

(Annex)



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Inspection Results of Imported Foods Monitoring and Guidance Plan for FY 2014

Interim Report

December 2014
Department of Food Safety
Pharmaceutical and Food Safety Bureau
Ministry of Health, Labour and Welfare

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1. Introduction

In order to monitor and provide instructions to ensure the safety of foods, etc., imported into Japan (hereafter referred to as “imported foods”), the government established the Imported Foods Monitoring and Guidance Plan in 2014 (hereinafter, “the plan”). The plan is based on the guidelines for monitoring and providing instructions in food safety (Ministry of Health, Labour and Welfare Notification No. 301, 2003) as per the regulations of Article 23, Paragraph 1 of the Food Sanitation Act (Act No. 233, 1947; hereinafter, “the Act”); public comments were collected and risk communication was conducted. The plan was published in the Official Gazette as an official report according to the regulations of Paragraph 3 of the same article, and the monitoring and instruction for imported foods is being conducted based upon the plan.

This document presents an outline of the implementation status of the monitoring and instruction for imported foods, etc., conducted in accordance with the plan, for the period from April to September 2014.

Reference: Website on “Imported Foods Inspection Services Home Page”

<http://www.mhlw.go.jp/english/topics/importedfoods/index.html>



2. Overview of the Imported Foods Monitoring and Guidance Plan for FY 2014

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

The Imported Foods Monitoring and Guidance Plan is a plan for the implementation of monitoring and guidance conducted by the national government with respect to imported foods (Article 23, paragraph 1 of the Act).

[Objective] To ensure greater safety of imported foods by promoting the national government to conduct inspections at the time of importation and to conduct monitoring of and guidance for importers in an intensive, effective and efficient manner.

(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 appropriate measures at each stage of the domestic and overseas food supply process), 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 whether violations of the Act exist at the time of import declaration
- Monitoring ^{*1} (Plan for FY2014: 94,000 items across 168 food groups)
- Inspection orders ^{*2} (as of September 30, 2014: 17 items from all exporting countries and 72 items from 29 countries and 1 region)
- Regulations for comprehensive import bans ^{*3}
- Emergency responses based on overseas information, etc.

(4) Promotion of Food Safety Measures in Exporting Countries

- Promotion of food safety measures on food exports to Japan through systematic information gathering on safety measures and on-site inspections
- Request for establishing sanitation control measures (e.g., enhanced monitoring systems for agricultural chemical residues, inspection before exportation) through on-site inspections and bilateral consultation
- Dissemination of information on Japanese food safety regulations to government officials and producers by holding explanatory meetings.

(5) Guidance for Importers on Voluntary Safety Control

- Pre-import guidance (so-called “import consulting”)
- Guidance for voluntary inspections before importing, at the first importation, and on a regular basis
- Instructions on the preparing and keeping of records
- Dissemination of knowledge on food safety to importers, etc.

*1: Systematic inspections based on statistical concepts that take into account the volume of imports and violation rates and others, for each food type.

*2: With regard to items having a high probability of being in violation of the Act, inspections are ordered to the importer by the Minister of Health, Labour and Welfare at each importation. Items are not permitted to import or distribute unless the results of the inspection comply with the regulations.

*3: Regulations by which the Minister of Health, Labour and Welfare can prevent the sale or import of specified foods, without the need for inspections, in cases where it is deemed specifically necessary from the perspective of preventing harm to public health.

3. Inspection Results of Imported Foods Monitoring and Guidance Plan for FY 2014 (Interim Report: Tentative)

Looking at the declarations, inspections and violations made from April through September of 2014 (Table 1), there were 1,138,913 [1,106,117] declarations, and the weight of declared items was 11,952,000 [12,321,000] tons.

Inspections were carried out on 99,165 items (there were inspection orders on 28,153 items, monitoring inspections on 27,719 items, and voluntary inspections on 47,739 items) [104,766 items (inspection orders on 30,983 items, monitoring inspections on 29,396 items, and voluntary inspections on 48,859 items)]. Of these, 430 cases [562 cases] were found to be in violation of the Act, and steps were taken for their reshipment, disposal, etc.

