

(Annex)



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Inspection Results of Imported Foods Monitoring and Guidance Plan for FY2016

Interim Report

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1. Introduction

In order to ensure the safety of foods, etc., imported into Japan (hereinafter, “imported foods”), the government established the Imported Foods Monitoring and Guidance Plan for 2016 (hereinafter, “the Plan”) as per the regulations of Article 23, paragraph 1 of the Food Sanitation Act (Act No. 233, 1947; hereinafter, “the Act”), and monitoring and guidance for imported foods is being conducted based upon the Plan.

(The Plan is formulated based on the Guidelines for Monitoring and Guidance for Food Sanitation (Ministry of Health, Labour and Welfare Notification No. 301 of 2003) after conducting collection of public comments and risk communication. The plan is published in the Official Gazette as an official report according to the regulations of Article 23, paragraph 3 of the Act.)

This document publishes an outline of the implementation status of the monitoring and guidance for imported foods, conducted in accordance with the plan, for the period from April to September 2016.

Reference: Website on “For the Safety of Imported Food”

<http://www.mhlw.go.jp/topics/yunyu/tp0130-1.html>



2. Overview of the Imported Foods Monitoring and Guidance Plan for FY 2016

(1) What is the Imported Foods Monitoring and Guidance Plan?

It is the plan for the implementation of monitoring and guidance for the import of foods by the Japanese government as stipulated by Article 23, paragraph 1 of the Act.

[Purpose] To further ensure the safety of imported foods by the national government promoting intensive, effective and efficient monitoring and guidance for imported foods and importers.

(2) Principles for Monitoring and Guidance on Imported Foods

Under the Article 4 of the Food Safety Basic Act (Act No.48 of 2003) (that is, Food safety shall be ensured by taking the necessary measures appropriately at each stage of the domestic and overseas Food Supply Processes.), the Plan is prepared in order that three stages of food safety measures are taken, namely, in the exporting country, at the time of importation, and at the time of domestic distribution.

(3) Priority Items for Monitoring and Guidance

- Confirmation of legality with respect to the Act at the time of import declaration
- Monitoring ^{*1} (Plan for FY2016: approximately 96,000 cases across 171 food groups)
- Inspection orders ^{*2}
- Regulations for comprehensive import bans ^{*3}
- Emergency measures based on overseas information, etc.

*1: Systematic inspections based on statistical approach considering that take into account the volume of imports, violation rates and other factors, for each food type, in order to broadly monitor a wide variety of imported foods.

*2: Inspection for products with a high probability of violation where an inspection is ordered for the importer, and import and distribution is not permitted without the results being in compliance with the Act (Article 26 of the Act).

*3: Regulations by which the Minister of Health, Labour and Welfare may prohibit the sale or import of specified foods, without inspections, in cases where it is deemed specifically necessary from the perspective of preventing harm to public health (Articles 8 and 17 of the Act).

(4) Promotion of Foods Safety Measures in Exporting Countries

- Informing the responsible governmental agencies and food business operators of food safety regulations of Japan through seminars held in exporting countries
- Request for unfolding causes of and taking recurrence prevention measures for violations of the Act, and promotion of safety measures by safety controls at the production stage, enhancement of monitoring systems, inspection before exportation, etc., through bilateral talks

- Systematic collection of information on safety measures for foods exported to Japan and promotion of food safety measures by exporting countries through on-site visits

| | |--| | (5) Guidance for Importers on Voluntary Safety Control | |--|

- Pre-import guidance (known as import consulting)
- Guidance for voluntary inspections at the import consulting, initial import, and continued import
- Guidance on preparation and storage of records on import and sales conditions of imported foods
- Raising awareness of food safety amongst importers

3. Results of Imported Foods Monitoring and Guidance Plan for FY 2016 (Interim Report: Tentative)

The number of import notifications made from April through September of 2016 was 1,161,978 [1,134,155], and the weight of notified items was 11,874,000 tons [11,416,000 tons] (Table 1).

