JOINT REPORT OF THE COMMITTEE ON FEED SAFETY AND COMMITTEE ON FOOD SAFETY

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The Committees met in Joint Session on October 21, 2007 from 12:30 pm to 5:00 pm at John Ascuaga's Nugget Hotel, Reno, Nevada. Committee on Feed Safety Vice Chair Richard Sellers and Committee on Food Safety Chair Daniel Lafontaine presided. Five Committee on Feed Safety members, nine Committee on Food Safety members and 41 guests were welcomed to the meeting by Sellers and Lafontaine. They introduced this year's topic, Melamine Contamination of Animal Feed – Lessons Learned and Future Impact. After welcoming remarks, the Chairs discussed the intricate interrelationship between feed safety and food safety during the melamine contamination incident in the spring of 2007. This interrelationship prompted the decision to conduct a joint session at this year's meeting. Following the Chairs' remarks, the Committee received a series of presentations offering perspectives of the incident from the United States Food and Drug Administration (FDA); the United States Department of Agriculture (USDA), Food Safety and Inspection Service (FSIS), field operations and the laboratory system; the feed industry; and a state directly impacted by the incident.

The first Committee presentation offered the FDA, Center for Veterinary Medicine (FDA-CVM) perspective. It was delivered jointly by Drs. Lynn Post and Randall Lovell. Dr. Post is the Director for the Division of Surveillance, Office of Surveillance and Compliance at FDA-CVM. Dr. Lovell is a Veterinary Medical Officer in the Division of Animal Feeds, Office of Surveillance and Compliance. They detailed the timeline and findings of the FDA as related to working with affected manufacturers and the Chinese government during a pet food recall prompted by the discovery of melamine contamination in pet foods. In mid-March, FDA received reports from a pet food firm that animals fed the firm's pet food in a palatability study died. Subsequent to this, FDA received 18,000 consumer complaints in two and one half months from pet owners claiming animals had died or were seriously ill from consumption of various pet foods. This is compared to the approximately 6,000 complaints per year the agency receives for all their regulated products. The agency continues follow-up on these complaints, which is made difficult by the frequent lack of veterinary involvement and/or reliable diagnostic testing or post mortem examinations. Working with corporate toxicologists, FDA and several state veterinary diagnostic labs discovered the toxic substance in pet foods was not melamine alone. Rather, it was melamine combined with

cyanuric acid to form an insoluble compound, melamine cyanurate, which forms crystals. Melamine and some of its analogs, one of which is cyanuric acid, was found to have been added to wheat gluten and rice protein concentrate. It is theorized that this was done to boost the protein levels in the ingredients imported from two firms in China. The melamine cyanurate was found to crystallize in kidney tubules, sometimes causing uremic toxicity, especially in cats. Further forensic studies by FDA determined that the ingredients imported as wheat gluten and rice protein concentrate were, in fact, both predominately wheat flour to which had been added melamine which breaks down to several metabolites including cyanuric acid, ammeline and ammelide.

Subsequent to this discovery, several pet food manufacturers reported distributing melamine contaminated pet food scraps to poultry and swine producers for incorporation into the feed for these animals. This was found to be a common practice for product that was not deemed suitable for the retail market, but was considered to have favorable nutritional attributes for animal feed, especially monogastric animals. Another firm reported that it had used melamine in place of urea-formaldehyde as a pellet binder used in aquaculture feeds. FDA required withdrawal of any aquaculture feed containing the binder, as well as any remaining binder. Many data sets showing the results of pet food analyses were presented. This was done to establish the thought process used to determine parameters for Class I, II and III recalls during this incident. Briefly, a Class I recall is declared for a situation in which there is a reasonable probability that the use of, or exposure to a violative product will cause serious adverse health consequences or death. A Class II recall is a situation in which use of, or exposure to a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote. A Class III recall is a situation in which use of, or exposure to a violative product is not likely to cause adverse health consequences. For this incident, FDA determined that a Class I recall for wet (>80% moisture) pet food was >100 parts per million (ppm) melamine provided that the wet pet food also contained similar levels of cyanuric acid. A Class II recall was established 33-100 ppm for wet pet food. A wet pet food containing less than 33 ppm of melamine was considered a Class III recall. For dry dog food, a Class I recall was >440 ppm melamine, Class II was >145 - 440 ppm and <145 was considered a Class III recall.