Records of violations categorized by Article (Table 2) show that violations of Article 11 of the Act, which is related to microbiological criteria for food, standards on agricultural chemical residues and standards for the use of additives, were the most common in 277 cases, followed by 114 cases violations of Article 6 which is related to contamination with hazardous or toxic substances such as aflatoxin, 28 cases violations of Article 18 which is related to standards for apparatus or containers and packaging, 22 cases violations of Article 10 which is related to restrictions on the sale of additives, 2 cases violations of Article 9 which is related to non-attachment of health certificates of meat or meat products, and 1 case violation of Article 18 (applied mutatis mutandis to Article 62) of the Act which is related to standards for toys.

Records of monitoring in FY 2014 (Table 3) show that, out of a total of 94,043 planned inspections, 55,770 were actually conducted (That's an implementation rate of about 59%). Of these, a total of 56 constituted violations of the Food Sanitation Act, resulting in recalls and enhanced monitoring to identify possible future violations (Table 4). Additionally, as a result of enhanced monitoring, inspection for the imported foods which are considered to have a high

probability of violating the Act, are strengthened and subject to inspection orders at the time of import (Table 5).

As of September 30, 2014, inspection orders had been applied to 17 items from all exporting countries and 72 items from 29 countries and 1 region. The records of inspection orders (Table 6) show that a total of 46,391 inspection orders were conducted and, of these, steps were taken for their re-shipment or disposal, etc. based on 105 violations of the Act.

Based on information from overseas on topics such as recalls of law-violating food products, reshipment was carried out and the monitoring system was enhanced, for issues such as the detection of diethylstilbestrol from pork in Denmark and the detection of Enterohemorrhagic E. coli O26 from natural cheese in France (Table 7).

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

**Table 1. Notification, Inspection and Violation Statuses
(Apr-Sep 2014: Tentative)**

No. of Notifications (cases) ^{*1}	Amount of Import (1,000 tons) ^{*1}	No. of Inspections ^{*2} (cases)	Percentage ^{*3} (%)	No. of Violations (cases)	Percentage ^{*3} (%)
1,138,913	11,952	99,165 (28,153) ^{*4}	8.7	430	0.04
(previous FY) 1,106,117	12,321	104,766	9.5	562	0.05

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

*2 Values obtained after excluding overlapping cases from the total values of inspections by governments, registered laboratories, and public organizations of the exporting country.

*3 Proportion of the number of inspections to the number of notifications

*4 Figures relate to inspection orders

Table 2. Major Violation Cases (Apr-Sep 2014: Tentative)

Violated Article	No. of Violations	Proportion (%)	Major Violations
Article 6 (Foods and Additives prohibited of sales and distribution)	114	25.7	Aflatoxin contamination in almonds, figs, chestnuts, walnuts, spices, sesame seeds, corn, lotus seeds, job's tears, pistachio nuts, peanuts etc.; detection of cyanide ; detection of <i>Listeria monocytogenes</i> from natural cheeses and unheated meat products; and decay, deterioration and generation of mold due to accidents during the transport of kidney beans, coffee beans, rice, wheat, soybeans, potatoes, etc.
Article 9 (Limitation on sales and distribution of diseased meats)	2	0.5	Non-attachment of health certificate
Article 10 (Limitation on sales and distribution of additives)	22	5.0	Use of undesignated additives (TBHQ, acid blue 3 sodium salt, azorubin, carbon monoxide, quinoline yellow, cyclamic acid, methyl-p-hydroxybenzoate, iodized salt, etc.)
Article 11 (Standards and specifications for foods and additives)	277	62.4	Violation of specifications for vegetables and frozen vegetables (violation of standards for residual pesticides); violation of specifications for seafood and processed products thereof (violation of standards for residual veterinary drugs, violation of standards for residual pesticides); violation of specifications for other processed products (positive reaction on coliform bacilli, etc.); non-conformity to standards for storage of heated meat products; non-conformity to standards for manufacturing food products in general; violation of standards for usage of additives (BHT, sorbic acid, sulfur dioxide, etc.); and violation of specifications for additives
Article 18 (Standards and specifications for instruments and containers/packages)	28	6.3	Violation of specifications/standards for instruments and containers/packages; violation of specification for raw materials.
Article 62 (Mutatis mutandis as applied to toys, etc.)	1	0.2	Violation of specifications for toys or their raw materials.
Total	444 (total) ^{*1} 430 (number of notified violations) ^{*2}		