Inspections were carried out on 98,172 items (monitoring inspections on 29,387 items, ordered inspection on 27,641, and independence inspection on 45,285 items, deducting duplicates) [101,922 items (monitoring inspections on 28,539 items, ordered inspection on 31,764 items, and independence inspections on 47,067 items, deducting duplicates)]. Of these, 358 cases [431 cases] were found to be in violation of the Act, and steps were taken for their reshipment, disposal, etc.

Regarding violations categorized by provision, violations of Article 11 of the Act (compositional standards for food (microbial, agricultural chemical residues and veterinary drug residues) and standards for the use of additives in food, etc.) were the most common in 224 cases, followed by 89 cases in violation of Article 6 (adhesion of hazardous or toxic substances such as aflatoxin), 38 cases in violation of Article 18 (standards for apparatus or containers and packaging), 12 cases in violation of Article 10 (use of undesignated additives), 3 cases in violation of Article 9 (absence of health certificates of meat), and 2 cases in violation of Article 62 (standards for toys) (Table 2).

Monitoring inspection was conducted for 29,387 cases (58,416 cases compared to the planned cumulative total of 95,929 (implementation rate: approx. 61%)), and of which, 72 cases (running total of 76 cases) were confirmed to be in violation of the Act, and steps were taken for their recalls, etc. (Table 3). For imported foods that were found to be in violation of the Act by monitoring inspection, the inspection rate to 30% as necessary, to identify probable of violations (Table 4). Additionally, for imported foods that are considered to have a high probability of violating the Act, inspections were strengthened by making them subject of ordered inspections (Table 5).

As of September 30, 2016, 17 items from all exporting countries and 72 items from 34 countries and 1 region were made subject to ordered inspection, and inspection was carried out for 27,641 cases (running total of 41,742 cases). Of these, violation of the Act was found in 111 cases (running total of 111 cases), and steps were taken for their reshipment or disposal, etc. (Table 6).

As an emergency measures based on information from overseas, etc., reshipment, etc., was carried out for frozen vegetables and fruits potentially contaminated with *Listeria monocytogenes* from the USA. (Table 7).

Figures in brackets are for the same period in the previous year.

Table 1. Notification, Inspection and Violation (Apr-Sep 2016: Tentative)

Notifications (cases) ^{*1}	Imported Weight (thousand tons) ^{*1}	Inspections ^{*2} (cases)	Proportion ^{*3} (%)	Violations (cases)	Proportion ^{*3} (%)
1,161,978	11,874	98,172 (27,641) ^{*4}	8.4	358	0.03
(FY2015) 1,134,155	11,416	101,922	9.0	431	0.04

*1 Cargoes of planned Import System (excluding time of first importation.) are not included.

*2 Inspections by authorities, registered inspection organizations and foreign official laboratories, deducting duplicates.

*3 Proportion as compared to notifications.

*4 Number of ordered inspections.

Table 2. Violations by Legal Provision (Apr-Sep 2016: Tentative)

Provision violated	Violations (cases)	Proportion (%)	Brief details of Violations
Article 6 (Foods and Additives prohibited to distribute)	89	24.2	Aflatoxin contamination in almonds, spices, corn, job's tears, pistachio nuts, peanuts etc.; detection of cyanide; decay, deterioration and generation of mold due to accidents during the transport of barley, coffee beans, rice, wheat, soybeans; detection of <i>Enterohemorrhagic Escherichia coli</i> O103 from kimchi etc.,
Article 9 (Limitation on distribution, etc. of diseased meat)	3	0.8	No health certificate attached or incomplete
Article 10 (Limitation of distribution, etc. of additives)	12	3.3	Use of undesigned additives (TBHQ, azorubin, carbon monoxide, cyclamic acid, sodium ethoxide, potassium iodized, etc.)
Article 11 (Standards and criteria for foods and additives)	224	60.9	Violation of standards for constituents for vegetables or frozen vegetables (excess of standards on residual agricultural chemicals), violation of standards for constituents for meat, aquatic foods and processed products (excess of standards on residual veterinary drugs, excess of standards on residual agricultural chemicals), violation of standards for constituents for other processed products (coliform bacteria positive, etc.), violation of criteria on use of additives (sucralose, sorbic acid, sulfur dioxide, etc.), violation of standards for constituents for additives, excess of standards on radioactive substance, detection of unauthorized genetically modified, etc.
Article 18 (Standards and criteria for apparatus, containers and packaging)	38	10.3	Violation of standards for apparatus, containers and packaging Violation of materials standards for raw materials
Article 62 (Mutatis mutandis application for toys)	2	0.5	Violations of standards for toys
Total	368(Gross) ^{*1} 358(Actual) ^{*2}		

