Japan’s 218th Food Safety Group Report

**Highlights**

On November 29, 2018, Japan’s Ministry of Health, Labor and Welfare (MHLW) announced revisions to Japan’s Maximum Residue Levels (MRLs) for the following agricultural chemicals, veterinary drugs and feed additives: Isopyrazam, Etofenprox, Fenpyroximate, Mandestrobin, Flumequine, Mono- and bis- (trimethylammoniummethylene chloride)-alkyltoluene, and Butylated Hydroxyanisole.  In addition, MHLW proposed the revision of standards for the feed additive Hypobromous Acid Water.  Lastly, MHLW summarized revisions to Japan’s Food Sanitation Act.  The embassy comment period these proposals is open until December 13, 2018.  MHLW will then notify the MRL revisions to the World Trade Organization (WTO), which will provide another opportunity for interested parties to comment.  MHLW will prepare and provide information explaining how the Food Sanitation Act revisions will change import procedures.

Keyword: JA8103

**General Information:**

<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, December 13, 2018**. After the given date, comments should be directed to the enquiry point in accordance with the WTO/SPS Agreement.

With regard to agenda item 1, the SPS notification will be made for the setting or revision of the MRL for the agricultural and veterinary chemicals except for Isopyrazam, Etofenprox, Mandestrobin and Butylated Hydroxyanisole for which regulations will not be strengthened by this amendment.

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.

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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 System1 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：Isopyrazam, Etofenprox, Fenpyroximate, Mandestrobin Veterinary drugs：Flumequine,

Mono, bis (trimethylammoniummethylene chloride)-alkyltoluene Feed additives：Butylated Hydroxyanisole

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1 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

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

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

**Fenpyroximate (pesticide: acaricide)**: Permitted for use in Japan. The MHLW is going to establish MRLs in one commoditiy 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).

**Mandestrobin (pesticide: fungicide)**: Permitted for use in Japan. The MHLW is going to establish MRLs in one commoditiy 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). This action will not strengthen the current regulation for any commodities.

**Flumequine (Veterinary drug: fungicide)**: Not 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.

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**Mono, bis (trimethylammoniummethylene chloride)-alkyltoluene (Veterinary drug: disinfectant)**: 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.

**Butylated Hydroxyanisole (Feed additive: antioxidizer)**: 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. This action will not strengthen the current regulation for any commodities.

Isopyrazam

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Commodity** | **MRL****(draft) ppm** | **MRL****(current) ppm** | **Registration** | **Reference MRL** |
| Codex ppm | National ppm |
| Wheat | ○ | 0.2 | 0.2 |  | 0.03 | 0.2 | EU |
| Barley | ○ | 0.6 | 0.6 |  | 0.6 | 0.6 | EU |
| Rye | ○ | 0.2 | 0.2 |  | 0.03 | 0.2 | EU |
| Other cereal grains | ○ | 0.6 | 0.2 |  | 0.03 | 0.6 | EU |
| Peanuts, dry | ○ | 0.01 |  |  | 0.01 |  |  |
| Chinese cabbage | ○ | 5 | 5 | § |  |  |  |
| Cabbage | ○ | 3 | 3 | § |  |  |  |
| Lettuce (including cos lettuce and leaf lettuce) | ○ | 10 | 10 | § |  |  |  |
| Carrot | ○ | 0.2 |  |  | 0.15 |  |  |
| Tomato | ○ | 3 | 3 | § | 0.4 |  |  |
| Pimiento (sweet pepper) | ○ | 0.09 |  |  | 0.09 |  |  |
| Egg plant | ○ | 2 | 2 | § | 0.4 |  |  |
| Cucumber (including gherkin) | ○ | 1 | 1 | § | 0.06 |  |  |
| Pumpkin (including squash) | ○ | 0.05 | 0.05 |  |  | 0.05 | New Zealand |
| Melons | ○ | 0.05 | 0.05 | § |  |  |  |
| Apple | ○ | 5 | 5 | § | 0.4 |  |  |
| Japanese pear | ○ | 3 | 3 | § | 0.4 |  |  |
| Pear | ○ | 3 | 3 | § | 0.4 |  |  |
| Quince | ○ | 0.4 |  |  | 0.4 |  |  |
| Peach | ○ | 0.2 | 0.2 | § |  |  |  |
| Apricot | ○ | 5 | 5 | § |  |  |  |
| Japanese plum (including prune) | ○ | 2 | 2 | § |  |  |  |
| Mume plum | ○ | 5 | 5 | § |  |  |  |
| Cherry | ○ | 5 |  | Request |  |  |  |
| Strawberry | ○ | 5 | 5 | § |  |  |  |
| Grape | ○ | 10 | 10 | § |  |  |  |
| Japanese persimmon | ○ | 2 | 2 | § | 0.4 |  |  |
| Banana | ○ | 0.06 | 0.06 |  | 0.06 |  |  |
| Other fruits | ○ | 0.4 |  |  | 0.4 |  |  |
| Rapeseeds | ○ | 0.2 |  |  | 0.2 |  |  |
| Cattle, muscle | ○ | 0.03 | 0.01 |  |  |  |  |
| Pig, muscle | ○ | 0.03 | 0.01 |  |  |  |  |
| Other terrestrial mammals, muscle | ○ | 0.03 | 0.01 |  |  |  |  |
| Cattle, fat | ○ | 0.03 | 0.01 |  | 0.03 |  |  |
| Pig, fat | ○ | 0.03 | 0.01 |  | 0.03 |  |  |
| Other terrestrial mammals, fat | ○ | 0.03 | 0.01 |  | 0.03 |  |  |
| Cattle, liver | ○ | 0.02 | 0.02 |  | 0.02 |  |  |
| Pig, liver | ○ | 0.02 | 0.02 |  | 0.02 |  |  |
| Other terrestrial mammals, liver | ○ | 0.02 | 0.02 |  | 0.02 |  |  |
| Cattle, kidney | ○ | 0.02 | 0.02 |  | 0.02 |  |  |
| Pig, kidney | ○ | 0.02 | 0.02 |  | 0.02 |  |  |
| Other terrestrial mammals, kidney | ○ | 0.02 | 0.02 |  | 0.02 |  |  |
| Cattle, edible offal | ○ | 0.02 | 0.02 |  | 0.02 |  |  |
| Pig, edible offal | ○ | 0.02 | 0.02 |  | 0.02 |  |  |
| Other terrestrial mammals, edible offal | ○ | 0.02 | 0.02 |  | 0.02 |  |  |
| Milk | ○ | 0.02 | 0.01 |  | 0.02 |  |  |
| Chicken, muscle | ○ | 0.01 | 0.01 |  | 0.01 |  |  |
| Other poultry, muscle | ○ | 0.01 | 0.01 |  | 0.01 |  |  |
| Chicken, fat | ○ | 0.01 | 0.01 |  | 0.01 |  |  |
| Other poultry, fat | ○ | 0.01 | 0.01 |  | 0.01 |  |  |
| Chicken, liver | ○ | 0.01 | 0.01 |  | 0.01 |  |  |

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| --- | --- | --- | --- | --- |
| **Commodity** | **MRL****(draft) ppm** | **MRL****(current) ppm** | **Registration** | **Reference MRL** |
| Codex ppm | National ppm |
| Other poultry, liver | ○ | 0.01 | 0.01 |  | 0.01 |  |  |
| Chicken, kidney | ○ | 0.01 | 0.01 |  | 0.01 |  |  |
| Other poultry, kidney | ○ | 0.01 | 0.01 |  | 0.01 |  |  |
| Chicken, edible offal | ○ | 0.01 | 0.01 |  | 0.01 |  |  |
| Other poultry, edible offal | ○ | 0.01 | 0.01 |  | 0.01 |  |  |
| Chicken eggs | ○ | 0.01 | 0.01 |  | 0.01 |  |  |
| Other poultry, eggs | ○ | 0.01 | 0.01 |  | 0.01 |  |  |
| Wheat bran ※ | ○ |  |  | 0.15 |  |  |

The residue definition is sum of isopyrazam (*syn* -isomers) and isopyrazam (*anti* -isomers).

* 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.
* Diagonal line means deletion of a food category to which an MRL applies.

○：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.

※ Food category "Wheat bran" will be deleted,and hereafter, MRLs in its raw commodity (i.e. Wheat) will also apply to such processed commodity, taking into account its processing factor. For this substance, JMPR estimated processing factor of 4.07 for Wheat.

