Notice No. 0324002 of the Department of Food Safety March 24, 2006

To: Head of each quarantine station

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

### **Development of Imported Foods Monitoring and Guidance Plan for FY 2006**

We appreciate your realization of the monitoring plan based on the Imported Foods Monitoring and Guidance Plan for FY 2005, and the appropriate implementation of other measures related to the monitoring and guidance 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 Ministry of Health, Labour and Welfare developed, as described in Annex 1, the Imported Foods Monitoring and Guidance Plan for FY 2006 (hereinafter referred to as "the Plan"), concerning the monitoring and guidance of imported foods, additives, equipment, containers and packages by the national government, under Section 1, Article 23 of the Food Sanitation Law (Law No. 233 in 1947), and published them in an official gazette in accordance with Section 3 of the same Article.

We ask you to implement the monitoring and guidance tasks appropriately in conformity with the Plan.

#### Annex 1

#### Imported Foods Monitoring and Guidance Plan for FY 2006

The total number of foods, additives, equipment, containers and packages, and toys (hereinafter correctively referred to as "the food(s)") imported into Japan was about 1.79 million annually and 34 million tons in volume, on a declaration basis (based on actual figures for 2004). The food self-sufficiency ratio is about 40% in Japan (food self-sufficiency ratio in relation to the total calorific value supplied, based on the Food Balance Sheet for FY 2004 by the Ministry of Agriculture, Forestry and Fisheries).

Under such circumstances, the Plan is intended to promote intensive, effective and efficient monitoring and guidance for the purpose of further ensuring safety with regard to foods imported into Japan (hereinafter referred to as "the imported foods").

In FY2005, the Ministry of Health, Labour and Welfare (hereinafter referred to as "the MHLW") and quarantine stations reinforced the monitoring inspection in accordance with the provision of Article 28 of the Food Sanitation Law (Law No. 233 in 1947, hereinafter referred to as "the Law"), as well as monitoring and guidance of inspection orders at the time of importation based on the provision of Article 26 of the Law. The MHLW also vigorously requested sanitation measures to be taken by exporting countries mainly responsible for the cases of violation of Article 11 of the Law concerning residual agricultural chemicals, and conducted on-site inspections on sanitation control in exporting countries with relation to residual synthetic antibacterial agents, bovine spongiform encephalopathy (hereinafter referred to as "BSE"), etc.

The interim report for the monitoring results of the Imported Foods Monitoring and Guidance Plan for FY 2005, published on November 7, 2005, provided preliminary figures of approximately 950,000 cases of declared imports and some 13 million tons in imported volume between April and September 2005, of which approximately 100,000 cases, or 10.2% of the overall declared number, were inspected. Among the inspected cases, 432 were identified as violations.

In FY 2006, the MHLW seeks to further promote the above measures and conduct on-site inspections and inspections at the time of importation to ascertain presence of attachment of or contamination by SRM (Specified Risk Material) in order to ensure conformity with an export program for Japan under the control of a government of an exporting country. The MHLW will also expand inspection items at the time of importation to ensure the systematic implementation of inspection systems, taking into consideration the introduction of the so-called "Positive List" system that prohibits in principle sales etc. of foods containing agricultural chemicals, veterinary drugs or feedstuff additives (hereinafter referred to as "the agricultural chemicals etc.") with no established residual standards over the amounts defined as posing no potential risks to human health. At the same time, the Ministry will conduct inspections in exporting countries as necessary in order to confirm preventing measures against residue at production stages of agricultural chemicals etc. In the meantime, there are also plans to review the items and other aspects of inspections, in light of the results of monitoring inspections based on the provision of Article 28 of the Law for 2005. Also, the MHLW will further reinforce the system of monitoring pathogenic microbes related to imported seafood, because many cases of violations of Article 11 of the Law occur concerning with standards for constituents of seafood.

### 1. Effective period of the Plan

The effective period of the Plan shall be from April 1, 2006 to March 31, 2007.

# 2. Basic concepts for the implementation of monitoring and guidance on imported foods

According to Article 4 of the Food Safety Basic Law (Law No. 48 in 2003), ensuring food safety must be achieved by taking appropriate measures at each step of the food supply process both in Japan and overseas. From this viewpoint, appropriate measures must be taken from the stages of production, manufacturing and processing (hereinafter referred to as "the production process") in exporting countries, to the stages of import and distribution in the domestic market for the purpose of maintaining the safety of the imported foods.

