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Japan

Food and Agricultural Import Regulations and Standards

Change to Specifications for HCB in Food Red No. 104 and No. 105 and Update on Approvals for GRAS Food Additives

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Report Highlights: On January 11 MHLW announced proposed changes to the food additive specifications for hexachlorobenzene (HCB) in Food Red No. 104 and No. 105. The period for comments directly to MHLW closed January 25th however after that time MHLW announced that they would notify their intent to the WTO/SPS committee. This report also contains an updated chart on the approval of the 46 food additives slated for review by MHLW without an application.

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

The Japanese Ministry of Health Labour and Welfare (MHLW) announced in mid-January proposed changes to the food additive specifications for hexachlorobenzene (HCB) in Food Red No. 104 (Phloxine) and No. 105 (Rose Bengal). The period for comments directly to MHLW closed January 25th however MHLW intends to notify these proposed changes to the WTO/SPS committee, which would be the last chance for public comments to be submitted on this subject. Then after the closing of a the comment period in the WTO, a report to the Minister of Health, Labour, and Welfare 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, and this will constitute the final decision.

If you have comments that you would like to be considered for inclusion in the official U.S. Government comments to the WTO, please send those as soon as possible to the Agriculture Section of the U.S. Embassy in Tokyo, at agtokyo@usda.gov

Summary of announcement:

Topic: Compositional specifications for food additives (Food Red No. 104 and No. 105)

Purpose: This activity is to newly establish a specification for the impurity hexachlorobenzene (HCB) in Food Red No. 104 (Phloxine) and No. 105 (Rose Bengal). The substance is covered by the Stockholm Convention on Persistent Organic Pollutants (POPs). It is derived from tetrachlorophthalic anhydride used as ingredient. Article 10 of the Food Sanitation Law specifies that no food additives may be used or marketed unless they are designated by the Minister of Health, Labour and Welfare as approved additives. Where use standards or compositional specifications have been established for additives based on Article 11 of the law, those additives may not be marketed unless they meet the established standards or specifications.

Outline: Based on Article 11 of the law, the specification for HCB including testing method, given in Attachment 3, will be added to the purity specification for Food Red No. 104 and No. 105.

Information provision: The progress of evaluating food additives that have been proven safe by the JECFA (Joint FAO/WHO Expert Committee on Food Additives) and that are widely used in the world (Attachment 4)

Food Red No. 104

Purity test

Hexachlorobenzene Not more than 5.0 µg/g

Test Solution: Weigh accurately about 0.02 g of the sample into a 50-ml centrifuge tube, and dissolve it in 30 ml of water. Add exactly 10 ml of hexane, and shake for 5 minutes. Transfer the hexane layer into a test tube with stopper, add 0.5 g of anhydrous sodium sulfate to the hexane layer, and shake. Use the hexane layer as the test solution.

Standard Solutions: Weigh accurately about 0.01 g of hexachlorobenzene, and dissolve it in hexane to make exactly 100 ml. Take exactly 5 ml of this solution, and add hexane to make exactly 100 ml. Then take exactly 1 ml of this solution, and add hexane to make exactly 100 ml. Measure exactly 1 ml, 4 ml, and 8 ml of the obtained solution, and to each, add hexane to make exactly 10 ml of each. Use these solutions as the standard solutions.

Procedure: Perform Gas Chromatography on 1 µl, exactly measured, of each of the

test solution and the standard solutions under the conditions given below. Measure the peak areas of hexachlorobenzene for standard solutions to prepare a calibration curve. Obtain the content of hexachlorobenzene in the test solution from the calibration curve and the peak area of hexachlorobenzene for test solution.

Operating conditions

Detector: Electron-capture detector.

Column: A silicate glass capillary of 0.25 mm in internal diameter and 30 m in length which is coated with a 0.25- μm thick mixture of 5% diphenyl/95% dimethyl polysiloxane for gas chromatography.

Column temperature: Hold the temperature at 60°C for 1 minute, thereafter raise to 280°C, and hold again for 5 minutes. The temperature increasing ratio should be adjusted so that the peak of hexachlorobenzene separated from other components appears 10–15 minutes after injection.

Injection port temperature: 260°C.

Detector temperature: 300°C.

Injection: Splitless.

Carrier gas: Nitrogen.

Flow rate: Adjust so that the peak of hexachlorobenzene appears 10–15 minutes after injection.

Reagents

Hexachlorobenzene C_6Cl_6 Contains not less than 98% of hexachlorobenzene.

Melting point: 226°C.

Food Red No. 105

Purity test

Hexachlorobenzene Not more than 6.5 $\mu\text{g/g}$

Test Solution: Weigh accurately about 0.02 g of the sample into a 50-ml centrifuge tube, and dissolve it in 30 ml of water. Add exactly 10 ml of hexane, and shake for 5 minutes. Transfer the hexane layer into a test tube with stopper, add 0.5 g of anhydrous sodium sulfate to the hexane layer, and shake. Use the hexane layer as the test solution.

