



Pet Food Recall

Exposing Holes in U.S. Food Safety Defenses

by Robert B. Nicholas, J.D.

Until recently, melamine, a minor industrial chemical, was largely unknown to the American public. Melamine is not approved for use as an ingredient in any food or drug for use in animals or humans in the United States.

In March of this year, melamine became a household name when a private label manufacturer of pet food announced what would turn out to be the beginning of the largest ever recall of cat and dog food. As the story unfolded over the next few months, it appears that melamine compounds¹ may have been deliberately added in China to wheat gluten and to rice protein concentrate and then exported to the United States for use in the manufacture of pet food. In a further demonstration of the interrelationship and vulnerability of the global food chain, some of the contaminated pet food was also used to feed swine and poultry intended for human consumption. An additional shipment of the contaminated rice protein was shipped to Canada, used to make fish food, and then supplied to U.S. commercial fishing operations and hatcheries. To date, federal scientists have concluded that any potential human food safety risk from consumption of animals that may have consumed the contaminated feed is “very low.”² The Food

and Drug Administration (FDA) also has concluded that there is no evidence that the tainted products have been directly added to food for human consumption.

Imported food now accounts for about 13 percent of the average American’s diet. In the new global economy, this percentage continues to increase. FDA inspects only about 1 percent of all imported foods.³ Chinese food imports to the United States amounted to about \$2.2 billion last year, up significantly over past years.⁴ While this most recent recall has focused attention on the vulnerability of the food safety system to imported food, additional recent recalls of *E. coli*-contaminated spinach originating in California and salmonella-contaminated peanut butter originating in Georgia have renewed questions about the sufficiency of the food safety laws. Not surprisingly, proposals to change the laws governing the safety of the human and animal food chain



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have been introduced again in Congress. It is unlikely, however, that Congress will vote to establish a new food safety agency, though some changes are likely to be made in this session as part of the reauthorization of user fees.

This article examines the recent pet food recall and ongoing investigation in the context of the calls for changes in food safety legislation. It begins with an anatomy of the recall: what do we know, when did we know it, and who did what?

The Recall

FDA reports it first learned that pet foods were sickening and killing cats and dogs on Mar. 14 and 15, 2007, when a private label manufacturer of pet food, Menu Foods, Inc., notified FDA it was recalling certain “wet” pet foods manufactured between Dec. 3, 2006 and Mar. 6, 2007. In response to consumer complaints, Menu Foods conducted studies of its pet food in February 2007. The results of these studies prompted the recall. The manufacturer's tests showed that some cats and dogs developed kidney failure after eating the affected product and that nine cats died in the trials.⁵ While the cause of the kidney failure had not been determined at that time, Menu Foods informed FDA that it had changed suppliers of one ingredient during the relevant time frame. That ingredient was wheat gluten, used as a thickening agent in the pet food gravy.⁶

As FDA traced the suspect ingredi-

ent back and forward through the importation and distribution chain, FDA and various manufacturers identified additional potentially contaminated pet food products and announced further recalls between Mar. 16 and May 23, 2007. As the investigation continued, an additional melamine-tainted ingredient, rice protein concentrate, from a different Chinese supplier, was also implicated, leading to further pet food recalls. The recall ultimately involved 18 companies and 153 brands of dog and cat food, representing 5,000 different products in about 60 million containers.⁷

Finding the Trail

In November 2006, a U.S. food broker, Chem Nutra, Inc., imported a shipment of wheat gluten from Xuzhou Anying Biologic Technology Development Company. A second U.S. broker, Wilbur-Ellis, Inc., imported a shipment of rice protein concentrate in early April 2007 from a different Chinese firm, Binzhou Futian Biotechnology Technology, Ltd.⁸ Neither product was imported for use in human food.⁹ Both shipments reportedly met the customer's specifications and came with “certificates of analysis” (COA). We do not know whether the brokers and the manufacturers who subsequently used the ingredients merely relied on the COAs or conducted independent testing or other quality control measures to assess the safety of the ingredients received. Both shipments would turn out

