

FSMA Hazard Evaluation Project to be Conducted by University of Minnesota

The American Feed Industry Association's foundation – the Institute for Feed Education and Research – has entered into an agreement with the University of Minnesota's Center for Animal Health and Food Safety to conduct a hazard evaluation of typical ingredients and processes associated with manufacturing and distributing animal feed and pet food that facilities may use to assist in meeting requirements established by FDA's preventive controls regulation for animal food under the Food Safety Modernization Act (FSMA).

Background on Need for Project: Hazard evaluation is the centerpiece of FDA's preventive controls regulation mandated under FSMA. Under the regulation, covered facilities – including feed and pet food manufacturers – are required to identify and evaluate, based upon experience, illness data, scientific reports, and other information, known or reasonably foreseeable hazards for each type of animal food manufactured/processed, packed, or held at the facility to determine whether there are “hazards requiring a preventive control.”

The hazard analysis is required to include an evaluation of the known or reasonably foreseeable hazards to assess: 1) the severity of the illness or injury if the hazard were to occur; and 2) the probability that the hazard will occur in the absence of preventive controls. The hazard evaluation also is required to consider the effect of the following on the safety of the finished animal food for the intended animal:

1. The formulation of the animal food;
2. The condition, function, and design of the facility and equipment;
3. Raw materials and ingredients;
4. Transportation practices;
5. Manufacturing/processing procedures;
6. Packaging activities and labeling activities;
7. Storage and distribution;
8. Intended or reasonably foreseeable use;
9. Sanitation, including employee hygiene; and
10. Any other relevant factors.

The determination of whether a facility's operation includes a “hazard requiring a preventive control” drives the facility's compliance obligations under the preventive controls regulation. If a facility can justify that it has no “hazards requiring a preventive control,” then its compliance obligations under the regulation are essentially complete.

However, if the facility identifies one or more “hazards requiring a preventive control,” the facility is required to implement a preventive control to address the hazard(s) and conduct extensive management activities to ensure the preventive control is effective. Such management activities include procedures and documentation for monitoring, validation, verification, corrective actions and recalls.

The Project: The University of Minnesota's Center for Animal Health and Food Safety's hazard evaluation of typical ingredients and processes associated with manufacturing and distributing animal feed and pet food will involve an extensive literature review and assessment. Dr. Tim Goldsmith, DVM, MPH, assistant professor at the University of Minnesota and co-director of the university's Veterinary Public Health and Preventive Medicine Residency Program, will be the project director for the hazard evaluation. Goldsmith also will be supported by several other staff members from the University of Minnesota.

In addition, and importantly, the project includes interaction and meetings with FDA officials to discuss the scope and framework of the work in an effort to maximize the degree to which the results will be credible with the agency. Another potential benefit of being associated with the project is that its results could provide a strong scientific basis to influence the hazard guidance currently being developed internally by FDA, which likely will be released in draft form by late 2016. For instance, if FDA's draft guidance characterizes a given hazard in a way that is unfavorable to industry, the University of Minnesota's results potentially could be used by industry during comments to FDA to affect change in the agency's final guidance.

Project Cost: The cost of the project is not-to-exceed \$169,000 for the University of Minnesota's literature review and analysis, plus \$10,000 for scientific peer review of the results that will be conducted at the Joint Annual Meeting of the American Society of Animal Science and American Dairy Science Association, scheduled for July 19-23, 2016 in Salt Lake City.

Target Completion Date for Project: The anticipated completion date for the project is October 2016. Under the current design of the project, once the project is completed, the results will be proprietary to AFIA and shared on an exclusive basis with AFIA members. It is anticipated that industry facilities will use the results of the project to make appropriate determinations defensible to FDA when performing their own required hazard evaluations.

Proposal for NGFF Involvement: Although the Institute for Feed Education and Research already has approved the project, AFIA has invited the NGFA's National Grain and Feed Foundation to be an equal partner by funding 50 percent of the total project cost – not to exceed \$89,500. NGFA's participation would provide an opportunity to influence the project's deliverables and allow the NGFA to distribute results to its member companies. NGFA Senior Vice President for Feed Services David Fairfield, along with representatives from AFIA and other industry firms, attended a preliminary scoping meeting for the project in January, and believes the project as outlined has merit and is being structured properly.