When the foods are imported, the MHLW and quarantine stations shall cooperate with customs houses and other related governmental agencies, and take the following measures in order to provide proper monitoring and guidance to the importers of the foods (hereinafter referred to as "the importer(s)") at the time of their importation:

- (1) Collection of basic data on imported foods through the import declaration documents submitted under Article 27 of the Law, and checking of the above data as to their compliance with the standards and criteria for foods (hereinafter referred as "the standards") under Section 1, Article 11 and Section 1, Article 18 of the Law.
- (2) Implementation of monitoring inspection under Article 28 of the Law, to provide extensive checking of the food sanitation conditions of various imported foods.
- (3) Issuance of inspection orders in accordance with Article 26 of the Law, for imported foods with a high probability of violating the Law in order to prevent harm to public health from the perspective of food sanitation.
- (4) If the MHLW specifically determines that the importation of foods manufactured in a specific country or area, or by a specific manufacturer, should be stopped to prevent possible harm to food sanitation conditions in Japan, the government shall ban the importation of such foods by issuing a comprehensive order for an import ban under Article 8 or Article 17 of the Law.
- (5) The government shall issue an order to importers who repeatedly violate the Law to stop or suspend their importation business under Section 2, Article 55 of the Law with the aim of improving causes for violations etc.

In addition, the government supports voluntary efforts by importers to control and maintain food sanitation, so that they will fulfill their responsibilities as business operators handling foods.

In order to prevent in advance any violation of the Law during the production process in the exporting countries, the MHLW makes a variety of information available on its website (hereinafter referred to as "the website") as well as providing related information to embassies located in Japan and to importers. These activities will contribute to a better understanding of Japanese rules and regulations under the Law and other related standards by the governments of the exporting countries, as well as the producers, manufacturers, and food processing businesses in such exporting countries (hereinafter referred to as "the producers"), thereby preventing violations of the Laws, regulations, and other requirements in advance. At the same time, the Japanese government shall support sanitation measures in the exporting countries by: i) holding bilateral discussions when a food sanitation problem arises, ii) dispatching experts, iii) providing technical support such as the reception of government officers from the exporting countries for training, and iv) promoting pre-export inspection by public organizations in the exporting countries, as well as other related measures.

In the distribution stage in the domestic market, subsequent to importation, each prefecture (including prefectures, cities and specially designated wards that operate public health centers – the same shall apply hereinafter) shall carry out monitoring and give guidance on imported foods. If quarantine stations or prefectural organizations identify any violation of the Law, the MHLW, the quarantine station and the prefecture concerned shall cooperate with each other and take appropriate measures to ensure that the importer concerned recalls the food as soon as possible.

# 3. 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 declaration document submitted under Article 27 of the Law

When the import declaration document is submitted for food importation under Article 27 of the Law, the quarantine stations shall confirm that the imported food concerned not be among those mentioned in each section of Article 6, or in Articles 9 and 16 of the Law, that it is not a food under an import ban in accordance with Section 1, Article 8 or Section 1, Article 17 of the Law, that the additive complies with regulations under Article 10 of the Law, and that it complies with standards, by checking as necessary the import declaration document submitted by the importer, the certificate issued by the government of the exporting country, and reports by the importer on compliance with the Law and other regulations concerned.

(2) Monitoring inspection under Article 28 of the Law

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

- 1) 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 imported foods, their volume, and the impact of violations on public health in each food group. The monitoring plan for FY 2006 is shown in Schedule 1.
- 2) The MHLW shall implement the monitoring plan, taking into account overseas regulation conditions etc. in order to conduct intensive, effective and efficient

monitoring inspections with the introduction of the Positive List system of agricultural chemicals etc.

- 3) Each quarantine station shall prepare an annual plan based on the number of foods subject to monitoring inspection assigned by the MHLW and implement inspection systematically on the assigned number of specimens.
- 4) When the MHLW receives information on the recall of a food or harm to health by a food in a producing country or other countries, or when such a food is found to violate the Law during monitoring inspection or otherwise, the MHLW shall instruct the quarantine stations to reinforce inspection of the relevant food as necessary.
- (3) Inspections other than the monitoring inspection under Article 28 of the Law

The quarantine stations shall also inspect imported foods based on the import declaration document when they are imported for the first time, when an accident occurs during transportation, or in other necessary occasions.

(4) Inspection order under Article 26 of the Law

The Minister of Health, Labour and Welfare shall issue an inspection order when the Minister determines that it is necessary to prevent any harm to the food sanitation. Importers must be inspected when this order is issued. More specifically, if an imported food has caused harm to health in the exporting country or in Japan, and if the same manufacturer or processor exports the same product to Japan, the product shall be immediately subject to the inspection order. When imported foods are regarded to have a high probability of violating the Law, for example, if the same product exported from the same country or by the same manufacturer or processor is found to violate the Law twice or more concerning residual agricultural chemicals or veterinary drugs in the monitoring inspection, these products shall be subject to an inspection order.

