(Annex)

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Results of Imported Foods Monitoring and Guidance Plan for FY 2019

Interim Report

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Pharmaceutical Safety and Environmental Health Bureau,
Ministry of Health, Labour and Welfare

Inspection Results of Imported Foods Monitoring and Guidance Plan for FY 2019 (Interim Report)

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 2019 (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 2019.

Reference: Website on “Imported Foods Monitoring for the Safety of Imported Food”
https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryou/shokuhin/yunyu_kanshi/index.html

2. Overview of the Imported Foods Monitoring and Guidance Plan for FY 2019

(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 each stage of food safety measures are taken, namely, from productions in the exporting country to domestic distribution after importation.

(3) Priority Items for Monitoring and Guidance

- ○ Confirmation of legality with respect to the Act at the time of import declaration
- ○ Monitoring Inspections[*1] (Plan for FY2019:approximately 99,000 cases across 171 food groups)
- ○ Inspection orders [*2]
- ○ Regulations for comprehensive import bans [*3]
- ○ Emergency measures based on overseas information, etc.

*1: Systematic inspections considered based on figures derived from statistical approach taking into account the volume of imports, violation rates and other factors, for each food type.

*2: Inspection is ordered for the importer for products with a high probability of violation, at the time of every import. and import and distribution is not permitted without the results being in compliance with 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.

(4) Promotion of Food Hygiene Control Measures in Exporting Countries

- ○ Informing the responsible governmental agencies, food business operators and other organizations 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, etc.
- ○ 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 Hygiene Control

- ○ Pre-import guidance (known as import consulting)
- ○ Guidance for voluntary inspections at the import consulting, initial import, and continued import

- ○ Guidance on preparation, storage, etc. of records on import and sales conditions of imported foods
- ○ Raising awareness of food safety amongst importers

3. Inspection Results of Imported Foods Monitoring and Guidance Plan for FY 2019 (Interim Report: Tentative)

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

The number of import notifications made from April through September of 2019 was 1,298,431 [1,228,569], and the weight of notified items was 12,488 thousand tons [12,197 thousand tons].
Inspections were carried out on 112,319 items [103,262 items] (monitoring inspections on 30,985 items [30,496 items], ordered inspection on 34,558 items [28,842 items], and independence inspection on 48,681 items [45,769 items], deducting duplicates) of these, 407 cases [385 cases] were found to be in violation of the Act, and steps were taken for their reshipment, disposal, etc. (Table 1)
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 248 cases, followed by 117 cases in violation of Article 6 (adhesion of hazardous or toxic substances such as aflatoxin, cyanide), 38 cases in violation of Article 10 (use of undesignated additives), 17 cases in violation of Article 18 (standards for apparatus or containers and packaging), 2 cases in violation of Article 62 (standards for toys), and 1 case in violation of Article 9 (absence of health certificates of meat) (Table 2).

Monitoring inspection was conducted for 30,985 cases (58,468 cases compared to the planned cumulative total of 99,059 (implementation rate: approx. 59%)), and of which, 76 cases (running total of 77 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 was increased 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, 2019, 17 items from all exporting countries and 76 items from 33 countries and 2 regions were made subject to ordered inspection, and inspection was carried out for 34,558 cases (running total of 48,813 cases). Of these, violation of the Act was found in 110 cases (running total of 110 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 natural cheese contaminated with Enterohemorrhagic Escherichia coli O26 or Salmonella spp. from France (Table 7).

