countries to carry out on-site investigations of the sanitary control measures of the exporting countries.

Furthermore, based on the “Memorandum on Japan-China Food Safety Promotion Initiative” signed by the ministers of both countries in May 2010, the MHLW will hold ministerial-level meetings, will formulate an action plan for promoting exchange and cooperation in the field of the safety of foods imported and exported by Japan and China, and will carry out working-level consultations and on-site inspections.

(iii) Technical cooperation, etc.

The MHLW and quarantine stations will promote technical cooperation, etc. that will contribute to the enhancement of the monitoring systems of exporting countries through information dissemination about the food sanitary control regulations of our country and through supports for the improvement of testing techniques of those countries about residual agricultural chemicals, mycotoxins and other substances.

(iv) Efforts concerning the enforcement of the revised Food Sanitation Law

MHLW is an exporter of meat and organs of livestock and poultry for which sanitary control measures based on HACCP are import requirements, and milk and dairy products for which sanitary certificates must be attached, in order to implement the revised Food Sanitation Law. , Promote hygiene control measures at the exporting country stage, such as by promoting bilateral discussions with the exporting countries of blowfish and raw oysters.

(3) Promotion of voluntary sanitary controls 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 processes based on the recognition that they bear the primary responsibility for ensuring food safety. Also, Paragraph 1, Article 3 of the Act 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 will promote voluntary sanitary controls among importers through the following guidance and measures with an aim to prevent violations of the Act before they occur.

(i) Basic guidance for importers

Quarantine stations will strive to make sure that importers have a thorough understanding of the regulations on food sanitary as well as their responsibilities as importers such as compliance with statutory import procedures, inspection systems and the standards as well as submission of sanitary certificates required to be attached to imported foods.

Meanwhile, from the standpoint of the promotion of voluntary sanitary controls by importers, quarantine stations will provide importers in a timely manner with information on imported foods violating the Act and sanitation problems, newly established standards, and food sanitary regulations at the stage of exporting countries, and will provide guidance to importers through seminars or at the time of import notification that may lead to prompt importers to voluntarily secure the safety of imported foods.

Basic guidance items 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 “Guidelines on Voluntary Hygiene Control of Import Processed Foods” (hereinafter referred to as the “Processed Foods Guidelines”) attached to the “Notification concerning the Guidelines on Voluntary Hygiene Control of Import Processed Foods”, FS

Notification No. 0605001, dated June 5, 2008, issued by the Director General of the Department of Food Safety, Pharmaceutical and Food Safety Bureau, MHLW, importers will be instructed to conduct necessary confirmation at the stage of the production process in exporting countries by taking into consideration the status of the development and implementation of food sanitary regulations in exporting countries and the level of sanitary controls implemented by the manufacturers.

Furthermore, quarantine stations will urge importers to make sure to confirm that foods to be imported have not been illegally produced in exporting countries and also to confirm, by using the checklist based on the processed foods guidelines, the conformance to the Act of raw materials, additives, manufacturing processes, inspection data and all other aspects.

As for food sold as “health food”, importers will be instructed to secure the safety by checking eating experiences etc. As for food containing ingredients to which the MHLW calls for attention in response to the cases of health damage at home and abroad, importers will be instructed to implement appropriate controls.

Due to the enforcement of the revised Food Sanitation Law, it is necessary for the equipment and containers and packaging made of synthetic resin that are subject to the positive list system ^{*4} to use only those that comply with the positive list. Therefore, the importer will be informed of the system and instructed to confirm it.

*4 Positive List System for equipment, containers and packages means a system that evaluates the safety and prohibits, in principle, the use of substances, except for those approved for use.