As a result of this event, FDA posted considerable information on its website regarding the recall, including the recalled products, analytical methodology and other relevant information. Also, FDA held many media conference calls, working with interested stakeholders and state counterparts. The agency mobilized twenty district offices and four hundred employees. FDA created a new assistant commissioner for food security after this event. One of the concluding recommendations of the presentations was that FDA needs to develop a better dialogue between the agency and state health officials rather than simply issuing proclamations.

Kenneth Petersen, Assistant Administrator, Office of Field Operations, Food Safety and Inspection Service (FSIS), USDA, was scheduled to present the USDA-FSIS field operations perspective on this incident. Due to a last minute conflict, he was unable to attend. However, Patrick McCaskey, Executive Associate for Laboratory Services, Office of Public Health and Science, USDA-FSIS presented Petersen's remarks for him. His remarks were presented in a chronological format of the five most critical weeks of the incident.

Week 1: For FSIS, the melamine contamination event started on April 17, 2007 when FDA alerted FSIS to the possibility that hogs had been fed pet food waste containing melamine. It was reported that some hogs may have gone to slaughter. On April 19th the FDA confirmed the presence of melamine in urine from 7 hogs.

Week 2: On April 26th, FSIS and FDA issued a joint press release announcing they had notified state authorities that eight pork producers had been identified who had purchased scrap pet food containing rice protein contaminated with melamine and related compounds and had fed it to their pigs. Several facts were determined. First, there had been no reported ill effects from lab animal studies from melamine, with the exception of one study showing bladder tumors in a rat fed doses of melamine far exceeding their body weight. Second, melamine in wheat gluten or rice protein concentrate was a small component of pet food. Third, the contaminated waste pet food was only part of the feed that was fed to the hogs. Fourth, melamine is not known to accumulate in the bodies of hogs and is excreted in their urine. Fifth, even if present in pork, pork is only a small part of the average American diet. Sixth, probably based on these dilution factors, there is no evidence of harm to the hogs fed from the contaminated feed. Further, being unaware of any human illness caused by exposure to melamine or related compounds, a subsequent press release was prepared. On April 28th, FSIS and FDA issued a joint press release regarding the continued investigation into imported wheat gluten and rice protein concentrate which has been found to contain melamine and melamine-related compounds. Based on the information currently available, USDA and FDA stated that the likelihood of illness is very low and that no recall would be issued. Also on April 28th, an Emergency Operations Center (EOC) was stood up at FDA headquarters in Rockville, Maryland. This was an effort to resolve conflicting information and conflicting internal interests of the agencies. FSIS was in attendance for the next 10 days.

Week 3: On April 30th, FSIS and FDA issued another joint press release, the third release in five days, stating that the investigation of adulterated feed had been expanded to include poultry in the state of Indiana and additional swine in several states. The release stated that 30 broiler farms and eight breeder poultry farms in

Indiana were included. On May 1st, the agencies stood up a Fusion Cell at Department of Health and Human Services (DHHS) headquarters. The goal of this cell was to translate complex information into analyzed information that characterized the scope of the incident. Additionally, it was to allow the EOC to track and receive information without also having to generate reports. In six days the event had evolved from rice protein in a few on-farm pigs not in commerce, to the added issue of wheat gluten, and broilers, 2.7 million of which were in commerce. The media was now fully engaged on the issue. On May 3rd, FSIS and FDA held a joint press briefing to discuss developments connected to the investigation associated with adulterated feed which was fed to swine and poultry in several states.

Week 4: On May 7th, FSIS and FDA issued a joint press release announcing the results of a human health risk assessment conducted by scientists from five federal agencies. The key points of the release were that the assessment concluded that the health risk to humans was very low. Assuming consumption of potentially contaminated meat, the possible adulterant level was 2,500 times below the dose that was considered safe. FSIS and FDA held a joint press briefing on May 8th. This briefing announced that the scientific panel was reevaluating "the appropriate course of action regarding swine and poultry that consumed the contaminated feed." Specifically, they were now conducting an animal health risk assessment. It was also announced that Illinois was added to the list of states affected by the event. Internally, the agencies determined that the Fusion Cell, stood up on May 1, was not working. It was not achieving the desired effect of centralization and analysis of data. On May 9th, there was a Congressional hearing before the full House Committee on Agriculture. A food and feed importation hearing was also conducted. At the May 10th press briefing, the situation remained the same. FDA bore the brunt of the questioning at this briefing because of the focus on human health risk.

