

Notice No.0328 Article 1 of the Environmental Health and Food Safety

March 28, 2016

To: Head of each quarantine station

From: Director of the Environmental Health and Food Safety,
Pharmaceutical Safety and Environmental Health Bureau
(Seal omitted)

Development of Imported Foods Monitoring and Guidance Plan for FY 2016

We appreciate the appropriate implementation of the monitoring plan based on the Imported Foods Monitoring and Guidance Plan for FY 2015, as well as the implementation of instruction of imported foods at the time of importation

Based on the implementation guidelines for monitoring and guidance on food sanitation (Notification No. 301 of the Ministry of Health, Labour and Welfare, 2003), the government developed the Imported Foods Monitoring and Guidance Plan in FY 2016 (hereinafter referred to as “the Imported Foods Monitoring and Guidance Plan for FY 2016”), as described in Annex 1, under paragraph 1, Article 23 of the Food Sanitation Act (Act No. 233 of 1947). The Imported Foods Monitoring and Guidance Plan for FY 2016 is a plan concerning the monitoring and guidance of imported foods, additives, equipment, containers and packages and toys by the national government which was published in an official gazette in accordance with paragraph 3 of the same Article.

Imported Foods Monitoring and Guidance Plan for FY 2016

The total number of foods, additives, equipment, containers and packages and toys (hereinafter referred to as "the food(s)") imported into Japan for the purpose of selling or business in 2014 was about 2.22 million cases of notifications and 32.41 million tons in volume on a notification basis. Based on the Food Balance Sheet by the Ministry of Agriculture, Forestry and Fisheries, the food self-sufficiency ratio is about 40% in Japan (food self-sufficiency ratio based on the total calorific value supplied), and about 60% of food supplies in Japan depends on supplies from abroad on a caloric-value-supplied basis.

In light of actual conditions of the food(s) imported into Japan, in FY 2015, the Ministry of Health, Labour and Welfare (hereinafter referred to as "the MHLW") and quarantine stations expanded the scope of items to be inspected at the time of importation by introducing testing equipment, and reinforced import inspections and guidance, such as monitoring inspections (meaning the inspections that are systematically implemented every fiscal year for the purpose of monitoring safety conditions of various foods based on the provision of paragraph 1, Article 28 of the Food Sanitation Act (Act No. 233 of 1947; hereinafter referred to as "the Act") and of taking measures including reinforced inspections when violations of the Act are identified; hereinafter the same applies) and inspection orders (meaning the orders requiring importers to have imported foods with a high possibility of violating the Act inspected each time that the goods are imported, based on the provision of paragraph 2 or 3, Article 26 of the Act; hereinafter the same applies). The MHLW and quarantine stations also systematically implemented a survey on the system in exporting countries with respect to food safety and conducted consultations and surveys on individual issues with exporting countries in order to prompt exporting countries to take appropriate safety measures on foods imported to Japan. Moreover, they conducted on-site inspections on safety control in exporting countries with relation to bovine spongiform encephalopathy (hereinafter referred to as "BSE"), etc.

As for these efforts, the interim report for the Inspection Results of the Imported Foods Monitoring and Guidance Plan for FY 2015 published in December 2015 provided preliminary figures of approximately 1.13 million cases of notification of imports and some 11.42 million tons in imported volume between April and September 2015. Out of these cases, 102,000 were inspected. Among the inspected cases, 431 were identified as violations. In FY2016, the MHLW will seek to further promote the above measures. As

for monitoring inspections, the MHLW will conduct a review in consideration of monitoring inspection results for FY2015, and other results of the survey into the regulations and the condition of safety control in exporting countries (hereinafter referred to as “the system survey”). Specifically, in consideration of detection information overseas the MHLW will steadily implement monitoring inspections on pathogenic microorganisms, continue to securely implement the Positive List system which in general prohibits sales of food products containing amounts of residual agricultural chemicals, that exceed the amount determined as harmless to health (hereinafter simply referred to as “the Positive List system”), and review inspections items, based on past inspection records. In particular based on the conditions of violation of specification of composition for frozen processed food products, an emphasis will continue to be placed on the monitoring inspection concerning specification of composition for processed food products. Based on such results, the MHLW will give instructions to importers on voluntary safety controls at the stage of production process in exporting countries by using checklist, based on the “Guidelines on Hygiene Control of Import Processed Foods” (hereinafter referred to as “the Guidelines on Processed Foods”), attached to the “Notification concerning the Guidelines on 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. The MHLW will also request exporting countries to promote safety measures during production, manufacturing and processing (hereinafter referred to as “the production process”) stages and, as necessary, will conduct onsite-inspections.

