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

Re: FDA–2011–N–0922; RIN 0910–AG10 – Revised "Current Good Manufacturing Practice and Hazard Analysis Risk-Based Preventive Controls for Food for Animals.

American Farm Bureau Federation (Farm Bureau) is the nation's largest general farm organization, representing approximately 6 million member families and growers of virtually every commodity. The implementation of the Food Safety and Modernization Act (FSMA) is a major challenge and we appreciate the Food and Drug Administration (FDA) recognizing that farmer and rancher input is integral in ensuring food safety goals are met.

We commend the FDA for issuing this Supplemental Notice of Proposed Rulemaking and are pleased to present viewpoints from the farm level on the modifications to the initial produce safety proposal. Moreover, we appreciate clear acknowledgment of concerns raised in Farm Bureau comments dated March 31, 2014, and the resulting modifications seen in the revised Current Good Manufacturing Practice and Hazard Analysis and Risk Based Preventative Controls for Food for Animals rule (Animal Feed).

General Food Safety Comments

AFBF members have a vital interest in how food safety is practiced, perceived and regulated. We believe that, while the U.S. food production system is among the best in the world, science-based, collaborative improvement is always an important element in the system. By their nature, food systems are biological and thus not failsafe nor ever "zero risk." It is critical for FDA to set forth science-based standards, accommodate the complexity of the food system, and distinguish between farm and facility within FSMA rules. Overall, Farm Bureau believes the revised preventative controls for animal food rule is a step in the right direction but we still have concerns. We appreciate the opportunity to articulate these concerns in these comments.

Facilities Regulated Under Preventive Controls Rule

Farm Bureau appreciates FDA's recognition of farms as appropriately exempt from facility registration generally and that FDA goes further to exempt farms from this rule specifically. However, as noted in our comments to the Revised Produce Safety and Preventative Controls for Human Food rules, we continue to have concerns within that definition.

Definition of Farm

In Farm Bureau's first set of comments, we raised numerous concerns within the definition of farm and mixed type facility. Congress did not contemplate imposition of safety standards that would ignore the

actual farm structures that exist in practice. In fact, FSMA states that the regulations should provide "sufficient flexibility to be *practicable* for all sizes and types of businesses" and "acknowledge differences in risk and minimize, as appropriate, the number of separate standards that apply to separate foods." FSMA § 105. We commend FDA for expanding the definition of farm activities to include culling, conveying, sorting, waxing, storing, labeling, packing, packaging and shipping of raw, intact produce, and storing including crop maintenance activities that occur during storing like fumigation, pest control, sprout inhibition and atmosphere control for ripening or ripening inhibition. Farm Bureau believes any normal handling, holding or packing activity performed on raw, intact produce that results in no significant change in the produce shape or structure, and creates no significant change in the hazard analysis for the product, should be considered consistent with the "farm" definition. Further, operations that perform only such activities should be covered under the Produce Rule, rather than the Preventative Controls for Human Food rule.

While FDA has made great strides in clarifying the separation between an establishment that is a farm and a facility that is required to register under this Preventive Controls rule, there remain concerns within the definition of farm and mixed type facility. There are certain practices and realities that are still not addressed in this revised proposal.

Under One Ownership

Farm Bureau raised the concern that the original proposed definitions required that farms "harvesting" or "packing" or "holding" raw agricultural commodities (RACs) grown on a farm under different ownership would have been forced to register as a food facility, subject to Preventive Controls for Human Food requirements. We commend FDA for recognizing that this approach presented no added food safety benefit and for eliminating the requirement for "packing" and "holding" and "harvesting" by allowing farms to harvest, pack or hold RACs grown on another farm under a different ownership. This change improves workability of the rule, while taking into account typical farm practices.

However, we remain concerned that defining a farm as being "under one ownership" ignores important farmland ownership and management structures that exist today. According to the USDA Economic Research Service, about 40 percent of U.S. farmland has been rented over the last 25 years. A definition of farm that does not take into account non-owner management of farmland would make complying with FSMA considerably more difficult and costly.

One General Physical Location

Farm Bureau has concerns regarding the "one general physical location" requirement within the farm definition. As FDA accurately points out, farms generally consist of non-contiguous parcels of land in various geographical locations, including different counties, states, regions, and countries. This reality must be contemplated in any interpretation of the "one general physical location" requirement.

