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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: FDA–2011–N–0920; RIN 0910–AG36 – Revised "Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food.

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 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 November 21, 2013, and the resultant modifications seen in the revised Current Good Manufacturing Practice and Hazard Analysis and Risk Based Preventative Controls for Human Food (Preventative Controls) rule.

General Food Safety Comments

AFBF has 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 an important element in the system.

By their nature, food systems are biological and thus not failsafe nor ever "zero risk." Recent improvements in reducing foodborne illness have occurred despite new challenges for food safety; such as changes in the typical American diet that include more imported foods and more food consumed away from home. The U.S. now imports food from more than 150 different countries through more than 300 ports of entry. About half of fresh fruits eaten in America are grown outside of the country, and these imports allow us to enjoy our favorite produce year-round. Trade in food permits a more varied and customized diet suited to today's consumer preferences. It permits our farmers and other food producers to sell their goods abroad. But it also means that food safety requires enhanced attention to the global food supply, and FDA must apply and enforce any new produce safety standards on imports in a manner similar to that for domestic producers.

Adding to the complexity presented by increased food sources, the number of people involved in preparing the food we consume also has increased. Approximately 50 cents of every food dollar today is spent on foods prepared outside the home in places like restaurants, vending machines, and schools. This reality increases the need to ensure adequate training for food service workers across the country

and to be vigilant against the potential of deliberate contamination of the food supply. As the supply chain gets longer, the potential for both accidental and intentional introduction of public health threats increases.

Because of all these factors, 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 the Preventative Controls rule. Overall, Farm Bureau believes this revised Preventative Controls rule is a step in the right direction, but we still have concerns. We appreciate the opportunity to voice these concerns in these comments.

Facilities Regulated Under Preventive Controls Rule

Farm Bureau understands that FSMA defines the term "facility" to mean "a domestic facility or a foreign facility that is required to register under section 415," and that it is FDA's intent that "conducting activities outside the definition of 'farm' triggers the requirements in the section 415 registration regulations and, thus, brings the facility within the scope of section 418 of the FD&C Act." While it is clear that FDA intends a sharp division between "facilities" subject to Preventive Controls and "farms" subject to Produce Safety based on the section 415 registration regulations, it is an artificial restriction, neither science- nor risk-based. We believe that the congressional intent of FSMA may be met if registered facilities that handle, hold, pack or package raw, intact produce are covered by the relevant requirements of the Produce Safety rule instead of Preventive Controls.

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 safety standards for farms that would ignore the actual farm structure that exists 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, and 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 realties 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 this approach presented no added food safety benefit and eliminating this requirement for "packing" and "holding" and "harvesting" by now allowing farms to harvest, pack or hold RACs grown on another farm under different ownership. This change improves workability of the rule, while recognizing 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 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 non-owner management of farmland into account 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 tailored 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 this manner may cause duplication of requirements, record keeping, 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 non-contiguous. Our membership demonstrates why food safety regulations must be scale-appropriate, recognizing the wide variation in the needs of farmers based on farm size and scope. One size does not fit all, which is why defining "one general physical location" becomes extremely difficult. Because the deficiencies 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 its overall workability. Therefore, we suggest an alternate 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.

Packing, Holding, & Harvesting

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. Notwithstanding, there are other tasks that we want to draw attention to that should be contemplated in the definition of "holding" and "harvesting." Farm Bureau recognizes that this is not an exclusive list, but we want to draw FDA's attention to a few other examples to better assist in future interpretation of harvest activities. 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. A second example is ripening (artificial or natural) of fruit. Ripening whether by natural means over time or stimulated by introduction of ethylene for climacteric fruits is done for the purpose of preparing a raw agricultural commodity for use as a food and hence should be defined as "harvesting" for the purposes of this regulation. Ripening is not a manufacturing or processing step as the RAC does not undergo any substantial transformation and is exactly the same food product being introduced into

commerce both before and after ripening. A third example that should be included in the definition of "holding" is fumigation. Fumigation of raw agricultural commodities is done for the safe effective storage of many fruits and vegetables and should be defined as "holding" for the purposes of this regulation.