○Table 1. Notification, Inspection and Violation (Apr-Sep 2019: Tentative)

Notifications[*1] (cases)	Imported Weight[*1] (thousand tons)	Inspections[*2] (cases)	Proportion[*3] (%)	Violations (cases)	Proportion[*3] (%)
1,298,431	12,488	112,319 (34,558[*4])	8.7	407	0.03
(FY2018) 1,228,569	12,197	103,262	8.4	385	0.03

*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 2019: Tentative)

Provision violated	Violations (cases)	Proportion (%)	Brief details of Violations
Article 6 (Foods and Additives prohibited to distribute)	117	27.7	Aaflatoxin contamination in almonds, peanuts, corn, dried fig, pistachio nuts, etc.; decay, deterioration and fungus formation due to accidents during the transport of rice, rapeseed, wheat, corn, barley and rye, detection of cyanide from cassava processed products, etc., and detection of paralytic shellfish poison from bivalves.
Article 9 (Limitation on distribution, etc. of diseased meat)	1	0.2	No health certificate attached or incomplete
Article 10 (Limitation of distribution, etc. of additives)	38	9.0	Use of undesignated additives (TBHQ, cyclamic acid, iodized salt, aspartate 1-decarboxylase, azorubine, dichloromethane, Quinoline Yellow WS)
Article 11 (Standards and criteria for foods and additives)	248	58.6	Violation of standards for constituents for agricultural products and processed products (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 frozen food, beverages, boiled crab, etc., (coliform bacteria positive, vibrio parahaemolyticus, etc.), violation of criteria on production of retort sterilized foods, violation of criteria on use of additives (sorbic acid, sulfur dioxide, etc.), violation of standards for constituents for additives, detection of unauthorized genetically modified foods, etc.
Article 18 (Standards and criteria for apparatus, containers and packaging)	17	4.0	Violation of standards and criteria for apparatus, containers and packaging
Article 62 (Provisions to be applied mutatis mutandis for toys)	2	0.5	Violation of standards and criteria for toys
Total	(Gross) 423*1 (Actual) 407*2		

*1 Gross number of Itemized cases violations

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

○Table 3. Implementation of Monitoring Inspections (Apr-Sep 2019: Tentative)

Food Groups	Inspected Substances[*1]	Planned Number	Actual Number	Violations
Livestock Foods Beef, pork, chicken, horse meat, other poultry meat, etc.	Antibacterial substances, etc.	2,178	1,285	0
	Residual agricultural chemicals	1,221	1,000	0
	Additives	118	119	0
	Pathogenic microorganism	657	453	0
	Standards for constituents	385	266	0
	Radiation irradiation	29	8	0
	Removal of SRM	-	1,007	1
Processed Livestock Foods Natural cheeses, processed meat products, ice cream, frozen (meat) products, etc.	Antibacterial substances, etc.	2,266	1,231	0
	Residual agricultural chemicals	1,637	993	0
	Additives	1,247	727	0
	Pathogenic microorganism	3,704	2,064	2
	Standards for constituents	2,057	1,274	3
	Mycotoxins	-	4	0
	Radiation irradiation	-	1	0
Aquatic Foods Bivalves, fish, crustacea (shrimps, crabs), etc.	Antibacterial substances, etc.	2,536	1,289	0
	Residual agricultural chemicals	1,458	1,071	1
	Additives	297	159	0
	Pathogenic microorganism	1,194	887	0
	Standards for constituents	324	255	0
	Genetically modified food	59	30	0
	Radiation irradiation	64	30	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.	3,574	2,618	1
	Residual agricultural chemicals	3,423	2,533	0
	Additives	1,594	1,237	0
	Pathogenic microorganism	3,851	2,599	0
	Standards for constituents	5,855	3,348	14
	Mycotoxins	-	2	0
	Radiation irradiation	-	5	0
Agricultural Foods Vegetables, fruits, wheat, maize, pulses, peanuts, nuts, seeds, etc.	Antibacterial substances, etc.	2,170	1,838	0
	Residual agricultural chemicals	11,078	6,199	27
	Additives	534	516	2
	Pathogenic microorganism	1,434	1,143	0
	Standards for constituents	355	198	0
	Mycotoxins	2,297	1,453	2
	Genetically modified food	502	257	0
	Radiation irradiation	119	74	0
Processed Agricultural Foods Frozen food (vegetables), processed vegetable products, processed fruit products, spices, instant noodles, etc	Antibacterial substances, etc.	299	243	0
	Residual agricultural chemicals	7,040	4,866	6
	Additives	4,282	3,202	0
	Pathogenic microorganism	2,210	1,216	0
	Standards for constituents	3,518	2,444	9
	Mycotoxins	2,834	1,731	4
	Genetically modified food	302	210	0
	Radiation irradiation	477	292	1
Other Foods Health foods, soups, seasonings, confectionery, cooking oil and fat, frozen food, etc.	Residual agricultural chemicals	1,074	721	0
	Additives	3,044	1,919	0
	Standards for constituents	1,196	483	2
	Mycotoxins	836	383	0
	Genetically modified food	-	3	0
	Radiation irradiation	-	12	0
Beverages Mineral waters, soft drinks, alcoholic drinks, etc.	Residual agricultural chemicals	118	115	0
	Additives	1,075	653	0
	Standards for constituents	657	394	0
	Mycotoxins	118	89	1
Additives **Apparatus, containers and packaging** **Toys**	Standards for constituents	1,762	1,319	1
Total (gross)		99,059[*2]	58,468[*3] Implementation rate of 59%	77[*3]

