

USDA Foreign Agricultural Service

# GAIN Report

Global Agricultural Information Network

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Voluntary - Public

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## Japan

**Post:** Tokyo

### Japan 223rd Food Safety Group

**Report Categories:**

Sanitary/Phytosanitary/Food Safety

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**Report Highlights:**

On June 13, 2019, Japan's Ministry of Health, Labor and Welfare (MHLW) announced revisions to Japan's Maximum Residue Levels (MRLs) for the following agricultural chemicals and a veterinary drug: Amisulbrom, Cyenopyrafen, Cymoxanil, Zoxamide, Furametpyr, Fluazinam, and Gentamicin. Embassies may submit comments until June 27, 2019. MHLW will then notify these revisions to the World Trade Organization (WTO), which will provide another opportunity for interested parties to comment.

Keyword: JA9074, Amisulbrom, Cyenopyrafen, Cymoxanil, Zoxamide, Furametpyr, Fluazinam, Gentamicin

## General Information:

*(The following is taken from Japan's documents at the Food Safety Group)*

<The manner of submitting comments>

The Ministry of Health, Labour and Welfare (MHLW) will amend the existing standards and specifications for food as shown in this document. Please provide comments in writing by **Thursday, June 27, 2019**. After the given date, comments should be directed to the enquiry point in accordance with the WTO/SPS Agreement.

If you wish to request Japan to adopt the same limits as your country's MRLs, you are requested to submit data supporting your country's MRLs, such as risk assessment and residue data.

<Contact person>

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Pesticides/Veterinary drugs (Item 1)

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## **Item 1. Establishment of the Maximum Residue Limits for Agricultural and Veterinary Chemicals in Foods**

The Food Sanitation Act authorizes the Ministry of Health, Labour and Welfare (MHLW) to establish residue standards (maximum residue limits, “MRLs”) for pesticides, feed additives, and veterinary drugs (hereafter referred to as “agricultural and veterinary chemicals”) that may remain in foods. Any food for which standards are established pursuant to the provisions in Article 11, Paragraph 1 of the act is not permitted to be marketed in Japan unless it complies with the established standards.

On May 29, 2006, Japan introduced the Positive List System<sup>1</sup> for agricultural and veterinary chemicals in food. All foods distributed in the Japanese marketplace are subject to regulation of the system.

The MHLW is going to modify or newly set MRLs in some commodities for the following substances:

Pesticides : Amisulbrom, Cyenopyrafen, Cymoxanil, Zoxamide, Furametpyr,

Fluazinam

Veterinary drugs : Gentamicin

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<sup>1</sup>The aim of the positive list system is to prohibit the distribution of any foods which contain agricultural chemicals at amounts exceeding a certain level (0.01 ppm) in the Japanese marketplace unless specific maximum residue limits (MRLs) have been set.

## Summary

**Amisulbrom (pesticide: fungicide):** Permitted for use in Japan. The MHLW is going to establish MRLs in one commodity in response to a request for setting MRL by the Ministry of Agriculture, Forestry and Fisheries (MAFF) with the intention to expand its use pattern. This action will not strengthen the current regulation for any commodities.

**Cyenoxyrafen (pesticide: acaricide):** Permitted for use in Japan. The MHLW is going to establish MRLs in some commodities in response to a request for setting MRL by the MAFF with the intention to expand its use pattern. This action will not strengthen the current regulation for any commodities.

**Cymoxanil (pesticide: fungicide):** Permitted for use in Japan. The MHLW is going to establish MRLs in some commodities in response to a request for setting MRL by the MAFF with the intention to expand its use pattern.

**Zoxamide (pesticide: fungicide):** Not permitted for use in Japan. The MHLW is going to establish MRLs in some commodities in response to a request for setting import tolerances based on the Guideline for Application for Establishment and Revision of Maximum Residue Limits for Agricultural Chemicals Used outside Japan (Shokuan No. 0205001, 5 February 2004).

**Furametpyr (pesticide: fungicide):** Permitted for use in Japan. The MHLW is going to establish MRLs in some commodities in response to a request for setting MRL by the MAFF with the intention to expand its use pattern. This action will not strengthen the current regulation for any commodities.

