December 15, 2014

U.S. Food and Drug Administration  
Division of Dockets Management, HFA-305  
5630 Fishers Lane, Room 1061  
Rockville, Maryland 20852

Re: **Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food; supplemental notice of proposed rulemaking (Docket No. 2011-N-0920/RIN 0910-AG36)**

To Whom It May Concern:

On behalf of our members, the Produce Marketing Association (PMA) respectfully submits the following comments to the proposed rule entitled, “Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food” supplemental notice of proposed rulemaking (Docket No. 2011-N-0920/RIN 0910-AG36). In addition to this executive summary, PMA submits the attached document that provides specific comments on the proposal. To assist both FDA and our PMA membership in reviewing the comments, we have organized them into specific categories and have also provided the titles and relevant passages (blue print) from the proposed rules to provide context to our comments. The general categories we have organized our comments around are as follows:

I. Overarching Issues  
   A. Preventive Controls and Produce Rule Coverage

II. Comments on Specific Provisions Set Forth in the Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food Rule Supplemental Proposal  
   A. Proposed Definitions for “Farm,” “Harvesting,” “Holding,” “Packing” and 10 Other Proposed Terms  
   B. Proposed Framework for Hazard Analysis and Risk-Based Preventive Controls  
   C. Proposed Supplier Control Program Requirements  
   D. Proposed Environmental Monitoring and Product Testing Requirements  
   E. Proposed Provisions for Withdrawal and Reinstatement of a “Qualified Exemption”

PMA is the largest trade association representing companies in the fresh fruits and vegetables industry. Our association represents more than 2,700 member companies
located in 45 countries. In the U.S., our members operate at every level in the supply chain from growing to shipping, processing/manufacturing, distribution, wholesaling, retail and foodservice. Collectively, our members handle more than 90 percent of fresh produce sold to domestic consumers. Regardless of member size or scope of operations, our members are committed at every level in the supply chain to food safety.

PMA’s vision is to strengthen and lead the global produce community to increase produce consumption. Fruits and vegetables are an integral part of a nutritious and healthful diet, offering great public health benefits. PMA believes that produce safety, taste, convenience, and nutrition are the cornerstones of increasing fruit and vegetable consumption and fighting obesity.

PMA has long been a champion of produce safety and has relied upon the expertise of produce safety professionals who serve as volunteer leaders on the PMA Science & Technology Committee and PMA members at large to develop the comments that follow. In preparing our comments, PMA engaged in numerous and frequent in-depth discussions with PMA member companies that grow, pack and ship fresh produce both domestically and internationally and companies that represent the diversity of produce commodities American consumers expect to be available to them year around. Throughout the discussion, PMA members carefully discussed and deliberated the ability of each proposed rule provision to enhance public health, while searching for practicable and easily implementable solutions to enhance the safety of fresh produce. As a result, our comments provide perspectives from the collective experiences of those who work diligently in the produce global supply chain to provide safe and nutritious produce to consumers daily.

PMA is also a strong supporter of the development of scientific and technical information as indicated by the association’s founding support of the Center for Produce Safety (CPS). CPS is a unique research foundation focused exclusively on produce-related food safety research in collaboration with industry, government and academia. CPS provides open access to scientific research results that are actionable and necessary to continually enhance the safety of produce. Companies of all sizes and locations benefit from CPS research. The research results generated by CPS have added significantly to the body of knowledge associated with produce safety. Scientific research regarding produce safety plays an important and integral role in informing produce company food safety practices, best practices guidance developed by industry, and government and rule-making policy decisions.

PMA has participated in the congressional debate about FSMA and has provided comments to FDA at every opportunity in the development of the proposed rules. We greatly appreciate those earlier opportunities and the opportunity here to provide detailed comments on the rules. Attached are those comments.
Respectfully,

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Executive Summary

Food safety is a top priority for the global produce industry. Implications of these proposals are critically important to PMA members’ businesses and to the industry’s overall objective of increasing produce consumption. PMA strongly supports advancing produce safety in ways that are meaningful for industry members and that also protect public health, including through the implementation of the Food Safety Modernization Act. PMA supports the implementation of science- and risk-based regulations throughout the supply chain that require the use of preventive controls that correspond with risks associated with the commodity, and practices and procedures employed during the production, handling, and holding of fresh produce.

Key issues from the perspective of PMA members regarding FDA’s Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food supplemental proposal are as follows:

I. Overarching Issues
   A. Preventive Controls and Produce Rule Coverage

II. Comments on Specific Provisions Set Forth in the Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food Rule Supplemental Proposal
   A. Proposed Definitions for “Farm,” “Harvesting,” “Holding,” “Packing” and 10 Other Proposed Terms
   B. Proposed Framework for Hazard Analysis and Risk-Based Preventive Controls
   C. Proposed Supplier Control Program Requirements
   D. Proposed Environmental Monitoring and Product Testing Requirements
   E. Proposed Provisions for Withdrawal and Reinstatement of a “Qualified Exemption”
I. Overarching Issues

A. Produce and Preventive Controls Rule Coverage

PMA recommends that FDA align the requirements of the produce and preventive controls rules for the produce industry. There is very serious produce industry concern that the regulatory lines of coverage between the produce safety rule and preventive controls for human foods rule are not workable for agriculture and do not reflect the realities of produce production and handling. For example, as proposed, an on-farm produce packing house would be regulated under the produce rule, an off-farm packing house with less than $1 million dollars in total food sales would be subject to the Current Good Manufacturing Practice (CGMP) provisions of the preventive controls rule for human food and an off-farm packing house with more than $1 million dollars in total food sales would be subject to both the CGMP and Hazard Analysis and Risk-Based Preventive Controls (HARPC) provisions of the preventive controls rule for human foods.

There is no science-based reason for treating a packing house differently based on where raw agricultural commodities (RACs) are packed or an enterprise size. Produce packing houses are not materially or compositionally changed or altered and do not undergo any manufacturing or processing activities and thus should be regulated under the produce rule.

II. Comments on Specific Provisions Set Forth in the Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food Produce Rule Supplemental Proposal

A. Proposed Definitions for “Farm,” “Harvesting,” “Holding,” “Packing” and 10 Other Proposed Terms

- PMA supports redefining “farm” to include establishments that solely engage in “packing” and “holding” activities performed on RACs. This would allow packinghouse operations to be considered “farm” establishments and be covered by the produce safety rule. This would also provide uniform and effective regulation of all packing activities irrespective of its physical location or enterprise size to be solely covered by the produce safety regulation. The definition of “farm” need not be predicated on the fact that growing must occur to consider an establishment a “farm.”
B. Proposed Framework for Hazard Analysis and Risk-Based Preventive Controls

- PMA respectfully request that FDA consider deferring action on issuance of implementing regulation provisions that address and require hazard analysis and preventive controls for economically motivated adulterants until after the preventive controls rule and FSVP rule are implemented.
- PMA supports proposed regulatory provisions that provide flexibility to operators to implement preventive controls that are appropriate to the facility and the food, procedures, practices and processes.
- PMA respectfully requests that FDA consider placing recall plan requirements in 21 CFR 117 Subpart B (Current Good Manufacturing Practices), as a recall plan should be requisite for all food facilities irrespective of enterprise size. As currently proposed, recall plans would only be required of food facilities that are subject to 21 CFR 117 Subpart C (Hazard Analysis and Risk-Based Preventive Controls) portions of the regulation.

C. Proposed Supplier Control Program Requirements

- PMA supports proposed regulatory provisions that align supplier program provisions set forth in the preventive controls for human foods supplemental proposed rule and the foreign supplier verification program supplemental proposed rule, as it avoids imposing duplicative requirements on entities that are subject to each of those sets of regulations because they are both registered food facilities and food importers.
- PMA supports proposed regulatory provisions that only require a facility to document the conclusions of onsite audits, thus maintaining the confidentiality of the original inspection reports and facilitating robust and thorough audits.
- PMA has concerns about supplier controls recordkeeping requirements, particularly for firms that have a corporate headquarters location and satellite operations. PMA recommends that FDA consider operational means to reduce redundant supplier control records review during routine compliance inspections and reduce the likelihood of the agency offering divergent interpretations of compliance for the same supplier control records.
- PMA supports proposed regulatory provisions that supplier verification activities be based on a combination of food risk and supplier risk as this will allow facility operators to target food safety resources to issues that are most likely to occur.

D. Proposed Environmental Monitoring and Product Testing Requirements

- PMA generally supports the proposed regulatory provisions regarding verification of implementation and effectiveness as the proposed provisions appropriately provide flexibility that allows operators to tailor their product testing and environmental monitoring programs, as verification activities, and as appropriate to the nature of the food, the facility, and the nature of the preventive control(s) being verified.
Additionally, PMA supports proposed regulatory provisions that provide flexibility set forth in §117.165 provisions that allow operators to take corrective actions arising from positive environmental testing findings (i.e., detection of a pathogen or presence of an indicator above a certain threshold) that are tailored and "as appropriate to the preventive control" being verified.