Standard Solutions: Weigh accurately about 0.01 g of hexachlorobenzene, and dissolve it in hexane to make exactly 100 ml. Take exactly 5 ml of this solution, and add hexane to make exactly 100 ml. Then take exactly 1 ml of this solution, and add hexane to make exactly 100 ml. Measure exactly 1 ml, 4 ml, and 8 ml of the obtained solution, and to each, add hexane to make exactly 10 ml of each. Use these solutions as the standard solutions.

Procedure: Perform Gas Chromatography on 1 μl , exactly measured, of each of the test solution and the standard solutions under the conditions given below. Measure the peak areas of hexachlorobenzene for standard solutions to prepare a calibration curve. Obtain the content of hexachlorobenzene in the test solution from the calibration curve and the peak area of hexachlorobenzene for test solution.

Operating conditions

Detector: Electron-capture detector.

A silicate glass capillary of 0.25 mm in internal diameter and 30 m in length which is coated with a 0.25- μm thick mixture of 5% diphenyl/95% dimethyl polysiloxane for gas chromatography.

Column temperature: Hold the temperature at 60°C for 1 minute, thereafter raise to 280°C, and hold again for 5 minutes. The temperature increasing ratio should be adjusted

so that the peak of hexachlorobenze separated from other components appears 10–15 minutes after injection.

Injection port temperature: 260°C.

Detector temperature: 300°C.

Injection: Splitless.

Carrier gas: Nitrogen.

Flow rate: Adjust so that the peak of hexachlorobenzene appears 10–15 minutes after injection.

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

January 2007

Substance name	Request for evaluation	Food Safety Commission		MHLW		
		Evaluation by expert committee ¹	Notification of result ³	Discussion by subcommittee ⁵	Closing date for comments ⁴	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 2004 20 May 2004 28 Jul 2005(fin.)	9 Sep 2004	26 Aug 2004(fin.)	14 Dec 2004	24 Feb 2005
Nitrous oxide	20 Oct 2003	17 Dec 2003 5 Oct 2004(fin.)	9 Dec 2004	17 Dec 2004(fin.)	19 Feb 2005	22 Mar 2005
Isopropanol	15 Dec 2003	24 Mar 2004 9 Apr 2004 8 Sep 2004 5 Oct 2004(fin.)	9 Dec 2004	28 Oct 2004(fin.)	4 Mar 2005	28 Apr 2005
Hydroxypropyl cellulose	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 2004 16 Nov 2004 26 Jan 2005(fin.)	6 May 2005	24 Mar 2005(fin.)	7 Sep 2005	28 Nov 2005
Acetaldehyde	21 Nov 2003	3 Mar 2004 9 Apr 2004 27 Apr 2004 23 Feb 2005 13 Apr 2005(fin.)	21 Jul 2005	23 Jul 2005(fin.)	12 Oct 2005	16 May 2006
2-Ethyl-3-methylpyrazine	7 Mar 2005	14 Jun 2005 22 Jul 2005(fin.)	22 Sep 2005	27 Oct 2005 24 Nov 2005(fin.)	26 Apr 2006	12 Sep 2006
5-Methylquinoxaline						
Butanol						
Ammonium alginate	28 Mar 2005	2 Dec 2005 14 Dec 2005(fin.)	30 Mar 2006	23 Mar 2006(fin.)	5 Sep 2006	26 Dec 2006
Potassium alginate						
Calcium alginate						
2-Methylbutanol	19 Dec 2005	14 Jul 2006 11 Aug 2006(fin.)	12 Oct 2006	8 Dec 2006 (under		
Isobutanol	19 Dec 2005	28 Jun 2006 14 Jul 2006 11 Aug 2006 13 sep 2006 13 oct 2006(fin.)	7 Dec 2006	8 Dec 2006 (under consideration)		
Nisin	20 Oct 2003	9 Apr 2004 16 Nov 2004 26 Jan 2005 (under consideration)				
Polysorbate 20, 60, 65, 80	8 Oct 2003	29 Oct 2003 27 Apr 2004 28 Jul 2004 (under consideration)				

Substance name	Request for evaluation	Food Safety Commission		MHLW		
		Evaluation by expert committee ¹	Notification of result ²	Discussion by subcommittee ³	Closing date for comments ⁴	Date of designation as food additives
Acetylated distarch adipate	26 Nov 2004	23 Mar 2005 17 May 2005 (under consideration)				
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						
Dimagnesium phosphate	28 Mar 2005	31 May 2006 28 Jun 2006 14 Jul 2006 11 Aug 2006 13 Sep 2006 13 Oct 2006 28 Nov 2006 (under consideration)				
Polyvinylpyrrolidone	20 Jun 2005	13 Sep 2006 13 Oct 2006 28 Nov 2006 19 Dec 2006 (under consideration)				
Sodium aluminum silicate	15 Aug 2005					
Calcium silicate						
Calcium aluminum silicate						
Magnesium silicate(synthetic)						
Calcium ascorbate	3 Oct 2005					
Butanal	19 Dec 2005	19 Dec 2006 (under consideration)				
Magnesium hydroxide	9 Mar 2006					
Calcium saccharin	22 May 2006					
Ammonium L-glutamate	22 May 2006					

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