With regards to ensuring that beef exported to Japan is free of BSE, the MHLW will continue to verify the status of the observance of programs of exports to Japan controlled by the governments of exporting countries through on-site inspections and inspections at the time of import.

Based on the economic partnership agreements including the Trans-Pacific Partnership (TPP), the MHLW will gather information on food sanitation in foreign countries and develop a monitoring system in response to import trends. With a focus on TPP member countries, the MHLW will hold explanatory meetings to provide information on the food sanitation regulations of Japan to the government officials and producers, manufacturers and processors (hereinafter referred to as “the producers”) of exporting countries.

In addition to these efforts, the MHLW will establish a system for facility registration in exporting countries by adding the sanitation control requirements under the Hazard

Analysis and Critical Control Point (HACCP) to the current imported food products pre-certification system, and will promote safety measures in exporting countries by communicating and disseminating that system to the governments and producers of exporting countries. The MHLW will also endeavor to systematically conduct system survey, for example, the status of introduction of the HACCP.

1. Purpose

The purpose of the Plan is to promote intensive, effective and efficient monitoring and guidance of imported foods, for ensuring further safety with regard to imported foods.

2. Effective period of the Plan

The Plan shall be effective from April 1, 2016 to March 31, 2017.

3. Basic concepts for the implementation of monitoring and guidance on imported foods According to Article 4 of the Food Safety Basic Act (Act No. 48 of 2003), food safety must be ensured by taking necessary measures appropriately at each step of the food supply process both in Japan and overseas. From this viewpoint, the following measures shall be taken from the stages of the production process in exporting countries, to the stage of distribution in the domestic market after importation for the purpose of maintaining the safety of the imported foods.

(1) In order to promote safety measures during the production process in exporting countries, the MHLW shall provide information on food-safety regulations to embassies located in Tokyo, importers, and the government staffs and producers of exporting countries and publish the information on the website of the MHLW (hereinafter simply referred to as “the website”). MHLW shall hold bilateral discussions with exporting countries, conduct on-site inspections, and provide technical support.

(2) If the MHLW specifically determines that foods manufactured in a specific country or area, or by a specific manufacturer, should no longer be imported in order to prevent possible harm to food-sanitation conditions in Japan, it shall ban the importation of such foods by issuing a comprehensive order for an import ban under paragraph 1, Article 8 or paragraph 1, Article 17 of the Act.

(3) The MHLW shall provide guidance and, where appropriate, issue in order to importers who repeatedly violate the Act to prohibit or suspend their

importation business under paragraph 2, Article 55 of the Act with the aim of improving causes for violations of the Act (hereinafter referred to as “the prohibition or suspension of business of importers”).

- (4) When a violation of the Act has been identified, the MHLW shall announce the violation under Article 63 of the Act.
 - (5) Through the import-notification documents submitted under Article 27 of the Act, the quarantine stations shall check as to their compliance with the specifications and standards for foods (hereinafter referred to as “the standards”) under paragraph 1, Article 11 and paragraph 1, Article 18 of the Act.
 - (6) The quarantine stations shall systematically implement monitoring inspections to provide extensive checking of the food-safety conditions of various imported foods.
 - (7) The quarantine stations shall issue inspection orders in accordance with paragraph 2 or 3, Article 26 of the Act for imported foods suspected to have a high possibility of violating the Act in order to prevent harm to public health from the perspective of food sanitation.
 - (8) The quarantine stations shall make efforts including the holding of seminars and provision of pre-import guidance in order to promote voluntary safety control which is the duty of importers as the food business operators.
 - (9) When a violation of the Act has been identified, quarantine stations shall give instructions on discarding relevant foods or other measures as well as measures to prevent recurrence of such violations including providing guidance to importers.
 - (10) In the distribution stage in the domestic market, subsequent to importation, prefectures and cities and specially designated wards that operate public health centers (hereinafter referred to as “the prefectures, etc.”) shall monitor and give guidance on imported foods. If any violation of the Act is identified, the MHLW, the quarantine station and the prefectures, etc. shall cooperate with each other to take appropriate measures to ensure that the importer concerned properly recalls the food as soon as possible.
4. Items subject to intensive monitoring and guidance in light of conditions in the producing areas and other related factors
- (1) Checking of imported foods based on the import-notification document submitted under Article 27 of the Act
When the import-notification document is submitted for food importation

