(Annex)



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Inspection Results of Imported Foods Monitoring and Guidance Plan for FY 2015

Interim Report

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Department of Environmental Health and Food Safety
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Inspection Results of Imported Foods Monitoring and Guidance Plan for FY 2015 (Interim Report)

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 2015 (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, conducted in accordance with the plan, for the period from April to September 2015.



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 2015

(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 FY2015: 95,000 items across 171 food groups)
- Inspection orders *2 (as of September 30, 2015: 17 items from all exporting countries and 75 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 2015 (Interim Report: Tentative)

Looking at the declarations, inspections and violations made from April through September of 2015 (Table 1), there were 1,134,155 [1,138,913] declarations, and the weight of declared items was approximately 11,416,000 [11,952,000] tons.

Inspections were carried out on 101,922 items (there were inspection orders on 31,764 items, monitoring inspections on 28,539 items, and voluntary inspections on 47,067 items) [99,165 items (inspection orders on 28,153 items, monitoring inspections on 27,719 items, and voluntary inspections on 47,739 items)]. Of these, 431 cases [430 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 312 cases, followed by 105 cases violations of Article 6 which is related to contamination with hazardous or toxic substances such as aflatoxin, 26 cases violations of Article 10 which is related to restrictions on the sale of additives, and 17 cases violations of Article 18 which is related to standards for apparatus or containers and packaging.

Records of monitoring in FY 2015 (Table 3) show that, out of a total of 95,090 planned inspections, 57,455 were actually conducted (That's an implementation rate of about 60%). Of these, a total of 93 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, 2015, inspection orders had been applied to 17 items from all

exporting countries and 75 items from 29 countries and 1 region. The records of inspection orders (Table 6) show that a total of 47,760 inspection orders were conducted and, of these, steps were taken for their reshipment or disposal, etc. based on 116 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 import examination was enhanced, for issues such as the contamination of glass pieces from bottled wine in South Africa, detection of Salmonella 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 2015: Tentative)

No. of Notifications (cases) *1	Amount of Import (1,000 tons)*1	No. of Inspections ^{*1} (cases)	Percentage *2 (%)	No. of Violations (cases)	Percentage *3 (%)
1,134,155	11,416	101,922 (31,764) ^{*4}	9.0	431	0.04
(previous FY)					
1,138,913	11,952	99,165	8.7	430	0.04

^{*1} Values obtained after excluding overlapping cases from the total values of inspections by governments, registered laboratories, and public organizations of the exporting country.

^{*2} Proportion of the number of inspections to the number of notifications

^{*3} Proportion of the number of violations to the number of notifications

^{*4} Figures relate to inspection orders

Major Violation Cases (Apr-Sep 2015: Tentative) Table 2.

Violated Article	No. of Violations	Proportion (%)	Major Violations
Article 6 (Foods and Additives prohibited of sales and distribution)	105	22.8	Aflatoxin contamination in almonds, figs, walnuts, spices, corn, chia seeds, job's tears, pistachio nuts, peanuts etc.; detection of cyanide; and decay, deterioration and generation of mold due to accidents during the transport of adzuki beans, coffee beans, rice, wheat, soybeans, butter beans, mixing with toxic fish, detection of <i>Kudoa septempunctata</i> from cultured olive flounder etc.,
Article 10 (Limitation on sales and distribution of additives)	26	5.7	Use of undesignated additives (TBHQ, azorubin, carbon monoxide, Orange II, cyclamic acid, Fast Red E, iodized salt, etc.)
Article 11 (Standards and specifications for foods and additives)	312	67.8	Violation of specifications for vegetables and frozen vegetables (violation of standards for residual pesticides); violation of specifications for meat, 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 food 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)	17	3.7	Violation of specifications/standards for instruments and containers/packages; violation of specification for raw materials
Total	460 (total) ^{*1} 431 (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 2015: Tentative)

