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| THIS REPORT CONTAINS ASSESSMENTS OF COMMODITY AND TRADE ISSUES MADE BY USDA STAFF AND NOT NECESSARILY STATEMENTS OF OFFICIAL U.S. GOVERNMENT POLICY |

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| Voluntary - | Public |

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|   **Date:** | 9/14/2018 |
|  **GAIN Report Number:** | JA8068 |

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| **Japan**

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| **Post:** | **Tokyo** |

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| **Japan 216th Food Safety Group** |
| **Report Categories:** |
| Sanitary/Phytosanitary/Food Safety |
| **Approved By:**  |
| Jess K. Paulson |
| **Prepared By:**  |
| Tomohiro Kurai |

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| **Report Highlights:** |
| On Thursday, September 13, 2018, Japan’s Ministry of Health, Labor and Welfare (MHLW) announced revisions to Japan’s Maximum Residue Levels (MRLs) for the following agricultural chemicals and veterinary drugs: Simeconazole, Tebufenpyrad, Triflumizole, Pyriofenone, Fluazifop-butyl, Fluensulfone, Metaflumizone and Thymol.  Further, MHLW proposes to designate Glucan extracted from brewing yeast as an exempted substance that does not require a MRL.  Lastly, MHLW proposes to approve Argon, Isobutylamine, Isopropylamine, sec-Butylamine, Propylamine, Hexylamine, Pentylamine, and 2-Methylbutylamineas as designated food additives.  The Embassy comment period for these proposals is open until Thursday, September 27, 2018.  MHLW will notify revisions with stricter standards to the World Trade Organization, which will provide another opportunity for interested parties to comment on these proposed changes. Keyword: JA8068 |

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| **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, September 27, 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 Simeconazole, Triflumizole, Pyriofenone, Fluensulfone, Metaflumizone and Thymol 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.

<Contact person>

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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：Simeconazole, Tebufenpyrad, Triflumizole, Pyriofenone, Fluazifop-butyl, Fluensulfone, Metaflumizone

Veterinary drugs：Thymol

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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

**Simeconazole (pesticide: fungicide)**: Permitted for use in Japan. The MHLW is going to establish MRL 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.

**Tebufenpyrad (pesticide: insecticide/miticide)**: Permitted for use in Japan. The MHLW is going to establish MRLs in some commodities in response to a request for setting MRLs by the MAFF with the intention to expand its use pattern and 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). The MHLW is also going to modify MRLs in some commodities that were provisionally set at the introduction of the Positive List System.

**Triflumizole (pesticide: fungicide)**: Permitted for use in Japan. The MHLW is going to establish MRLs in some commodities 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.

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

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

**Fluensulfone (pesticide: insecticide)**: 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). This action will not strengthen the current regulation for any commodities.

**Metaflumizone (pesticide: insecticide)**: Permitted for use in Japan. The MHLW is going to establish MRLs in some commodities 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.

**Thymol (veterinary drug: ectoparasiticide)**: Not permitted for use in Japan. The Minister of Agriculture, Forestry and Fisheries asked the minister of Health, Labour and Welfare for comments about application for manufacture and sales approval as a veterinary drug, and modification of the application of this substance, under the Act on Securing Quality, Efficacy and Safety of Pharmaceuticals, Medical Devices, Regenerative and Cellular Therapy Products, Gene Therapy Products, and Cosmetics. In response to this, the MHLW is going to establish MRLs in some commodities. This action will not strengthen the current regulation for any commodities.

Simeconazole

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Commodity** | **MRL****(draft) ppm** | **MRL****(current) ppm** | **Registration** | **Reference MRL** |
| Codex ppm | National ppm |
| Rice (brown rice) | ○ | 0.1 | 0.1 | § |  |  |  |
| Corn (maize, including pop corn and sweet corn) | ○ | 0.05 |  | Request |  |  |  |
| Soybeans, dry | ○ | 0.2 | 0.2 | § |  |  |  |
| Konjac | ○ | 0.1 | 0.1 | § |  |  |  |
| Cabbage | ○ | 0.05 | 0.05 | § |  |  |  |
| Burdock | ○ | 0.3 | 0.3 | § |  |  |  |
| Lettuce (including cos lettuce and leaf lettuce) | ○ | 0.7 | 0.7 | § |  |  |  |
| Welsh (including leek) | ○ | 0.2 | 0.2 | § |  |  |  |
| Garlic | ○ | 0.1 | 0.1 | § |  |  |  |
| Nira | ○ | 0.1 | 0.1 | § |  |  |  |
| Tomato | ○ | 0.2 | 0.2 | § |  |  |  |
| Other solanaceous vegetables | ○ | 2 | 2 |  |  | 2.0 | Korea |
| Cucumber (including gherkin) | ○ | 0.3 | 0.3 | § |  |  |  |
| Pumpkin (including squash) | ○ | 0.2 | 0.2 | § |  |  |  |
| Water melon | ○ | 0.1 | 0.1 | § |  |  |  |
| Melons | ○ | 0.1 | 0.1 | § |  |  |  |
| Spinach | ○ | 0.1 | 0.1 | § |  |  |  |
| Ginger | ○ | 0.3 | 0.3 | § |  |  |  |
| Unshu orange, pulp | ○ | 0.1 | 0.1 | § |  |  |  |
| Citrus natsudaidai, whole | ○ | 0.3 | 0.3 | § |  |  |  |
| Lemon | ○ | 0.3 | 0.3 | § |  |  |  |
| Orange (including navel orange) | ○ | 0.3 | 0.3 | § |  |  |  |
| Grapefruit | ○ | 0.3 | 0.3 | § |  |  |  |
| Lime | ○ | 0.3 | 0.3 | § |  |  |  |
| Other citrus fruits | ○ | 0.3 | 0.3 | § |  |  |  |
| Apple | ○ | 0.5 | 0.5 | § |  |  |  |
| Japanese pear | ○ | 0.5 | 0.5 | § |  |  |  |
| Pear | ○ | 0.5 | 0.5 | § |  |  |  |
| Peach | ○ | 0.7 | 0.7 | § |  |  |  |
| Nectarine | ○ | 0.5 | 0.5 | § |  |  |  |
| Apricot | ○ | 1 | 1 | § |  |  |  |
| Japanese plum (including prune) | ○ | 0.2 | 0.2 | § |  |  |  |
| Mume plum | ○ | 1 | 1 | § |  |  |  |
| Cherry | ○ | 3 | 3 | § |  |  |  |
| Strawberry | ○ | 3 | 3 | § |  |  |  |
| Grape | ○ | 0.2 | 0.2 | § |  |  |  |
| Japanese persimmon | ○ | 0.2 | 0.2 | § |  |  |  |
| Tea | ○ | 10 | 10 | § |  |  |  |
| Other spices | ○ | 0.3 | 0.3 | § |  |  |  |
| Other herbs | ○ | 30 | 30 | § |  |  |  |
| Fish | ○ | 0.02 | 0.02 |  |  |  |  |

The residue definition is simeconazole 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.