Etofenprox

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| **Commodity** | **MRL****(draft) ppm** | **MRL****(current) ppm** | **Registration** | **Reference MRL** |
| Codex ppm | National ppm |
| Rice (brown rice) | ○ | 0.5 | 0.5 | § |  |  |  |
| Wheat | ○ | 0.5 | 0.5 | § |  |  |  |
| Barley | ○ | 0.5 | 0.5 |  |  | 0.5 | EU |
| Rye | ○ | 0.5 | 0.5 |  |  | 0.5 | EU |
| Corn (maize, including pop corn and sweet corn) | ○ | 0.3 | 0.3 | § | 0.05 |  |  |
| Other cereal grains | ○ | 5 | 5 | § |  |  |  |
| Soybeans, dry | ○ | 0.2 | 0.2 | § | 0.05 |  |  |
| Beans, dry | ○ | 0.05 | 0.05 | § | 0.05 |  |  |
| Peas | ○ | 0.05 | 0.05 | § |  |  |  |
| Broad beans | ○ | 0.05 | 0.05 | § | 0.05 |  |  |
| Peanuts, dry | ○ | 0.05 | 0.05 | § |  |  |  |
| Other pulses | ○ | 0.05 | 0.05 | § | 0.05 |  |  |
| Potato | ○ | 0.05 | 0.05 | § |  |  |  |
| Taro | ○ | 0.03 | 0.03 | § |  |  |  |
| Sweet potato | ○ | 0.03 | 0.03 | § |  |  |  |
| Japanese yam (including Chinese yam) | ○ | 0.02 | 0.02 | § |  |  |  |
| Sugar beet | ○ | 0.3 | 0.3 | § |  |  |  |
| Sugarcane | ○ | 0.03 | 0.03 | § |  |  |  |
| Japanese radish, roots (including radish) | ○ | 0.2 | 0.2 | § |  |  |  |
| Japanese radish, leaves (including radish) | ○ | 5 | 5 | § |  |  |  |
| Chinese cabbage | ○ | 5 | 5 | § |  |  |  |
| Cabbage | ○ | 1 | 1 | § |  |  |  |
| Brussels sprouts | ○ | 2 | 2 |  |  | 2 | EU |
| Broccoli | ○ | 10 | 10 | § |  |  |  |
| Other cruciferous vegetables | ○ | 1 | 1 | § |  |  |  |
| Lettuce (including cos lettuce and leaf lettuce) | ○ | 2 | 2 | § |  |  |  |
| Other composite vegetables | ○ | 10 | 2 | §・Request |  |  |  |
| Welsh (including leek) | ○ | 2 | 2 | § |  |  |  |
| Mitsuba | ○ | 5 | 5 | § |  |  |  |
| Other umbelliferous vegetables | ○ | 2 | 2 | § |  |  |  |
| Tomato | ○ | 2 | 2 | § |  |  |  |
| Pimiento (sweet pepper) | ○ | 5 | 5 | § |  |  |  |
| Egg plant | ○ | 2 | 2 | § |  |  |  |
| Other solanaceous vegetables | ○ | 2 | 2 |  |  | 2.0 | Korea |
| Cucumber (including gherkin) | ○ | 1 | 1 | § |  |  |  |
| Pumpkin (including squash) | ○ | 1 | 1 | § |  |  |  |
| Water melon | ○ | 0.03 | 0.03 | § |  |  |  |
| Melons | ○ | 0.2 | 0.2 | § |  |  |  |
| Other cucurbitaceous vegetables | ○ | 1 | 1 | § |  |  |  |
| Okra | ○ | 3 | 3 | § |  |  |  |
| Ginger | ○ | 3 | 3 | § |  |  |  |
| Peas, immature (with pods) | ○ | 2 | 2 | § |  |  |  |
| Kidney beans, immature (with pods) | ○ | 3 | 3 | § |  |  |  |
| Green soybeans | ○ | 3 | 3 | § |  |  |  |
| Other vegetables | ○ | 10 | 10 | § |  |  |  |
| Unshu orange, pulp | ○ | 0.2 | 0.2 | § |  |  |  |
| Citrus natsudaidai, whole | ○ | 3 | 3 | § |  |  |  |
| Lemon | ○ | 5 | 5 | § |  |  |  |
| Orange (including navel orange) | ○ | 5 | 5 | § |  |  |  |
| Grapefruit | ○ | 5 | 5 | § |  |  |  |
| Lime | ○ | 5 | 5 | § |  |  |  |

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| **Commodity** | **MRL****(draft) ppm** | **MRL****(current) ppm** | **Registration** | **Reference MRL** |
| Codex ppm | National ppm |
| Other citrus fruits | ○ | 5 | 5 | § |  |  |  |
| Apple | ○ | 2 | 2 | § | 0.6 |  |  |
| Japanese pear | ○ | 2 | 2 | § | 0.6 |  |  |
| Pear | ○ | 2 | 2 | § | 0.6 |  |  |
| Peach | ○ | 0.1 | 0.1 | § |  |  |  |
| Nectarine | ○ | 0.6 | 0.6 |  | 0.6 |  |  |
| Grape | ○ | 4 | 4 |  | 4 |  |  |
| Japanese persimmon | ○ | 2 | 2 | § |  |  |  |
| Mango | ○ | 5 | 5 | § |  |  |  |
| Rapeseeds | ○ | 0.01 | 0.01 |  | 0.01 |  |  |
| Chestnut | ○ | 0.05 | 0.05 | § |  |  |  |
| Tea | ○ | 10 | 10 | § |  |  |  |
| Other spices | ○ | 20 | 20 | § |  |  |  |
| Other herbs | ○ | 0.7 | 0.7 | § |  |  |  |
| Cattle, muscle | ○ | 0.2 | 0.2 |  |  |  |  |
| Pig, muscle | ○ | 0.2 | 0.2 |  |  |  |  |
| Other terrestrial mammals, muscle | ○ | 0.2 | 0.2 |  |  |  |  |
| Cattle, fat | ○ | 6 | 6 |  | 0.5 |  |  |
| Pig, fat | ○ | 6 | 6 |  | 0.5 |  |  |
| Other terrestrial mammals, fat | ○ | 6 | 6 |  | 0.5 |  |  |
| Cattle, liver | ○ | 0.3 | 0.3 |  | 0.05 |  |  |
| Pig, liver | ○ | 0.3 | 0.3 |  | 0.05 |  |  |
| Other terrestrial mammals, liver | ○ | 0.3 | 0.3 |  | 0.05 |  |  |
| Cattle, kidney | ○ | 0.4 | 0.4 |  | 0.05 |  |  |
| Pig, kidney | ○ | 0.4 | 0.4 |  | 0.05 |  |  |
| Other terrestrial mammals, kidney | ○ | 0.4 | 0.4 |  | 0.05 |  |  |
| Cattle, edible offal | ○ | 0.4 | 0.4 |  | 0.05 |  |  |
| Pig, edible offal | ○ | 0.4 | 0.4 |  | 0.05 |  |  |
| Other terrestrial mammals, edible offal | ○ | 0.4 | 0.4 |  | 0.05 |  |  |
| Milk | ○ | 0.4 | 0.4 |  | 0.02 |  |  |
| Chicken, muscle | ○ | 0.02 | 0.02 |  | 0.01 |  |  |
| Other poultry, muscle | ○ | 0.02 | 0.02 |  | 0.01 |  |  |
| Chicken, fat | ○ | 1 | 1 |  |  | 1.0 | USA |
| Other poultry, fat | ○ | 1 | 1 |  |  | 1.0 | USA |
| Chicken, liver | ○ | 0.07 | 0.07 |  | 0.01 |  |  |
| Other poultry, liver | ○ | 0.07 | 0.07 |  | 0.01 |  |  |
| Chicken, kidney | ○ | 0.07 | 0.07 |  | 0.01 |  |  |
| Other poultry, kidney | ○ | 0.07 | 0.07 |  | 0.01 |  |  |
| Chicken, edible offal | ○ | 0.07 | 0.07 |  | 0.01 |  |  |
| Other poultry, edible offal | ○ | 0.07 | 0.07 |  | 0.01 |  |  |
| Chicken eggs | ○ | 0.4 | 0.4 |  | 0.01 | 0.40 | USA |
| Other poultry, eggs | ○ | 0.4 | 0.4 |  | 0.01 | 0.40 | USA |
| Fish | ○ | 0.8 | 0.8 |  |  |  |  |
| Raisin ※ |  |  |  | 8 |  |  |

The residue definition is etofenprox 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.
* Diagonal line means deletion of a food category to which an MRL applies.
* 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.

※ Food category "Raisin" will be deleted,and hereafter, MRLs in its raw commodity (i.e. Grape) will also apply to such processed commodity, taking into account its processing factor. For this substance, JMPR estimated processing factor of

2.1 for Raisin.