We support the inclusion of activities performed incidental to storage of food in the definition of holding of RACs (other than Fruits and Vegetables). The activities articulated in the supplemental rule do not alter the nature of the RAC and are, therefore, rightfully included as farming activities. Farm Bureau also supports the inclusion of activities incidental to packing, such as sorting, culling, and grading, within the definition of packing. We appreciate FDA's recognition of these incidental activities as part of the farming process and not subjecting farms which conduct those activities to Preventative Controls.

Exemptions for On-Farm/Low-Risk Activity/Food Combinations

In the original proposed rule, FDA specifically identified processes as low-risk in the preamble and provided that there would be exemptions for on-farm activity conducted by farm-mixed type facilities that are small and very small businesses. Farm Bureau believes FDA inappropriately restricts the proposed exemption to companies based on size because activities considered low-risk for small and very small on-farm businesses are also low-risk for larger operations.

Farm Bureau also has concerns regarding the "on-farm" distinction. Many farmers who otherwise qualify under this exemption may perform the low-risk manufacturing/processing activities in a cooperative setting or at a different location. Conducting these same activities at a different site or in a cooperative does not alter the food safety risk. FDA should consider that common arrangement when determining how to define "on-farm" under this exemption.

Exemptions Based on Size

Because food safety is size-neutral, all covered producers should meet necessary standards. However, the financial ability of a large producer to implement practices and systems to reduce or limit liability should not overburden smaller producers with unnecessary practices that would drive them out of business.

Product Testing, Environmental Monitoring, and Supplier Verification

<u>Product Testing:</u>

Farm Bureau recommends against 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. This opinion considers the limited technology available to do testing of fresh produce, the added cost of implementing a product testing process, and the limited time available due to testing because of the perishable nature of the commodity. Overall, we believe that the established preventative control and monitoring go further to protect safety, without the added cost of sampling.

Environmental Monitoring:

Farm Bureau does not support the inclusion of environmental monitoring tools in the rule; rather 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. 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).

Withdrawal and Reinstatement of Qualified Exemption

Farm Bureau supports the modified requirements required prior to withdrawing a qualified exemption. We raised concerns in our original comments that a farmer would not have the opportunity to take corrective actions before having his exempt status fully withdrawn. We support FDA's proposal to require FDA issuance of a warning letter, recall, administrative detention, refusal of food offered for import, seizure, and an injunction. This would provide an intermediary step prior to a full withdrawal. It is also critical that the farm have the opportunity to respond to any alleged problems identified by the FDA and that the FDA consider the farm's response prior to issuing an order to withdraw the exemption. Farm Bureau appreciates FDA's recognition of the farms due process rights within the supplemental rules.

Farm Bureau also supports FDA's addition of a process to reinstate a qualified exemption. This process recognizes that farms and mixed-type facilities can manage a food safety risk and return to compliance. Moreover, this process is especially critical where an alleged outbreak is not directly linked to the farm or mixed-type facility at all.

Recordkeeping

Records and other documentation should not increase production costs for diversified farm-based operations, most of whom operate small businesses. Farm Bureau members currently maintain a plethora of records, yet most farms (like many small businesses) do not have the technical or financial resources available to make their record-keeping systems interoperable with government or others in the food chain.

According to USDA's National Agricultural Statistics Service (NAAS), 70 percent of farms have access to a computer, 68 percent own or lease a computer and 40 percent of U.S. farms used a computer for farm business in 2013. NAAS also concludes that 2/3 of U.S. farms have Internet access, but some farms still rely on dial-up access. Therefore, if recordkeeping is determined necessary, there must be acceptable, basic alternatives to an electronic format.

The privacy and confidentiality of individual businesses must be considered in the development of new regulations. Any recordkeeping requirements must be accompanied by assurance that information accessed by federal government authorities in regards to food safety protocols will remain confidential.

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 for flexibility and 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 a 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

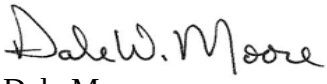
Communication and coordination with producers and processors is essential. We commend FDA for continuing stakeholder discussions exemplified by issuing the supplemental rules. FDA should continue to work with stakeholders to clearly define education and outreach needs. FDA must provide substantive training, 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 growers 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 produce safety in a targeted, scientific, and risk-based manner. We look forward to continuing our working partnership with FDA to promote the safety of fresh produce.

Sincerely,



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