DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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STATEMENT OF
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BEFORE THE
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U.S. HOUSE OF REPRESENTATIVES

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INTRODUCTION

Good morning, Mr. Chairman and Members of the Committee. I am Dr. David Acheson, Assistant Commissioner for Food Protection at the U.S. Food and Drug Administration (FDA or the Agency). Commissioner von Eschenbach has charged me, in this newly created position, with providing advice and counsel on strategic and substantive food safety and food defense matters, and serving as a liaison from his office to the Department of Health and Human Services, of which we are a part, and to other Federal Departments and agencies.

Thank you for the opportunity to discuss FDA's response to the importation of contaminated animal feed ingredients and the impact of this incident on food safety and animal health. I am pleased to be here with my colleague, Dr. Kenneth Petersen, from the U.S. Department of Agriculture (USDA).

FDA's COMMITMENT TO FOOD SAFETY

FDA's primary mission is to protect the public health. Ensuring that FDA-regulated products are safe and secure is a vital part of that mission. The Agency regulates everything Americans eat except for meat, poultry, and processed egg products, which are regulated by our partners at USDA. FDA's responsibility extends to live food animals and animal feed.

FDA is committed to ensuring that America's food supply continues to be among the safest in the world. But we face significant challenges. One of those challenges is the rapid increase in the volume of imported products. The volume of FDA-regulated imports has doubled in the last five years, and 60 percent of these imported shipments are food. Currently, there are over 10 million entries of imported food annually and most are large volume commercial shipments. It is estimated approximately 15 percent of the U.S. food supply is imported, but for some products such as fresh fruits, imports account for 50 to 60 percent of the supply.

Another challenge is the significant increase during the past decade in the consumption of produce, particularly "ready-to-eat" products. This is a positive development from a nutrition perspective, but it represents a new dynamic that challenges our food safety efforts. Americans usually consume these products in their raw state, harvested from the vine, stem, or soil and with minimal or no additional processing to reduce or eliminate any pathogens that may be present. Consequently, the manner in which these products are grown, harvested, packed, processed, and distributed is crucial to ensuring that microbial contamination is minimized, and the risk of illness to consumers is reduced. If even a small percentage of a harvest is contaminated, severe and widespread illness can result.

In response to the recent produce-related outbreaks, FDA has sharpened its focus in this area. To reduce the risk of foodborne illness at all points in the food chain, FDA has adopted a "farm-to-fork" approach to food safety. This approach systematically applies

risk management principles at each step as food moves from growers and producers to consumers. In view of the recent recalls involving wheat gluten and rice protein concentrate in various pet foods, FDA, in conjunction with other Federal and state regulatory authorities, is testing for the presence of melamine and other potential contaminants in a variety of plant protein ingredients and finished products commonly found in the U.S. food and feed supply.

The Agency is focusing and renewing its food safety efforts in three key areas: strengthening the scientific basis for FDA's food safety program, enhancing effective partnerships, and improving risk-based targeting of inspection resources. To enhance the safety of all human and animals foods, domestic and imported, we work closely with states, produce growers, processors, and distributors to develop and implement programs at each point in the supply chain to prevent and minimize contamination from, for example, harmful micro-organisms. In March and April of 2007, FDA held two public hearings to share information about recent outbreaks of foodborne illness associated with microbial contamination of fresh produce, and to solicit comments, data, and additional scientific information on this issue. We are soliciting input from all our stakeholders on ways to improve the safety of fresh produce.

FDA is examining recent incidents of foodborne illness and product contamination to determine what additional changes may be necessary to improve the safety of food, including animal feed. In order to better address the food safety challenges we are facing, we will pursue a vision of FDA as a multi-disciplined, science-led organization

that can lead the world in food safety and disease prevention while promoting the highest standards for public health.

ANIMAL FEED CONTAMINATION

Overview

FDA's investigations into contaminated pet food and farm animal feed are an ongoing priority for the Agency which continues unabated. The information presented herein is accurate as of this date, but we note that as we obtain more investigative and scientific information, preliminary assumptions and conclusions have changed, and may continue to do so. The investigations that began in March 2007 have revealed that the sources of the contamination were imported pet food ingredients, which contained the industrial chemical melamine and melamine analogs. So far, FDA has received thousands of reports of pet illness that owners suspect are connected with the consumption of contaminated pet food. Moreover, FDA has determined that production waste (also referred to as salvage) from the pet food manufacturing process involving these contaminated ingredients was used as an ingredient in animal feed for hogs and chickens.

At this point in time, FDA has identified the Chinese supplier, the importer, and all of the parties directly involved with the distribution of commercial pet food containing wheat gluten contaminated with melamine and melamine analogs. The Agency has conducted investigations at all pet food manufacturers that have used such wheat gluten and all have initiated recalls, the scope of which have evolved as the investigations progressed and

new information was learned. In mid-April, FDA became aware of a suspicious shipment of a product identified in labeling and import entry records as rice protein concentrate that was also used in the manufacture of pet foods. Upon inspection, FDA detected the presence of melamine and melamine analogs in the imported rice protein concentrate and the finished pet food. Some of this contaminated pet food was unknowingly sent as salvaged feed to various hog producers in several states. Additionally, FDA has learned that salvage from pet food manufactured with contaminated wheat gluten was used in chicken feed on some farms in the states of Indiana, Missouri and Arkansas.

