November 15, 2013

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


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, “Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption” (Docket No. FDA-2011-N-0921 / RIN 0910–AG35). 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 traversing the comments made here, we have organized them into specific categories and have also provided the titles (gray print) and relevant passages (blue print) from the proposed rules to provide context to our comments. The general categories we have organized are comments around are as follows:

I. Overarching Issues
   a. Proposed Produce Rule Regulatory Approach and Assessment of Risk
   b. Grouping Commodities Based on Outbreak Data
   c. Commodity Characteristics Versus Contamination Risks
   d. Market Channels and Produce Risk
   e. Commodity Exemptions and Exclusions
   f. Produce Safety Rule and Preventive Controls for Human Foods Regulatory Scope

II. Comments on Specific Provisions set forth in Subparts A through R

III. Additional Requirements for Consideration
   a. Operational Assessment, Food Safety Plans
   b. Written Food Safety Plan
   c. Product Testing
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 Produce Safety Science & Technology Committee and PMA members at large to develop the comments which 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 which American consumers have come to expect to be available to them. Throughout the discussion, PMA members carefully discussed and deliberated the ability of each proposed produce safety rule provision to enhance public health, while searching for practicable and easily implementable solutions to enhance the safety of fresh produce. Hence, 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 fresh produce-based science 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. However, there are significant data and research gaps regarding on-farm produce safety preventive controls which make finalization of FDA produce safety standards in some areas difficult, if not impossible, and significant investment in on-farm food safety research will be required. While there is currently ongoing industry sponsored research at institutions like the CPS regarding means to ensure the safe use of biological
soil amendments of animal origin and agricultural water, more research is needed before mandated numerical preventive controls should be imposed.

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 protects 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, practices, and procedures employed during the production, handling, and holding of fresh produce.

Key issues from the perspective of PMA members regarding FDA’s proposed produce safety rule are as follows:

- Produce Rule Scope and Coverage (Exemptions and Exclusions)
- Produce and Preventive Controls Rule Coverage
- Premature Use of Mandated Numerical Preventive Control Standards
- Produce Rule Finalization

Produce Rule Scope and Coverage (Exemptions and Exclusions)

Produce growers need to minimize the potential for microorganisms of public health significance on produce regardless of:

- the product,
- where and how it’s grown and handled,
- particular business size, and
- market channel or geographic radius.

However, modified requirements may apply in certain situations. This is why PMA strongly supports that all farms should perform an assessment of risk for their operations and develop and implement a food safety plan with specific preventive controls to address likely microbial hazards and routes of contamination. FDA has a statutory obligation to promote and protect the public health of all consumers who receive food products from all market channels, not just for certain market channels. Therefore, PMA has taken the following policy positions in our comments regarding the produce rule scope and coverage.
Commercial Processing Exclusion: PMA is supportive of the FDA produce safety regulation exempting commodities destined to receive commercial processing that adequately reduces the presence of pathogenic microorganisms (should they be present).

Exclusion of farms with less than $25,000 in annual food sales: PMA opposes this exclusion based solely on revenue (<$25K annual food sales) and recommends that this exclusion be eliminated. Exclusion of farms with less than $25,000 in annual food sales is not science- or risk-based. Produce contamination can occur in any operation that uses unsafe processes and practices. There is no scientific basis to support the exclusion.

Qualified Exemption (Tester/Hagen Amendment): PMA opposes the “qualified exemption” and recommends 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.

Produce Rarely Consumed Raw Exclusion: PMA opposes the use of a list of exempted commodities based on consumer preparation for consumption and recommends that this exemption be eliminated. PMA does not support the approach of using a commodity-specific list of exempt products based on current likely means of consumer preparation and consumption for produce commodities.

