November 18, 2013

TO: **Division of Dockets Management [HFA-305]**
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
(Fed Register – Vol. 78, No. 11 – Pages 3647-3824)

Thank you for the opportunity to provide comments on FDA's Proposed Preventive Controls Rule.

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.

First and foremost, OTA would like to express 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 an obligation to supply safe food to the public.

While OTA supports the overall efforts of FDA to ensure a safer food supply and we agree with many sections of the proposed rule, we are concerned with a handful of sections that need further work. The following is a summary of the key issues we have identified that need additional consideration and revision. Our more detailed comments and suggestions for improvement follow thereafter.

- Many handlers/processors currently use and understand voluntary food safety management systems such as Hazard Analysis and Critical Control Points (HACCP) and HACCP-based certification programs like the Global Food Safety Initiative (GFSI). Handlers will likely not stop requesting these audits because these are what customers and produce buyers recognize and markets currently demand. The effectiveness of HACCP principles is well established, so FDA can enhance (or further the goals of) FSMA by building on the existing HACCP-based programs. It is neither operationally sound nor efficient to create a separate inspection framework for FSMA programs without taking steps to integrate with existing food safety programs. OTA recommends that FDA re-evaluate the proposed rules, compare them with existing programs, and identify where current programs may be adequate and where programs need upgrading. We suggest creating a list of recognized food safety programs prior to the issuance of the final rule.

- OTA does not agree that a farm or farm mixed-type facility that places others' Raw Agricultural Commodities (RACs) into consumer containers should be classified as packaging (manufacturing/process), and therefore subject to the Preventive Controls Rule. It is the view of OTA that the activities described under harvesting, holding, and packing more appropriately fit

under the Produce Safety Rule and not the Preventive Controls Rule, provided RACs are not transformed into a processed product. Rather than focusing on the ownership of the product, we suggest FDA focus on "risk" and supplier verification. Farms should be required to assess their suppliers and accept produce from farms under different ownership provided they are receiving produce that was grown and harvested in a safe manner, either under the Produce Safety Rule, or a similar food safety program deemed acceptable by FDA.

- Environmental and product testing are important verification measures used 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. 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 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. Therefore, rather than mandating supplier verification, OTA recommends that FDA issue guidance that can be adapted to each operation.

- As written, the rule will have significant impact on establishments throughout the country. Considering the number of questions asked in the preamble of the proposed rule and the number of tentative conclusions, the quality and legitimacy of a final rule would be improved if FDA were to consider and respond to the extensive comments received, and then issue a second proposed rule.

OTA respectfully submits the following more specific comments:

General	OTA's comments on the proposed rule 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.
General	Imports should be regulated in the same manner as domestic products. Consumers need to know that imported products are as safe as those from the U.S.A. Also, unless imported products are held to the same standards as domestic products, domestic firms could be placed at an unfair disadvantage. Requirements for imports and domestic products should be consistent, and the method of enforcement for imports is important for ensuring both food safety and market fairness. Adequate oversight and certification of third-party inspection firms is vital, and variances for imports must be as strictly controlled as those for states.
General	To follow the rule, establishments need to understand what is expected of them. Those enforcing the rule need to know what compliance looks like. A phased approach to education and enforcement—having guidance before the rule is to be implemented—can help remove uncertainty for both producers and regulators. It is not enough to simply develop and distribute guidance materials. Ongoing education, outreach and compliance assistance also will be needed to make the rule effective. Guidance documents should be timely and written in plain language. Multiple formats will be needed for different uses and audiences. Communication may best be accomplished by locally based efforts. This will require considerable coordination and adequate funding.