PMA does not support proposed provisions that environmental monitoring be required to verify effectiveness of preventive controls whenever a ready-to-eat (RTE) product is exposed to the environment prior to packaging and the packaged food does not receive a treatment that would significantly minimize an environmental pathogen that could contaminate the food when it is exposed. PMA respectfully requests that FDA consider amending this proposed rule provision so as to be explicit that there are circumstances when product testing, particularly finished product testing, and environmental monitoring would not be necessary.

PMA does not support mandatory environmental monitoring for facilities that handle raw agricultural commodities until FDA amends its policies regarding the regulatory consequences of a single detection of potentially transient and low levels of L. monocytogenes on a food contact surface. Fresh produce poses a unique challenge among FDA regulated foods, and FDA’s current “no tolerance” policy for L. monocytogenes has unintended consequences of dis-incentivizing the implementation of a “seek and destroy” environmental monitoring strategy and will likely lead to resistance to routine testing of food contact surfaces.

PMA concurs with FDA that the presence of certain pathogens in ready-to-eat foods is unacceptable. PMA believes, however, it is important for FDA to clarify in the final rule that the nature and extent of any corrective actions should be commensurate to the nature of the test findings. Corrective actions, if any, need to take into account the nature of the hazard (i.e., particular testing results, including the type of organism and the levels found) and the nature of the control measure(s) being verified.

### E. Proposed Provisions for Withdrawal and Reinstatement of a “Qualified Exemption”

*Qualified Exemption (Tester/Hagen Amendment):* PMA has historically opposed the “qualified exemption” and has repeatedly recommended that this exemption be eliminated. PMA understands that FDA is statutorily obliged to provide this “qualified exemption”; however, it should be noted that the “qualified exemption” is not science- or risk-based, as food safety risks are not limited to any particular business size, market channel or geographic radius. Produce contamination can occur in any operation that uses unsafe processes and practices. There is no scientific basis to support the “qualified exemption.”

PMA supports the proposed administrative procedures that FDA has proposed regarding re-instatement of a “qualified exemption” when FDA determines, after finishing an active investigation of a foodborne illness outbreak, that the
outbreak is not directly linked to the farm that had its "qualified exemption" withdrawn.

- PMA does not support inclusion of administrative procedures for the re-instatement of withdrawn "qualified exemption" in the case where a food facility has been linked to a foodborne illness outbreak.
Table of Contents

I. Overarching Issues
   A. Preventive Controls and Produce Rule Coverage ............................................ Page 11

II. Comments on Specific Provisions Set Forth in the Preventive Controls for Human Foods Supplemental Rule Proposal
   A. Definitions of “Farm,” “Harvesting,” “Packing,” “Holding,” and 10 other proposed terms ............................................................. Page 12
   B. Proposed Framework For Hazard Analysis and Risk-Based Preventive Controls ........................................................... Page 21
   C. Proposed Supplier Control Program Requirements .................................................. Page 26
   D. Proposed Environmental Monitoring and Product Testing Requirements ................................. Page 32
   E. Proposed Provisions for Withdrawal and Reinstatement of a “Qualified Exemption” .................................................. Page 40
Produce Marketing Association Comments
“Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food”
(Docket No. 2011-N-0920/RIN 0910-AG36)

The Produce Marketing Association (PMA) on behalf of its members respectively submits the following comments in response to the U.S. Food and Drug Administration’s (FDA) Federal Register Notice entitled, “Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food” supplemental notice of proposed rulemaking (Docket No. 2011-N-0920/RIN 0910-AG36) issued on September 29, 2014. PMA is the largest trade association representing companies that market fresh fruits and vegetables. We represent 2,700 companies in 45 countries including members that handle more than 90 percent of fresh produce sold to consumers in the United States. Member companies are representative of the U.S. produce industry supply chain. They vary in size from small to large and their operations range from supermarket retailing, wholesaling, and distribution, to shipping and growing. PMA’s members of every size and at every level in the supply chain are committed to food safety and share the FDA’s focus on food safety.

PMA is also a strong supporter of the development of science-based produce safety knowledge to assist industry and government in making informed produce safety decisions, as indicated by the association’s support of the Center for Produce Safety (CPS). CPS is a unique research entity focused exclusively on produce-related food safety research in collaboration with industry, government and academia. CPS provides open access to scientific research results that are actionable and necessary to continually enhance the safety of produce. Companies of all sizes and locations throughout the produce value chain benefit from CPS research.

PMA applauds the FDA for the tremendous effort made in developing supplemental proposed Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food. PMA supports the use of science-based standards in the produce industry. Recognizing the profound impact the final preventive controls for human food rule and other rules currently under development will have on the produce industry, PMA offers its support to the FDA, our membership, allied trade associations, USDA and state and local agencies on implementing the final rule and all of its provisions. PMA understands the importance of these rules in preventing produce associated foodborne illnesses and is committed to improving the safety of fresh produce. PMA’s comments are provided below on select topic areas set forth in the FDA’s supplemental proposed rule and notice.
I. Overarching Issues

A. Preventive Controls and Produce Rule Coverage

PMA recommends that FDA align the requirements of the produce and preventive controls rules for the produce industry. There is very serious produce industry concern that the regulatory lines of coverage between the produce safety rule and preventive controls for human foods rule are not workable for agriculture and do not reflect the realities of produce production and handling. For example, as proposed, an on-farm produce packing house would be regulated under the produce rule, an off-farm packing house with less than $1 million dollars in total food sales would be subject to the GMP provisions of the preventive controls rule for human food and an off-farm packing house with more than $1 million dollars in total food sales would be subject to both the GMP and HARPC provisions of the preventive controls rule for human foods.

This is not a risk-based approach as it sets up a system of dual, divergent standards and regulatory requirements (e.g. environmental testing, product testing, food safety plan, etc.) for produce packing houses with similar operational risk profiles. While we understand the complicated legal constraints involving the Bioterrorism Act that lead FDA to this result, it fails to recognize the basic business structure in the produce industry and the many operational configurations that ensure highly perishable raw agricultural commodities are harvested, sorted, packed and shipped to consumers to meet their demands for healthy, nutritious products.

There is no science-based reason for treating a packing house differently based on where raw agricultural commodities (RACs) are packed or the enterprise size. Produce packing houses do not materially or compositionally change or alter fresh produce and do not engage in what would traditionally be considered “manufacturing/processing”, as the same product entering the packing house is what is introduced into commerce and no substantial transformation of the product has occurred in the packing house. Hence, all packing houses should be regulated under the produce rule. PMA supports the approach that bases facility inclusion in the preventive controls rule on substantial transformation of the product being handled and not on who owns the product.

PMA respectfully requests that FDA consider that all activities related to growing, harvesting, packing and holding of RACs be subject to the produce rule no matter which party, the grower or the buyer is responsible for the activities, and that all facilities processing crops into value-added products be covered by the preventive controls rule. This would entail expanding the produce rule to include cGMP provisions for packing in a facility. However, we do not support subjecting field-packing activities to cGMP since most Subpart B provisions were intended to address hazards in and around a building food facilities and would be difficult to implement in an open-field environment.
PMA respectfully requests that FDA consider amending the preventive controls for human foods rule and produce safety rule so as to align the requirements of these two rules for the produce industry by:

- Amending the definition of “farm”, “harvesting”, “holding” and “packing” as outlined below in our comments, OR
- Amending 21 CFR 117 by adding provisions that would permit registered establishments that only “pack”, “hold” or “store” raw agricultural commodities to be in compliance with the preventive controls for human foods regulation 21CFR117, if they are found to be in compliance with produce rule 21CFR112 Subparts C, D, K, L and O for relevant activities.

II. Comments on Specific Provisions Set Forth in the Preventive Controls for Human Foods Supplemental Rule Proposal

A. Definitions of “Farm,” “Harvesting,” “Holding,” “Packing” and 10 Other Proposed Terms

This section addresses definitions for the following terms:
- “Farm”
- “Harvesting”
- “Holding”
- “Packing”
- “Allergen cross-contact”
- “Environmental pathogen”
- “Pathogen”
- “Qualified auditor”
- “Receiving facility”
- “Hazard”
- “Known or reasonably foreseeable hazard”
- “Significant hazard”
- “Supplier”
- “Very small business”

§1.227 What definitions apply to this subpart?
§1.328 What definitions apply to this subpart?