FDA also rightly notes that a narrow interpretation could impact the amount of covered farms and the application of the produce safety standards. Farm Bureau believes food safety is size-neutral; all growers of covered produce should meet necessary standards. The expansion of exemptions that could arise due to a narrow interpretation may undermine the overall goals of the rule. However, FDA must consider that the financial ability of growers to implement practices and systems to reduce or limit

liability should not overburden smaller growers with unnecessary practices that would drive them out of business. We believe food safety regulations should be appropriate to the size, type and capacity of the farm.

Farm Bureau does not see a benefit to including the "one general physical location" requirement. Limiting farms in that manner may cause duplication of requirements, recordkeeping, and costs. If this requirement is included, it should be interpreted as broadly as possible. Farm sizes and structure vary due to regional factors, climatic conditions, production practices, and marketing and distribution channels. In fact, the average farm spans over 434 acres and consists of several parcels of land, some contiguous and some not. Our membership reflects why food safety regulations must be scale-appropriate, recognizing the wide variation in the needs of farmers based on farm size and scope. Clearly, one size does not fit all. As a result, the definition of "one general physical location" becomes extremely difficult. Given that the shortcomings outweigh any potential benefit, we believe it should be deleted.

While we do believe FDA has made improvements to the definition of "farm" as noted above, Farm Bureau remains concerned about the definition's overall workability. Therefore, we suggest an alternative definition as follows:

Farm means *an establishment where raw agricultural commodities are grown, harvested, packed and/or held, animals are raised (including seafood), or both and which has a common, owner, operator(s) or agent in charge and which is operated under a common food safety management scheme. The term "farm" includes establishments that, in addition to these activities:*

(i) Pack or hold processed food, provided that all processed food used in such activities is either consumed on that farm or another farm under the same ownership, or is processed food identified in paragraph (iii)(B)(1) of this definition; and

(ii) Manufacture/process food, provided that:

(A) All food used in such activities is consumed on that farm or another farm under the same ownership; or

(B) Any manufacturing/processing of food that is not consumed on that farm or another farm under the same ownership consists only of:

(1) Drying/dehydrating raw agricultural commodities to create a distinct commodity, and packaging and labeling such commodities, without additional manufacturing/processing; and

(2) Packaging and labeling raw agricultural commodities, when these activities do not involve additional manufacturing/processing.

This definition addresses all concerns raised above. First it is inclusive of the various individuals that might be responsible for the operation of a "farm." The use of pronouns to refer to the "owner, operator or agent in charge" is appropriate. Second, we believe "one general physical location" is an irrelevant descriptor that cannot be clearly defined without being arbitrary or capricious. Hence, it should be removed from the definition of farm. It also allows packing and holding activities performed on RACs, as this allows for packing house operations to be considered "farm" establishments and be covered by the produce safety rule. This provides uniform and effective regulation of all packing activities irrespective of their physical location to be solely covered by the produce safety regulation.

Harvesting

There continue to be other tasks that we want to draw attention to that should be contemplated in the definition of "harvesting." Farm Bureau recognizes that this is not an exclusive list, but we want to draw FDA's attention to an example of a harvest activity that would be impacted under the current Animal Feed rule. One such example is seed conditioning, which is the act of cleaning seed, including removal of leaves, stems, and husks, in order to prepare it for marketing. The conditioning is done as a harvest activity prior to any transformation of the RAC. The act of seed conditioning, to the extent that seed enters the food or feed chain, should be considered a harvest activity subject to this rule rather than the preventive controls for human food or preventative control for animal feed rules. Seed conditioning is the act of cleaning seed, including removal of leaves, stems, and husks, in order to prepare the seed for marketing. Conditioning is done as a harvest activity prior to any transformation of the RAC. The CGMPs and preventive controls requirements in the proposed rule present considerable compliance challenges for these facilities, but the required changes would have no significant impact on the safety of animal feed because the products are inherently safe. The act of seed conditioning, to the extent that seed enters the food or feed chain, should be considered a harvest activity subject to the Produce Rule rather than the Preventative Controls for Human Food rule or the Preventative Control for Animal Feed rules.

Packing & Holding

As stated above, Farm Bureau commends FDA for expanding the definitions of packing, holding, and harvesting. We generally support the updated versions of the definitions as provided in this supplemental proposal. Additionally, Farm Bureau is pleased to see in this revised rule an expansion of the definition of "holding" to account for activities performed incidental to storage – such as drying, screening, cleaning, conditioning, fumigating, soring, culling, grading, and blending – of animal food. This better encompasses on the ground practices necessary in proper storage of grain. Therefore, we believe that FDA's revised "holding" definition and proposed exemptions for facilities holding raw agricultural commodities other than fruits and vegetables appropriately reflect the limited public health risk pertaining to such facilities and the fact that outbreaks of foodborne illness have not been traced back to facilities solely engaged in the storage of non-fruit or vegetable raw agricultural commodities. Therefore, we urge FDA to codify the proposed definition and exemptions within its final regulation.