Fenpyroximate

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| --- | --- | --- | --- | --- |
| **Commodity** | **MRL****(draft) ppm** | **MRL****(current) ppm** | **Registration** | **Reference MRL** |
| Codex ppm | National ppm |
| Corn (maize, including pop corn and sweet corn) | ○ | 0.01 |  |  | 0.01 |  |  |
| Soybeans, dry | ○ | 0.05 | 0.05 | § |  |  |  |
| Beans, dry | ○ | 0.05 | 0.05 | § |  |  |  |
| Peas | ○ | 0.1 | 0.1 | § |  |  |  |
| Potato | ○ | 0.05 |  |  | 0.05 |  |  |
| Sugar beet | ○ | 0.02 | 0.02 | § |  |  |  |
| Other composite vegetables | ● | 0.5 |  |  |  |  |
| Parsley | ● | 0.5 |  |  |  |  |
| Mitsuba | ● | 2 |  |  |  |  |
| Other umbelliferous vegetables | ● | 0.5 |  |  |  |  |
| Tomato | ● | 0.5 | 0.7 | § |  |  |  |
| Pimiento (sweet pepper) | ○ | 1 | 1 | § | 0.2 |  |  |
| Egg plant | ○ | 0.5 | 0.5 | § | 0.3 |  |  |
| Other solanaceous vegetables | ○ | 2 | 2 | § | 0.3 |  |  |
| Cucumber (including gherkin) | ○ | 0.5 | 0.5 | § | 0.3 |  |  |
| Pumpkin (including squash) | ○ | 0.06 | 0.05 | IT | 0.06 | 0.1 | Brazil |
| Water melon | ● | 0.02 | 1 | § |  |  |  |
| Melons | ● | 0.02 | 1 | § |  |  |  |
| Other cucurbitaceous vegetables | ○ | 0.5 | 0.5 | § |  |  |  |
| Spinach | ○ | 0.5 | 0.5 | § |  |  |  |
| Bamboo shoots | ● | 5 |  |  |  |  |
| Okra | ● | 0.2 |  |  |  |  |
| Peas, immature (with pods) | ● | 0.5 | 2 | § | 0.5 |  |  |
| Kidney beans, immature (with pods) | ● | 0.7 | 2 | § | 0.5 |  |  |
| Green soybeans | ○ | 2 | 2 | § | 0.5 |  |  |
| Shiitake mushroom | ● | 0.2 |  |  |  |  |
| Other mushrooms | ● | 0.2 |  |  |  |  |
| Other vegetables | ○ | 5 | 5 | § |  |  |  |
| Unshu orange, pulp | ● | 0.1 | 0.5 | § |  |  |  |
| Citrus natsudaidai, whole | ○ | 1 | 1 | § | 0.6 |  |  |
| Lemon | ○ | 1 | 1 | § | 0.6 |  |  |
| Orange (including navel orange) | ○ | 1 | 1 | § | 0.6 |  |  |
| Grapefruit | ○ | 1 | 1 | § | 0.6 |  |  |
| Lime | ○ | 1 | 1 | § | 0.6 |  |  |
| Other citrus fruits | ○ | 1 | 1 | § | 0.6 |  |  |
| Apple | ● | 0.3 | 0.5 | § | 0.2 |  |  |
| Japanese pear | ● | 0.5 | 1 | § | 0.2 |  |  |
| Pear | ● | 0.5 | 1 | § | 0.2 |  |  |
| Quince | ● | 0.3 |  |  |  |  |
| Loquat | ○ | 0.1 | 0.1 | § |  |  |  |
| Peach | ● | 0.03 | 0.1 | § |  |  |  |
| Nectarine | ○ | 1 | 1 | § | 0.4 |  |  |
| Japanese plum (including prune) | ○ | 1 |  | Request | 0.4 |  |  |
| Mume plum | ○ | 2 | 2 | § | 0.4 |  |  |
| Cherry | ○ | 2 | 0.7 | § | 2 |  |  |
| Strawberry | ○ | 0.5 | 0.5 | § | 0.3 |  |  |
| Raspberry | ○ | 0.2 |  |  | 0.2 |  |  |
| Other berries | ● | 0.5 | 1 |  |  |  |  |
| Grape | ● | 1 | 2 | § | 0.1 |  |  |
| Japanese persimmon | ○ | 0.5 | 0.5 | § |  |  |  |
| Kiwifruit | ○ | 0.05 | 0.05 | § |  |  |  |

The residue definition of fenpyroximate for plant commodities for compliance with the MRL is fenpyroximate. Residue definition of fenpyroximate for animal commodities for compliance with MRL is sum of fenpyroximate, G2 【 1- hydroxylmethyl-1-methylethyl (*E* )-*α* -(1,3-dimethyl-5-phenoxypyrazol-4-ylmethyleneamino-oxy)-*p* -toluate】 and M-3【(*E* )-4- [(1,3-dimethyl-5-phenoxypyrazol-4-yl)methyleneaminooxymethyl]benzoic acid】, expressed as fenpyroximate. Current

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Commodity** | **MRL****(draft) ppm** | **MRL****(current) ppm** | **Registration** | **Reference MRL** |
| Codex ppm | National ppm |
| Avocado | ○ | 0.2 |  |  | 0.2 |  |  |
| Mango | ○ | 1 | 1 |  |  | 0.5 | Taiwan |
| Other fruits | ○ | 0.5 | 0.5 | § |  |  |  |
| Cotton seeds | ○ | 0.1 | 0.1 |  |  |  |  |
| Ginkgo nut | ○ | 0.05 | 0.05 |  | 0.05 |  |  |
| Chestnut | ○ | 0.05 | 0.05 |  | 0.05 |  |  |
| Pecan | ○ | 0.05 | 0.05 |  | 0.05 |  |  |
| Almond | ○ | 0.05 | 0.05 |  | 0.05 |  |  |
| Walnut | ○ | 0.05 | 0.05 |  | 0.05 |  |  |
| Other nuts | ○ | 0.05 | 0.05 |  | 0.05 |  |  |
| Tea | ○ | 40 | 40 | § | 8 |  |  |
| Coffee beans | ○ | 0.07 |  |  | 0.07 |  |  |
| Hop | ○ | 15 | 15 | § | 15 |  |  |
| Other spices | ○ | 5 | 5 | § |  |  |  |
| Other herbs | ○ | 2 | 2 | § |  |  |  |
| Cattle, muscle | ○ | 0.1 | 0.01 |  |  |  |  |
| Pig, muscle | ○ | 0.1 | 0.01 |  |  |  |  |
| Other terrestrial mammals, muscle | ○ | 0.1 | 0.01 |  |  |  |  |
| Cattle, fat | ○ | 0.1 | 0.02 |  | 0.1 |  |  |
| Pig, fat | ○ | 0.1 | 0.02 |  | 0.1 |  |  |
| Other terrestrial mammals, fat | ○ | 0.1 | 0.02 |  | 0.1 |  |  |
| Cattle, liver | ○ | 0.5 | 0.01 |  | 0.5 |  |  |
| Pig, liver | ○ | 0.5 | 0.01 |  | 0.5 |  |  |
| Other terrestrial mammals, liver | ○ | 0.5 | 0.01 |  | 0.5 |  |  |
| Cattle, kidney | ○ | 0.5 | 0.01 |  | 0.5 |  |  |
| Pig, kidney | ○ | 0.5 | 0.01 |  | 0.5 |  |  |
| Other terrestrial mammals, kidney | ○ | 0.5 | 0.01 |  | 0.5 |  |  |
| Cattle, edible offal | ○ | 0.5 | 0.01 |  | 0.5 |  |  |
| Pig, edible offal | ○ | 0.5 | 0.01 |  | 0.5 |  |  |
| Other terrestrial mammals, edible offal | ○ | 0.5 | 0.01 |  | 0.5 |  |  |
| Milk | ○ | 0.01 | 0.005 |  | 0.01 |  |  |
| Pepper,dried ※ | ● | 5 |  | 1 |  |  |
| Raisin ※ | ● | 5 |  | 0.2 |  |  |

residue definition: Fenpyroximate for compliance with the MRL (both for animal and plant commodities).

* 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.
* Diagonal line means deletion of a food category to which an MRL applies.

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

○：Commodities for which MRLs are to be maintained, increased or newly set..(\* It should be noted that the residue definition will be changed.)

§：Permitted for use in Japan.

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

※ Food category ”Pepper,dried" and "Raisin" will be deleted,and hereafter, MRLs in its raw commodity (i.e. Other solanaceous vegetables,Grape) will also apply to such processed commodity, taking into account its processing factors. For this substance, JMPR estimated processing factors of 7 for Other solanaceous vegetables and 2.7 for Raisin.