*1 Gross number of inspection cases by inspected substances

*2 Number of notification cases for which inspections were carried out

Table 3. Implementation of Monitoring Inspections (Apr-Sep 2016: Tentative)

Food Groups	Inspected Substances ^{*1}	Planned Number in FY ^{*2}	Actual Number	Violations
Livestock Foods Beef, pork, chicken, horse meat, other poultry meat, etc.	Antibacterial substances, etc.	1,879	1,054	1
	Residual agricultural chemicals	1,191	974	0
	Additives	118	65	0
	Pathogenic microorganism	657	340	0
	Standards for constituents	415	260	0
	Radiation irradiation	29	18	0
	Removal of SRM	-	1,102	3
Processed Livestock Foods Natural cheeses, processed meat products, ice cream, frozen (meat) products, etc.	Antibacterial substances, etc.	2,182	1,354	0
	Residual agricultural chemicals	1,697	1,139	0
	Additives	1,247	820	0
	Pathogenic microorganism	3,584	2,231	0
	Standards for constituents	1,937	1,224	2
	Mycotoxins	-	3	0
	Genetically modified food	-	2	2
Aquatic Foods Bivalves, fish, crustacea(shrimps, crabs), etc.	Antibacterial substances, etc.	2,572	1,407	1
	Residual agricultural chemicals	1,134	1,080	0
	Additives	297	166	0
	Pathogenic microorganism	1,074	792	0
	Standards for constituents	354	265	0
	Radiation irradiation	34	21	0
Processed Aquatic Foods Processed fish products (fillet, dried or minced fish, etc.), frozen food (aquatic animals, fish), processed marine product eggs, etc.	Antibacterial substances, etc.	4,234	3,033	3
	Residual agricultural chemicals	4,111	3,012	0
	Additives	1,894	1,424	0
	Pathogenic microorganism	4,661	3,176	1
	Standards for constituents	4,930	2,734	20
	Radiation irradiation	-	3	0
Agricultural Foods Vegetables, fruits, wheat, maize, pulses, peanuts, nuts, seeds, etc.	Antibacterial substances, etc.	2,559	1,975	0
	Residual agricultural chemicals	9,190	5,507	15
	Additives	474	384	0
	Pathogenic microorganism	1,495	997	0
	Standards for constituents	355	250	0
	Mycotoxins	2,273	1,279	0
	Genetically modified food	469	241	0
	Radiation irradiation	119	111	0
Processed Agricultural Foods Frozen food(vegetables), processed vegetable products, processed fruit products, spices, instant noodles, etc	Antibacterial substances, etc.	598	440	0
	Residual agricultural chemicals	6,800	4,781	5
	Additives	4,551	3,425	1
	Pathogenic microorganism	956	914	1
	Standards for constituents	2,648	1,844	4
	Mycotoxins	2,774	1,759	0
	Genetically modified food	252	185	0
	Radiation irradiation	424	285	0
Other Foods Health foods, soups, seasonings, confectionery, cooking oil and fat, frozen food, etc.	Antibacterial substances, etc.	-	2	0
	Residual agricultural chemicals	1,074	716	0
	Additives	3,344	1,981	1
	Pathogenic microorganism	-	1	0
	Standards for constituents	598	319	4
	Mycotoxins	955	639	0
	Genetically modified food	-	2	0
Beverages Mineral waters, soft drinks, alcoholic drinks, etc.	Residual agricultural chemicals	118	130	0
	Additives	1,075	743	0
	Standards for constituents	657	404	1
	Mycotoxins	178	94	0
Additives / Apparatus, containers and packaging / Toys	Standards for constituents	1,762	1,309	11
Total (gross)		95,929 ^{*3}	58,416 <u>Implementation</u> <u>rate of 61%</u>	76