Week 5: On May 15th, FSIS and FDA held a joint press briefing and news release. Petersen announced that FSIS now had validated the test for the presence of melamine in swine. Consequently, hogs fed contaminated feed are safe for human consumption. The hogs that were on hold could be released for inspection and processing. The announcement further stated that a separate test was being developed for poultry. The FSIS and FDA joint press release of May 18th announced that approximately 80,000 birds being held on farms in Indiana would be released and approved for processing due to the results from a validated test for the presence of melamine in poultry.

From the initial notification to FSIS by FDA until the May 18th press release, the event took about four weeks to run its course. On June 14, the FDA science board concurred with the findings and methods.

McCaskey then presented his own remarks to the Committees in a presentation entitled Melamine Contamination: Lessons Learned, Future Impact. As the incident first started, it appeared that the laboratories would be uninvolved bystanders. Initial indications were that pigs had been fed contaminated feed on or about April 18th, but that the pigs that had consumed this feed were retained. However, the story quickly unfolded from there. Reports indicated that some hogs had been slaughtered and carcasses may have been released. The contaminated ingredient importation dates became unclear. Previously imported product was also potentially contaminated. Then poultry products were involved. The lab became fully engaged. The incident had been ongoing for several days in California. The California Animal Health and Food Safety Lab (CAHFS) reported a testing method sensitive down to 10 ppb of melamine in pork muscle. The immediate question from FSIS and FDA was how was the method validated? CAHFS sent their method to the FDA Forensic Chemistry Lab. However, FDA's lab didn't have the same equipment so they began work on separate methods. FSIS had a validated method but it was not currently supported by equipment or reagents and it lacked the required sensitivity. After numerous FSIS/ FDA/ CAHFS conference calls, several labs started identifying methods for melamine. The FSIS Western Lab (WL) began working on the CAHFS method. FDA later focused its efforts on fish feed methods. WL ran into problems immediately. It attempted to run CAHFS method liquid chromatography/mass spectroscopy /mass spectroscopy quadrapole (LC/MS/MS quadrapole). The extraction procedures were inefficient. They did not have the correct columns for LC/MS/MS quadrapole. They did not have the internal standard used in the CAHFS method. And they did not have a melamine standard. Consequently, FSIS shifted their focus and began using the Food Emergency Response Network (FERN) method validation Standard Operating Procedure, with a sensitivity of 10 parts per billion (ppb) as the target for the method.

While the lab efforts were progressing furiously, there were many ongoing concurrent activities. FSIS and FDA were conducting risk assessments in an effort to ascertain the correct level of concern. Challenges included a lack of data on human exposure, determining the levels in feed and determining the levels of significance in body tissues. Department of Homeland Security (DHS) input was sought. After two weeks of work and significant inter-lab collaboration on attempting to validate the 10 ppb protocol, risk assessment data was suggesting that sensitivity to that level was probably not required. The labs' focus shifted to initiating validation at the 50 ppb level based on established tolerance. On May 8th, the GC/MS method for feed was validated and posted on e-lexnet. The liquid chromatography/mass spectroscopy (LC/MS) method preliminary work was completed and they started the "official" pork method validation. Lab personnel worked overnight to complete the validation work (normally 3 days worth of work). On May 9th, FSIS submitted the modified CAHFS method to the FERN method validation

committee and started the validation process for poultry. On May 12th, FSIS was advised that they needed to redo the pork validation based on feedback from FERN Methods group. Finally, on May 14th, a FERN "Approved" validated method for Emergency Level 1, PORK was completed. This was followed on May 18th by a FERN "Approved" validated method for Emergency Level 1, POULTRY.

Experience gained during the incident revealed several issues:

- Lack of a validated method
- Lack of proper columns for the LC/MS
- Inadequate extraction procedures
- Lack of internal standards
- Lack of appropriate negative control samples

In this incident, the effects on public health were nil. But it highlighted many unresolved concerns. What if:

- Somebody intentionally wanted to hurt us…
- Had the time and money needed
- Used food as a vehicle
- Gained access to a variety of foods and/or the food distribution systems
- The agent was of significant public health concern and people became ill or died
- They used an unknown agent or combination of agents

There are over 80,000 chemicals; many biological, radiological agents; and over 50,000 food matrices. Any combination of these is possible. There is a lack of analytical methodologies and a lack of laboratory capacity to rapidly develop valid methodologies. This event shows that teamwork works, but significant continued efforts are needed.