FDA, in consultation with our colleagues from the USDA's Food Safety and Inspection Service (FSIS), and the Centers for Disease Control and Prevention (CDC) believes that the likelihood of human illness from eating products containing pork or chicken fed the contaminated feed is very low, in large part due to the considerable dilution of the contaminants. Because there is no evidence of harm to humans, no recall of products processed from these animals has been issued.

FDA is conducting a thorough investigation of the pet food and farm feed contamination. During the past eight weeks we have aggressively worked to identify the source and scope of the contamination, to assure the removal of all contaminated products from the supply chain and store shelves, and to keep the public informed. As an added precaution, we have asked CDC to use its surveillance network to monitor for signs of human illness, such as increased renal failure, which could indicate contamination of the

human food supply. Testing and the joint FDA/FSIS investigation continue. If any evidence surfaces to indicate there is potential harm to humans, appropriate and aggressive action will be taken.

FDA Regulation of Pet Food & Farm Animal Feed

The Federal Food, Drug, and Cosmetic Act (FFDCA) requires that pet foods, like human foods, be safe to eat, produced under sanitary conditions, contain no harmful substances, and be truthfully labeled. In addition, canned pet foods must be processed in conformance with the low acid canned food regulations to ensure safety from harmful bacteria or their toxins. The law requires that the ingredients used in pet food are safe and have an appropriate function in the pet food. Some ingredients, such as many mineral and vitamin sources, colorings, flavorings, and preservatives, are generally recognized as safe. Other ingredients must have approval as food additives. Absent such approval, addition of such ingredients to a food product would likely result in the product being considered "adulterated" under the FFDCA.

Assisting the pet food industry with recalls of adulterated pet food is always a regulatory priority for FDA. FDA alerts the public, classifies the recall, and works with states and industry to identify the contamination source and underlying problem. FDA carefully examines the facts behind a pet food contamination, assesses whether actions taken by the firm were appropriate, monitors the effectiveness of the recall and if appropriate,

provides guidance for the industry to alert them of the problems identified and help prevent reoccurrence.

FDA works closely with state feed control officials in establishing standards for animal feed, including pet food products. FDA prioritizes and conducts risk-based inspections targeted toward products that pose the greatest risks to public health. However, inspections cannot identify every potential contaminant and they are only one aspect of our work to detect and contain potential safety problems. It is important for all participants in the production and distribution process to maintain the highest standards for safety to protect the American consumer, whether that consumer is human or animal. As with human food safety, FDA recognizes that we need to use strong science capable of identifying both the sources of risk and effective control measures. To that end, FDA is working to develop a risk-based Animal Feed Safety System that describes how animal feed production, distribution, and use can be designed to minimize risks to humans and animals. Information on the proposed Animal Feed Safety System is available through the FDA website *(http://www.fda.gov/cvm/AFSS.htm)*.

Investigation of Contaminated Pet Food Ingredients

FDA's investigation has been aggressive and comprehensive. As soon as FDA received word that cats and dogs were becoming sick and dying from certain pet foods, our first priority was to limit the risk of animal injury and death. Within 24 hours of being notified of the problem by Menu Foods, our investigators were on-site at the Menu Foods

Emporia, Kansas plant searching for the source of contamination. Our response to the pet food contamination has been a team effort in which the Agency has:

- dedicated personnel in each of its 20 district offices to take consumer calls and conduct inspections and investigations;
- mobilized more than 400 employees to collect pet food and animal feed samples, monitor the effectiveness of the recall, and prepare consumer complaint reports;
- conducted numerous inspections of manufacturing facilities and warehouses to trace all of the contaminated product;
- analyzed more than 700 pet food and ingredient samples in six FDA field laboratories and FDA's Forensic Chemistry Center;
- issued press releases, conducted media interviews, and developed a Web site to provide current information to consumers, veterinarians, and our regulatory counterparts;
- worked with its regulatory partners in all 50 state agriculture and health agencies to share information and collaborate on investigative and analytical efforts;
- activated its Emergency Operations Center, with staff available to all FDA offices on a 24-hour basis to manage incoming information from pet owners, veterinarians, and others; and
- dispatched an investigative team to China at the earliest opportunity.

FDA identified the supplier of the contaminated wheat gluten as a Chinese firm, Xuzhou Anying Biologic Technology Development Company, and we issued an import alert

providing for detention without physical examination of all wheat gluten imported from that firm to assure that contaminated product does not enter U.S. commerce. FDA's import controls have evolved as new information has been learned during the investigation. The import alert currently covers all vegetable protein products from China. All entries from China are detained by FDA upon arrival into the U.S. by FDA and not released into domestic commerce unless third party analysis demonstrates the entry is not contaminated with melamine or melamine analogs.

We have issued a high-priority domestic food defense protein surveillance assignment to our field staff to focus on imported protein extracts and finished products within the United States, and the Prior Notice Center directed assignments for ingredients and products of interest being imported to the United States (with the exception of corn, wheat and rice extracts, which are covered under a separate ongoing assignment).