In regard to "packing," under FDA's newly proposed definitions, the agency proposes to differentiate requirements associated with packing between establishments that are "facilities" and those that are "farms." A "farm" that packs raw agricultural commodities other than fruits and vegetables, regardless of ownership of such commodities, **would not be** subject to CGMPs and preventive control regulations because the establishment would still meet the definition of a "farm." In contrast, a "facility" that packs raw agricultural commodities other than fruits and vegetables, regardless of ownership of such commodities, **would be** subject to CGMPs and preventive control regulations. The NGFA believes that this proposed regulatory distinction between two types of operations that perform identical activities lacks sound reasoning and is not justified when a risk-based approach to food safety is applied.

Based upon the minimal level of public health risk and the authority provided to the agency, the NGFA strongly recommends that FDA expressly exempt facilities that pack raw agricultural commodities other

than fruits and vegetables intended for further distribution or processing from the CGMPs and preventive controls requirements to be established under its regulations.

Accordingly, Farm Bureau recommends that FDA modify proposed § 507.5(g) and § 507.5(h) to read as follows *[new language boldfaced and underscored]*:

- § 507.5(g): "Subpart C of this part does not apply to facilities that are solely engaged in the storage **or packing** of raw agricultural commodities (other than fruits and vegetables) intended for further distribution or processing."

- § 507.5(h): "Subpart B of this part does not apply to the holding or transportation of one or more 'raw agricultural commodities,' **or the packing of 'raw agricultural commodities' (other than fruits and vegetables),** as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act."

Feed Mills

Under the original proposed Animal Food rule, fully vertical farming feed mills would be considered farms. In the supplemental proposal, FDA seeks comment regarding whether to change this distinction and treat fully vertical farming feed mills as facilities. Farm Bureau opposes treating fully vertical farming feed mills as facilities under section 415. If FDA makes this distinction many dairies, feedlots, and other livestock farms would be pulled within the scope of the Animal Feed rule subjecting them to CGMPs and Preventative Controls as unintended by Congress. Farm Bureau strongly supports maintaining these establishments as farms, regardless of the number of animals being fed or animal food being fed as both are irrelevant to food safety.

HAACP Implications

We appreciate the removal of the language "reasonably likely to occur," and replacing it with "significant hazard." However, we fear the same hazard analysis and critical control point (HAACP) implications could occur. We concur with the rewrite proposed by the feed manufacturing industry as follows:

> *(a) The owner, operator, or agent in charge of a facility is responsible to ensure that ~~must identify and evaluate~~ known or reasonably foreseeable hazards for each type of food manufactured, processed, packed, or held at the facility are identified and evaluated by a qualified individual to determine, based on their probability and severity, ~~whether there are hazards that are reasonably likely to occur~~ the hazards that are of such a nature that control measures to significantly minimize or prevent them are necessary for the production of a safe food and therefore must be addressed in the food safety plan.*

CGMPs Requirements

We commend FDA for altering the CGMPs in the revised rule, which are now more appropriate for animal feed and pet food. The flexibility provided better reflects the fact that the innate hygienic

standards of humans exceed the hygienic standards of livestock, poultry and other animals. We continue to urge FDA to consider the difference between production of pet food and Animal feed.

Exemptions

We appreciate FDA exempting very small businesses from the animal food preventive controls requirements and including only sales of animal food in its calculation to define a very small business for purposes of this rule. We support the adoption of $2.5 million total annual sales of animal food threshold for a very small business.

Brewers' Spent Grain

Farm Bureau appreciates the recognition that processors already complying with human food safety requirements would not need to implement additional requirements when selling byproduct as animal feed.

Product Testing, Environmental Monitoring and Supplier Verification

Product Testing:

Farm Bureau does not recommend the inclusion of product testing – whether incoming raw material or finished product, regular or periodic, regardless of 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:

Farm Bureau does not support the inclusion of environmental monitoring tools in the rule; rather, we encourage monitoring to be conducted through facility specific food safety plans. The risk associated with certain exposures of a ready-to-eat food depends on multiple factors that must be considered in any environmental monitoring tool. Additionally, 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.

Supplier Verification:

Farm Bureau believes that there is value in supplier verification that is flexible and risk based. The risk must take into account the ingredient and the supplier. However, verification activities should not be mandatory for all facilities and all suppliers because the benefits of conducting these activities will not outweigh the cost. Food safety risk should be an elemental factor in determining verification measures and facilities should have the ability to maximize the use of their resources and determine the need for these activities. In addition, the requirements of any domestic supplier verification program should align with the Foreign Supplier Verification Program (FSVP).