to be contaminated with melamine.¹⁰

The brokers distributed the imported products to pet food manufacturers, including Menu Foods, a Canadian-based manufacturer. Two of Menu Foods' U.S. facilities received the tainted gluten and used it to produce pet food that was distributed nationwide under various well-known store and national brand labels. Some of the pet food produced by Menu Foods and others wound up as an ingredient in animal feed when the manufacturers sold surplus pet food (pet food scraps) to animal feed manufacturers and feeding operations. This tainted animal feed was fed to chickens, turkeys and swine. Humans consumed meat from a small percentage of these animals before FDA discovered that the animals had been fed tainted pet food scraps. Other animals were withheld from slaughter for further testing.¹¹ Additionally, one of the brokers sold gluten from China to a fish food manufacturer in Canada, the shipment going directly from China to the Canadian company. The Canadian company sold the fish food containing the gluten to 198 firms in the United States, including two commercial fisheries who supply fish for direct public consumption and 196 hatcheries who supply fish for release into streams and lakes. Subsequently, the fish were cleared for human consumption. According to FDA, there is no evidence that the wheat and rice products were directly added in the manufacture of food for human consumption.

Identification of Melamine

FDA and Menu Foods identified pet food as likely causing the illnesses and deaths and gluten as the suspect ingredient, but it took several weeks after the recall began to pinpoint the contaminant. Cornell University,

conducting studies on behalf of Menu Foods, and FDA identified melamine as the contaminant in late March 2007. Further analysis in mid-April identified that melamine-related chemicals were also present.

The limited toxicological data on melamine indicate that melamine is not highly toxic, particularly in the doses found in the pet food and gluten samples. FDA and other scientists now believe that melamine and cyanuric acid combine to form crystals in the urine and kidneys of cats and dogs. This is thought to lead to kidney failure as the cause of illness and death in pets. FDA and the U.S. Department of Agriculture (USDA) have speculated that melamine may have been added to the imported products to mask the low protein content of the ingredients. Melamine is high in nitrogen, which is used as a surrogate marker to measure protein content. In mid-April 2007, FDA's laboratory also determined that the wheat gluten was misbranded and was in fact wheat flower.

Health Risk Assessment

The federal investigation initially focused on identifying all potentially contaminated products and preventing the product from being consumed by pets. Once FDA determined that the tainted pet food had been fed to animals used for human food, efforts began to identify and test the feed and animals who may have consumed the potentially tainted animal feed to determine whether there was any risk to animal health. Additionally, parallel efforts were undertaken to assess the potential risk to humans from consumption of food from animals who had been fed the tainted feed.

In addition to developing and validating test methods for detection

of melamine compounds in the gluten and concentrate, methods needed to be developed to test for the compounds in the pet food, animal feed and tissue of each species believed to have consumed the tainted feed. Using exposure and toxicity data available on the melamine compounds and standardized risk assessment methodologies, several federal

- In contrast to pets who ordinarily eat a single diet, humans eat many different foods. Therefore, even if meat contained a very low residue of melamine, it is not expected to result in a significant exposure to melamine. The federal risk assessment acknowledges several important data and information gaps.¹²

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agencies conducted a safety risk assessment. Several factors seemed critical in leading federal regulators to declare that the food products from animals that may have eaten tainted feed presented an "extremely low risk" to people, including:

- The amount of melamine compounds possibly consumed by people was very low because the melamine compounds found in the gluten and rice concentrate tested between 0.2 and 8.0 percent. Additionally, the gluten and rice protein concentrate constituted only a part of the pet food products, an even smaller fraction of the animal feed (5 percent), and a smaller, if any, residue in any meat product that may be consumed by humans;
- Melamine compounds are readily excreted in the urine of the food animals, so melamine accumulation in the tissue or fat of the animals is unlikely;
- There was no apparent illness in any of the food animals who may have consumed the tainted feed; and