Mandestrobin

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Commodity** | **MRL****(draft) ppm** | **MRL****(current) ppm** | **Registration** | **Reference MRL** |
| Codex ppm | National ppm |
| Soybeans, dry | ○ | 0.3 | 0.3 | § |  |  |  |
| Beans, dry | ○ | 0.2 | 0.2 | § |  |  |  |
| Peas | ○ | 0.3 | 0.3 | § |  |  |  |
| Broad beans | ○ | 0.3 | 0.3 | § |  |  |  |
| Other pulses | ○ | 0.3 | 0.3 | § |  |  |  |
| Chinese cabbage | ○ | 5 |  | Request |  |  |  |
| Cabbage | ○ | 5 | 5 | § |  |  |  |
| Kale | ○ | 40 | 40 | § |  |  |  |
| Komatsuna (Japanese mustard spinach) | ○ | 40 | 40 | § |  |  |  |
| Kyona | ○ | 25 | 25 | § |  |  |  |
| Qing-geng-cai | ○ | 40 | 40 | § |  |  |  |
| Other cruciferous vegetables | ○ | 40 | 40 | § |  |  |  |
| Shungiku | ○ | 50 |  | Request |  |  |  |
| Lettuce (including cos lettuce and leaf lettuce) | ○ | 40 | 40 | § |  |  |  |
| Tomato | ○ | 10 | 10 | § |  |  |  |
| Egg plant | ○ | 2 | 2 | § |  |  |  |
| Cucumber (including gherkin) | ○ | 2 | 2 | § |  |  |  |
| Water melon | ○ | 0.1 | 0.1 | § |  |  |  |
| Melons | ○ | 0.05 | 0.05 | § |  |  |  |
| Peas, immature (with pods) | ○ | 5 | 5 | § |  |  |  |
| Kidney beans, immature (with pods) | ○ | 10 | 10 | § |  |  |  |
| Green soybeans | ○ | 10 | 10 | § |  |  |  |
| Other vegetables | ○ | 10 | 10 | § |  |  |  |
| Apple | ○ | 5 | 5 | § |  |  |  |
| Japanese pear | ○ | 2 | 2 | § |  |  |  |
| Pear | ○ | 2 | 2 | § |  |  |  |
| Peach | ○ | 0.2 | 0.2 | § |  |  |  |
| Nectarine | ○ | 5 | 5 | § |  |  |  |
| Apricot | ○ | 5 | 5 | § |  |  |  |
| Japanese plum (including prune) | ○ | 2 | 2 | § |  |  |  |
| Mume plum | ○ | 5 | 5 | § |  |  |  |
| Cherry | ○ | 5 | 5 | § |  |  |  |
| Strawberry | ○ | 3 | 3 |  |  | 3 | USA |
| Grape | ○ | 10 | 10 | § |  |  |  |
| Japanese persimmon | ○ | 3 | 3 | § |  |  |  |
| Rapeseeds | ○ | 0.5 |  | IT |  | 0.5 | Canada |
| Tea | ○ | 40 | 40 | § |  |  |  |
| Other herbs | ○ | 40 | 40 | § |  |  |  |

The residue definition is sum of R and L isomers of mandestrobin.

* 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. IT：Import tolerance

Flumequine

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Commodity** | **MRL****(draft) ppm** | **MRL****(current) ppm** | **Registration** | **Reference MRL** |
| Codex ppm | National ppm |
| Cattle, muscle | ○ | 0.5 | 0.5 |  | 0.5 |  |  |
| Pig, muscle | ○ | 0.5 | 0.5 |  | 0.5 |  |  |
| Other terrestrial mammals, muscle | ○ | 0.5 | 0.5 |  | 0.5 |  |  |
| Cattle, fat | ○ | 1 | 1 |  | 1 |  |  |
| Pig, fat | ○ | 1 | 1 |  | 1 |  |  |
| Other terrestrial mammals, fat | ○ | 1 | 1 |  | 1 |  |  |
| Cattle, liver | ○ | 0.5 | 0.5 |  | 0.5 |  |  |
| Pig, liver | ○ | 0.5 | 0.5 |  | 0.5 |  |  |
| Other terrestrial mammals, liver | ○ | 0.5 | 0.5 |  | 0.5 |  |  |
| Cattle, kidney | ○ | 3 | 3 |  | 3 |  |  |
| Pig, kidney | ○ | 3 | 3 |  | 3 |  |  |
| Other terrestrial mammals, kidney | ○ | 3 | 3 |  | 3 |  |  |
| Cattle, edible offal | ○ | 3 | 0.2 |  |  |  |  |
| Pig, edible offal | ○ | 3 | 0.2 |  |  |  |  |
| Other terrestrial mammals, edible offal | ○ | 3 | 0.2 |  |  |  |  |
| Milk | ● | 0.05 | 0.1 |  |  | 0.05 | EU |
| Chicken, muscle | ○ | 0.5 | 0.5 |  | 0.5 |  |  |
| Chicken, fat | ○ | 1 | 1 |  | 1 |  |  |
| Chicken, liver | ○ | 0.5 | 0.5 |  | 0.5 |  |  |
| Chicken, kidney | ○ | 3 | 3 |  | 3 |  |  |
| Chicken, edible offal | ○ | 3 | 0.5 |  |  |  |  |
| Salmoniformes (such as salmon and trout) | ○ | 0.6 | 0.5 |  | 0.5 | 0.6 | EU |
| Anguilliformes (such as eel) | ○ | 0.6 | 0.6 |  |  | 0.6 | EU |
| Perciformes (such as bonito, horse mackerel, mackerel, sea bass, sea bream and tuna) | ○ | 0.6 | 0.04 |  |  | 0.6 | EU |
| Other fish | ○ | 0.6 | 0.6 |  |  | 0.6 | EU |

The residue definition is flumequine 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.
* Shaded figures indicate provisional MRLs.
* 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.

Mono, bis (trimethylammoniummethylene chloride)］-alkyltoluene

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Commodity** | **MRL****(draft) ppm** | **MRL****(current) ppm** | **Registration** | **Reference MRL** |
| Codex ppm | National ppm |
| Cattle, muscle | ○ | 1 | 1 | § |  |  |  |
| Pig, muscle | ○ | 1 | 1 | § |  |  |  |
| Cattle, fat | ○ | 1 | 1 | § |  |  |  |
| Pig, fat | ○ | 1 | 1 | § |  |  |  |
| Cattle, liver | ○ | 2 | 2 | § |  |  |  |
| Pig, liver | ○ | 2 | 2 | § |  |  |  |
| Cattle, kidney | ○ | 1 | 1 | § |  |  |  |
| Pig, kidney | ○ | 1 | 1 | § |  |  |  |
| Cattle, edible offal | ○ | 2 | 2 | § |  |  |  |
| Pig, edible offal | ○ | 2 | 2 | § |  |  |  |
| Milk | ● | 0.1 | 1 | § |  |  |  |
| Chicken, muscle | ○ | 1 | 1 | § |  |  |  |
| Chicken, fat | ○ | 1 | 1 | § |  |  |  |
| Chicken, liver | ○ | 2 | 2 | § |  |  |  |
| Chicken, kidney | ○ | 1 | 1 | § |  |  |  |
| Chicken, edible offal | ○ | 2 | 2 | § |  |  |  |
| Chicken eggs | ○ | 1 | 1 | § |  |  |  |

The residue definition for milk is sum of mono (trimethylammoniummethylene chloride)-alkyl (C11H23) toluene, mono (trimethylammoniummethylene chloride)-alkyl (C12H25) toluene, mono (trimethylammoniummethylene chloride)-alkyl (C13H27) toluene and bis (trimethylammoniummethylene chloride)-alkyl (C12H25) toluene. For animal products except for milk, the residue difiniton is mono, bis (trimethylammoniummethylene chloride)-alkyltoluene.

* 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.
* Shaded figures indicate provisional MRLs.
* 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.(\* It should be noted that the residue definition will be changed.)

§：Permitted for use in Japan.

Butylated Hydroxyanisole

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Commodity** | **MRL****(draft) ppm** | **MRL****(current) ppm** | **Registration** | **Reference MRL** |
| Codex ppm | National ppm |
| Pig, muscle | ○ | 0.03 | 0.03 | § |  |  |  |
| Pig, fat | ○ | 0.1 | 0.04 | § |  |  |  |
| Pig, liver | ○ | 0.04 | 0.03 | § |  |  |  |
| Pig, kidney | ○ | 0.05 | 0.02 | § |  |  |  |
| Pig, edible offal | ○ | 0.1 | 0.02 | § |  |  |  |
| Chicken, muscle | ○ | 0.02 | 0.02 | § |  |  |  |
| Chicken, fat | ○ | 0.05 | 0.02 | § |  |  |  |
| Chicken, liver | ○ | 0.02 | 0.02 | § |  |  |  |
| Chicken, kidney | ○ | 0.02 | 0.02 | § |  |  |  |
| Chicken, edible offal | ○ | 0.05 | 0.02 | § |  |  |  |
| Chicken eggs | ○ | 0.06 | 0.02 | § |  |  |  |
| Salmoniformes (such as salmon and trout) | ○ | 0.5 | 0.5 | § |  |  |  |
| Anguilliformes (such as eel) | ○ | 0.5 | 0.5 | § |  |  |  |
| Perciformes (such as bonito, horse mackerel, mackerel, sea bass, sea bream and tuna) | ○ | 0.5 | 0.5 | § |  |  |  |
| Other fish | ○ | 0.5 | 0.5 | § |  |  |  |

The residue definition is butylated hydroxyanisole 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.
* Shaded figures indicate provisional MRLs.
* In the Commodity column, for the food categories to which the word other is added, refer to the Notes given in the last two

○：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 (pulp), citrus *natsudaidai* (pulp), citrus *natsudaidai* (peel), citrus *natsudaidai* (whole), 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 animals” 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.