*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: 10,000 cases planned as enhanced monitoring were added to the number

*3 Running total by inspected substances Actual number is 30,985 (Monitoring Inspections), and 76 (Violations).

○Table 4. Items Subject to Enhanced Monitoring Inspections[*1] (Apr-Sep 2019)

Country/Region	Subject Item	Inspected Substances
All exporting countries	Shellfish for raw consumption (ark shell, razor clam, cockle and sea urchin)	Most probable number of vibrio parahaemolyticus [*2]
	Cultured olive flounder for raw consumption	Kudoa septempunctata[*3]
Vietnam	PUK WHAN (Sauropus androgynus)	Hexaconazole
	Shrimp	Furazolidone
	Culantro	Tebuconazole
		Pyridaben
		Fenbuconazole
	Frog	Furazolidone
	Tabasco pepper	Tricyclazole
		Hexaconazole
	Carrot	Hexaconazole
	Winter melon	Metalaxyl and Mefenoxam
China	Red pepper	Paclobutrazol
	Chinese date	Pyraclostrobin
		Propiconazole
	Carrot	Quintozene
		Triadimenol
	Spring onions	Thiamethoxam
	Unripe field peas	Diniconazol
	Lychee	4-Chlorophenoxyacetic Acid
	Wasabi (Japanese horseradish)	Procymidone
USA	Celery	Acephate
		Methamidophos
	Pop corns	Deltamethrin and tralomethrin
	Raspberry	Methoxyfenozide
Uganda	Sesame seeds	Thiamethoxam
Australia	Processed almond products	Aflatoxin
The Netherlands	Celeriac	Chlorpropham
Thailand	Boiled crab for raw consumption	Vibrio parahaemolyticus [*4]
Taiwan	Cultured eel	Fenitrothion
Turkey	Dried apple	Aflatoxin
New Zealand	Persimmon	Methoxyfenozide
Brazil	Cassava	Pirimiphos-methyl

*1 Include the Items which were rescinded from inspection order, and exclude the items which were transferred to inspection order.

*2 Item which 20% of import declarations were inspected as a measure to enhance inspections during the summer period, (Jun-Oct 2019)

*3 Planned Number in FY2019: 598 cases

*4 Item which 30% of import declarations were inspected as a measure to enhance inspections during the summer period, (Jun-Oct 2019)

○Table 5. Items transferred to Inspection Order (Apr-Sep 2019)