Tebufenpyrad

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Commodity** | **MRL****(draft) ppm** | **MRL****(current) ppm** | **Registration** | **Reference MRL** |
| Codex ppm | National ppm |
| Beans, dry | ○ | 0.2 | 0.2 | § |  |  |  |
| Peas | ● | 0.2 |  |  |  |  |
| Broad beans | ● | 0.2 |  |  |  |  |
| Peanuts, dry | ● | 0.2 |  |  |  |  |
| Other pulses | ● | 0.2 |  |  |  |  |
| Taro | ○ | 0.05 |  | Request |  |  |  |
| Tomato | ○ | 0.8 | 0.5 | IT |  | 0.8 | EU |
| Pimiento (sweet pepper) | ● | 0.5 |  |  |  |  |
| Egg plant | ○ | 0.5 | 0.5 | § |  |  |  |
| Other solanaceous vegetables | ● | 0.5 |  |  |  |  |
| Cucumber (including gherkin) | ○ | 0.5 | 0.5 | § |  | 0.5 | EU |
| Pumpkin (including squash) | ● | 0.5 |  |  |  |  |
| Oriental pickling melon (vegetable) | ● | 0.5 |  |  |  |  |
| Water melon | ● | 0.05 | 0.1 | § |  |  |  |
| Melons | ● | 0.05 | 0.1 | § |  |  |  |
| Makuwauri melon | ● | 0.1 |  |  |  |  |
| Other cucurbitaceous vegetables | ● | 0.5 |  |  |  |  |
| Other vegetables | ○ | 3 | 0.5 | IT |  | 5.0 | Korea |
| Unshu orange, pulp | ● | 0.05 | 0.1 | § |  |  |  |
| Citrus natsudaidai, whole | ● | 0.7 | 1 | § |  |  |  |
| Lemon | ○ | 1 | 1 | § |  |  |  |
| Orange (including navel orange) | ○ | 1 | 1 | § |  |  |  |
| Grapefruit | ○ | 1 | 1 | § |  |  |  |
| Lime | ○ | 1 | 1 | § |  |  |  |
| Other citrus fruits | ○ | 1 | 1 | § |  |  |  |
| Apple | ○ | 1 | 0.5 | §・Request |  |  |  |
| Japanese pear | ○ | 0.5 | 0.5 | § |  |  |  |
| Pear | ○ | 0.5 | 0.5 | § |  |  |  |
| Quince | ● | 0.1 |  |  |  |  |
| Loquat | ● | 0.1 |  |  |  |  |
| Peach | ● | 0.03 | 0.5 | §・IT |  |  |  |
| Nectarine | ● | 0.4 | 0.5 | IT |  | 0.4 | EU |
| Apricot | ● | 0.4 | 2 | IT |  | 0.4 | EU |
| Japanese plum (including prune) | ● | 0.2 | 2 |  |  | 0.2 | EU |
| Mume plum | ● | 2 |  |  |  |  |
| Cherry | ● | 1 | 2 | § |  |  |  |
| Strawberry | ○ | 1 | 1 | § |  |  |  |
| Raspberry | ● | 0.2 | 2 |  |  | 0.15 | EU |
| Blackberry | ● | 2 |  |  |  |  |
| Blueberry | ● | 2 |  |  |  |  |
| Cranberry | ● | 2 |  |  |  |  |
| Huckleberry | ● | 2 |  |  |  |  |
| Other berries | ○ | 2 | 2 |  |  | 1.5 | EU |
| Grape | ○ | 0.5 | 0.5 | § |  |  |  |
| Japanese persimmon | ● | 0.3 | 0.5 | § |  |  |  |
| Banana | ● | 0.5 |  |  |  |  |
| Kiwifruit | ● | 0.1 |  |  |  |  |
| Papaya | ○ | 0.5 | 0.5 | § |  |  |  |
| Avocado | ● | 0.5 |  |  |  |  |
| Pineapple | ● | 0.5 |  |  |  |  |
| Guava | ● | 0.5 |  |  |  |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Commodity** | **MRL****(draft) ppm** | **MRL****(current) ppm** | **Registration** | **Reference MRL** |
| Codex ppm | National ppm |
| Mango | ● | 0.2 | 0.5 | § |  |  |  |
| Passion fruit | ● | 0.5 |  |  |  |  |
| Date | ● | 2 |  |  |  |  |
| Other fruits | ● | 0.3 | 0.5 | § |  |  |  |
| Tea | ○ | 2 | 2 | § |  |  |  |
| Other spices | ○ | 5 | 1 | § |  |  |  |
| Other herbs | ● | 0.5 |  |  |  |  |

The residue definition is tebufenpyrad 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 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

Triflumizole

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Commodity** | **MRL****(draft) ppm** | **MRL****(current) ppm** | **Registration** | **Reference MRL** |
| Codex ppm | National ppm |
| Rice (brown rice) | ○ | 0.05 | 0.05 | § |  |  |  |
| Wheat | ○ | 0.7 | 0.7 | § |  |  |  |
| Barley | ○ | 0.7 | 0.7 | § |  |  |  |
| Rye | ○ | 0.7 | 0.7 | § |  |  |  |
| Corn (maize, including pop corn and sweet corn) | ○ | 0.5 | 0.5 | § |  |  |  |
| Other cereal grains | ○ | 0.7 | 0.7 | § |  |  |  |
| Konjac | ○ | 1 | 1 | § |  |  |  |
| Burdock | ○ | 0.3 | 0.3 | § |  |  |  |
| Other composite vegetables | ○ | 0.5 | 0.5 | § |  |  |  |
| Onion | ○ | 0.2 | 0.2 | § |  |  |  |
| Welsh (including leek) | ○ | 0.5 | 0.5 | § |  |  |  |
| Garlic | ○ | 0.3 | 0.3 | § |  |  |  |
| Nira | ○ | 3 | 3 | § |  |  |  |
| Asparagus | ○ | 0.5 | 0.5 | § |  |  |  |
| Other liliaceous vegetables | ○ | 2 | 2 | § |  |  |  |
| Carrot | ○ | 0.5 | 0.5 | § |  |  |  |
| Parsley | ○ | 1 | 1 | § |  |  |  |
| Celery | ○ | 15 | 15 | § |  |  |  |
| Tomato | ○ | 2 | 2 | § |  |  |  |
| Pimiento (sweet pepper) | ○ | 3 | 3 | § |  |  |  |
| Egg plant | ○ | 1 | 1 | § |  |  |  |
| Other solanaceous vegetables | ○ | 1 | 1 | § |  |  |  |
| Cucumber (including gherkin) | ○ | 0.7 | 0.7 | § | 0.5 |  |  |
| Pumpkin (including squash) | ○ | 0.5 | 0.5 | § |  |  |  |
| Oriental pickling melon (vegetable) | ○ | 0.3 | 0.3 | § |  |  |  |
| Water melon | ○ | 0.2 | 0.2 | § |  |  |  |
| Melons | ○ | 0.3 | 0.3 | § |  |  |  |
| Other cucurbitaceous vegetables | ○ | 1 | 1 | § |  |  |  |
| Okra | ○ | 0.5 | 0.5 | § |  |  |  |
| Ginger | ○ | 0.5 | 0.5 | § |  |  |  |
| Peas, immature (with pods) | ○ | 5 | 5 | § |  |  |  |
| Apple | ○ | 0.7 | 0.7 | § |  |  |  |
| Japanese pear | ○ | 1 | 1 | § |  |  |  |
| Pear | ○ | 1 | 1 | § |  |  |  |
| Quince | ○ | 2 | 2 | § |  |  |  |
| Peach | ○ | 0.7 | 0.7 | § |  |  |  |
| Japanese plum (including prune) | ○ | 1 | 1 | § |  |  |  |
| Mume plum | ○ | 1 | 1 | § |  |  |  |
| Cherry ※1 | ○ | 3 | 3 | § | 4 |  |  |
| Strawberry | ○ | 1 | 1 | § |  |  |  |
| Grape ※1 | ○ | 2 | 2 | § | 3 |  |  |
| Japanese persimmon | ○ | 1 | 1 | § |  |  |  |
| Papaya ※1 | ○ | 1 | 1 |  | 2 |  |  |
| Pineapple ※2 | ○ | 2 | 2 |  |  |  |  |
| Mango | ○ | 0.7 | 0.7 | § |  |  |  |
| Other fruits | ○ | 1 | 0.7 | §・Request |  |  |  |
| Tea | ○ | 15 | 15 | § |  |  |  |
| Hop ※3 | ○ | 8 | 8 |  | 30 | 50 | USA |
| Other herbs | ○ | 0.5 | 0.5 | § |  |  |  |
| Cattle, muscle | ○ | 0.03 | 0.03 |  | 0.03 |  |  |
| Pig, muscle | ○ | 0.03 | 0.03 |  | 0.03 |  |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Commodity** | **MRL****(draft) ppm** | **MRL****(current) ppm** | **Registration** | **Reference MRL** |
| Codex ppm | National ppm |
| Other terrestrial mammals, muscle | ○ | 0.03 | 0.03 |  | 0.03 |  |  |
| Cattle, fat | ○ | 0.03 | 0.03 |  |  |  |  |
| Pig, fat | ○ | 0.03 | 0.03 |  |  |  |  |
| Other terrestrial mammals, fat | ○ | 0.03 | 0.03 |  |  |  |  |
| Cattle, liver | ○ | 0.1 | 0.1 |  | 0.1 |  |  |
| Pig, liver | ○ | 0.1 | 0.1 |  | 0.1 |  |  |
| Other terrestrial mammals, liver | ○ | 0.1 | 0.1 |  | 0.1 |  |  |
| Cattle, kidney | ○ | 0.1 | 0.1 |  | 0.1 |  |  |
| Pig, kidney | ○ | 0.1 | 0.1 |  | 0.1 |  |  |
| Other terrestrial mammals, kidney | ○ | 0.1 | 0.1 |  | 0.1 |  |  |
| Cattle, edible offal | ○ | 0.1 | 0.1 |  | 0.1 |  |  |
| Pig, edible offal | ○ | 0.1 | 0.1 |  | 0.1 |  |  |
| Other terrestrial mammals, edible offal | ○ | 0.1 | 0.1 |  | 0.1 |  |  |
| Milk | ○ | 0.02 | 0.02 |  | 0.02 |  |  |
| Chicken, muscle | ○ | 0.02 |  | Request |  |  |  |
| Other poultry, muscle | ○ | 0.02 |  | Request |  |  |  |
| Chicken, fat | ○ | 0.02 |  | Request |  |  |  |
| Other poultry, fat | ○ | 0.02 |  | Request |  |  |  |
| Chicken, liver | ○ | 0.05 |  | Request |  |  |  |
| Other poultry, liver | ○ | 0.05 |  | Request |  |  |  |
| Chicken, kidney | ○ | 0.05 |  | Request |  |  |  |
| Other poultry, kidney | ○ | 0.05 |  | Request |  |  |  |
| Chicken, edible offal | ○ | 0.05 |  | Request |  |  |  |
| Other poultry, edible offal | ○ | 0.05 |  | Request |  |  |  |
| Chicken eggs | ○ | 0.02 |  | Request |  |  |  |
| Other poultry, eggs | ○ | 0.02 |  | Request |  |  |  |
| Fish | ○ | 0.3 | 0.3 |  |  |  |  |