### Item 2. Revision of Standards for Food Additive

The government of Japan will revise the existing compositional specifications of Hypobromous acid water.

**Summary**

The Food Sanitation Act, in Article 10, prohibits the use and the sale of the food additives the Minister of Health, Labour and Welfare (hereinafter referred to as “the Minister”) does not designate. In addition, when specifications or standards for food additives are stipulated in the Ministry of Health and Welfare Notification (Notification No. 370, 1959) pursuant to Article 11 of the Act, those additives shall not be used or sold unless they meet the standards or the specifications.

On October 24, 2018, the Committee on Food Additives of the Food Sanitation Council established under the Pharmaceutical Affairs and Food Sanitation Council (hereinafter referred to as “the Committee”) discussed whether it is adequate to revise the existing compositional specifications of Hypobromous acid water. The Committee has concluded that the Minister should revise the standards pursuant to Article 11 of the Act. See Attachment 2-1 for the details.

**Notes**

Hypobromous acid water is an aqueous solution consisting mainly of hypobromous acid. In Japan, Hypobromous acid water is designated as a food additive consisting mainly of hypobromous acid that is obtained by hydrolyzing

1,3-dibromo-5,5-dimethylhydantoin. It is permitted for use in meat as a surface disinfectant.

The United States and Canada approve Hypobromous acid water obtained by mixing hydrogen bromide with chlorine sources, such as sodium hypochlorite, potassium hypochlorite or calcium hypochlorite besides Hypobromous acid water currently approved in Japan. In those countries, Hypobromous acid water is generally used as a processing aid to disinfect water and ices for treatment of meat.

The Codex Alimentarius Commission does not categorize processing aids as food additives. The Codex Committee on Food Additives, therefore, dose not established use standards for Hypobromous acid water, its precursor hydrogen bromid, and choline sources (sodium hypochlorite, potassium hypochlorite, and calcium hypochlorite) in the General Standard for Food Additives.

In addition, Hypobromous acid water has not been evaluated by the Joint FAO/WHO Expert Committee on Food Additives (JECFA).

**Additional Information**

Progress in the designation procedure of food additives (54 flavorings and 45

non-flavoring additives) that have been proven safe by JECFA and that are widely used in countries other than Japan.

As of November 29, 2018, all flavorings and 41 non-flavoring additives are designated. See Attachment 2-2 for the details.

**Attachment 2-1**

### Revision of Compositional Specifications Hypobromous Acid Water

**Compositional Specifications（draft）**

Compositional specifications of Hypobromous acid water will be revised as follows：

|  |  |
| --- | --- |
| Revised regulations | Current regulations |
| **Definition** Hypobromous Acid Water is an aqueous solution consisting mainly of hypobromous acid. It is obtained by hydrolyzing 1,3-dibromo-5,5- dimethylhydantoin or by mixing hydrogen bromide with an aqueous solution of sodium hypochlorite, potassium hypochlorite or calcium hypochlorite. | **Definition** Hypobromous Acid Water is an aqueous solution consisting mainly of hypobromous acid. It is obtained by hydrolyzing 1,3-dibromo-5,5- dimethylhydantoin. |

(The underlined part will be newly added.)

**Progress of evaluation of food additives that have been proven safe and are widely used in the world**

Attachment 2-2

29 November, 2018

|  |  |  |  |
| --- | --- | --- | --- |
| **Substance name** | **Request for evaluation** | **Food Safety Commission** | **MHLW** |
| **Evaluation by expert committee1** | **Notification of result2** | **Discussion by subcommittee3** | **Closing date for comments4** | **Date of designation as food additives** |
| Isobutanol | 21 Nov 2003 | 24 Mar 2004(fin.) | 27 May 2004 | 23 Apr 2004(fin.) | 19 Aug 2004 | 24 Dec 2004 |
| 2-Ethyl-3, (5 or 6)- dimethylpyrazine | 3 Mar 2004(fin.) | 27 May 2004 | 8 Apr 2004(fin.) | 26 Jul 2004 | 24 Dec 2004 |
| 2,3,5,6-Tetramethylpyrazine | 3 Mar 2004(fin.) | 27 May 2004 | 8 Apr 2004(fin.) | 26 Jul 2004 | 24 Dec 2004 |
| Calcium stearate | 4 Mar 2004 | 20 May 2004(fin.) | 29 Jul 2004 | 24 Jun 2004(fin.) | 21 Oct 2004 | 24 Dec 2004 |
| Propanol | 21 Nov 2003 | 24 Mar 200420 May 200428 Jul 2004(fin.) | 9 Sep 2004 | 26 Aug 2004(fin.) | 14 Dec 2004 | 24 Feb 2005 |
| Nitrous oxide | 20 Oct 2003 | 17 Dec 20035 Oct 2004(fin.) | 9 Dec 2004 | 17 Dec 2004(fin.) | 19 Feb 2005 | 22 Mar 2005 |
| Isopropanol | 15 Dec 2003 | 24 Mar 20049 Apr 20048 Sep 20045 Oct 2004(fin.) | 9 Dec 2004 | 28 Oct 2004(fin.) | 4 Mar 2005 | 28 Apr 2005 |
| Hydroxypropyl cellulse | 16 Aug 2004 | 22 Dec 2004(fin.) | 10 Mar 2005 | 24 Feb 2005(fin.) | 14 Jun 2005 | 19 Aug 2005 |
| Isoamylalcohol | 5 Nov 2004 | 14 Jan 2005(fin.) | 17 Mar 2005 | 24 Feb 2005(fin.) | 14 Jun 2005 | 19 Aug 2005 |
| 2,3,5-Trimethylpyrazine |
| Amylalcohol |
| Natamycin | 20 Oct 2003 | 9 Jan 200416 Nov 200426 Jan 2005(fin.) | 6 May 2005 | 24 Mar 2005(fin.) | 7 Sep 2005 | 28 Nov 2005 |
| Acetaldehyde | 21 Nov 2003 | 3 Mar 20049 Apr 200427 Apr 200423 Feb 200513 Apr 2005(fin.) | 21 Jul 2005 | 23 Jun 2005(fin.) | 12 Oct 2005 | 16 May 2006 |
| 2-Ethyl-3-methylpyrazine | 7 Mar 2005 | 14 Jun 2005(fin.) | 18 Aug 2005 | 28 Jul 2005(fin.) | 19 Dec 2005 | 16 May 2006 |
| 5-Methylquinoxaline |
| Butanol | 14 Jun 200522 Jul 2005(fin.) | 22 Sep 2005 | 27 Oct 200524 Nov 2005(fin.) | 26 Apr 2006 | 12 Sep 2006 |
| Ammonium alginate | 28 Mar 2005 | 2 Dec 200514 Dec 2005(fin.) | 30 Mar 2006 | 23 Mar 2006(fin.) | 5 Sep 2006 | 26 Dec 2006 |
| Potassium alginate |
| Calcium alginate |

|  |  |  |  |
| --- | --- | --- | --- |
| **Substance name** | **Request for evaluation** | **Food Safety Commission** | **MHLW** |
| **Evaluation by expert committee1** | **Notification of result2** | **Discussion by subcommittee3** | **Closing date for comments4** | **Date of designation as food additives** |
| 2-Methylbutanol | 19 Dec 2005 | 14 Jul 200611 Aug 2006(fin.) | 12 Oct 2006 | 8 Dec 200616 Jan 2007 (Fin.) | 22 May 2007 | 3 Aug 2007 |
| Isobutyraldehyde | 19 Dec 2005 | 28 Jun 200614 Jul 200611 Aug 200613 Sep 200613 Oct 2006(fin.) | 7 Dec 2006 | 8 Dec 200616 Jan 2007 (Fin.) | 22 May 2007 | 3 Aug 2007 |
| Butyraldehyde | 19 Dec 2005 | 19 Dec 200626 Jan 2007(fin.) | 22 Mar 2007 | 20 Mar 2007(fin.) | 27 Aug 2007 | 26 Oct 2007 |
| Polysorbate 20, 60, 65, 80 | 8 Oct 2003 | 29 Oct 200327 Apr 200428 Jul 200423 Mar 2007(fin.) | 7 Jun 2007 | 4 Jul 20079 Aug 2007(fin.) | 16 Dec 2007 | 30 Apr 2008 |
| Calcium silicate | 15 Aug 2005 | 28 Feb 200723 Mar 200717 Apr 200729 May 2007(fin.) | 26 Jul 2007 | 9 Aug 2007(fin.) | 16 Dec 2007 | 30 Apr 2008 |
| Calcium ascorbate | 3 Oct 2005 | 23 Mar 200717 Apr 200729 May 200722 Jun 2007(fin.) | 23 Aug 2007 | 9 Aug 2007(fin.) | 16 Dec 2007 | 30 Apr 2008 |
| Nisin | 20 Oct 2003 | 9 Apr 200416 Nov 200426 Jan 200530 Jul 200727 Aug 2007(fin.) | 31 Jan 2008 | 26 Sep 200724 Oct 200728 Feb 2008(fin.)24 Sep 2008(fin.) | 18 Jul 2008 | 2 Mar 2009 |