Food Group	Category of Inspected Items*1	No. of Programs Planned in FY ^{*2}	No. of Programs Implemented	No. of Violations
	Antibacterial		·	4
	substances, etc.	1,879	1,146	4
	Residual agricultural chemicals	1,191	1,069	0
Livestock foods Beef, pork, chicken,	Additives	118	104	0
horse meat, poultry Meat and other meats	Pathogenic microorganism	657	333	0
meat and other meats	Standards for constituents	295	254	0
	Exposure to radiation	29	16	0
	Removal of SRM	-	601	0
	Antibacterial substances, etc.	2,236	1,347	1
Processed livestock foods	Residual agricultural chemicals	1,697	1,169	0
Natural cheeses, meat	Additives	1,247	844	0
products, ice cream, frozen products (meat	Pathogenic microorganism	3,584	1,866	2
products), and others	Standards for constituents	2,236	1,305	2
	Mycotoxins	-	1	0
	Antibacterial substances, etc.	2,572	1,510	0
Seafood products	Residual agricultural chemicals	1,014	1,229	0
Bivalves, fish, shellfish	Additives	297	176	2
(shrimps, crabs) and others	Pathogenic microorganism	1,074	821	1
	Standards for constituents	359	251	0
	Exposure to radiation	34	20	0
	Antibacterial substances, etc.	4,114	2,938	1
Processed seafoods Processed fish products	Residual agricultural chemicals	4,051	3,048	0
(fillet, dried or minced fish, etc.), frozen food	Additives	1,924	1,497	1
(seafood, fish), processed fish roe	Pathogenic microorganism	4,661	3,340	3
products, and others	Standards for constituents	4,930	2,543	24
	Exposure to radiation	-	7	0
Agricultural foods Vegetables, fruits, wheat and barley, corn, beans, peanuts, nuts, seeds, and others	Antibacterial substances, etc.	2,559	1,839	0
	Residual agricultural chemicals	8,831	5,494	17
	Additives	474	391	2
	Pathogenic microorganism	1,495	1,120	0
	Standards for constituents	355	186	0
	Mycotoxins	2,513	1,309	1
	GMOs	464	223	0
	Exposure to radiation	119	78	0

Food Group	Category of Inspected Items*1	No. of Programs Planned in FY ^{*2}	No. of Programs Implemented	No. of Violations
	Antibacterial substances, etc.	598	403	0
Processed agricultural foods	Residual agricultural chemicals	6,980	4,918	6
Frozen products	Additives	4,551	3,440	2
(processed vegetables), processed vegetable	Pathogenic microorganism	956	741	0
products, processed fruit products, spices, instant	Standards for constituents	2,349	1,805	8
noodles, and others	Mycotoxins	2,774	1,712	1
	GMOs	198	128	1
	Exposure to radiation	424	281	0
	Antibacterial substances, etc.	-	1	0
Other foods Health foods, soups,	Residual agricultural chemicals	1,014	647	0
seasonings, confectionaries, edible	Additives	2,984	1,951	2
oils, fat, frozen products, and others	Standards for constituents	598	262	5
and others	Mycotoxins	1,135	620	0
	GMOs	-	1	0
	Residual agricultural chemicals	88	109	0
Drinks and beverages Mineral water, soft	Additives	1,075	714	1
drinks, alcoholic beverages, and others	Standards for constituents	657	460	1
beverages, and others	Mycotoxins	118	83	0
	GMOs	-	2	0
Additives Equipment, containers and packages Toys	Standards for constituents	1,582	1,102	5
Total (number) 10,000 were added to the No. of Programs Planned in FY as "foods subject to enhanced monitoring inspections."		95,090	57,455 Rate of program implemented: about 60%	93

- *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.
 - Pathogenic microorganisms (*Enterohemorrhagic* E. coli O26, O103, O104, O111, O121, O145 and O157, *Listeria monocytogenes*, etc.)
 - Standards for constituents, etc.: Items stipulated in the compositional standards (bacteria count, coliform bacteria etc.), 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.
 - 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 2015)

