

Notice No.0329 Article 1 of the Department of Food Safety

March 29 , 2010

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 2010

We appreciate the appropriate implementation of the monitoring plan based on the Imported Foods Monitoring and Guidance Plan for FY 2009, as well as the implementation of monitoring and 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 2010 (hereinafter referred to as “the Imported Foods Monitoring and Guidance Plan for FY 2010”), as described in Annex 1, under Article 23, paragraph 1 of the Food Sanitation Act (Act No. 233 of 1947). The Imported Foods Monitoring and Guidance Plan for FY 2009 is a plan concerning the monitoring and guidance of imported foods, additives, equipment, containers and packages by the national government which was published in an official gazette in accordance with paragraph 3 of the same Article.

We ask you to appropriately implement the monitoring and guidance tasks in conformity with the Imported Foods Monitoring and Guidance Plan for FY 2010.

Also, we would add that a notice has been given to prefectural governments, etc. as Annex 2.

(Annex 1)

## Imported Foods Monitoring and Guidance Plan for FY 2010

The total number of foods, additives, equipment, containers and packages, and toys (hereinafter referred to as “the food(s)”) imported into Japan was about 1.76 million annually and 31.55 million tons in volume on a notification basis (based on actual figures for 2008). The food self-sufficiency ratio is about 40% in Japan (food self-sufficiency ratio based on the total calorific value supplied; based on the Food Balance Sheet for FY 2008 by the Ministry of Agriculture, Forestry and Fisheries).

In light of actual conditions of the foods, etc. imported into Japan (hereinafter referred to as “the imported foods”), in FY 2009, 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 increasing the number of food sanitation inspectors and introducing testing equipment and reinforced import inspections, such as monitoring inspection that is systematically implemented every fiscal year (hereinafter referred to as “the monitoring inspection”) for the purpose of monitoring sanitary conditions of various foods based on the provision of Article 28 of the Food Sanitation Act (Act No. 233 of 1947; hereinafter referred to as “the Act”) and inspection orders requiring importers to have imported foods with a high probability of violating the Act inspected each time that the goods are imported (hereinafter referred to as “the inspection order”). They also conducted consultations and survey on individual issues with exporting countries and also conducted surveys concerning exporting countries’ safety measures in order to prompt exporting countries to take appropriate sanitation measures. Moreover, they conducted on-site inspections on sanitation control in exporting countries with relation to bovine spongiform encephalopathy (hereinafter referred to as “BSE”), etc.

At a Japan-China summit meeting in October 2009, Japan proposed a “Japan-China Food Safety Promotion Initiative,” calling for regular consultations between the two countries for the enhancement of food safety. China expressed its approval for the initiative. The two countries’ ministers in charge of food safety reached an agreement at the recent Summit Meeting to create at an early date a framework for cooperation that includes substantial content so as to provide peace of mind to citizens. Officials of the two countries then began consultations on specific steps toward conclusion of a treaty.

At a meeting of health ministers of Japan, China and South Korea, the three countries signed a memorandum calling for the establishment of a framework for consultations to promote exchanges and cooperation in the field of food safety among the three countries.

In relation to these efforts, the interim report for the Inspection Results of the

Imported Foods Monitoring and Guidance Plan for FY 2009, published in December 2009, provided preliminary figures of approximately 900,000 cases of notification of imports and some 12 million tons in imported volume between April and September 2008. Out of these cases, approximately 108,000 of them, or 12.0% of the overall number of notifications, were inspected. Among the inspected cases, 660 were identified as violations.

In FY 2010, the MHLW will seek to further promote the above measures as well as reexamining factors of inspection in consideration of monitoring inspection results and survey results on the condition of sanitation control in exporting countries in FY 2009. The MHLW will also continue to further expand inspection items at the time of importation for steady execution of the Positive List system, which in general prohibits sales of food products containing amounts of residual agricultural chemicals etc. that exceed the amount determined as not causing health damage (hereinafter referred as “the Positive List system”), and also request the promotion of sanitary measures during the production and processing stage in exporting countries, and, as necessary, conduct on-site inspections in exporting countries to confirm the management of residual agricultural chemicals, etc. Furthermore, for foods subject to inspection orders for residual agricultural chemicals, etc., there is the possibility of insufficient management of residual agricultural chemicals and changes in the agricultural chemicals being used in exporting countries, and there is fear that agricultural chemicals other than those subject to inspection orders may exceed standard values consequently. Therefore, monitoring inspections must be strengthened for the purpose of verifying the management of residual agricultural chemicals, etc. in exporting countries. Also, taking account of the increase in restrictions on toys and revisions etc. of other codes and standards based on Article 18 of the Act, instructions will be given on the implementation of periodic, voluntary inspections for importers regarding mainly the new codes and standards, and monitoring inspections will be expanded.