Furthermore, importers are instructed to make proper import notifications based on accurate and latest information obtained from producers, etc., and also to confirm the identity of actual goods referring to the contents of import notification documents for foods imported for the first time and foods which especially need sanitary control in exporting countries of meat, fishery products, etc. When importers intend to import foods on a regular basis, they will be instructed to make sure to sufficiently confirm that there are no changes in raw materials and manufacturing process used for the foods as well as the identity of actual goods referring to the contents of import notification documents, and the conformity of goods of import notification with the items of the results of voluntary inspections presented in the import notification.

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

(ii) Pre-import guidance

Based on the guidance items as mentioned in (i) above, quarantine stations will instruct importers to pre-confirm whether foods to be imported contain any of the pharmaceutical ingredients regulated under the Act on Securing Quality, Efficacy and Safety of Pharmaceuticals, Medical Devices, Regenerative and Cellular Therapy Products, Gene Therapy Products, and Cosmetics (the Act No. 145 of 1960) by referring to materials or information obtained from producers. When they do not contain pharmaceutical ingredients, importers are instructed to check their safety as foods for human consumption.

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

Quarantine stations will encourage importers, through their websites and/or seminars, to consult with import foods counselors of a quarantine station before they import foods for the first time or foods falling under the same category as those that have violated the Act or caused any sanitation problem in the past, and thereby will further promote the pre-import guidance.

When the results of voluntary inspections have been verified in the course of the pre-import guidance, those results will be utilized when quarantine stations check imported foods with import notification documents from the standpoint of promoting voluntary inspection before importation.

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

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

When a food being imported by an importer has been proved, through a pre-import safety check by the importer, not to comply with the Act, the relevant quarantine station will instruct the importer to take appropriate measures to make the food comply with the Act and also direct the importer to delay the importation until the violating state has been rectified.

Even if the food is proved, through document check, etc., to be in compliance with the Act as a result of the rectification, the quarantine station will, when necessary, instruct the importer to carry out an inspection to verify that the food is actually meeting the standards.

(iv) Voluntary inspection

As for any food imported into Japan for the first time, the relevant quarantine station will thoroughly instruct the importer to carry out voluntary inspections with respect to inspection items required to verify that the food is in compliance with the Act in accordance with the standards and with respect to additives used in the product.

Meanwhile, in the case where the food is to be imported on a regular basis, the importer will be instructed to carry out voluntary inspections in accordance with the guidance as mentioned in (i) above by referring to the standards and by checking additives used in the food at regular intervals and also taking into consideration confirmed violations of similar foods.

(v) Preparation and maintenance of records of imported foods

Based on the “Guidelines concerning 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 concerning the Guidelines concerning Preparation and Retention of Records by Food Business Operators based on Provisions in Paragraph 2, Article 1-3 of the Food Sanitation Act,” FS Notification No. 0829001, dated August 29, 2003, issued by the Director General of the Department of Food Safety, Pharmaceutical and Food Safety Bureau, MHLW, importers will be instructed to properly prepare and maintain records of the importation, sales and other details of the imported foods in order to allow the quarantine stations to monitor the conditions of importation and distribution of those foods at all times. Importers will also be instructed to maintain such information in a way that they will be 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 violating foods from human consumption, quarantine stations will instruct importers to provide such records as notified in the “Guidelines concerning the Implementation of “the Imported Foods Monitoring and Guidance Plan for FY 2016”” (ESI Notification 1007 No. 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 quarantine stations will be able to carry out distribution surveys and the recall of violating foods swiftly upon detection of any violation through monitoring inspections.

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

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

Meanwhile, quarantine stations will strive to enhance the knowledge of importers, for example, by prompting 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

proper indication of expiration dates.

(4) Responses upon detection of a violation

The quarantine station, the MHLW and relevant local governments will, in cooperation with each other, instruct the importer to promptly abandon or recall the violating food and at the same time direct the importer to investigate into the cause of the violation and take appropriate preventive measures to secure the safety of imported foods in accordance with the following procedures. In addition to these responses, other necessary measures including the reinforcement of inspection on importation will be introduced:

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

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

The relevant quarantine station will instruct the importer to discard or otherwise dispose of the violating food and to report on the progress of such disposal.