Country/Region	Subject Food	Test Item
	Oolong tea	Indoxacarb
	Shrimp	Chlortetracycline
China	Wood ears (Auricularia spp.)	Chlorpyrifos
	Taro	Chlorpyrifos
	Cultured shrimp	Furazolidone (as AOZ)
	Fresh lime leaves	Profenofos
Thailand	Pork	Furazolidone
Titalianu	Balsam pear	Metalaxyl
	Shrimp (for raw consumption)	Vibrio parahaemolyticus*3
Egypt	Calendula (Calendula officinalis)	Chlorpyrifos
Едурі	Calendula (Calendula Officinalis)	Profenofos
Philippines	Mangos	Azoxystrobin
Тішрршез	Papaya	Cypermethrin
USA	Raspberry	Methoxyfenozide
USA	Propolis	Chloramphenicol
Argentina	Chia seed	2,4-D
Italy	Non-glutinous rice	Pirimiphos-methyl
India	Cumin seeds	IBP (Iprobenfos)
United Kingdom	Parsnip	Tebuconazole
Ecuador	Cacao beans	Diuron (DCMU)
Australia	Rape or colza seeds	Fenitrothion
Austria	Horseradish	Difenoconazole
Canada	Propolis	Chloramphenicol
South Korea	Freshwater clam	Endosulfan
Greece	Honey	Coumaphos
Colombia	Coffee beans	Chlorpyrifos
Chile	Grape	Profenofos
France	Apple juice	Patulin
Peru	Quinoa	Fipronil
Bolivia	Chia seed	2,4-D
South Africa	Grapefruit	Epoxiconazole
Mexico	Star fruit	Fludioxonil
Morocco	Chaste tree berries (Vitex agnus-castus)	Aflatoxin

^{*1} In FY2015, 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 2015).

Table 5. Items Shifted to Inspection Orders (Apr-Sep 2015)

Country/Region	Subject Food	Test Item
	Chicken	Nicarbazin
France	Natural cheese (limited to the specified manufacturers)	Enterohemorrhagic <i>E. coli</i> O26, O145, O157
Italy	Natural cheese (limited to the specified manufacturers)	Listeria monocytogenes
Australia	Processed almond products	Aflatoxin
South Korea	Cultured olive flounder (limited to the specified farmers)	Kudoa septempunctata
Thailand	Shrimp for raw consumption (limited to the specified manufacturers)	Vibrio parahaemolyticus
Taiwan	Foods (limited to the specified manufacturers)	Cyclamic acid
China	Foods (limited to the specified manufacturers)	Cyclamic acid
Philippines	Okra (limited to the specified exporters)	Fluazifop

Table 6. Items Subject to Inspection Orders and Inspection Results (Apr-Sep 2015: Tentative)

Country/Region	Main subject food	Main test item	No. of tests	No. of violations
	Almond, Chili pepper, Peanut, etc.	Aflatoxin	5,521	34
All exporting countries	Salted salmon roe	Nitrite	260	0
(17 items)	Cassava, Beans containing cyanide	Cyanide	237	6
	Puffer fish	Identification of fish species	2	1
	Vegetables, Fruits, Seafood, etc. (Green soybean, Onion, Spinach, Lychees, Bivalves, etc.)	Endrin, Difenoconazole, Thiamethoxam, Dieldrin (including aldrin), Prometryn, etc.	11,253	19
China (19 items)	Eel, Shrimp, Soft-shelled turtle	Enrofloxacin, Oxolinic acid, Chlortetracycline, Sulfadimidine, Malachite green	3,348	0
	Bivalves	Paralytic shellfish poison, Diarrhetic shellfish poison	2,730	0
	All processed products	Cyclamic acid	379	0
	Lotus seed	Aflatoxin	9	0
	Tomato, Red chili, Freshwater clam, etc.	Endosulfan, Difenoconazole, Fluquinconazole, etc.	399	3
South Korea (12 items)	Bivalves	Paralytic shellfish poison, Diarrhetic shellfish poison	68	0
	Cultured olive flounder	Enrofloxacin, Oxytetracycline	18	0
Thailand (9 items)	Red chili, Okra, Green asparagus, Banana, Mangos, etc.	EPN, Chlorpyrifos, Difenoconazole, Cypermethrin, Profenofos, etc.	1,039	0
	Cultured shrimp	Furazolidone	842	1
India	Cassia torea, Chickpea, Fenugreek seed	Aflatoxin	110	0
(8 items)	Cumin seeds, Red chili, etc.	Glyphosate, Triazophos, Profenofos, Hexaconazole, etc.	79	1
Italy (7 itams)	Chestnuts, Corns, Pistachio nuts	Aflatoxin	220	4
(7 items)	Natural cheese.	Listeria monocytogenes	55	0
Other (25 countrie	es and 1 region, total 37 items)		21,191	47
Total			47,760	116