Country/Region	Subject Item	Inspected Substances
Italy	Natural cheese (limited producers)	Listeria monocytogenes
	Processed pistachio nut product	Aflatoxin
India	Processed almond products	Aflatoxin
Thailand	Durian	Procymidone
China	Szechuan pepper	Aflatoxin
	Food Groups (limited producers)	Cyclamic acid
	Broccoli	Procymidone
Turkey	Chickpeas	Aflatoxin
Paraguay	Chia seed	Aflatoxin
Brazil	Processed Brazilian nuts	Aflatoxin
France	Natural cheese (limited producers)	Enterohemorrhagic Escherichia coli O26
Vietnam	Culantro	Profenofos
		Hexaconazole
	Food Groups (limited producers)	Cyclamic acid
Mexico	Avocado	Bifenthrin

○Table 6. Major Items subject to Ordered Inspections and Inspection Outcomes (Apr-Sep 2019: Tentative)

Country/Region	Major subject foods	Major Inspected Substances	Inspections	Violations
All exporting countries (17 items)	Almond, Chili pepper, Peanut, etc.	Aflatoxin	6,383	56
	Cassava, Beans containing cyanide	Cyanide	263	6
	Salted salmon roe	Nitrite	104	0
China (19 items)	Vegetables (Onion, Spinach, Broccoli, etc.), Lychee, Short-neck clam	Residual agricultural chemicals (Endrin, Chlorpyrifos, Thiamethoxam, Dieldrin (including aldrin), 4-Chlorophenoxyacetic acid, Prometryn, etc.)	13,307	6
	Bivalves	Paralytic shellfish poison, Diarrhetic shellfish poison	3,935	1
	All processed products	Cyclamic acid	506	0
	Eel, Soft-shelled turtle	Enrofloxacin, Oxolinic acid, Sulfadimidine	41	1
	Szechuan pepper, Sunflower seeds, Sorghum	Aflatoxin	109	1
South Korea (12 items)	Bivalves	Paralytic shellfish poison, Diarrhetic shellfish poison	81	0
	Cultured olive flounder	Enrofloxacin, Oxytetracycline	6	0
Thailand (10 items)	Okra, Green asparagus, Durian, Banana, Mango, Mangosteen	Residual agricultural chemicals (EPN, Imazalil, Chlorpyrifos, Cypermethrin, Procymidone, Propiconazole)	752	0
	Boiled crab	Vibrio parahaemolyticus	6	0
USA (7 items)	Dried dates, Corn, Pistachio	Aflatoxin	1,931	16
	Natural cheese	Listeria monocytogenes	5	0
Italy (6 items)	Pistachio nuts	Aflatoxin	26	0
	Natural cheese	Pathogenic microorganisms (Listeria monocytogenes, Enterohemorrhagic Escherichia coli O26)	19	1
	Rice	Pirimiphos-methyl	15	0
India (6 items)	Cultured shrimp	Furazolidone	1,022	1
	Cassia seeds, Corns	Aflatoxin	62	1
	Pepper	Triazophos	19	0
Philippines (6 items)	Okra, Mango, Banana	Residual agricultural chemicals (Chlorpyrifos, Cypermethrin, Tebufenozide, Fipronil, Phenthoate, Fluazifop-butyl, Methamidophos)	3,606	3
	Tuna for raw consumption	Salmonella spp.	131	0
Vietnam (6 items)	Squid, Shrimp, Filefish	Enrofloxacin, Chloramphenicol, Sulfadiazine, Furazolidone	14,764	5
	Culantro	Residual agricultural chemicals (Chlorpyrifos, Profenofos, Hexaconazole)	5	1
	All processed products	Cyclamic acid	49	0
Other countries (Total of 38 items in 25 countries and 2 regions)			1,666	11
Total (Gross) *1			48,813	110
(Actual) *2			34,558	110

*1 Gross number of Itemized cases violations

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

○Table 7. Major Enhanced Monitoring based on Overseas Information (Apr-Sep 2019)

Month of enhancement	Subject country	Subject food and details	Background and status
May	France	Natural cheese (Enterohemorrhagic Escherichia coli O26)	Information was received stating that in the France a manufacturer was conducting voluntary recall of natural cheese due to the detection of Enterohemorrhagic Escherichia coli O26 (pathogenic microorganism). When an import notification was made for such recall products, steps were taken for reshipment, etc.
Sep.	France	Natural cheese (Salmonella spp.)	Information was received stating that in the France a manufacturer was conducting voluntary recall of natural cheese due to the detection of Salmonella spp. (pathogenic microorganism). When an import notification was made for such recall products, steps were taken for reshipment, etc.