Response: Import Alert and Investigation

Initially, FDA issued an import alert that focused on wheat gluten imported from the specific Chinese firm identified as the exporter of the wheat gluten. Ultimately, the alert was extended to all bulk vegetable protein (wheat gluten, rice gluten, rice protein, rice protein concentrate, corn gluten meal, corn by-products, soy protein, soy gluten and other proteins, including mung beans) exported from China to the United States.¹³ The import alert directed FDA's field staff to detain at import, without needing to conduct a physical examination, all such protein products originating in China. Detained products are not released until FDA is provided third-party laboratory data demonstrating that at least five consecutive shipments are melamine-compound free and the manufacturer is certified as inspected by the Chinese government's Administration of Quality Supervision, Inspection and Quarantine (AQSIQ) with adequate controls in place.¹⁴

A domestic “Protein Surveillance Assignment” also was initiated to proactively visit, in conjunction with state regulatory officials, manufacturers of animal feed and pet food using vegetable concentrate protein. The stated purpose of the program was to increase awareness of suppliers about the known risks of melamine contamination and to encourage testing of any vegetable protein products on site for melamine compounds. As part of this program, FDA sampled products of Chinese origin for testing.¹⁵

On May 30, 2007, FDA alerted livestock and fish/shrimp feed manufacturers about another voluntary recall of feed products believed to contain melamine compounds. The twist this time is that the source of the tainted products was homegrown. Melamine was reported to have been added as a binding agent in feed ingredients by an Ohio feed company, Tembec BTL SR Inc. Tembec manufactured and distributed feed for a Colorado company, Uniscope, Inc. Uniscope also manufactured and distributed feed using the tainted ingredients supplied by Tembec. Melamine was detected when Uniscope decided to test the feed ingredients it was buying, as FDA had been encouraging manufacturers to do.

In addition to testing by FDA and USDA’s Food Safety and Inspection Service (FSIS), the Department of Homeland Security’s Customs and Border Protection apparently has been sampling and testing imports of vegetable protein from China initially and subsequently from all countries.

Remaining Questions on the Recall

As of the end of May 2007, FDA’s investigation was continuing, and it is unclear:

- Who actually manufactured the melamine-tainted feed ingredients in China, whether the same manufacture supplied other U.S. sources, and when the spiking started;¹⁶
- Whether the melamine was deliberately added to enhance the apparent nutritional value of the gluten or accidentally contaminated the gluten and protein;
- Whether melamine is more widely used in the feed industry, in light of the most recent recall involving domestic use of melamine;
- What additional facts will be learned as the investigation continues; and
- What regulatory and enforcement actions will follow, if any. For example, will the domestic importers, food or feed manufacturers, Chinese suppliers¹⁷ or U.S. company involved in the latest recall be charged with violations of the Federal Food, Drug, and Cosmetic Act (FDCA) or other laws?

In the larger and more important context, the question remains as to what lessons can be learned from the recall in order to better secure the safety of the food and feed supply in the United States.

Proposals for Reform

The Senate passed in early May 2007 the Food and Drug Administration Revitalization Act to renew the FDA’s authority to collect drug and device user fees under the FDCA. The bill contains provisions intended to improve the surveillance and safety of the human and pet food supply.¹⁸ The bill also prohibits imports from foreign food facilities that deny access to U.S. food inspectors.¹⁹ While the user fee provisions are considered “must pass” legislation, prospect for House passage of the food safety

amendments less certain at this time. The House has introduced a companion bill that grants the FDA the authority to audit and certify the food safety programs of foreign governments.²⁰

As in past years, bills proposing the establishment of the Food Safety Administration, a single agency that would consolidate all food safety activity in the United States, have been introduced in the Senate and the House.²¹ Such legislation is not likely to pass.

Meanwhile, FDA’s Center for Veterinary Medicine (CVM) has been reviewing the animal feed safety system for some time. The latest public meeting was held on May 22, 2007. CVM works closely with state officials and the Association of American Feed Control Officials in establishing labeling and safety requirements for animal feed for food animals.