With regard to ensuring that beef exported to Japan is free of BSE, the MHLW will continue to verify the status of conformity with an export program for Japan under the control of governments of exporting countries through on-site inspection and inspections at the time of importation.

In addition to these measures, the MHLW will make efforts to prevent problems from occurring by continuing to encourage importers to voluntarily conduct sanitation control in exporting countries and urging exporting countries to actively gather information on sanitary measures.

## 1. Purpose

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

## 2. Effective period of the Plan

The Plan shall be effective from April 1, 2010, to March 31, 2011.

## 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 production, manufacturing and processing (hereinafter referred to as “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) Collection of basic data on imported foods through the import-notification documents submitted under Article 27 of the Act, and checking of the above data as to their compliance with the specifications and standards for foods (hereinafter referred as “the standards”) under Article 11 and Article 18 of the Act
- (2) Implementation of monitoring inspection under Article 28 of the Act 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 Act for imported foods suspected to have a high probability of violating the Act in order to prevent harm to public health from the perspective of food sanitation
- (4) 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 Article 8 or Article 17 of the Act.
- (5) The MHLW shall provide guidance and issue an order to importers who repeatedly violate the Act to stop or suspend their importation business under Article 55, paragraph 2 of the Act with the aim of improving causes for violations, etc.
- (6) In order to promote sanitary measures during the production process in exporting countries, the MHLW shall conduct the following: (i) provide information on food-sanitation regulations to embassies and such located in Japan and to importers, (ii) hold bilateral discussions, (iii) conduct on-site inspections, and (iv) provide technical support.
- (7) By holding training courses and giving instructions before importing, provision of

support for voluntary efforts made by importers to control and maintain food sanitation to fulfill their responsibilities as business operators handling foods

- (8) When a violation of the Act has been identified, instructions on discarding relevant foods or other measures shall be taken. In addition, measures to prevent recurrence of such violation shall be taken, including publishing examples of violations and giving guidance to importers.
- (9) 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 monitor and give guidance on imported foods. If a quarantine station or prefectural organization identifies any violation of the Act, the MHLW, the quarantine station and the prefecture concerned shall cooperate with each other to take appropriate measures to ensure that the importer concerned 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, Article 9, paragraph 2, or Article 16 of the Act, (ii) that the food is not under an import ban in accordance with Article 8, paragraph 1 or Article 17, paragraph 1 of the Act, (iii) that the additives comply with regulations under Article 10 of the Act, and (iv) that it complies 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 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 sanitation, 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 imported foods, their volume, and the impact of violations on public health with respect to each food group. In addition, the MHLW shall make a monitoring plan, taking into account the conditions of regulations on agricultural chemicals, etc., status of their use and cases of detection of agricultural chemicals, etc. in other countries, in order to steadily conduct the Positive List system.

The monitoring plan for FY 2010 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 give 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 around the middle of FY 2010 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 producing 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 prefectural organization, etc., the MHLW shall instruct the quarantine stations to reinforce inspection of the relevant food as necessary.

For reinforcement of inspection of residual agricultural chemicals, etc., in light of the control system for residual agricultural chemicals, etc. 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) Inspections other than the monitoring inspection under 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 Article 26 of the Act

When the Minister of the Health, Labour and Welfare deems it necessary in order to prevent any harm to food sanitation, the Minister shall order importers to have imported foods with a high probability of violating the Act inspected each time that the foods are imported.

1) Issuance of an inspection order

In the following cases and other cases, the Minister of Health, Labour and Welfare shall issue an inspection order concerning imported foods that are regarded to have a high probability of violating the Act.