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. The term "farm" includes establishments that, in addition to these activities:
(1) Pack or hold raw agricultural commodities;
(2) 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 (3)(ii)(A) of this definition; and
(3) Manufacture/process food, provided that:
   (i) All food used in such activities is consumed on that farm or another farm under the same ownership; or
   (ii) Any manufacturing/processing of food that is not consumed on that farm or another farm under the same ownership consists only of:
       (A) Drying/dehydrating raw agricultural commodities to create a distinct commodity, and packaging and labeling such commodities, without additional manufacturing/processing; and
       (B) Packaging and labeling raw agricultural commodities, when these activities do not involve additional manufacturing/processing.

PMA Comment: PMA respectfully requests that FDA consider amending the definition of “farm” 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 has a common, owner, operator(s) or agent in charge and is operated under a common food safety management scheme. The term “farm” includes establishments that, in addition to these activities:

(1) 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
(2) 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.
PMA respectfully requests that FDA consider redefining the term “farm” to include 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. The definition of “farm” need not be predicated on the fact that growing must occur to consider an establishment a “farm.”

Use of the term “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. The term “in one general physical location” also creates ambiguity and has implications as it relates to the clause “establishment under one ownership” in so far as many fresh produce growers, for varying reasons, conduct farm activities in non-contiguous locations.

PMA respectfully requests that FDA consider use of the descriptor “owner, operator, or agent in charge” in the “farm” definition so that it is consistent with preventive controls for human foods rule. The proposed descriptor 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.

PMA supports FDA’s tentative conclusion to remove the term “facility” from the farm definition and replace with the word “establishment” as this will assist clarity and reduce confusion related to the facility registration requirements.

§1.227 What definitions apply to this subpart?
§1.328 What definitions apply to this subpart?
§117.3 Subpart A—General Provisions

Harvesting applies to farms and farm mixed-type facilities and means activities that are traditionally performed on 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 a farm. 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 are examples of harvesting.

PMA Comment: PMA respectfully requests that FDA consider amending the definition of “harvesting” as follows:
Harvesting applies to farms and farm mixed-type facilities and means activities that are traditionally performed on 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 a farm. 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, ripening (artificial or natural), field coring and cooling raw agricultural commodities grown on a farm are examples of harvesting.

- PMA supports the inclusion of activities traditionally done in the field, such as field coring in the “harvesting” definition.
- 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.

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)), 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.

PMA Comment: PMA respectfully requests that FDA consider amending the definition of “holding” as follows:

- PMA supports the inclusion of activities traditionally done in the field, such as field coring in the “harvesting” definition.
- 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.

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)), 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.
warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks.

- 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.
- Fumigation 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.
- PMA supports the inclusion of activities performed incidental to storing a food as part of the “holding” definition.

**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.

**PMA Comment:** PMA agrees with the proposed definition of “packing.”
- PMA supports the inclusion of activities performed incidental to packing a food as part of the “packing” definition.

§ 117.3 Definitions

**Allergen cross-contact** means the unintentional incorporation of a food allergen into a food.

**PMA Comment:** PMA supports the proposed definition of the term “allergen cross-contact” in this rule as it is concise and provides clarity.

**Environmental pathogen** means a pathogen capable of surviving and persisting within the manufacturing, processing, packing, or holding environment such that food may be contaminated and may result in foodborne illness if that food is consumed without treatment to significantly minimize the environmental pathogen. Environmental pathogen does not include the spores of pathogenic sporeformers.

**PMA Comment:** PMA supports the proposed definition of the term “environmental pathogen,” specifically in that it links contamination of the food from the environment with the potential of the food to cause human illness, and it appropriately excludes of pathogenic spore-formers.
Pathogen means a microorganism of public health significance.

PMA Comment: PMA supports the proposed definition of the term “pathogen” in this rule.

Qualified auditor means a person who is a qualified individual as defined in this part and has technical expertise obtained by a combination of training and experience appropriate to perform the auditing function as required by § 117.180(c)(2).

PMA Comment: PMA supports the proposed definition of the term “qualified auditor” in this rule.

Receiving facility means a facility that is subject to subpart C of this part and that manufactures/processes a raw material or ingredient that it receives from a supplier.

PMA Comment: PMA supports the proposed definition of the term “receiving facility” in this rule.

Hazard means any biological, chemical (including radiological), or physical agent that is reasonably likely to cause illness or injury in the absence of its control.

PMA Comment: PMA generally supports the proposed definition of the term “hazard” in this rule as it is concise, provides clarity and appropriately categorized radiological hazards as a chemical hazard. However, please see further comments regarding differentiation and clarification of “hazard” versus “known or reasonably foreseeable hazard” versus “significant hazard” in comments under “significant hazard.”

Known or reasonably foreseeable hazard means a biological, chemical (including radiological), or physical hazard that has the potential to be associated with the facility or the food.

PMA Comment: PMA generally supports the proposed definition of the term “known or reasonably foreseeable hazard” in this rule. However, please see further comments regarding differentiation and clarification of “hazard” versus “known or reasonably foreseeable hazard” versus “significant hazard” in comments under “significant hazard.”

Significant hazard means a known or reasonably foreseeable hazard for which a person knowledgeable about the safe manufacturing, processing, packing, or holding of food
would, based on the outcome of a hazard analysis, establish controls to significantly minimize or prevent the hazard in a food and components to manage those controls (such as monitoring, corrections or corrective actions, verification, and records) as appropriate to the food, the facility, and the control.

**PMA Comment:** PMA generally supports the proposed definition of the term “significant hazard” in that the definition implies that the implementation of a preventive control be based both on the severity and likelihood of the hazard.

- PMA supports the proposed removal of the term “reasonably likely to occur” in this rule, as the term “reasonably likely to occur” may be confused with the HACCP terminology “reasonably likely to occur,” which has a specific implications regarding the designation of a Critical Control Point (CCP).
- Use of the proposed term “significant hazard” more closely aligns with the principles put forth in the FSMA statute terminology (“reasonably foreseeable” and “significantly minimize or prevent”) so as to provide operators the flexibility to implement a range of preventive controls that are commensurate to the risk and probability posed by a specific hazard.
- However, PMA suggests that FDA consider the development and use of an alternative term to “significant hazard” so that it will not be confused with the HACCP terminology “significant hazard” and the implications of that HACCP term.
- Additionally, PMA has concerns regarding how the definition may be divergently interpreted by both industry and regulators. Hence, PMA wishes to express a strong desire to engage early and often with FDA on the development of applicable guidance documents regarding what constitutes a “significant hazard” for produce industry operations and provide an opportunity to explain and discuss current industry best practices and preventive controls to address identified “significant hazards.” FDA may also wish to develop an administrative procedure to adjudicate differences in professional opinion between a regulated firm and federal or state regulatory agency regarding hazard “significance.”

“Hazard” versus “Known or reasonably foreseeable hazard” versus “Significant Hazard”

- FDA has proposed the following definitions for “hazard,” “known or reasonably foreseeable hazard,” and “significant hazard.”

**Hazard** means any biological, chemical (including radiological), or physical agent that is **reasonably likely to cause illness or injury** in the absence of its control.

**Known or reasonably foreseeable hazard** means a biological, chemical (including radiological), or physical hazard that **has the potential to be associated with the facility or the food.**
**Significant hazard** means a known or reasonably foreseeable hazard for which a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would, based on the outcome of a hazard analysis, establish controls to significantly minimize or prevent the hazard in a food and components to manage those controls (such as monitoring, corrections or corrective actions, verification, and records) as appropriate to the food, the facility, and the control.

The supplemental proposal preamble explains that the framework established by the newly defined term “significant hazard” will require facilities to conduct a two-part hazard analysis whereby a facility would first “narrow ‘hazards’ to those hazards that are “known or reasonably foreseeable,” and then further narrow and categorize hazards that would be considered a “significant hazard” within the meaning of the rule. However, upon close examination of the proposed definitions of “hazard” and “significant hazard” do not seem to provide a discernable distinction between “hazards” and “significant hazard” in that the proposed definition of “hazard” currently takes into account whether or not a “hazard” is or is not controlled. It is therefore suggested that the phrase “in the absence of its control” be deleted from the final definition of “hazard” to make clear that hazards are simply the agents that are reasonably likely to cause illness or injury. Further analysis is needed by the food facility to determine: 1) the potential (or probability) of a specific hazard being associated with a particular facility or food product and 2) if an identified hazard is a “significant hazard” that requires control.

- As currently proposed these definitions are problematic in that they do not sufficiently allow for operators to differentiate between “hazards” that are possible but not likely or probable to occur in a particular food or food facility and hazards that are possible and probable to occur in a food facility and require identification and implementation of appropriate preventive controls. This outcome would be contrary to FDA’s preamble discussion regarding “narrow[ing]” the universe of risks based on the assessment of two key issues: (1) the severity of the illness or injury if the hazard were to occur, and (2) the probability that the hazard will occur in the absence of preventive controls.
- PMA concurs with FDA’s tentative conclusion that hazard analysis should involve a risk-based narrowing to identify hazards that require preventive controls.
- PMA respectfully requests that FDA consider amending the definition of “significant hazard” to clarify and distinguish the two steps of the hazard analysis as follows:
  - “Significant hazard” is a known or reasonably foreseeable hazard for which there is a reasonable probability, based on experience, illness data, scientific reports, or other information relevant to the food or the
facility, that adverse health consequence or death will occur in the absence of its control.