under Article 27 of the Act, the quarantine stations shall confirm; (i) that the imported food concerned is not among those mentioned in each item of Article 6, paragraph 2, Article 9, or Article 16 of the Act; (ii) that the food is not under an import ban in accordance with paragraph 1, Article 8 or paragraph 1, Article 17, of the Act; (iii) that the additives comply with regulations under Article 10 of the Act; (iv) that the foods comply with standards, by checking the import-notification document submitted by the importer and in addition, as necessary, the certificate issued by the government of the exporting country and reports by the importer on compliance with the Act and other regulations concerned.

(2) Monitoring inspection under paragraph 1, Article 28 of the Act

The purposes of monitoring inspection implemented by the quarantine stations are to extensively monitor the conditions of various imported foods in relation to food safety, as well as to enhance the inspection at the time of importation when a violation has been identified.

1) Development of Monitoring Plans

To conduct intensive, effective and efficient monitoring inspections, the MHLW shall determine the number of imported foods subject to monitoring inspection and items to be monitored and inspected (hereinafter referred to as “the monitoring plan”), so that inspection will identify violations with a certain statistical reliability, taking into account the violation rate, the number of notifications of imported foods, their volume and the impact of violations on public health with respect to each food group. In addition, the MHLW shall establish a monitoring plan, taking into account the conditions of regulations on agricultural chemicals, status of their use and cases of detection of agricultural chemicals in other countries, in order to steadily conduct the Positive List system. In particular based on the conditions of violation of specification of composition for frozen processed food products, the MHLW will continue to intensively conduct monitoring inspections concerning specification of composition for processed food products. In case of emergency, the MHLW will engage any of registered conformity assessment bodies, as necessary, to handle examination affairs of monitoring inspections pursuant to paragraph 4, Article 28 of the Act.

Furthermore, if it is confirmed, based on results of the system survey, information on occurrence of health hazards caused by food and on

recalls of unsanitary foods in exporting countries, the monitoring inspection will be reexamined.

Furthermore, for foods subject to inspection orders for residual agricultural chemicals, there are possibilities of insufficient management of residual agricultural chemicals and changes in the agricultural chemicals being used in exporting countries and there are fears that agricultural chemicals other than those subject to inspection orders may consequently exceed standard values. Therefore, monitoring inspections must be strengthened for the purpose of verifying the management of residual agricultural chemicals, etc., in export countries.

The monitoring plan for FY 2016 is shown in Schedule 1.

2) Planned implementation of monitoring inspections

Each quarantine station shall prepare an annual plan based on the number of foods subject to monitoring inspection assigned by the MHLW and systematically implement inspection on the assigned number of specimens.

The MHLW shall properly check the circumstances of inspections based on monitoring plans and provide necessary instructions to the quarantine stations and when quarantine stations find it difficult to implement station-by-station or food group-by-food group inspections, review the monitoring plan during this fiscal year as necessary so that inspections will be implemented in a way meeting the actual import conditions.

3) Strengthening of monitoring inspections

When the MHLW receives information on the recall of a food or harm to health by a food in a exporting country or the like, or when such a food is found to violate the Act during monitoring inspection or otherwise, or when a violation of the Act is identified through monitoring and guidance by a prefecture, etc., the MHLW shall instruct the quarantine stations to reinforce inspection of the relevant food as necessary.

As for reinforcement of inspection of residual agricultural chemicals, in order to grasp the control system for residual agricultural chemicals in exporting countries, the MHLW shall continuously conduct monitoring inspection on a higher proportion of imported foods concerned and for more inspection items for a certain period of time so that inspection will identify violations with a certain statistical reliability.