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General	OTA thanks FDA for its thoughtful approach and inclusion of specific questions for comments throughout the preamble. The numerous questions and tentative conclusions expressed, however, reflect a very tentative rule. To avoid unintended consequences, we respectfully request FDA consider the extensive comments submitted by thousands of stakeholders across the country, make changes accordingly, and release a second proposed rule. An additional comment opportunity will prompt further discussion and exchange of information, and ultimately result in a better final product.
Subpart A	**GENERAL PROVISIONS**
§ 117.3	**<u>Definitions related to mixed-type facilities</u>** 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." Our comments below discuss our position on the definition of a farm, and the kinds of activities that should fall outside the definition of a "farm" and would therefore be subject to the proposed Preventive Controls Rule. ***Farm*** The proposed rule defines "farm" as: *Farm* means a facility (as defined in § 1.227 of this chapter) in one general physical location devoted to the growing and harvesting of crops, the raising of animals (including seafood), or both. Farm includes: (i) Facilities that pack or hold food, provided that all food used in such activities is grown, raised, or consumed on that farm or another farm under the same ownership; and (ii) Facilities that manufacture/process food, provided that all food used in such activities is consumed on that farm or another farm under same ownership. We recognize that FDA has adopted the definition of "farm" from § 1.227 in the section 415 registration regulations in order to position the requirements of the proposed Produce Rule within a complex regulatory framework that already exists under Chapter 4 of the FDA&C Act, including Section 415 (Bioterrorism Act) and proposed Section 418 (Hazard analysis and risk-based preventive controls). As explained in the Preamble in the proposed Preventive Controls Rule, a farm is considered an "establishment" within the definition of "facility." Although the definition of "farm" proposed by FDA for use in the proposed Produce Rule and Preventive Controls Rule may be appropriate in the legal context of the existing regulatory framework, on a practical level the description of a "farm" as a "facility" is potentially confusing because industry typically understands a "farm" to be an area of land and its buildings. **OTA recommendation:** OTA recommends that FDA, within the constraints of the FD&C Act, clarify the proposed Produce Rule's definition of a "farm" by adding "an area of land and its

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buildings" to its definition.

> *Farm* means a facility (as defined in § 1.227 of this chapter), typically an area of land and its buildings, in one general physical location devoted to the growing and harvesting of crops, the raising of animals (including seafood) or both. Farm includes: (i) Facilities that pack or hold food, provided that all food used in such activities is grown, raised, or consumed on that farm or another farm under the same ownership; and (ii) Facilities that manufacture/process food, provided that all food used in such activities is consumed on that farm or another farm under same ownership.

Mixed-Type Facility
As proposed:

> *Mixed-type facility* means an establishment that engages in both activities that are exempt from registration under section 415 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350d) and activities that require the establishment to be registered. An example of such a facility is a ''farm mixed-type facility,'' which is an establishment that grows and harvests crops or raises animals and may conduct other activities within the farm definition, but also conducts activities that require the establishment to be registered.

OTA agrees with this definition and the fact that an establishment may engage in activities that are within the definition of "farm" (and therefore are exempt from FDA registration) and activities outside the definition of a "farm" (and therefore require FDA registration).

Manufacturing/Processing
As proposed:

> *Manufacturing/processing* means making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients. Examples of manufacturing/processing activities are cutting, peeling, trimming, washing, waxing, eviscerating, rendering, cooking, baking, freezing, cooling, pasteurizing, homogenizing, mixing, formulating, bottling, milling, grinding, extracting juice, distilling, labeling, or packaging. For farms and farm mixed-type facilities, manufacturing/ processing does not include activities that are part of harvesting, packing, or holding.

OTA agrees with this definition, particularly that "for farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding."

Harvesting
As proposed:

> "*Harvesting* applies to farms and farm mixed-type facilities, and means activities that are traditionally performed by farms for the purpose of removing raw agricultural commodities from the place they were grown or raised and preparing them for use as food. Harvesting is limited to activities performed on raw agricultural commodities on the farm on which they were grown or raised, or another farm under the same ownership.

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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, 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."

We agree with the definition of "harvesting" except for the condition that the RACs be grown on the farm or another farm under the same ownership. At first glance, this requirement is perfectly logical because it would follow that "harvesting" should only happen on a farm where a RAC is grown and is "for the purpose of removing raw agricultural commodities from the place they are grown or raised and preparing them for use as food." However, advanced farming practices, unique crop harvesting methods, and the incredible expenses of such systems make the sole ownership of such equipment not possible in all situations. As a result, it is common to perform job sharing and equipment sharing for harvesting functions.

OTA Recommendation: OTA requests that FDA consider removing the sentence "[h]arvesting is limited to activities performed on raw agricultural commodities on the farm on which they were grown, raised, or another farm under the same ownership" from the definition of harvest. Removing this limitation will allow "harvesting" activities to remain part of "farm" activities.

Holding and Packing

Consistent with FDA's proposed definition of "harvesting," the proposed definitions for "holding" and "packing" include two conditions that must be met if those activities are to fall under the definition of a "farm" (and are therefore not subject to FDA registration and the Preventive Controls Rule):

1) Limited to activities that are performed on raw agricultural commodities grown or raised on the same farm or another farm under the same ownership; and

2) Does not include activities that transform an RAC, 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.

