FSIS Testing Results for Melamine in Retail Meat and Poultry Products

Prepared by

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Introduction

The purpose of this exploratory assessment was to determine if melamine from imported food ingredients was present in meat and poultry products regulated by the United States Department of Agriculture, Food Safety and Inspection Service (USDA/FSIS). If melamine was found at or above the safety level, further testing for melamine compounds (MC) would be indicated.

Background

Melamine is an organic compound commonly used to produce various products, including dishes, plastic resins, and components of paper and paperboard that may come into contact with food. As a result, trace amounts of melamine and its three analogues, cyanuric acid, ammelide, and ammeline, referred to as melamine compounds (MC), may be present in food. The average concentration of melamine in food from approved industrial uses is estimated to be less than 0.015 parts per million (ppm).[1,2] These levels of melamine in food are extremely minute and do not pose a public health concern.[1] Intentional addition of melamine to foods, however, does pose a significant risk. In China, melamine was added to diluted milk in the manufacture of powdered infant formula. The adulterated infant formula resulted in 50,000 cases of kidney stones (and, in some cases, renal failure), mostly among children under three years of age. Many of these illnesses were severe, resulting in over 13,000 hospitalizations and at least six deaths. A national investigation by China's General Administration of Quality Supervision, Inspection and Quarantine revealed that over 22 companies produced powdered infant formula contaminated with melamine concentrations ranging from 0.1 ppm to greater than 2,500 ppm.[1, 2]

Prompted by public health concerns regarding potential melamine contamination of imported milk-derived food ingredients, the U.S. Food and Drug Administration (FDA), in collaboration with the USDA/FSIS, conducted a safety/risk assessment for melamine, and its analogues, in infant formula and in other foods. In food products other than infant formula, FDA concluded that levels of melamine and melamine-related compounds below 2.5 parts per million (ppm) do not raise public health concerns.[1,2] For infant formula, melamine levels, or one of its analogues alone, at or below 1.0 ppm do not raise a public health concern.[1] Subsequently, FSIS determined that it is prudent to sample retail meat and poultry products for the presence of melamine.

Methods

Overview

Meat and poultry products for sampling and testing were selected by collaboration between the Office of Policy and Program Development (OPPD) and the Office of Public Health Science (OPHS). Investigators from the Compliance and Investigations Division (CID), Office of Program Evaluation, Enforcement and Review (OPEER) collected the identified RTE products at retail stores while scientists at the Food Emergency Response

Network's (FERN) laboratory, OPHS analyzed the samples for the presence of melamine.

Laboratory Method

The Laboratory Quality Assurance Division (LQAD) verified and published method CLG-MEL1.01 *Determination and Confirmation of Melamine by LC/MS/MS* on November 6, 2008. The method's minimum proficiency level (MPL) is 0.050 ppm in ground beef and 1.0 ppm melamine in ready-to-eat (RTE) products. This method is validated for the determination and confirmation of melamine in ground beef at ≥ 0.050 ppm using triple quad and linear ion trap, and RTE products at ≥1 ppm using linear ion trap.[4] The MPL is the minimum concentration of a residue at which an analytical result will be used to assess a laboratory's quantification capability. This concentration is an estimate of the smallest concentration for which the average coefficient of variation (CV) for reproducibility (i.e., combined within and between laboratory variability) does not exceed 20 percent.[5]

Sampling

In early December 2008, protocol and notice development began. A sample size of 500 was determined to be sufficient. This number was obtained with statistical support from the Microbiology Division (MD), OPHS. A major factor in deriving this sample size was the assumption that milk ingredients would be uniformly distributed throughout the food industry. FSIS was scheduled to collect and test approximately 45 samples per week over a 12-week period. This would result in approximately 540 samples and would account for any inconsistencies in sample collection, shipment, or analysis.

The sampling plan developed and executed by CID is reflected in Table 1. The specific products submitted for laboratory analysis are reflected in Table 2. The products selected for this exploratory assessment were based on the FDA Import Alert 99-30, Nov 12, 2008 [6] and were limited to five categories of RTE meat and poultry products containing milk ingredients such as non-fat dried milk, casein, whey, evaporated milk, and milk powder. The five categories were: 1) baby food (containing a significant amount of meat or poultry products); 2) cooked sausages (including hot dogs or frankfurters with and without cheese products); 3) breaded chicken (bite-sized morsels or nuggets with and without cheese products); 4) meatballs; and 5) Dough Items (e.g., meat and poultry products, such as stuffed sandwiches and snacks, enrobed in dough).

FSIS Notice12-37 [7] was published December 11, 2008 and sample collection began on December 15, 2008. Testing began shortly thereafter and finished the week of April 5, 2009.