When no similar case of violation is identified for one year or in more

than 60 cases of inspections conducted after the monitoring inspections are reinforced, the inspection system will return to normal.

- (3) Administrative inspections other than the monitoring inspection under paragraph 1, Article 28 of the Act

The quarantine stations shall also inspect imported foods based on the import-notification document when they are imported for the first time, when an accident occurs during transportation, or in other necessary occasions, in addition to the inspection they conduct based on the monitoring plan.

- (4) Inspection order under paragraph 2 or 3, Article 26 of the Act

- 1) Issuance of an inspection order

When the MHLW deems it necessary in order to prevent any harm to food sanitation, the MHLW shall order importers to have imported foods with a high possibility of violating the Act inspected.

When publishing the addition to a list of foods subject to inspection order, their health effects should be explained in an easy-to-understand way.

i. If imported foods have caused or are likely to cause harm to health in the exporting country or in Japan, or when a violation of the Act is identified as a result of the monitoring inspection of aflatoxin, pathogenic microorganisms, etc., relevant imported foods manufactured by the same manufacturer, processed by the same processor, or imported from the same exporting country shall be immediately subject to an inspection order.

ii. If the same imported foods manufactured by the same manufacturer, processed by the same processor or exported from the same country are found in the monitoring inspection to have violated the Act several times with regard to residual agricultural chemicals, all or part of the relevant imported foods shall be subject to an inspection order, taking into account the conditions of regulations and safety control in the exporting country and history of compliance with the Act concerning the imported foods.

- 2) Cancellation of an inspection order

If it is found that there is no risk that foods violating the Act will be exported to Japan, the MHLW shall cancel the inspection order to return the monitoring system to an ordinary state.

i. Where the exporting country has taken preventive measures, such as investigation of causes, issuance of new regulations corresponding to

the results of investigation and enhancement of the condition of control of agricultural chemicals and inspection system, and the measures have been determined to be effective through bilateral discussions, on-site inspections or inspections at the time of importation, the inspection order shall be cancelled.

- ii. For imported foods subject to an inspection order concerning residual agricultural chemicals for which there have been no violations during two years from the most recent date of detection of a violation after the issuance date of inspection order (or from the issuance date of inspection order if there are no violations after the issuance date of inspection order,) or the number of the imported foods inspected under the order is more than 300 and no violations during one year after the issuance date of inspection order, the inspection order shall be cancelled. The monitoring inspection shall be subsequently carried out on a higher proportion of the imported foods and for more inspection items for a certain period of time so that inspection will identify violations with a certain statistical reliability and, if a violation is identified, an inspection order will be issued immediately.

- (5) Comprehensive import ban under paragraph 1, Article 8 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 those inspected and if it is highly likely that the importation of violating foods will continue, due to the state of food-sanitation control in the exporting country, the Minister of Health, Labour and Welfare shall ban the importation of such foods after consulting the Pharmaceutical Affairs and Food Sanitation Council, as long as such a ban is considered to be specifically necessary to prevent food-sanitation problems, taking into account the extent to which such foods may harm human health.

- (6) Emergency measures based on information on related problems from overseas
The MHLW shall collect information on food-safety problems from the governments of the exporting countries through the International Food Safety Authorities Network (INFOSAN) or otherwise in cooperation with related ministries and agencies in order to ensure safety of imported foods and publish major cases on the website. When it finds that foods violating the Act

may be imported into Japan, it shall check the status of their importation into Japan. If such foods are being or actually have been imported, the MHLW shall ask the quarantine stations and/or prefectures concerned to investigate their distribution and inventories in Japan and instruct the importers to inspect and recall them if necessary. The MHLW shall also instruct the quarantine stations to reinforce inspection of those foods and publish the progress of countermeasures.

5. Promotion of safety measure in exporting countries.

The MHLW shall promote safety measures in exporting countries through the following efforts in order to prevent any violation of the Act during the production process in the exporting countries.

- (1) Provision of information on food-safety regulations and related standards in Japan the MHLW shall provide, in its website, information on food-safety regulations in Japan, concerning foods that are subject to an inspection order or enhanced-monitoring inspection as well as the results of the Plan and monitoring and guidance under the Plan in English.