Following Dr. McCaskey's remarks, three leaders in the feed industry provided their insight regarding the incident and detailed their actions and responses to findings by FDA and FSIS. Richard Sellers, Vice President of Feed Regulation and Nutrition, American Feed Industry Association (AFIA), explained his organization's actions and response to reports from USDA and FDA. He explained that his association's primary focus was to provide accurate, timely information to its members and to highlight the association's Safe Feed/Safe Food Certification Program to government. Further, AFIA is holding a National Dialogue on Import Ingredient Safety, November 28-29, 2007 to determine the best course of action for firms importing ingredients. The results of this meeting will be the development of draft guidance for the industry that will be presented to the FDA for action. AFIA has urged the federal government to partner with industry stakeholders in advocating and supporting third-party feed/food safety program. He also detailed the Food and Drug Amendments Act of 2007 (HR 3580), which contains multiple references to both human and pet food safety, specifically, Section 1003 details communication requirements to be followed during recalls of pet and human foods.

Nancy Cook, Vice President for Technical and Regulatory Affairs for the Pet Food Institute (PFI), provided insight into her institute's view of the melamine actions. She cautioned that she was not able to delve into extensive details due to pending lawsuits. She noted that this recall amounted to about one day's consumption of pet food throughout the United States. She expressed concern that FDA was unable to provide the industry updated information due to the fact it was conducting an investigation. She further noted that industry initiated a recall much more quickly than FDA would have done. She provided an interesting perspective about how a contamination incident of this nature could have gotten directly into the human food chain. Wheat gluten provides protein and assists in holding the shape of many products, not just pet food. About 600 million pounds of wheat gluten is used in the United States annually and it only produces 20% of the total used. The pet food industry uses about 25 percent of the total 600 million pounds. So, it was essentially the luck of the draw this time that the contaminated gluten went into pet food. It begs the question of how many human food products are routinely tested for melamine. In closing, she detailed the formation of the National Pet Food Commission chaired by Angele Thompson. The commission consisted of a mixture of academics, industry experts and an FDA advisor. She will provide the report of the commission soon.

David Meeker, Vice President for Scientific Services, National Renderers Association, presented his organization's view on the issue focusing on his industry's Code of Practice. The rendering industry adopted the Rendering Code of Practice in 2004 to ensure that biosecurity is maintained and that finished products are safe and in compliance with all state and federal regulations and tolerances. The Code of Practice uses Hazard Analysis and Critical Control Points (HACCP)-like process control programs and good manufacturing practices that require (1) an evaluation of the entire rendering process; (2) identification of potential biological, physical, or chemical hazards; (3) identification of critical points in the process where the hazard(s) can be controlled; and (4) development of procedures to control these processes and ensure the hazard is eliminated or reduced to acceptable levels for each product. As of October 15, 2007, there are 63 plants (more than 80% of the rendering production capacity in the United States) certified in the Rendering Code of Practice by independent third party

auditors. He also noted that the rendering industry is part of the food industry too. Some of his organization's firms processed meat scraps that ended up in pet food that was subsequently caught up in the contamination incident and sent to poultry/swine farms.