*1 Total number of item-by-item inspections

*2 Number of notifications for which inspection was carried out

Table 3. Implementation Status of Monitoring Inspections (Apr-Sep 2014: Tentative)

Food Group	Category of Inspected Items ^{*1}	No. of Programs Planned in FY ^{*2}	No. of Programs Implemented	No. of Violations
Livestock foods Beef, pork, chicken, horse meat, poultry Meat and other meats	Antibacterial substances, etc.	1,909	1,064	0
	Residual agricultural chemicals	1,191	992	0
	Additives	118	111	0
	Pathogenic microorganism	686	344	0
	Standards for constituents	295	259	0
	Exposure to radiation	29	22	0
	Removal of SRM	2,500	844	0
Processed livestock foods Natural cheeses, meat products, ice cream, frozen products (meat products), and others	Antibacterial substances, etc.	2,266	1,315	0
	Residual agricultural chemicals	1,697	1,126	0
	Additives	1,247	892	0
	Pathogenic microorganism	3,584	1,986	3
	Standards for constituents	1,547	1,067	0
Seafood products Bivalves, fish, shellfish (shrimps, crabs) and others	Antibacterial substances, etc.	2,752	1,423	1
	Residual agricultural chemicals	1,613	1,228	0
	Additives	297	163	0
	Pathogenic microorganism	1,074	910	0
	Standards for constituents	539	333	0
	Exposure to radiation	34	19	0
Processed seafoods Processed fish products (fillet, dried or minced fish, etc.), frozen food (seafood, fish), processed fish roe products, and others	Antibacterial substances, etc.	3,757	2,717	2
	Residual agricultural chemicals	3,904	2,976	2
	Additives	1,927	1,502	0
	Pathogenic microorganism	4,063	2,771	1
	Standards for constituents	2,867	1,795	11
Agricultural foods Vegetables, fruits, wheat and barley, corn, beans, peanuts, nuts, seeds, and others	Antibacterial substances, etc.	2,979	1,724	0
	Residual agricultural chemicals	9,129	5,884	12
	Additives	774	538	0
	Pathogenic microorganism	1,495	1,131	0
	Standards for constituents	355	237	0
	Mycotoxins	2,871	1,400	2
	GMOs	235	220	0
	Exposure to radiation	119	87	0

Food Group	Category of Inspected Items ^{*1}	No. of Programs Planned in FY ^{*2}	No. of Programs Implemented	No. of Violations
Processed agricultural foods Frozen products (processed vegetables), processed vegetable products, processed fruit products, spices, instant noodles, and others	Antibacterial substances, etc.	598	320	0
	Residual agricultural chemicals	8,148	4,970	5
	Additives	4,222	3,096	0
	Pathogenic microorganism	956	781	0
	Standards for constituents	2,499	1,763	6
	Mycotoxins	2,594	1,482	0
	GMOs	427	71	1
	Exposure to radiation	424	240	0
Other foods Health foods, soups, seasonings, confectionaries, edible oils, fat, frozen products, and others	Residual agricultural chemicals	1,434	737	0
	Additives	2,685	1,647	3
	Standards for constituents	598	266	1
	Mycotoxins	1,135	545	0
Drinks and beverages Mineral water, soft drinks, alcoholic beverages, and others	Residual agricultural chemicals	358	301	0
	Additives	1,374	876	0
	Standards for constituents	657	441	1
	Mycotoxins	118	78	0
Additives Equipment, containers and packages Toys	Standards for constituents	1,433	1,050	5
Total (number) 6,530 were added to the No. of Programs Planned in FY as “foods subject to enhanced monitoring inspections.”		94,043	55,770 Rate of program implemented: about 59%	56