- This alternate definition sets forth criteria for facility operators to use that is based on both hazard severity and hazard probability to identify “significant hazards,” which would be narrower than the known and reasonably foreseeable hazards identified in the first step of the analysis.

- PMA wishes to point out that the proposed definition of “significant hazard,” which contains the phrase “for which a person . . . would establish controls” is problematic in that covered firms subject to the final rule are likely to have already established preventive controls for a variety of hazards; however, these hazards may to not rise to the level of control management required for a “significant hazard.” These type of hazards are routinely addressed in what many in industry would term “prerequisite” programs. Of concern is that identification of these hazards in and of themselves should not elevate control of these hazards to the category of being a “significant hazard.” There is also concern that as proposed the supplemental proposed rule definitions may create a disincentive for facilities to voluntarily implement preventive controls for hazards that only pose a remote risk or are very rarely encountered, as such implementing preventive controls for very low probability and severity hazards controls may be misinterpreted as making requisite regulatory requirements set forth for a “significant hazard” even if the hazard does not meet the definition of a “significant hazard.” PMA respectfully requests that FDA consider amending the definition of “significant hazard” to provide facility operators with the flexibility and discretion to establish appropriate preventive controls for hazards that do not rise to the criteria of a “significant hazard” as well as ensuring that preventive controls that address remote or very unlikely hazards not be subject to the food safety management requirements for a “significant hazard.”

- PMA also respectfully requests that FDA harmonize as much as possible the concepts and definitions within the Preventive Controls for Human Foods final rule, Preventive Controls for Animal Foods final rule and Foreign Supplier Verification Programs final rule to ensure a consistent regulatory approach and assist with understanding by all stakeholders.

**Supplier** means the establishment that manufactures/processes the food, raises the animal, or harvests the food that is provided to a receiving facility without further manufacturing/processing by another establishment, except for further manufacturing/processing that consists solely of the addition of labeling or similar activity of a *de minimis* nature.

**PMA Comment:** PMA supports the proposed definition of the term “supplier.”
PMA supports the proposed definition of “supplier” as it means that a facility that doesn’t manufacture/process food such, as for example a distribution center, would not be required to establish a supplier program as per §117.136 of this regulation.

Very small business means, for purposes of this part, a business that has less than $1,000,000 in total annual sales of human food, adjusted for inflation.

PMA Comment: PMA generally supports the proposed definition of the term “very small business” in this rule.

- PMA respectfully requests that FDA consider using the same units of measure to determine whether a business entity is “small business” or a “very small business”;
- PMA respectfully requests that FDA consider not using “annual sales” and use the total amount of “volume of product” or “amount of product” handled or sold. The approach using product volume or amount is more risk based as it correlates more closely to consumer exposures than product dollar amounts which can be skewed by product values.

B. Proposed Framework for Hazard Analysis and Risk-Based Preventive Controls

Subpart C—Hazard Analysis and Risk-Based Preventive Controls

117.130 Hazard analysis.
117.135 Preventive controls.
117.137 Recall plan.
117.150 Corrective actions and corrections.

§ 117.130 Hazard analysis.

(a) Requirement for a hazard analysis.
   (1) You must identify and evaluate, based on experience, illness data, scientific reports, and other information, known or reasonably foreseeable hazards for each type of food manufactured, processed, packed, or held at your facility to determine whether there are significant hazards.
   (2) The hazard analysis must be written.

(b) Hazard identification. The hazard identification must consider:
   (1) Hazards that include:
      (i) Biological hazards, including microbiological hazards such as parasites, environmental pathogens, and other pathogens;
      (ii) Chemical hazards, including radiological hazards, substances such as pesticide and drug residues, natural toxins, decomposition, unapproved food or color additives, and food allergens; and
      (iii) Physical hazards; and
   (2) Hazards that may be present in the food for any of the following reasons:
(i) The hazard occurs naturally;
(ii) The hazard may be unintentionally introduced; or
(iii) The hazard may be intentionally introduced for purposes of economic gain.

(c) Hazard evaluation.

(1)

(i) The hazard analysis must include an evaluation of the hazards identified in paragraph (b) of this section to assess the severity of the illness or injury if the hazard were to occur and the probability that the hazard will occur in the absence of preventive controls.
(ii) The hazard evaluation required by paragraph (c)(1)(i) of this section must include an evaluation of environmental pathogens whenever a ready-to-eat food is exposed to the environment prior to packaging and the packaged food does not receive a treatment that would significantly minimize the pathogen.

(2) The hazard evaluation must consider the effect of the following on the safety of the finished food for the intended consumer:

- The formulation of the food;
- The condition, function, and design of the facility and equipment;
- Raw materials and ingredients;
- Transportation practices;
- Manufacturing/processing procedures;
- Packaging activities and labeling activities;
- Storage and distribution;
- Intended or reasonably foreseeable use;
- Sanitation, including employee hygiene; and
- Any other relevant factors.

Hazard Analysis for Economically Motivated Adulteration

**PMA Comment:** PMA has concerns about proposed provisions set forth in §117.130(b)(2)(iii). Ingredient substitution or ingredient addition without working foreknowledge of the buyer is the basis by which economic deception is perpetrated by unscrupulous suppliers. Inclusion of hazards that may be intentionally introduced for purposes of economic gain will likely be difficult for importers to identify or even be aware of when conducting a hazard analysis. There are potentially an unlimited number of unknown or yet to be identified hazards that could be intentionally introduced for purposes of economic gain by an unscrupulous supplier. Additionally, the misbranding and adulteration provisions of the Federal Food Drug and Cosmetic Act already sufficiently provide safeguards. Therefore the provision that importers be required to analyze for hazards that may be intentionally introduced for purposes of economic gain, should be removed from the final FSVP rule. PMA recommends that FDA defer action on issuance of implementing regulation provisions that require hazard analysis and preventive controls for economically motivated adulterants until after the preventive controls rule and FSVP.
rule are fully implemented. If FDA attempts to address both economically motivated adulteration and unintentional adulteration, it will be likely be too much too fast for the produce industry to implement effectively and efficiently.

§ 117.135 Preventive controls.

(a) You must identify and implement preventive controls to provide assurances that significant hazards will be significantly minimized or prevented and the food manufactured, processed, packed, or held by your facility will not be adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act or misbranded under section 403(w) of the Federal Food, Drug, and Cosmetic Act.

(2) Preventive controls required by paragraph (a)(1) of this section include, as appropriate to the facility and the food:

(i) Controls at critical control points (CCPs), if there are any CCPs; and

(ii) Controls, other than those at CCPs, that are also appropriate for food safety.

(b) Preventive controls must be written.

(c) Preventive controls include, as appropriate to the facility and the food:

(1) Process controls. Process controls include procedures, practices, and processes to ensure the control of parameters during operations such as heat processing, acidifying, irradiating, and refrigerating foods. Process controls must include, as appropriate to the applicable control:

(i) Parameters associated with the control of the hazard; and

(ii) The maximum or minimum value, or combination of values, to which any biological, chemical, or physical parameter must be controlled to significantly minimize or prevent a significant hazard.

(2) Food allergen controls. Food allergen controls include procedures, practices, and processes to control food allergens. Food allergen controls must include those procedures, practices, and processes employed for:

(i) Ensuring protection of food from allergen cross-contact, including during storage and use; and

(ii) Labeling the finished food, including ensuring that the finished food is not misbranded under section 403(w) of the Federal Food, Drug, and Cosmetic Act.

(3) Sanitation controls. Sanitation controls include procedures, practices, and processes to ensure that the facility is maintained in a sanitary condition adequate to significantly minimize or prevent hazards such as environmental pathogens, biological hazards due to employee handling, and food allergen hazards. Sanitation controls must include, as
appropriate to the facility and the food, procedures, practices, and processes for the:

(i) Cleanliness of food-contact surfaces, including food-contact surfaces of utensils and equipment;
(ii) Prevention of allergen cross-contact and cross-contamination from insanitary objects and from personnel to food, food packaging material, and other food-contact surfaces and from raw product to processed product.

(4) Supplier controls. Supplier controls include the supplier program as required by § 117.136.
(5) Recall plan. Recall plan as required by § 117.137.
(6) Other controls. Preventive controls include any other procedures, practices, and processes necessary to satisfy the requirements of paragraph (a) of this section. Examples of other controls include hygiene training and other current good manufacturing practices.