**Fluazinam (pesticide: insecticide):** Permitted for use in Japan. The MHLW is going to establish MRLs in some commodities in response to requests for setting MRLs by the MAFF with the intention to expand its use pattern and for setting import tolerances based on the Guideline for Application for Establishment and Revision of Maximum Residue Limits for Agricultural Chemicals Used outside Japan (Shokuan No. 0205001, 5 February 2004).

**Gentamicin (veterinary drug: antibiotic):** Permitted for use in Japan. The MHLW is going to modify MRLs in some commodities that were provisionally set at the introduction of the Positive List System.

Amisulbrom

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL	
				Codex ppm	National ppm
Rice (brown rice)	0.05	0.05	§		
Soybeans, dry	0.3	0.3	§		
Beans, dry	0.2	0.2	§		
Potato	0.05	0.05	§		
Taro	0.05		Request		
Konjac	0.05	0.05	§		
Sugar beet	1	1	§		
Japanese radish, roots (including radish)	0.3	0.3	§		
Japanese radish, leaves (including radish)	25	25	§		
Turnip, roots (including rutabaga)	0.5	0.5	§		
Turnip, leaves (including rutabaga)	30	30	§		
Chinese cabbage	10	10	§		
Cabbage	3	3	§		
Kale	20	20	§		
Komatsuna (Japanese mustard spinach)	15	15	§		
Kyona	20	20	§		
Qing-geng-cai	20	20	§		
Cauliflower	2	2	§		
Broccoli	2	2	§		
Other cruciferous vegetables	20	20	§		
Lettuce (including cos lettuce and leaf lettuce)	20	20	§		
Onion	0.05	0.05	§		
Welsh (including leek)	3	3	§		
Other liliaceous vegetables	0.05	0.05	§		
Tomato	2	2	§		
Pimiento (sweet pepper)	3	3	§		
Egg plant	1	1	§		
Other solanaceous vegetables	5	5	§		
Cucumber (including gherkin)	0.7	0.7	§		
Pumpkin (including squash)	2	2	§		
Water melon	0.05	0.05	§		
Melons		0.05	§		
Melons(whole commodity after removal of stems.)	1		§		
Spinach	30	30	§		
Ginger	2	2	§		
Green soybeans	10	10	§		
Unshu orange, pulp		0.1	§		
Unshu orange(whole commodity.)	3		§		
Citrus natsudaidai, whole	2	2	§		
Lemon	2	2	§		
Orange (including navel orange)	2	2	§		
Grapefruit	2	2	§		
Lime	2	2	§		
Other citrus fruits	2	2	§		
Strawberry	0.05	0.05	§		
Grape	5	5	§		
Other fruits	1	1	§		
Other spices	15	15	§		
Other herbs	20	20	§		

The residue definition is amisulbrom only.

\* The uniform limit 0.01 ppm will be applied to commodities for which draft MRLs are not given in this table and to commodities not listed above.

\* In the Commodity column, for the food categories to which the word other is added, refer to the Notes given in the last two pages of the Attachment.

○: Commodities for which MRLs are to be maintained, increased or newly set.

§: Permitted for use in Japan.

Request: Request for setting/revising MRL was made by the MAFF.

Cyenoptyrafen

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL	
				Codex ppm	National ppm
Other composite vegetables	○ 10	10	§		
Asparagus	○ 0.5		Request		
Pimiento (sweet pepper)	○ 1	1	§		
Egg plant	○ 0.7	0.7	§		
Other solanaceous vegetables	○ 5	5	§		
Cucumber (including gherkin)	○ 1	1	§		
Water melon	/	0.05	§		
Water melon (whole commodity after removal of stems.)	○ 0.3		§		
Melons	/	0.05	§		
Melons (whole commodity after removal of stems.)	○ 0.5		§		
Other vegetables	○ 0.7	0.7	§		
Unshu orange, pulp	/	0.05	§		
Unshu orange (whole commodity.)	○ 3		§		
Citrus natsudaidai, whole	○ 2	2	§		
Lemon	○ 2	2	§		
Orange (including navel orange)	○ 2	2	§		
Grapefruit	○ 2	2	§		
Lime	○ 2	2	§		
Other citrus fruits	○ 2	2	§		
Apple	○ 2	2	§		
Japanese pear	○ 2	2	§		
Pear	○ 2	2	§		
Peach	/	0.1	§		
Peach (whole commodity after removal of stems and stones but the residue calculated and expressed on the whole commodity without stems.)	○ 2		§		
Nectarine	○ 1	1	§		
Apricot	○ 5	5	§		
Japanese plum (including prune)	○ 0.2	0.2	§		
Mume plum	○ 5	5	§		
Cherry	○ 2	2	§		
Strawberry	○ 3	3	§		
Grape	○ 5	5	§		
Japanese persimmon	○ 0.7	0.7	§		
Other fruits	○ 2	2	§		
Tea	○ 60	60	§		
Other spices	○ 15	15	§		
Other herbs	○ 30	30	§		