- i. If imported foods have caused or are likely to cause harm to health in the exporting country or in Japan, relevant imported foods imported from the same exporting country, or by the same manufacturer or processor shall be immediately subject to an inspection order.
- ii. If the same imported foods exported from the same country or by the same manufacturer or processor are found in the monitoring inspection to have violated the Act several times with regard to residual agricultural chemicals, etc., all or part of the relevant imported foods shall be subject to an inspection order, taking into account the conditions of regulations and sanitation control in the exporting country and history of compliance with the Act concerning the imported foods.
- iii. When publishing the addition of new foods to a list of foods subject to inspection order, their health effects should be explained in an easy-to-understand way.

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, like in the following cases, the Minister 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, etc. 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
- ii. For imported foods subject to an inspection order concerning residual agricultural chemicals, etc. for which there have been no violations for the last

two years or the number of the imported foods inspected under the order is more than 300, where no violation occurs when the inspection order is temporarily cancelled and monitoring inspection is 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 (however, if a violation is identified during the period of reinforced monitoring inspection, an inspection order will be issued).

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

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 Act 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-sanitation problems from the governments of the exporting countries in cooperation with related ministries in order to ensure safety of imported foods and publish major cases on its website (hereinafter referred to as “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, instruct the importer(s) to inspect and recall them if necessary. The MHLW shall also and instruct the quarantine stations to reinforce inspection of those foods and publish the progress of countermeasures.

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

The MHLW shall support promotion of sanitation 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-sanitation regulations and related standards in Japan

The MHLW shall provide information on sample cases of violations of the Act 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 will also link its web pages to those in English of the Japan External Trade Organization (JETRO), which describe food-sanitation regulations in Japan, in order to promote the dissemination of information in English version.

The MHLW shall promote the understanding of Japanese food-sanitation regulations by governments as well as producers, manufacturers and processors (hereinafter referred to as the “producers, etc.”) in the exporting countries by providing such information through means such as explanatory meetings to embassies etc. located in Japan when existing codes and standards are reviewed and through seminars on food-sanitation regulations held by the Japan International Cooperation Agency (JICA).

## (2) Bilateral discussions and on-site inspections

For imported foods that are subject to inspection orders at the time of importation, as well as those with a high probability 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 sanitation measures, such as control of sanitation in the production, manufacture, and processing stages, the enhancement of monitoring systems, and the introduction of pre-export inspections in the exporting countries

Moreover, as the majority of cases of violations were discovered in FY 2009 in which imported foods violated Article 6 of the Act due to the presence of toxic or hazardous substances such as mycotoxins, or Article 11 of the Act concerning residual agricultural chemicals, etc., the MHLW plans in FY 2010 to actively demand exporting countries, especially those whose exported foods have repeatedly violated laws and regulations, to introduce proper food-sanitation measures. In addition, for smooth implementation of the Positive List system and ensured sanitation for imported beef and other foods, if it is necessary to verify sanitation measures in the production stage etc. in the exporting countries, the MHLW shall dispatch experts to the exporting countries of the relevant imported foods in order to actively confirm the sanitation measures in the exporting countries. Furthermore, to prevent problems from occurring, the MHLW shall promote sanitation measures in exporting countries by systematically collecting information on safety measures for foods to be exported to Japan and by conducting on-site inspections.

## (3) Technical support, etc.

The MHLW and quarantine stations shall provide technical support to exporting

countries as necessary so as to contribute to the strengthening of monitoring systems and the improvement of testing techniques for residual agricultural chemicals, etc. by dispatching experts and accepting trainees through JICA Technical Cooperation Projects.

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

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, Article 3, paragraph 1 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 sanitation 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 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 notification, along with providing to importers, when it is deemed appropriate, information on violating imported foods, newly established specifications or standards, food-sanitation regulatory systems in the exporting countries, and other information obtained from the producers, thereby supporting the importers in achieving 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. Especially for processed food, importers will be instructed to conduct necessary confirmation in the exporting countries at the stages of acquiring raw materials, production and processing, storing, and transportation based on the “Guidelines on Hygiene Control of Import Processed

Foods” and taking consideration of the circumstances of development and implementation of restrictions regarding food hygiene and hygiene control standards for manufacturers in exporting countries.