In addition to calls for a food safety super agency, other ideas being discussed include giving FDA mandatory recall authority; providing more coordination and resources for inspection and testing; establishing more stringent current Good Manufacturing Practices (cGMPs) for food manufacturers; establishing a surveillance system for animals to perform some of the same functions performed by the Centers for Disease Control (CDC) for humans; and placing more pressure on our trading partners.

Conclusion

Some will suggest that the current system worked well: the hazard was quickly identified; the recall was voluntarily initiated; the tainted product was traced back and forward; the public was kept informed; and humans had no adverse health effects. In the context of the present recall, even a more rigorous or frequent food inspection system would not likely have caught

the Chinese imports, which were not declared at export from China or import into the United States as for feed or food use. Others will readily challenge this assumption—questioning a system that appears to largely depend on the proverbial “canary in the mine” to identify a problem, rather than having a more robust sentinel system and more robust requirements for quality control at the supplier/manufacturer end, enforced with more regular inspections.

Given the apparent ease with which the mislabeled Chinese imports entirely skirted FDA’s jurisdiction upon entry and became widely disseminated, the fact that there does not appear to have been adverse human health effects may be more a matter of “luck.” A more malign intent, using a more toxic agent, might well have produced much more serious consequences.

Given the practical impossibility of testing every import shipment and domestic facility for every contaminant, it is impossible to establish a fail-safe system. Yet can we do more? Δ

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tion Service and Food and Drug Administration Expenditures, Hearing on Food Safety Before the S. Comm. on Agriculture, Nutrition, and Forestry, 106th Cong. 3 (2000) (statement of Lawrence J. Dyckman, Director, Food and Agriculture Issues Resources, Community, and Economic Development Division, GAO).

⁴ According to FDA’s Import for Refusal Reports for OASIS from May 2006 to April 2007, China, including Hong Kong, had 2,085 (2,003 + 82) shipments refused initial admission into the United States, more than any other country. India was a close second (2,050) followed by Mexico (1,831) and Canada (740). See FDA, IMPORT REFUSAL REPORTS FOR OASIS, http://www.fda.gov/ora/oasis/ora_ref_cntry.html (follow month and year and then follow country).

⁵ FDA has received about 17,000 complaints alleging sickness or death of pets who reportedly consumed recalled pet food. About 50 percent of the reports involved deaths, but it is unclear how many of the incidents can actually be attributed to consumption of the contaminated pet food. To date, only 14 cases have been confirmed (13 cats and 1 dog). FDA’s investigation is ongoing. Banfield, The Pet Hospital, has supplied FDA with information from its database showing that out of 237,844 dogs and cats examined in the first 3 weeks in April, 5 cats and 1 dog died as a result of eating a recalled food (0.003 percent morbidity rate). Banfield has 615 veterinary hospitals nationwide.

⁶ Wheat gluten is the principal protein component of wheat flour. Wheat gluten has many human and animal food uses, and it is GRAS affirmed for direct addition to human food. See 21 C.F.R. § 1322.

⁷ The Pet Food Institute, the manufacturers’ trade association, has stated that the potentially contaminated pet food recalled represents only 1 percent of the pet food supply.

⁸ Importation of rice protein from the Chinese company by the U.S. broker began in July to August 2006. The first report to FDA from the broker was in April 2007 when a shipment of rice protein also contained a bag stenciled with “melamine.”

⁹ According to the Chinese government, Xuzhou Anying declared the export to be for “non-food use” and, therefore, it was not subject to mandatory inspection by China before export.

¹⁰ Out of 700 hundred samples of pet food, rice protein and wheat gluten tested by FDA by early May 2007, 400 tested positive for melamine and/or melamine-related chemicals. All positive samples came from ingredients originating with the two importers. Samples tested positive contained from 0.2 to 8.0 percent melamine and melamine-related chemicals.