Meanwhile, the MHLW will introduce necessary measures including the reinforcement of inspection on importation.

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

The relevant prefectural government having jurisdiction over the area where the place of business of the importer is located will order the importer to recall or otherwise dispose of the violating food and to report on the progress of such disposal.

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

Meanwhile, the MHLW will provide information concerning the violating food to the relevant local government that has jurisdiction over the area where the place of business of the importer is located, and will take other necessary measures including the reinforcement of inspection on importation.

The quarantine station will, while directing the discard or other disposal of the violating food as temporary measures, instruct the importer to act as directed by the prefectural government having jurisdiction over the area where the place of business of the importer is located.

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

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

Upon notification from any local government of any violating 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 will provide information relevant to the violating food to quarantine stations and, based on the information, will take necessary measures including the enhancement of inspection on importation.

Should there be any reported health damage originating from the imported food, the MHLW will make prompt notification to quarantine stations in the case of a food before importation and to local governments in the case of a food, etc. already released into the domestic market and at the same time will take necessary measures to prevent further expansion of the damage.

(iii) Instructions, etc. to importers for the prevention of the recurrence

In order for the prevention of the recurrence of violations, quarantine stations will 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 will require the importer to investigate and report into the cause of the violation, will give instructions to the importer to prevent recurrence of law violations. If the cause is not identified after three months from the detection of the violation, quarantine stations will 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 will confirm the rectification of the cause of the violation through the investigation as mentioned in a. above. If necessary, quarantine stations will verify the rectification of the cause by referring to field investigations conducted by the importer in the exporting country and/or other inspections carried out by the exporting country and will also 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 55 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 importing foods causing or that may cause damage to the public health, in order to have them rectify the cause of the violation and take preventive and any other measures necessary from a sanitary viewpoint.

In addition, as for importers whose violation rate is almost in excess of 5 % and who may be

subjected to the disposition by prohibition or suspension of business, the MHLW will require them to submit explanations about their preventive measures and will provide guidance so that no more violations will be committed by them, in accordance with the “Guidelines for the Prohibition or Suspension of Business of Importers under Paragraph 2, Article 55 of the Act” attached to the “Notification concerning the Guidelines for the Prohibition or Suspension of Business of Importers under Paragraph 2, Article 55 of the Act”, FS Notification No. 0110003 dated January 10, 2006 issued by the Director General of the Department of Food Safety, Pharmaceutical and Food Safety Bureau, MHLW.

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

(v) Indictment of malicious cases

Quarantine stations will 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 will release the information about such indictment in a timely manner.

(vi) Publication of violations

In order to alert the public against food sanitation hazards, the MHLW will promptly publish 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 violating food imported by the importer (as for the names of violating importers, the publication period will be limited to one year) in accordance with the provisions of Article 63 of the Act. In addition to the publication of the names of violating importers, the progress of the response measures including the disposal or recall of violating food products, the details of corrective actions and the causes of the violations will also be published as soon as such information becomes available.

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

By utilizing the websites, their official SNS (food safety information twitter, etc.) accounts and any other means, the MHLW and quarantine stations will actively provide the general public with easy-to understand information about their efforts for ensuring the safety of imported foods, and will hold sessions for information exchange and facilitate risk communication.

(i) Provision of information about the monitoring plan, etc.

Quarantine stations will communicate the notices concerning the monitoring plan, inspection

orders, the enhancement of inspections and other measures widely among importers, customs brokers and bonded warehouse operators with an aim to facilitate the smooth implementation of the monitoring and guidance under the Plan.

The MHLW will also make public such information as 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 will publish information concerning bilateral discussions and on-site inspections that have been held or conducted in order to promote sanitary control measures at the stage of exporting countries, including discussions under the “Memorandum on Japan-China Food Safety Promotion Initiative.”