The residue definition for agricultural products is sum of triflumizole and metabolite FM-6-1 【 (*E* )-4-Chloro-*α,α,α* -Trifluoro- *N* -(1-amino-2-propoxyethylidene)-*o* -toluidine】, expressed as triflumizole. For animal products, the residue definition is sum of triflumizole and metabolites converted to FA-1-1【4-Chloro-*α,α,α* -Trifluoro-*o* -toluidine】in basic condition, expressed as triflumizole. For aquatic products, triflumizole 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.

※1 The MRLs for cherries, papayas, and grapes are based on the Codex MRLs. Japan’s MRLs are derived by multiplying the Codex MRLs by the corresponding factors (0.66 for cherries and papayas, 0.72 for grapes) which are caluculated based on the plant metabolism studies because different residue definitions are used between Japan and Codex（The residue definition is residues analysed as FA-1-1 and expressed as parent triflumizole in Codex）.

※2 The MRL for pineapple maintaine the formal MRL set in before the positive list sysytem because there was detected record.

※3 The MRL for hop is set based on the residue data from the supervised residue trials in which analysed residue definition in Japan.

Pyriofenone

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Commodity** | **MRL****(draft) ppm** | **MRL****(current) ppm** | **Registration** | **Reference MRL** |
| Codex ppm | National ppm |
| Wheat | ○ | 1 | 1 | § |  |  |  |
| Tomato | ○ | 1 |  | Request |  |  |  |
| Pimiento (sweet pepper) | ○ | 1 | 1 | § |  |  |  |
| Egg plant | ○ | 1 | 1 | § |  |  |  |
| Cucumber (including gherkin) | ○ | 1 | 1 | § |  |  |  |
| Pumpkin (including squash) | ○ | 0.7 | 0.7 | § |  |  |  |
| Water melon | ○ | 0.05 | 0.05 | § |  |  |  |
| Melons | ○ | 0.2 | 0.2 | § |  |  |  |
| Other cucurbitaceous vegetables | ○ | 0.3 |  | IT |  | 0.30 | USA |
| Peas, immature (with pods) | ○ | 2 |  | Request |  |  |  |
| Apple | ○ | 1 | 1 | § |  |  |  |
| Japanese pear | ○ | 1 | 1 | § |  |  |  |
| Strawberry | ○ | 2 | 2 | § |  |  |  |
| Raspberry | ○ | 0.9 |  | IT |  | 0.90 | USA |
| Blackberry | ○ | 0.9 |  | IT |  | 0.90 | USA |
| Blueberry | ○ | 2 |  | IT |  | 1.5 | USA |
| Huckleberry | ○ | 2 |  | IT |  | 1.5 | USA |
| Other berries | ○ | 2 |  | IT |  | 1.5 | USA |
| Grape | ○ | 3 | 3 | § |  |  |  |
| Japanese persimmon | ○ | 0.7 |  | Request |  |  |  |
| Guava | ○ | 2 |  | IT |  | 1.5 | USA |
| Passion fruit | ○ | 2 |  | IT |  | 1.5 | USA |
| Other fruits | ○ | 2 |  | IT |  | 1.5 | USA |

The residue definition is pyriofenone 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. IT：Import tolerance