*1: Examples of tested substances

- Antibacterial substances, etc.: antibiotics, synthetic antimicrobials, hormone drugs, etc.
- Residual agricultural chemicals: organophosphorus, organochlorine, carbamates, pyrethroid, etc.
- Additives: preservatives, coloring agents, sweetener, antioxidant, antimold agents, etc.
- Standards for constituents, etc.: Items stipulated in the compositional standards (bacteria count, coliform bacteria, *Vibrio parahaemolyticus*, radioactive substances, etc.), shellfish poisons (diarrhetic shellfish toxin, paralytic shellfish poison), etc.
- Pathogenic microorganisms (Enterohemorrhagic E. coli O26, O103, O104, O111 and O157, *Listeria monocytogenes*, etc.)
- Mycotoxin: aflatoxin, deoxynivalenol, patulin, etc.
- Genetically modified organisms (GMOs): genetically modified foods, etc. that have not been assessed for safety.
- Exposure to radiation: whether the item is exposed to radiation

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

Table 4. Items Subject to Enhanced*¹ Monitoring Inspections*² (Apr-Sep 2014)

Country/Region	Subject Food	Test Item
China	Constricted tagelus	Prometryn
	Sea urchin (for raw consumption)	<i>Vibrio parahaemolyticus</i> * ⁴
	Chinese pepper (Zanthoxylum bungeanum)	Aflatoxin
	Sesame seed	Dicofol
	Taro	Chlorpyrifos
	Octopus	Furazolidone
	Carrot	Triadimenol
	Allium Wakegi	Difenoconazole
Thailand	Green soybeans	Triazophos
	Feverweed	Chlorpyrifos
	Holy basil	EPN
	Pandanus palm leaf	2,4-D
South Korea	Arch shell (for raw consumption)	<i>Vibrio parahaemolyticus</i> * ³
	Eel	Ofloxacin
New Zealand	Green peas	Haloxfop
	Carrot	Methamidophos
USA	Celery	Bifenthrin
	Blueberry	Buprofezin
India	Chickpeas	Glyphosate
Indonesia	Boiled crab (for consumption without reheating)	<i>Vibrio parahaemolyticus</i> * ³
Ethiopia	Coffee beans	Chlorpyrifos
Australia	Cottonseed	Aflatoxin
Netherlands	Cabbage	Pencycuron
Ghana	Cacao beans	Fenvalerate
Taiwan	Carrot	Methamidophos
Philippines	Sea urchin (for raw consumption)	<i>Vibrio parahaemolyticus</i> * ³
Honduras	Coffee beans	Chlorpyrifos

*1 In FY2014, enhanced monitoring inspections, which are to be implemented after a violation has been detected, were usually conducted on 30% of all import declarations. Items which had seen inspection orders rescinded as a result of import or inspection results were also handled in the same manner. However, if no similar violations were detected over 60 enhanced monitoring inspections or over 1 year, the items were returned to the normal inspection system.

*2 Excludes items in Table 5.

*3 As a measure to enhance inspections during the summer period, all (100%) import declarations were inspected (Jun-Oct 2014).

*4 As a measure to enhance inspections during the summer period, 30% of import declarations were inspected (Jun-Oct 2014).

