

(Annex)



厚生労働省

Ministry of Health, Labour and Welfare

Office of Import Food Safety,
Food Inspection and Safety Division,
Pharmaceutical Safety and
Environmental Health Bureau,
Ministry of Health, Labour and Welfare

Inspection Results of Imported Foods Monitoring and Guidance Plan for FY2018

Interim Report

December 2018

Food Inspection and Safety Division
Pharmaceutical Safety and Environmental Health Bureau
Ministry of Health, Labour and Welfare

Inspection Results of Imported Foods Monitoring and Guidance Plan for FY 2018 (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 2018 (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 2018.

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 2018

(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 FY2018:approximately 98,500 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 2018 (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 2018 was 1,228,569 [1,225,011], and the weight of notified items was 12,197 thousand tons [12,255 thousand tons] (Table 1).

Inspections were carried out on 103,262 items [102,756 items] (monitoring inspections on 30,496 items [29,709 items], ordered inspection on 28,842 items [30,130 items], and independence inspection on 45,769 items [46,119 items], deducting duplicates) of these, 385 cases [384 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 249 cases, followed by 124 cases in violation of Article 6 (adhesion of hazardous or toxic substances such as aflatoxin, cyanide), 14 cases in violation of Article 18 (standards for apparatus or containers and packaging), 9 cases in violation of Article 10 (use of undesignated additives), 2 cases in violation of Article 9 (absence of health certificates of meat) (Table 2).

Monitoring inspection was conducted for 30,496 cases (60,295 cases compared to the planned cumulative total of 98,521 (implementation rate: approx. 61%)), and of which, 82 cases (running total of 84 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, 2018, 17 items from all exporting countries and 70 items from 30 countries and 1 region were made subject to ordered inspection, and inspection was carried out for 28,842 cases (running total of 43,386 cases). Of these, violation of the Act was found in 118 cases (running total of 118 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 from France, and wheat suspected to be contaminated with unauthorized genetically modified wheat from Canada. In addition, based on the information that food poisoning cases caused by *Vibrio parahaemolyticus* suspected to be caused by raw consumption sea urchin from china have occurred in Japan, independence inspection was carried out for raw consumption sea urchin from the suspected manufacture. (Table 7).

Table 1. Notification, Inspection and Violation (Apr-Sep 2018: Tentative)

Notifications (cases) *1	Imported Weight (thousand tons)*1	Inspections*2 (cases)	Proportion *3 (%)	Violations (cases)	Proportion *3 (%)
1,228,569	12,197	103,262 (28,842) *4	8.4	385	0.03
(FY2017) 1,225,011	12,255	102,756	8.4	384	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 2018: Tentative)

Provision violated	Violations (cases)	Proportion (%)	Brief details of Violations
Article 6 (Foods and Additives prohibited to distribute)	124	31.2	Aflatoxin contamination in almonds, peanuts, dried fig, corn, pistachio nuts etc.; decay, deterioration and fungus formation due to accidents during the transport of wheat, rice, coffee beans, buckwheat etc. detection of cyanide from cassava processed products, etc; detection of methanol from brandy etc.,
Article 9 (Limitation on distribution, etc. of diseased meat)	2	0.5	No health certificate attached or incomplete
Article 10 (Limitation of distribution, etc. of additives)	9	2.3	Use of undesignated additives (cyclamic acid, azorubin, patent blue, carmine, TBHQ)
Article 11 (Standards and criteria for foods and additives)	249	62.6	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 (sulfur dioxide, tar dye, etc.), violation of standards for constituents for additives, detection of unauthorized genetically modified, etc.
Article 18 (Standards and criteria for apparatus, containers and packaging)	14	3.5	Violation of standards for apparatus, containers and packaging
Total	398(Gross) ^{*1} 385(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 2018: 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.	2,178	1,184	0
	Residual agricultural chemicals	1,221	1,022	0
	Additives	118	76	0
	Pathogenic microorganism	657	374	0
	Standards for constituents	385	252	0
	Radiation irradiation	29	20	0
	Removal of SRM	-	1,030	2
Processed Livestock Foods Natural cheeses, processed meat products, ice cream, frozen (meat) products, etc.	Antibacterial substances, etc.	2,266	1,288	1
	Residual agricultural chemicals	1,637	1,074	0
	Additives	1,247	803	0
	Pathogenic microorganism	3,704	2,225	0
	Standards for constituents	2,057	1,327	4
	Radiation irradiation	-	3	0
Aquatic Foods Bivalves, fish, crustacea(shrimps, crabs), etc.	Antibacterial substances, etc.	2,057	1,162	0
	Residual agricultural chemicals	1,458	1,080	0
	Additives	297	179	0
	Pathogenic microorganism	1,194	764	0
	Standards for constituents	324	266	0
	Genetically modified food	59	54	0
	Radiation irradiation	64	28	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.	3,873	2,799	0
	Residual agricultural chemicals	3,423	2,763	0
	Additives	1,594	1,340	1
	Pathogenic microorganism	3,851	2,575	0
	Standards for constituents	5,825	3,221	25
	Mycotoxins	-	1	0
	Radiation irradiation	-	6	0
Agricultural Foods Vegetables, fruits, wheat, maize, pulses, peanuts, nuts, seeds, etc.	Antibacterial substances, etc.	2,170	1,852	0
	Residual agricultural chemicals	9,999	5,889	16
	Additives	534	483	3
	Pathogenic microorganism	1,434	1,191	0
	Standards for constituents	355	226	0
	Mycotoxins	2,297	1,371	7
	Genetically modified food	443	269	0
	Radiation irradiation	119	86	0
Processed Agricultural Foods Frozen food(vegetables), processed vegetable products, processed fruit products, spices, instant noodles, etc	Antibacterial substances, etc.	299	419	0
	Residual agricultural chemicals	7,040	5,183	6
	Additives	4,761	3,487	0
	Pathogenic microorganism	2,210	1,415	1
	Standards for constituents	3,518	2,512	10
	Mycotoxins	2,535	1,716	1
	Genetically modified food	302	178	0
	Radiation irradiation	448	265	0
Other Foods Health foods, soups, seasonings, confectionery, cooking oil and fat, frozen food, etc.	Residual agricultural chemicals	1,074	743	0
	Additives	3,883	2,409	0
	Pathogenic microorganism	-	2	0
	Standards for constituents	1,196	498	4
	Mycotoxins	656	418	0
	Genetically modified food	-	3	0
Beverages Mineral waters, soft drinks, alcoholic drinks, etc.	Residual agricultural chemicals	118	126	0
	Additives	1,075	762	1
	Standards for constituents	657	442	0
	Mycotoxins	118	97	0
Additives / Apparatus, containers and packaging / Toys	Standards for constituents	1,762	1,337	2
Total (gross)		98,521*2	60,295*3 Implementation rate of 61%	84*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 of items by item of each food groups