Fluazifop-butyl

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Commodity** | **MRL****(draft) ppm** | **MRL****(current) ppm** | **Registration** | **Reference MRL※1** |
| Codex ppm | National ppm |
| Soybeans, dry ※2 | ○ | 3 | 3 | § | 15 | 2.5 | USA |
| Beans, dry ※3 | ○ | 47 | 5 | § | 40 |  |  |
| Peas ※3 | ○ | 4 | 0.2 |  | 3 |  |  |
| Broad beans | ○ | 0.2 | 0.2 |  |  | 0.15 | Canada |
| Peanuts, dry | ○ | 2 | 2 |  |  | 1.5 | USA |
| Other pulses ※3 | ○ | 47 | 0.1 |  | 40 |  |  |
| Potato ※3 | ○ | 0.7 | 0.1 | § | 0.6 |  |  |
| Sweet potato | ○ | 0.05 | 0.05 | § |  |  |  |
| Yam | ○ | 0.05 | 0.05 | § |  |  |  |
| Sugar beet ※3 | ○ | 0.6 | 0.2 | § | 0.5 |  |  |
| Sugarcane ※4 |  |  |  | 0.01 |  |  |
| Japanese radish, roots (including radish) | ○ | 0.2 | 0.2 | § |  |  |  |
| Japanese radish, leaves (including radish) | ○ | 0.2 | 0.2 | § |  |  |  |
| Turnip, roots (including rutabaga) ※3 | ○ | 5 |  |  | 4 |  |  |
| Cabbage ※3 | ○ | 4 | 2 | § | 3 |  |  |
| Broccoli | ○ | 1 | 1 | § |  |  |  |
| Lettuce (including cos lettuce and leaf lettuce) ※4 |  |  |  | 0.01 |  |  |
| Onion ※2 | ○ | 0.3 | 0.3 | § | 0.3 |  |  |
| Garlic ※2 | ○ | 0.3 | 0.3 | § | 0.3 |  |  |
| Asparagus | ○ | 3 | 3 | § |  | 3.0 | USA |
| Carrot | ○ | 1 | 1 | § | 0.6 |  |  |
| Other umbelliferous vegetables ※3 | ○ | 0.5 |  |  | 0.4 |  |  |
| Tomato ※3 | ○ | 0.5 | 0.05 | § | 0.4 |  |  |
| Egg plant ※3 | ○ | 0.5 |  |  | 0.4 |  |  |
| Peas, immature (with pods) ※3 | ○ | 2 |  |  | 2 |  |  |
| Kidney beans, immature (with pods) ※3 | ○ | 7 |  |  | 6 |  |  |
| Green soybeans | ○ | 2 | 0.1 | §・Request |  |  |  |
| Unshu orange, pulp | ○ | 0.05 | 0.05 | § |  |  |  |
| Citrus natsudaidai, whole | ○ | 0.05 | 0.05 | § | 0.01 |  |  |
| Lemon | ○ | 0.05 | 0.05 | § | 0.01 |  |  |
| Orange (including navel orange) | ○ | 0.05 | 0.05 | § | 0.01 |  |  |
| Grapefruit | ○ | 0.05 | 0.05 | § | 0.01 |  |  |
| Lime | ○ | 0.05 | 0.05 | § | 0.01 |  |  |
| Other citrus fruits | ○ | 0.05 | 0.05 | § | 0.01 |  |  |
| Apple ※4 |  |  |  | 0.01 |  |  |
| Japanese pear ※3 | ● | 0.01 | 0.05 |  | 0.01 |  |  |
| Pear ※3 | ● | 0.01 | 0.05 |  | 0.01 |  |  |
| Quince ※4 |  |  |  | 0.01 |  |  |
| Nectarine ※4 |  |  |  | 0.01 |  |  |
| Apricot ※4 |  |  |  | 0.01 |  |  |
| Japanese plum (including prune) ※4 |  |  |  | 0.01 |  |  |
| Cherry ※4 |  |  |  | 0.01 |  |  |
| Strawberry ※3 | ○ | 0.4 |  |  | 0.3 |  |  |
| Other berries ※4 |  |  |  | 0.01 |  |  |
| Grape ※4 |  |  |  | 0.01 |  |  |
| Banana | ○ | 0.1 | 0.1 |  | 0.01 |  |  |
| Pineapple | ○ | 0.05 | 0.05 |  |  |  |  |
| Other Fruits ※4 |  |  |  | 0.01 |  |  |
| Sunflower seeds ※3 | ○ | 8 |  |  | 7 |  |  |
| Cotton seeds ※3 | ○ | 0.8 |  |  | 0.7 |  |  |
| Pecan ※4 |  |  |  | 0.01 |  |  |
| Almond ※4 |  |  |  | 0.01 |  |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Commodity** | **MRL****(draft) ppm** | **MRL****(current) ppm** | **Registration** | **Reference MRL** |
| Codex ppm | National ppm |
| Walnut ※4 |  |  |  | 0.01 |  |  |
| Other nuts ※4 |  |  |  | 0.01 |  |  |
| Coffee beans ※3 | ● | 0.01 | 0.1 |  | 0.01 |  |  |
| Other spices | ○ | 0.3 | 0.3 | § |  | 0.3 | Canada |
| Other herbs ※3 | ○ | 0.4 |  |  | 0.3 |  |  |
| Cattle, muscle | ○ | 0.04 | 0.03 |  |  |  |  |
| Pig, muscle | ○ | 0.04 | 0.03 |  |  |  |  |
| Other terrestrial mammals, muscle | ○ | 0.04 | 0.03 |  |  |  |  |
| Cattle, fat ※3 | ○ | 0.1 | 0.03 |  | 0.09 |  |  |
| Pig, fat ※3 | ○ | 0.1 | 0.03 |  | 0.09 |  |  |
| Other terrestrial mammals, fat ※3 | ○ | 0.1 | 0.03 |  | 0.09 |  |  |
| Cattle, liver ※3 | ○ | 0.2 | 0.03 |  | 0.2 |  |  |
| Pig, liver ※3 | ○ | 0.2 | 0.03 |  | 0.2 |  |  |
| Other terrestrial mammals, liver ※3 | ○ | 0.2 | 0.03 |  | 0.2 |  |  |
| Cattle, kidney ※3 | ○ | 0.2 | 0.03 |  | 0.2 |  |  |
| Pig, kidney ※3 | ○ | 0.2 | 0.03 |  | 0.2 |  |  |
| Other terrestrial mammals, kidney ※3 | ○ | 0.2 | 0.03 |  | 0.2 |  |  |
| Cattle, edible offal ※3 | ○ | 0.2 | 0.03 |  | 0.2 |  |  |
| Pig, edible offal ※3 | ○ | 0.2 | 0.03 |  | 0.2 |  |  |
| Other terrestrial mammals, edible offal ※3 | ○ | 0.2 | 0.03 |  | 0.2 |  |  |
| Milk ※5 | ○ | 0.03 | 0.03 |  | 0.2 |  |  |
| Chicken, muscle ※3 | ○ | 0.04 | 0.02 |  | 0.03 |  |  |
| Other poultry, muscle ※3 | ○ | 0.04 | 0.02 |  | 0.03 |  |  |
| Chicken, fat ※3 | ○ | 0.04 | 0.02 |  | 0.03 |  |  |
| Other poultry, fat ※3 | ○ | 0.04 | 0.02 |  | 0.03 |  |  |
| Chicken, liver ※3 | ○ | 0.1 | 0.04 |  | 0.09 |  |  |
| Other poultry, liver ※3 | ○ | 0.1 | 0.04 |  | 0.09 |  |  |
| Chicken, kidney ※3 | ○ | 0.1 | 0.04 |  | 0.09 |  |  |
| Other poultry, kidney ※3 | ○ | 0.1 | 0.04 |  | 0.09 |  |  |
| Chicken, edible offal ※3 | ○ | 0.1 | 0.04 |  | 0.09 |  |  |
| Other poultry, edible offal ※3 | ○ | 0.1 | 0.04 |  | 0.09 |  |  |
| Chicken eggs ※3 | ● | 0.04 | 0.05 |  | 0.03 |  |  |
| Other poultry, eggs ※3 | ● | 0.04 | 0.05 |  | 0.03 |  |  |

The residue definition is sum of fluazifop-butyl and metabolite D【2-[4-(5-trifluoromethyl-2-pyridyloxy)phenoxy]propionic

acid】(including metabolites that can be hydrolyzed to metabolite D), expressed as fluazifop-butyl. Fluazifop-butyl includes fluazifop-P-butyl and metabolite D includes metabolite E【(R)-2-[4-(5-trifluoromethyl-2-pyridyloxy)phenoxy]propionic acid】(including metabolites that can be hydrolyzed to metabolite E).

* 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.

※1 Reference MRLs are expressed as metabolite D or metabolite E.

※2 For soybeans, dry, onion and garlic in which Codex has set MRLs, the dietary exposure of fluazifop-butyl estimated by using the STMR of the supervised residue trials submitted to the JMPR and national food consumption data of these commodities would exceed an ADI of 0.0024 mg/kg bw/day which was set by the Food Safety Commission of Japan.

Therefore, the MHLW has decided to set the MRLs for these commodities based on the residue data from the USA or domestic supervised residue trials.

