

USDA Foreign Agricultural Service

GAIN Report

Global Agricultural Information Network

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

Voluntary Public

Date: 11/14/2012

GAIN Report Number: JA2029

Japan

Post: Tokyo

MHLW Proposes New MRLs for Norflurazon

Report Categories:

Sanitary/Phytosanitary/Food Safety

Approved By:

Jennifer Clever

Prepared By:

Suguru Sato

Report Highlights:

On November 13, 2012, the Government of Japan (GOJ) announced changes to the Maximum Residue Levels (MRLs) for norflurazon. The Embassy comment period for these changes will close on Tuesday, November 27, 2012. After that, there will be a domestic public comment period, and a WTO notification by the Ministry of Health, Labor, and Welfare (MHLW). These will be other opportunities for interested parties to comments on this subject.

On November 13, 2012, the Government of Japan (GOJ) briefed Embassies on proposed changes to the Maximum Residue Levels (MRLs) for norflurazon. The Embassy comment period for these changes will close on Tuesday, November 27, 2012. After that, there will be a domestic public comment period, and a WTO notification by the Ministry of Health, Labor, and Welfare (MHLW). These will be other opportunities for interested parties to comments 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

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 point of contacts:

Comments pertaining to changes in MRLs

Ryouhei SHIMIZU, Mr.

Standards and Evaluation Division,

Department of Food Safety,

Pharmaceutical and Food Safety Bureau,

Ministry of Health, Labour and Welfare

1-2-2, Chiyoda-ku, Kasumigaseki, Tokyo, 100-8916

Tel: 03-5253-1111, ext. 2487

Fax: 03-3501-4868

shimizu-ryouhei@mhlw.go.jp

Post requests that the U.S. Embassy - Tokyo also be copied on any comments at 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 newly established MRLs (draft) for some food commodities as well as has comprehensively reviewed the current MRLs. This activity is targeted to the herbicide Norflurazon. 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

Norflurazon (herbicide): 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. The new MRLs are based on data provided from the United States Government and related stakeholder.

Norflurazon

Commodity	MRL (draft) ppm	MRL (current) ppm
Soybeans, dry		0.1
Peanuts, dry	0.05	0.05
Asparagus	0.05	0.05
Green soybeans		0.1

Unshu orange, pulp		0.2
Citrus <i>natsudaïdai</i> , whole	0.2	0.2
Lemon	0.2	0.2
Orange (including navel orange)	0.2	0.2
Grapefruit	0.2	0.2
Lime	0.2	0.2
Other citrus fruits	0.2	0.2
Apple	0.1	0.2
Japanese pear	0.1	0.2
Pear	0.1	0.2
Quince		0.2
Loquat		0.2
Peach		0.2
Nectarine	0.1	0.2
Apricot	0.1	0.2
Japanese plum (including prune)	0.1	0.2
Mume plum		0.2
Cherry	0.1	0.2
Raspberry	0.2	0.2
Blackberry	0.1	0.1
Blueberry	0.2	0.2
Cranberry		0.1
Grape	0.1	0.1
Avocado	0.2	0.2
Other fruits		0.2
Cotton seeds		0.1
Ginkgo nut		0.2
Chestnut		0.2
Pecan		0.2
Almond	0.1	0.2
Walnut	0.1	0.2
Other nuts	0.1	0.2
Hop	3	3
Other spices	0.2	0.2
Cattle, muscle	0.1	0.1
Pig, muscle	0.1	0.1
Other terrestrial mammals, muscle	0.1	0.1
Cattle, fat	0.1	0.1
Pig, fat	0.1	0.1
Other terrestrial mammals, fat	0.1	0.1
Cattle, liver	0.5	0.3
Pig, liver	0.5	0.3
Other terrestrial mammals, liver	0.5	0.3
Cattle, kidney	0.1	0.1
Pig, kidney	0.1	0.1

Other terrestrial mammals, kidney	0.1	0.1
Cattle, edible offal ("Edible offal" refers to all edible parts, except muscle, fat, liver, and kidney)	0.1	0.1
Pig, edible offal	0.1	0.1
Other terrestrial mammals, edible offal	0.1	0.1
Milk	0.1	0.1
Chicken, muscle		0.1
Other poultry animals, muscle		0.1
Chicken, fat		0.1
Other poultry animals, fat		0.1
Chicken, liver		0.1
Other poultry animals, liver		0.1
Chicken, kidney		0.1
Other poultry animals, kidney		0.1
Chicken, edible offal		0.1
Other poultry animals, edible offal		0.1

Note: The MRLs are expressed as the sum of norflurazon and its metabolite 4-chloro-5-(amino)-2-alpha, alpha, alpha-trifluoro- m -tolyl)-3(2 H)-pyridazinone in or on the following raw agricultural commodities, calculated as norflurazon

* 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, 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.

12

“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.