PMA Comment: PMA supports the proposed provisions set forth in §117.135 (preventive controls) and in particular the flexibility provided to operators to implement preventive controls that are appropriate to the facility and the food, procedures, practices and processes.

§ 117.137 Recall plan.
For food with a significant hazard:
(a) You must establish a written recall plan for the food.
(b) The written recall plan must include procedures that describe the steps to be taken, and assign responsibility for taking those steps, to perform the following actions as appropriate to the facility:
   (1) Directly notify the direct consignees of the food being recalled, including how to return or dispose of the affected food;
   (2) Notify the public about any hazard presented by the food when appropriate to protect public health;
   (3) Conduct effectiveness checks to verify that the recall is carried out; and
   (4) Appropriately dispose of recalled food (e.g., through reprocessing, reworking, diverting to a use that does not present a safety concern, or destroying the food).

PMA Comment: PMA generally supports the proposed provisions set forth in §117.137 (recall plan). However, PMA recommends that FDA consider removing recall plan requirements from 21 CFR 117 Subpart C Hazard Analysis and Risk-Based Preventive Controls and placing the proposed recall plan provisions in 21 CRR 117 Subpart B Current Good Manufacturing Practices, as a recall plan should be requisite for all food facilities irrespective of enterprise size. Additionally, a recall plan is not a true “preventive control”
in that a recall is most likely to have occurred when “preventive control(s)” have failed or “preventive control(s)” not been implemented appropriately.

§ 117.150 Corrective actions and corrections.
(a) Corrective action procedures. As appropriate to the preventive control, except as provided by paragraph (c) of this section:
(1)  
(i) You must establish and implement written corrective action procedures that must be taken if preventive controls are not properly implemented.
(ii) The corrective action procedures required by paragraph (a)(1)(i) of this section must include procedures to address, as appropriate:
(A) The presence of a pathogen or appropriate indicator organism in a ready-to-eat product detected as a result of product testing conducted in accordance with § 117.165(a)(2); and
(B) The presence of an environmental pathogen or appropriate indicator organism detected through the environmental monitoring conducted in accordance with § 117.165(a)(3).
(2) The corrective action procedures must describe the steps to be taken to ensure that:
(i) Appropriate action is taken to identify and correct a problem that has occurred with implementation of a preventive control;
(ii) Appropriate action is taken, when necessary, to reduce the likelihood that the problem will recur;
(iii) All affected food is evaluated for safety; and
(iv) All affected food is prevented from entering into commerce, if you cannot ensure that the affected food is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act or misbranded under section 403(w) of the Federal Food, Drug, and Cosmetic Act.
(b) Corrective action in the event of an unanticipated food safety problem.
(1) Except as provided by paragraph (c) of this section, you are subject to the requirements of paragraph (b)(2) of this section if any of the following circumstances apply:
(i) A preventive control is not properly implemented and a specific corrective action procedure has not been established;
(ii) A preventive control is found to be ineffective; or
(iii) A review of records in accordance with § 117.165(a)(4) finds that the records are not complete, the activities conducted did not occur in accordance with the food safety plan, or appropriate decisions were not made about corrective actions.
(2) If any of the circumstances listed in paragraph (b)(1) of this section apply, you must:
(i) Take corrective action to identify and correct the problem, reduce the likelihood that the problem will recur, evaluate all affected food for safety, and, as necessary, prevent affected food from entering commerce as would be done following a corrective action procedure under paragraphs (a)(2)(i) through (iv) of this section; and
(ii) When appropriate, reanalyze the food safety plan in accordance with § 117.170 to determine whether modification of the food safety plan is required.

(c) Corrections applicable to food allergen controls and sanitation controls. You do not need to comply with the requirements of paragraphs (a) and (b) of this section for conditions and practices that are not consistent with the food allergen controls in § 117.135(c)(2)(i) or the sanitation controls in § 117.135(c)(3)(i) or (ii) if you take action, in a timely manner, to correct such conditions and practices.

(d) Documentation. All corrective actions (and, when appropriate, corrections) taken in accordance with this section must be documented in records. These records are subject to verification in accordance with § 117.155(a)(3) and records review in accordance with §117.165(a)(4)(i).

PMA Comment: PMA generally supports the proposed provisions set forth in §117.150 (corrective actions and corrections) and in particular the flexibility provided to operators in §117.150(c), which does not require actions set forth in §117.150 (a) and (b) for conditions and practices that are not consistent with the food allergen controls in § 117.135(c)(2)(i) or the sanitation controls in § 117.135(c)(3)(i) or (ii) if you take action, in a timely manner, to correct such conditions and practices. Because of its compliance implications, clearly defining the situation specific distinctions between “corrective actions” and “corrections” for both industry stakeholders and FDA/state inspectors will be imperative moving forward and should be articulated in further detail in FDA Level 1 guidance.

C. Proposed Supplier Program Requirements

Subpart C—Hazard Analysis and Risk-Based Preventive Controls

§ 117.136 Supplier program.
(a) Supplier program.
(1) (i) Except as provided in paragraph (a)(1)(ii) of this section, the receiving facility must establish and implement a risk-based supplier program for those raw materials and ingredients for which the receiving facility has identified a significant hazard when the hazard is controlled before receipt of the raw material or ingredient.
(ii) The receiving facility is not required to establish and implement a supplier program for raw materials and ingredients for which:
(A) There are no significant hazards;
(B) The preventive controls at the receiving facility are adequate to significantly minimize or prevent each of the significant hazards; or
(C) The receiving facility relies on its customer to control the hazard and annually obtains from its customer written assurance that the customer has established and is following procedures (identified in the written assurance) that will significantly minimize or prevent the hazard.

(2) The supplier program must be written.
(3) The supplier program must include:
(i) Verification activities, as appropriate to the hazard, and documentation of these activities, to ensure raw materials and ingredients are received only from suppliers approved for control of the hazard(s) in that raw material or ingredient (or, when necessary and appropriate, on a temporary basis from unapproved suppliers whose raw materials or ingredients the receiving facility subjects to adequate verification activities before acceptance for use); and
(ii) Verification activities and documentation of these activities, as required by paragraph (b) of this section, to verify that:
(A) The hazard is significantly minimized or prevented;
(B) The incoming raw material or ingredient is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act or misbranded under section 403(w) of the Federal Food, Drug, and Cosmetic Act; and
(C) The incoming raw material or ingredient is produced in compliance with the requirements of applicable FDA food safety regulations.

(4) When supplier verification activities are required under paragraph (c) of this section for more than one type of hazard in a food, the receiving facility must conduct the verification activity or activities appropriate for each of those hazards.

(5) For some hazards, in some situations under paragraph (b) it will be necessary to conduct more than one verification activity and/or to increase the frequency of one or more verification activities to provide adequate assurances that the hazard is significantly minimized or prevented.

(b) Determination and documentation of the appropriate verification activities. In determining and documenting the appropriate verification activities, the receiving facility must consider the following:
(1) The hazard analysis, including the nature of the hazard, applicable to the raw material and ingredients;
(2) Where the preventive controls for those hazards are applied for the raw material and ingredients – such as at the supplier or the supplier’s supplier;
(3) The supplier’s procedures, processes, and practices related to the safety of the raw material and ingredients;
(4) Applicable FDA food safety regulations and information relevant to the supplier’s compliance with those regulations, including an FDA warning letter or import alert relating to the safety of the food;
(5) The supplier’s food safety performance history relevant to the raw materials or ingredients that the receiving facility receives from the supplier, including available information about results from testing raw materials or ingredients for hazards, audit results relating to the safety of the food, and responsiveness of the supplier in correcting problems; and
(6) Any other factors as appropriate and necessary. Examples of factors that a receiving facility may determine are appropriate and necessary are storage and transportation practices.

(c) Supplier verification activities for raw materials and ingredients.

(1) Except as provided in paragraph (c)(2) or (3) of this section, the receiving facility must conduct and document one or more of the following supplier verification activities as determined by the receiving facility under paragraph (b) of this section, for each supplier before using the raw material or ingredient and periodically thereafter:
   (i) Onsite audits;
   (ii) Sampling and testing of the raw material or ingredient, which may be conducted by either the supplier or receiving facility.
   (iii) Review by the receiving facility of the supplier’s relevant food safety records;
   or
   (iv) Other appropriate supplier verification activities based on the risk associated with the ingredient and the supplier.

(2) 
   (i) Except as provided by paragraph (c)(2)(ii) of this section, when a hazard in a raw material or ingredient will be controlled by the supplier and is one for which there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans, the receiving facility must have documentation of an onsite audit of the supplier before using the raw material or ingredient from the supplier and at least annually thereafter.
   (ii) The requirements of paragraph (c)(2)(i) of this section do not apply if the receiving facility documents its determination that other verification activities and/or less frequent onsite auditing of the supplier provide adequate assurance that the hazards are controlled.