Economic Impact

Farm Bureau has long advocated utilizing sound science and a risk-based approach to strengthen the nation's food- and animal-feed safety systems. However, too many new standards may unnecessarily complicate the marketplace without increasing the overall safety of the food supply. While we understand the need for continuous food/feed safety improvement, the farm-level impact on producers must be considered in any new regulations. Furthermore, in an era of tight budgets for everyone in the food chain, it is increasingly important to target limited resources in a manner that achieves the greatest result for all accountable parties. Commitment to a robust cost-benefit analysis of any Preventive Controls rule is necessary to ensure that the cost of enhanced measures does not outweigh the benefits.

The cost of this rule to farmers and the feed industry has the potential to be substantial. A study commissioned by the United Soybean Board prior to publication of the proposed rule found the cost of compliance with the statutory requirements $265 million, $65 million more than FDA has estimated in the rule. In addition, the National Grain and Feed Association has analyzed the economic impact of this rule in a document that we have attached as an appendix. We encourage FDA to review these analyses thoroughly when evaluating potential changes that may be published in the second proposed or final rule. In fact, we would encourage FDA to consider holding a special comment period for the purpose of reviewing and adjusting its overall economic analysis of the combined rules' impacts.

Implementation, Compliance, and Enforcement

Regulatory Consultation and Coordination - Implementation

Institutional relationships between state and federal food safety personnel will need to be developed to implement FSMA successfully. We encourage FDA to consult extensively with state and local food regulatory agencies that are willing to participate in the implementation of FSMA and integration of state and federal food safety systems, and to pursue mutually workable strategies for future collaboration. State Departments of Agriculture are a valuable resource that should be utilized in any contact with, outreach to or education for rural areas.

Compliance and Enforcement

One of the most important ways FDA can demonstrate commitment to implementation and workability of these rule is by developing world-class training programs for inspection staff. The supplemental rules provide for much flexibility. At the same time, to ensure workability and proper compliance, inspectors must be thoroughly trained in a manner that is consistent and uniform, such that all inspectors are able and willing to enforce rules competently and fairly.

It is imperative that FDA inspectors understand that the farm is vastly different from a food manufacturing facility. FDA must train inspectors to understand routine, acceptable on-farm practices. Training relevant FDA staff at all levels will be critical to ensuring that the Preventive Controls rule functions as intended. As a preferred alternative to the expenditure of considerable FDA resources to establish qualified inspection personnel, we urge FDA to utilize partnerships with existing well-trained regulators already knowledgeable about these practices. In particular, we encourage more cooperative

agreements with state departments of agriculture that are closer to the farm level and have a strong history of largely successful inspection processes.

We have heard concerns from state partners about the lack of information FDA has provided on the nature of future cooperation. Exactly how inspections will be carried out, and the structure of state-federal relationships must be established as soon as possible in order to ensure uniform enforcement among states.

Specifically, we request that FDA answer the following questions to provide a framework for transparent and reasonable expectations:

- What mechanisms will FDA use to delegate authority to the states?
- Will FDA create commissions or credentialing of state personnel to conduct inspections?
- If a state is unable to actively support one or more FSMA requirements, will FDA chose to implement the rules with its own inspectors?

Outreach

Communication and coordination with farmers and the feed industry is essential. FDA should work with stakeholders to clearly define education and outreach needs. FDA must provide substantive training, guidance and scientific information to both industries and local regulators. The implementation of any new rule in the absence of appropriate guidance and support will lead to negative unintended consequences for farmers and ranchers and will impede the progress of protecting public health as intended by FSMA. Education should come before regulation to increase the ultimate likelihood of successful adoption of any new food safety standards.

FDA must include robust funding for education and outreach in its budget for FSMA. Additional resources are by far the greatest component needed to create a more thorough educational delivery system. The federal-state-local scope of USDA's National Institute for Food and Agriculture, agricultural universities and extension professionals offer excellent infrastructure, but the budgets of these entities are insufficient to take on new efforts. We strongly encourage FDA to direct FSMA funding to this partnership and others like it that are already well-suited and ideally positioned to disseminate educational programming and curriculum.

Conclusion

We are committed to improving food and feed safety in a targeted, scientific, and risk-based manner. We look forward to continuing our working partnership with FDA to promote the safety of the food and feed provided and utilized by America's farmers and ranchers.

Sincerely,

Dale W. Moore

Dale Moore
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