(iii) Announcement of monitoring results under the Plan

The MHLW will publish the summary report of the progresses and the results of monitoring inspections carried out under this Plan and inspections conducted in response to inspection orders, etc., the yearly trends of the results of its monitoring and guidance and the summary report of the monitoring and guidance over importers and the results around August of the following fiscal year. Meanwhile, information about those matters for the first half of this fiscal year (from April to September) will be published around December.

(iv) Efforts to facilitate risk communication about food safety

The MHLW will introduce a public comment process to gather opinions about the Monitoring and Guidance Plan. In addition, as risk communication about food safety, the MHLW will hold sessions for information exchange in cooperation with local governments and other concerned ministries and agencies, and concerned bodies, as well as will provide consumers, business operators, etc. with information about the details of the Monitoring and Guidance Plan and the details of its monitoring and guidance by utilizing the website and official SNS of the MHLW (food safety information twitter, etc.), and thereby striving for mutual understanding on efforts and knowledges related to food safety.

(v) Others

Quarantine stations will strive to gain public understanding of the actual conditions of monitoring and guidance on imported foods through such activities as observation tours of 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 will hold seminars and training sessions to improve the knowledge and skills concerning food safety for food sanitation inspectors engaging in monitoring, guidance, testing and inspection of foods at quarantine stations.

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

Based on advice from the MHLW's regional offices, the MHLW will systematically carry out the evaluation of the management of the tests and inspections at quarantine stations and will provide instructions in order to ensure the proper implementation of monitoring inspections and other related operations by quarantine stations.

Schedule 1

Food type	Category of inspection items*1	Number of inspection specimens*2	Total number of Inspection specimens*3
Livestock foods Beef, pork, chicken, horse meat, poultry meat, and other meats	Antibacterial substances	2,200	4,580
	Residual agricultural chemicals	1,200	
	Additives	100	
	Pathogenic microorganisms	650	
	Standards for constituents	400	
	Radiation irradiation	30	
Processed livestock foods Natural cheeses, processed meat products, ice cream, frozen products (meat products), and other products	Antibacterial substances	2,400	11,000
	Residual agricultural chemicals	1,600	
	Additives	1,200	
	Pathogenic microorganisms	3,700	
	Standards for constituents	2,100	
Seafood products Bivalves, fish, shellfish (shrimps, prawns, crabs) and other products	Antibacterial substances	2,400	6,120
	Residual agricultural chemicals	1,500	
	Additives	300	
	Pathogenic microorganisms	1,500	
	Standards for constituents	300	
	GMOs	60	
Processed seafood Processed fish products (fillet, dried or minced fish, etc.), frozen products (aquatic animals and fish), processed fish roe products, and other products	Antibacterial substances	3,600	19,200
	Residual agricultural chemicals	3,400	
	Additives	1,600	
	Pathogenic microorganisms	4,900	
	Standards for constituents	5,700	
Agricultural foods Vegetables, fruit, wheat, barley, corn, beans, peanuts, nuts, seeds, and other products	Antibacterial substances	2,200	19,150
	Residual agricultural chemicals	11,500	
	Additives	800	
	Pathogenic microorganisms	1,400	
	Standards for constituents	350	
	Mycotoxins	2,300	
	GMOs	500	
	Radiation irradiation	100	
Processed agricultural foods Frozen products (processed vegetables), processed vegetable products, processed fruit products, spices, instant noodles, and other products	Antibacterial substances	300	19,850
	Residual agricultural chemicals	7,000	
	Additives	3,700	
	Pathogenic microorganisms	1,900	
	Standards for constituents	3,500	
	Mycotoxins	2,700	
	GMOs	300	
	Radiation irradiation	450	
Other foods Health foods, soups, flavorings, seasonings, sweets, edible oils, fat, frozen products, and other products	Residual agricultural chemicals	1,100	6,000
	Additives	2,900	
	Standards for constituents	1,200	
	Mycotoxins	800	
Drinks and beverages Mineral water, soft drinks, alcoholic beverages, and other products	Residual agricultural chemicals	100	2,000
	Additives	1,100	
	Standards for constituents	700	
	Mycotoxins	100	
Additives Equipments, containers and packages, Toys	Standards for constituents	1,800	1,800
Foods subject to enhanced inspection*3	Antibacterial substances, residual agricultural chemicals, additives, pathogenic microorganism, standards for constituents, mycotoxins, GMOs, radiation irradiation, Removal of SRMs	10,000	10,000
Overall total*2			99,700