*1: Examples of inspected substances

- Antibacterial substances, etc.: antibiotics, synthetic antimicrobials, hormone drugs, etc.
- Residual agricultural chemicals: organophosphorus, organochlorine, carbamates, pyrethroid, etc.
- Additives: preservatives, coloring agents, sweetener, antioxidants, antimold agents, etc.
- Pathogenic microorganisms: *Enterohemorrhagic E. coli* O26, O103, O104, O111, O121, O145 and O157, *Listeria monocytogenes*, *Vibrio parahaemolyticus*, etc.
- Standards for constituents, etc.: Items stipulated in the standards for constituents (bacteria count, coliform bacteria, radioactive substance (excludes pathogenic microorganism)), shellfish poisons (diarrhetic shellfish toxin, paralytic shellfish poison), etc.
- Mycotoxin: aflatoxin, deoxynivalenol, patulin, etc.
- Genetically modified organisms (GMOs): genetically modified foods, etc. that have not been assessed for safety.
- Radiation irradiation: with or without of irradiation

*2: The number of item by item programs planned of antibacterial substances, agricultural chemicals, etc.

*3: 10,000 cases planned as enhanced monitoring were added to the number of items by item of each food groups

Table 4. Items Subject to Enhanced Monitoring Inspections*¹ (Apr-Sep 2016*²)

Country/Region	Subject Item	Inspected Substances
India	Cardamom immature fruit	Triazophos
	Cumin seeds	Iprobenfos
	Chickpea	Aflatoxin
	Fennel seed	Iprobenfos
		Profenofos
China	Taro	Chlorpyrifos
	Lotus seeds	Aflatoxin
	Cultured shrimp	Malachite green
	Lychees (Liche)	4-Chlorophenoxyacetic acid
Thailand	Red hot pepper	Propiconazole
	Shrimp for raw consumption	<i>Vibrio parahaemolyticus</i> (MPN) * ³
	Boiled crab for raw consumption	<i>Vibrio parahaemolyticus</i> * ³
Vietnam	Shrimp	Chloramphenicol
	Cultured shrimp	Sulfadiazine
		Sulfamethoxazole
Philippines	Sea urchin for raw consumption	<i>Vibrio parahaemolyticus</i> (MPN) * ³
	Boiled octopus	<i>Vibrio parahaemolyticus</i> * ³
Ecuador	Cacao beans	Malathion
South Korea	Ark shells for raw consumption	<i>Vibrio parahaemolyticus</i> (MPN) * ⁴
Spain	Pistachio processed products	Aflatoxin
France	Pigeon meat	Oxytetracycline
USA	Corn (popcorn only)	Pirimiphosmethyl

*1 Include the Items which were rescinded from inspection orders. If no similar violations were detected within 60 enhanced monitoring inspections or within 1 year, the items in question were subjected to the normal inspection state.

*2 Excludes items included in Table 5.

*3 Item which all (100%) import declarations were inspected as a measure to enhance inspections during the summer period, (Jun-Oct 2016).