※3 Regarding food citing Codex MRL, MRL is set by multiplying Codex MRL by a conversion factor of 1.17 in order to take into account differences in residue definition.

※4 For sugarcane, lettuce (including cos lettuce and leaf lettuce), apple, quince, nectarine, apricot, japanese plum (including prune), cherry, other berries, grape, other fruits pecan, almond, walnut and other nuts in which Codex has set MRLs, the dietary exposure of fluazifop-butyl estimated by using the STMR of the supervised residue trials submitted to the JMPR and national food consumption data of these commodities would exceed an ADI of 0.0024 mg/kg bw/day which was set by the Food Safety Commission of Japan. Therefore, the MHLW has decided to maintain the current MRLs (i.e. the uniform limit of 0.01 ppm) in these commodities.

※5 For milk in which Codex has set MRL, the dietary exposure of fluazifop-butyl estimated by using the STMR of the supervised residue trials submitted to the JMPR and national food consumption data of milk would exceed an ADI of 0.0024 mg/kg bw/day which was set by the Food Safety Commission of Japan. Therefore, the MHLW has decided to set the MRL for milk based on the residue data estimated from the domestic maximum dietary burden (MDB).

Fluensulfone

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Commodity** | **MRL****(draft) ppm** | **MRL****(current) ppm** | **Registration** | **Reference MRL** |
| Codex ppm | National※ ppm |
| Potato | ○ | 0.8 |  | IT | 0.8 | 0.50 | USA |
| Taro | ○ | 3 |  | IT | 3 |  |  |
| Sweet potato | ○ | 5 | 3 | § | 3 |  |  |
| Yam | ○ | 3 |  | IT | 3 |  |  |
| Other potatoes | ○ | 3 |  | IT | 3 |  |  |
| Japanese radish, roots (including radish) | ○ | 4 | 3 |  | 4 |  |  |
| Japanese radish, leaves (including radish) | ○ | 50 | 30 |  | 50 |  |  |
| Turnip, roots (including rutabaga) | ○ | 4 | 3 |  | 4 |  |  |
| Turnip, leaves (including rutabaga) | ○ | 30 | 30 |  | 10 | 30 | USA |
| Horseradish | ○ | 4 | 3 |  | 4 |  |  |
| Watercress | ○ | 3 | 2 |  | 1 | 2.0 | USA |
| Chinese cabbage | ○ | 2 | 2 |  | 1 | 1.50 | USA |
| Cabbage | ○ | 2 | 2 |  | 1.5 | 1.50 | USA |
| Brussels sprouts | ○ | 2 | 2 |  | 1.5 | 1.50 | USA |
| Kale | ○ | 15 | 9 |  | 1 | 9.0 | USA |
| Komatsuna(Japanese mustard spinach) | ○ | 15 | 9 |  | 9 | 9.0 | USA |
| Kyona | ○ | 15 | 9 |  | 1 | 9.0 | USA |
| Qing-geng-cai | ○ | 15 | 9 |  | 1 | 9.0 | USA |
| Cauliflower | ○ | 2 | 2 |  | 1.5 | 1.50 | USA |
| Broccoli | ○ | 2 | 2 |  | 1.5 | 1.50 | USA |
| Other cruciferous vegetables | ○ | 15 | 9 |  | 1.5 | 9.0 | USA |
| Burdock | ○ | 3 | 3 |  | 3 | 3.0 | USA |
| Salsify | ○ | 3 | 3 |  | 3 | 3.0 | USA |
| Endive | ○ | 3 | 2 |  | 1 | 2.0 | USA |
| Shungiku | ○ | 3 | 2 |  | 1 | 2.0 | USA |
| Lettuce (including cos lettuce and leaf lettuce) | ○ | 3 | 2 |  | 2 | 2.0 | USA |
| Other composite vegetables | ○ | 30 | 30 |  | 30 | 30 | USA |
| Carrot | ○ | 4 | 3 |  | 4 |  |  |
| Parsnip | ○ | 4 | 3 |  | 4 |  |  |
| Parsley | ○ | 3 | 2 |  |  | 2.0 | USA |
| Celery | ○ | 3 | 2 |  | 2 | 2.0 | USA |
| Other umbelliferous vegetables | ○ | 30 | 30 |  | 4 | 30 | USA |
| Tomato | ○ | 1 | 0.7 | § | 0.7 |  |  |
| Pimiento (sweet pepper) | ○ | 0.7 | 0.5 | § | 0.7 |  |  |
| Egg plant | ○ | 0.7 | 0.3 | § | 0.7 |  |  |
| Other solanaceous vegetables | ○ | 0.7 | 0.5 |  | 0.7 |  |  |
| Cucumber (including gherkin) | ○ | 1 | 0.7 | § | 0.7 |  |  |
| Pumpkin (including squash) | ○ | 2 | 1 | § | 0.7 |  |  |
| Water melon | ○ | 0.2 | 0.1 | § |  |  |  |
| Melons | ○ | 2 | 1 | § |  |  |  |
| Other cucurbitaceous vegetables | ○ | 3 | 0.5 |  | 3 |  |  |
| Spinach | ○ | 4 | 2 |  | 4 |  |  |
| Okra | ○ | 0.7 | 0.5 |  | 0.7 |  |  |
| Ginger | ○ | 0.8 |  | IT |  | 0.50 | USA |
| Other vegetables | ○ | 30 | 30 |  | 4 | 30 | USA |
| Strawberry | ○ | 0.5 | 0.3 |  | 0.5 |  |  |
| Blueberry | ○ | 0.5 | 0.3 |  | 0.5 |  |  |
| Cranberry | ○ | 0.5 | 0.3 |  | 0.5 |  |  |
| Other berries | ○ | 0.5 | 0.3 |  | 0.5 |  |  |
| Other fruits | ○ | 0.7 | 0.5 |  | 0.7 |  |  |
| Other spices | ○ | 0.5 |  | IT | 0.5 |  |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Commodity** | **MRL****(draft) ppm** | **MRL****(current) ppm** | **Registration** | **Reference MRL** |
| Codex ppm | National ppm |
| Other herbs | ○ | 20 | 9 |  | 20 |  |  |
| Cattle, muscle | ○ | 0.01 |  |  | 0.01 |  |  |
| Pig, muscle | ○ | 0.01 |  |  | 0.01 |  |  |
| Other terrestrial mammals, muscle | ○ | 0.01 |  |  | 0.01 |  |  |
| Cattle, fat | ○ | 0.01 |  |  | 0.01 |  |  |
| Pig, fat | ○ | 0.01 |  |  | 0.01 |  |  |
| Other terrestrial mammals, fat | ○ | 0.01 |  |  | 0.01 |  |  |
| Cattle, liver | ○ | 0.01 |  |  | 0.01 |  |  |
| Pig, liver | ○ | 0.01 |  |  | 0.01 |  |  |
| Other terrestrial mammals, liver | ○ | 0.01 |  |  | 0.01 |  |  |
| Cattle, kidney | ○ | 0.01 |  |  | 0.01 |  |  |
| Pig, kidney | ○ | 0.01 |  |  | 0.01 |  |  |
| Other terrestrial mammals, kidney | ○ | 0.01 |  |  | 0.01 |  |  |
| Cattle, edible offal | ○ | 0.01 |  |  | 0.01 |  |  |
| Pig, edible offal | ○ | 0.01 |  |  | 0.01 |  |  |
| Other terrestrial mammals, edible offal | ○ | 0.01 |  |  | 0.01 |  |  |
| Milk | ○ | 0.01 |  |  | 0.01 |  |  |
| Chicken, muscle | ○ | 0.01 |  |  | 0.01 |  |  |
| Other poultry, muscle | ○ | 0.01 |  |  | 0.01 |  |  |
| Chicken, fat | ○ | 0.01 |  |  | 0.01 |  |  |
| Other poultry, fat | ○ | 0.01 |  |  | 0.01 |  |  |
| Chicken, liver | ○ | 0.01 |  |  | 0.01 |  |  |
| Other poultry, liver | ○ | 0.01 |  |  | 0.01 |  |  |
| Chicken, kidney | ○ | 0.01 |  |  | 0.01 |  |  |
| Other poultry, kidney | ○ | 0.01 |  |  | 0.01 |  |  |
| Chicken, edible offal | ○ | 0.01 |  |  | 0.01 |  |  |
| Other poultry, edible offal | ○ | 0.01 |  |  | 0.01 |  |  |
| Chicken eggs | ○ | 0.01 |  |  | 0.01 |  |  |
| Other poultry, eggs | ○ | 0.01 |  |  | 0.01 |  |  |