Produce and Preventive Controls Rule Coverage
FDA must align the requirements of the produce and preventive controls rules. A more seamless integration of the two rules will strengthen enforcement and reduce confusion. Growers, handlers and others in the marketing chain will be able to better understand the requirements and direct their attention to those activities that can make products safer. 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 packing house would be regulated under the produce rule until it accepts fruit from a neighbor’s farm, which under the proposal would then trigger the preventive controls rule. PMA acknowledges that as per the Food Safety Modernization Act, food facilities that must register with FDA per the requirements of the Bioterrorism Act of 2002 are to be regulated by the preventive controls for human foods regulation. However, the unintended consequences would mean that packing houses that
are FDA registered facilities will be required to comply with the preventive controls for human foods regulation, while on-farm packing houses performing the exact same procedures and practices while handling the exact same commodity would be required to comply with the produce safety regulation. This is not a risk-based approach as it sets up a system of dual, divergent standards 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) come from. They 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. The rules should provide for modified requirements for facilities that handle raw agricultural commodities, even those that originate on another farm; those modified requirements for fresh fruits and vegetables should be those found in the produce rule. PMA proposes for FDA consideration that the proposed produce safety rule be deemed comparable to preventive controls for human foods rule for the purposes of compliance and enforcement. If a packing facility is in compliance with provisions of the produce safety rule, the pack facility would be in compliance with the preventive controls rule. Additionally, PMA has also provided alternative draft definitions for: “Farm,” “Harvesting,” “Holding,” “Manufacturing/Processing,” “Packing,” and “Packaging” which if adopted by FDA would provide the opportunity to make the produce rule workable for agriculture and reflect the realities of food production. The proposed framework provided by PMA would mean that some pack houses may have to register as FDA Food Facilities per the Bioterrorism Act, but they would not be subject to the preventive controls for human food regulation. Instead they would be “farms” for the purposes of coverage under the produce safety regulation.

Premature Use of Mandated Numerical Preventive Control Standards
PMA opposes FDA mandated numerical preventive controls to ensure the safe use of agricultural water and treated biological soil amendments of animal origin application using harvest intervals, as more research is needed before mandated numerical preventive controls could be imposed. PMA is concerned that as more information about these two mandated numerical preventive controls become available these quantitative standards will be obsolete and would not protect public health or would be overly protective of public health and overly burdensome to produce growers.
As an alternative, PMA strongly supports that all farms should perform an operational assessment of risk for their operations and develop and implement a food safety plan with specific preventive controls to address the identified likely microbial hazards and routes of contamination, including preventive controls to ensure the safe use of agricultural water and treated biological soil amendments of animal origin application using harvest intervals.

Quantitative Agricultural Water Microbial Standards: PMA does not support the use of quantitative generic \( E. \ coli \) levels as the criteria in the regulation to determine when agricultural water is not of safe and of adequate sanitary quality and would require the discontinuation of use. Monitoring for generic \( E. \ coli \) may provide information regarding the potential for overt fecal contamination but it is not a definitive indicator of human pathogens in agricultural water. Nor does agricultural water with generic \( E. \ coli \) levels below the proposed quantitative criteria mean that the agricultural water is definitively free of human pathogens. PMA contends that the body of scientific knowledge is currently inadequate to establish quantitative metrics based solely on the use of generic \( E. \ coli \) as an indicator organism. Additionally, as new scientific knowledge becomes available, growers must be able to utilize updated and improved testing and sampling methodologies which can better assess the safety of the agricultural water that they will use. PMA is concerned that as more information about generic \( E. \ coli \) and other indicators become available the quantitative criteria set forth in the proposed produce rule will be obsolete and not protective of public health or overly protective of public health. Use of the U.S. Environmental Protection Agency (EPA) recreational water standard may be appropriate for some crops such as lettuce and leafy greens but this quantitative criteria is likely overly protective for many other crops and may be not protective enough in other instances.