The MHLW shall provide this information to governments and producers, etc. in exporting countries through explanatory meetings for embassies, etc., located in Japan held at the time when specifications and standards are reviewed, seminars on food-safety regulations held by the Japan International Cooperation Agency (JICA) and explanatory meetings held in exporting countries.

- (2) Bilateral discussions and on-site inspections

For foods that are subject to inspection orders at the time of importation, as well as those with a high possibility of violating the Act, the MHLW shall ask the governments of the exporting countries to investigate the causes of such violations and to take corrective actions based on the results of such investigations, through bilateral discussions and other means. In addition, the MHLW shall promote such measures as safety control in the production stages, the enhancement of monitoring systems and the introduction of pre-export inspections in the exporting countries.

According to the interim report for the Inspection Results of the Imported Foods Monitoring and Guidance Plan for FY 2015, the majority of cases of violations consist of the cases which violated items in Article 6 of the Act due to the presence of toxic or hazardous substances such as mycotoxins, or

paragraph 2 or 3, Article 11 of the Act concerning residual agricultural chemicals, veterinary drugs, microorganisms, etc. In FY 2016, the MHLW will continue to systematically collect information relating with safety measures of foods exported to Japan mainly from countries who have repeatedly violated laws and have large amount of export. And the MHLW promote sanitary measure in exporting countries by on-site inspection.

Further, in order to ensure safety for imported beef, etc., if it is necessary to verify safety measures in the production stage etc. in exporting countries, the MHLW shall dispatch experts to the exporting countries of the relevant imported foods to confirm the safety measures in the exporting countries.

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

(3) Technical support, etc.

The MHLW and quarantine stations shall provide technical support to exporting countries so as to contribute to the strengthening of monitoring systems, including improvement of testing techniques for residual agricultural chemicals, mycotoxins, etc.

(4) Dissemination of the system for facility registration in exporting countries

In order to promote safety measures in exporting countries based on the sanitation controls under the HACCP, the MHLW will establish a system for facility registration in exporting countries by adding the sanitation control requirements under the HACCP to the current imported food products pre-certification system, and will promote safety measures in exporting countries by communicating and disseminating that system to the governments and producers of exporting countries. The MHLW will also gather information on the status of introduction of the HACCP in exporting countries.

6. Guidance for importers on voluntary safety control

Paragraph 1, Article 8 of the Food Safety Basic Act stipulates that food business operators, including importers, must recognize their own responsibility for securing the safety of food and calls for taking appropriate measures at each stage of the

food supply process with the necessary measures to insure food safety. Also, paragraph 1, Article 3 of the Act stipulates that it is the responsibility of food business operators, including importers, to acquire the necessary knowledge and technology, to ensure the safety of raw materials and to implement voluntary checks for the purpose of ensuring the safety of imported foods at their own discretion.

Based on this, the quarantine stations shall promote voluntary safety controls for importers, through the following guidance and measures in order to prevent violations of the Act before they occur.

(1) Basic guidance for importers

The quarantine stations shall make sure that importers have a thorough understanding of the regulations on food safety and their responsibilities as importers, such as compliance with statutory import procedures, inspection systems, standards and provision of sanitation certificates that must be attached to imported foods.

For the standpoint of promoting voluntary safety control, the quarantine stations shall provide importers with information on imported foods violation and sanitation problems, newly established specifications and standards, and food safety regulations in the exporting countries in a timely and appropriate manner, and provide guidance to importers through seminars or upon the submission of import notification so that importers may endeavor to secure the safety of imported food products by themselves.

The basic items of guidance for importers are listed in Schedule 2. Additional guidance shall be given depending on the types of imported foods that the importers handle and the relevant exporting countries. For processed foods, based on the guidelines for processed foods, importers will be instructed to conduct necessary confirmation in the exporting countries at the stages of the production process, taking consideration of the circumstances of development and implementation of restrictions regarding food safety and safety control standards for manufacturers in exporting countries.