If the exporting country takes sufficient preventive measures, such as investigation of causes, issuance of new regulations, and/or enhancement of inspections after the above inspection order is issued in Japan, and if the Japanese government acknowledges that such preventive measures will eliminate the risk of importation of violating foods into Japan, the Minister shall cancel the order.

(5) Comprehensive import ban under Article 8 or Article 17 of the Law

As for imported foods produced in a specific country or area, or by a specific business entity, if the number of imported foods violating the Law 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 given reasons such as the state of food sanitation control in the exporting country, the Minister of Health, Labour and Welfare shall ban the importation of such foods, as far 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, after consulting the Pharmaceutical Affairs and Food Sanitation Council. (6) Emergency measures based on information on related problems from overseas

The MHLW shall collect information on food sanitation problems from overseas. When it finds that foods with problems 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 Ministry shall ask the quarantine stations and/or prefectures concerned to investigate their distribution and inventories in Japan, ask the importer(s) to recall them if necessary, and instruct the quarantine stations to reinforce inspection of those foods.

# 4. Promotion of measures to achieve better sanitation conditions in exporting countries

(1) The MHLW shall provide information on foods that are subject to inspection orders or enhanced monitoring inspection, and sample cases of violations of the Law on its English website, as well as further developing and disclosing information in English by linking its web pages to those of the Japan External Trade Organization (JETRO), which describe food sanitation regulations and related standards in Japan, in order to promote the dissemination of information in English version.

The MHLW promotes the understanding of Japanese food sanitation regulations by governments and producers in the exporting countries by providing such information to embassies located in Japan and importers. Information may also be provided through seminars on food sanitation regulations held by the Japan International Cooperation Agency (JICA) and other means.

- (2) For imported foods that are subject to inspection orders at the time of importation, as well as those with a high probability of violating Japanese laws and regulations, the MHLW shall ask the governments of the exporting countries to investigate the causes of such violations, and to take appropriate measures to prevent the recurrence of such violations based on the results of such investigations. In addition, the MHLW shall promote measures to enhance food safety, through field investigations and bilateral discussions, proper control of agricultural chemicals, veterinary drugs and foodstuff additives on farms, the enhancement of monitoring systems, and the introduction of pre-import inspections in the exporting countries. The MHLW shall also dispatch experts and provide technical support as necessary, to contribute to the strengthening of monitoring systems and the improvement of testing techniques for residual agricultural chemicals in those countries.
- (3) The MHLW shall cooperate with related governmental agencies to collect information required for the achievement of safety of imported foods. If it is necessary to confirm sanitation measures in the production process of certain food(s) in the exporting countries, the Ministry shall also dispatch experts to the exporting countries of the relevant food(s), to have them carry out such confirmation.
- (4) As there were many cases in FY 2005 in which imported foods violated Article 6 of the Law due to presence of toxic or hazardous substances such as mycotoxins, or Article 11 of the Law concerning residual agricultural chemicals and veterinary drugs, the MHLW plans in FY 2006 to actively request exporting countries, especially those whose exported foods have repeatedly violated the laws and regulations, to introduce proper food sanitation measures.

### 5. Guidance for importers on voluntary sanitation control

Section 1, Article 3 of the Law 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.

The quarantine stations shall promote voluntary sanitation controls, implemented by the importers, through the following guidance and measures.

(1) Basic guidance for importers

The quarantine stations shall make sure that importers have a thorough understanding of the regulations on food sanitation 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 purpose of promoting voluntary activities by the importers with the aim of improving sanitation control, the quarantine stations shall give guidance to importers through seminars, or upon the submission of import declarations, referring the information on violating imported foods, food sanitation regulatory systems in the exporting countries, and other information obtained from the producers, thereby supporting the importers to achieve a greater level of safety for imported foods.

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.

Whenever a standard or criterion is revised, inspection is enhanced, sales are prohibited, or otherwise related changes are made, the quarantine stations shall provide importers with the necessary information.

(2) Pre-import guidance

Based on the guidance principles for importers mentioned in (1), the quarantine stations shall instruct importers that they should obtain materials from the producers and manufactures to check the safety of the food to be imported, and whether it contains drug substances regulated under the Pharmaceutical Affairs Law (Law No. 145 of 1960), prior to importation. In particular, the quarantine stations shall actively recommend through its website and/or seminars that importers consult with them before importing a food for the first time that falls in the same category as products with previous violations.