Quantitative: Application to Harvest Intervals for Treated Soil Amendments of Animal Origins: PMA supports the concept of an application-to-harvest interval for treated biological soil amendments of animal origin based on an individual entity’s operational assessment of risk. The application-to harvest interval for treated biological soil amendments of animal origin should not be tied to a specific quantitative standard in the regulation that prohibits use within shorter time intervals due to scientific uncertainty as to applicability of a static 45-day interval. PMA supports that growers should consider the application-to-harvest interval for treated soil amendments of animal origin but the interval should correspond with risk of soil amendment-to-crop contamination based on the grower’s operational assessment of risk. The use of the quantitative preventive control, that being a 45-day application-to-harvest interval for treated biological soil amendments of animal origin in the final produce safety rule, is unsupported by science in all cases and
hence, it is arbitrary and capricious. Establishment of quantitatively risk-based application-to-harvest intervals for treated soil amendments is needed but it will require further research that can customize the application-to-harvest interval based on the commodity, agro-ecological growing conditions and practices. Additionally, as new scientific knowledge becomes available, growers must be able to utilize updated and improved knowledge regarding safe application-to-harvest intervals for treated biological soil amendments of animal origin. PMA is concerned that as more information about application-to-harvest intervals for the use of treated biological soil amendment of animal origin becomes available the quantitative criteria set forth in the proposed produce rule will be obsolete and not protective of public health or overly protective of public health and overly burdensome to produce growers.

**Produce Rule Finalization**

PMA supports the expeditious finalization and implementation of FSMA regulations, however PMA members have very serious concerns regarding many of the proposed provisions set forth in the proposed produce safety rule and preventive controls rule for human food, as many of the proposed provisions will adversely affect how produce businesses operate and the proposed provisions simply do not reflect the realities of produce production, handling, and storage. It is critically important that FDA get the final produce safety and preventive controls rules right to truly enhance the safety of produce available to the consumer while not adversely affecting how produce businesses operate.

PMA supports providing FDA with the time that the agency needs to get the final produce safety and preventive controls for human food rules. FDA is currently working under very tight FSMA statutory and court-ordered deadlines to issue final rules, and the agency must have sufficient time to formulate effective and practical final rules in consultation with all stakeholders. Development of effective and practical produce safety regulations is a complex, large and arduous undertaking. PMA supports providing FDA with adequate time to get the final rules right, but the risks of marketplace uncertainty regarding produce safety standards demand diligence by FDA and the Administration in finalizing and implementing FSMA regulations. As outlined in the PMA comments, the FSMA rules must take into account the numerous factors associated with the multitude of produce commodities, practices, procedures, and agro-ecological growing conditions that affect the safety of produce where it’s grown, harvested, packed, and held. Produce farms to date have not been pervasively regulated regarding produce safety practices and procedures. FDA needs industry input to make sure that the final produce safety and preventive controls rules are both effective and practical to implement. There is also significant need to provide sufficient time and resources to train growers so that they can comply with final
rules, as well as training FDA and state regulatory officials regarding agricultural practices and the various means by which growers may comply with this new set of food safety regulations.

PMA has participated in the congressional debate about FSMA and has provided comment 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.

Thank you for the opportunity.

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Produce Marketing Association

“Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption”

(Docket No. FDA-2011-N-092 / RIN 0910–AG35)

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) proposed rule entitled, “Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption” (Docket No. FDA-2011-N-0921) issued on January 4, 2013. 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, 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 produce standards that are intended to be science-based as required under the Food Safety Modernization Act (FSMA). In previously submitted comments to the FDA¹, PMA has indicated its support for science-based standards in the produce industry. Recognizing the profound impact the final produce rule and other rules currently under development will have on the produce industry, PMA offers its support to the FDA, our membership, related trade associations, and the produce industry.

¹ PMA submitted written comments dated July 23, 2010 on “Preventive Controls for Fresh Produce,” and on August 22, 2011 regarding “Preventive Controls for Registered Human food and Animal Feed Facilities.”
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 proposed rule and notice:

**Regulatory Approach (QRA & Section IV C. of Preamble)**

**Proposed Produce Rule Regulatory Approach and Assessment of Risk**

As per the proposed produce safety rule (FR 78(11): 3515), “FSMA directs us to establish science-based minimum standards for produce safety. These standards are to include procedures, processes, and practices that we determine to be reasonably necessary to prevent the introduction of known or reasonably foreseeable biological, chemical, and physical hazards into covered produce and to provide reasonable assurances that produce is not adulterated under section 402 of the FD&C Act.”