Furthermore, the quarantine stations provide complete instructions for confirming that imported foods are not illegal produced in exporting countries and for checking that raw materials, additives, manufacturing process, inspection data and all other aspects conform to the Act, using the checklist in the Guidelines on Processed Foods.

In addition, the quarantine stations provide instructions for making proper

import-notification documents based on accurate and the latest information obtained from producers or manufactures. At the same time, especially for cases of continuing imports, the quarantine stations provide instructions to sufficiently confirm that there are no changes in raw materials and manufacturing process and that the results of voluntary inspections presented in the notification and the actual goods are the same.

Whenever specifications and standards are revised, inspection is enhanced, sales are prohibited, or otherwise related changes are made, the necessary information shall be provided to importers through the quarantine stations, etc.

(2) Pre-import guidance

Based on the guidance principles for importers mentioned in (1) above, the quarantine stations shall instruct importers that they should obtain materials from the producers, etc. to check the safety of the food to be imported and whether it contains drug substances regulated under the Act on Securing Quality, Efficacy and Safety of Pharmaceuticals, Medical Devices, Regenerative and Cellular Therapy Products, Gene Therapy Products, and Cosmetics (Act No. 145 of 1960), prior to importation. In particular, the quarantine stations shall actively recommend through their websites and/or seminars that importers consult with imported foods counselors of the quarantine stations before first importing food that falls in the same category as products with previous violations or sanitation problems.

From the standpoint of promoting voluntary inspection before importation, the results of such inspections shall be utilized when quarantine stations check imported foods, as described in 4. (1) above.

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

When an importer finds out through a pre-import safety check that the food being imported does not comply with the Act, the quarantine stations shall instruct the importers to take appropriate measures to achieve compliance and to delay importation until improvements have been made.

If the food is proven to comply with the Act through documents, etc. as a result of the improvements, the relevant quarantine station shall instruct the importer, as necessary, to confirm that the food actually meets the required standards.

(4) Voluntary inspection

The first time the food(s) is imported, the quarantine stations shall instruct

importers to conduct voluntary checks on required items to confirm that the food complies with the Act, based on specifications and standards for the imported food and the use of additives. Further if the importer plans to import the food on a regular basis, the relevant quarantine station shall instruct the importer to conduct voluntary checks, combined with the regular confirmation of specifications and standards for the imported food and additives in that food and with reference to violation information of similar foods, in accordance with the guidance principle for importers mentioned in (1).

(5) Preparing and retaining records of imported foods

Taking into account 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, the quarantine stations shall instruct importers to properly prepare and retain records of the importation, sales and other details for the imported foods in order to allow the quarantine stations to check and identify the conditions of import and distribution of those foods at all times. The quarantine stations shall also instruct importers to assure that relevant information be immediately provided to the quarantine stations and prefectures, etc. concerned when a violation of the Act has been identified.

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

The quarantine stations shall hold seminars for importers, customs brokers and bonded warehouse operators concerning the instructed items in (1) to (5) and shall dispatch their staff members to seminars held by the associated organizations, with the aim to improve the business operators’ knowledge about food safety and to ensure the safety of imported foods.

The quarantine stations shall also prompt the importers to consult in advance with the prefectures, etc. having jurisdiction over their locations as necessary with regard to labels such as proper expiration dates on imported foods.

7. When a violation or the like has been identified

The quarantine station that has accepted the import notification for the relevant food(s), the MHLW and prefecture(s) shall mutually cooperate in instructing the importer to dispose of, return or convert the relevant food(s) to uses other than for food or otherwise promptly recall the relevant food(s), and to take necessary measures for identifying the cause(s) and preventing recurrence. At the same time, other required measures including the reinforcement of inspection upon importation shall be taken as follows:

(1) When a violation has been identified in an inspection etc. at the time of importation.

1) If the food(s) that has been identified as violating the Act has not yet cleared customs

The quarantine stations shall instruct the importers to discard or otherwise take a measure for the relevant food(s), and instruct them to report measures taken against food violations.

The MHLW shall take other required measures including the reinforcement of inspection upon importation.

2) If the food(s) that has been identified as violating the Act has already cleared customs

The prefectures that have jurisdiction over the locations of importers shall, as necessary, order them to recall or otherwise take a measure for the relevant food(s) and instruct them to report measures taken against food violations.