(3) If a supplier is a qualified facility as defined by §117.3, the receiving facility need not comply with paragraphs (c)(1) and (2) of this section if the receiving facility:
   (i) Documents, at the end of each calendar year, that the supplier is a qualified facility as defined by §117.3; and
(ii) Obtains written assurance, at least every 2 years, that the supplier is producing the raw material or ingredient in compliance with applicable FDA food safety regulations and that the raw material or ingredient is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act or misbranded under section 403(w) of the Federal Food, Drug, and Cosmetic Act. The written assurance must include a brief description of the processes and procedures that the supplier is following to ensure the safety of the food.

(4) If a supplier is a farm that is not subject to the requirements established in part 112 of this chapter in accordance with § 112.4 regarding the raw material or ingredient that the receiving facility receives from the farm, the receiving facility does not need to comply with paragraphs (c)(1) and (2) of this section if the receiving facility:

(i) Documents, at the end of each calendar year, that the raw material or ingredient provided by the supplier is not subject to part 112 of this chapter; and
(ii) Obtains written assurance, at least every 2 years, that the supplier is producing the raw material or ingredient in compliance with applicable FDA food safety regulations and that the raw material or ingredient is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act.

(d) Onsite audit.

(1) An onsite audit of a supplier must be performed by a qualified auditor.

(2) If the raw material or ingredient at the supplier is subject to one or more FDA food safety regulations, an onsite audit must consider such regulations and include a review of the supplier’s written plan (e.g., HACCP plan or other food safety plan), if any, including its implementation, for the hazard being audited.

(e) Substitution of inspection by FDA or an officially recognized or equivalent food safety authority.

(1) Instead of an onsite audit, a receiving facility may rely on the results of an inspection of the supplier by FDA or, for a foreign supplier, by FDA or the food safety authority of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States, provided that the inspection was conducted within 1 year of the date that the onsite audit would have been required to be conducted.

(2) For inspections conducted by the food safety authority of a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent, the food that is the subject of the onsite audit must be within the scope of the official recognition or equivalence determination, and the foreign supplier must be in, and under the regulatory oversight of, such country.

(f) Supplier non-conformance. If the owner, operator, or agent in charge of a receiving facility determines through auditing, verification testing, relevant consumer, customer or other complaints, or otherwise that the supplier is not controlling
hazards that the receiving facility has identified as significant, the receiving facility must take and document prompt action in accordance with § 117.150 to ensure that raw materials or ingredients from the supplier do not cause food that is manufactured or processed by the receiving facility to be adulterated under section 402 of the Federal Food, Drug, or Cosmetic Act or misbranded under section 403(w) of the Federal Food, Drug, and Cosmetic Act.

(g) Records. The receiving facility must document the following in records and review such records in accordance with § 117.165(a)(4).

(1) The written supplier program;
(2) Documentation of the appropriate verification activities;
(3) The annual written assurance that a receiving facility’s customer who is controlling a significant hazard has established and is following procedures (identified in the written assurance) that will significantly minimize or prevent the hazard;
(4) Documentation demonstrating that products are received only from approved suppliers;
(5) Documentation of an onsite audit. This documentation must include:
   (i) Documentation of audit procedures;
   (ii) The dates the audit was conducted;
   (iii) The conclusions of the audit;
   (iv) Corrective actions taken in response to significant deficiencies identified during the audit; and
   (v) Documentation that the audit was conducted by a qualified auditor.
(6) Records of sampling and testing. These records must include:
   (i) Identification of the raw material or ingredient tested (including lot number, as appropriate) and the number of samples tested;
   (ii) Identification of the test(s) conducted, including the analytical method(s) used;
   (iii) The date(s) on which the test(s) were conducted;
   (iv) The results of the testing;
   (v) Corrective actions taken in response to detection of hazards; and
   (vi) Information identifying the laboratory conducting the testing.
(7) Records of the review by the receiving facility of the supplier’s relevant food safety records. These records must include:
   (i) The date(s) of review;
   (ii) Corrective actions taken in response to significant deficiencies identified during the review; and
   (iii) Documentation that the review was conducted by a qualified individual.
(8) Records of other appropriate supplier verification activities based on the risk associated with the ingredient.
(9) Documentation of any determination that verification activities other than an onsite audit, and/or less frequent onsite auditing of a supplier, provide adequate assurance that the hazards are controlled;
(10) Documentation of an alternative verification activity for a supplier that is a qualified facility, including:
   (i) The documentation that the supplier is a qualified facility as defined by §117.3; and
   (ii) The written assurance that the supplier is producing the raw material or ingredient in compliance with applicable FDA food safety regulations and that the raw material or ingredient is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act or misbranded under section 403(w) of the Federal Food, Drug, and Cosmetic Act.

(11) Documentation of an alternative verification activity for a supplier that is a farm that supplies a raw material or ingredient that is not subject to part 112 of this chapter, including:
   (i) The documentation that the raw material or ingredient provided by the supplier is not subject to part 112 of this chapter; and
   (ii) The written assurance that the supplier is producing the raw material or ingredient in compliance with applicable FDA food safety regulations and that the raw material or ingredient is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act.

(12) Evidence of an inspection of the supplier by FDA or the food safety authority of another country.

(13) Documentation of actions taken with respect to supplier non-conformance.

PMA Comment: PMA generally supports proposed provisions set forth in §1.502(c) and §1.502(d) in that they align supplier verification provisions in the preventive controls §117.136 regulations with the FSVP regulations to avoid imposing duplicative requirements on entities that are subject to each of those sets of regulations because they are both registered food facilities and food importers. This type of seamless integration and harmonization of the preventive controls regulation for human foods supplier controls regulations and FSVP regulations is needed to reduce costly verification activity redundancy.

- PMAs respectfully requests that FDA consider classifying “supplier programs” as a verification activity and not a “preventive control” as it is important that FDA acknowledges the fundamental difference between a control step and a verification program and modify the regulations to make them risk based and outcome oriented.
- PMA supports the proposed provisions that supplier verification activities be based on a combination of food risk and supplier risk as this will allow facility operators to target food safety resources to issues that are most likely to occur.
- PMA supports the proposed removal of the provision that would have required operators to provide FDA original audit reports created through supplier verification activities.
PMA supports the proposed provisions that only require a facility to document the conclusions of onsite audits, thus maintaining the confidentiality of the original inspection reports and facilitating robust and thorough audits.

PMA supports the proposed provisions pertaining to a hybrid approach to onsite audits, which requires onsite audits when there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans or animals (called a SAHCODHA hazard) has been identified, but allowing flexibility if other appropriate verification is in place. This proposed approach allows facilities to have the flexibility to conduct onsite audits when necessary and allocate resources based on risk.

PMA has concerns about supplier controls recordkeeping requirements set forth in §117.136, particularly for firms that have a corporate headquarters location and satellite operations. Specifically, corporate headquarter locations may be the entity that maintains and holds supplier control records for satellite facilities, as the firm may use one supplier for multiple satellite food facility locations. This operational scenario is likely to lead to redundant requests to the firm to review supplier control records during routine compliance inspections done at the various times and locations. It should also be anticipated that multiple FDA inspectional records reviews will likely lead to multiple and possibly conflicting interpretations regarding compliance by the multiple FDA inspectors. Therefore, PMA recommends that FDA consider operational means to reduce redundant supplier control records review during routine compliance inspections and reduce the likelihood of the agency offering divergent interpretations of compliance for the same supplier control records.

PMA supports the proposed definition of “supplier” as it means that a facility that doesn’t manufacture/process food, for example a distribution center, would not be required to establish a supplier program as per §117.136 of this regulation.

PMA has concerns regarding proposed supplier program provisions set forth in §117.136, in that it is currently difficult to search publicly available FDA warning letters or FDA import alerts by entity. PMA requests that FDA consider development of online databases searchable by firm name and address to facilitate the importing firm’s ability to conduct compliance status reviews. Additionally, it is difficult, if not impossible for firms to determine if their suppliers are in fact even registered as FDA food facilities because this information is not available from FDA. This puts receivers in a difficult position, since they may search online FDA databases for import alerts and warning letters but unbeknownst to the receiver the potential supplier does not even know to and/or is not registered with FDA.