PMA supports science and risk-based regulations that require implementation of preventive controls that are commensurate with risks associated with the commodity, practices and procedures employed during the production, handling and holding of fresh produce. Additionally, to truly enhance produce safety for consumers, science and risk-based standards must be adopted throughout the entire supply chain without exception. Entity or company level operational assessment of risks that evaluate the likelihood of the introduction of a microbiological hazard during the growing, harvesting, handling and holding of a particular commodity based on the practices and procedures utilized and implementation of effective preventive controls for the identified hazards are the most effective means of assuring produce safety. Allowing small companies and/or those that sell directly to consumers and restaurants to not have to implement produce preventive controls because the standards may be financially burdensome is not consistent with the FDA’s FSMA mandated goal of improving the safety of produce. Likewise, designating commodities as covered or exempt from rule coverage, based on a previous association with foodborne illness outbreaks or current consumer means of preparation and consumption, is not a preventive approach to assuring the safety of fresh produce.

In the proposed produce rule the “FDA intends to adopt a regulatory approach that considers the risk posed by both the commodity and relevant agronomic practices, and provides the most appropriate balance between public health protection and flexibility” (FR 78(11): 3515). The produce industry and the government must work together to determine minimum standards based on the best available science. Additionally, the FDA produce
safety standard must have a mechanism so that it may be easily and readily amended as new scientific information, learnings from foodborne illness outbreaks, contamination events and new best practices become available. Much of what is known regarding routes of produce contamination and preventive controls to prevent such contamination is nascent and newly emerging. Therefore, a nimble amendment process for the FDA produce safety rule must be in place so that the standard can readily and easily incorporate new science and preventive controls as they become available. It would be insufficient to update the FDA produce safety standard, for example, every five years as this lag time in implementation of best practices does not best serve public health.

**Grouping Commodities Based on Outbreak Data**

*FDA could develop a commodity specific list and add to that list (or subtract as data becomes available). Would this approach adequately minimize the risk of serious adverse health consequences or death and whether it would sufficiently move toward a prevention-based food safety system? If commodities were exempted based on a lack of history of outbreaks, what would the likely reductions in the costs of the rule be and what would the likely increase in human illnesses be from this approach? FDA also looked at using pathogen surveillance data to establish commodity risk. FDA seeks comments on this approach. (FR 78(11): 3515)*

PMA does not support the grouping of produce commodities based on historic outbreak data. Using the CDC’s outbreak surveillance data to group commodities is problematic for several reasons. First, surveillance data is based on consumer recall often requiring consumers to remember what they ate several days to weeks prior to becoming ill. Second, even if a consumer does recall what food they ate, the ability to definitively link consumption to a specific food vehicle causing two or more illnesses is difficult and in many cases the suspected food vehicle never tests positive for the microorganism which caused the foodborne illness outbreak. Grouping commodities based on outbreak data alone, not coupled with a qualitative or quantitative risk assessment provides an incomplete, limited picture of commodity based produce risk. Additionally, CDC data is retrospective and its use as a predictive risk ranking tool for individual produce commodities is severely limited because it is based solely on past foodborne illness outbreak occurrences. As per the FDA discussion in the proposed rule preamble, if the agency had proposed the same rule based on outbreak data in 2008, jalapeno and Serrano peppers would not have been included if the list of covered commodities was solely based on occurrence past foodborne illness outbreaks. Since 2008, a number of commodities not previously associated with foodborne illness or microbially driven product
recalls have emerged, e.g. cucumbers, watermelons, strawberries, hazelnuts, mangoes, papayas, etc. These instances support the contention that CDC data would not have been predictive of these outbreaks. Additionally, use of retrospective data for predictive purpose does account for changes and improvements in agricultural food safety practices and hence, has actually overestimated risk.