*3: Running total of Inspected Substances. Actual number is 30,496 (Monitoring Inspections), and 82 (Violations)

Table 4. Items Subject to Enhanced Monitoring Inspections*1 (Apr-Sep 2018*2)

Country/Region	Subject Item	Inspected Substances
China	Green soybean	Difenoconazole, Haloxyfop
	Broccoli	Haloxyfop , Metolachlor
	Red pepper	Propiconazole
	Chrysanthemum flower	Chlorpyrifos
	Perilla	Atrazine
	Buckwheat	Haloxyfop
	Rape flower	Haloxyfop
	Parsley	Chlorfenapyr
Australia	Broad beans	Fluquinconazole
	Apple juice	Patulin
Thailand	Durian	Metalaxyl and Mefenoxam
	Boiled crab for raw consumption	<i>Vibrio parahaemolyticus</i> *2
Philippines	Banana	Fipronil
	Boiled crab for raw consumption	<i>Vibrio parahaemolyticus</i> *3
Peru	Quinoa	Methamidophos
	Corns	Methamidophos
Iran	Processed pistachio nut product	Aflatoxin
Ghana	Cacao beans	Chlorpyrifos
Cambodia	Coffee beans	Chlorpyrifos
Taiwan	Bee larva	Oxytetracycline
Turkey	Processed almond product	Aflatoxin
Paraguay	Chia seed	Aflatoxin
USA	Raspberry	Etoxazole
Vietnam	Straw mushroom	Chlorpyrifos
Mexico	Red pepper	Propiconazole
Russia	Honey	Chloramphenicol

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

*2 Item which all (100%) import declarations were inspected as a measure to enhance inspections during the summer period, (Jun-Oct 2018).

*3 Item which 30% of import declarations were inspected as a measure to enhance inspections during the summer period, (Jun-Oct 2018)

Table 5. Items transferred to Inspection Order (Apr-Sep 2018)

Country/Region	Subject Item	Inspected Substances
China	Ginger	Thiamethoxam
	Sorghum	Aflatoxin
Ghana	Cacao beans	Fenvalerate
France	Natural cheese	Enterohemorrhagic Escherichia coli O26
Myanmar	Sesame seeds	Aflatoxin

