



Melamine: What You Need to Know

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By the end of 2008, almost everyone had heard of melamine and its issues in the Chinese food industry. The first time melamine made headlines was in 2007 when companion pets in the United States died from pet food contaminated with melamine. The FDA tests found that wheat gluten and rice protein, imported from China to make pet food and treats, tested positive for melamine and some also tested positive for cyanuric acid. It was speculated at that time that melamine had been illegally added to increase the apparent amount of protein in the ingredients. Shortly thereafter, the FDA reported that millions of Americans had eaten chicken fattened on feed containing melamine tainted gluten from China. It had also been found that hogs had eaten tainted feed, but no recalls were made. It would soon become known that using scrap from the production of melamine to falsely increase the apparent protein content of milk and feeds was common place in China.

Tragically, the most recent event, precipitating recalls,

destruction of product, import bans, detention of imported product, bankruptcy, jail time and death of conspirators, was the illegal contamination of milk that would end up in infant formula. Early reports had over 50,000 infants suffering illness, 13,000 hospitalized, and at least 6 deaths due to the contaminated infant formula. Most suffered from kidney failure and kidney stones, unusual in infants and small children. In September 2008, tests conducted by the AQSIQ (China's General Administration for Quality, Safety, Inspection and Quarantine) found samples from 21 suppliers of baby milk powder to have melamine ranging from 0.09 ppm to 619 ppm. Sanlu, a leading supplier of inexpensive infant formula in China, had the highest content found in all of its tested samples, with 2,563 ppm found. There are possibly more health consequences of this contamination, but it is hard to determine at this time due to long term or chronic exposure to contaminated products. These elevated levels increased the apparent protein of lesser quality products sold to manufacturers in China.

So what is melamine and why is it being added to food products?

Traditionally, melamine is used in the manufacture of plastics and fertilizers. It is a metabolite of cyromazine, a pesticide that is legal in the United States. It is commonly used in most industrial societies in making dishes, plastic resins, countertops, etc., and is approved for food contact in the United States. Traditional protein analysis relies on the amount of nitrogen found in a sample to determine the amount of protein. It is based on the assumption that all nitrogen present in food is only from amino acids in protein. Considering that melamine and its analogues are rich with nitrogen (approximately 66% of their mass), small amounts added to food can increase the amount of nitrogen and falsely increase the apparent amount of protein.

Testing for melamine is performed by various methodologies, from Elisa tests, GC/MS (Gas Chromatography - Mass Spectrometry), HPLC/MS (High Performance Liquid Chromatography - Mass Spectrometry), LC/MS/MS (Liquid Chromatography-tandem Mass Spectrometry) and GC/MS/MS (Gas Chromatography-tandem Mass Spectrometry). Testing involves looking for melamine and its analogues: cyanuric acid, ammelide and ammeline. Cyanuric acid is a by-product of melamine, ammeline is a product of hydrolysis of melamine, and ammelide is a product formed by the hydrolysis of ammeline, and hence can indicate the presence of contamination. The FDA requires that a method that can meet the detection limit of the FDA LC/MS/MS method of 0.25 ppm or 250 ppb be used in detention testing. However, the method does not have to be the LC/MS/MS method. The most sensitive techniques are LC/MS/MS and GC/MS/MS.

Since October 10, 2008, the FDA has had an import alert in

place for certain imported products from China, and has since expanded its import controls on dairy products, food and feed manufactured in China. There have been more occurrences of melamine contamination in China, including the finding of it in eggs. To date, no illnesses have been reported in the United States from products contaminated with melamine. It should be noted that there have been recalls in the United States, and melamine is not approved for direct addition to human and pet foods. Therefore, no level is actually allowed, but the FDA has stated that less than 2.5 ppm in foods other than infant formula and less than 1 ppm in infant formula do not raise public health concerns. After the initial scare, the FDA pulled and tested samples of infant formula manufactured in the U.S. for the presence of melamine and its analogues, and found one with melamine and one with cyanuric acid, but at such low levels (below 1 ppm) that no health risk was issued.

The two main concerns for US manufacturers are 1) to know the origin of all milk-derived products and 2) to determine that milk-derived ingredients originating in China are free of melamine and its analogues. This includes any items that may have been imported before the import alerts were issued. Practicing established GMPs, many U.S. manufacturers have chosen to pull samples and have them tested for melamine and its analogues. In light of the severe issues in China, this testing is well worth the time and expense to insure our products are safe.

The following website is a valuable resource to locate information on recalls, import updates and information for food manufacturers: <http://www.fda.gov/oc/opacom/hottopics/melamine.html>.

To inquire about analysis of melamine and its derivatives, please contact FSNS at 817-228-9795 or sboleman@food-safetynet.com. ■

For questions or comments about this article, email jstuller@food-safetynet.com.