Table 5. Items Shifted to Inspection Orders (Apr-Sep 2014)

Country/Region	Subject Food	Test Item
Italy	Unheated meat products (limited to the specified manufacturers)	<i>Listeria monocytogenes</i>
	Processed pistachio nuts products	Aflatoxin
Spain	Unheated meat products (limited to the specified manufacturers)	<i>Listeria monocytogenes</i>
	Processed pistachio nuts products	Aflatoxin
China	Onion	Thiamethoxam
	Foods (limited to the specified manufacturers)	Cyclamic acid
France	Natural cheese (limited to the specified manufacturers)	Enterohemorrhagic E. coli O26
	Unheated meat products (limited to the specified manufacturers)	<i>Listeria monocytogenes</i>
Ghana	Cacao beans	Cypermethrin
South Korea	Cultured olive flounder (limited to the specified farmers)	<i>Kudoa septempunctata</i>
Nigeria	Sesame seeds	Aflatoxin
Bangladesh	Cumin seeds	Profenofos
Burkina Faso	Sesame seeds	Imidacloprid

**Table 6. Items Subject to Inspection Orders and Inspection Results
(Apr-Sep 2014: Tentative)**

Country/Region	Main subject food	Main test item	No. of tests	No. of violations
All exporting countries (17 items)	Peanut, almond, chili pepper, etc.	Aflatoxin	5,511	32
	Salted salmon roe	Nitrite	177	2
	Beans containing cyanide, cassava	Cyanide	247	4
China (20 items)	Eel, shrimp, soft-shelled turtle, etc.	Sulfadimidine, malachite green, chlortetracycline, sulfamethoxazole, enrofloxacin, etc.	3,922	1
	Vegetables, nuts, seafood, etc. (green soybean, onion, spinach, peanut, bivalves, etc.)	Difenoconazole, thiamethoxam, prometryn, dieldrin (including aldrin), endrin, etc.	7,629	20
	Bivalves	Paralytic shellfish poison, diarrhetic shellfish toxin	3,206	0
	All processed products	Cyclamic acid	325	0
	Chinese pepper(<i>Zanthoxylum bungeanum</i>), lotus seed	Aflatoxin	35	1
South Korea (11 items)	Bivalves	Paralytic shellfish poison, diarrhetic shellfish toxin	82	0
	Red chili, freshwater clam	Difenoconazole, endosulfan	58	2
	Olive flounder	Enrofloxacin, oxytetracycline	12	0
	Arch shells	<i>Vibrio parahaemolyticus</i>	2	0
Thailand (8 items)	Okra, mango, green asparagus, banana, red chili, etc.	EPN, chlorpyrifos, profenofos, cypermethrin, difenoconazole, etc.	1,275	1
Italy (7 items)	Cheese, unheated meat products, etc.	<i>Listeria monocytogenes</i>	1,019	6
	Chestnut, pistachio nuts, etc.	Aflatoxin	248	3
India (6 items)	Cultured shrimp	Furazolidone	723	5
	Cassia torea, chickpea	Aflatoxin	56	0
	Cumin seeds, red chili, etc.	Profenofos, glyphosate, triazophos, etc.	43	1
Other (24 countries and 1 region, total 40 items)			21,821	27
Total			46,391	105

**Table 7. Major Examples of Enhanced Monitoring Based on Overseas Information
(Apr-Sep 2014)**

Month of enhancement	Subject country	Subject food and details	Background and status
July	Denmark	Danish pork processed by DANISH CROWN (EST.71) (May contain diethylstilbestrol)	Information was received stating that in Denmark diethylstilbestrol was detected in urine of pigs processed by DANISH CROWN (EST.71) and the relevant products were being voluntarily recalled. When an import notification was made for pork processed at the relevant facility, steps were taken for re-shipment etc.
July	France	Soft and semi-soft type natural cheese (May be contaminated with Enterohemorrhagic E. coli O26)	Information was received stating that in France enterohemorrhagic E. coli O26 was detected in soft and semi-soft type natural cheese and the relevant products were being voluntarily recalled. When an import notification was made for such recall products, steps were taken for re-shipment.
September	France	Natural cheese (May be contaminated with Enterohemorrhagic E. coli O26)	Information was received stating that in France enterohemorrhagic E. coli O26 was detected in semi-hard type natural cheese and the relevant products were being voluntarily recalled. Steps were taken to specify the relevant manufacturer subject to inspection orders.