|  |  |  |  |
| --- | --- | --- | --- |
| **Substance name** | **Request for evaluation** | **Food Safety Commission** | **MHLW** |
| **Evaluation by expert committee1** | **Notification of result2** | **Discussion by subcommittee3** | **Closing date for comments4** | **Date of designation as food additives** |
| Acetylated distarch adipate | 26 Nov 2004 | 23 Mar 200517 May 200527 Aug 200728 Sep 2007(fin.) | 29 Nov 2007 | 28 Nov 2007(fin.)4 Jul 2008(fin.) | 29 May 2008 | 1 Oct 2008 |
| Acetylated distarch phosphate |
| Acetylated oxidized starch |
| Starch sodium octenylsuccinate |
| Hydroxypropyl starch |
| Hydroxypropyl distarch phosphate |
| Phosphated distarch phosphate |
| Monostarch phosphate |
| Distarch phosphate |
| Oxidized starch |
| Starch acetate |
| Magnesium hydroxide | 9 Mar 2006 | 22 Jun 200730 Jul 200727 Aug 2007(fin.) | 1 Nov 2007 | 24 Oct 2007(fin.) | 7 Feb 2008 | 4 Jul 2008 |
| Magnesium Monohydrogen Phosphate | 28 Mar 2005 | 31 May 200628 Jun 200614 Jul 200611 Aug 200613 Sep 200628 Nov 200625 Oct 201129 Nov 201116 Dec 2011(fin) | 22 Mar 2012 | 6 Mar 2012(fin.) | 22 Jul 2012 | 2 Nov 2012 |
| Polyvinylpyrrolidone | 20 Jun 2005 | 13 Sep 200613 Oct 200628 Nov 200619 Dec 200626 Jan 200718 Dec 201222 Jan 201322 Feb 201327 Mar 201325 Apr 2013(fin.) | 30 Jul 2013 | 21 Jun 201330 Oct 201329 Jan 2014(fin) | ― | 18 Jun 2014 |

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| **Substance name** | **Request for evaluation** | **Food Safety Commission** | **MHLW** |
| **Evaluation by expert committee1** | **Notification of result2** | **Discussion by subcommittee3** | **Closing date for comments4** | **Date of designation as food additives** |
| Magnesium silicate(synthetic) | 15 Aug 2005 | 28 Feb 200723 Mar 200717 Apr 200728 Sep 200917 Nov 2009(fin.) | 21 Jan 2010 | 25 Dec 2009(fin) | 6 Jun 2010 | 20 Oct 2010 |
| Sodium aluminium silicate | 15 Aug 2005 | 28 Feb 200730 May 201216 May 201328 Jun 201330 Jul 201320 Aug 2013(under consideration) |  |  |  |  |
| Calcium aluminium silicate | 15 Aug 2005 | 28 Feb 200730 May 201227 Jul 201216 May 201328 Jun 201330 Jul 201320 Aug 2013(under consideration) |  |  |  |  |
| Calcium saccharin | 22 May 2006 | 27 Aug 200728 Sep 200726 Oct 200726 Apr 201131 May 201128 Jun 2011(fin) | 25 Aug 2011 | 2 Nov 2011 (fin) | 12 May 2012 | 28 Dec 2012 |
| Ammonium L-glutamate | 22 May 2006 | 15 Jan 2008(fin.) | 13 Mar 2008 | 11 Apr 2008 (fin.) | 10 Oct 2008 | 20 Oct 2010 |
| Sodium stearoyl-2-lactylate | 6 Feb 2007 | 24 Mar 200815 Apr 2008(fin.) | 10 Jul 2008 | 4 Jul 2008(fin.) | 1 Dec 2008 | 28 May 2010 |
| Potassium lactate | 6 Feb 2007 | 17 Jun 200829 Sep 200821 Aug 201226 Sep 201225 Oct 2012(fin.) | 21 Jan 2013 | 6 Dec 2012 | 11 Mar 2013 | 15 May 2013 |

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| **Substance name** | **Request for evaluation** | **Food Safety Commission** | **MHLW** |
| **Evaluation by expert committee1** | **Notification of result2** | **Discussion by subcommittee3** | **Closing date for comments4** | **Date of designation as food additives** |
| Calcium sorbate | 19 Mar 2007 | 26 Mar 200817 Jun 200829 Aug 2008(fin.) | 20 Nov 2008 | 25 Nov 2008(fin) | 25 Apr 2009 | 28 May 2010 |
| Valeraldehyde | 19 Mar 2007 | 1 Feb 2008(fin.) | 27 Mar 2008 | 4 Jul 2008(fin.) | 1 Dec 2008 | 4 Jun 2009 |
| Isovaleraldehyde | 19 Mar 2007 | 1 Feb 2008(fin.) | 27 Mar 2008 | 4 Jul 2008(fin.) | 1 Dec 2008 | 4 Jun 2009 |
| 2,3-Dimethylpyrazine | 7 Feb 2008 | 15 Apr 200826 May 2008(fin.) | 31 Jul 2008 | 24 Sep 2008(fin.) | 3 Feb 2009 | 4 Jun 2009 |
| 2,5-Dimethylpyrazine | 7 Feb 2008 | 15 Apr 200826 May 2008(fin.) | 31 Jul 2008 | 24 Sep 2008(fin.) | 3 Feb 2009 | 4 Jun 2009 |
| 2,6-Dimethylpyrazine | 7 Feb 2008 | 15 Apr 200826 May 2008(fin.) | 31 Jul 2008 | 24 Sep 2008(fin.) | 3 Feb 2009 | 4 Jun 2009 |
| 2-Ethylpyrazine | 22 May 2008 | 29 Sep 2008(fin.) | 27 Nov 2008 | 22 Oct 2008(fin.) | 25 Apr 2009 | 28 May 2010 |
| 2-Methylpyrazine | 22 May 2008 | 29 Sep 2008(fin.) | 27 Nov 2008 | 22 Oct 2008(fin.) | 25 Apr 2009 | 28 May 2010 |
| 2-Pentanol | 14 Oct 2008 | 11 Nov 2008(fin.) | 22 Jan 2009 | 28 Apr 2009(fin.) | 20 Sep 2009 | 28 May 2010 |
| 2-Methylbutyraldehyde | 14 Oct 2008 | 11 Nov 2008(fin.) | 22 Jan 2009 | 22 Dec 2008(fin.) | 29 May 2009 | 28 May 2010 |
| Propionaldehyde | 20 Nov 2008 | 2 Feb 2009(fin.) | 2 Apr 2009 | 28 Apr 2009(fin.) | 20 Sep 2009 | 28 May 2010 |
| 6-Methylquinoline | 20 Nov 2008 | 23 Mar 2009(fin) | 21 May 2009 | 28 Apr 2009(fin.) | 20 Sep 2009 | 28 May 2010 |
| 2-Ethyl-5-methylpyrazine | 12 Mar 2009 | 29 Jun 200928 Sep 2009(fin.) | 8 Oct 2009 | 25 Dec 2009(fin) | 6 Jun 2010 | 20 Oct 2010 |
| 5,6,7,8-Tetrahydroquinoxaline | 12 Mar 2009 | 29 Jun 2009(fin) | 27 Aug 2009 | 3 Sep 2009(fin.) | 2 Feb 2010 | 28 May 2010 |
| 3-Methyl-2-butanol | 12 Mar 2009 | 18 May 2009(fin.) | 23 Jul 2009 | 3 Sep 2009(fin.) | 2 Feb 2010 | 28 May 2010 |
| Isopentylamine | 12 Aug 2009 | 7 Sep 2009(fin.) | 12 Nov 2009 | 25 Dec 2009(fin) | 6 Jun 2010 | 20 Oct 2010 |
| Butylamine | 10 Sep 2009 | 20 Oct 200917 Nov 2009(fin) | 4 Mar 2010 | 5 Mar 2010(fin) | 30 Aug 2010 | 10 Nov 2010 |
| Phenetylamine | 5 Nov 2009 | 17 Nov 2009(fin) | 18 Mar 2010 | 5 Mar 2010(fin) | 30 Aug 2010 | 10 Nov 2010 |
| Trimethylamine | 26 Nov 2009 | 15 Dec 2009(fin) | 29 Jul 2010 | 2 Nov 2011 (fin) | 19 Mar 2012 | 28 Dec 2012 |
| 1-Penten-3-ol | 2 Feb 2010 | 23 Feb 2010(fin) | 28 Apr 2010 | 9 Feb 2011(fin) | 24 May 2011 | 19 Jul 2011 |
| 3-Methyl-2-butenol | 2 Feb 2010 | 23 Feb 2010(fin) | 28 Apr 2010 | 9 Feb 2011(fin) | 24 May 2011 | 19 Jul 2011 |
| Piperidine | 15 Mar 2010 | 30 Mar 2010(fin) | 20 May 2010 | 23 Jun 2010(fin) | 23 Oct 2010 | 13 Dec 2010 |
| Pyrrolidine | 5 Apr 2010 | 20 Apr 2010(fin) | 3 Jun 2010 | 23 Jun 2010(fin) | 23 Oct 2010 | 13 Dec 2010 |
| 2,6-Dimethylpyridine | 13 May 2010 | 2 Jun 2010(fin) | 15 Jul 2010 | 9 Sep 2010(fin) | 3 Jan 2011 | 15 Mar 2011 |
| 3-Ethylpyridine | 14 Jun 2010 | 29 Jun 201023 Aug 201115 Nov 2012(fin.) | 18 Feb 2013 | 18 Jan 2013 | 18 May 2013 | 6 Aug 2013 |