To ensure the efficient implementation of recall, etc. by importers, the quarantine station shall immediately report the lot numbers, name and address of the importer and other information on the violating food (hereinafter referred to as “information on the violating food”) to the MHLW.

In addition, the MHLW shall also provide this information to the prefecture that has jurisdiction over the location of the importer, and take other required measures including the reinforcement of inspection upon importation.

The quarantine station shall temporarily instruct the importer to discard or otherwise deal with all the violating foods as necessary and to follow the instructions from the prefecture that has jurisdiction over its location. In addition, the MHLW shall, under provisions in paragraph 1, Article 12

of the Consumer Safety Act (Act No. 50 of 2009), strive to share information with the Consumer Affairs Agency.

- (2) When a violation of the Act has been identified in an inspection when the food is put into distribution in the domestic market

If the MHLW receives correspondence from a prefecture, etc. identifying a violation of the Act with concern to an imported food when the food is put into distribution in the domestic market 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 seller, etc., the MHLW shall in turn provide the quarantine station concerned with information on the violating food. The MHLW shall also take any necessary measures based on that information, such as enhancement of import inspections. Also, if there is information on health hazards that originate from imported food, the MHLW shall promptly report foods for later importation to quarantine stations and foods in domestic distribution to prefectures, etc. and take other necessary measures to prevent further expansion of damage.

- (3) Instruction to importers to prevent the recurrence of violations

The quarantine stations shall require the importers who have violated the Act to take the following actions to prevent the recurrence of such a violation.

- 1) Inspection and reports of the cause of violation

The quarantine stations shall require the importer to investigate the causes of the violation and immediately report the results to the quarantine station. The importer shall report the progress of the investigation to the quarantine station if the causes of the violation are still not identified after three months have passed since the detection as violation.

- 2) Report of improvement results at the time of reopening imports

When the importer plans to import the same food again, the quarantine station shall require the importer to investigate the causes as mentioned in 1), and confirm that the corrective action has already been taken. The quarantine station shall also require the importer to carry out field investigations in the exporting country as necessary, as well as inspections for each check item that did not previously comply with the Act and report the corrective action to the quarantine station.

- (4) Prohibition or suspension of business of importers based on provisions in paragraph 2, Article 55 of the Act

For the purpose of ensuring food safety, the MHLW may order a prohibition or suspension of business with respect to importers who commit repeated violations, or food importers who have caused harm or posed risks to public health by violating the Act, in order to make them improve the causes of the violation, prevent recurrence and take other required sanitary measures.

In addition, the MHLW shall submit measures to prevent recurrence and instruct importers who have violated the Act for more than about 5% of all cases of importation and have become subject to consideration on the prohibition or suspension of business of importers to ensure that they do not commit repeated violations of the Act, based on 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, Pharmaceutical and Food Safety Bureau, MHLW. Quarantine stations will strengthen monitoring inspections of foods imported by such importers in accordance with the details of violation and will verify measures to prevent recurrence by the concerned importers.

(5) Indictments for malicious cases

The quarantine stations will indict if it considers that any (potential) crime is committed, for example, submission of a false import notification document and illegal importation of foods violating the Act or foods with a high possibility of suspicion, and make a publication of such indictments.

(6) Publication of cases of violations

In accordance with the provision in Article 63 of the Act, the MHLW shall promptly list the names of importers who have violated the Act or any actions taken under the Act, as well as the names of the violating imported foods on the MHLW website (names for one year), for the purpose of disclosing information to the public regarding any potential harm from the viewpoint of food sanitation. (If the violation is not very serious and if the importer remedies it immediately, such importers are excluded from the list.) In addition to the listing of the names of violating importers, measures taken against food violations, such as disposal or recall and corrective actions and causes of the violations shall also be published as soon as the information is available.

8. Provision of information to the public

By utilizing its website, official social networking service (SNS) and any other means, the MHLW and quarantine stations shall provide the general public with information on ensuring the safety of imported foods.

(1) Provision of information concerning the monitoring plan etc.

The quarantine stations shall actively inform importers, customs brokers and bonded warehouse operators of the notices on monitoring plan, inspection orders, the enhancement of inspections and other matters in order to ensure smooth implementation of monitoring and guidance under the Plan.