Furthermore, the quarantine stations provide complete instructions for checking that production etc. of imported foods are not illegal in exporting countries and that raw materials, additives, manufacturing process, inspection data, and all other aspects conform to the Act. The ministry performs examinations and develops testing methods related to residual agricultural chemicals, etc. in processed foods that contribute to the importers' verification of management of raw materials.

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 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 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 Act (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.

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 a food 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 standards for constituents of the food, and/or the use of 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 of standards for constituents 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 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 concerned when a violation of the Act has been identified.

(6) Enhancement of knowledge of food sanitation 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) - (5) and make them dispatch their staff members who handle imported foods to seminars held by the associated organizations to improve their knowledge of food sanitation for the purpose of ensuring the safety of imported foods.

The quarantine stations shall also prompt the importers to consult in advance with the prefectures 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

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

The quarantine station that has accepted the import notification for the relevant food(s), the MHLW, and/or the prefecture(s) concerned 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 in

implementing other required measures including the reinforcement of inspection upon importation.

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

The quarantine stations shall instruct the importers to discard, return or otherwise respond as necessary, and instruct them to report measures taken against food violations.

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

The prefectures that have jurisdiction over the locations of importers shall instruct them to recall the food and instruct them to report measures taken against food violations.

To facilitate instructions, etc. on recall 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 appropriately taken.

The quarantine station shall 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. In addition, the MHLW shall strive to share information with the Cabinet Office.

(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 ministry receives correspondence from a prefectural organization 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 removal inspections (removal or inspection based on the provision of Article 28, paragraph 1 of the Act) and/or voluntary inspections of sales, 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, MHLW shall promptly report foods for later importation to quarantine stations and foods in domestic distribution to prefectural organizations 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 discovery of the 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 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, etc. who have caused harm or posed risks to public health by violating the Act, in accordance with Article 55, paragraph 2 of the Act (hereinafter referred to as the “prohibition or suspension of business of importers”), in order to make them improve the causes of the violation, prevent recurrence, and take other required sanitary measures.

In addition, the MHLW shall 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 Article 55, paragraph 2 of the Act.” 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 may indict if a violation is serious and malicious, for example, submission of a false import notification document and illegal importation of foods violating the Act and or foods with a high probability of suspicion, as well as 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 and addresses 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 and addresses for one year), 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 due to the violation. However, 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 and other persons concerned

On its website and by other means, the MHLW and/or quarantine stations shall provide the general public and other persons concerned with information on ensuring the safety of imported foods.

##### (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, the issuance of inspection orders and notices on 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 and the enhancement of inspections.

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

The MHLW shall publish a summary of monitoring inspection status based on this plan 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 and the results of these inspections, monitoring and guidance given to the importers and their brief results. The situation in the middle of the fiscal year (April to September) shall also be published about November.

##### (3) Efforts for risk communication concerning food safety

The MHLW shall 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 through efforts for risk communication concerning food safety and strive to gain appropriate understanding of food safety etc.

##### (4) Others

The quarantine stations shall conduct activities, such as allowing general consumers to visit them, as long as their operations such as monitoring and instruction are not obstructed, for the purpose of gaining broad 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 sanitation

