



December 15, 2014

**TO: Division of Dockets Management [HFA-305]  
U.S. Food and Drug Administration  
5630 Fishers Lane, Rm. 1061  
Rockville, MD 20852**

**RE: Docket No. FDA-2011-N-0920 RIN 0910—AG36**  
Preventive Controls for Human Food: Current Good Manufacturing Practice and Hazard and Analysis and Risk Based Preventive Controls for Human Food (Preventive Controls Rule for Humans) (Fed Register – Vol. 78, No. 11 – Pages 3647-3824)

Thank you for the opportunity to provide comments on FDA’s supplemental notice relative to the revisions made to the 2013 Proposed Preventive Controls Rule for Humans.

The Organic Trade Association (OTA) is the membership-based business association for organic agriculture and products in North America, representing organic businesses across 49 states. Our members include growers, shippers, processors, certifiers, farmers’ associations, distributors, importers, exporters, consultants, retailers and others. OTA's mission is to promote and protect the growth of organic trade to benefit the environment, farmers, the public and the economy.

OTA’s comments are guided by three critical factors: 1) FDA’s mandate to establish **science-based** and **risk-based** minimum standards that will minimize the risk of serious adverse health consequences or death; 2) FDA’s mandate to develop rules that do not duplicate or conflict with existing organic regulations; and 3) FDA’s intention to create a flexible regulation that will accommodate future changes in science and technology.

First and foremost, OTA would like to state that the organic industry takes food safety seriously, and we fully embrace FDA’s efforts and the intended outcome of a safer food supply. We believe that **every** food producer has a legal obligation to supply safe food to the public. Since the draft rules were released in January 2013, OTA’s Food Safety Task Force, with support of our membership, has worked to raise awareness on the issue throughout the organic sector, and develop comments to proposing solutions to align with the organic regulations without a reduction in food safety. The supplemental proposals clearly indicate that FDA listened to the feedback from OTA and other organic producers and handlers. OTA applauds FDA's work and its extensive outreach to organic stakeholders across the country. We expressly thank you for listening and responding to the concerns you have heard.

OTA is largely supportive of the changes made to the Proposed Preventive Controls Rule for Humans. Although we are pleased with most of the revisions, we still have a few concerns that deserve additional attention. Directly below is a summary of our comments. Our more detailed comments and suggestions for improvement follow thereafter.

**Summary:**

- **Definition of a “farm:”** OTA agrees with FDA’s revised definition of a “farm.” We recognize, however, that a farm may have multiple sites located in “one general physical location” and one or more of these sites may be designated for packing operations. OTA requests that FDA issue guidance to

clarify the boundaries intended by the phrase “one general physical location,” and clarify the extent to which this would apply to holding or packing operations located within the close proximity of a farm and under its ownership, but not on the farm itself.

- ***Farms that pack or hold food from other farms:*** OTA supports FDA’s revisions to the following definitions: “farm,” “harvesting,” “holding,” and “packing.” Specifically, we agree that a farm should not be required to register as a food facility merely because it packs or holds raw agricultural commodities (RACs) grown on another farm under a different ownership. We agree that on-farm packing and holding of produce should be subject to the Proposed Produce Safety Rule, not the Preventive Controls Rule, provided RACs are not transformed into a processed product. Farms that conduct additional processing or manufacturing should be subject to the preventive controls rule for those activities. FDA’s revision supports a collaborative approach to local and regional agriculture. It clarifies the rules, and reduces unwarranted burdens for farming operations that pack and distribute produce on their own farms as well as produce from neighboring farms.
- ***Operations that pack and hold produce but are not growing produce:*** OTA recognizes that many off-farm produce operations pack and hold produce but they do not grow the produce. The activities carried out by such operations are no different than the post-harvest activities described under the proposed definition of a “farm” and the definitions of “packing” and “holding.” The only difference is that the off-farm operation is devoted to packing and holding and is not involved in growing produce. Regardless, as the proposed rule is now written, the off-farm operation would be subject to the Preventive Controls Rule for Humans, and would therefore be subject to additional requirements that a farm performing the same activities would not. This creates an un-level playing field and causes unnecessary burden to the off-farm operation. OTA suggests that off-farm operations that perform the same post-harvest activities (packing and holding) as an on-farm operation be subject to the Preventive Controls Rule for Humans (and therefore required to register under the Bioterrorism Act), BUT only be subject to the specific preventive requirements that are consistent with packing and holding activities described under the Produce Safety Rule.
- ***Environmental and product testing:*** OTA maintains its position that environmental and product testing are important verification measures to ensure that preventive controls are effectively controlling hazards. Environmental and product testing may be appropriate in certain instances as verification activities, but they do not constitute a **control step**, and should not be included in the rule itself. Guidance on this matter would be more appropriate. OTA believes that FDA should continue to express the importance of testing as an effective part of a food safety plan, and focus on providing useful guidance to industry on best practices and methods for monitoring and testing protocols.
- ***Supplier approval and verification:*** Supplier approval and verification programs can be important parts of a preventive approach to food safety. The role and need for supplier approval and verification vary depending on the type of facility and type of food. Given the flexibility built into this supplemental proposed rule, OTA supports the addition of supplier verification requirements into the rule itself. OTA supports FDA’s proposed approach of providing each facility with the flexibility to determine the appropriate verification activity (e.g., onsite audit; sampling and testing of the raw material or ingredient; review of the supplier’s food safety records; or other appropriate verification activity). We strongly recommend, however, that FDA issue guidance that can be adapted to each operation.