The MHLW shall also publish information on the monitoring plan, the issuance of inspection orders, the enhancement of inspections and other matters.

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

The MHLW shall publish information on bilateral discussions and on-site inspections that have been held or conducted in order to promote safety measures taken by exporting countries, including discussions under the Memorandum on Japan-China Food Safety Promotion Initiative.

(3) Announcement of the results of monitoring implemented in accordance with the Plan

The MHLW shall publish the status of monitoring and guidance under the Plan, including a summary of the actual implementation of inspections into imported foods, such as monitoring inspections and inspection orders, and the results of these inspections and year-over-year changes, as well as monitoring and guidance given to the importers and their brief results, by around August of the following fiscal year. The situation in the middle of the fiscal year (from April to September) shall also be published by around December.

(4) Efforts for risk communication concerning food safety

As the efforts for risk communication concerning food safety, etc., the MHLW shall, in cooperation with prefectures and other ministries and agencies, provide information to and exchange information with consumers, business operators, etc. on the details of the plan and the status of monitoring and guidance on imported foods and strive to gain appropriate understanding of food safety.

(5) Others

The quarantine stations shall conduct activities, such as allowing general consumers to visit them for the purpose of gaining public understanding of the actual conditions of monitoring and guidance on imported foods.

9. Other matters necessary for the implementation of monitoring and guidance

(1) Development and skill enhancement of personnel in charge of food safety

The MHLW shall hold seminars and training to improve the knowledge and skills with regard to food safety for food sanitation inspectors at quarantine stations who are engaged in monitoring, guidance, testing and inspection at the stations.

(2) Checking tests and inspections of foods implemented by quarantine stations

The MHLW, with advice from the MHLW's regional offices, shall implement systematic checks and instructions on the control of tests and inspections at quarantine stations, to ensure that monitoring inspection and other related operations are conducted appropriately.

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	1,900	4,280
	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	2,200	10,600
	Residual agricultural chemicals	1,700	
	Additives	1,200	
	Pathogenic microorganisms	3,600	
	Standards for constituents	1,900	
Seafood products Bivalves, fish, shellfish (shrimps, prawns, crabs) and other products	Antibacterial substances	2,600	5,480
	Residual agricultural chemicals	1,100	
	Additives	300	
	Pathogenic microorganisms	1,100	
	Standards for constituents	350	
	Radiation irradiation	30	
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	4,200	19,800
	Residual agricultural chemicals	4,100	
	Additives	1,900	
	Pathogenic microorganisms	4,700	
	Standards for constituents	4,900	
Agricultural foods Vegetables, fruit, wheat, barley, corn, beans, peanuts, nuts, seeds, and other products	Antibacterial substances	2,600	16,970
	Residual agricultural chemicals	9,200	
	Additives	470	
	Pathogenic microorganisms	1,500	
	Standards for constituents	350	
	Mycotoxins	2,300	
	GMOs	450	
	Radiation irradiation	100	
Processed agricultural foods Frozen products (processed vegetables), processed vegetable products, processed fruit products, spices, instant noodles, and other products	Antibacterial substances	600	19,050
	Residual agricultural chemicals	6,800	
	Additives	4,600	
	Pathogenic microorganisms	1,000	
	Standards for constituents	2,600	
	Mycotoxins	2,800	
	GMOs	250	
	Radiation irradiation	400	
Other foods Health foods, soups, flavorings, seasonings, sweets, edible oils, fat, frozen products, and other products	Residual agricultural chemicals	1,100	6,000
	Additives	3,300	
	Standards for constituents	600	
	Mycotoxins	1,000	
Drinks and beverages Mineral water, soft drinks, alcoholic beverages, and other products	Residual agricultural chemicals	100	2,020
	Additives	1,100	
	Standards for constituents	650	
	Mycotoxins	170	
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			96,000

*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, O104, O111, and O157, *Listeria monocytogenes*, *Vibrio parahaemolyticus*, 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

	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

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) 	<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"> • 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 • Checking the history of ingestion in the exporting country 	Ensuring that no drug substance is included by testing and inspection	
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 	