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December 15, 2014

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane Room 1061
Rockville, MD 20852

Re: Docket No. FDA-2011-N-0922 and RIN 0910-AG10, Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals

To Whom It May Concern:

As New York State's largest general farm organization, representing nearly 25,000 members, New York Farm Bureau (NYFB) appreciates the opportunity to comment on the Food and Drug Administration (FDA) proposed "Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals." Our members are involved in growing and producing feed for animals and raising animals, so they will be impacted by this rule and they are interested in a common-sense and scientific-based final rule that can be practicably implemented.

Food safety is of utmost importance to our food system in the U.S. so implementing the Food Safety Modernization Act (FSMA) in a way that is meaningful and effective for the entire food chain is essential to our members and to our country. The health and well-being of the animals in their care is a key priority for New York's farmers. Dairy production is the largest agricultural activity in New York, making up half of the farm-gate receipts, but farmers here also raise beef, pork, eggs, poultry and a variety of other animals from bison to sheep and goats. The safety of our food system is dependent on these animals receiving healthy, nutritious, safe food.

NYFB submitted comments during the first comment period on this proposed rule. We greatly appreciate FDA taking the time to review all the comments submitted and providing stakeholders a look at changes and the ability to respond during a second comment period. This is a complex rule and how it interacts with other rules under FSMA is important and we are pleased that FDA recognized this.

While we acknowledge FDA taking into account many of our greatest concerns in the supplemental rule, several issues remain.

Co-Products and Spent Brewers' Grains

In the first round of comments, NYFB urged FDA to take into consideration the limited risk of co-products from human food production and the use of spent brewers' grains as animal feed. Both of these practices are common in New York, help lower the costs for both the livestock farmer and the food or beverage business, and have not been demonstrated to lead to an increased food safety risk for the humans consuming those animal products.

Therefore, we appreciate FDA recognizing this and including in the supplemental rule that human food processors already complying with FDA human food safety requirements (including brewers) would not need to implement additional preventive controls or Current Good Manufacturing Practice regulations when supplying a co-product as animal feed.

CGMP Requirements

The standards of good manufacturing processes for human food and animal feed are necessarily different and we appreciate revisions by FDA that are now more appropriate for animal feed. While health is a concern for both, there must be a clear distinction between manufacturing conditions and practices necessary for safety of human food compared to animal feed.

Product Testing and Environmental Monitoring

Product Testing

We do not recommend the inclusion of product testing – whether incoming raw material or finished product, regular or periodic, regardless the size of the operation – as a requirement in Preventative Controls for Animal Food. At a minimum, we believe any product testing should be used as a verification activity when appropriate, and requirements should be based on the food, facility and the nature of the risk.

Environmental Monitoring

We also do not support the inclusion of environmental monitoring tools in the rule. Rather we encourage monitoring be conducted through facility specific food safety plans. Any regulatory requirement will soon be outdated as products change and science improves. Therefore, addressing the environmental risks within the food safety plan, rather than regulation, provides the flexibility necessary to monitor any risk successfully.

Resources for Training and Inspection

It is very important to farmers that FDA ensure there are adequate resources for training of inspectors. It is important that inspectors are properly trained and familiar with agricultural practices and the true risks associated with various activities on a farm and at mixed-type facilities. It is important that inspectors understand that farms—even those manufacturing feed—are fundamentally different from a human food manufacturing facilities. Inspectors that are not adequately trained in acceptable farm practices will not be able to implement the rule consistently and fairly across the U.S and would needlessly put some growers at a competitive disadvantage. This training must take into consideration the differences in crops, feed products and feed usages.

State Partner Cooperation

It is still unclear how FDA will cooperate with state partners to implement this rule. Exactly how inspections will be carried out and the structure of state-federal partnerships must be established as soon as possible in order to ensure uniform enforcement and enough time for state partners to prepare.

Furthermore, we support delegating inspection authority to state departments of agriculture as they are best prepared to conduct on-farm assessments and inspections and are already knowledgeable in farming practices. ***But this must be combined with adequate funding and other resources for both producer and state education and outreach, possible state staff, and other needs necessary to implement this rule*** so already stretched agencies can assist farmers and implement the rule fairly.

In New York, our State Department of Agriculture and Markets already has a long history of successful inspection processes, but inspection staff in recent years has been significantly cut back. We are concerned that the agency would not be able to take on a significant new responsibility without sufficient resources to do so. We remain very concerned that delegation of duties is combined with adequate resources to carry out those requirements.

Data Privacy and Recordkeeping Requirements

Farmers are concerned about the privacy of their personal information and proprietary information regarding their farm business. ***FDA must take measures to ensure data privacy and confidentiality of individual farm businesses, even if they are mixed-type facilities, and their proprietary information.*** This must be considered in any information farmers will be required to submit to state or federal agencies and any information that inspectors or educators may collect.

Furthermore, the records and other documentation necessary to implement these rules should not increase production costs for our farms, many of which are small businesses that cannot afford to purchase data programs or hire an additional staff member to maintain complicated records. Recordkeeping requirements should be flexible enough to allow farmers to integrate into their current system with limited burden.

Additionally***, recordkeeping requirements now and in the future must consider the fact that not all farmers have access to high-speed or broadband internet access.*** Many areas of New York State are rural and remote and do not permit growers to access the internet on a reliable and regular basis. In fact, according to a 2013 farm computer usage survey conducted by the U.S. Department of Agriculture, 69 percent of farms in New York have internet access. This leaves 31 percent of our farms—or more than 11,000 operations—that do not currently have internet access.

For this reason, requirements like an email address in order to register as a food facility with FDA make it difficult for some farmers to comply. Email should not be the only method from FDA to communicate with a producer; rather a producer should be able to select a preferred communication and registration method that recognizes the hardship of internet access on some farms and for some of the farm community. Failure to do this will certainly undermine the effectiveness of this rule and ability of farmers to comply.

Outreach

FSMA will only be successful if farmers are able to understand its requirements and efficiently implement any needed changes, so communication and coordination with this community is key. FDA has already done an admirable job of reaching out to stakeholders, but the agency must continue to identify education and outreach needs and provide a plan for meeting these. We anticipate that substantial training, guidance and scientific information will need to be provided to both industry and regulators in advance of this rule being implemented. We feel strongly that education should come before regulation and enforcement to increase the success of these new food safety rules.

To this end, FDA must include robust funding for education and outreach in its budget for FSMA. Right now our farmers are clamoring for educational material and while our land-grant Cornell University and excellent Cooperative Extension have helped immensely, they will need even more resources to provide the best information to our farmers. These entities do not have budgets that can easily take on the new efforts that FSMA training will require, so we strongly encourage FDA to earmark FSMA funding for partnerships like these which will be able to deliver educational programming.

Conclusion

New York Farm Bureau appreciates FDA's efforts to improve this rule in response to farmer comments and we encourage the agency to continue its efforts as suggested above to ensure a targeted, science-based and risk-based approach. Produce farmers here in New York consider food safety a top priority and want to partner with FDA and our state Department of Agriculture and Markets to accomplish this. However, we remain committed to a standard that can be scientifically supported, demonstrate real human health benefits and be reasonably attained by producers without inadvertently discouraging or disadvantaging domestic production.

Thank you in advance for considering these concerns.

Sincerely,

Dean E. Norton
President