*1: Examples of inspection items

- Antibacterial substances: antibiotics, synthetic antibacterial agents, hormone preparations, and others
- Residual agricultural chemicals: organophosphorus, organochlorines, carbamates, pyrethroids, and others
- Additives: preservatives, food coloring, sweeteners, antioxidants, antimold agents, and others
- Pathogenic microorganisms: enterohemorrhagic *Escherichia coli* O26, O103, O104, O111, O121, O145, and O157, *Listeria monocytogenes*, etc.
- Standards for constituents: items defined in the standards for constituents (such as the number of bacteria, coliform bacteria, and radioactive materials), shellfish poisons (diarrheic shellfish poisons, paralytic shellfish poisons), and others
- Mycotoxins: aflatoxin, deoxynivalenol, patulin, and others
- GMOs: Genetically modified organisms whose safety has not yet been certified
- Radiation irradiation: existence of radiation irradiation

*2: The total numbers of specimens are approximate aggregations of the numbers of inspections in the relevant inspection categories, such as antibacterial substances and residual agricultural chemicals.

*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

note) * is based on the enforcement of the revised Food Sanitation Law

	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 or foreign matter 	<ul style="list-style-type: none"> Taking measures to prevent hazardous or toxic materials from being included 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 included, by regular testing and inspection 	<ul style="list-style-type: none"> Whether any corruption or deterioration occurred due to accidents or improper temperature control Whether the food processed by salting or other measures 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 microorganisms 	<ul style="list-style-type: none"> Taking measures to prevent contamination by pathogenic microorganisms 	<ul style="list-style-type: none"> Ensuring that no pathogenic microorganisms are present through regular testing and inspections 	<ul style="list-style-type: none"> Whether proper temperature control is implemented to prevent harm due to the growth of microorganisms
	<ul style="list-style-type: none"> Use of unapproved additives Use of additives for unapproved 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 unapproved additives are used, including those used for raw material Ensuring that additives that 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 unapproved additives are used, and that the proper amount of additives is used, by regular testing and inspection 	
	<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 testing and inspection, as necessary 	<ul style="list-style-type: none"> Ensuring that no change has been made in the manufacturing process and the raw materials Ensuring conformity with the standards for constituents, by regular testing and inspection Ensuring compliance with the Food Sanitation Act, by checking 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"> GMO foods whose safety has not been certified 	<ul style="list-style-type: none"> Whether or not there is a need for safety review among food derived from genome editing technology 	<ul style="list-style-type: none"> 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 	

