Voluntary - Public

Date: 2009/11/18
GAIN Report Number: JA9073

Japan

Post: Tokyo

Pesticide and food safety regulation update

Report Categories:

Sanitary/Phytosanitary/Food Safety

Approved By:
Jeffrey Nawn
Prepared By:
Suguru Sato

Report Highlights:
On November 5, 2009, Government of Japan (GOJ) announced proposed changes to the MRLs for Oxadiazon, Dimethenamid, Tebufenozide, Pyributicarb and Metaldehyde, as well as maximum level for cadmium in rice. The requirement to established import tolerance (i.e. MRL) was also explained. The domestic comment period was closed on November 21, 2009 but GOJ will then notify those proposal to the TWO/SOS Committee, which will provide a chance for public comments to be submitted.

General Information:
On November 5, 2009, Government of Japan (GOJ) announced proposed changes to the MRLs for Oxadiazon, Dimethenamid, Tebufenozide, Pyributicarb and Metaldehyde, as well as maximum level

for cadmium in rice. The requirement to established import tolerance (i.e. MRL) was also explained. The domestic comment period was closed on November 21, 2009 but GOJ will notify those proposals to the TWO/SOS Committee, which will provide a chance for public comments to be submitted.
After the closing of a the comment period in the WTO, a final report will be made based on the conclusions of a session of the Pharmaceutical Affairs and Food Sanitation Council slated to be held at a later date; this will constitute the final decision.

Author Defined:

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

Purpose and Background

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

Under the provisions of Article 11, Paragraph 1 of the Food Sanitation Law, the MHLW 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 such food 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.

MHLW has proposed newly established MRLs (draft) for some food commodities as well as has comprehensively reviewed the current MRLs. This activity is targeted at five chemicals: **Oxadiazon** (herbicide), **Dimethenamid**(herbicide), **Tebufenozide**(Insecticide), **Pyributicarb** (herbicide) and **Metaldehyde**(molluscide). 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

Oxadiazon (herbicide): This chemical is already permitted for use in Japan. The MHLW has newly established a MRL (draft) for the "aquatic animals" category and has comprehensively reviewed the existing MRLs. For draft MRLs, see Attachment 1-1.

Dimethenamid (herbicide): This chemical has two optical isomers. Currently, the racemic form of this chemical is permitted for use in Japan. This time the Ministry of Agriculture, Forestry and Fisheries (MAFF) has decided to approve a non-racemic compound with a different ratio of the two isomers from the approved compound, based on the Agricultural Chemicals Regulation Law. In response to the MAFF's action, the MHLW has newly established MRLs (draft) for some crops and has comprehensively reviewed the existing MRLs. For draft MRLs, see Attachment 1-2.

Tebufenozide (insecticide): This chemical is already permitted for use in Japan. The MHLW has newly established a MRL (draft) for the "aquatic animals" category and has comprehensively reviewed the existing MRLs. For draft MRLs, see Attachment 1-3.

Pyributicarb (herbicide): This chemical is already permitted for use in Japan. The MHLW has newly established a MRL (draft) for the "aquatic animals" category and has comprehensively reviewed the existing MRLs. For draft MRLs, see Attachment 1-4.

Metaldehyde (molluscide): This chemical is already permitted for use in Japan. This time MAFF will expand the scope of target crops for which the use of the chemical is permitted. In response to the MAFF's action, the MHLW has newly established MRLs (draft) for some crops. In addition, the MHLW has newly established an MRL (draft) for the "aquatic animals" category. For draft MRLs, see Attachment 1-5.

The existing MRLs for **Oxadiazon, Dimethenamid** and **Tebufenozide** appear in either of the MRLs List (the Item 6, Section A "General Compositional Standards for Food," Part I "Food" of the Specifications and Standards for Food, Food Additives, Etc.) or Provisional MRLs List (Item 7, Section A), according to food commodities. These MRLs have been modified as necessary. Finalized MRLs will be placed on the MRLs List in Item 6, and the MRLs currently placed in Item 7 will be deleted.