The MHLW shall hold seminars and training to improve the knowledge and skills with regard to 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, 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*2
Livestock foods Beef, pork, chicken, horse meat, poultry meat, and other meats	Antibacterial substances	2,250	4,880
	Residual agricultural chemicals	1,900	
	Standards for constituents	700	
	Radiation irradiation	30	
Processed livestock foods Natural cheeses, processed meat products, ice cream, frozen products (meat products), and other products	Antibacterial substances	2,400	7,510
	Residual agricultural chemicals	900	
	Additives	1,900	
	Standards for constituents	2,300	
	Radiation irradiation	10	
Seafood products Bivalves, fish, shellfish (shrimps, prawns, crabs) and other products	Antibacterial substances	2,900	6,570
	Residual agricultural chemicals	2,000	
	Additives	200	
	Standards for constituents	1,450	
	Radiation irradiation	20	
Processed seafood Processed fish products (fillet, dried or minced fish, etc.), frozen products (aquatic animals and fish), processed fish roe products, and other products	Antibacterial substances	3,950	12,360
	Residual agricultural chemicals	2,900	
	Additives	1,950	
	Standards for constituents	3,550	
	Radiation irradiation	10	
Agricultural foods Vegetables, fruit, wheat, barley, corn, beans, peanuts, nuts, seeds, and other products	Antibacterial substances	900	22,280
	Residual agricultural chemicals	15,500	
	Additives	1,000	
	Standards for constituents	1,200	
	Mycotoxins	2,950	
	GMOs	700	
	Radiation irradiation	30	
Processed agricultural foods Frozen products (processed vegetables), processed vegetable products, processed fruit products, spices, instant noodles, and other products	Antibacterial substances	100	17,150
	Residual agricultural chemicals	8,000	
	Additives	3,800	
	Standards for constituents	2,750	
	Mycotoxins	1,950	
	GMOs	100	
	Radiation irradiation	450	
Other foods Health foods, soups, flavorings, seasonings, sweets, edible oils, fat, frozen products, and other products	Residual agricultural chemicals	150	4,800
	Additives	3,050	
	Standards for constituents	900	
	Mycotoxins	700	
Drinks and beverages Mineral water, soft drinks, alcoholic beverages, and other products	Residual agricultural chemicals	350	2,200
	Additives	800	
	Standards for constituents	950	
	Mycotoxins	100	
Additives Equipment, containers and packages Toys	Standards for constituents	2,250	2,250
Foods subject to enhanced inspection*3	Antibacterial substances, residual agricultural chemicals, additives, standards for constituents, mycotoxins, GMOs, radiation	5,000	5,000
Overall total*2			85,000

\*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
- 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 monocytogenes*), 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

\*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"> <li>Containing hazardous or toxic materials in the food</li> <li>Mixing with rotten or deteriorated matter, or unclean or foreign matter</li> </ul>	<ul style="list-style-type: none"> <li>Taking measures to prevent hazardous or toxic materials from being included at the point of receiving raw material and manufacturing and processing process</li> </ul>	<ul style="list-style-type: none"> <li>Ensuring that no hazardous or toxic materials are included, by regular testing and inspection</li> </ul>	<ul style="list-style-type: none"> <li>Whether any corruption or deterioration occurred due to accidents or improper temperature control</li> <li>Whether the food processed by salting or other measures is stored outdoors for a long time</li> <li>Whether the any contamination occurred with pesticides, etc. used in the warehouse</li> </ul>
	<ul style="list-style-type: none"> <li>Contamination by pathogenic microorganism</li> </ul>	<ul style="list-style-type: none"> <li>Taking measures to prevent contamination by pathogenic microorganisms</li> </ul>	<ul style="list-style-type: none"> <li>Ensuring that no pathogenic microorganisms are present through regular testing and inspections</li> </ul>	<ul style="list-style-type: none"> <li>Whether proper temperature control is implemented to prevent harm due to the growth of microorganisms</li> </ul>
	<ul style="list-style-type: none"> <li>Use of unapproved additives</li> <li>Use of additives for unapproved purposes, or the use of additives that does not conform with the standards for their use, such as overuse</li> </ul>	<ul style="list-style-type: none"> <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>	<ul style="list-style-type: none"> <li>Ensuring that no unapproved additives are used, and that the proper amount of additives is used, by regular testing and inspection</li> </ul>	
	<ul style="list-style-type: none"> <li>Non-conformity with standards (soft drinks, meat products, frozen foods, and other products)</li> </ul>	<ul style="list-style-type: none"> <li>Ensuring that standards for constituents, manufacturing and processing standards, and other standards are met</li> <li>Ensuring that no sterilization by irradiation, etc. is conducted (excluding those for controlling germination of potatoes)</li> <li>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</li> <li>Ensuring that the final product conforms with the Food Sanitation Act by testing and inspection, as</li> </ul>	<ul style="list-style-type: none"> <li>Ensuring that no change has been made in the manufacturing process and the raw materials</li> <li>Ensuring conformity with the standards for constituents, by regular testing and inspection</li> <li>Ensuring compliance with the Food Sanitation Act, by checking the final products</li> </ul>	<ul style="list-style-type: none"> <li>Compliance with storage standards</li> <li>Checking whether any accident has occurred</li> </ul>
Agricultural products and related processed foods	<ul style="list-style-type: none"> <li>Mycotoxins such as aflatoxin and patulin (cereals, beans, spices, apple juice, etc.)</li> </ul>	<ul style="list-style-type: none"> <li>Taking measures to prevent mold from growing at the time of ingathering and transportation/storage</li> </ul>	<ul style="list-style-type: none"> <li>Ensuring that no mycotoxins are present by regular testing and inspection</li> </ul>	<ul style="list-style-type: none"> <li>Whether proper control of temperature and humidity is carried out to prevent the growth of mold</li> </ul>

