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Food manufacturers will face decisions in complying with FSMA's animal feed rule

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By Joan Murphy

Food manufacturers that divert product to animal feed markets will have to decide whether to follow animal feed or human food preventive controls under the Food Safety Modernization Act (FSMA) -- in just one of many complex compliance challenges posed by FDA's animal feed proposal issued Oct. 29.

Late last month, the agency released *Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals*, which mirrors many of the provisions in the human food proposal released earlier this year (see *FCN* Nov. 1, 2013, Page 1). The proposal, for the first time, establishes current good manufacturing practices (CGMPs) for animal feed facilities and requires domestic and imported feed firms to implement hazard analysis and preventive controls for animal products.

Members of the Grocery Manufacturers Association (GMA) were briefed Tuesday during a webinar on the latest FSMA proposal by Daniel McChesney, director of the office of surveillance and compliance at FDA's Center for Veterinary Medicine (CVM). McChesney, who headed the FSMA committee that drafted the animal feed rule, was also scheduled to speak at FDA's first public meeting on the animal feed rule in College Park, Md., on Thursday.

Under the new proposal, companies that make human foods, such as potato chips, may divert product to animal food markets based on quality issues and that firm has a choice to apply the human food preventive controls throughout the entire operation or apply just the animal food provisions to the animal side of the business. Companies will need to weigh the advantages and disadvantages of choosing the human food controls or having separate animal feed controls for ingredients sent to feed.

The decision will probably be based on the size of the animal feed segment and the degree to which the food is further processed into feed, McChesney said. If the potato chips are mixed with other ingredients for a feed product, the firm may want to look into developing a separate animal feed program, he advised.

When asked whether companies that donate products to animal feed manufacturers for a tax benefit or to avoid dumping it in a landfill would be forced to comply, McChesney refrained from answering the question and said he would look into it.

FDA wants the rule's CGMPs to be flexible for companies, so the agency is asking for comment on whether CGMPs should apply to pet foods where consumers may be exposed to potential contaminants and perhaps not in the case of feed mills.

Companies following the animal feed proposal will be required to conduct a hazard analysis for animal health, as

well as factor in the potential of secondary exposure for consumers in the case of pet food, he said.

Allergens and Nutrients

One difference between the two rules is that allergens, which are a hazard in the human preventive controls, are not considered a hazard for animal foods. But FDA does identify nutrient imbalance as a hazard in animals. The reason nutrient imbalance is identified as a hazard is that animals are fed a fixed daily diet and imbalances can lead to safety concerns, he explained. For example, too much or too little salt in poultry diets can become a health problem.

Another difference in the animal feed proposal is that FDA changed the threshold for very small businesses that manufacture animal feed. For human foods, FDA offers the following three possible options: $250,000, $500,000 or $1 million in corporate-wide annual sales. FDA bumps up the exemption for the feed industry to $500,000, $1 million, or $2.5 million in annual sales. These dollar figures represent the amount of revenue sold on the animal side and does not include human food sales in the calculation, McChesney said.

Feed plans will have to factor in intentional adulteration in their food safety plans as well as any known economically motivated hazards, he said. The proposal establishes new requirements for a written food safety plan, preventive controls for hazards that are reasonably likely to occur, recall plans, monitoring, corrective action, verification and recordkeeping.

McChesney said the feed proposal, just like the human food rule, asks for comment on product and environmental testing. Originally, these provisions were in the human food proposal but were removed during White House review for cost reasons and moved to an appendix for further comment.

Finished product testing may be appropriate for pet food, but the agency is looking for comment on whether there is any value in requiring finished product testing at feed mills. Environmental testing at a pet food processing facility makes sense, he said, because of the potential for consumers to handle a *Salmonella*-contaminated product. It may make less sense in a feed mill where the product is dumped on the ground, he said.

As it will do with other FSMA rules, FDA is proposing a final rule phase-in period based on business size. Very small business would have three years to comply, small businesses would have two years and all other businesses would have just one year to achieve compliance after publication of the final rule.

There may be some room for negotiating on the compliance dates. The animal feed industry says it's not sure about the timeframes and is suggesting an option of having companies follow the phase-in schedule for CGMPs first, and then give animal feed businesses one more year to comply with the rest of the law, McChesney said.

Some groups have already asked FDA to consider extending the Feb. 26, 2014 comment deadline.

"FDA is under a court order to have all comment periods closed by March 31. If there was an extension of comment periods, it really wouldn't be very long," he said.