D. Proposed Environmental Monitoring and Product Testing Requirements

Subpart C—Hazard Analysis and Risk-Based Preventive Controls

§ 117.165 Verification of implementation and effectiveness.
(a) Verification activities. You must verify that the preventive controls are consistently implemented and are effectively and significantly minimizing or preventing the significant hazards. To do so you must conduct activities that include the following, as appropriate to the facility, the food, and the nature of the preventive control:

1. Calibration of process monitoring instruments and verification instruments;
2. Product testing, for a pathogen (or appropriate indicator organism) or other hazard;
3. Environmental monitoring, for an environmental pathogen or for an appropriate indicator organism, if contamination of a ready-to-eat food with an environmental pathogen is a significant hazard, by collecting and testing environmental samples; and
4. Review of the following records within the specified timeframes, by (or under the oversight of) a qualified individual, to ensure that the records are complete, the activities reflected in the records occurred in accordance with the food safety plan, the preventive controls are effective, and appropriate decisions were made about corrective actions:
   (i) Records of monitoring and corrective action records within a week after the records are created.
   (ii) Records of calibration, product testing, environmental monitoring, and supplier verification activities within a reasonable time after the records are created.

(b) Written procedures. As appropriate to the facility, the food, and the nature of the preventive control, you must establish and implement written procedures for the following activities:

1. The method and frequency of calibrating process monitoring instruments and verification instruments as required by paragraph (a)(1) of this section.
2. Product testing as required by paragraph (a)(2) of this section. Procedures for product testing must:
   (i) Be scientifically valid;
   (ii) Identify the test microorganism(s) or other analyte(s);
   (iii) Specify the procedures for identifying samples, including their relationship to specific lots of product;
   (iv) Include the procedures for sampling, including the number of samples and the sampling frequency;
   (v) Identify the test(s) conducted, including the analytical method(s) used;
   (vi) Identify the laboratory conducting the testing; and
   (vii) Include the corrective action procedures required by § 117.150(a)(1).
3. Environmental monitoring as required by paragraph (a)(3) of this section. Procedures for environmental monitoring must:
   (i) Be scientifically valid;
   (ii) Identify the test microorganism(s);
   (iii) Identify the locations from which samples will be collected and the number of sites to be tested during routine environmental monitoring. The number and
location of sampling sites must be adequate to determine whether preventive controls are effective;
(iv) Identify the timing and frequency for collecting and testing samples. The timing and frequency for collecting and testing samples must be adequate to determine whether preventive controls are effective;
(v) Identify the test(s) conducted, including the analytical method(s) used;
(vi) Identify the laboratory conducting the testing; and
(vii) Include the corrective action procedures required by § 117.150(a)(1).

PMA Comments: PMA generally supports proposed provisions set forth in §117.165 (verification of implementation and effectiveness) as the proposed provisions appropriately provide flexibility that allows operators to tailor their product testing and environmental monitoring programs, as verification activities, and as appropriate to the nature of the food, the facility, and the nature of the preventive control(s) being verified. However, PMA believes that product and environmental testing should be used as a verification activity only when appropriate based on the food, facility and the nature of the preventive control. We respectfully request that FDA would please refer back to and review PMA’s comments to the originally proposed Preventive Controls for Human Food rule, as these original PMA comments on product and environmental testing provide detailed background information and discussion as to our association’s positions on these proposed provision areas. In the interest of brevity we will not repeat them in the comments below. PMA wishes to express a strong desire to engage early and often with FDA on the development of applicable guidance documents regarding product and environmental testing for the produce industry and provide an opportunity to explain and discuss current industry best practices regarding testing. Additionally, defining via guidance when environmental and product testing is an appropriate verification activity and what situation specific procedures and practices should be implemented requires further in-depth discussion and development.

PMA Comments: PMA generally supports the following proposed provisions set forth in §117.165 (verification of implementation and effectiveness) regarding product testing and environmental monitoring.
- PMA supports the proposed definition of "product testing" so as including raw material testing, ingredient testing, in-process testing, and finished product testing and to not narrowly define product testing as only finished product testing.
- PMA concurs with FDA’s preamble analysis that acknowledges there are severe limitations to product testing and that any testing programs must be appropriately tailored to the facility, the food, and the nature of the preventive control(s) being verified. As put forward in detail in PMA’s comments to the originally proposed Preventive Control Rule for Human Food rule, it is commonly agreed upon that finished product testing is of limited utility for products and
processes that are under control, but may be relevant where information from verification activities raises concerns about the hygienic status of a processing line or ingredient. In most cases, finished product testing is not a reliable or cost effective tool and other verification activities are more appropriate to evaluate the effectiveness of control measures.

- PMA supports the proposed definition of the term “environmental pathogen,” specifically in that it links contamination of the food from the environment with the potential of the food to cause human illness and it appropriately excludes of pathogenic spore-formers such as *C. Botulinum* because such spores in the environment, as FDA noted, generally do not pose a risk to human health.
- PMA supports the proposed definition of “pathogen” to mean “microorganism of public health concern” and the use of “pathogen” throughout the regulation.
- PMA supports the flexible nature of provisions set forth in §117.165 that allow facilities to determine the timing, number, location, and frequency of environmental monitoring programs in a risk-based manner, and in not prescribing specific locations for testing (e.g., food contact surfaces or “zones”). Routine testing of food contact surfaces for the presence of environmental pathogens, as part of an environmental monitoring program, is neither preventive nor the most effective use routine sampling resources, as it is unlikely to detect transient/incidental contamination.
- PMA supports the flexibility set forth in §117.165 provisions that allow operators to use indicator organisms in testing programs as appropriate.
- PMA supports the flexibility set forth in §117.165 provisions that allow operators to take corrective actions arising from positive environmental testing findings (i.e., detection of a pathogen or presence of an indicator above a certain threshold) that are tailored and "as appropriate to the preventive control" being verified.

**PMA Comments:** PMA recommends that FDA consider the following suggested amendments to proposed provisions set forth in §117.165 (verification of implementation and effectiveness) regarding product testing and environmental monitoring, so as to assure final codified provisions reflect the flexibility articulated by FDA in the preamble to the supplemental proposal.

**Flexible, Risk-Based Use of Product Testing and Environmental Monitoring**

- PMA agrees with FDA’s supplemental proposal preamble discussion that the agency intends to afford “flexibility for a facility to make risk-based decisions on when product testing would be appropriate” by providing that the facility can take into account the facility, the food, and the nature of the preventive control.” PMA believes, and we request clarification from FDA, that based on this preamble discussion FDA believes there are circumstances when product testing, particularly finished product testing, would not be necessary.
In addition, we believe that there are circumstances where environmental monitoring would not be necessary.

- However, the proposed section §117.165(a)(2) and (3) states regarding verification activities that “you must conduct activities that include....(2) Product testing, for a pathogen (or appropriate indicator organism) or other hazard” and (3) Environmental monitoring, for an environmental pathogen or for an appropriate indicator organism, if contamination of a ready-to-eat food with an environmental pathogen is a significant hazard, by collecting and testing environmental samples.” This may be misinterpreted to mean that product testing and environmental testing in some form is always required. Therefore, we respectfully request that FDA consider amending §117.165(a) as follows to avoid an ambiguity and to be consistent with FDA’s explanatory statements in the preamble discussion:
  o “To do so you must evaluate the need to conduct activities that include the following, if as appropriate...”; or
  o “To do so you must conduct activities that include the following, if and when as appropriate and necessary...”

These suggested amendments would also clarify that facilities have the flexibility to make risk-based decisions regarding product and environmental monitoring.

- Additionally, for continuity PMA respectfully requests that FDA consider amending §117.165(a)(4)), which deals with a qualified individual being required to review the completeness of product testing and environmental monitoring records, by striking references to “product testing” and “environmental monitoring” records and replacing those terms with “verification testing (e.g., product testing and/or environmental monitoring as applicable), . . . .” This amendment would assure continuity in that a qualified individual would not be required to ensure the completeness of records that are not required to exist and hence don’t exist.

Fresh Produce: A Unique Case Regarding Product Testing and Environmental Monitoring

- Many FDA regulated manufacturerprocessors routinely conduct product testing; however, this is not the case for most fresh produce establishments that handle RACs, as the industry has determined that adherence and verification of adherence to Current Good Agricultural Practices for RACs provides greater assurances of product safety. Produce contamination typically occurs sporadically with a very low prevalence rate of human pathogens and when detected, it is typically very low numbers. In the originally proposed produce rule describing RAC production, FDA “tentatively concludes that product testing would be impracticable as a component of science-based minimum standards.” PMA agrees with this assessment and there is a body of scientific literature that demonstrates the very low
prevalence, low concentrations and random nature of raw product contamination events in RACs. Therefore, PMA again respectfully requests that FDA consider PMA’s suggested amendments that allow all produce operations that handle RACs to be covered by the produce rule and not the preventive controls for human foods rule. This will assure that produce establishments will not be expending resources environmental monitoring and product testing that could be better directed to implementation of preventive controls.