(Reference) Description of Key Terms

Term	Description
Aflatoxin	Mycotoxin (produced by the fungus Aspergillus, 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.
Imazalil	Agricultural chemical (imidazole fungicide)
Enrofloxacin	Veterinary drug (new quinolone synthetic antibacterial agent)
Oxytetracycline	Veterinary drug (tetracycline antibiotical agent)
Oxolinic acid	Veterinary drug (quinolone synthetic antibacterial agent)
Quintozene	Agricultural chemical (organochlorine fungicide)
Kudoa septempunctata	A type of parasite which causes food poisoning (Myxosporidia)
Chloramphenicol	Veterinary drug (synthetic antibacterial agent)
Chlorpyrifos	Agricultural chemical (organophosphorus insecticide)
Chlorpropham	Agricultural chemical (carbamate herbicides)
Diarrhetic shellfish toxin	Shellfish poison (mainly refers to toxins produced by a harmful plankton accumulated in clams)
Cyclamic acid	Undesignated additives
Salmonella spp.	Pathogenic microorganism (A bacterium that is ubiquitous in the intestines of animals as well as in nature, such as rivers, sewage and lakes. It contaminates meat, mostly poultry and eggs, and causes acute abdominal pain, diarrhea, fever and vomiting.)
Cyanide	Harmful or poisonous compound (cyanide-related compounds (e.g., cyanogenic glycoside) found in vegetables such as some varieties of beans.
Diniconazol	Agricultural chemical (triazole fungicide)
Cypermethrin	Agricultural chemical (pyrethroid insecticide)
Sulfadiazine	Veterinary drug (synthetic antibacterial agent)
Sulfadimidine	Veterinary drug (synthetic antibacterial agent)
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 together with large amounts of blood after early cold-like symptoms.)
Deoxynivalenol	Mycotoxin (produced by the fungus Fusarium)
Tebuconazole	Agricultural chemical (triazole fungicide)
Deltamethrin and tralomethrin	Agricultural chemical (pyrethroid insecticide)
Tricyclazole	Agricultural chemical (benzothiazole herbicides)
Sulfur dioxide	Additive (antioxidant agents)
Paclobutrazol	Agricultural chemical (triazole growth regulator)
Patulin	Mycotoxin (produced by fungi such as Penicillium and Aspergillus, etc.)
Pyraclostrobin	Agricultural chemical (strobilurin fungicide)
Pyridaben	Agricultural chemical (Insecticide with pyridazinone structure)
Pirimiphos-methyl	Agricultural chemical (organophosphorus insecticide)
Fipronil	Agricultural chemical (phenylpyrazole synergist)
Fenitrothion	Agricultural chemical (organophosphorus insecticide)
Phenthoate	Agricultural chemical (organophosphorus insecticide)
Fenbuconazole	Agricultural chemical (triazole fungicide)
Furazolidone	Veterinary drug (nitrofuran synthetic antibacterial agent), generates AOZ when metabolized
Procymidone	Agricultural chemical (dicarboximide fungicide)
Propiconazole	Agricultural chemical (triazole fungicide)
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)
Methamidophos	Agricultural chemical (organophosphorus insecticide)
Metalaxyl and Mefenoxam	Agricultural chemical (anilide fungicide)
Methoxyfenozide	Agricultural chemical (Benzoylhydrazine insecticide)
Listeria monocytogenes	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)
4-Chlorophenoxyacetic acid	Agricultural chemical (plant growth regulator)
EPN	Agricultural chemical (organophosphorus insecticide)