The residue definition is cyenoptyrafen only.

\* The uniform limit 0.01 ppm will be applied to commodities for which draft MRLs are not given in this table and to commodities not listed above.

\* In the Commodity column, for the food categories to which the word other is added, refer to the Notes given in the last two pages of the Attachment.

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Request: Request for setting/revising MRL was made by the MAFF.

Cymoxanil

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL	
				Codex ppm	National ppm
Soybeans, dry	○ 0.05	0.05	§		
Beans, dry	○ 0.02	0.02	§		
Peas	●	0.5			
Potato	○ 0.2	0.2	§		
Taro	○ 0.05		Request		
Watercress	○ 19	19			19 USA
Chinese cabbage	● 0.1	0.2	§		
Broccoli	○ 1	1	§		
Artichoke	●	0.1			
Endive	○ 19	19			19 USA
Lettuce (including cos lettuce and leaf lettuce)	○ 2	2			
Onion	○ 0.05	0.05	§		0.05 USA
Welsh (including leek)	○ 1	1	§		1.1 USA
Garlic	○ 0.05	0.05			0.05 USA
Nira	○ 1	1			1.1 USA
Other liliaceous vegetables	○ 0.05	0.05	§		
Parsley	○ 19	19			19 USA
Celery	○ 6	6			6.0 USA
Tomato	○ 0.7	0.7	§		
Pimiento (sweet pepper)	○ 0.2	0.2			0.2 USA
Egg plant	○ 0.5	0.5	§		
Other solanaceous vegetables	○ 0.2	0.2			0.2 USA
Cucumber (including gherkin)	○ 0.3	0.3	§		
Pumpkin (including squash)	○ 0.1	0.1	§		#0.1 EU
Oriental pickling melon (vegetable)	○ 0.05	0.05			0.05 USA
Water melon	○ 0.2	0.2	§		
Melons		0.05	§		
Melons(whole commodity after removal of stems.)	○ 1				
Makuwauri melon		0.04			
Makuwauri melon(whole commodity after removal of stems.)	○ 0.1				#0.1 EU
Other cucurbitaceous vegetables	○ 0.1	0.1			#0.1 EU
Peas, immature (with pods)	● 0.2	0.5			0.15 EU
Raspberry	○ 4	4			4.0 USA
Blackberry	○ 4	4			4.0 USA
Other berries	○ 4	4			4.0 USA
Grape	○ 0.1	0.1	§		
Sunflower seeds	●	0.1			
Hop	○ 7	7			7.0 USA
Other spices	●	0.1			
Other herbs	○ 19	19	§		19 USA

The residue definition is cymoxanil only.

\* The uniform limit 0.01 ppm will be applied to commodities for which draft MRLs are not given in this table and to commodities not listed above.

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● : Commodities for which MRLs are to be lowered or deleted.

○ : Commodities for which MRLs are to be maintained, increased or newly set.

§ : Permitted for use in Japan.

Request : Request for setting/revising MRL was made by the MAFF.