Attachment 1-1
Oxadiazon（herbicide）

Commodity	MRL（draft） ppm	Current MRL ppm
Rice (brown rice)	0.02	0.1
Cattle, muscle		0.01
Pig, muscle		0.01

Other terrestrial mammals[17], muscle		0.01
Cattle, fat		0.01
Pig, fat		0.01
Other terrestrial mammals, fat		0.01
Cattle, liver		0.01
Pig, liver		0.01
Other terrestrial mammals, liver		0.01
Cattle, kidney		0.01
Pig, kidney		0.01
Other terrestrial mammals, kidney		0.01
Cattle, edible offal		0.01
Pig, edible offal		0.01
Other terrestrial mammals, edible offal[18]		0.01
Milk		0.1
Fish and shelfish	0.6	

The uniform limit (0.01 ppm) is applied to commodities for which draft MRLs are not given.

Attachment 1-2

Dimethenamid（herbicide）

Commodity	MRL（draft） ppm	Current MRL ppm
Barley		0.1
Rye		0.1
Corn (maize, including pop corn and sweet corn)	0.05	0.1
Buckwheat		0.1
Other cereal grains[1]	0.01	0.01
Soybeans, dry	0.05	0.1
Beans, dry[2]		0.01
Peanuts, dry	0.01	0.01
Potato	0.01	0.01
Taro		0.01
Sweet potato	0.01	0.01
Yam		0.01
Other potatoes[3]		0.01
Sugar beet	0.05	0.01
Turnip, roots (including rutabaga)	0.01	
Turnip, leaves (including rutabaga)	0.1	
Horseradish		0.01
Chinese cabbage		0.1
Cabbage	0.05	0.1
Brussels sprouts		0.1
Onion	0.01	0.01
Garlic	0.01	0.01
Other liliaceous vegetables[6]	0.01	0.01
Cucumber (including gherkin)	0.01	

Pumpkin (including squash)	0.01	
Oriental pickling melon (vegetable)	0.01	
Water melon	0.01	
Melons	0.01	
Makuwauri melon	0.01	
Other cucurbitaceous vegetables[9]	0.01	0.01
Ginger		0.01
Green soybeans	0.05	
Other vegetables[10]	0.01	0.01
Hop	0.05	
Other spices[15]		0.01
Other herbs[16]		0.01
Cattle, muscle	0.01	
Pig, muscle	0.01	
Other terrestrial mammals[17], muscle	0.01	
Cattle, fat	0.01	
Pig, fat	0.01	
Other terrestrial mammals, fat	0.01	
Milk	0.01	
Chicken, muscle	0.01	
Other poultry animals[19], muscle	0.01	
Chicken, fat	0.01	
Other poultry animals, fat	0.01	
Chicken, liver	0.01	
Other poultry animals, liver	0.01	
Chicken, kidney	0.01	
Other poultry animals, kidney	0.01	
Chicken, edible offal	0.01	
Other poultry animals, edible offal[18]	0.01	
Chicken, eggs	0.01	
Other poultry, eggs	0.01	

The uniform limit (0.01 ppm) is applied to commodities for which draft MRLs are not given.

MRLs for indoxacarb are established for the sum of residues of dimethenamid (S-enantiomer) and R-enantiomer of dimethenamid.

Attachment 1-3

Tebufenozide（insecticide）

Commodity	MRL（draft） ppm	Current MRL ppm
Rice (brown rice)	0.3	0.5
Barley		5
Rye		5
Corn (maize, including pop corn and sweet corn)		5
Buckwheat	5	5