Concluding the formal program, Clyde Hoskins, Assistant Director, South Carolina Meat-Poultry Inspection Department then presented, Melamine Contamination of Feed – State Perspective. For South Carolina, the melamine incident started on April 20, 2007 when the State Veterinarian was notified of two issues regarding potentially contaminated feed. First, some pet food scraps regularly purchased by a South Carolina hog farmer were from contaminated lots. Second, fifty-two hogs fed contaminated feed at a farm in North Carolina were delivered to a South Carolian slaughter house on April 19th. The hogs at the slaughter house were immediately retained. Feed samples were collected by South Carolina Department of Agriculture, under FDA contract. Samples from the pet food plant (collected previously) had tested positive for melamine contamination. Three feed samples were collected from the farm on the 20th. A trace forward was initiated on forty-one hogs shipped from the hog farm. Fifteen hogs went to a South Carolina-inspected slaughter and processing facility. The owner verbally agreed to voluntary restriction, suspending further hog movement. Signed affidavits from the hog farmer stated that, based on production and delivery dates, contaminated feed was not fed to his hogs. On-site visits by state meat-poultry inspection compliance officers supported the farmer's statement. Thirteen urine samples were collected from the South Carolina hog farm and delivered to a FERN lab in Richmond, Virginia. The urine sample results were reported as positive; ranging from 184 ppb – 3 ppm. But the three feed sample results, from the farm, were reported as negative by the FDA lab in Atlanta. Written confirmation was requested. The significance of these results was undetermined during a State-requested FSIS/ FDA/ State conference call. On April 26th, FDA reconfirmed that the initial feed sample tests from the hog farm were negative, but were now deemed incomplete. Further testing was directed by FDA-Washington, using a revised testing protocol for melamine and melamine analogs. On the same day, USDA announced that compensation was going to be made available for depopulation of hogs exposed to potentially contaminated feed. Consequently, on April 27th the initial planning for depopulation of the hog farm in South Carolina began. Initial steps were animal inventory planning, pre-planning visits to land fills and initial contact to various affected agencies. On April 30th the hogs at the slaughter facility were ear tagged and shipped from the South Carolina slaughter facility back to the North Carolina farm of origin under Animal and Plant Health Inspection Services (APHIS) seal. At that time, they had been retained at the slaughter facility for eleven days. On May 2nd, USDA-APHIS-Veterinary Services and Clemson University Livestock Poultry Health (CULPH) personnel inventoried the hogs on the farm to assist in determining depopulation compensation. A full depopulation planning meeting was held later that day. Primary stakeholders present included: the State Veterinarian, USDA-APHIS, CULPH, South Carolina Department of Health and Environmental Control, Public Affairs POCs, and the County Sheriff's Department. It was noted that similar efforts were in various stages in other affected states. On May 7, 7:00 a.m., a joint USDA-FDA press release announced that hogs on farms with negative fed samples could be released for inspection and processing, citing a "… very low risk to human health." However, hogs on farms with positive or undetermined feed samples should continue to be withheld from processing. Depopulation compensation was suspended, pending completion of an animal health risk assessment. During a conference call that afternoon, the South Carolina State Veterinarian requested clarification of the status of hogs on the South Carolina farm. During that conference call, another call advised that further testing of feed samples from the South Carolina farm revealed positive results for melamine and melamine analogs. Therefore, the hogs were to remain on voluntary restricted movement. Based on the May 7th press release, citing a "… very low risk to human health …" the State Veterinarian formally stated his position to FDA that he lacked legal authority to hold animals if the farmer ceased voluntary restriction. His state law states that he can hold animals "… which present significant health hazard to humans …" On May 11th, USDA-FSIS was advised of the State Veterinarian's position. The response was that an announcement clarifying the situation would be issued soon. On May 15th USDA and FDA announced that hogs fed contaminated feed are safe for human consumption and can be released and approved for processing. The hog farmer was contacted. Hogs were released for movement after twenty-six days of voluntary restriction. On May 17th the ear-tagged hogs from the North Carolina farm were returned to the South Carolina slaughter facility for processing.

The direct impacts on South Carolina were:

- Over five hundred hogs were voluntarily restricted from movement for 26 days. There was an associated decrease in market value, added feed costs, compensation delays and difficulty in subsequent marketing due to public perception.
- Fifty-two hogs retained at South Carolina slaughter house for 11 days. Direct costs and public perception were factors.
- Meat from 15 hog carcasses at South Carolina plant was held for 22 days (frozen).

Indirect impacts were associated with incident management. There was frustration and difficulty in getting information and updates. This led to complications in assessing of breadth and scope of the problem.

Coordinating for the planned depopulation, while an interesting exercise, ended up being a significant manpower drain. There were delays in providing compensation to the affected farmer. Sample testing, method validation and result interpretation all led to confusion and concern.

Recommendations stemming from this event are:

- Implement ICS early and include affected states in assessment and planning.
- Establish clear chains of command and lines of communication.
- Coordinate press releases with affected states since they must deal with the media also.
- Consider the impact of national level decisions on local news releases.
- Resolve the issue of authority to initiate restricted movement, quarantines, etc.

There was subsequent discussion about how states and the federal government could cooperate better and share information in future incidents that have heavy state involvement. Chair Lafontaine provided summary comments of the day's presentations.

In a separate meeting, the Committee on Feed Safety heard a report on the recent Joint Expert Meeting on the Impact of Animal Feed on Food Safety and the World Organization for Animal Health (OIE) report on feed safety. There was also a note on the Codex Alimentarius Commission's (CAC) circular letter that requests comments by March 2008 regarding the formation of a new working group on good animal feeding. A Code of Good Animal Feeding Practice was approved at by the CAC in 2004.