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Japan

Sanitary / Phytosanitary / Food Safety

New MRLs and food additive designations

2004

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Report Highlights:
Japan invited foreign Embassies to comment on establishment of maximum residue limits for an insecticide, ethiprole, designation of calcium stearate, and withdrawal of madder color from the list of food additives. The deadline for comments is July 21, 2004. This proposal will be submitted to the WTO for a further opportunity for comments.

Includes PSD Changes: No
Includes Trade Matrix: No
Unscheduled Report
Tokyo [JA1]
[JA]

On June 4, 2004, the Ministry of Labor, Health and Welfare (MHLW) invited foreign Embassies in Tokyo to comment on; 1) the establishment of maximum residue limits (MRLs) an insecticide, ethiprole, 2) designation of calcium stearate, and 3) withdrawal of madder color from the list of food additives. The deadline for comments is July 21, 2004.

1) The MRLs for ethiprole shown in Attachment 1 are NOT a part of the provisional MRLs MHLW is drafting (See GAIN Report JA3071 and JA4051). MHLW will open the proposal to comments from a wider audience and notify the WTO SPS Committee before final review and adoption. Ethiprole has not been registered in either the U.S. or EU.

2) Calcium stearate may be designated by MHLW with the use standards and compositional specifications given in Attachment 2.

3) Based on the fact that madder color had been shown to be genotoxic as well as carcinogenic to the rat kidney, MHLW will prohibit the use of the coloring agent and withdraw it from the list of food additives (Attachment 3).

All interested parties are encouraged to send their comments, well before the deadline, for consideration by Foreign Agricultural Service, USDA. The office responsible for the comments is as follows:

Food Safety and Technical Services
International Trade Policy division
USDA Foreign Agricultural Service
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Attachment 1

List of Maximum Residue Limits for Pesticides in Foods (draft)

(Newly established)

ETHIPROLE (Insecticide)

foods	MRLs (draft) ppm
Rice (brown rice)	0.2
Apple	0.5
Tea (Green, Black, Oolong, Wulung tea)	10

Attachment 2

Calcium Stearate

Use Standards (draft)

No standard is established.

Compositional specifications (draft)

Definition Calcium Stearate consists mainly of calcium salts of stearic acid ($C_{18}H_{36}O_2$) and palmitic acid ($C_{16}H_{32}O_2$).

Content Calcium Stearate, when dried, contains 6.4–7.1% of calcium (Ca= 40.08).
Description Calcium Stearate occurs as a white, light, bulky powder. It is odorless or has a faint, characteristic odor.

Identification (1) To 3.0 g of Calcium Stearate, add 20 ml of diluted hydrochloric acid (1-2) and 30 ml of diethyl ether, shake vigorously for 3 minutes, and allow to stand. The separated water layer responds to test (1) for calcium as described in the Qualitative Tests.

(2) Separate the diethyl ether layer obtained in (1), and wash it successively with one 20-ml potion then one 10 ml-portion of dilute hydrochloric acid and one 20-ml potion of water. Evaporate the diethyl ether on a water bath. The melting point of the residue is not lower than 54°C.

Purity (1) Heavy metals Not more than 10 µg/g as Pb.
Test Solution Take 1.0 g of Calcium Stearate, heat gently with care at first, and heat further, gradually rising the temperature to incineration. After cooling, add 2 ml of hydrochloric acid, and evaporate on a water bath to dryness. To the residue, add 20 ml of water and 2 ml of dilute acetic acid, warm for 2 minutes, cool, and filter. Wash the residue with 15 ml of water, combine the filtrate and washings, and add water to make 50 ml. Using this solution as the test solution, perform the test as directed under the Arsenic Limit Test.
Control Solution Evaporate 2 ml of hydrochloric acid on a water bath to dryness, and add 2 ml of dilute acetic acid, 1.0 ml of Standard Lead Solution, and water to make 50 ml.
(2) Arsenic Not more than 4 µg/g.
Test Solution To 1.0 g of Calcium Stearate, add 5 ml of hydrochloric acid (1-2) and 20 ml of chloroform, shake vigorously for 3 minutes, allow to stand, and separate the water layer. Using the water layer as the test solution, perform the test as directed under the Arsenic Limit Test. Use apparatus B.
(3) Free fatty acids Not more than 3.0% as stearic acid.
Weigh accurately about 2 g of Calcium Stearate, place to an Erlenmeyer flask, add 50 ml of acetone, heat in a water bath for 10 minutes with a condenser attached to the flask, and cool. Filter it with two-ply No. 2 paper filters, wash the inside of the flask, the residue, and the filter paper with 50 ml of acetone, and combine the washings with the filtrate. Add 2 to 3 drops of phenolphthalein TS and 5 ml of water, and titrate with 0.1 mol/L sodium hydroxide. Perform a blank test using a mixture of 100 ml of acetone and 5 ml of water.
1 ml of 0.1 mol/L sodium hydroxide = 28.45 mg $C_{18}H_{36}O_2$
(4) Loss on drying Not more than 4.0% (105°C, 3 hours)

Assay Weigh accurately about 0.5 g of Calcium Stearate, place to a crucible, heat gently with care at first, and then ignite at 700°C for 3 hours in an electric furnace to incineration. After cooling, add 10 ml of hydrochloric acid to the residue, and warm on a water bath for 10 minutes. Transfer the contents into a flask with the aid of two 10-ml potions and one 5-ml potion of warm water. Add sodium hydroxide TS until the solution becomes slightly turbid, and then add 25 ml of 0.05mol/L EDTA, 10 ml of ammonia-ammonium chloride buffer solution (pH 10.7), 4 drops of eriochrome black T TS, and 5 drops of methyl yellow TS. Immediately titrate the excess EDTA with 0.05 mol/L magnesium chloride. The endpoint is when green color of the solution disappears and a red color is produced. Separately, perform a blank test.
1 ml of 0.05 mol/L EDTA = 2.0039 mg Ca
Regents and solutions
Methyl yellow (Guaranteed)
Methyl yellow TS: Dissolve 0.10 g of methyl yellow in 200 ml of ethanol.

Attachment 3

Withdrawal of Madder Color, Coloring Agent, out of the List of Existing Food Additives

Background

The Ministry of Health, Labour and Welfare requested the Food Safety Commission on June 18, 2004 to evaluate the health risk of madder color, coloring agent. The commission reported on July 2 to the MHLW that the substance had been shown to be genotoxic as well as carcinogenic to the rat kidney from the available documents and that no ADI (Acceptable Daily Intake.) could be established for the substance. The commission also reported that further evaluations were necessary for organs/tissues other than the kidney. In response to the commission's report, the MHLW held a session of the Pharmaceutical Affairs and Food Sanitation Council on July 5 to hear council's opinion about the substance. The council concluded that the substance should be withdrawn from the List of Existing Food Additives. The council also mentioned that this action should be urgently taken in order to prevent the occurrence of food safety hazards.

Based on the council's conclusion, the MHLW will prohibit the production, distribution, and importation of madder color and foods containing the substance.

Outline of Legal Action

Based on Article 2-2 Paragraph 1 of the Supplementary Provisions of the Law to Partially Amend the Food Sanitation Law and the Health Promotion Law, madder color will be withdrawn from the List of Existing Food Additives (at about the end of this week), and based on Paragraph 4 of the same article, this measure will be published in the official gazette, kanpo. By this legal action, any person will be prohibited from producing, distributing, and importing the substance and any food containing the substance. This action will take effect on the date when the three-month period from the date of publication has passed (early October). The MHLW will carry out formalities for the WTO notification as soon as possible.