OTA respectfully submits the following more specific comments:

Subpart A	GENERAL PROVISIONS
§ 117.3	<p><b>DEFINITIONS RELATED TO MIXED-TYPE FACILITIES</b></p> <p><i>FDA’s proposed revisions to definitions:</i>            FSMA mandates that FDA issue regulations clarifying on-farm manufacturing, processing, packing, and holding activities that trigger the requirement to register with FDA. The Preambles to both the proposed Preventive Controls Rule and the proposed Produce Rule provide perspective on the applicability of the regulation based on whether or not a facility is required to register with FDA under Section 415, and where the facility falls within the definitions of “farm,” “mixed-type facility,” “harvesting,” “holding,” “packing,” “packaging,” and “manufacturing/processing.”</p> <p>In response to comments expressing concern about farms that pack or hold food from other farms, FDA has made the following revisions to the definition of “farm,” “harvesting,” “packing,” and “holding,”</p> <p><i>Farm</i>            The revised proposed rule defines “farm” as:</p> <p style="padding-left: 40px;">Farm means an <b>facility establishment under one ownership</b> in one general physical location devoted to the growing and harvesting of crops, the raising of animals (including seafood), or both. The term "farm" includes <b>establishments that, in addition to these activities:</b></p> <ul style="list-style-type: none"> <li>(1) <b>Facilities that p</b> Pack or hold raw agricultural commodities;</li> <li>(2) <b>Pack or hold processed</b> food, provided that all <b>processed</b> food used in such activities is <b>either</b> consumed on that farm or another farm under the same ownership, <b>or is processed food identified in paragraph (3)(ii)(A) of this definition;</b> and</li> <li>(3) <b>Manufacture/process</b> food, provided that:           <ul style="list-style-type: none"> <li>(i) All food used in such activities is consumed on that farm or another farm under the same ownership; <b>or</b></li> <li>(ii) Any manufacturing/processing of food that is not consumed on that farm or another farm under the same ownership consists only of:               <ul style="list-style-type: none"> <li>(A) <b>Drying/dehydrating raw agricultural commodities to create a distinct commodity, and packaging and labeling such commodities, without additional manufacturing/processing;</b> and</li> <li>(B) <b>Packaging and labeling raw agricultural commodities, when these activities do not involve additional manufacturing/processing.</b></li> </ul> </li> </ul> </li> </ul> <p><i>Harvesting</i>            The revised proposed rule defines “harvesting” as:</p> <p style="padding-left: 40px;">“<i>Harvesting</i> applies to farms and farm mixed-type facilities, and means activities that are traditionally performed <b>on by</b> farms for the purpose of removing raw agricultural commodities from the place they were grown or raised and preparing them for use as food.</p>

Harvesting is limited to activities performed on raw agricultural commodities on ~~the a farm on which they were grown or raised, or another farm under the same ownership.~~ Harvesting does not include activities that transform a raw agricultural commodity, as defined in Section 201(r) of the Federal Food, Drug, and Cosmetic Act, into a processed food as defined in Section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Gathering, **field coring**, washing, trimming of outer leaves of, removing stems and husks from, sifting, filtering, threshing, shelling, and cooling raw agricultural commodities grown on a farm or another farm under the same ownership are examples of harvesting.”