Other cereal grains[1]		5
Soybeans, dry	0.3	0.5
Potato		0.1
Taro	0.015	0.1
Sweet potato	0.05	0.1
Yam	0.015	0.1
Konjac		0.1
Other potatoes[3]	0.015	0.1
Sugar beet	0.05	0.1
Sugarcane	1	1
Japanese radish, leaves (including radish)	10	10
Turnip, roots (including rutabaga)	0.3	9
Turnip, leaves (including rutabaga)	10	10
Watercress	10	10
Chinese cabbage	10	10
Cabbage	5	5
Brussels sprouts	5.0	5
Kale	10	10
Komatsuna(Japanese mustard spinach)	10	10
Kyona	10	10
Qing-geng-cai	10	10
Cauliflower	0.5	0.5
Broccoli	0.5	0.5
Other cruciferous vegetables[4]	10	10
Chicory	10	10
Endive	10	10
Shungiku	10	10
Lettuce (including cos lettuce and leaf lettuce)	10	10
Other composite vegetables[5]	10	10
Parsley	10	10
Celery	2.0	2
Other umbelliferous vegetables[7]	10	2
Tomato	1	1
Pimiento (sweet pepper)	1	1
Egg plant	1.0	1
Other solanaceous vegetables[8]	10	10
Water melon		0.1
Melons		0.1
Makuwauri melon		0.1
Other cucurbitaceous vegetables[9]	10	10
Spinach	10	10
Ginger	0.015	0.02
Other vegetables[10]	10	20
Unshu orange, pulp		2
Citrus *natsudaidai*, whole	2	2
Lemon	2	2

Orange (including navel orange)	2	2
Grapefruit	2	2
Lime	2	2
Other citrus fruits[11]	2	2

Tebufenozide(Continued)

Commodity	MRL (draft) ppm	Current MRL ppm
Apple	1	1.0
Japanese pear	1	1
Pear	1	1
Quince	1	1
Loquat	1	1
Peach	0.05	0.5
Nectarine	0.5	0.5
Apricot		1
Japanese plum (including prune)		1
Mume plum		1
Cherry	1	1
Strawberry	1	1
Raspberry	2	2
Blackberry	3.0	1
Blueberry	3	3
Cranberry	0.5	0.5
Huckleberry	3	1
Other berries[12]	3.0	1
Grape	2	0.5
Japanese persimmon		1
Banana		1
Kiwifruit (including peel)	0.5	0.5
Papaya		1
Avocado	1	1
Pineapple		1
Guava		1
Mango	0.7	1
Passion fruit		1
Date		1
Other fruits[13]	1.0	1
Cotton seeds	1.5	2
Rapeseeds	2	2
Chestnut	0.1	0.1
Pecan	0.01	0.01
Almond	0.05	0.05

Walnut	0.1	0.1
Other nuts[14]	0.1	0.08
Tea (green,black,oolong and wulung tea)	25	25
Coffee beans		0.05
Other spices[15]	2.0	20
Other herbs[16]	20	20
Cattle, muscle	0.05	0.02
Pig, muscle	0.05	0.02
Other terrestrial mammals[17], muscle	0.05	0.02
Cattle, fat	0.2	0.05
Pig, fat	0.2	0.05
Other terrestrial mammals, fat	0.2	0.05
Cattle, liver	0.05	0.02
Pig, liver	0.05	0.02
Other terrestrial mammals, liver	0.05	0.02
Cattle, kidney	0.02	0.02
Pig, kidney	0.02	0.02
Other terrestrial mammals, kidney	0.02	0.02

Tebufenozide(Continued)

Commodity	MRL (draft) ppm	Current MRL ppm
Cattle, edible offal[18]	0.05	0.02
Pig, edible offal	0.05	0.02
Other terrestrial mammals, edible offal	0.05	0.02
Milk	0.02	0.01
Chicken, muscle	0.02	0.02
Other poultry animals[19], muscle	0.02	0.02
Chicken, fat	0.02	0.02
Other poultry animals, fat	0.02	0.02
Chicken, liver		0.02
Other poultry animals, liver		0.02
Chicken, kidney		0.02
Other poultry animals, kidney		0.02
Chicken, edible offal		0.02
Other poultry animals, edible offal		0.02
Chicken, eggs	0.02	0.02
Other poultry, eggs	0.02	0.02
Fish and shelfish	0.3	
Pepper, dried	10	
Grape, dried	2	2

The uniform limit (0.01 ppm) is applied to commodities for which draft MRLs are not given.