(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 Law, the quarantine stations shall instruct importers to take appropriate measures to achieve compliance, and to delay importation until improvements have been made. If the food is proved to comply with the Law 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 by such means as the importation of samples.

(4) Voluntary inspection

The first time a food is imported, the quarantine stations shall instruct importers to make voluntary checks on required items to confirm that the food complies with the Law, including standards for constituents of the food, and/or the use of agricultural chemicals, veterinary drugs and additives. If the importer plans to import the food on a regular basis, the relevant quarantine station shall instruct the importer to conduct regular voluntary checks, combined with the regular confirmation on the use of agricultural chemicals, veterinary drugs and additives in that food, and with reference to violation information of similar foods, in consideration of the frequency of the planned importation, as well as in accordance with the guidance principle for importers mentioned in (1).

(5) Preparing and retaining records of imported foods

The quarantine stations shall request the importers to properly prepare and retain records of the importation, sales and other details for the imported foods, to allow the quarantine stations to check and identify the distribution situation of those foods at any time.

(6) Appropriate indications

The quarantine stations shall instruct the importers to consult in advance with the prefectures that have jurisdiction over their locations, so that the indications on imported foods will satisfy the provisions of applicable laws and regulations in Japan.

(7) Enhancement of knowledge of food sanitation among importers, customs brokers, and bonded warehouse operator

The quarantine stations shall request importers, customs brokers, and bonded warehouse operators, to send their staff members who handle imported foods to seminars held by the quarantine stations or associated organizations, to improve their knowledge of food sanitation.

### 6. When a violation has been identified

- (1) If a violation has been identified in an inspection by a quarantine station or by an importer, the quarantine station that has accepted the import declaration for the relevant food(s), the MHLW, and/or the prefecture(s) concerned shall cooperate in urging the importer to recall the relevant food(s) or otherwise take necessary measures, and in implementing other required measures including the reinforcement of inspection upon importation.
  - 1) If the relevant food has not yet cleared customs, the quarantine station shall instruct the importers to discard, return or otherwise respond as necessary.
  - 2) If the food has already cleared customs, the prefectures that have jurisdiction over the locations of importers shall instruct them to recall the food.

To ensure the smooth fulfillment of a recall instruction from the prefecture(s), 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. The MHLW shall also ask the prefecture that has jurisdiction over the location of the importer to ensure that recall by the importer and other necessary measures are taken.

If all the foods subsequent to customs clearance are still stored in a bonded warehouse, the quarantine station shall, in addition to the above measures, temporarily instruct the importer to discard, return or otherwise deal with all the stored foods as necessary, and to follow the instructions from the prefecture that has jurisdiction over its location.

- (2) If a prefectural organization identifies a food in violation of the Law, the prefecture shall report the fact to the MHLW, which 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 inspections at the time of importation.
- (3) The quarantine station shall instruct the importers who have violated the Law to take the following actions to prevent the recurrence of such a violation.
  - 1) The importer should investigate the causes of the violation and report the results immediately to the quarantine station.
  - 2) When the importer plans to import the same food again, the importer must confirm that the causes have been identified in step 1), and that the required improvements have already been made. The importer may also need to carry out field investigations in the exporting country as necessary, as well as inspections and/or sample checks for each check item that did not previously comply with the Law, and report the results to the quarantine station.
- (4) The MHLW may order a prohibition or suspension of business with respect to importers who commit repeated violations, or to food importers etc. who caused harm or posed risk to public health by violating the Law, in accordance with Section 2, Article 55 of the Law, in order to make them improve the causes of the violence, prevent the recurrence, and take other required sanitary measures.
- (5) The quarantine station may make an indictment where the case of violation is serious and malicious.
- (6) In accordance with the provision in Article 63 of the Law, the MHLW shall list the names and addresses of importers who have violated the Law or any actions taken under the Law, as well as the names of the violating imported foods, for the purpose of disclosing information to the public regarding any potential harm from the viewpoint of food sanitation (in principle, the list includes importers who are subject to administrative actions in writing, concerning the violation. However, if the violation is not very serious and if the importer remedies it immediately, such importers are excluded from the list). The list is published on the MHLW website, which is updated every one or two weeks. In

addition to the listing of the names of violating importers, the remedies and causes of the violations shall also be published as soon as the information is available.

### 7. Other items required for the implementation of monitoring and guidance

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

The quarantine stations shall inform importers, customs brokers and bonded warehouse operators, of the monitoring plan to ensure smooth implementation of monitoring inspection.

The MHLW shall publish other related information such as the issuance of inspection orders and the enhancement of inspections.