The residue definition for agricultural products is sum of fluensulfone and metabolite BSA【3,4,4-trifluorobut-3-ene-1- sulfonic acid 】 , expressed as fluensulfone. For animal products, fluensulfone only. The current residue definition is metabolite BSA【3,4,4-trifluorobut-3-ene-1-sulfonic acid】 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. (\* It should be noted that the residue definition will be changed.)

§：Permitted for use in Japan.

IT：Import tolerance

※ USA MRLs are expressed as metabolite BSA.

Metaflumizone

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Commodity** | **MRL****(draft) ppm** | **MRL****(current) ppm** | **Registration** | **Reference MRL** |
| Codex ppm | National ppm |
| Corn (maize, including pop corn and sweet corn) | ○ | 0.2 | 0.2 | § |  |  |  |
| Soybeans, dry | ○ | 0.5 | 0.5 | § |  |  |  |
| Potato | ○ | 0.02 | 0.02 |  | 0.02 |  |  |
| Taro | ○ | 0.2 | 0.2 | § |  |  |  |
| Sweet potato | ○ | 0.2 | 0.2 | § |  |  |  |
| Japanese radish, roots (including radish) | ○ | 0.5 | 0.5 | § |  |  |  |
| Japanese radish, leaves (including radish) | ○ | 30 | 30 | § |  |  |  |
| Turnip, roots (including rutabaga) | ○ | 0.5 |  | Request |  |  |  |
| Turnip, leaves (including rutabaga) | ○ | 30 |  | Request |  |  |  |
| Chinese cabbage | ○ | 10 | 10 | § | 6 |  |  |
| Cabbage | ○ | 5 | 5 | § |  |  |  |
| Brussels sprouts | ○ | 0.8 | 0.8 |  | 0.8 |  |  |
| Kale | ○ | 40 | 40 | § |  |  |  |
| Komatsuna (Japanese mustard spinach) | ○ | 40 | 40 | § |  |  |  |
| Kyona | ○ | 40 | 40 | § |  |  |  |
| Qing-geng-cai | ○ | 10 | 10 | § |  |  |  |
| Broccoli | ○ | 10 | 10 | § |  |  |  |
| Other cruciferous vegetables | ○ | 40 | 40 | § |  |  |  |
| Burdock | ○ | 0.2 | 0.2 | § |  |  |  |
| Lettuce (including cos lettuce and leaf lettuce) | ○ | 50 | 50 | § | 7 |  |  |
| Welsh (including leek) | ○ | 10 | 10 | § |  |  |  |
| Asparagus | ○ | 0.7 | 0.7 | § |  |  |  |
| Carrot | ○ | 0.3 | 0.3 | § |  |  |  |
| Tomato | ○ | 5 | 5 | § | 0.6 |  |  |
| Pimiento (sweet pepper) | ○ | 5 | 5 | § | 0.6 |  |  |
| Egg plant | ○ | 3 | 3 | § | 0.6 |  |  |
| Other solanaceous vegetables | ○ | 0.6 | 0.6 |  | 0.6 |  |  |
| Spinach | ○ | 70 | 70 | § |  |  |  |
| Ginger | ○ | 0.3 | 0.3 | § |  |  |  |
| Green soybeans | ○ | 10 | 10 | § |  |  |  |
| Unshu orange, pulp | ○ | 0.3 |  | Request |  |  |  |
| Citrus natsudaidai, whole | ○ | 5 |  | Request |  |  |  |
| Lemon | ○ | 5 |  | Request |  |  |  |
| Orange (including navel orange) | ○ | 5 |  | Request |  |  |  |
| Grapefruit | ○ | 5 |  | Request |  |  |  |
| Lime | ○ | 5 |  | Request |  |  |  |
| Other citrus fruits | ○ | 5 |  | Request |  |  |  |
| Mume plum | ○ | 10 | 10 | § |  |  |  |
| Strawberry | ○ | 0.2 | 0.2 | § |  |  |  |
| Kiwifruit | ○ | 0.3 |  | Request |  |  |  |
| Other spices | ○ | 25 |  | Request |  |  |  |
| Other herbs | ○ | 40 | 40 | § |  |  |  |
| Cattle, muscle | ○ | 0.02 | 0.02 |  | 0.02 |  |  |
| Pig, muscle | ○ | 0.02 | 0.02 |  | 0.02 |  |  |
| Other terrestrial mammals, muscle | ○ | 0.02 | 0.02 |  | 0.02 |  |  |
| Cattle, fat | ○ | 0.02 | 0.02 |  |  |  |  |
| Pig, fat | ○ | 0.02 | 0.02 |  |  |  |  |
| Other terrestrial mammals, fat | ○ | 0.02 | 0.02 |  |  |  |  |
| 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 |  |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Commodity** | **MRL****(draft) ppm** | **MRL****(current) ppm** | **Registration** | **Reference MRL** |
| Codex ppm | National ppm |
| 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 | ○ | 0.01 | 0.01 |  | 0.01 |  |  |
| Fish | ○ | 2 | 2 |  |  |  |  |
| Pepper,dried ※ |  |  |  | 6 |  |  |

The residue definition for agricultural products is sum of *E* and *Z* isomers of metaflumizone and metabolite D【p-[m-

(trifluoromethyl)phenacyl]benzonitrile】, expressed as metaflumizone. For animal and aquatic products, the residue definition is sum of *E* and *Z* isomers of metaflumizone.

* 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.

※ For food category “Pepper,dried”, MRL will not be set, and hereafter, MRL in its raw commodity (i.e. other solanaceous vegetables) will also apply to such processed commodity, taking into account its processing factor. For this substance, JMPR estimated processing factor of 10 for pepper,dried.

Thymol

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Commodity** | **MRL****(draft) ppm** | **MRL****(current) ppm** | **Registration** | **Reference MRL** |
| Codex ppm | National ppm |
| Honey | ○ 30 |  | Request |  |  |  |

The residue definition is thymol only.

* Not the uniform limit of 0.01 ppm but the regulation that foods shall not exceed physiological level contained in each commodity will be applied to the commodities for which current MRLs are to be deleted, since this substance is contained in agricultural commodities naturally.
* 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. Request：Request for setting/revising MRL was made by the MAFF.

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

“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. Designation of Substances Having No Potential to Cause Damage to Human Health (Exempt Substance)

The MHLW is going to designate the following agricultural and veterinary chemicals as substances having no potential to cause damage to human health, which is also referred to as “exempt substance,” based on the provision of Paragraph 3, Article 11 of the Food Sanitation Act:

Pesticide：Glucan extracted from brewing yeast

## Summary

**Glucan extracted from brewing yeast (pesticide: fungicide)**: Not permitted for use in Japan. The MHLW requested the Food Safety Commission of Japan (FSC) to conduct a risk assessment for this substance. The FSC concluded that glucan extracted from brewing yeast is not considered to have no potential to cause damage to human health from its residue in foods. Based on the assessment, the MHLW has decided to designate glucan extracted from brewing yeast as an exempt substance.