*4 Item which 30% of import declarations were inspected as a measure to enhance inspections during the summer period, (Jun-Oct 2016)

Table 5. Items transferred to Inspection Order (Apr-Sep 2016)

Country/Region	Subject Item	Inspected Substances
South Korea	Kimchi (manufacturers limited)	<i>Enterohemorrhagic E. coli</i> O103
	Oriental melon	Chlorfenapyr
Egypt	Calendula (<i>Calendula officinalis</i>)	Chlorpyrifos
Spain	Non glutinous rice	Tebuconazole
Thailand	Boiled crab (manufacturers limited)	<i>Vibrio parahaemolyticus</i>
China	Cumin seeds	Profenofos
Chile	Kiwi fruit	Fenhexamid
France	Natural cheese (manufacturers limited)	<i>Listeria monocytogenes</i>
USA	Celery	Bifenthrin
Peru	Cacao beans	2, 4-D

**Table 6. Major Items subject to Ordered Inspections and Inspection Outcomes
(Apr-Sep 2016: Tentative)**

Country/Region	Major subject item	Major Inspected Substances	Inspections	violations
All exporting countries (17 items)	Almond, Chili pepper, Peanut, etc.	Aflatoxin	5,588	53
	Cassava, Beans containing cyanide	Cyanide	277	2
	Salted salmon roe	Nitrite	225	0
China (16 items)	Vegetables (Green soybean, Onion, Spinach, etc.), Lychees, short-neck clam, Clam	Endrin, Chlorpyrifos, Difenoconazole, Diflubenzuron Thiamethoxam, Dieldrin (including aldrin), Prometryn, etc.	10,628	9
	Bivalves	Paralytic shellfish poison, Diarrhetic shellfish poison	4,024	0
	Processed products	Cyclamic acid	333	0
	Eel, Soft-shelled turtle	Enrofloxacin, Oxolinic acid, Sulfadimidine	138	0
	Lotus seed	Aflatoxin	2	0
South Korea (13 items)	Tomato, Paprika, Cherry tomato	Chlorpyrifos , Fluquinconazole	62	0
	Bivalves	Paralytic shellfish poison, Diarrhetic shellfish poison	60	0
	Cultured olive flounder	Enrofloxacin, Oxytetracycline	4	0
Thailand (10 items)	Okra, Green asparagus, Durian, Banana, Mango, Mangosteen	EPN, Imazalil, Chlorpyrifos, Cypermethrin, Propiconazole, Metalaxyl, mefenoxam	1,351	0
	Boiled crab	<i>Vibrio parahaemolyticus</i>	10	0
Italy (7 items)	Almond, Pistachio	Aflatoxin	150	0
	Rice	Pirimiphos-methyl	18	0
	Natural cheese	<i>Listeria monocytogenes</i>	16	1
India (7 items)	Cultured shrimp	Furazolidone	898	1
	Cumin seed, Black tea, Chili pepper, Chickpea	Glyphosate, Triazophos, Profenofos, Hexaconazole	96	3
	Cassia torea, Fenugreek seed	Aflatoxin	92	3
USA (7 items)	Corn, Pistachio	Aflatoxin	1,594	3
	Celery	Bifenthrin	90	1
	Natural cheese	<i>Listeria monocytogenes</i>	5	0
Other (28 countries and 1 region, total 36 items)			16,081	35
Total (Gross)			41,742	111

**Table 7. Major Enhanced Monitoring based on Overseas Information
(Apr-Sep 2016)**

Month of enhancement	Subject country	Subject food and details	Background and status
May	USA	Frozen vegetables and fruits (Possible contamination with <i>Listeria monocytogenes</i>)	Information was received stating that in the USA, a manufacturer was conducting voluntary recall of frozen vegetables and fruits for potential contamination with <i>Listeria monocytogenes</i> . When an import notification was made for such recall products, steps were taken for reshipment, etc.