Likewise, using pathogen surveillance data to establish commodity risk is an incomplete approach. Human pathogen prevalence data is the only factor which should be used in a qualitative or quantitative risk assessment for any given produce commodity. Surveillance data is only of limited value as it is highly dependent on the number of samples analyzed. Low sample numbers limit data reliability and in most instances, the number of samples needed to have robust and reliable data is cost prohibitive. Additionally, surveillance data does not take into account differences in practices, procedures or differences in agro-ecological growing conditions over time. What is really needed is identification of likely contributing factors associated with produce contamination events. Unfortunately, CDC, FDA, States and growers are often never able to definitively identify “the” route of produce contamination and factors which likely contributed to the contamination event. Without such data it remains difficult to assess the risk associated with specific commodities, practices and/or procedures used in production, harvest, handling and holding of any given specific fresh produce item.

**Commodity Characteristics Versus Contamination Risks**

_Growth characteristics and physical attributes were examined. FDA requests comments on this approach (FR 78(11): 3527)._**

PMA does not support the use of commodity growth characteristics and physical attributes characteristics as a means for determining what commodities should or should not be covered by the produce rule. Qualitative and quantitative risk assessment for specific produce items may incorporate such data regarding the relative risks posed or correlated to inherent product attributes such as exterior surfaces and growth characteristics if the data exists. While there has been a great deal of commodity-specific food safety research conducted since 2006, there are still many unknowns regarding the impact of commodity specific growth characteristics and physical attributes on produce safety. Produce-specific qualitative and quantitative risk assessments cannot and should not be based solely on growth characteristics and physical attributes as they are likely to yield spurious results. PMA supports science and risk-based regulations that require implementation of preventive controls that are commensurate with risks associated with the commodity,
practices and procedures employed during the production, handling and holding of fresh produce.

**Market Channels and Produce Risk**

The FDA seeks comment on their conclusions that it is not a valid approach ((FR 78(11): 3527). This conclusion was based on a lack of solid data that differentiates risk based on direct market channels versus commercial channels. Further, since some farms are exempt if they sell directly to consumers or other "qualified" end users and therefore not subject to the requirements of the proposed rule, FDA does not feel it can use market channels as a basis for risk characterization. They also seek comment on that conclusion.

After harvest, human pathogens can contaminate produce at any point along the supply chain, including packing/repacking operations, handling at retail, or in the consumer’s home (e.g. consumers using the same cutting board for meats and vegetables). However, there is currently limited or no in-depth data available to determine or risk rank where produce contamination is most likely to occur throughout various configurations of produce supply chains or to compare the relative risk of various supply chains. This is an area where further produce safety research is needed.

**Commodity Exemptions**

The QAR identified bananas and coconuts as a lower risk for illness (FR 78(11): 3528) because they are peeled or shelled before consumption. Should these commodities be covered by the rule? Or, should they be covered but be subject to less stringent requirements? Commodities like pears, grapefruits, oranges and lemons were shown by the QAR to have fewer routes of contamination and/or lower potential for contamination (based on outbreak data and rankings in the QAR). Should commodities that meet both of these requirements be covered by the rule? Should they be covered but subject to a less stringent set of requirements? How should the rule address the changing nature of outbreak data over time?

**Peeling**

The scientific literature clearly demonstrates that the edible portion of a fresh produce commodity may be contaminated by use of a knife to peel and cut up a fresh produce item. This is because if the outer rind of the commodity is contaminated, this contamination may be transferred to the edible portion of the commodity by the cutting
knife during peeling and cutting. Peeling fresh produce with a utensil or tool as the above described scenario demonstrates is not sufficiently protective of public health to warrant exclusion from the produce safety rule. Although bananas do not require the use of a tool to peel them before consumption and hence may require special consideration, bananas are sometimes cut in half by consumers, when the individual banana finger may be too large for consumption at one time. Thus the edible portion of bananas when cut with a knife may be contaminated.