**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	6,105	64
	Cassava, Beans containing cyanide	Cyanide	226	3
	Salted salmon roe	Nitrite	123	0
China (16 items)	Vegetables (Green soybean, Onion, Spinach, etc.), Lychees, Short-neck clam	Endrin, Chlorpyrifos, Difenoconazole Thiamethoxam, Dieldrin (including aldrin), 4-Chlorophenoxyacetic acid, Prometryn, etc.	11,896	14
	Bivalves	Paralytic shellfish poison, Diarrhetic shellfish poison	4,030	0
	All processed products	Cyclamic acid	340	0
	Eel, Soft-shelled turtle	Enrofloxacin, Oxolinic acid, Sulfadimidine	66	0
	Lotus seed, Sorghum	Aflatoxin	24	0
South Korea (12 items)	Bivalves	Paralytic shellfish poison, Diarrhetic shellfish poison	103	0
	Tomato, Cherry tomato	Fluquinconazole	34	0
	Cultured olive flounder	Enrofloxacin, Oxytetracycline	2	0
	Arch shell	<i>Vibrio parahaemolyticus</i> (MPN)	1	0
USA (8 items)	Dried dates, Corn, Pistachio	Aflatoxin	1,747	10
	Celery	Bifenthrin	371	0
	Natural cheese	<i>Listeria monocytogenes</i>	3	0
Thailand (7 items)	Okra, Green asparagus, Banana, Mango, Mangosteen	EPN, Imazalil, Chlorpyrifos, Cypermethrin, Propiconazole,	708	0
	Boiled crab	<i>Vibrio parahaemolyticus</i>	31	0
Italy (6 items)	Processed almond products	Aflatoxin	57	0
	Natural cheese	<i>Listeria monocytogenes</i>	15	0
	Rice	Pirimiphos-methyl	7	0
Philippines (5 items)	Okra, Mango	Chlorpyrifos, Cypermethrin, Phenthoate etc.	123	0
	Tuna	<i>Salmonella spp.</i>	120	2
Vietnam (5 items)	Squid, Shrimp, Filefish	Enrofloxacin, Chloramphenicol, Sulfadiazine, Furazolidone	14,807	9
	All processed products	Cyclamic acid	76	0
	Fishery foods	Shigella	6	0
Other (23 countries and 1 region, total 30 items)			2,365	16
Total (Gross) ^{※1}			43,386	118
(Actual) ^{※2}			28,842	118

*1 Gross number of Itemized cases violations

*2 Item number of the consultation to be a violation of the law

**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	France	Natural cheese (Contamination with Enterohemorrhagic Escherichia coli O26)	Information was received stating that in the France a manufacturer was conducting voluntary recall of natural cheese for contamination with Enterohemorrhagic Escherichia coli O26. When an import notification was made for such recall products, steps were taken for reshipment, etc.
Jun	Canada	Wheat (Unauthorized genetically modified wheat)	Information was received stating that unauthorized genetically modified wheat was confirmed in Canada. When an import notification was made for wheat from Canada, steps were taken for the inspection.
Sep.	China	Raw consumption sea urchin (Contamination with <i>Vibrio parahaemolyticus</i>)	Information was received stating that food poisoning cases caused by <i>Vibrio parahaemolyticus</i> suspected to be caused by raw consumption sea urchin from china have occurred in Japan. When an import notification was made for raw consumption sea urchin from the suspected manufacture, steps were taken for the independence inspection.

(Reference) Description of Key Terms

Term	Description
Atrazine	Agricultural chemical (triazine herbicide)
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.
Imazalil	Agricultural chemical (imidazole fungicide)
Etoxazole	Agricultural chemical (oxazoline insecticide)
Endrin	Agricultural chemical (organochlorine insecticide)
Enrofloxacin	Veterinary drug (new quinolone synthetic antibacterial agent)
Oxytetracycline	Veterinary drug (tetracycline antibiotal agent)
Oxolinic acid	Veterinary drug (quinolone synthetic antibacterial agent)
Chloramphenicol	Veterinary drug (chloramphenicol antibiotal agent)
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)
<i>Salmonella spp.</i>	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.
Difenoconazole	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)
<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.)
<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.)

Term	Description
Dieldrin (including aldrin)	Agricultural chemical (organochlorine insecticide)
Deoxynivalenol	Mycotoxin (produced by the fungus <i>Fusarium</i>)
Sulfur dioxide	Additive (antioxidant agents)
Patulin	Mycotoxin (produced by fungi such as <i>Penicillium</i> and <i>Aspergillus</i> , etc.)
Haloxfop	Agricultural chemical (herbicide)
Bifenthrin	Agricultural chemical (pyrethroid insecticide)
Pirimiphos-methyl	Agricultural chemical (organophosphorus insecticide)
Fipronil	Agricultural chemical (phenylpyrazole synergist)
Phenthoate	Agricultural chemical (Organophosphorus insecticide)
Furazolidone	Veterinary drug (nitrofurantoin synthetic antibacterial agent), generates AOZ when metabolized
Fluquinconazole	Agricultural chemical (triazole fungicide)
Propiconazole	Agricultural chemical (triazole fungicide)
Prometryn	Agricultural chemical (triazine herbicide)
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)
Metolachlor	Agricultural chemical (acid amide herbicides)
<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)
4-Chlorophenoxyacetic acid	Agricultural chemical (plant growth regulator)
EPN	Agricultural chemical (organophosphorus insecticide)