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| **Substance name** | **Request for evaluation** | **Food Safety Commission** | **MHLW** |
| **Evaluation by expert committee1** | **Notification of result2** | **Discussion by subcommittee3** | **Closing date for comments4** | **Date of designation as food additives** |
| 5-Ethyl-2-methylpyridine | 14 Jun 2010 | 29 Jun 2010(fin) | 26 Aug 2010 | 9 Sep 2010(fin) | 3 Jan 2011 | 15 Mar 2011 |
| 2-(3-Phenylpropyl)pyridine | 9 Jul 2010 | 27 Jul 2010(fin) | 7 Oct 2010 | 22 Dec 2010(fin) | 1 Apr 2011 | 28 Jun 2011 |
| 2,3-Diethyl-5-methylpyrazine | 9 Jul 2010 | 27 Jul 2010(fin) | 7 Oct 2010 | 22 Dec 2010(fin) | 1 Apr 2011 | 28 Jun 2011 |
| 5-methyl-6,7-Dihydro-5*H* - cyclopentapyrazine | 12 Aug 2010 | 31 Aug 2010(fin) | 27 Jan 2011 | 22 Dec 2010(fin) | 1 Apr 2011 | 28 Jun 2011 |
| Pyrazine | 12 Aug 2010 | 31 Aug 2010(fin) | 4 Jan 2011 | 9 Feb 2011(fin) | 24 May 2011 | 19 Jul 2011 |
| 3-Methyl-2-butenal | 9 Sep 2010 | 27 Sep 2010(fin) | 27 Jan 2011 | 9 Feb 2011(fin) | 24 May 2011 | 19 Jul 2011 |
| *trans* -2-Pentenal | 29 Oct 2010 | 12 Nov 201021 Dec 201027 Sep 2011(fin) | 1 Dec 2011 | 6 Mar 2012(fin) | 22 Jul 2012 | 2 Nov 2012 |
| Isoquinolin | 29 Oct 2010 | 12 Nov 2010(fin) | 3 Feb 2011 | 11 May 2011(fin) | 8 Aug 2011 | 27 Dec 2011 |
| 2-Ethyl-6-methylpyrazine | 6 Dec 2010 | 21 Dec 2010(fin) | 31 Mar 2011 | 2 Nov 2011 (fin) | 19 Mar 2012 | 28 Dec 2012 |
| *trans* -2-Methyl-2-butenal | 4 Jan 2011 | 18 Jan 2011(fin) | 21 Apr 2011 | 2 Nov 2011 (fin) | 19 Mar 2012 | 28 Dec 2012 |
| Pyrrole | 4 Jan 2011 | 18 Jan 2011(fin) | 31 Mar 2011 | 11 May 2011(fin) | 8 Aug 2011 | 27 Dec 2011 |
| (3-Amino-3-carboxypropyl)dimethylsulfonium chloride | 17 Feb 2011 | 22 Feb 2011(fin) | 12 May 2011 | 2 Nov 2011 (fin) | 19 Mar 2012 | 28 Dec 2012 |
| Ammonium isovalerate | 3 Mar 2011 | 26 Apr 201131 May 201115 Nov 2012(fin.) | 18 Feb 2013 | 16 Feb 2015 | 21 May 2015 | 29 Jul 2015 |
| 28 Nov 2014 | - | 9 Dec 2014 |
| β-apo-8’-carotenal | 19 Apr 2011 | 27 Mar 201227 Jul 201216 May 201328 Jun 201330 Jul 201320 Aug 2013(fin.) | 25 Nov 2013 | 27 Nov 2013 | － | 18 Jun 2014 |
| Carmine | 19 Apr 2011 | 26 Jul 201123 Aug 201130 May 2012(under consideration) |  |  |  |  |

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| --- | --- | --- | --- |
| **Substance name** | **Request for evaluation** | **Food Safety Commission** | **MHLW** |
| **Evaluation by expert committee1** | **Notification of result2** | **Discussion by subcommittee3** | **Closing date for comments4** | **Date of designation as food additives** |
| Canthaxanthin | 19 Apr 2011 | 27 Mar 201227 Jul 201220 Aug 201324 Sep 201317 Oct 201320 Nov 201325 Dec 201330 Jun 2014(fin) | 14 Oct 2014 | 5 Sep 2014 | 18 Nov 2014 | 20 Feb 2015 |
| Sodium aluminium phosphate,acidic | 19 Apr 2011 | 30 May 201216 May 201328 Jun 201330 Jul 201320 Aug 2013(under consideration) |  |  |  |  |
| Calcium acetate | 19 Apr 2011 | 24 Apr 201215 Nov 201218 Dec 201222 Jan 2013(fin) | 15 Apr 2013 | 13 Mar 2013 | 22 Jun 2013 | 4 Dec 2013 |
| Calcium oxide | 19 Apr 2011 | 24 Apr 201215 Nov 201218 Dec 201222 Jan 2013(fin） | 15 Apr 2013 | 13 Mar 2013 | 22 Jun 2013 | 22 Oct 2013 |
| Potassium sulfate | 19 Apr 2011 | 24 Apr 201226 Sep 201225 Oct 2012(fin.) | 21 Jan 2013 | 6 Dec 2012 | 11 Mar 2013 | 15 May 2013 |
| Triethyl citrate | 19 Apr 2011 | 30 May 201218 Dec 201222 Jan 201322 Feb 201329 Sep 201429 Oct 2014(fin.) | 17 Feb 2015 | 25 Dec 2014 | 3 Mar 2015 | 19 May 2015 |

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| --- | --- | --- | --- |
| **Substance name** | **Request for evaluation** | **Food Safety Commission** | **MHLW** |
| **Evaluation by expert committee1** | **Notification of result2** | **Discussion by subcommittee3** | **Closing date for comments4** | **Date of designation as food additives** |
| Isopropanol | 19 Apr 2011 | 29 Nov 201116 Dec 2011(fin) | 29 Mar 2012 | 31 May 2013 | 8 Oct 2013 | 4 Dec 2013 |
| 16 May 2013 | ― | 27 May 2013 |
| 2,3-Diethylpyrazine | 12 Feb 2014 | 13 Mar 201422 May 2014（fin） | 26 Aug 2014 | 20 Jun 2014 | 23 Oct 2014 | 17 Nov 2014 |
| 1-Methylnaphthalene | 5 Nov 2014 | 12 Dec 201414 Jan 20155 Feb 2015(fin.) | 19 May 2015 | 24 Apr 2015 | 12 Jun 2015 | 18 Sep 2015 |

 flavouring agents

1. Date when discussion was conducted by the expert committee.
2. Date when the evaluation result was filed with the MHLW.
3. Date when discussion was conducted by the Subcommittee on Food Additives under the Pharmaceutical Affairs and Food Sanitation Council.
4. Closing date for comment on WTO notification

<Provisional Translation>

**Ensuring safety of imported food**

**Ensuring safety of imported food**

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Schedule for enforcement

Confirmation of implementation of hygiene control based on HACCP・・・from 2021（enforcement in 2020 + 1 year interval) Obligation to attach health certificates ① and ② ・・・from 2020

→Ministerial orders etc. on these new measures are planning to be published by June 2019, following notification of the

proposals to WTO and call for public comments. MHLW will explain the progress in a timely manner.