**Item 3. Designation of Food Additives**

**Summary**

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

1. Argon

In August 2, 2018, the Committee on Food Additives of the Pharmaceutical Affairs and Food Sanitation Council deliberated on Argon, and concluded that the Minister should designate Argon as a food additive that is unlikely to harm human health pursuant to Article 10 of the Act and should establish specifications and standards for the additive pursuant to Article 11 of the Act (See Attachment 3-1).

Situations in other countries and Japan:

The Codex Alimentarius Commission listed Argon in the inventory of processing aids as a packaging gas in 1991, and the Joint FAO/WHO Expert Committee on Food Additives (JECFA) established the specifications in 1999.

The United States has classified Argon as a GRAS (Generally Recognized as Safe) substance and has permitted to use it in fruit juice, vegetable juice, and wine. The European Union (EU) has permitted to use it in basically all food products.

The Scientific Committee on Food (SCF) also permitted to use Argon as a packaging gas and propellant, and concluded that there is no need to set acceptable daily intake for Argon in1990.

In Japan, Argon has not been designated as a food additive at the present.

1. Isobutylamine, Isopropylamine, *sec*-Butylamine, Propylamine, Hexylamine, Pentylamine and 2-Metylbutylamine

In August 2, 2018, the Committee on Food Additives of the Pharmaceutical Affairs and Food Sanitation Council deliberated on Isobutylamine, Isopropylamine, *sec*- Butylamine, Propylamine, Hexylamine, Pentylamine and 2-Metylbutylamine (hereinafter referred to as “the requested flavorings”), and concluded that the Minister should designate the requested flavorings as food additives that are unlikely to harm human health pursuant to Article 10 of the Act and should establish specifications and standards for the additives pursuant to Article 11 of the Act (See Attachment 3-2).

Situations in other countries and Japan:

JECFA and the European Food Safety Authority have evaluated some flavorings including the requested flavorings as a group of aliphatic and aromatic amines and amides. Among these amines, the Food Safety Commission of Japan (FSCJ) evaluated Isopentylamine in 2009 and Butylamine in 2010 on aliphatic primary amines; and Phenetylamine, Trimethylamine, Piperidine and Pyrrolidine in 2010 on the amines other than aliphatic primary ones. FSCJ has concluded that these amines are unlikely to harm human health when used as flavoring enhancers.

The EU, the United States, Australia, and New Zealand have permitted to use the requested flavorings as food additives, and have not established standards for use such as concentrations. In the United States, the requested flavorings are used in processed foods including baked goods, icings, snack foods, cheese, milk products, and dried fruit.

In Japan, the requested flavorings have not been permitted to use at the present.

**Additional Information**

Progress in the designation procedure of food additives (54 flavorings and 45 non- flavoring additives) that have been proven safe by JECFA (Joint FAO/WHO Expert Committee on Food Additives) and that are widely used in countries other than Japan.

As of September 13, 2018, all flavorings and 41 non-flavoring additives are designated. See Attachment 3-3 for the details.

(Attachment 3-1）

**Argon**

**Standards for use（draft）**

Not specified **Compositional Specifications（draft）**

**Argon**

アルゴン

Argon gas

Ar Mol. Wt. 39.95

Argon [7440-37-１]

**Definition** Argon is a substance produced using the air liquefaction separation method. **Content** Argon contains not less than 99.0% (vol) of argon (Ar).

**Description** Argon is a colorless gas having no odor.

**Identification**

* 1. When a burning wood chip with a flame is placed in a test tube containing Argon, the flame goes off.
	2. Introduce Argon into a 1-mL gas measuring tube for gas chromatography, and analyze it by gas chromatography using the operation conditions given in Purity (ii) below. The retention time of the main peak corresponds to that of the main peak obtained when the reagent argon is analyzed in the same manner.

**Purity** Oxygen and Nitrogen Not more than 1.0% (vol) as the total amount.

* + 1. Oxygen

Measure oxygen in Argon using a yellow phosphor luminescent oxygen analyzer and determine the amount (% (vol)). If the amount of oxygen obtained exceeds the measurement range of the meter, exactly dilute the sample gas with oxygen-free nitrogen, and determine the amount.

* + 1. Nitrogen

Introduce Argon into a 1-mL gas measuring tube for gas chromatography at constant flow rate of 50–150 mL/min, analyze it using the operating conditions below, and obtain the peak area (AT) of nitrogen. Separately, prepare a constant amount of a uniform gas mixture with the nitrogen concentration of about 0.5% (vol) by mixing a constant amount of nitrogen, measured exactly, with the carrier gas given below. Use this as the standard gas mixture. Introduce the standard gas mixture into a gas measuring tube with same amount at the same flow rate, proceed as directed for Argon, and obtain the peak area (AS) of nitrogen in the gas mixture. Determine the amount (% (vol)) of nitrogen in Argon by the formula:

Amount (% (vol)) of nitrogen (N2)= VS × T

A

VS : Amount (% (vol)) of nitrogen in the standard gas mixture

*Operating Conditions*

Detector: Thermal conductivity detector

Column: A stainless steel tube (about 3 mm internal diameter and about 3 m length) Column packing material: 180–250 μm zeolite for gas chromatography

Column temperature: A constant temperature of 50–150C Carrier gas: Hydrogen or helium

Flow rate: A constant rate of 20–40 mL/min Injection: Loop injection using a gas measuring tube

* + 1. Total amount

Determine the total amount of oxygen and nitrogen from the amount (% (vol)) of oxygen obtained in (i) and the amount (% (vol)) of nitrogen obtained in (ii) by the formula:

Total amount (% (vol)) of oxygen and nitrogen (% (vol))= VO + VN Vo ：Amount (% (vol)) of oxygen obtained in (i)

VN ：Amount (% (vol)) of nitrogen obtained in (ii)

**Water content** Not more than 0.05% (vol)

Measure using capacitance moisture meter and determine the amount (% (vol)) of the water content from the obtained value.

**Assay** Calculate the content of Argon from the total amount of oxygen and nitrogen, and water content obtained in Purity (iii) by the formula:

Content of argon (% (vol)) =100 − VO N − VW

VO N ：Total amount (% (vol)) of oxygen and nitrogen

VW : Amount (% (vol)) of water content

**Reagent and Test Solutions** Argon Ar [K1105, Second grade] [7440-37-1]

**Measurement instruments**

Yellow phosphor luminescent oxygen analyzer

Use a unit meeting with the performance of the yellow phosphor luminescent oxygen analyzer specified in Japanese Industrial Standards K1105.

Capacitance moisture meter

Use a unit meeting with the performance of the capacitance moisture meter specified in Japanese Industrial Standards K1105.

(Attachment 3-2)

# Isobutylamine

## Standard for use（draft）

Only for flavoring **Compositional Specifications（draft）**

**Isobutylamine**

イソブチルアミン

H3C

CH3

NH2

C4H11N Mol. Wt. 73.14

2-Methylpropan-1-amine [78-81-9]

**Content** Isobutylamine contains not less than 95.0% of isobutylamine (C4H11N).

**Description** Isobutylamine occurs as a colorless to yellow, clear liquid having a characteristic odor. **Identification** Determine the infrared absorption spectrum of Isobutylamine as directed in the

Liquid Film Method under Infrared Spectrophotometry, and compare it with the Reference Spectrum. Both spectra exhibit similar intensities of absorption at the same wavenumbers.