Table 1: Melamine Sampling Plan (number and type of sample collected)

	Monday	Tuesday	Wednesday	Thursday	Friday
WEEK	**Western**	**Southwest**	**Midwest**	**Southeast**	**Northeast**
1	2 - Meatballs 2 – Baby* 2 – Sausage** 2 – Pizza*** 1 – Nuggets****	2 - Meatballs 2 - Baby 2 - Sausage 2 - Nuggets 1 - Pizza	2 - Meatballs 2 - Baby 2 - Pizza 2 - Nuggets 1 - Sausage	2 - Meatballs 2 - Sausage 2 - Pizza 2 - Nuggets 1 - Baby	2 - Baby 2 - Sausage 2 - Pizza 2 - Nuggets 1 - Meatballs
2	2 - Meatballs 2 - Baby 2 - Sausage 2 - Pizza 1 - Nuggets	2 - Meatballs 2 - Baby 2 - Sausage 2 - Nuggets 1 - Pizza	2 - Meatballs 2 - Baby 2 - Pizza 2 - Nuggets 1 - Sausage	2 - Meatballs 2 - Sausage 2 - Pizza 2 - Nuggets 1 - Baby	2 - Baby 2 - Sausage 2 - Pizza 2 - Nuggets 1 - Meatballs
3	2 - Meatballs 2 - Baby 2 - Sausage 2 - Pizza 1 - Nuggets	2 - Meatballs 2 - Baby 2 - Sausage 2 - Nuggets 1 - Pizza	2 - Meatballs 2 - Baby 2 - Pizza 2 - Nuggets 1 - Sausage	2 - Meatballs 2 - Sausage 2 - Pizza 2 - Nuggets 1 - Baby	2 - Baby 2 - Sausage 2 - Pizza 2 - Nuggets 1 - Meatballs
4	2 - Meatballs 2 - Baby 2 - Sausage 2 - Pizza 1 - Nuggets	2 - Meatballs 2 - Baby 2 - Sausage 2 - Nuggets 1 - Pizza	2 - Meatballs 2 - Baby 2 - Pizza 2 - Nuggets 1 - Sausage	2 - Meatballs 2 - Sausage 2 - Pizza 2 - Nuggets 1 - Baby	2 - Baby 2 - Sausage 2 - Pizza 2 - Nuggets 1 - Meatballs
5	2 - Meatballs 2 - Baby 2 - Sausage 2 - Pizza 1 - Nuggets	2 - Meatballs 2 - Baby 2 - Sausage 2 - Nuggets 1 - Pizza	2 - Meatballs 2 - Baby 2 - Pizza 2 - Nuggets 1 - Sausage	2 - Meatballs 2 - Sausage 2 - Pizza 2 - Nuggets 1 - Baby	2 - Baby 2 - Sausage 2 - Pizza 2 - Nuggets 1 - Meatballs
6	2 - Meatballs 2 - Baby 2 - Sausage 2 - Pizza 1 - Nuggets	2 - Meatballs 2 - Baby 2 - Sausage 2 - Nuggets 1 - Pizza	2 - Meatballs 2 - Baby 2 - Pizza 2 - Nuggets 1 - Sausage	2 - Meatballs 2 - Sausage 2 - Pizza 2 - Nuggets 1 - Baby	2 - Baby 2 - Sausage 2 - Pizza 2 - Nuggets 1 - Meatballs
7	2 - Meatballs 2 - Baby 2 - Sausage 2 - Pizza 1 - Nuggets	2 - Meatballs 2 - Baby 2 - Sausage 2 - Nuggets 1 - Pizza	2 - Meatballs 2 - Baby 2 - Pizza 2 - Nuggets 1 - Sausage	2 - Meatballs 2 - Sausage 2 - Pizza 2 - Nuggets 1 - Baby	2 - Baby 2 - Sausage 2 - Pizza 2 - Nuggets 1 - Meatballs
8	2 - Meatballs 2 - Baby 2 - Sausage 2 - Pizza 1 - Nuggets	2 - Meatballs 2 - Baby 2 - Sausage 2 - Nuggets 1 - Pizza	2 - Meatballs 2 - Baby 2 - Pizza 2 - Nuggets 1 - Sausage	2 - Meatballs 2 - Sausage 2 - Pizza 2 - Nuggets 1 - Baby	2 - Baby 2 - Sausage 2 - Pizza 2 - Nuggets 1 - Meatballs
9	2 - Meatballs 2 - Baby 2 -Sausage 2 - Pizza 1 - Nuggets	2 - Meatballs 2 - Baby 2 - Sausage 2 - Nuggets 1 - Pizza	2 - Meatballs 2 - Baby 2 - Pizza 2 - Nuggets 1 - Sausage	2 - Meatballs 2 - Sausage 2 - Pizza 2 - Nuggets 1 - Baby	2 - Baby 2 - Sausage 2 - Pizza 2 - Nuggets 1 - Meatballs
10	2 - Meatballs 2 - Baby 2 - Sausage 2 - Pizza 1 - Nuggets	2 - Meatballs 2 - Baby 2 - Sausage 2 - Nuggets 1 - Pizza	2 - Meatballs 2 - Baby 2 - Pizza 2 - Nuggets 1 - Sausage	2 - Meatballs 2 - Sausage 2 - Pizza 2 - Nuggets 1 - Baby	2- Baby 2 - Sausage 2 - Pizza 2 - Nuggets 1 - Meatballs

*Baby Food, **Cooked Sausage, ***Dough Items (e.g., meat and poultry products, such as stuffed sandwiches and snacks enrobed in dough), and ****Breaded Chicken.