〇 For the purpose to confirm that the inspections and control have properly been conducted in the exporting countries for insurance of safety of imported food, hygiene control based on HACCP and attachment of health certificates of milk products and aquatic food are required as a requisite of import.

**Previous regulations Revision**

Confirmation of implementation of hygiene control based on HACCP

\* Confirmation of implementation of hygiene control based on HACCP is not conducted under the existing regulation.

Hygiene control based on HACCP is required for a part of imported food.

Scope: Food that are required to be subject to hygiene

control based on HACCP in Japan (Meat, poultry, etc. are considered.)

\* Regulated by the ministerial order.

Milk and milk products is added to the scope.

\* Appropriate risk management is especially required as they may contain bacteria having a risk of food poisoning, .

Obligation to attach health certificates ② (Confirmation of the situation etc. of hygiene control at the places of production)

 Scope: Puffer fish, oysters for eating raw

\* Notification under the existing regulation

Obligation to attach health certificate is legislated.

\* Certification that the status of hygiene control at the area is appropriate in terms of food sanitation is required for them, depending on the situation of its control.

Confirmation of implementation of hygiene control based on HACCP

Obligation to attach health certificates ①

(Confirmation that the food is derived from healthy livestock)

Obligation to attach health certificates ①

(Confirmation that the food is derived from healthy livestock)

Scope: Meat, offal, meat products, milk, milk products\* ar considered

\* Regulated by the Act (Article 10, Clause 2 of the Act)

Scope: Meat, offal, meat products

Obligation to attach health certificates ②

(Confirmation of the situation etc. of hygiene control at the places of production)

Scope: Puffer fish, oysters for eating raw\* are considered.

\*Regulated by the ministerial order.

Ensuring safety of imported food

<Provisional Translation>

１．Confirmation of implementation of hygiene control based on HACCP

（1. of Article 11, Revision of the Food Sanitation Act, 13 June 2018）

Designate foods requiring measures to control processes particularly important to prevent occurrence of adverse health effects (food hygiene control based on HACCP) in exporting country

* Designation of food（Regulated by the ministerial order）

→ “meat and poultry meat” are considered, which require food hygiene control based on HACCP in

Japan

Designated foods shall not be imported for sale, unless they are slaughtered or processed in countries and regions, or establishments where the Minister of Health, Labour and Welfare recognizes that such measures are taken.

* + Designation of countries, regions or establishments (Regulated by ministerial announcements)

## ・Recognition and supervision of establishments complying with criteria for exportation to Japan by exporting country’s competent authorities

・Notification of a list on establishments eligible for exportation to Japan from the competent authorities to MHLW

・Regular audit and verification of the status of control in the exporting country by MHLW

* + - Before entering into force, MHLW needs to consult with an exporting country and conduct on-site inspection in order to make sure the equivalence of its control system (e.g. a mechanism to ensure hygiene control based on HACCP and a structure on how to supervise it) with Japan’s system.

※If it is impossible for an exporting country’s competent authority to follow the process, an establishment in the country which wishes for recognition as those eligible for exportation to Japan may request MHLW, through the competent authority to recognize them, to designate it in accordance with procedures set by MHLW.

# →MHLW will develop guidelines on the basic principles, criteria and procedures for designation of countries and regions, or establishments.

Ensuring safety of imported food

<Provisional Translation>

２．Obligation to attach certificates ①：Confirmation that the food is derived from healthy livestock

## （2. of Article 10, Revision of the Food Sanitation Act, 13 June 2018）

When importing foods which may be at increased risk on food hygiene depending on hygiene control, request to attach to them health certificates issued by the exporting country’s competent authorities which certify the status of food hygiene control.

* + Milk and milk products will be within the scope, in addition to meat, offal and meat products derived from healthy livestock

Scope of milk and milk products

(Regulated by the ministerial order)

→Select products within those which are provided in the Ministerial Ordinance for Milk and Milk Products Concerning Compositional Standards, etc.\*, taking into account products currently requiring a certificate in terms of animal health (e.g. milk, cream, butter milk, whey, butter, cheese).

\* Milk (cow’s milk, special milk, pasteurized goat’s milk, composition modified milk, low fat milk, skimmed milk and processed milk)

Milk products (cream, butter, butter oil, cheese, concentrated whey, ice cream products, concentrated milk, concentrated skimmed milk, evaporated milk, evaporated skimmed milk, sweetened condensed milk, sweetened condensed skimmed milk, whole milk powder, skimmed milk powder, cream powder, whey powder, protein concentrated whey powder, buttermilk powder, sweetened milk powder, formulated milk powder, fermented milk, fermented milk drink (only containing min.

3.0% of milk solids-not-fat) and milk drink)

Entries of health certificate for milk and milk products (Regulated by the ministerial order)

## →Take into account the entries currently required for meat etc. and for milk and milk products in terms of animal health.

＜Entries in certificates (under consideration)＞

１．Types of milk or milk products and animal species of dairy ingredient\*1\*2

２．Country of origin\*2

３．Quantity (No. of packages) and weight\*1\*2

４．Address and name of consignor (for a juridical person, its name and location) \*1\*2

５． Address and name of consignee (for a juridical person, its name and location) \*1\*2

６．Address and name of facilities where the products are manufactured\*1

７．The fact that raw milk is not derived from livestock with diseases, abnormity or dead (i.e. raw milk is from clinically healthy livestock) \*1\*2

８．The fact that production was carried out in a sanitary manner based on equal or better criteria than those of Japan\*1

９．Date when the production was carried out \*1\*2

\*1Items required in the certificate for meat etc.

\*2iItems required in the certificate for milk etc. in terms of animal health

Underline: requirements in addition to those on animal health.

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Ensuring safety of imported food

<Provisional Translation>

３．Obligation to attach sanitation certificates ②: Confirmation of the situation etc. of hygiene control at the places of production （2. of Article 11, Revision of the Food Sanitation Act, 13 June 2018）

For certain foods, request to conduct hygiene control and attach health certificates in order to confirm that inspection and control in the exporting country is appropriate and to ensure safety of imported food

* + Require health certificates for puffer fish and oysters for eating raw by the Ministerial Order (currently by a notification) for confirmation of the status of hygiene control at the places of production

Previous regulations Revision

* Requiring health certificates from the countries exporting oysters for eating raw

【**Oysters for eating raw** (notification)】

countries which are able to export oysters for eating raw to Japan

U.S.A, Canada, Australia, New Zealand, Ireland and South Korea

※ These countries are subject to taking hygiene control measures in the harvest waters equivalent to those in Japan.

Obligation to attach health certificate is legislated

to Japan by the Ministerial Order on Food Sanitation Act 《**The order will provide the targeted foods and entries in the certificate**》

[2. of Art. 11 of the Act] For food and food additives which require certification on the status of hygiene control at the places of production in terms of food sanitation and are designated by the Minister of Health, Labour and Welfare, anyone shall not import them for sale if a certificate or the copy issued by the competent authorities of the exporting country\* and certifying such status is not attached.

\* including local governments which have authorization to certify the status

【 Entries in certificates (under consideration) 】

1. Name and address of consignor and consignee
2. Name and address of processing facility
3. Waters where the product is harvested and the date
4. Quantity and weight
5. If purification is performed, name and address of the facility
6. The fact that production was processed in the facility authorized by the competent authority and the hygiene control is equivalent to those based on processing criteria in Japan, etc.

【**Puffer fish** (notification)】

* + Requiring health certificates for puffer fish exported to Japan by the Ministerial Order on Food Sanitation Act 《**The order will provide the targeted foods and**
* In importation, need to attach a health certificate Obligation to **entries in the certificate**》

issued by the exporting country’s competent attach health

authority certificate is

* For puffer fish exported to Japan, the harvest legislated

waters\*1 and the types of fish\*2 are limited.

\*1 limited to fish which are caught at the Japan Sea (East Sea),

the Bohai Sea, the Yellow Sea or the East China Sea

\*2 limited to *Takifugu rubripes*, *Takifugu porphyreus*, *Takifugu*

*pardalis*, *Lagocephalus wheeleri*, *Lagocephalus inermis* etc.

[Relevant Article of the Act] same as oysters for eating raw

【 Entries in certificates (under consideration) 】

1. Types of puffer fish (scientific name)
2. Name of sea
3. Name and address of consignor and consignee
4. Name and address of processing facility
5. Waters where the product is caught and the date
6. Quantity and weight, the status of storage
7. If processing is performed, the fact that production was processed properly and in a sanitary manner in the facility supervised by the competent authority, etc.

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