(2) Announcement of the results of monitoring, implemented in accordance with the monitoring plan

The MHLW shall publish a summary of monitoring inspection status for FY 2006 in around June of the following fiscal year. The summary shall include the actual implementation of monitoring inspections and other inspections under inspection orders on imported foods, the results of these inspections, monitoring and guidance given to the importers, their brief results, and the actual implementation of sanitary measures taken in exporting countries with their results. The current situation is also published in the middle of the fiscal year.

(3) Development and skill enhancement of personnel in charge of food sanitation

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

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

The MHLW and quarantine stations shall implement systematic checks and instructions on the control of tests and inspections, to ensure that monitoring inspection and other related operations are conducted appropriately.

#### **Schedule 1**

| Seneuale 1  |   | i  |   |  |
|---|---|--|---|--|
| Food type   | Category of items inspected <sup>*2, *3</sup>   | Number of specimens<br>inspected <sup>*1, *2</sup> | Total number of<br>specimens<br>inspected <sup>*1</sup> |  |
| Livestock foods   | Antibiotics   | 2,850  |   |  |
| Beef, pork, chicken, horse meat, poultry meat, and other      | Residual agricultural chemicals   | 1,700  | 5,200   |  |
| meats   | Standards for constituents  | 650  |   |  |
| Processed livestock foods                                     | Antibiotics   | 1,050  | 3,950   |  |
| Natural cheeses, processed meat products, ice cream,          | Additives   | 1,300  |   |  |
| frozen products (meat products), and other products           | Standards for constituents  | 1,600  |   |  |
| Seafood products  | Antibiotics   | 3,100  | 5.150   |  |
| Bivalves, fish, shellfish (shrimps and prawns, crabs) and     | Residual agricultural chemicals   | 850  |   |  |
| other products  | Additives   | 300  | 5,150   |  |
|   | Standards for constituents  | 900  |   |  |
| Processed seafood   | Antibiotics   | 4,150  |   |  |
| Processed fish products (fillet, dried or minced fish, etc.), | Residual agricultural chemicals   | 250  | 12 500  |  |
| frozen products (aquatic animals and fish), processed fish    | Additives   | 2,250  | 12,700  |  |
| roe products, and other products                              | Standards for constituents  | 6,050  |   |  |
| Agricultural foods  | Antibiotics   | 650  |   |  |
| Vegetables, fruit, wheat and barley, corn, beans, peanuts,    | Residual agricultural chemicals   | 18,000   |   |  |
| nuts, seeds, and other products                               | Additives   | 600  | 24.250  |  |
|   | Standards for constituents  | 750  | 24,250  |  |
|   | Mycotoxins  | 2,700  |   |  |
|   | GMO   | 1,550  |   |  |
| Processed agricultural foods                                  | Residual agricultural chemicals   | 4,800  |   |  |
| Frozen products (processed vegetables), processed             | Additives   | 4,300  |   |  |
| vegetable products, processed fruit products, spices,         | Standards for constituents  | 1,950  | 13,500  |  |
| instant noodles, and other products                           | Mycotoxins  | 2,300  |   |  |
|   | GMO   | 150  |   |  |
| Other foods   | Antibiotics   | 150  |   |  |
| Health foods, soups, flavorings and seasonings, sweets,       | Residual agricultural chemicals   | 250  |   |  |
| edible oils and fat, frozen products, and other products      | Additives   | 2,950  | 4,900   |  |
|   | Standards for constituents  | 1,250  |   |  |
|   | Mycotoxins  | 300  |   |  |
| Drinks and beverages  | Residual agricultural chemicals   | 300  | 2,550   |  |
| Mineral water, soft drinks, alcoholic beverages, and other    | Additives   | 1,200  |   |  |
| products  | Standards for constituents  | 900  | 2,550   |  |
|   | Mycotoxins  | 150  |   |  |
| Additives<br>Equipment, containers and packages<br>Foys       | Standards for constituents  | 1,300  | 1,300   |  |
| Foods subject to enhanced inspection                          | Antibiotics, residual agricultural<br>chemicals, additives, standards for<br>constituents, mycotoxins, and<br>GMO | 4,500  | 4,500   |  |
| Overall total *1  |   |  | 78,000  |  |

\*1 The total numbers of specimens inspected are approximate aggregations of the numbers inspected in the relevant inspection categories.

\*2 In comparison with FY 2005, residual agricultural chemicals are added for the categories of seafood products, processed seafood and other foods and drinks and beverages, while antibiotics etc. are added for the categories of agricultural foods and other foods.