#### *Holding*

The revised proposed rule defines “holding” as:

Holding means storage of food **and also includes activities performed incidental to storage of a food [e.g., activities performed for the safe or effective storage of that food and activities performed as a practical necessity for the distribution of that food (such as blending of the same raw agricultural commodity and breaking down pallets)]**  ~~Holding facilities include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks. For farms and farm mixed-type facilities, holding also includes activities traditionally performed by farms for the safe or effective storage of raw agricultural commodities grown or raised on the same farm or another farm under the same ownership,~~ but does not include activities that transform a raw agricultural commodity, as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act, into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. **Holding facilities could include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks.**

#### *Packing*

The revised proposed rule defines “packing” as:

Packing means placing food into a container other than packaging the food, **and also includes activities performed incidental to packing a food [e.g., activities performed for the safe or effective packing of that food (such as sorting, culling and grading)],** but does not include activities that transform a raw agricultural commodity, as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act, into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act.  ~~For farms and farm mixed-type facilities, packing also includes activities (which may include packaging) traditionally performed by farms to prepare raw agricultural commodities grown or raised on the same farm or another farm under the same ownership for storage and transport, but does not include activities that transform a raw agricultural commodity, as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act, into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act.~~

#### **OTA’s Comments:**

The definition of a “farm”

OTA agrees with FDA’s revised definition of a “farm.” We agree that a farm means “an establishment under one ownership in one general physical location devoted to the growing and harvesting of crops, the raising of animals (including seafood), or both.” We recognize, however,

that a farm may have multiple sites located in “one general physical location,” and one or more of these sites may be designated for packing and holding operations. For example, it’s not uncommon for a farm devoted to the growing and harvesting of crops to establish packing operations (warehouses, cold storage facilities, etc.) located “down the road” from the farm/growing fields. We assume that the designation of “one general physical location” would cover this type of scenario, provided that the packing and holding locations fall under the “farm” ownership devoted to the growing and harvesting of crops. Guidance may be necessary to clarify the term “general.”

**OTA recommendation:** OTA recommends that FDA issue guidance that will clarify and further designate the boundaries of “one general physical location.”

#### Farms that pack or hold food from other farms

OTA agrees that farms that pack or hold food from other farms are not subject to the preventive control rule. We agree that a farm or farm mixed-type facility that places others’ Raw Agricultural Commodities (RACs) into consumer containers should NOT be subject to the Preventive Control Rule provided the activity does not change the “status” of the RAC into a processed product. Placing a farm’s own RACs or a neighbor’s RACs into consumer containers that contact the food (e.g., a strawberry farm placing strawberries in clamshell packages, an apple farm placing apples into bags) should be considered “packing” within the “farm” definition. The effect of the revised definitions would be that a farm would no longer be required to register as a food facility merely because it packs or holds RACs grown on another farm not under the same ownership. A farm operating in compliance with the Produce Safety Rule will be able to ensure the safe production, harvesting, **holding and packing** of raw fruits and vegetables regardless of the ownership of the farm the produce was grown on.

OTA also agrees that drying and dehydrating raw agricultural commodities to create a distinct commodity, and packaging and labeling such commodities without additional manufacturing/processing are both activities that should fall under the “farm” definition. Operations carrying out such activity should not be subject to the Preventive Controls Rule for Human Food.

#### Operations that pack or hold produce but do not grow produce

OTA recognizes many off-farm produce facilities simply perform packing, holding and storage activities. The activities carried out by such operations are no different than the post-harvest activities described under the proposed definition of a “farm.” The only difference is that the off-farm operation is devoted to packing, holding and storage rather than growing produce. If, however, the off-farm packing operation were subject to the Produce Safety Rule only, and packing/storing/holding produce from several different farms all under different ownerships, traceability could become an issue since the Produce Safety Rule does not require supplier verification and traceability records.

**OTA recommendation:** To remedy the traceability concern described above, while recognizing the unfair burdens that would be incurred by off-farm operations subject to the Preventive Controls Rule engaged exclusively in the holding and packing of RACs, OTA suggests that off-farm operations that perform the same functions as an on-farm operation be subject to the Preventive Control Rule (and therefore required to register under the Bioterrorism Act), BUT only be subject

