

IA #99-30, 11/12/2008, IMPORT ALERT #99-30, "DETENTION WITHOUT PHYSICAL EXAMINATION OF ALL MILK PRODUCTS, MILK DERIVED INGREDIENTS AND FINISHED FOOD PRODUCTS CONTAINING MILK FROM CHINA DUE TO THE PRESENCE OF MELAMINE AND/OR MELAMINE ANALOGS"

TYPE OF ALERT: Detention Without Physical Examination (Countrywide)

(Note: This import alert represents the Agency's current guidance to FDA field personnel regarding the manufacturer(s) and/or products(s) at issue. It does not create or confer any rights for or on any person, and does not operate to bind FDA or the public).

PRODUCTS: All milk products
All milk derived ingredients
Finished food products containing milk

PRODUCT

CODES: 03 [] [] [] [] Bakery Products/Doughs/Mixes/Icings

05Y [] [] [] Cereal Preparations

05A [] [] [] Breakfast Food Ready to Eat

05B [] [] [] Breakfast Food Quick Cook

07 [] [] [] [] Snack Foods

09 [] [] [] [] Milk/Butter/Dried Milk Products

12 [] [] [] [] Cheese/Cheese Products

13 [] [] [] [] Ice Cream Products

14 [] [] [] [] Filled Milk/imitation Milk Products

29A [] [] 70 Soft Drink, Milk Based (Chocolate Flavored),
Noncarbonated

29A [] [] 99 Noncarbonated Soft Drink, N.E.C.

29Y [] [] 99 Soft Drink/Waters N.E.C.

29B [] [] 70 Soft Drink, Milk Based (Chocolate Flavored,
Etc.) Carbonated

29B [] [] 99 Carbonated Soft Drink, N.E.C.

30F [] [] [] Beverage Base N/Fruit (Cola Rootbeer Etc)

30G [] [] [] Beverage Base Non-Fruit Liquid

33G[] [] [] Soft Candy w/ Nut, seeds, w/out Coconut
33H[] [] [] Soft Candy w/ Coconut
33J[] [] [] Soft Candy w/ Fruit
33K[] [] [] Soft Candy w/ Nuts & Fruits
33L[] [] [] Soft Candy, w/out Nut/Fruit
33S[] [] [] Candy Specialties
33Y[] [] [] Candy w/out Chocolate, N.E.C.

34[] [] [] [] Chocolate/Cocoa Products

35C[] [] [] Custard Pudding mix
35D[] [] [] Pudding Mix (Not Custard)

40[] [] [] [] Baby Food Products

67A[] [] 28 Iodinated Casein (Cat. I, Type A med. Article)
67C[] [] 28 Iodinated Casein (Combo Cat. I& II, type A, med)

69A[] [] 28 Iodinated Casein (Cat. I med. feed)
69C[] [] 28 Iodinated Casein (Combo Cat. I & II, med. feed)

71C[] [] [] Dairy Byproducts for Animals
71E[] [] [] Animal Waste Feed Products
71Y[] [] [] Byproducts for Animals, N.E.C.

72A[] [] [] Pet Cat Foods
72B[] [] [] Pet Dog Foods
72D[] [] [] Pet Fish Foods
72E[] [] [] Other Pet Foods, N.E.C.
72L[] [] [] Laboratory Animal Feeds
72Y[] [] [] Pet and Laboratory Animal Foods, N.E.C.

PROBLEM: Unsafe Food Additive
Poisonous or Deleterious Substance
Unfit For Food

PAF: PES

COUNTRY: China (CN)

MANUFACTURER/
SHIPPER: All

CHARGES: "The article is subject to refusal of admission pursuant to Section 801(a)(3) in that it appears to bear or contain a food additive, namely melamine and/or a melamine analog, that is unsafe within the meaning of section 409

[Adulteration, section 402(a)(2)(C)(i)]"
OASIS charge code: MELAMINE

and/or

"The article is subject to refusal of admission pursuant to section 801(a)(3) in that it appears to bear or contain a poisonous or deleterious substance which may render it injurious to health [Adulteration, section 402(a)(1)]"
OASIS charge code: POISONOUS

and/or

"The article is subject to refusal of admission pursuant to section 801(a)(3) in that it appears to be unfit for food [Adulteration, 402(a)(3)]"

OASIS charge
code:

UNFIT4FOOD

RECOMMENDING

OFFICE:

Division of Import Operations and Policy, HFC-170
Center for Food Safety and Applied Nutrition, HFS-600

REASON FOR

ALERT:

In September, 2008, FDA became aware of thousands of infant illnesses in China due to the consumption of infant formula reported to contain melamine. Reports indicated over 53,000 illnesses, including almost 13,000 hospitalizations, and at least four deaths of infants. The illnesses involved the formation of kidney stones and crystals and related complications.