<ul style="list-style-type: none"> <li>Natural poisons such as cyanogenic glycosides</li> </ul>	<ul style="list-style-type: none"> <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>	<ul style="list-style-type: none"> <li>Ensuring that no natural poisons are present by regular testing and inspection</li> </ul>	
<ul style="list-style-type: none"> <li>Radioactive contamination (mushrooms, herbs, etc.)</li> </ul>	<ul style="list-style-type: none"> <li>Ensuring that the harvesting area is not contaminated by radioactivity</li> </ul>	<ul style="list-style-type: none"> <li>Checking the level of radioactivity by regular testing and inspection</li> </ul>	
<ul style="list-style-type: none"> <li>Pathogenic microorganisms such as Enterohemorrhagic Escherichia coli O157 (fresh vegetables)</li> </ul>	<ul style="list-style-type: none"> <li>Taking measures to prevent contamination by pathogenic microorganisms</li> </ul>	<ul style="list-style-type: none"> <li>Ensuring that no pathogenic microorganisms are present by regular testing and inspection</li> </ul>	<ul style="list-style-type: none"> <li>Whether proper temperature control is carried out to prevent harm due to the growth of any microorganisms</li> </ul>
<ul style="list-style-type: none"> <li>Residual agricultural chemicals</li> </ul>	<ul style="list-style-type: none"> <li>Checking how agricultural chemicals are used</li> <li>Raw materials of processed foods must conform with residue standards</li> </ul>	<ul style="list-style-type: none"> <li>Ensuring compliance with proper use and dosage of agricultural chemicals, before and after ingathering</li> <li>Ensuring that residual agricultural chemicals are below proper levels, by regular testing and inspection</li> </ul>	<ul style="list-style-type: none"> <li>Checking whether any agricultural chemicals were used after ingathering</li> </ul>
<ul style="list-style-type: none"> <li>GMO foods whose safety has not been certified (corn, papaya, etc.)</li> </ul>	<ul style="list-style-type: none"> <li>Checking whether GMO food has been approved</li> <li>Taking measures to prevent any uncertified GMO food from being included</li> </ul>	<ul style="list-style-type: none"> <li>Ensuring that no GMO food whose safety has not been certified is included through regular testing and inspection</li> </ul>	<ul style="list-style-type: none"> <li>Whether proper control is carried out</li> </ul>
<ul style="list-style-type: none"> <li>Use of additives that may mislead consumers in the determination of quality and freshness (fresh vegetables)</li> </ul>	<ul style="list-style-type: none"> <li>Ensuring that no colorant, bleach, or other additives that may mislead consumers in the determination of quality or freshness have been used</li> </ul>	<ul style="list-style-type: none"> <li>Checking the types of additives used through regular testing and inspection</li> </ul>	