\*3 Examples of inspected items

- Antibiotics: antibiotics, antibacterial material residues, and others
- Residual agricultural chemicals: organophosphorus, organochlorines, carbametes, pyrethroids, and others
- Additives: sorbic acid, benzoic acid, sulfur dioxide, colorants, polysorbate, sodium cyclamate, TBHQ (tert-Butylhydroquinone), • fungicide, and others
- Standards for constituents: items defined in the standards for constituents (such as the number of bacteria, coliform bacteria, and Vibrio parahaemolyticus), pathogenic microorganisms (such as enterohemorrhagic Escherichia coli O157, and listeria), shellfish poisons (diarrheic shellfish poisons, paralytic shellfish poisons), and others
- Mycotoxins: aflatoxin, deoxynivalenol, patulin, and others
- GMO: Genetically modified organisms whose safety has not yet been certified

## Schedule 2

|   | Risk factors at the time of<br>importation<br>(typical examples)   | Items to be checked in advance  | Items to be checked regularly<br>(including at the time of first<br>importation)  | Items to be checked during the transportation and storage processes   |
|---|--|---|---|---|
| <ul> <li>(Items in common)</li> <li>Mixing with rotten or deteriorated matter, or unclean or foreign matter</li> <li>Contamination by pathogenic microorganis</li> <li>Use of unapproved additi</li> <li>Use of additives for unapproved purposes, or use of additives that does not conform with the standards for their use</li> <li>Non-conformity with standards (soft drinks, m</li> </ul> | toxic materials in the food<br>• Mixing with rotten or<br>deteriorated matter, or<br>unclean or foreign matter | • Taking measures to prevent<br>hazardous or toxic materials<br>from being included   | • Ensuring that no hazardous<br>or toxic materials are<br>included, by regular testing<br>and inspection  | <ul> <li>Whether any corruption or<br/>deterioration occurred due to<br/>accidents or improper<br/>temperature control</li> <li>Whether the food processed by<br/>salting or other measures is<br/>stored outdoors for a long time</li> </ul> |
|   | Contamination by<br>pathogenic microorganism   | • Taking measures to prevent<br>contamination by pathogenic<br>microorganisms   | • Ensuring that no pathogenic<br>microorganisms are present<br>through regular testing and<br>inspections   | • Whether proper temperature<br>control is implemented to<br>prevent the growth of<br>microorganisms  |
|   | • Use of additives for<br>unapproved purposes, or the<br>use of additives that does<br>not conform with the    | <ul> <li>Ensuring that no unapproved additives are used, including those used for raw material</li> <li>Ensuring that additives that do not comply with the standards are not used, and that the appropriate amount is used</li> </ul>  | • Ensuring that no<br>unapproved additives are<br>used, and that the proper<br>amount of additives is used,<br>by regular testing and<br>inspection   |   |
|   | standards (soft drinks, meat products, frozen foods, and   | <ul> <li>Ensuring that standards for<br/>constituents, manufacturing and<br/>processing standards, and other<br/>standards are met</li> <li>Ensuring that no sterilization by<br/>irradiation etc. is conducted<br/>(excluding those for controlling<br/>germination of potatoes)</li> </ul>  | manufacturing process and the raw materials   | <ul> <li>Compliance with storage<br/>standards</li> <li>Checking whether any acciden<br/>has occurred</li> </ul>  |
|   |  | <ul> <li>Requesting manufacturers and<br/>producers to provide the formal<br/>names and percentages of raw<br/>materials and additives used in<br/>the manufacturing process and<br/>the final products</li> <li>Ensuring that the final product<br/>conforms with the Food<br/>Sanitation Law by testing and<br/>improvement to the final product and the final product</li> </ul> | mal the Food Sanitation Law,<br>w by checking the final<br>in products<br>nd  |   |
| products and<br>related<br>processed<br>foods   | • Mycotoxins such as<br>aflratoxin and patulin<br>(cereals, beans, spices,<br>apple juice, etc.)               | <ul> <li>inspection, as necessary</li> <li>Taking measures to prevent<br/>mold from growing at the time<br/>of ingathering and<br/>transportation/storage</li> </ul>  | • Ensuring that no<br>mycotoxins are present by<br>regular testing and<br>inspection  | • Whether proper control of<br>temperature and humidity is<br>carried out to prevent the<br>growth of mold  |
|   | • Natural poisons such as cyanogenic glycosides  | <ul> <li>Checking whether any natural poisons are present in the food</li> <li>Measures should be taken to remove any natural poisons, during the manufacturing, processing and other processes</li> <li>Taking measures to prevent any hazardous or toxic plants from being included</li> </ul>  | • Ensuring that no natural poisons are present by regular testing and inspection  |   |
|   | • Radioactive contamination (mushrooms, herbs, etc.)   | • Ensuring that harvesting area is not contaminated by radioactivity  | • Checking the level of radioactivity by regular testing and inspection   |   |
|   | • Pathogenic microorganisms<br>such as enterohemorrhagic<br><i>Escherichia coli</i> O157<br>(fresh vegetables) | • Taking measures to prevent<br>contamination by pathogenic<br>microorganisms   | • Ensuring that no pathogenic<br>microorganisms are present<br>by regular testing and<br>inspection   | • Whether proper temperature<br>control is carried out to preven<br>the growth of any<br>microorganisms   |
|   | Residual agricultural<br>chemicals   | <ul> <li>Checking how agricultural chemicals are used</li> <li>Raw materials of processed foods must conform with residue standards</li> </ul>  | <ul> <li>Ensuring compliance with<br/>proper use in terms of<br/>method and volume of<br/>agricultural chemicals,<br/>before and after ingathering</li> <li>Ensuring that residual<br/>agricultural chemicals are<br/>below proper levels, by<br/>regular testing and<br/>inspection</li> </ul> | Checking whether any<br>agricultural chemicals were<br>used after ingathering   |