Under the proposed revisions to part 1, FDA explains that there would be a change in how FDA considers the act of placing RACs into consumer containers (1) off-farm and (2) on a farm or farm mixed-type facility with respect to others' RACs. Off-farm, the expanded definition of packing would not apply, so this activity would now be classified as packaging (and, therefore, manufacturing/processing). Off-farm, this change should have no practical impact because off-farm establishments that conduct this activity are already required to register under Section 415 of the FD&C Act, and therefore already are subject to Section 418 of the FD&C Act, whether this activity is classified as packing or manufacturing/processing.

However, on a farm or farm mixed-type facility that places others' RACs into consumer containers, this activity would now be classified as packaging and therefore manufacturing/processing, because the expanded definition of packing would only apply to a farm's own RACs. This change in classification would impact a farm or farm mixed-type facility that conducts such activities if it is not currently required to register.

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	OTA does not agree that a farm or farm mixed-type facility that places others' RACs into consumer containers should be classified as packaging (manufacturing/process), and therefore subject to the Preventive Controls Rule. Foodborne pathogens do not care about the ownership of a farm. It's the farm activities that matter. A farm operating in compliance with the Produce Safety Rule will be able to ensure the safe production, **harvesting and packing** of raw fruits and vegetables regardless of the ownership of the farm on which the produce was grown. **Placing a farm's own RACs or a neighbor's RACs into consumer containers that contact the food should be considered "packing" within the "farm" definition.** To restrict otherwise would negatively impact community-based food systems such as farmers' markets, food hubs, and community supported agriculture farms (CSAs). Many farmers and ranchers are challenged by the lack of distribution and processing infrastructure of appropriate scale that would give them wider access to retail, institutional, and commercial foodservice markets, where demand for local and regional foods continues to rise. Many farmers and ranchers are challenged on how to best move product from the farm to the marketplace. This is especially crucial for small and mid-size farmers who may not have enough capital to own their own trucks, their own refrigeration units, or their own warehouse space. It's not uncommon for several smaller farms to send their produce to a larger farm with on-site packing sheds where the produce is packed for distribution. These kinds of situations offer a combination of production, aggregation, distribution, and marketing services, and make it possible for producers to gain entry into new and additional markets that would be difficult or impossible to access on their own. The proposed Produce Safety Rule includes standards directed to harvesting, packing, and holding activities that will adequately ensure safe food regardless of the ownership of the farm on which the produce was grown. In this type of situation, records must clearly document the farm from which the produce was received, including a lot number or some system of easily allowing traceability back to the farm of origin. **OTA Recommendation:** OTA recommends that FDA revise the criteria for applicability of the proposed Produce Rule and proposed Preventive Controls Rule such that, regardless of ownership of the RACs, all activities (including harvesting) would be treated consistently under either the proposed Produce Rule or the proposed Preventive Controls Rule. It is the view of OTA that the activities described under harvesting, holding, and packing more appropriately fit under the Produce Safety Rule and not the Preventive Controls Rule, provided RACs are not transformed into a processed product. Rather than focusing on the ownership of the product, we suggest FDA focus on "risk" and supplier verification. Farms should be required to assess their suppliers and accept produce from farms under different ownership provided they are receiving produce that was grown and harvested in a safe manner, either under the Produce Safety Rule or a similar food safety program deemed acceptable by FDA.
Subpart B	**CURRENT GOOD MANUFACTURING PRACTICES**
	OTA supports the proposed current GMP updates.
Subparts	**HAZARD ANALYSIS AND RISK-BASED PREVENTIVE CONTROLS**