¹¹ When the contamination was traced to the feeding operations, the animals were placed on “withhold” from slaughter, either voluntarily by processors or under state authority. About 350 hogs and about 3 million chickens were consumed before they were identified to have eaten the contaminated feed. 30 million chickens were initially withheld from slaughter, out of the 9 billion slaughtered annually. All but 80,000 were quickly released by FSIS, which has jurisdiction over the processing and safety of meat and poultry. 56,000 hogs in 7 states were also withheld from processing out of about 100 millions hogs slaughtered annually. The hogs were released for processing by FSIS on May 15, 2007 and the remaining

chickens on May 18. Release was based on testing for melamine residues and the completion of an interim health risk assessment (RA). See *supra* note 3 (“Based on the currently available data and information, the results of the safety/risk assessment indicate that the consumption of pork, chicken, domestic fish, and eggs from animals inadvertently fed animal feed containing melamine and its analogues is very unlikely to pose a human health risk.”).

¹² As of mid-May 2007, validated methodologies have been developed to test for melamine and melamine-related chemicals in the raw materials (wheat gluten and rice protein concentrate), pet food, animal feed, and fish and hogs.

¹³ According to FDA’s FIARS database, China, when Hong Kong is included, has the most outstanding IAs, 39 (16 + 13), followed by Mexico (20), and Canada (16). See http://www.fda.gov/ora/fiars/ora_import_country.html.

¹⁴ From April 27 through May 17, 2007, 46 shipments of vegetable protein concentrate from China were detained. As of May 17, none had demonstrated to FDA by testing that the products did not contain melamine.

¹⁵ As of mid-May 2007, 63 samples had been collected in 6 states. 37 tested negative and the balance are pending test results or cannot be tested.

¹⁶ According to the Chinese government and FDA, it appears that Xuzhou Anying may have only been a broker and that the tainted product was manufactured by a third, as yet unknown, company.

¹⁷ By the time the FDA inspectors arrived in China to inspect the facilities of the Chinese suppliers, the facilities were cleaned out and closed. The owners were reportedly being held in custody by the Chinese authorities. FDA has stated that it is satisfied with the cooperation provided by the Chinese authorities. However, FDA was not given access to the suppliers for interviews.

¹⁸ See Food and Drug Administration Revitalization Act, S. 1082., 110th Cong. §§ 602, 603 (2007).

¹⁹ See *id.* at § 513.

²⁰ See Human and Pet Food Safety Act of 2007, H.R. 2108, 110th Cong. § 419 (2007).

²¹ See Safe Food Act of 2007, S. 654, 110th Cong. (2007); Safe Food Act of 2007, H.R. 1148, 110th Cong. (2007). Senator Richard Durbin of Illinois and Representative Rosa DeLauro of Connecticut are the bills’ sponsors. *Id.* One purpose of the proposed legislation is to remedy the “increasing volume of imported food, without adequate monitoring and inspection” under the existing federal food safety system. S. 654, § 2(a)(4)(C); H.R. 1148 § 2(a)(4)(C). The measure also contains a provision granting the Food Safety Administration mandatory recall authority, unlike the existing food safety system’s reliance on voluntary compliance. See S. 654, § 204(d)(2)(B); H.R. 1148 § 204(d)(2)(B).

¹ Initial testing indicated that melamine was the primary suspected toxic agent. Additional melamine-related chemicals have now been identified, including cyanuric acid, used as a pool cleaner in the United States, and ammeline and ammelide. Collectively, melamine and the related compounds are referred to as “melamine compounds.”

The facts presented in this article have been derived largely from various FDA press releases, press conference transcripts, and related technical documents. These documents can be found on FDA’s pet food recall web page at <http://www.fda.gov/oc/opacom/hottopics/petfood.html>. Generally, unless otherwise cited, all factual data comes from these sources.

² CFSAN, FDA, INTERIM MELAMINE AND ANALOGUES SAFETY/RISK ASSESSMENT (May 25, 2007), <http://www.cfsan.fda.gov/~dms/melamra.html>.

³ See *Food Safety: Overview of Food Safety and Inspec-*