

**Background Document for  
Overview of Current Methods for Detection of Contaminants in FDA Regulated Products  
Agenda Topic**  
(available at <http://www.fda.gov/oc/opacom/hottopics/melamine.html>)

## **Melamine Contamination in China** (Updated: October 18, 2008)

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### **Introduction**

On September 12, 2008, in light of reports from China of infant formula contaminated with melamine, the FDA issued a Health Information Advisory to proactively reassure the American public that there is no known threat of contamination in infant formula manufactured by companies that have met the requirements to sell such products in the United States. That advisory also warned members of Asian communities in the United States that infant formula manufactured in China, possibly available for purchase at Asian markets, could pose a risk to infants. No Chinese manufacturers of infant formula have fulfilled the requirements to sell infant formula in the United States.

The FDA contacted the companies that manufacture infant formula for distribution in the United States and received information from the companies that they are not importing formula and do not source milk-based ingredients from China.

In addition, the FDA -- in conjunction with state and local officials -- continues to check Asian markets for food items that are imported from China and that could contain a significant amount of milk or milk proteins.

The FDA has broadened its domestic and import sampling and testing of milk-derived ingredients and finished food products containing milk or milk-derived ingredients from Chinese sources. FDA has recommended that consumers not consume certain products because of possible contamination with melamine. A list of those products is below.

## Update on FDA's Investigation

**October 10, 2008:** The FDA issued a product-specific Import Alert, which prevents certain products from entering U.S. commerce and provides another layer of protection to consumers. [http://www.fda.gov/ora/fiars/ora\\_import\\_ia9931.html](http://www.fda.gov/ora/fiars/ora_import_ia9931.html)

## FDA's Warnings/Advisories

The FDA is advising consumers not to consume the following products because of possible melamine contamination:

- Koala's March Crème filled Cookies **New!**
- YILI Brand Sour Milk Drink
- YILI Brand Pure Milk Drink
- Blue Cat Flavored Drinks
- White Rabbit Candies
- Mr. Brown Mandehling Blend Instant Coffee (3-in-1)
- Mr. Brown Arabica Instant Coffee (3-in-1)
- Mr. Brown Blue Mountain Blend Instant Coffee (3-in-1)
- Mr. Brown Caramel Macchiato Instant Coffee (3-in-1)
- Mr. Brown French Vanilla Instant Coffee (3-in-1)
- Mr. Brown Mandehling Blend instant Coffee (2-in-1)
- Mr. Brown Milk Tea (3-in-1)
- Infant formula manufactured in China

## News Updates

- [FDA Detects Melamine Contamination in Flavored Drink](#) (October 6, 2008)
- [FDA Updates Health Information Advisory on Melamine Contamination](#) (Sept 26, 2008)
- [FDA Updates Health Information Advisory on Melamine Contamination](#) (Sept 23, 2008)
- [FDA Updates Health Information Advisory on Melamine Contamination](#) (Sept.20, 2008)
- [FDA Issues Health Information Advisory on Infant Formula](#) (Sept. 12, 2008)

## Company Recalls

- [Lotte USA, Inc. Initiates Nationwide Recall of Koala's March Crème filled Cookies](#) (Oct. 17, 2008) **New!**
- [HUA XIA Food Trade USA, Inc. Recalls YILI Brand Sour Milk Drink and YILI Brand Pure Milk Drink, Because of Possible Health Risk](#) (Oct. 10, 2008)
- [Tristar Food Wholesale, Inc. Issues a Nationwide Recall of Blue Cat Flavored Drink Because of Possible Health Risk](#) (Oct. 3, 2008)
- [Mr. Brown 3-In-1 & and 2-In-1 Powdered Packets in Bag Coffee Mixes Due To Health Risk](#) (Oct. 1, 2008)
- [QFCO, Inc. Recalls White Rabbit Candy Because of Possible Health Risk](#) (Sept. 26,

2008)

## Information for Industry

[Letter to the United States Food Manufacturing Industry Regarding Melamine](#)

### FDA's Interim Safety and Risk Assessment of Melamine and Melamine-Related Compounds in Food

The FDA issued the results of its interim safety and risk assessment of melamine and melamine-related compounds in food, including infant formula. The purpose of the FDA interim safety/risk assessment was to identify the level of melamine and melamine-related compounds in food which would not raise public health concerns.

For infant formula, the safety/risk assessment concludes that at this time FDA is unable to establish any level of melamine and melamine-related compounds in infant formula that does not raise public health concerns. In large part, this is because of gaps in our scientific knowledge.

In food products other than infant formula, the safety/risk assessment concludes that levels of melamine and melamine-related compounds below 2.5 ppm do not raise public health concerns. This conclusion assumes a worst case exposure scenario in which 50% of the diet is contaminated at this level, and applies a 10-fold safety factor to the Tolerable Daily Intake (TDI) to account for uncertainties.

[FDA's Interim Safety and Risk Assessment of Melamine and its Analogues in Food](#)  
[Interim Safety and Risk Assessment of Melamine and Its Analogues in Food for Humans](#)

### FDA's Testing Methods

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The FDA Field laboratories are using LC-MS/MS methods that are capable of determining melamine and cyanuric acid at levels of 0.25 ppm in powdered infant formula and other dairy-containing food products or ingredients. These and a GC/MS method for melamine and its analogues are:

#### Melamine Methodology

- [Determination of Melamine and Cyanuric Acid Residues in Infant Formula using LC-MS/MS](#)
- [Interim Method for Determination of Melamine and Cyanuric Acid Residues in Foods using LC-MS/MS](#)
- [GC/MS method for melamine and analogues](#)

### Other Resources

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[WHO web site on melamine](#)  
[CDC web site on melamine](#)