	<p>to the subparts of the Produce Safety Rule that apply to those activities, such as Subparts C, D, K, L and O. To accomplish this, a new subpart under Subpart 117 of the Preventive Controls Rule could be created permitting registered establishments (that only hold, store or pack RACs) to meet their obligation by compliance with subparts of the Produce Safety Rule applicable to holding and packing.</p> <p>Finally, USDA’s National Organic Program (NOP) requires every certified organic operation (organic farms and organic handlers/processors) to maintain records allowing complete traceability from each field of crop production to the point of retail sale. Whether subject to the Produce Safety Rule or the Preventive Control Rule, organic farms packing or holding produce will be able to provide records allowing complete traceability back to the farm (and field) where the produce was grown.</p>
<p><b>Subparts C</b></p>	<p><b>HAZARD ANALYSIS AND RISK-BASED PREVENTIVE CONTROLS</b></p>
<p><b>§ 117.136</b></p>	<p><b>SUPPLIER PROGRAM</b></p> <p><b><i>FDA Revisions to Include Supplier Approval and Verification</i></b>          FDA is requesting comments on whether the final rule should require supplier approval and verification, and when and how supplier approval and verification are appropriate means to implement the statutory directives in FD&amp;C Act § 418. While these potential provisions were referenced in the preamble of the 2013 proposed rule, they were not included in the regulatory text. FDA is now providing an opportunity for input on specific language and seeking comment on whether to mandate supplier approval and verification.</p> <p>In both the preamble and an appendix to the proposed rule, FDA explains its views on supplier approval and supplier verification. FDA believes that a supplier approval and verification program can be an important part of a preventive approach to food safety. FDA states that the role and need for supplier approval and verification vary depending on the type of facility and type of food. FDA appears to use the term “supplier approval” to refer to a program for acceptance of suppliers, and the term “supplier verification” to refer to initial and ongoing activities to verify that suppliers are adequately controlling hazards in raw materials and ingredients. Verification activities may include auditing suppliers (self-auditing or third-party auditing), testing of raw materials and ingredients, requiring certificates of analysis, and reviewing suppliers’ food safety plans and records.</p> <p><b><i>OTA Comments:</i></b>          OTA agrees that the role and need for supplier approval and verification will vary depending on the type of facility and type of food. Given the flexibility that FDA has built into this supplemental proposed rule, OTA supports the requirement for supplier verification in the rule itself. Specifically, facilities must be able to establish supplier controls if there are no hazards, or if the hazard(s) is controlled (either by the facility or customer).</p> <p>OTA supports FDA’s proposed approach to providing each facility with the flexibility to determine the appropriate verification activity (e.g., onsite audit; sampling and testing of the raw material or ingredient; review of the supplier's food safety records; or other appropriate verification activity). We strongly recommend that FDA issue guidance that can be adapted to each operation.</p>

§117.165

Finally, certified organic handlers are well positioned to comply with supplier verification requirements. The organic regulations require each certified operation to maintain records and lot numbers allowing complete traceability of certified organic products throughout the supply chain, from farm to point of retail sale.

**VERIFICATION OF IMPLEMENTATION AND EFFECTIVENESS:  
 Environmental Monitoring and Product Testing**

***FDA Revisions to Include Environmental and Product Testing in the Rule***

FDA is requesting comments on whether to include environmental monitoring or product testing requirements in the final rule. While these potential provisions were referenced in the preamble of the 2013 proposed rule, they were not included in the regulatory text. FDA is now providing an opportunity for input on specific language and seeking comment on whether to mandate environmental monitoring and product testing in the final rule.

FDA is seeking comment on whether the preventive controls for human food should require:

- A facility, as appropriate to the facility, the food, and the nature of the preventive control, to conduct product testing to verify implementation and effectiveness of preventive controls.
- A facility, as appropriate to the facility, the food, and the nature of the preventive control, to conduct environmental monitoring to verify implementation and effectiveness of preventive controls if contamination of a ready-to-eat food with an environmental pathogen is a significant hazard.

***OTA Comments:***

OTA agrees with FDA that testing is an important verification measure to ensure that preventive controls are effectively controlling hazards. Moreover, environmental monitoring and product testing may be appropriate in certain instances as verification activities, but they do not constitute a control step and should not be included in the rule itself.

In the preamble to the 2013 proposed rule, FDA makes very clear that it believes such testing is an essential part of an effective food safety plan for many facilities. In both the preamble and an appendix to the proposed rule, FDA explains its views on testing. FDA sees testing as an important verification measure (*i.e.*, a way to ensure that preventive controls are effectively controlling hazards). FDA acknowledges that testing is rarely an effective preventive control, because testing generally cannot ensure the absence of a hazard. Furthermore, the FD & C Act § 418 provides that preventive controls **may** include “an environmental monitoring program to verify the effectiveness of pathogen controls in processes where a food is exposed to a potential contaminant in the environment.”