Livestock products and related processed foods	<ul style="list-style-type: none"> <li>• Pathogenic microorganisms such as Enterohemorrhagic Escherichia coli O157 and listeria (meat, natural cheeses, etc.)</li> </ul>	<ul style="list-style-type: none"> <li>• Taking measures to prevent contamination by pathogenic microorganisms</li> </ul>	<ul style="list-style-type: none"> <li>• Ensuring that no pathogenic microorganisms are present through regular testing and inspections</li> </ul>	<ul style="list-style-type: none"> <li>• Whether proper temperature control is implemented to prevent harm due to the growth of microorganisms</li> </ul>
	<ul style="list-style-type: none"> <li>• Radioactive contamination (reindeer meat, beef extracts, etc.)</li> </ul>	<ul style="list-style-type: none"> <li>• Ensuring producing area is not contaminated by radioactivity</li> </ul>	<ul style="list-style-type: none"> <li>• Checking the level of radioactivity by regular testing and inspection</li> </ul>	
	<ul style="list-style-type: none"> <li>• Errors concerning sanitation certificates (meat and meat products)</li> </ul>	<ul style="list-style-type: none"> <li>• Checking each item on the sanitation certificate issued by the governmental agency of the producing and/or exporting country</li> </ul>		<ul style="list-style-type: none"> <li>• Ensuring that a complete sanitation certificate is attached</li> </ul>
	<ul style="list-style-type: none"> <li>• Bovine spongiform encephalopathy (beef and beef-derived products)</li> </ul>	<ul style="list-style-type: none"> <li>• The producing area is not a country or area from which import is prohibited</li> <li>• No specified risk material (SRM) is included in the product</li> <li>• No beef, etc. originated from countries or areas from which import is prohibited is included or used</li> </ul>		
	<ul style="list-style-type: none"> <li>• Bovine spongiform encephalopathy (mutton, goat meat, etc.)</li> </ul>	<ul style="list-style-type: none"> <li>• No BSE animal has been found in the producing area</li> <li>• No specified risk material (SRM) is included in the product</li> </ul>		
	<ul style="list-style-type: none"> <li>• Residual agricultural chemicals, veterinary drugs, and feedstuff additives</li> </ul>	<ul style="list-style-type: none"> <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 style="list-style-type: none"> <li>• Checking compliance with proper dose, administration, and drug holidays for veterinary drugs and feedstuff additives</li> <li>• Checking levels of residual agricultural chemicals, veterinary drugs, and feedstuff additives, by regular testing and inspection</li> </ul>	
	<ul style="list-style-type: none"> <li>• Use of additives that may mislead consumers in the determination of quality and freshness (meat)</li> </ul>	<ul style="list-style-type: none"> <li>• Ensuring that no colorant or other additives that may mislead consumers in the determination of quality or freshness have been used</li> </ul>	<ul style="list-style-type: none"> <li>• Checking the types of additives used through regular testing and inspection</li> </ul>	
Seafood and processed seafood	<ul style="list-style-type: none"> <li>• Pathogenic microorganisms such as Vibrio parahaemolyticus (fillet, shelled and/or peeled fish and shellfish to be eaten raw)</li> </ul>	<ul style="list-style-type: none"> <li>• Taking measures to prevent contamination by pathogenic microorganisms in cleaning water used at processing plants, etc.</li> <li>• Compliance with processing standards</li> </ul>	<ul style="list-style-type: none"> <li>• Ensuring that no pathogenic microorganisms are present through regular testing and inspections</li> </ul>	<ul style="list-style-type: none"> <li>• Compliance with storage standards</li> <li>• Whether proper temperature control is carried out to prevent harm due to the growth of any microorganisms</li> </ul>