# : The EU's MRL referenced when setting the current MRL.

Zoxiamide

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL		
				Codex ppm	National ppm	
Potato	● 0.02	0.06		0.02	0.06	USA
Onion	○ 0.7		IT		0.7	USA
Tomato	○ 2	2		2		
Pimiento (sweet pepper)	○ 0.3	0.3			0.3	Korea
Cucumber (including gherkin)	○ 2	1		2		
Pumpkin (including squash)	○ 2	1		2		
Oriental pickling melon (vegetable)	○ 2	1		2		
Water melon		1				
Water melon(whole commodity after removal of stems.)	○ 2			2		
Melons		1				
Melons(whole commodity after removal of stems.)	○ 2			2		
Makuwauri melon		1				
Makuwauri melon(whole commodity after removal of stems.)	○ 2			2		
Other cucurbitaceous vegetables	○ 2	1		2		
Grape	○ 5	5		5		
Banana	○ 0.2		IT		0.2	USA
Raisin	○ 15	15		15		

The residue definition is zoxiamide only.

\* The uniform limit 0.01 ppm will be applied to commodities for which draft MRLs are not given in this table and to commodities not listed above.

\* In the Commodity column, for the food categories to which the word other is added, refer to the Notes given in the last two pages of the Attachment.

● : Commodities for which MRLs are to be lowered or deleted.

○ : Commodities for which MRLs are to be maintained, increased or newly set. Request : Request for setting/revising MRL was made by the MAFF.

IT : Import Tolerance

Furametpyr

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL	
				Codex ppm	National ppm
Rice (brown rice)	○ 0.5	0.5	§		
Potato	○ 0.01		Request		
Sugar beet	○ 0.2	0.2	§		
Welsh (including leek)	○ 10		Request		
Fish	○ 0.2	0.2			

The residue definition is furametpyr only.

\* The uniform limit 0.01 ppm will be applied to commodities for which draft MRLs are not given in this table and to commodities not listed above.

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§ : Permitted for use in Japan.

Request : Request for setting/revising MRL was made by the MAFF.

Fluazinam

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL	
				Codex ppm	National ppm
Wheat	● 0.05	0.1	§		
Beans, dry	○ 0.1	0.1	§		
Peanuts, dry	○ 0.05	0.05	§		
Potato	○ 0.1	0.1	§		
Japanese yam (including Chinese yam)	○ 0.05	0.05	§		
Sugar beet	○ 0.5	0.5	§		
Japanese radish, roots (including radish)	○ 0.05	0.05	§		
Japanese radish, leaves (including radish)	○ 0.1	0.1	§		
Turnip, roots (including rutabaga)	○ 0.05	0.05	§		
Turnip, leaves (including rutabaga)	● 0.05	0.1	§		
Chinese cabbage	● 0.05	0.1	§		
Cabbage	● 0.05	0.1	§		
Brussels sprouts	● 0.05	0.1	§		
Komatsuna (Japanese mustard spinach)	○ 0.05	0.05	§		
Kyona	○ 0.05	0.05	§		
Qing-geng-cai	● 0.05	0.1	§		
Cauliflower	● 0.05	0.1	§		
Broccoli	○ 0.1	0.1	§		
Other cruciferous vegetables	● 0.05	0.1	§		
Burdock	○ 0.2	0.05	§- Request		
Lettuce (including cos lettuce and leaf lettuce)	● 0.05	0.1	§		
Onion	○ 0.2	0.1	§- Request		
Welsh (including leek)	● 0.05	0.1	§		
Nira	● 0.05	0.1	§		
Asparagus	● 0.05	0.1	§		
Other liliaceous vegetables	○ 5	2	§- Request		
Carrot	○ 0.3	0.3	§		
Other solanaceous vegetables	○ 0.3	0.3		0.3	Korea
Other vegetables(except for stem of taro and rotus root)	○ 5	5	§		
Unshu orange, pulp	○ 2	0.5	§		
Unshu orange(whole commodity.)	○ 2		§		
Citrus natsudaidai, whole	○ 5	5	§		
Lemon	○ 5	5	§		
Orange (including navel orange)	○ 5	5	§		
Grapefruit	○ 5	5	§		
Lime	○ 5	5	§		
Other citrus fruits	○ 5	5	§		
Apple	● 0.2	0.5	§		
Japanese pear	● 0.2	0.5	§		
Pear	● 0.2	0.5	§		
Loquat	○ 2	0.5	§		
Loquat(whole commodity after removal of stems.)	○ 2		§		
Peach	○ 2	0.5	§		
Peach (whole commodity after removal of stems and stones but the residue calculated and expressed on the whole commodity without stems.)	○ 0.7		§		
Nectarine	○ 0.05	0.05	§		
Apricot	○ 0.05	0.05	§		
Japanese plum (including prune)	○ 0.05	0.05	§		
Mume plum	● 0.1	0.5	§		
Cherry	● 0.05	0.5	§		