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OTA General Comment	The preamble to the proposed rule makes clear that these new requirements would be based largely on HACCP principles. FDA tentatively concludes for several reasons that HACCP is the appropriate framework to reference in interpreting and implementing section 103 of FSMA. The preamble discusses the FDA HACCP regulations for fish and fishery products (21 C.F.R. Part 123) and juice products (21 C.F.R. Part 120), the U.S. Department of Agriculture HACCP regulations for meat and poultry (9 C.F.R. Part 415), the Pasteurized "Grade A" Milk Ordinance (PMO) HACCP pilot, and the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) "Hazard Analysis and Critical Control Point Principles and Application Guidelines." It also discusses various international and foreign HACCP guidelines and regulations, including the CODEX Alimentarius Commission's HACCP Annex to the Codex General Principles on Food Hygiene. Reference 193 in the proposed rule provides a table comparing proposed Subpart C to various domestic and international HACCP regulations and guidelines. However, FDA recognizes that there are significant differences between a HACCP plan and a preventive controls plan. For example, a HACCP plan applies controls at critical control points (CCPs), and each CCP has a critical limit (*i.e.*, a maximum or minimum value to which a biological, chemical, or physical parameter must be controlled in order to prevent, eliminate, or reduce a hazard to an acceptable level). On the other hand, a preventive controls plan would include preventive controls at points other than critical control points, and preventive controls may or may not include critical limits. Both Codex GENERAL PRINCIPLES OF FOOD HYGIENE and the NATIONAL ADVISORY COMMITTEE ON MICROBIOLOGICAL CRITERIA FOR FOODS (NACMCF) refer to control measures, which are defined as "Any action or activity that can be used to prevent, eliminate or reduce a significant hazard." In HACCP principle #1, the HACCP team is expected to identify control measures, if any, which can be applied to control the hazards of concern. This is directly analogous to the FSMA definition of Preventive Controls: "The term `preventive controls' means those risk-based, reasonably appropriate procedures, practices, and processes that a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would employ to significantly minimize or prevent the hazards identified under the hazard analysis." FDA extends this definition to include what are generally referred to as Prerequisite Programs such as sanitation procedures, recall plans, etc. In addition, FDA conducted its own equivalency assessment of FSMA and the PMO voluntary HACCP program (which follows the HACCP principles outlined in NACMCF). In the agency's words, "The proposed rule would require a food safety plan, and outlines specific components that are very similar but not identical to the requirements for a HACCP plan in the PMO HACCP Appendix." It goes on to invite comments regarding "how the PMO voluntary HACCP program satisfies the proposed rule's requirements." Assuming public comments support equivalence, it would logically extend to any HACCP Plan that was developed and implemented with rigorous application of the principles set forth in NACMCF and Codex. **OTA Recommendation:** The differences between the proposed preventive rule and HACCP are insignificant. HACCP programs focus on identifying preventive measures for hazards of concerns, and satisfy the proposed requirements for a food safety plan and the specific components therein.

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	Furthermore, the meat, juice and seafood industries currently work under federal HACCP guidelines identifying risks and applying appropriate control and mitigation strategies, which are well accepted in those industries. OTA urges FDA to recognize operations that have an established HACCP Program implemented by a qualified individual (including the PMO voluntary HACCP program) as meeting the requirements of the Preventive Control Rule. Recognizing HACCP and HACCP-based programs in general as equivalent would allow FDA to maintain consistent regulation of the industry through codifying a well-established program with proven efficacy. This, in turn, would reduce the regulatory burden on industry.
§ 117.126 **Pg. 3807**	**Requirement for a food safety plan.** See general comment on HACCP
§ 117.130 **Pg. 3806**	**Hazard analysis.** See general comment on HACCP
§ 117.135 **Pg. 3806**	**Preventive controls for hazards that are reasonably likely to occur.** See general comment on HACCP
§ 117.150 **Pg. 3807**	**Verification** ***Request for Comment on Environmental and Product Testing*** FDA requests comments on whether to include environmental or product testing requirements in the final rule. FDA requests comments on when and how product testing programs are an appropriate means of implementing the statutory directives in FD&C Act § 418. The proposed rule does not mandate any testing requirements (*e.g.,* testing of raw materials or ingredients, finished product testing, environmental monitoring). This is consistent with FD & C Act § 418, which 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." However, in the preamble, FDA makes 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. OTA agrees with FDA that testing is an important verification measure to ensure that preventive controls are effectively controlling hazards. Moreover, environmental and product testing may be appropriate in certain instances as verification measures, but they do not constitute a control step and should not be included in the rule itself. 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 in most cases not a practical preventive control or critical control point. It is typically used as a verification tool. **OTA Recommendation:** OTA urges 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 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

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	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 appropriate • 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. Consistent with our comments above, we do not believe the activity should be included in the rule itself. Guidance on this matter would be more appropriate. ***Request for Comment on Supplier Approval and Verification*** FDA requests 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&C Act § 418. The proposed rule does not mandate any requirements for approval or verification of suppliers. However, 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. In both the preamble and an appendix to the proposed rule, FDA explains its views on supplier approval and supplier verification. 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. **OTA Recommendation:** The role and need for supplier approval and verification vary depending on the type of facility and type of food. Rather than mandating supplier verification, OTA recommends that FDA issue guidance that can be adapted to each operation.
Subpart D	**MODIFIED REQUIREMENTS**
	No Comment
Subpart E	**Withdrawal of an Exemption Applicable to a Qualified Facility**
	No Comment
Subpart F	**Requirements Applying to Records That Must be Established and Maintained**
117.325	**Public Disclosure** Public disclosure of records as specified in 117.325 is not aligned with other risk-based preventive controls programs, and must be amended so it is. Subpart 117.325 should preserve the privacy of

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information maintained as a result of the regulation unless otherwise made publicly available.