**Shelling**

The scientific literature clearly demonstrates that the edible portion of tree nuts may be contaminated by the transference of human pathogens from the inedible outer portion of a tree nut to the edible inner kernel during hulling, shelling or handling operations. Many nuts are sutured which provides human pathogens with access to the edible kernels of tree nuts during harvest hulling, shelling and postharvest handling. However, some tree nuts undergo heat treatments before consumption which are validated to eliminate the risk posed by the presence of human pathogens (e.g. California almonds). Therefore, the need for inclusion of shelled tree nuts in the produce safety rule is already addressed in that tree nuts that will undergo validated commercial heat treatments (e.g. California almonds) before consumption are excluded from the proposed produce rule. As per the proposed produce rule individual operators must determine whether or not the processes to which their products will be subjected are sufficient to control, reduce or eliminate human pathogens in the products that they are producing and hence be exempt from the produce rule. Produce items which are shelled and consumed without the preventive control of a heat or other treatment to control, reduce or eliminate the risk of human pathogens on the edible portion of the produce item should be covered by the produce safety rule.

Additionally, FDA has embarked upon a qualitative microbial risk assessment for tree nuts and PMA applauds this effort to take a science and risk-based approach so as to assure that mandatory preventive controls are commensurate with risks associated with the commodity, practices and procedures employed during the production, handling and holding of tree nuts.

**Modified Standards**

PMA does not support the concept of modified standards for some commodities based on the number of routes of contamination nor whether the produce item must be peeled or shelled before consumption. However, alternative preventive controls approaches which provide an equal level of public health protection should be allowable to fulfill compliance requirements of “ALL” or “ANY” of the FDA produce safety rule provisions. Instead of
modified requirements for specific commodities FDA should utilize its enforcement, inspection and sampling assignment discretion in a risk-based manner, focusing enforcement, inspect and sampling assignments on commodities which have definitively been associated with foodborne illness outbreaks and have sampled positive for the presence of human pathogens or have been recalled because they have tested positive for the presence of human pathogens due to contamination during on-farm production, harvest, handling or holding.

**Produce Safety Rule and Preventive Controls for Human Foods Regulatory Scope**

FDA must align the requirements of the produce and preventive controls rules. A more seamless integration of the two rules will strengthen enforcement and reduce confusion. Growers, handlers and others in the marketing chain will be able to better understand the requirements and direct their attention to those activities which can make products safer.

There is very serious produce industry concern that the regulatory lines of coverage between the produce safety rule and preventive controls for human foods are not workable for agriculture and do not reflect the realities of produce production and handling. For example, as proposed an on-farm packing house would regulated under the produce rule until it accepts fruit from a neighbor's farm, which under the proposals then triggers the preventive controls rule. PMA acknowledges that as per the Food Safety Modernization Act, food facilities that must register with FDA as per the requirements of the Bioterrorism Act of 2002 are to be regulated by the preventive controls for human foods regulation. However, the unintended consequences of this are that packing houses that are FDA registered facilities will be required to comply with the preventive controls for human foods regulation, while on-farm packing houses performing the exact same procedures and practices while handling the exact same commodity will be required to comply with the produce safety regulation. This is not a risk-based approach as it sets up a system of dual, divergent standards 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 insure 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 the packing house differently based on where raw agricultural commodities (RACs) come from. They 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. The rules should provide
for modified requirements for facilities that handle raw agricultural commodities, even those that originate on another farm; those modified requirements for fresh fruits and vegetables should be those found in the produce rule. As such, PMA proposes for FDA consideration that the proposed produce safety rule be deemed comparable to preventive controls for human foods rule for the purposes of compliance and enforcement. Hence, if a packing facility is in compliance with provisions of the produce safety rule the pack facility would be in compliance with preventive controls rule. Additionally, PMA has also provided alternative draft definitions for: “Farm”, “Harvesting”, “Holding”, “Manufacturing/Processing”, “Packing” and “Packaging” which if adopted by FDA would provide the opportunity to make the produce rule workable for agriculture and reflect the realities of food production. The proposed framework provided by PMA would mean that some packhouses may have to register as FDA Food Facilities as per the Bioterrorism Act but they would not be subject to the Preventive Controls for Human Food Regulation. Instead they would be “farms” for the purposes of coverage under the Produce Safety Regulation.