The milk used in the infant formula has been implicated as the source of the melamine contamination. According to sources, at a bulk fluid milk collection point, water is added to the bulk fluid milk to increase the apparent volume of product. Melamine is added to the water/milk mixture to increase the nitrogen content in order to inflate the apparent protein content found in the product. Milk is transported from the collection centers to milk processing facilities.

The problem of melamine contamination is not limited to infant formula products. Chinese government sources indicate contamination of milk components, especially dried milk powder, which are used in the manufacture of a variety of finished foods. These contaminated milk components

appear to have been dispersed throughout the Chinese food supply chain.

FDA analyses have detected melamine and cyanuric acid in a number of products that contain milk or milk-derived ingredients, including candy and beverages. In addition, information received from government sources in a number of countries indicates a wide range and variety of products from a variety of manufacturers have been manufactured using melamine-contaminated milk or milk-derived ingredients, including: fluid and powdered milk, yogurt, frozen desserts, biscuits, cakes and cookies, taffy-like soft candy products, chocolates, and beverages. These products appear to contain at least one milk-derived ingredient and they are of Chinese origin. Reports of contamination have come from more than thirteen countries in Asia, Europe, and Australia, in addition to the United States. Additional products from various manufacturers continue to be found to be contaminated with melamine.

The problem of melamine contamination in Chinese food products is a recurring one. In 2007, bulk vegetable protein products imported from China were contaminated with melamine and melamine analogs, apparently from deliberate contamination.

GUIDANCE: Districts may detain without physical examination all milk products, all milk derived ingredients, and finished food products containing milk from China.

Appropriate screening criteria have been set.

For questions or issues concerning science, science policy, sample collection, analysis, preparation, or analytical methodology, contact Mr. Thomas Savage, Division of Field Science, at 301-827-1026.

In order to secure release of an individual shipment detained pursuant to this Import Alert, the importer should provide either:

1. Results of a third-party laboratory analysis, of a representative sample of the lot, which verifies the product does not contain melamine or cyanuric acid. Third-party laboratories may use any method that is found acceptable to FDA and which meets the method

performance of the LC-MS/MS methods available at
<http://www.cfsan.fda.gov/~comm/labmeth.html#melamine>

OR

2. Documentation supplied in English which shows there are no milk or milk-derived ingredients in the product, to include product formulation and product labeling (for example; process or batch records from the manufacturer, and the actual product labeling or a facsimile of the product labeling).

If a firm, shipper or importer wishes to request removal from detention without physical examination, they should forward information supporting their request to FDA at the following address:

Food and Drug Administration
Division of Import Operations and Policy (HFC-170)
5600 Fishers Lane, Room 12-36
Rockville, MD 20857

The request should include information for FDA to adequately assess whether a manufacturer has appropriate controls and processes, including:

1. Documentation showing a minimum of five (5) consecutive non-violative shipments have been released by FDA based upon results of third party laboratory analyses, using methods found acceptable to FDA of a representative sample of the lot, that verify the products do not contain melamine or cyanuric acid.

AND

2. Documentation from a third-party, in whom FDA has sufficient confidence, which demonstrates controls are in place such that products will not be contaminated with melamine and melamine analogs. To gain sufficient confidence in a third party, FDA may determine it needs to conduct a paper or on-site review of the work of the third party.

AND

3. Documentation that the firm is in compliance with all Chinese government requirements for exporting the

products to the U.S. Documentation should include copies of any registration that may be required by the Chinese government.

All requests for removal from detention without physical examination will be referred by DIOP to CFSAN (HFS-606) or CVM (HFV-232) for evaluation.

PRIORITIZATION

GUIDANCE: I

FOI: No purging required

KEYWORDS: Human food, pet food, animal feed, melamine, milk, milk-derived ingredients

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DATE LOADED

INTO FIARS: November 12, 2008