Contamination of Hog Feed

On April 16, FDA began an additional investigation into product labeled and identified in import records as rice protein concentrate imported by San Francisco-based Wilbur-Ellis, an importer and distributor of agricultural products. The Agency detected the presence of melamine and melamine analogs in the imported rice protein concentrate, and found that it was used to manufacture pet food.

FDA determined that the product was supplied by Binzhou Futian BiologicalTechnology Company in China. Prior to expanding the import alert to cover all vegetable protein products from China, FDA immediately put this company on import alert to prevent any further introduction of adulterated ingredients. As it did with the wheat gluten from Xuzhou Anying, FDA also reviewed import records to ensure all importations originating from this company were identified and fully traced. FDA's investigation is ongoing in order to fully trace all contaminated products originating from Binzhou Futian.

Some of the contaminated pet food was sent unknowingly as salvage feed to various hog producers in several states, and some hogs were found to have levels of melamine in their urine. Pork producers in the states of California, Illinois, Kansas, North Carolina, New York, South Carolina, and Utah are known to have purchased the feed. Some of these animals are currently being held from commerce.

On April 26, FDA and USDA/FSIS notified state authorities that these hogs were not being approved to enter the food supply. Currently, hogs and poultry on farms suspected of receiving contaminated feed are being held under state quarantine or voluntarily by the owners. In several of these cases, feed samples have tested negative for melamine and related compounds. These tests were conducted by federal laboratories or state laboratories using approved methods. It is assumed that because only small amounts of the contaminated feed were mixed with other rations, the melamine and related compounds were no longer detectable. On May 7, the two agencies announced that a human health risk assessment had been completed with the input of scientists from FDA,

CDC and FSIS, as well as the Environmental Protection Agency and the Department of Homeland Security. FSIS has concluded that, based on the human risk assessment and the inability to detect melamine in the feed samples, animals on farms with a negative feed test no longer need to be quarantined or withheld from processing.

In other cases, animals continue to be withheld from processing, but are not yet being culled, pending the results of an animal risk assessment. These are cases where feed samples have tested positive for melamine and related compounds; feed samples were not available; or feed samples have not yet been submitted for testing.

Contamination of Chicken Feed

In late April, through further investigations, FDA and USDA learned that salvage feed from pet food manufactured with contaminated wheat gluten had been used in chicken feed on some farms in three states. At this time, the investigation indicates that approximately 30 broiler poultry farms and eight breeder poultry farms in Indiana received contaminated feed in early February and fed it to poultry within days of receiving it. All of the broilers believed to have been fed contaminated product have since been processed. The breeders that were fed the contaminated product are under voluntary hold by the flock owners. As with exposure from hogs fed contaminated pet food, and based on risk assessment, FDA and USDA believe the likelihood of illness after eating chicken fed the contaminated product is very low.

HUMAN HEALTH IMPACT

At this time, we have no evidence of harm to humans associated with the processed pork or poultry products. Testing and the joint investigation continue. If any evidence surfaces to indicate there is harm to humans, the appropriate action will be taken.

The assessment that, if there were to be risk to human health, it would be very low, is based on a number of factors, including the dilution of the contaminating melamine and melamine analogs from the original protein concentrates as they move through the feed system. With respect to hog or poultry populations, the contaminated rice protein is only one ingredient in the pet food; and it is only part of the total feed given to the hogs. Additionally, melamine and melamine analogs are not known to accumulate in the animals and the animals excrete melamine in their urine. Finally, pork is only a small part of the average American diet.

In addition to the dilutional factor and the lack of evidence of illnesses in the animals fed the salvaged pet food, we are not aware of any human illness that has occurred from exposure to melamine or its by-products. While the CDC detection systems would have limited ability to identify subtle problems due to melamine and melamine analogs, no such problems have been detected to date.

To further evaluate any potential harm to humans, FDA is developing and implementing additional tests and risk assessments based on the toxicity of the melamine and melamine

analogs and how much of the compounds consumers could be expected to actually consume. FDA has also begun testing a variety of protein ingredients and finished products commonly found in the U.S. food and feed supply for the presence of melamine and melamine analogs. Some of the protein concentrates being tested include wheat gluten, corn gluten, corn meal, soy protein, rice bran, and rice protein concentrate.

CONCLUSION

The animal feed investigation has been a massive effort drawing from many parts of FDA and it will continue until we are completely satisfied that the underlying cause has been determined, the scope identified, and corrective action is initiated and found effective. Many dedicated professionals from Federal and state agencies are working to respond to this contamination. USDA and FDA continue to conduct a full, comprehensive examination to protect the nation's food supply and will provide updates to the public as new information is confirmed.

FDA is working hard to ensure the safety of all food, including animal feed, in collaboration with our Federal, state, local, and international food safety partners, and with industry, consumers, and academia. In spite of the challenges which face us, the American food supply continues to be among the safest in the world. We have made significant progress, and we will continue striving to reduce the incidence of foodborne illness.

Thank you for the opportunity to discuss these important food safety issues with you. I will be glad to answer any questions you may have.