



The American Companies

"News Flash"

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FDA Restrictions on Wide Range of Milk-derived Products from China

Reports of infant & child illnesses in China related to melamine-contaminated milk products became world-wide news in September of this year. Melamine is added to milk in the manufacturing process in order to enhance the protein measurements and disguise the dilution of the product with water to extend volume and enhance profit. Since then a number of countries including the US, who are importing milk-derived products from China have been investigating this situation. They have discovered that the melamine contamination is far more widespread affecting many common food products that use milk-derived ingredients, including bakery and cereal products, candy, cheese and ice cream. See the link immediately below for a complete list.

The US FDA issued instructions to their offices on Nov 12 (http://www.fda.gov/ora/fiars/ora_import_ia9930.html), effective immediately, to detain all such milk-products from China. They have also opened several field offices in China in order to better monitor the situation, according to news reports this morning.

If an importer has milk-related goods from China that have been already been detained, the FDA decision gives specific instruction for requesting release without physical sampling and testing: importers are advised to submit test results from a third party testing company (using any FDA-accepted methodology) which verify that 'representative sample lots' are found to be free of melamine (and cyanuric acid). For acceptable testing methods, access <http://www.cfsan.fda.gov/~frf/lib4421.html>. For questions or concerns related to the science and testing standards, a contact has been provided: Mr Thomas Savage, 301-827-1026.

Alternatively, if the product is wrongly detained, meaning that the product contains no milk products, importers can provide a document in English that substantiates that fact. Such document would provide product formulation from the manufacturer and product labels, for example, that would clearly establish the absence of these substances.

To support FDA assessment of these requests, the guidance requests presentation of further documentation showing that a) five (5) previous shipments of the same product have been released on the basis of third party testing, and b) a statement from a third-party tester (who has FDA's confidence) that clearly demonstrates the existence of controls throughout the procurement and manufacturing process that precludes contamination in the future and c) documentation that supports the claim that the manufacturer is in compliance with all Chinese government requirements for exporting to the US.

This entire package, third-party test results, certificates on the absence of milk-products, and the recommended supporting documents must be mailed in hard-copy to Food and Drug Administration, Division of Import Operations and Policy (DIOP HFC-170), 5600 Fishers Lane, Room 12-36, Rockville, MD 20857. These requests will be forwarded by DIOP to Center for Food Safety and Nutrition (CFSAN) for consideration.

While FDA appears to be extending the means of releasing imported product to the trade community caught in this unfortunate situation, it seems safe to say that quick release of the detained milk products in either case is an extremely remote possibility.

The entire Melamine contamination story is available at <http://www.fda.gov/oc/opacom/hottopics/melamine.html>

An informative FAQ on Melamine is available on the FDA web-site at http://www.fda.gov/oc/opacom/hottopics/melamine_ga.html

The American Companies will follow-up on this emerging situation closely and report developments. For questions and clarifications, do not hesitate to contact our corporate compliance manager, Jim Carroll at 201-478-4682 (direct) and jamesc@americanshipping.com

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