Pyributicarb（herbicide）

Commodity	MRL (draft) ppm	Current MRL ppm
Rice (brown rice)	0.03	0.1
Fish and shelfish	0.4	

The uniform limit (0.01 ppm) is applied to commodities for which draft MRLs are not given.

Attachment 1-5

Metaldehyde（molluscide）

Commodity	MRL (draft) ppm	Current MRL ppm
Rice (brown rice)	0.2	0.2
Wheat	0.2	0.2
Corn (maize, including pop corn and sweet corn)	0.2	0.2
Lettuce (including cos lettuce and leaf lettuce)	3	
Unshu orange, pulp	0.2	
Rapeseeds	0.2	0.2
Other spices[15]	0.7	0.2
Fish and shelfish	0.02	

The uniform limit (0.01 ppm) is applied to commodities for which draft MRLs are not given.

Note:

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

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

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

4. “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.

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

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

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

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

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

10. “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.

11. “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.

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

13. “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.

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

15. “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.

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

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

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

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

2. Persistence data required to establish import tolerances (maximum residue limits) for agricultural chemicals

In applying for the establishment of import tolerances (MRLs) for agricultural chemicals, the Ministry of Health, Labour and Welfare requires applicants to submit study data on persistence in crops. The data should be equivalent to that required for pesticide registration in Japan, based on the Guideline for Application for Establishment and Revision of Maximum Residue Limits for Agricultural Chemicals used outside Japan, published on 5 February 2004 (Director Notice Syoku-An No. 0205001, 5 February 2004). The following is an abstract of the guideline.

III. Required Documents

1. Data Sets and GLP Compliance

A. Data Sets

a. Establishment of MRLs

Pesticides

A set of toxicity data (excluding effects on aquatic animals and plants, effects on beneficial creatures other than aquatic animals and plants, study data on water contamination) and residue data (excluding soil residue data), specified in Appendix Table 1 of the guidelines related to the study reports for the registration application of pesticide–Appendix to Director General Notification, No. 12-Nousan-8147, 24 November 2000, Agricultural Production Bureau, Ministry of Agriculture, Forestry and Fisheries of Japan .*The notification is available in English at

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

*Refer to the attachment

Notwithstanding the requirements mentioned above, Japan may adopt, as Japanese standards, limits derived by extrapolation from a number of tests less than required for pesticide registration if target crops are categorized as "minor crops"** judging from food consumption in Japan, and the MRLs derived are unlikely to pose problems with exposure assessment.

* Minor crops refer to those whose consumption is approximately 0.4 g/person/day or less.

Residue studies should be conducted using appropriate requirements in which the maximum residue levels can be scientifically evaluated within the range accepted in the applicant countries in accordance with critical Good Agricultural Practice (cGAP). The requirements include the cultivation method of the target crop, the application method of the target chemical such as the dilution factor or concentration in case of a liquid, the amount sprayed (by weight or volume/10 ares), the total number of times of application/cultivation period, and the pre-harvest interval. The acceptable maximum

deviation from cGAP is about ±25 percent.

3. Amendment of Maximum Level for Cadmium in Rice

Purpose and Background

Under the provisions of Article 11, Paragraph 1 of the Food Sanitation Law, the Ministry of Health, Labour and Welfare is authorized to establish maximum levels for contaminants 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.

the MHLW has amended the maximum level of cadmium in rice.

Outline of Revision

- The maximum level of total cadmium (cadmium and its compound) in rice will be revised to "not more than 0.4 ppm as Cd in brown rice and polished rice, respectively*" from "less than 1.0 ppm as Cd in brown rice."
- The Dithizone-chloroform method will be deleted from the analytical methods for cadmium in rice, because this method uses harmful reagents including chloroform.

The Codex standard of cadmium is not more than 0.4 ppm in polished rice. However, Japanese people customarily eat brown rice, and some data show that cadmium concentrations in rice are approximately the same before and after polishing. Therefore, Japan will apply the same standard value to both brown rice and polished rice.