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 testing and inspection 	<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 the food • Measures should be taken to remove any natural poisons during the manufacturing, processing and other processes • Taking measures to prevent any hazardous or toxic plants from being included 	<ul style="list-style-type: none"> • Ensuring that no natural poisons are present by regular testing and inspection 	
	<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 radioactivity 	<ul style="list-style-type: none"> • Checking the level of radioactivity by regular testing and inspection 	
	<ul style="list-style-type: none"> • Pathogenic microorganisms such as Enterohemorrhagic Escherichia coli O157 (fresh vegetables) 	<ul style="list-style-type: none"> • Taking measures to prevent contamination by pathogenic microorganisms 	<ul style="list-style-type: none"> • Ensuring that no pathogenic microorganisms are present by regular testing and inspection 	<ul style="list-style-type: none"> • Whether proper temperature control is carried out to prevent harm due to the growth of any microorganisms
	<ul style="list-style-type: none"> • Residual agricultural chemicals 	<ul style="list-style-type: none"> • Checking how agricultural chemicals are used • Raw materials of processed foods must conform with residue standards 	<ul style="list-style-type: none"> • Ensuring compliance with proper use and dosage of agricultural chemicals, before and after ingathering • Ensuring that residual agricultural chemicals are below proper levels, by regular testing and inspection 	<ul style="list-style-type: none"> • Checking whether any agricultural chemicals were used after ingathering
	<ul style="list-style-type: none"> • GMO foods whose safety has not been certified (corn, papaya, etc.) 	<ul style="list-style-type: none"> • Checking whether GMO food has been approved • Taking measures to prevent any uncertified GMO food from being included 	<ul style="list-style-type: none"> • Ensuring that no GMO food whose safety has not been certified is included through regular testing and inspection 	<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 determination 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 determination of quality or freshness have been used 	<ul style="list-style-type: none"> • Checking the types of additives used through regular testing and inspection 	

Livestock products and related processed foods	<ul style="list-style-type: none"> • Pathogenic microorganisms such as Enterohemorrhagic Escherichia coli O157 and listeria (meat, natural cheeses, etc.) 	<ul style="list-style-type: none"> • Taking measures to prevent contamination by pathogenic microorganisms 	<ul style="list-style-type: none"> • Ensuring that no pathogenic microorganisms are present through regular testing and inspections 	<ul style="list-style-type: none"> • Whether proper temperature control is implemented to prevent harm due to the growth of microorganisms
	<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 radioactivity 	<ul style="list-style-type: none"> • Checking the level of radioactivity by regular testing and inspection 	
	<ul style="list-style-type: none"> • Errors concerning sanitation certificates (meat and meat products) (milk and dairy products^{**}) 	<ul style="list-style-type: none"> • Checking each item on the sanitation certificate issued by the governmental agency of the producing and/or exporting country 		<ul style="list-style-type: none"> • Ensuring that a complete sanitation 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 area from which import is prohibited • No specified risk material (SRM) is included in the product • No beef, etc. originated from countries or areas from which import is prohibited is included or used. 		
	<ul style="list-style-type: none"> • Bovine spongiform encephalopathy (mutton, goat meat, etc.) 	<ul style="list-style-type: none"> • No BSE animal has been found in the producing area • No specified risk material (SRM) is included in the product • No mutton, goat meat, etc. originated from countries prohibited or areas from which import is included or used. 		
	<ul style="list-style-type: none"> • Residual agricultural chemicals, veterinary drugs, and feedstuff additives 	<ul style="list-style-type: none"> • Checking how agricultural chemicals, veterinary drugs and/or feedstuff additives were used • Raw materials of processed foods must conform with residue standards 	<ul style="list-style-type: none"> • Checking compliance with proper dose, administration, and drug holidays for veterinary drugs and feedstuff additives • Checking levels of residual agricultural chemicals, veterinary drugs, and feedstuff additives, by regular testing and inspection 	
	<ul style="list-style-type: none"> • Use of additives that may mislead consumers in the determination of quality and freshness (meat) 	<ul style="list-style-type: none"> • Ensuring that no colorant or other additives that may mislead consumers in the determination of quality or freshness have been used 	<ul style="list-style-type: none"> • Checking the types of additives used through regular testing and inspection 	