^{*}Total number means number of tests and violation item-by-item inspections

Table 7. Major Examples of Enhanced Inspection Based on Overseas Information (Apr-Sep 2015)

Month of enhancement	Subject country	Subject food and details	Background and status
April	France	Natural cheese (May be contaminated with Salmonella)	Information was received stating that in France Salmonella was detected from natural cheese and the relevant products were being voluntarily recalled. When an import notification was made for such recall products, steps were taken for reshipment.
May	France	Natural cheese (May be contaminated with Salmonella)	Information was received stating that in France Salmonella was detected from natural cheese and the relevant products were being voluntarily recalled. When an import notification was made for such recall products, steps were taken for reshipment.
June	South Africa	Bottled wine (May contain the glass pieces)	Information was received stating that in South Africa the glass pieces were found in bottled wine and the relevant products were being voluntarily recalled. When an import notification was made for such recall products, steps were taken for reshipment.

(Reference) Description of key terms in the interim report

Term	Description	
Nitrite	Additive (color former)	
Azoxystrobin	Agricultural chemical (fungicide)	
Azorubin	Undesignated additive	
Aflatoxin	Mycotoxin (produced by fungi such as Aspergillus)	
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	
Indoxacarb	Agricultural chemical (insecticide)	
Epoxiconazole	Agricultural chemical (fungicide)	
Endosulfan	Agricultural chemical (organochlorine insecticide)	
Endrin	Agricultural chemical (organochlorine insecticide)	
Enrofloxacin	Veterinary drug (new quinolone synthetic antibacterial agent)	
Oxytetracycline	Veterinary drug (tetracycline antibiotic)	
Oxolinic acid	Veterinary drug (quinolone synthetic antibacterial agent)	
Orange II	Undesignated additive	
Coumaphos	Agricultural chemical (organophosphorus insecticide)	
Glyphosate	Agricultural chemical (organophosphorus herbicide)	
Chloramphenicol	Veterinary drug (chloramphenicol antibiotic)	
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	
Salmonella	Pathogenic microorganism (A bacterium that is ubiquitous in nature. It contaminates mostly eggs and meat, and causes acute abdominal pain, diarrhea and fever.)	
Cyanide	Harmful or poisonous substance (cyanide-related compounds (e.g., cyanogenic glycoside) found in vegetables such as some varieties of beans)	
Diuron (DCMU)	Agricultural chemical (herbicide)	
Difenoconazole	Agricultural chemical (triazole fungicide)	
Cypermethrin	Agricultural chemical (pyrethroid insecticide)	
Sulfadimidine	Veterinary drug (synthetic antibacterial agent)	
Sorbic acid	Additive (preservative)	

Term	Description	
Thiamethoxam	Agricultural chemical (neonicotinoid insecticide)	
Vibrio parahaemolyticus	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)	
Tebuconazole	Agricultural chemical (triazole fungicide)	
Triazophos	Agricultural chemical (phenoxy insecticide)	
Sulfur dioxide	Additive (antioxidant agents)	
Patulin	Mycotoxin (produced by fungi of the genus Penicillium, Aspergillus, etc.)	
Pirimiphos-methyl	Agricultural chemical (insecticide)	
Fast red E	Undesignated additive	
Fipronil	Agricultural chemical (heterocyclic insecticide)	
Fenitrothion	Agricultural chemical (organophosphorus insecticide)	
Furazolidone	Veterinary drug (nitrofuran synthetic antibacterial agent), generates AOZ when metabolized	
Fluazifop	Agricultural chemical (herbicide)	
Fluquinconazole	Agricultural chemical (fungicide)	
Fludioxonil	Agricultural chemical (antifungal agent)	
Profenofos	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 bivalves)	
Malachite green	Veterinary drug (triphenylmethane synthetic antibacterial agent)	
Metalaxyl	Agricultural chemical (organophosphorus insecticide)	
Methoxyfenozide	Agricultural chemical (insecticide)	
lodized salt	Undesignated additive	
Listeria monocytogenes	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
BHT (butylhydroxytoluene)	Additive (antioxidant agent)
EPN	Agricultural chemical (organophosphorus insecticide)
IBP (Iprobenfos)	Agricultural chemical (fungicide)
Kudoa septempunctata	Parasite that causes food poisoning (Myxosporidia)
TBHQ	Undesignated additive