Table 2: Specific Products Collected and Submitted for Laboratory Analysis

Product Collected	Number Submitted for Laboratory Analysis
Meatballs	107
Dough Items*	110
Cooked Sausages	108
Breaded Chicken	106
Baby Food	112
Total	**543**

* "Dough items" are meat and poultry products (such as stuffed sandwiches and snacks) enrobed in dough.

Results

Table 3 lists a total of 543 samples that were collected by CID and sent to the FERN laboratory for melamine analyses. Two samples were not analyzed and two samples were not received by the laboratory. A total of 539 samples were analyzed by the FERN laboratory and all were reported as "not detected" (i.e., test results were below the 1.0 ppm MPL). Eight samples tested positive for melamine (range: 0.013 ppm to 0.256 ppm) had test results well below the MPL of 1.0 ppm for the test method and were, therefore, reported as non-detects. The presence of melamine at levels much below the MPL can be detected because they are within the calibration curve used for quantification. The calibration curve is based on standards (fortified samples) and aims to cover a wide range around the MPL.

Table 3: Number of Samples Analyzed and Laboratory Results

Number of Samples Analyzed	Laboratory Results
543	Total submitted for analysis
02	Not analyzed*
02	Not received **
539	Not detected***
00	At or above public health level of concern****

* *These two samples were raw dough samples: Chicken Sausage Calzone and Piroshkies Chicken, Rice, and Cheese. The method was validated on ready to eat products or cooked products or items that only need heating. The method was validated using hot dogs, chicken nuggets, baby food, meatballs, and sausages. No uncooked item or dough items were used during the validation; therefore, these two samples were not tested. New instructions were developed on how to analyze these types of samples.*

** *Two samples were not received by the FERN laboratory and therefore, could not be analyzed.*

****All below the 1.0 ppm minimum proficiency level of the test method.*

***** No foods contained melamine at or above the level of public health concern established by the U.S. Food and Drug Administration (2.5 ppm for foods; 1.0 ppm for infant formula).*

Summary of Findings

The Food Safety and Inspection Service collected 543 retail samples of ready-to-eat meat and poultry products to test for the presence of melamine. Five hundred and forty-one of these samples arrived at the laboratory and two of these were discarded as inappropriate for analysis. Of the 539 samples tested for melamine, 531 samples were negative. The positive samples had melamine concentrations that were well below the level of public health concern (2.5 ppm for food and 1.0 ppm for infant formula, respectively) established by the U.S. Food and Drug Administration. No meat and poultry products tested by FSIS for melamine posed a public health concern.

References

1. United State Food and Drug Administration, Center for Food Safety and Applied Nutrition. *Interim Safety and Risk Assessment of Melamine and Its Analogues in Food for Humans*. October 28, 2008. Website: http://www.cfsan.fda.gov/~dms/melamra3.html
2. United State Food and Drug Administration, Center for Food Safety and Applied Nutrition. *Update: Interim Safety and Risk Assessment of Melamine and Its Analogues in Food for Humans* Melamine Safety. November 28, 2009. Website: http://www.cfsan.fda.gov/~dms/melamra4.html
3. United State Food and Drug Administration, Center for Food Safety and Applied Nutrition. *Interim Melamine and Analogues Safety/Risk Assessment*. May 27, 2007. Website: http://www.cfsan.fda.gov/~dms/melamra.html
4. United States Department of Agriculture, Food Safety and Inspection Service, Office of Public Health Science (November 6, 2008). Determination and Confirmation of Melamine by LC/MS/MS. Website: http://www.fsis.usda.gov/PDF/CLG_MEL_1_00.pdf
5. United States Code of Federal Regulations. Title 9: Animal and Animal Products. Section 439: Accreditation of Non-Federal Laboratories. Website: http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=5806299c7e6297e0326a3fcbcf6f5f11&rgn=div5&view=text&node=9:2.0.2.4.43&idno=9
6. United States Food and Drug Administration, Office of Regulatory Affairs. 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*. Revised on February 23, 2009. Website: http://www.fda.gov/ora/fiars/ora_import_ia9930.html (accessed May15, 2009
7. United States Department of Agriculture, Food Safety and Inspection Service. FSIS Notice 97-08: Melamine Testing of Retail Meat and Poultry Products. December 11, 2008. Website: http://www.fsis.usda.gov/OPPDE/rdad/FSISNotices/97-08.pdf