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL	
				* ppm	National ppm
Strawberry	○ 0.05	0.05	§		
Blueberry	○ 4	0.1	§ - IT		7 USA
Other berries	○ 4		IT		7 USA
Grape	● 0.05	0.5	§		
Japanese persimmon	● 0.3	0.5	§		
Kiwifruit	○	0.5	§		
Kiwifruit(whole commodity.)	○ 3		§		
Pineapple	● 0.05	0.5	§		
Guava	○ 4		IT		7 USA
Other fruits	○ 0.05	0.05	§		
Tea	○ 5	5	§		
Other spices	○ 10	10	§		
Cattle, muscle	○ 0.01		Request		
Cattle, fat	○ 0.02		Request		
Cattle, liver	○ 0.01		Request		
Cattle, kidney	○ 0.01		Request		
Cattle, edible offal	○ 0.01		Request		
Milk	○ 0.01		Request		

The residue definition for agricultural products is fluazinam only. The residue definition for muscle and fat in animal products is fluazinam, metabolite D (4-chloro-6-(3-chloro-5-trifluoromethyl-2-pyridylamino)- $\alpha,\alpha,\alpha$ -trifluoro-5-nitro-*m*-toluidine), and metabolite E (4-chloro-2-(3-chloro-5-trifluoromethyl-2-pyridylamino)-5-trifluoromethyl-*m*-phenylenediamine). The residue definition for milk and other tissues (except for muscle and fat) in animal products is fluazinam, metabolite D (including conjugates<sup>6</sup>), and metabolite E (including conjugates<sup>6</sup>).

<sup>6</sup>Mainly analyzed conjugates hydrolyzed at 37°C for 1 hour with concentrated hydrochloric acid are sulfamate conjugates.

\* The uniform limit 0.01 ppm will be applied to commodities for which draft MRLs are not given in this table and to commodities not listed above.

\* In the Commodity column, for the food categories to which the word other is added, refer to the Notes given in the last two pages of the Attachment.

● : Commodities for which MRLs are to be lowered or deleted.

○ : Commodities for which MRLs are to be maintained, increased or newly set.

§ : Permitted for use in Japan.

Request : Request for setting/revising MRL was made by the MAFF. IT :

Import Tolerance

Gentamicin

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL	
				Codex ppm	National ppm
Cattle, muscle	○ 0.1	0.1	§	0.1	
Pig, muscle	○ 0.1	0.1	§	0.1	
Cattle, fat	○ 0.1	0.1	§	0.1	
Pig, fat	○ 0.1	0.1	§	0.1	
Cattle, liver	○ 2	2.0	§	2	
Pig, liver	○ 2	2.0	§	2	
Cattle, kidney	○ 5	5.0	§	5	
Pig, kidney	○ 5	5.0	§	5	
Cattle, edible offal	○ 5	2	§		
Pig, edible offal	○ 5	2	§		
Milk	○ 0.2	0.2		0.2	
Chicken, muscle	●	0.1			
Other poultry, muscle	●	0.1			
Chicken, fat	●	0.1			
Other poultry, fat	●	0.1			
Chicken, liver	●	0.1			
Other poultry, liver	●	0.1			
Chicken, kidney	●	0.1			
Other poultry, kidney	●	0.1			
Chicken, edible offal	●	0.1			
Other poultry, edible offal	●	0.1			

The residue definition is sum of gentamicin C<sub>1</sub>, gentamicin C<sub>1a</sub>, gentamicin C<sub>2</sub> and gentamicin C<sub>2a</sub>. The current residue definition is gentamicin only.

\* The compound shall not be included in any commodity for which MRL is not given in the above table and in any commodity not listed above.