Seafood and processed seafood	<ul style="list-style-type: none"> • Pathogenic microorganisms such as <i>Vibrio parahaemolyticus</i> (fillet, shelled and/or peeled fish and shellfish to be eaten raw) 	<ul style="list-style-type: none"> • Taking measures to prevent contamination by pathogenic microorganisms in cleaning water used at processing plants, etc. • Compliance with processing standards 	<ul style="list-style-type: none"> • Ensuring that no pathogenic microorganisms are present through regular testing and inspections 	<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 microorganisms
	<ul style="list-style-type: none"> • Non-conformity with standards for constituents, standards for processing, and standards for storage for oysters eaten raw 	<ul style="list-style-type: none"> • Checking whether the standards for processing in the producing country are at the same level as in Japan 	<ul style="list-style-type: none"> • Ensuring conformity with the standards for constituents by regular testing and inspection 	<ul style="list-style-type: none"> • 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 clams are 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 by regular testing and inspection 	
	<ul style="list-style-type: none"> • Mixing with poisonous blowfish 	<ul style="list-style-type: none"> • Ensuring that only fish of the approved type(s) are imported • Taking measures to prevent different types of blowfish 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 blowfish are included, through proper identification of fish types
	<ul style="list-style-type: none"> • Errors concerning sanitation certificates (raw oyster and blowfish*) 	<ul style="list-style-type: none"> • Checking each item on the sanitation certificate issued by the governmental agency of the producing 		<ul style="list-style-type: none"> • Ensuring that a complete sanitation certificate is attached
	<ul style="list-style-type: none"> • Mixing with poisonous fish such as fish with ciguatoxin (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 included, through proper identification of fish types
	<ul style="list-style-type: none"> • Residual veterinary drugs and feedstuff additives 	<ul style="list-style-type: none"> • Checking on the use of veterinary drugs • Raw materials of processed foods must conform with the residue standards 	<ul style="list-style-type: none"> • Checking compliance with proper dose, administration, and drug holidays for veterinary drugs and feedstuff additives • Checking the levels of residual veterinary drugs and feedstuff additives, by regular testing and inspection 	
	<ul style="list-style-type: none"> • Use of additives that may mislead consumers in the determination 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 determination of quality or freshness have been used 	<ul style="list-style-type: none"> • Checking the types of additives used, by regular testing and inspection 	<ul style="list-style-type: none"> • Checking the color of the product (scarlet, etc.)
	<ul style="list-style-type: none"> • Histamine 	<ul style="list-style-type: none"> • Checking at the point of receiving raw material • Temperature control must be proper during the manufacturing, processing and other processes. 	<ul style="list-style-type: none"> • Checking the level of histamine, by regular testing and inspection 	<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 drug substance 	<ul style="list-style-type: none"> • Ensuring that no drug substances designated by the Pharmaceutical Affairs Act are included 	Ensuring that no drug substance is included by testing and inspection	
	<ul style="list-style-type: none"> • Containing hazardous or toxic substance 	<ul style="list-style-type: none"> • Checking the history of ingestion in the exporting country • Checking the cases of health damage 		
Additives and their preparation	<ul style="list-style-type: none"> • Use of unapproved additive • Non-conformity with the standards 	<ul style="list-style-type: none"> • Checking the correct names of the additives and their types of source materials and extractants • Checking the formal names and content rates if additive preparation is used • Ensuring that no unapproved additives are used • Ensuring that the product conforms to the related standards, such as standards for constituents and manufacturing standards • GMO technology whose safety has not been certified shall not be used. 	<ul style="list-style-type: none"> • Ensuring conformity with the standards for constituents, by regular testing and inspection 	<ul style="list-style-type: none"> • Checking compliance with storage standards
Equipments, containers and packages, and toys	<ul style="list-style-type: none"> • Non-conformity with standards 	<ul style="list-style-type: none"> • Checking the materials, shape, colors and patterns, 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 raw materials conform with general standards for raw materials and standards for each material, by regular testing and inspection 	
	<ul style="list-style-type: none"> • Inclusion of substances other than the positive list (Instruments and containers and packaging made of synthetic resin[※]) 	<ul style="list-style-type: none"> • Must be a substance listed on the positive list 	<ul style="list-style-type: none"> • Ensuring that positive list regularly 	