|  | • GMO foods whose safety has not been certified (corn, papaya, etc.)  | <ul> <li>Checking whether GMO food<br/>has been approved</li> <li>Taking measures to prevent any<br/>uncertified GMO food from<br/>being included</li> </ul>   | • Ensuring that no GMO food<br>whose safety has not been<br>certified is included through<br>regular testing and<br>inspection   | carried out  |
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|  | • Use of additives that may<br>mislead consumers in the<br>determination of quality and<br>freshness (fresh vegetables)                       | • Ensuring that no colorant,<br>bleach, or other additives that<br>may mislead consumers in the<br>determination of quality or<br>freshness have been used   | • Checking the types of<br>additives used through<br>regular testing and<br>inspection   |  |
| Livestock<br>products and<br>related<br>processed<br>foods | • Pathogenic microorganisms<br>such as Enterohemorrhagic<br><i>Escherichia coli</i> O157 and<br>listeria (meat, natural<br>cheeses, etc.)     | Taking measures to prevent<br>contamination by pathogenic<br>microorganisms  | • Ensuring that no pathogenic microorganisms are present through regular testing and inspections   | • Whether proper temperature<br>control is implemented to<br>prevent the growth of<br>microorganisms   |
|  | • Radioactive contamination (reindeer meat, beef extracts, etc.)  | • Ensuring producing area is not contaminated by radioactivity   | • Checking the level of radioactivity by regular testing and inspection  |  |
|  | • Errors concerning sanitation certificates (meat and meat products)  | • Checking each item on the<br>sanitation certificate issued by<br>the producing and/or exporting<br>country   |  | • Ensuring that a complete sanitation certificate is attached  |
|  | Bovine spongiform<br>encephalopathy (beef and<br>beef-derived products)   | <ul> <li>No BSE animal has been found<br/>in the producing area</li> <li>No specified risk material<br/>(SRM) is included in the<br/>product</li> <li>No beef etc. originated from<br/>countries or areas from which<br/>import is prohibited is not<br/>included or used</li> </ul> |  |  |
|  | • Bovine spongiform<br>encephalopathy (mutton,<br>goat meat, etc.)  | <ul> <li>No BSE animal has been found<br/>in the producing area</li> <li>No specified risk material<br/>(SRM) is included in the<br/>product</li> </ul>  |  |  |
|  | • Residual agricultural<br>chemicals, veterinary drugs,<br>and feedstuff additives  | <ul> <li>Checking how agricultural chemicals, veterinary drugs and/or feedstuff additives were used</li> <li>Raw materials of processed foods must conform with residue standards</li> </ul>   | <ul> <li>Checking compliance with<br/>proper dose, administration,<br/>and drug holidays for<br/>veterinary drugs and<br/>feedstuff additives</li> <li>Checking levels of residual<br/>agricultural chemicals,<br/>veterinary drugs, and<br/>feedstuff additives, by<br/>regular testing and<br/>inspection</li> </ul> |  |
|  | • Use of additives that may mislead consumers in the determination of quality and freshness (meat)  | • Ensuring that no colorant or<br>other additives that may<br>mislead consumers in the<br>determination of quality or<br>freshness have been used  | • Checking the types of<br>additives used through<br>regular testing and<br>inspection   |  |
| Seafood and<br>processed<br>seafood                        | • Pathogenic microorganisms<br>such as Vibrio<br>parahaemolyticus (fillet,<br>shelled and/or peeled fish<br>and shellfish to be eaten<br>raw) | <ul> <li>Taking measures to prevent<br/>contamination by pathogenic<br/>microorganisms in the use of<br/>cleaning water at processing<br/>plants, etc.</li> <li>Compliance with processing<br/>standards</li> </ul>  | • Ensuring that no pathogenic microorganisms are present through regular testing and inspections   | <ul> <li>Compliance with storage<br/>standards</li> <li>Whether proper temperature<br/>control is carried out to prevent<br/>the growth of any<br/>microorganisms</li> </ul> |
|  | • Non-conformity with<br>standards for constituents,<br>standards for processing,<br>and standards for storage for<br>oysters eaten raw       | • Checking whether the standards<br>for processing in the producing<br>country are at the same level as<br>in Japan  | • Ensuring conformity with<br>the standards for<br>constituents by regular<br>testing and inspection   | • Compliance with storage standard   |
|  | • Diarrheic shellfish poisons<br>or paralytic shellfish<br>poisons (shellfish)  | • Checking that clams are<br>gathered in sea areas where<br>proper monitoring of shellfish<br>poisoning is implemented   | • Ensuring that no shellfish<br>poisons are present by<br>regular testing and<br>inspection  |  |