(Reference) Description of key terms in the interim report

Term	Description
Acid blue 3 sodium salt	Undesignated additive
Nitrite	Additive (color former)
Azorubin	Undesignated additive
Aflatoxin	Mycotoxin (produced by fungi such as <i>Aspergillus</i>)
Carbon monoxide	Undesignated additive
Genetic modification	Technology, for instance, to fragment bacterial genes and arrange the gene sequences or introduce the fragmented genes into other organism's genes
Imidacloprid	Agricultural chemical (chloronicotinyl insecticide)
Endosulfan	Agricultural chemical (organochlorine insecticide)
Endrin	Agricultural chemical (organochlorine insecticide)
Enrofloxacin	Veterinary drug (new quinolone synthetic antibacterial agent)
Oxytetracycline	Veterinary drug (tetracycline antibiotic)
Ofloxacin	Veterinary drug (new quinolone synthetic antibacterial agent)
Quinoline yellow	Undesignated additive
Glyphosate	Agricultural chemical (organophosphorus herbicide)
Chlortetracycline	Veterinary drug (tetracycline antibiotic)
Chlorpyrifos	Agricultural chemical (organophosphorus insecticide)
Diarrhetic shellfish toxin	Shellfish poison (mainly refers to toxins produced by a harmful plankton accumulated in bivalves)
Cyclamic acid	Undesignated additive
Cyanide	Harmful or poisonous substance (cyanide-related compounds (e.g., cyanogenic glycoside) found in vegetables such as some varieties of beans)
Diethylstilbestrol	Veterinary drug (hormonal agent)
Dicofol	Agricultural chemical (organochlorine insecticide)
Difenoconazole	Agricultural chemical (triazole fungicide)
Cypermethrin	Agricultural chemical (pyrethroid insecticide)
Sulfadimidine	Veterinary drug (synthetic antibacterial agent)
Sulfamethoxazole	Synthetic antibacterial agent (sulfur agent)

Term	Description
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)
Enterohemorrhagic E. coli	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 with large amounts of fresh blood after early cold-like symptoms)
Dieldrin (including aldrin)	Agricultural chemical (organochlorine insecticide)
Deoxynivalenol	Mycotoxin (produced by Fusarium fungi)
Triadimenol	Agricultural chemical (phenoxy fungicide)
Triazophos	Agricultural chemical (phenoxy insecticide)
Patulin	Mycotoxin (produced by fungi of the genus Penicillium, Aspergillus, etc.)
Methyl-p-hydroxybenzoate	Undesignated additive
Haloxfop	Agricultural chemical (organochlorine herbicide)
Bifenthrin	Agricultural chemical (pyrethroid insecticide)
Fenvalerate	Agricultural chemical (pyrethroid insecticide)
Buprofezin	Agricultural chemical (heterocyclic fungicide)
Furazolidone	Veterinary drug (nitrofurantoin synthetic antibacterial agent), generates AOZ when metabolized
Profenofos	Agricultural chemical (organophosphorus insecticide)
Prometryn	Agricultural chemical (triazine herbicide)
Pencycuron	Agricultural chemical (urea fungicide)
Paralytic shellfish poison	Shellfish poison (mainly refers to toxins produced by a harmful plankton accumulated in bivalves)
Malachite green	Veterinary drug (triphenylmethane synthetic antibacterial agent)
Methanol	An alcohol used as organic solvent etc.
Methamidophos	Agricultural chemical (organophosphorus insecticide)
Iodized salt	Undesignated additive
<i>Listeria monocytogenes</i>	Pathogenic microorganism (a microorganism widely found in the natural environment that mainly contaminates dairy products and processed meat products, and causes influenza-like symptoms with tiredness and fever)
2,4-D	Agricultural chemical (phenoxy acid herbicide)

Term	Description
EPN	Agricultural chemical (organophosphorus insecticide)
<i>Kudoa septempunctata</i>	Parasite that causes food poisoning (Myxosporidia)
TBHQ	Undesignated additive