The role and need for product testing and environmental monitoring vary depending on the type of products and processing operation. It should be the facility’s responsibility to determine the testing needed to verify that its preventive controls are effective. It is generally acknowledged that testing, especially microbiological, is not a practical preventive control or critical control point. It is typically used as a verification tool. This is consistent with FD & C Act § 418, and with the principles of HACCP.

For these reasons, OTA continues to urge FDA to focus on ensuring that preventive measures are properly designated and effective, instead of relying on environmental or finished product testing. We recommend that FDA in the rule itself continue to require verification activities be a part of an operation’s food safety plan. In guidance, we recommend that FDA express the importance of testing as an effective part of that plan, and focus on providing useful guidance to industry on best practices and methods for monitoring and testing protocols. Guidance could address the following:

- Product testing as appropriate to the facility and the food to verify the effectiveness of preventive controls
- Particular hazards, situations, or product types for which finished product testing is required
- Frequency of monitoring or testing depending on the product type
- Appropriate sampling plans for monitoring and/or testing
- Corrective actions

OTA views periodic testing for trend analysis and statistical process control as a verification activity. We believe operations subject to the preventive controls rule should be required to carry out verification activities. Consistent with our comments above, we do not believe the product testing however should be included in the rule itself. Guidance on this matter would be more appropriate.

### **Conclusion**

The *Organic Trade Association’s 2014 Organic Industry Survey* shows the industry has grown from \$3.6 billion in 1997 to \$35.1 billion in 2013, with an annual growth rate of 19% from 1997-2008. As our country has been dramatically affected by the worst economic downturn in 80 years, the organic industry has remained in positive growth territory, and has come out of the recession hiring employees, adding farmers, and increasing revenue. The latest data indicate that 78% of organic farms report planning to maintain or increase organic production levels over the next five years. The organic sector will continue to play a contributing role in revitalizing America’s rural economy through diversity in agriculture.

As a federally regulated and certified process, the organic food industry is uniquely positioned to respond to food safety requirements in ways that are not in effect in other food sectors. The organic foods industry has legally mandated safeguards that contribute to food safety for consumers, including full food product traceability, accountability of food production methods, and strict controls on known potential sources of food contamination. Organic producers and handlers are already familiar with planning, regulatory oversight, third-party certification, and independent inspections. Certified organic growers follow strict guidelines for organic food production and, as with all food producers, must comply with local, state and federal food safety and health standards. Familiarity with these requirements positions the organic sector well in terms of complying with a regulation to improve food safety systems in the United States.

In closing, OTA appreciates the opportunity to provide comments on behalf of our members across the supply chain and the country. We respectfully request that FDA accept the following recommendations:

- OTA recommends that FDA issue guidance that will clarify and further designate the boundaries of “one general physical location” as used in the definition of a “farm.”

- OTA recommends that off-farm operations that perform the same functions as an on-farm operation be subject to the Preventive Control Rule (and therefore required to register under the Bioterrorism Act), BUT only be subject to the subparts of the Produce Safety Rule that apply to those activities, such as Subparts C, D, K, L and O. To accomplish this, a new subpart under Subpart 117 of the Preventive Controls Rule could be created permitting registered establishments (that only hold, store or pack RACs) to meet their obligation by compliance with subparts of the Produce Safety Rule applicable to holding and packing.
- OTA agrees with FDA that testing is an important verification measure to ensure that preventive controls are effectively controlling hazards. However, we continue to urge FDA to focus on ensuring that preventive measures are properly designated and effective, instead of relying on environmental or finished product testing. We recommend that FDA in the rule itself continue to require verification activities be a part of an operation's food safety plan. In guidance, we recommend that FDA express the importance of testing as an effective part of that plan, and focus on providing useful guidance to industry on best practices and methods for monitoring and testing protocols.
- Given the flexibility that FDA has built into this supplemental proposed rule, OTA supports the requirement for supplier verification in the rule itself. We strongly recommend that FDA issue guidance that can be adapted to each operation.

We again thank FDA for its extensive outreach to organic stakeholders and for taking these comments into consideration. We look forward to a final rule that will ensure the success and safety of this segment of the food supply.

Respectfully submitted,



Gwendolyn Wyard  
Regulatory Director of Organic Standards and Food Safety  
Organic Trade Association

cc: Laura Batcha  
Executive Director  
Organic Trade Association