(Reference) Description of Key Terms

Term	Description
Nitrite	Additive (color fixative agent)
Aflatoxin	Mycotoxin (produced by the fungus <i>Aspergillus</i> , etc.)
Genetic modification	Technology such as fragmentation of bacterial genes, followed by arrangement of the gene sequences or introducing the arranged genes into other organism's genes.
Iprobenfos	Agricultural chemical (organophosphorus fungicide)
Imazalil	Agricultural chemical (imidazole fungicide)
Endrin	Agricultural chemical (organochlorine insecticide)
Enrofloxacin	Veterinary drug (new quinolone synthetic antibacterial agent)
Oxytetracycline	Veterinary drug (tetracycline antibacterial agent)
Oxolinic acid	Veterinary drug (quinolone synthetic antibacterial agent)
Glyphosate	Agricultural chemical (organophosphorus herbicide)
Chloramphenicol	Veterinary drug
Chlorpyrifos	Agricultural chemical (organophosphorus insecticide)
Chlorfenapyr	Agricultural chemical (Insecticide with pyrrole ring)
Diarrhetic shellfish toxin	Shellfish poison (mainly refers to toxins produced by a harmful plankton accumulated in bivalves)
Cyanide	Harmful or poisonous compound (cyanide-related compounds (e.g., cyanogenic glycoside)) found in vegetables such as some varieties of beans.
Difenoconazole	Agricultural chemical (triazole fungicide)
Diflubenzuron	Agricultural chemical (urea insecticide)
Cypermethrin	Agricultural chemical (pyrethroid insecticide)
Sucralose	Additive (sweetener)
Sulfadiazine	Veterinary drug (synthetic antibacterial agent)
Sulfadimidine	Veterinary drug (synthetic antibacterial agent)
Sulfamethoxazole	Veterinary drug (synthetic antibacterial agent)
Sorbic acid	Additive (preservative)
Thiamethoxam	Agricultural chemical (neonicotinoid insecticide)
<i>Vibrio parahaemolyticus</i>	Pathogenic microorganism (A bacterium living in seawater (estuaries, coastal areas, etc.) that commonly contaminates fish and shellfish, and causes abdominal pain, watery diarrhea, fever and vomiting.)

Term	Description
<i>Enterohemorrhagic E. coli</i>	Pathogenic microorganism (A bacterium that normally lives in the intestines of animals. It contaminates foods and drinking water by way of feces and urine, and causes acute abdominal pain and bloody diarrhea together with large amounts of blood after early cold-like symptoms.)
Dieldrin (including aldrin)	Agricultural chemical (organochlorine insecticide)
Deoxynivalenol	Mycotoxin (produced by the fungus <i>Fusarium</i>)
Tebuconazole	Agricultural chemical (triazole fungicide)
Triazophos	Agricultural chemical (organophosphorus insecticide)
Sulfur dioxide	Additive (antioxidant agents)
Patulin	Mycotoxin (produced by fungi such as <i>Penicillium</i> and <i>Aspergillus</i> , etc.)
Bifenthrin	Agricultural chemical (pyrethroid insecticide)
Pirimiphos-methyl	Agricultural chemical (organophosphorus insecticide)
Fenhexamid	Agricultural chemical (hydroxyanilide fungicide)
Furazolidone	Veterinary drug (nitrofurantoin synthetic antibacterial agent), generates AOZ when metabolized
Fluquinconazole	Agricultural chemical (triazole fungicide)
Propiconazole	Agricultural chemical (triazole fungicide)
Prothionos	Agricultural chemical (organophosphorus insecticide)
Prometryn	Agricultural chemical (triazine herbicide)
Hexaconazole	Agricultural chemical (triazole fungicide)
Paralytic shellfish poison	Shellfish poison (mainly refers to toxins produced by a harmful plankton accumulated in clams)
Malachite green	Veterinary drug (triphenylmethane synthetic antibacterial agent)
Malathion	Agricultural chemical (organophosphorus insecticide)
Metalaxyl	Agricultural chemical (anilide fungicide)
Mefenoxam	Agricultural chemical (anilide fungicide)
<i>Listeria monocytogenes</i>	Pathogenic microorganism (A normal flora in the natural environment that contaminates daily products and processed meat products, and causes influenza-like symptoms including tiredness and fever)
2,4-D	Agricultural chemical (phenoxy acid herbicide)
4-Chlorophenoxyacetic acid	Agricultural chemical (plant growth regulator)
EPN	Agricultural chemical (organophosphorus insecticide)