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## Japan

**Post:** Tokyo

### **Japan Proposes New MRLs for Formetanate Hydrochloride and a New Additive (3-Ethylpyridine)**

**Report Categories:**

Sanitary/Phytosanitary/Food Safety

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**Report Highlights:**

On January 28, 2013, the Government of Japan (GOJ) announced changes to the Maximum Residue Levels (MRLs) for formetanate hydrochloride. The Ministry of Health, Labor and Welfare (MHLW) also proposed the approval of a new food additive, 3-Ethylpyridine. The Embassy comment period for these changes will close on February 12, 2013. After that, there will be a domestic public comment period and a WTO notification by MHLW. These will be other opportunities for interested parties to comment on this subject.

**General Information:**

On January 28, 2013, the Government of Japan (GOJ) announced changes to the Maximum Residue Levels (MRLs) for formetanate hydrochloride. The Ministry of Health, Labor and Welfare (MHLW) also proposed the approval of a new food additive, 3-Ethylpyridine. The Embassy comment period for these changes will close on February 12, 2013. After that, there will be a domestic public comment period and a WTO notification by MHLW. These will be other opportunities for interested parties to comment on this subject.

Any parties interested in submitting comments to MHLW should do so as soon as possible. In the case of MRL changes, if you are requesting that Japan adopt the same limits as the U.S. maximum residue limits, the request should be accompanied by data supporting U.S. MRLs, such as risk assessment and residue data. The information MHLW requires would include toxicity data for target chemicals, residue trial data that support the MRLs, and target food commodities. Please be advised that Limit of Quantitation (LOQ) and Limit of Detection (LOD) data cannot be used as reference data to set up Japanese MRLs. For Japan's MRLs and the details of the information MHLW needs, please visit the following MRLs websites:

Pesticides: <http://www.mhlw.go.jp/english/topics/foodsafety/residue/dl/01.pdf>

Feed additives: <http://www.mhlw.go.jp/english/topics/foodsafety/residue/dl/02.pdf>

Veterinary drugs: <http://www.mhlw.go.jp/english/topics/foodsafety/residue/dl/03.pdf>

MHLW will also notify these proposed changes to the WTO/SPS committee, which will provide an additional chance for interested parties to submit comments on this subject. The actual WTO/SPS notifications can be found at the site below.

[http://www.wto.org/english/tratop\\_e/sps\\_e/work\\_and\\_doc\\_e.htm](http://www.wto.org/english/tratop_e/sps_e/work_and_doc_e.htm)

After the WTO comment period closes, a final report will be released based on the conclusions reached by a session of the Pharmaceutical Affairs and Food Sanitation Council scheduled to be held at a later date. The Council's report will constitute the final decision.

Comments to the GOJ can be made either in Japanese or English and can be sent to the below points of contact:

Comments pertaining to changes in MRLs

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Comments pertaining to changes in food additives

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Post requests that the U.S. Embassy - Tokyo also be copied on any comments at [agtokyo@usda.gov](mailto:agtokyo@usda.gov) to allow them to be considered as part of the official U.S. Government comments to the WTO.

**Item 1. Establishment of Maximum Residue Limits for Agricultural Chemicals in Food**

The Ministry of Health, Labour and Welfare (MHLW) is going to develop compositional specifications for food.

**Summary**

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

On May 29, 2006, the MHLW introduced the positive list system for agricultural chemicals in food.\* Basically, all foods distributed in the Japanese marketplace are subject to regulation based on the system.

This time the MHLW has comprehensively reviewed the current MRLs for Formetanate hydrochloride. Details are given below.

*Note: The positive list system was established based on the 2003 amendment of the Food Sanitation Law. The system aims to prohibit the distribution of any food in the Japanese marketplace if it contains agricultural chemicals at amounts exceeding a certain level (0.01 ppm) specified under the Law.*

**Outline of revision**

Formetanate hydrochloride (**insecticide**): Not permitted for use in Japan.

The MHLW has reviewed the MRLs that had been provisionally established at the introduction of the positive list system.

## Formetanate hydrochloride

Commodity	MRL (draft) ppm	MRL (current) ppm
<i>Unshu</i> orange, pulp		4
Lemon	0.6	4
Orange (including navel orange)	2	4
Grapefruit	2	4
Lime	0.03	4
Other citrus fruits	0.03	4
Apple	0.5	3
Japanese pear	0.5	3
Pear	0.5	3
Peach		4
Apricot	0.4	4
Japanese plum (including prune)		0.5
Other spices		4

\* Shaded figures indicate provisional MRLs.

\* 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.

Notes:

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

“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, pimienta (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 shiitakemushroom.

“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 natsudaikai (pulp), citrus natsudaikai (peel), citrus natsudaikai (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.

“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 Food Additives**

Japan is going to designate 3-Ethylpyridine as an authorized additive.

Under Article 10 of the Food Sanitation Law, food additives shall not be used or marketed without authorization by the Minister of Health, Labour and Welfare. When compositional specifications or standards for use or manufacturing are established for food additives based on Article 11 of the law, those additives shall not be used or marketed unless they meet the standards or specifications.

In response to a request from the Minister, the Committee on Food Additives of the Food Sanitation Council that is established under the Pharmaceutical Affairs and Food Sanitation Council has discussed the adequacy of the designation of 3-Ethylpyridine (CAS No. 536-78-7).

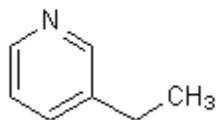
The committee has concluded that the Minister should designate 3-Ethylpyridine based on Article 10 of the Food Sanitation Law as a food additive unlikely to harm human health, and establish compositional specifications for the substance based on Article 11 of the law. (Attachment 2-1)

Note: 3-Ethylpyridine is widely used abroad as a flavoring agent. It is used in various processed foods including confectionaries like baked cakes, gelatin puddings, soft candies; frozen dairy products; meat products; non-alcoholic beverages to reproduce lost flavors and improve flavors.

### **Attachment 2-1**

#### **3-Ethylpyridine**

3-エチルピリジン



**Standard for use**

It shall not be used for purposes other than flavoring.

**Compositional specifications**

**Substance name** 3-Ethylpyridine

**Molecular formula** C<sub>7</sub>H<sub>9</sub>N

**Mol. Weight** 107.15

**Chemical name [CAS number]**

3-Ethylpyridine [536-78-7]

**Content** 3-Ethylpyridine contains not less than 98.0% of 3-Ethylpyridine (C<sub>7</sub>H<sub>9</sub>N).

**Description** 3-Ethylpyridine occurs as a colorless to brown liquid having a characteristic odor.

**Identification** Determine the infrared absorption spectrum of 3-Ethylpyridine as directed in the Liquid Film Method under Infrared Spectrophotometry, and compare with the Reference Spectrum. Both spectra exhibit absorptions having about the same intensity at the same wavenumbers.

**Purity**

(1) **Refractive index**  $n_D^{20}$  : 1.499–1.505.

(2) **Specific gravity**  $d_{44}^{20}$  : 0.937–0.943.

**Assay** Proceed as directed in the Peak Area Percentage Method in the Gas Chromatographic Assay under the Flavor Substance Tests. Use operating conditions (1).