\* In the Commodity column, for the food categories to which the word other is added, refer to the Notes given in the last two pages of the Attachment.

- : Commodities for which MRLs are to be lowered or deleted.
- : Commodities for which MRLs are to be maintained, increased or newly set.
- § : Permitted for use in Japan.

## Notes:

“Other cereal grains” refers to all cereal grains, except rice (brown rice), wheat, barley, rye, corn (maize), and buckwheat.

“Beans, dry” including butter beans, cowbeans (red beans), lentil, lima beans, pegia, sultani, sultapya and white beans.

“Other legumes/pulses” refers to all legumes/pulses, except soybeans (dry), beans (dry), peas, broad beans, peanuts (dry), and spices.

“Other potatoes” refers to all potatoes, except potato, taro, sweet potato, yam, and konjac.

“Other cruciferous vegetables” refers to all cruciferous vegetables, except Japanese radish roots and leaves (including radish), turnip roots and leaves, horseradish, watercress, Chinese cabbage, cabbage, brussels sprouts, kale, *komatsuna* (Japanese mustard spinach), *kyona*, qing-geng-cai, cauliflower, broccoli, and herbs.

“Other composite vegetables” refers to all composite vegetables, except burdock, salsify, artichoke, chicory, endive, *shungiku*, lettuce (including cos lettuce and leaf lettuce), and herbs.

“Other liliaceous vegetables” refers to all liliaceous vegetables, except onion, welsh (including leek), garlic, *nira*, asparagus, multiplying onion, and herbs.

“Other umbelliferous vegetables” refers to all umbelliferous vegetables, except carrot, parsnip, parsley, celery, *mitsuba*, spices, and herbs.

“Other solanaceous vegetables” refers to all solanaceous vegetables, except tomato, pimiento (sweet pepper), and egg plant.

“Other cucurbitaceous vegetables” refers to all cucurbitaceous vegetables, except cucumber (including gherkin), pumpkin (including squash), oriental pickling melon (vegetable), watermelon, melons, and *makuwauri* melon.

“Other mushrooms” refers to all mushrooms, except button mushroom, and *shiitake* mushroom.

“Other vegetables” refers to all vegetables, except potatoes, sugar beet, sugarcane, cruciferous vegetables, composite vegetables, liliaceous vegetables, umbelliferous vegetables, solanaceous vegetables, cucurbitaceous vegetables, spinach, bamboo shoots, okra, ginger, peas (with pods, immature), kidney beans (with pods, immature), green soybeans, mushrooms, spices, and herbs.

“Other citrus fruits” refers to all citrus fruits, except *unshu* orange, citrus *natsudaidai*, lemon, orange (including navel orange), grapefruit, lime, and spices.

“Other berries” refers to all berries, except strawberry, raspberry, blackberry, blueberry, cranberry, and huckleberry.

“Other fruits” refers to all fruits, except citrus fruits, apple, Japanese pear, pear, quince, loquat, peach, nectarine, apricot, Japanese plum (including prune), mume plum, cherry, berries, grape, Japanese persimmon, banana, kiwifruit, papaya, avocado, pineapple, guava, mango, passion fruit, date and spices.

“Other oil seeds” refers to all oil seeds, except sunflower seeds, sesame seeds, safflower seeds, cotton seeds, rapeseeds and spices.

“Other nuts” refers to all nuts, except ginkgo nut, chestnut, pecan, almond and walnut.

“Other spices” refers to all spices, except horseradish, *wasabi* (Japanese horseradish) rhizomes, garlic, peppers chili, paprika, ginger, lemon peels, orange peels (including navel orange), *yuzu* (Chinese citron) peels and sesame seeds.

“Other herbs” refers to all herbs, except watercress, *nira*, parsley stems and leaves, celery stems and leaves.

“Edible offal” refers to all edible parts, except muscle, fat, liver, and kidney.

“Other terrestrial mammals” refers to all terrestrial mammals, except cattle and pig.

“Other poultry” refers to all poultry, except chicken.

“Other fish” refers to all fish, except salmoniformes, anguilliformes, and perciformes.

“Other aquatic animals” refers to all aquatic animal, except fish, shelled molluscs and crustaceans.