**Refractive Index** n2D O : 1.391–1.400

**Specific Gravity** d22 55 : 0.724–0.737

**Assay** Proceed as directed in the Peak Area Percentage Method in the Gas Chromatographic Assay of Flavoring Agents under the Flavoring Substances Tests. Use operating conditions (2) except for the column. Use a fused silica tube (0.25–0.53 mm in internal diameter and 30–60 m in length) coated with a 0.25–1 m thick layer of dimethylpolysiloxane for gas chromatography.

Reference Spectrum Isobutylamine

# Isopropylamine

## Standard for use（draft）

Only for flavoring **Compositional Specifications（draft）**

**Isopropylamine**

イソプロピルアミン

C3H9N Mol. Wt. 59.11

Propan-2-amine [75-31-0]

**Content** Isopropylamine contains not less than 95.0% of isopropylamine (C3H9N).

**Description** Isopropylamine occurs as a colorless to yellow, clear liquid having a characteristic odor. **Identification** Determine the infrared absorption spectrum of Isopropylamine as directed in the Liquid Film Method under Infrared Spectrophotometry, and compare it with the Reference

Spectrum. Both spectra exhibit similar intensities of absorption at the same wavenumbers.

**Refractive index** n2D O : 1.367–1.378 **Specific Gravity** d22 55 : 0.681–0.693

**Assay** Proceed as directed in the Peak Area Percentage Method in the Gas Chromatographic Assay of Flavoring Agents under the Flavoring Substances Tests. Use operating conditions (2) except for the column. Use a fused silica tube (0.25–0.53 mm in internal diameter and 30–60 m in length) coated with a 0.25–1 m thick layer of dimethylpolysiloxane for gas chromatography.

Reference Spectrum

Isopropylamine

## Standard for use（draft）

***sec-*Butylamine**

Only for flavoring **Compositional Specifications（draft）**

***sec-*Butylamine** *sec*-ブチルアミン

C4H11N Mol. Wt. 73.14

Butan-2-amine [13952-84-6]

**Content** *sec*-Butylamine contains not less than 95.0% of *sec*-butylamine (C4H11N).

**Description** *sec*-Butylamine occurs as a colorless to yellow, clear liquid having a characteristic odor. **Identification** Determine the infrared absorption spectrum of *sec*-Butylamine as directed in the Liquid Film Method under Infrared Spectrophotometry, and compare it with the Reference Spectrum. Both spectra exhibit similar intensities of absorption at the same wavenumbers.

**Refractive Index** n2D O : 1.387–1.396

**Specific Gravity** d22 55 : 0.715–0.724

**Assay** Proceed as directed in the Peak Area Percentage Method in the Gas Chromatographic Assay of Flavoring Agents under the Flavoring Substances Tests. Use operating conditions (2) except for the column. Use a fused silica tube (0.25–0.53 mm in internal diameter and 30–60 m in length) coated with a 0.25–1 m thick layer of dimethylpolysiloxane for gas chromatography.

Reference Spectrum

*sec-*Butylamine

## Standard for use（draft）

**Propylamine**

Only for flavoring **Compositional Specifications（draft）**

**Propylamine**

プロピルアミン

C3H9N Mol. Wt. 59.11

Propan-1-amine [107-10-8]

**Content** Propylamine contains not less than 95.0% of propylaminje (C3H9N).

**Description** Propylamine occurs as a colorless to yellow, clear liquid having a characteristic odor. **Identification** Determine the infrared absorption spectrum of Propylamine as directed in the Liquid

Film Method under Infrared Spectrophotometry, and compare it with the Reference Spectrum. Both spectra exhibit similar intensities of absorption at the same wavenumbers.

**Refractive Index** n2D O : 1.384–1.392

**Specific Gravity** d22 55 : 0.710–0.720

**Assay** Proceed as directed in the Peak Area Percentage Method in the Gas Chromatographic Assay of Flavoring Agents under the Flavoring Substances Tests. Use operating conditions (2) except for the column. Use a fused silica tube (0.25–0.53 mm in internal diameter and 30–60 m in length) coated with a 0.25–1 m thick layer of dimethylpolysiloxane for gas chromatography.

Reference Spectrum Propylamine

## Standard for use（draft）

**Hexylamine**

Only for flavoring **Compositional Specifications（draft）**

**Hexylamine**

ヘキシルアミン

C6H15N Mol. Wt. 101.19

Hexan-1-amine [111-26-2]

**Content** Hexylamine contains not less than 95.0% of hexylamine (C6H15N).

**Description** Hexylamine occurs as a colorless to yellow, clear liquid having a characteristic odor. **Identification** Determine the infrared absorption spectrum of Hexylamine as directed in the Liquid

Film Method under Infrared Spectrophotometry, and compare it with the Reference Spectrum. Both spectra exhibit similar intensities of absorption at the same wavenumbers.

**Refractive Index** n2D O :1.415–1.421

**Specific Gravity** d22 55 : 0.761–0.767

**Assay** Proceed as directed in the Peak Area Percentage Method in the Gas Chromatographic Assay of Flavoring Agents under the Flavoring Substances Tests. Use operating conditions (2) except for the column. Use a fused silica tube (0.25–0.53 mm in internal diameter and 30–60 m in length) coated with a 0.25–1 m thick layer of dimethylpolysiloxane for gas chromatography.

Reference Spectrum Hexylamine

## Standard for use（draft）

**Pentylamine**

Only for flavoring **Compositional Specifications（draft）**

**Pentylamine**

ペンチルアミン

C5H13N Mol. Wt. 87.16

Pentan-1-amine [110-58-7]

**Content** Pentylamine contains not less than 95.0% of pentylamine (C5H13N).

**Description** Pentylamine occurs as a colorless to yellow, clear liquid having a characteristic odor. **Identification** Determine the infrared absorption spectrum of Pentylamine as directed in the Liquid

Film Method under Infrared Spectrophotometry, and compare it with the Reference Spectrum. Both spectra exhibit similar intensities of absorption at the same wavenumbers.

**Refractive Index** n2D O : 1.408–1.424

**Specific Gravity** d22 55 : 0.750–0.759

**Assay** Proceed as directed in the Peak Area Percentage Method in the Gas Chromatographic Assay of Flavoring Agents under the Flavoring Substances Tests. Use operating conditions (2) except for the column. Use a fused silica tube (0.25–0.53 mm in internal diameter and 30–60 m in length) coated with a 0.25–1 m thick layer of dimethylpolysiloxane for gas chromatography.

Reference Spectrum Pentylamine

## Standard for use（draft）

**２-Methylbutylamine**

Only for flavoring **Compositional Specifications（draft）**

**2-Methylbutylamine** 2-メチルブチルアミン

C5H13N Mol. Wt. 87.16

2-Methylbutan-1-amine [96-15-1]

**Content** 2-Methylbutylamine contains not less than 95.0% of 2-methylbutylamine (C5H13N).

**Description** 2-Methylbutylamine occurs as a colorless to yellow, clear liquid having a characteristic odor.

**Identification** Determine the infrared absorption spectrum of 2-Methylbutylamine as directed in the Liquid Film Method under Infrared Spectrophotometry, and compare it with the Reference Spectrum. Both spectra exhibit similar intensities of absorption at the same wavenumbers.

**Refractive Index** n2D O : 1.408–1.423

**Specific Gravity** d22 55 : 0.752–0.779

**Assay** Proceed as directed in the Peak Area Percentage Method in the Gas Chromatographic Assay of Flavoring Agents under the Flavoring Substances Tests. Use operating conditions (2) except for the column. Use a fused silica tube (0.25–0.53 mm in internal diameter and 30–60 m in length) coated with a 0.25–1 m thick layer of dimethylpolysiloxane for gas chromatography.

Reference Spectrum

2-Methylbutylamine

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

13 September, 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 |

|  |  |  |  |
| --- | --- | --- | --- |
| **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