• We respectfully request that FDA please refer back to and review PMA’s comments to the originally proposed preventive controls for human food rule, as these original PMA comments on product and environmental testing provide detailed background information and discussion PMA’s positions on these provision areas. PMA discussed at length in our original comments the unique challenges that product testing and environmental monitoring pose to the fresh and fresh-cut produce industry due to the short shelf-life and perishability of fresh and fresh-cut produce, the need for microbial tests to be validated for each produce commodity, and as mentioned above the very low prevalence, low concentrations and random nature of fresh produce and fresh-cut contamination events.

• PMA does not support §117.165 provisions that environmental monitoring is required to verify effectiveness of preventive controls whenever a ready-to-eat (RTE) product is exposed to the environment prior to packaging and the packaged food does not receive a treatment that would significantly minimize an environmental pathogen that could contaminate the food when it is exposed. PMA does not support mandatory environmental monitoring for facilities that handle raw agricultural commodities until FDA amends its policy’s regarding the regulatory consequences of a single detection of potentially transient L. monocytogenes on a food contact surface. The produce industry is acutely aware of the adverse public health consequences that can be associated with L. monocytogenes and wants to aggressively use a strategy of seeking, destroying and preventing harborage of L. monocytogenes in produce facilities. However, FDA’s current “no tolerance” policy for L. monocytogenes has unintended consequences of disincentivizing the use of the “seek and destroy” environmental monitoring strategy. Additionally, fresh produce poses a unique challenge among FDA regulated foods in that L. monocytogenes is a microorganism that is routinely found in the outdoor environment and its occasional transient detection on raw produce in low numbers does not necessarily indicate poor practices or that a contamination event has occurred due to insanitary conditions or that it presents an elevated public health risk. This means the occasional detection of transient L. monocytogenes in low numbers on food contact surfaces where fresh produce is handled is to be expected and must be considered
and addressed in the drafting of environmental monitoring procedures for fresh produce facilities covered by the preventive controls rule.

- If FDA does not amend its “no tolerance” policy for *L. monocytogenes* detections on food contact surfaces, it will likely lead to resistance to routine testing of food contact surfaces and lead to practices designed to ensure that *Listeria* will not be detected, rather than employment of the desirable seek and destroy strategy to eliminate environmental pathogens. It is recommend that FDA consider in development of science- and risk-based guidance regarding environmental monitoring for fresh produce raw agricultural commodities that specifically incentivizes operators to seek and destroy resident environmental pathogen niches and harboriges of public health significance in fresh produce facilities, while allowing for occasional detections of low levels of transient environmental pathogens that are not at a level of public health significance. This would assure that corrective actions or corrections are commensurate with risks associated with the food, the facility, and the nature of the preventive control(s) being verified (see discussion below regarding corrective actions being commensurate with risks). For example, if a food contact surface in a fresh produce packing house were to test positive for *Listeria spp.* or *Listeria*-like organisms, corrective actions including intensified cleaning and sanitizing as well as retesting of the food contact surface should be recommended. If re-testing reveals that there is not a persistent resident *Listeria spp.* niche or harborage, then no further actions should be required. PMA respectfully requests that FDA also consider aligning FDA *Listeria* guidance with for example the USDA FSIS “Compliance Guidelines to control *Listeria monocytogenes* in post-lethality exposed tread-to-eat meat and poultry products”. As for example, the aforementioned USDA FSIS policy guidance seems to provide industry with regulatory flexibility that does not dis-incentivize use of a seek and destroy strategy when transient positive detections of *Listeria spp.* or *Listeria-like* organisms occurs.

### Corrective Actions that are Commensurate with Risks

- Proposed §117.150 would require registered facilities to establish, in advance, corrective action procedures to address:
  - (A) The presence of a pathogen or appropriate indicator organism in a ready-to-eat product detected as a result of product testing conducted in accordance with §117.165(a)(2); and
  - (B) The presence of an environmental pathogen or appropriate indicator organism detected through the environmental monitoring conducted in accordance with §117.165(a)(3).

- PMA agrees that the presence of certain pathogens in ready-to-eat foods is unacceptable. However, PMA believes it is important for FDA to clarify in the
final rule that the nature and extent of any corrective actions should be commensurate to the nature of the test findings. For example, some microorganisms (both pathogens and indicators) have thresholds that need to be taken into account when assessing potential concern for human health. There are some pathogens that are only of concern to human health if they are present in food at high levels and/or their toxin is consumed. Examples of these pathogens include *Staphylococcus aureus*, *Clostridium perfringens* and *Bacillus cereus*.

- In addition, the location of any environmental monitoring results would play a significant role in determining what follow-up actions, if any, are needed. Corrective actions, if any, need to take into account the nature of the hazard (i.e., particular testing results, including the type of organism and the levels found) and the nature of the control measure(s) being verified. For example, areas distant to the food contact surfaces and outside the manufacturing area can be sampled and tested to gather information regarding microbial load (e.g., raw product areas could be tested for surveillance purposes). Also the finding of a pathogen or indicator may lead to corrections instead of corrective actions (e.g., finding *Listeria spp.* in the drain in a zone 4 area). Further, it is crucial that the regulations and FDA’s enforcement of them account for the fact that strong environmental monitoring programs incorporate a “seek and destroy” approach.

- To assure that any corrective actions are required to be commensurate to the nature of the test findings and the nature of the control(s) being verified, PMA respectfully requests that FDA consider amending proposed §117.150 as follows to assure that corrective actions be commensurate to the nature of the test findings.

  o **Corrective action procedures.** As appropriate to the preventive control and the hazard, except as provided by paragraph (c) of this section:

    (1)(i) You must establish and implement written corrective action procedures, as appropriate to the nature of the hazard, the nature of the control measure, and the extent of the deviation, that must be taken if preventive controls are not properly implemented.

    (ii) The corrective action procedures required by paragraph (a)(1)(i) of this section must include procedures to address, as appropriate:

    (A) The presence of a pathogen or appropriate indicator organism above actionable levels in accordance with the written testing program in a ready-to-eat product detected as a result of product testing conducted in accordance with §117.165(a)(2); and
(B) The detection presence of an environmental pathogen or appropriate indicator organism detected above actionable levels and/or at identified critical environmental locations that have been established through the environmental monitoring conducted in accordance with § 117.165(a)(3).

OR

(B) The detection presence of an environmental pathogen or appropriate indicator organism detected at a level and/or location of concern which have been established through the environmental monitoring conducted in accordance with § 117.165(a)(3).

Definition of "scientifically valid" testing procedures

- PMA respectfully requests that FDA consider amending §117.165(b)(2)(i) and (3)(i), which require that product testing and environmental monitoring procedures be “scientifically valid.” PMA fully agrees that testing and procedures for testing be “scientifically valid”; however, we are concerned that the term “valid” could be misinterpreted to mean “validated” and not all testing protocols can be validated. For example, some elements of environmental monitoring programs rely on the use of target microorganisms that were chosen based on data and scientific information derived from similar products that have been implicated in food borne illness outbreaks; however, these procedures would not be considered “validated.” Additionally, sampling sites are routinely selected based on historical knowledge of the product, the facility, and the manufacturing process. PMA recommends that FDA clearly articulate that use of the term “scientifically valid” in this context does not mean “validated” but simply means “technically sound” and consider use of this term.

G. Proposed Procedures for Withdrawal and Reinstatement of a “Qualified Exemption”

§ 117.251 Circumstances that may lead FDA to withdraw an exemption applicable to a qualified facility.

§ 117.254 Issuance of an order to withdraw an exemption applicable to a qualified facility.

§ 117.257 Contents of an order to withdraw an exemption applicable to a qualified facility.

§ 117.260 Compliance with, or appeal of, an order to withdraw an exemption applicable to a qualified facility.
§ 117.264 Procedure for submitting an appeal.
§ 117.267 Procedure for requesting an informal hearing.
§ 117.287 Reinstatement of an exemption that was withdrawn.

**PMA Comment:** PMA opposes the “qualified exemption” based on revenues and market channels (direct to a consumer, restaurant or retail food establishment) and has repeatedly recommended that this exemption be eliminated.

**PMA Comment:** PMA supports the administrative procedures that FDA has proposed regarding withdrawal of a “qualified exemption.”

**PMA Comment:** PMA supports the administrative procedures that FDA has proposed regarding re-instatement of a “qualified exemption” when FDA determines, after finishing an active investigation of a foodborne illness outbreak, that the outbreak is not directly linked to the food facility which had its “qualified exemption” withdrawn.

**PMA Comment:** PMA does not support inclusion of administrative procedures for the re-instatement of withdrawn qualified exemption in the case where “food facility” has been linked to a foodborne illness outbreak. The FSMA statute does not provide for reinstatement of the “qualified exemption” and FDA should not provide for re-qualification and reinstatement of a withdrawn “qualified exemption.” Once a “qualified exemption” has been withdrawn due to a foodborne illness being associated with produce from a specific farm, a permanent withdrawal of the “qualified exemption” should occur, with no possibility for re-instatement.

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