	<ul style="list-style-type: none"> <li>• Non-conformity with standards for constituents, standards for processing, and standards for storage for oysters eaten raw</li> </ul>	<ul style="list-style-type: none"> <li>• Checking whether the standards for processing in the producing country are at the same level as in Japan</li> </ul>	<ul style="list-style-type: none"> <li>• Ensuring conformity with the standards for constituents by regular testing and inspection</li> </ul>	<ul style="list-style-type: none"> <li>• Compliance with storage standards</li> </ul>
	<ul style="list-style-type: none"> <li>• Diarrheic shellfish poisons or paralytic shellfish poisons (shellfish)</li> </ul>	<ul style="list-style-type: none"> <li>• Checking that clams are gathered in sea areas where proper monitoring of shellfish poisoning is implemented</li> </ul>	<ul style="list-style-type: none"> <li>• Ensuring that no shellfish poisons are present by regular testing and inspection</li> </ul>	
	<ul style="list-style-type: none"> <li>• Mixing with poisonous blowfish</li> </ul>	<ul style="list-style-type: none"> <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 in, through proper identification of fish types</li> </ul>		<ul style="list-style-type: none"> <li>• Checking the certificates issued by the governmental agency of the exporting country</li> <li>• Ensuring that no different types of blowfish are included, through proper identification of fish types</li> </ul>
	<ul style="list-style-type: none"> <li>• Mixing with poisonous fish such as fish with ciguatoxin (southern groupers, parrot fish, barracudas, etc.)</li> </ul>	<ul style="list-style-type: none"> <li>• Checking the seas where the fish are caught</li> <li>• Taking measures to prevent poisonous fish from being mixed in, through proper identification of fish types</li> </ul>		<ul style="list-style-type: none"> <li>• Ensuring that no poisonous fish are included, through proper identification of fish types</li> </ul>
	<ul style="list-style-type: none"> <li>• Residual veterinary drugs and feedstuff additives</li> </ul>	<ul style="list-style-type: none"> <li>• Checking on the use of veterinary drugs</li> <li>• Raw materials of processed foods must conform with the residue standards</li> </ul>	<ul style="list-style-type: none"> <li>• Checking compliance with proper dose, administration, and drug holidays for veterinary drugs and feedstuff additives</li> <li>• Checking the levels of residual veterinary drugs and feedstuff additives, by regular testing and inspection</li> </ul>	
	<ul style="list-style-type: none"> <li>• Use of additives that may mislead consumers in the determination of quality and freshness (fresh fish and shellfish)</li> </ul>	<ul style="list-style-type: none"> <li>• Ensuring that no colorant, carbon monoxide or other additives that may mislead consumers in the determination of quality or freshness have been used</li> </ul>	<ul style="list-style-type: none"> <li>• Checking the types of additives used, by regular testing and inspection</li> </ul>	<ul style="list-style-type: none"> <li>• Checking the color of the product (scarlet, etc.)</li> </ul>
Health foods in general	<ul style="list-style-type: none"> <li>• Containing drug substance</li> </ul>	<ul style="list-style-type: none"> <li>• Ensuring that no drug substances designated by the Pharmaceutical Affairs Act are included</li> <li>• Checking the history of ingestion in the exporting country</li> </ul>	<ul style="list-style-type: none"> <li>• Ensuring that no drug substance is included by testing and inspection</li> </ul>	

<p>Additives and their preparation</p>	<ul style="list-style-type: none"> <li>• Use of unapproved additive</li> <li>• Non-conformity with the standards</li> </ul>	<ul style="list-style-type: none"> <li>• Checking the correct names of the additives and their types of source materials and extractants</li> <li>• Checking the formal names and content rates if additive preparation is used</li> <li>• Ensuring that no unapproved additives are used</li> <li>• Ensuring that the product conforms to the related standards, such as standards for constituents and manufacturing standards</li> </ul>	<ul style="list-style-type: none"> <li>• Ensuring conformity with the standards for constituents, by regular testing and inspection</li> </ul>	<ul style="list-style-type: none"> <li>• Checking compliance with storage standards</li> </ul>
<p>Equipment, containers and packages, and toys</p>	<ul style="list-style-type: none"> <li>• Non-conformity with standards</li> </ul>	<ul style="list-style-type: none"> <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>	<ul style="list-style-type: none"> <li>• Ensuring that the raw materials conform with general standards for raw materials and standards for each material, by regular testing and inspection</li> </ul>	

Annex 2

Notice No. 0329 Article 2 of the Department of Food Safety

March 29 , 2010

To: Prefectural Governors

Mayors of cities that operate public health centers

Mayors of specially designated wards

Director of the Department of Food Safety,  
Pharmaceutical and Food Safety Bureau,  
Ministry of Health, Labour and Welfare

Development of Imported Foods Monitoring and Guidance Plan for FY 2010

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 for FY 2010 (hereinafter referred to as “the Imported Foods Monitoring and Guidance Plan for FY 2010”), as described in the Annex, under Article 23, paragraph 1 of the Food Sanitation Act (Act No. 233 of 1947). The Imported Foods Monitoring and Guidance Plan for FY 2008 concerns the monitoring and guidance of imported foods, additives, equipment, containers and packages by the national government, and was published in an official gazette in accordance with paragraph 3 of the same Article.

We would ask prefectures, etc. to use the Imported Foods Monitoring and Guidance Plan for FY 2010 as a reference when monitoring imported foods, etc. that are distributed in the domestic market and giving guidance to importers, as well as to provide cooperation for smooth implementation of monitoring and guidance under the Imported Foods Monitoring and Guidance Plan for FY 2010.