For example, both the food safety programs for juice and for fish and fishery products make records not subject to disclosure unless previously disclosed or otherwise sufficiently generic. These same requirements should be applied to all other food facilities subject to the proposed preventive control regulation.

> **21 CFR Part 120. Hazard Analysis and Critical Control Point (HACCP) Systems**
>
> 120.12(f) Public disclosure. (1) All records required by this part are not available for public disclosure unless they have been previously disclosed to the public, as defined in § 20.81 of this chapter, or unless they relate to a product or ingredient that has been abandoned and no longer represent a trade secret or confidential commercial or financial information as defined in § 20.61 of this chapter.
> (2) Records required to be maintained by this part are subject to disclosure to the extent that they are otherwise publicly available, or that disclosure could not reasonably be expected to cause a competitive hardship, such as generic type HACCP plans that reflect standard industry practices.
>
> **21 CFR Part 123. Fish & Fishery Products**
>
> 123.9(d) Public disclosure. (1) Subject to the limitations in paragraph (d)(2) of this section, all plans and records required by this part are not available for public disclosure unless they have been previously disclosed to the public as defined in § 20.81 of this chapter, or they relate to a product or ingredient that has been abandoned and they no longer represent a trade secret or confidential commercial or financial information as defined in § 20.61 of this chapter.
> (2) However, these records and plans may be subject to disclosure to the extent that they are otherwise publicly available, or that disclosure could not reasonably be expected to cause a competitive hardship, such as generic-type HACCP plans that reflect standard industry practices.

OTA Recommendation: In order to maintain alignment with public disclosure of records as specified in parts 120.12(f) and 123.9(d), OTA proposes the following revision as indicated in italics:

> 117.325 Public Disclosure, as currently proposed:
> "Records required by this part are subject to the disclosure requirements under part 20 of this chapter."
>
> OTA proposes deleting the currently proposed 117.325 and replacing with the following:
>
> *(1) All records required by this part are not available for public disclosure unless they have been previously disclosed to the public, as defined in 20.81 of this chapter, or unless they relate to a product or ingredient that has been abandoned and no longer represent a trade secret or confidential commercial or financial information as defined in 20.61 of this chapter.*

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	(2) Records required to be maintained by this part are subject to disclosure to the extent that they are otherwise publicly available, or that disclosure could not reasonably be expected to cause a competitive hardship, such as generic food safety plans that reflect standard industry practices.

Conclusion

The *Organic Trade Association's 2013 Organic Industry Survey* shows the organic industry has grown from $3.6 billion in 1997 to $31.5 billion in 2012, with an annual growth rate of 19% from 1997-2008. As our country has been 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 the same as other food sectors. The organic foods industry has federally-mandated safeguards that result in 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, they 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 thank FDA for taking these comments into consideration as it moves forward with its programs for assuring the safety of the U.S. food supply.

Our suggested revisions and recommendations for improvement are summarized as follows:

- OTA recommends that FDA reevaluate the proposed rules, compare them with existing food safety programs, and identify where current food safety programs may be adequate and where programs need upgrading. We also urge FDA to recognize operations that have established HACCP-based food safety management systems implemented by a qualified individual as meeting the requirements to the Preventive Control Rule.
- OTA recommends that FDA revise the criteria for applicability of the proposed Produce Rule and proposed Preventive Controls Rule such that, regardless of ownership of the RACs, all activities (including harvesting) would be treated consistently under either the proposed Produce Rule or the proposed Preventive Controls Rule.
- Rather than focusing on the ownership of the product, OTA suggests that FDA focus on "risk" and supplier verification. Farms should be required to assess their suppliers and accept produce from farms under different ownership provided they are receiving produce that was grown and harvested in a safe manner, either under the Produce Safety Rule, or a similar food safety program deemed acceptable by FDA.
- Rather than mandating supplier verification, OTA recommends that FDA issue **guidance** that can be adapted to each operation.

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- Periodic testing for trend analysis and statistical process control is a verification activity. OTA recommends that FDA continue to express the importance of testing as an effective part of a food safety plan, and focus on providing useful **guidance** to industry.
- Public disclosure of records as specified in 117.325 should preserve the privacy of information maintained as a result of the regulation unless otherwise made publicly available.
- The final rule would be improved if FDA were to consider and respond to the extensive comments received, and then issue a second proposed rule with opportunity for comment.

We thank you for carefully considering our comments and look forward to a final rule that will ensure the success and safety of this segment of the food supply.

Respectfully submitted,

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