|  | Mixing with poisonous<br>blowfish  | <ul> <li>Ensuring that only fish of the approved type(s) are imported</li> <li>Taking measures to prevent different types of blowfish from being mixed, through proper identification of fish types</li> </ul>  |   | <ul> <li>Checking the certificates issued<br/>by the government of the<br/>exporting country</li> <li>Ensuring that no different types<br/>of blowfish are included,<br/>through proper identification of<br/>fish types</li> </ul> |
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|  | • Mixing with poisonous fish<br>such as fish with ciguatoxin<br>(southern groupers, parrot<br>fish, barracudas, etc.)              | <ul> <li>Checking the seas where the<br/>fish are caught</li> <li>Taking measures to prevent<br/>poisonous fish from being<br/>mixed in, through proper<br/>identification of fish types</li> </ul>   |   | • Ensuring that no poisonous fish<br>are included, through proper<br>identification of fish types   |
|  | Residual veterinary drugs<br>and feedstuff additives   | <ul> <li>Checking on the use of<br/>veterinary drugs and feedstuff<br/>additives</li> <li>Raw materials of processed<br/>foods must conform with the<br/>residue standards</li> </ul>   | <ul> <li>Checking compliance with<br/>proper dose, administration,<br/>and drug holidays for<br/>veterinary drugs and<br/>feedstuff additives</li> <li>Checking the levels of<br/>residual veterinary drugs<br/>and feedstuff additives, by<br/>regular testing and<br/>inspection</li> </ul> |   |
|  | • Use of additives that may<br>mislead consumers in the<br>determination of quality and<br>freshness (fresh fish and<br>shellfish) | • Ensuring that no colorant,<br>carbon monoxide or other<br>additives that may mislead<br>consumers in the determination<br>of quality or freshness have<br>been used   | • Checking the types of additives used, by regular testing and inspection   | • Checking the color of the product (scarlet, etc.)   |
| Health foods<br>in general                           | • Containing drug substance  | <ul> <li>Ensuring that no drug<br/>substances designated by the<br/>Pharmaceutical Affairs Law are<br/>included</li> <li>Checking the history of<br/>ingestion in the exporting<br/>country</li> </ul>  | • Ensuring that no drug<br>substance is included by<br>testing and inspection   |   |
| Additives and<br>their<br>preparation                | <ul> <li>Use of unapproved additive</li> <li>Non-conformity with the standards</li> </ul>  | <ul> <li>Checking the correct names of<br/>the additives and the types of<br/>their source materials and<br/>extractants</li> <li>Checking the formal names and<br/>content rates if additive<br/>preparation is used</li> <li>Ensuring that no unapproved<br/>additives are used</li> <li>Ensuring that the product<br/>conforms to the related<br/>standards, such as standards for<br/>constituents and manufacturing<br/>standards</li> </ul> | • Ensuring conformity with<br>the standards for<br>constituents, by regular<br>testing and inspection   | Checking compliance with storage standards  |
| Equipment,<br>containers and<br>packages, and<br>toy | • Non-conformity with standards  | <ul> <li>Checking the materials, shape, colors and patterns, targeted ages, and the purpose of use</li> <li>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</li> </ul>  | • Ensuring that the raw<br>materials conform with<br>general raw material<br>standards and standards for<br>each material, by regular<br>testing and inspection   |   |