Subpart A. General Provisions - Scope of Coverage

Definition of Produce

FDA Proposes: “Produce means any fruit or vegetable (including mixes of intact fruits and vegetables) and includes mushrooms, sprouts (irrespective of seed source), peanuts, tree nuts and herbs. A fruit is the edible reproductive body of a seed plant or tree nut (such as apple, orange and almond) such that fruit means the harvestable or harvested part of a plant developed from a flower. A vegetable is the edible part of an herbaceous plant (such as cabbage or potato) or fleshy fruiting body of a fungus (such as white button or shiitake) grown for an edible part such that vegetable means the harvestable or harvested part of any plant or fungus whose fruit, fleshy fruiting bodies, seeds, roots, tubers, bulbs, stems, leaves, or flower parts are used as food and includes mushrooms, sprouts, and herbs (such as basil or cilantro). Produce does not include food grains meaning the small, hard fruits or seeds of arable crops, or the crops bearing these fruits or seeds, that are grown and processed for use as meal, flour, baked goods, cereals and oils rather than for fresh consumption (including cereal grains, pseudo cereals, oilseeds and other plants used in the same fashion). Examples of food grains include barley, dent- or flint-corn, sorghum, oats, rice, rye, wheat, amaranth, quinoa, buckwheat, cotton seed, and soybeans.

PMA Comment: PMA supports the FDA’s definition of produce as described.

- PMA requests clarification from FDA as to whether or not seeds consumed raw such as sunflower seeds would be covered by the produce safety rule.
- PMA requests clarification from FDA as to whether or not edible flowers consumed raw would be covered by the produce safety rule.

**Definition of a Raw Agricultural Commodity (RAC)**
FDAs proposes: Raw agricultural commodity (RAC) means “raw agricultural commodity” as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act. Section 201(r) defines “raw agricultural commodity” as any food in its raw or natural state, including all fruits that are washed, colored, or otherwise treated in their unpeeled natural form prior to marketing.”

**PMA Comment:** PMA agrees with the proposed definition of RAC.

**Produce Rule Coverage of Domestic and Imported Produce**
Proposed, § 112.1 establishes the scope of food that is subject to this rule. Under proposed § 112.1(a), food that meets the definition of produce in § 112.3(c) and that is a raw agricultural commodity (RAC) as defined in section 201(r) of the FD&C act, would be covered by part 112, unless it is excluded by § 112.2. This includes produce RACs grown domestically and produce RACs that will be imported or offered for import in any State or territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico.

**PMA Comment:** PMA agrees with FDA’s interpretation of produce rule coverage to include produce RACs grown domestically and produce RACs that will be imported or offered for import in any State or territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico. However, PMA encourages the FDA to work with PMA and other trade organizations to assure compliance in produce growing regions both inside and outside the United States to assure an economic equity between domestic and imported produce.

- Food safety transcends geopolitical boundaries, thus food produced either domestically or imported into the United States should be produced with the same level of care when offered for sale to consumers in the United States.
- Differing requirements for imported and domestic produce is not acceptable as it would be a violation of international trade agreements and would potentially have adverse economic consequences.

**On-Farm Produce Rule Activities Coverage Versus On-Farm Processing/Manufacturing Preventive Controls for Human Foods Rule Coverage**
FDA tentatively articulated five organizing principles (FR 78(11): 3515), to explain the basis for the proposed definitions that would classify activities on-farm and off-farm for the purpose of this proposed rule.

**PMA Comment:** The complexity of the produce industry supply chain requires modifications to the organizing principles. Food safety regulations need to be organized based on crop ownership and transference of ownership rather than company ownership. PMA provides further comment on these organizing principals in our comments to Docket No. FDA-2011-N-0920; Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food.

**Coverage of Only Biological Hazards**

FDA tentatively concludes that the proposed rule should be limited in scope to biological hazards and science-based standards necessary to minimize the risk of serious adverse health consequences or death associated with biological hazards. FDA also requested comment on whether we should instead use the term “biological hazards” in this rule?

**PMA Comment:** PMA agrees with FDA’s conclusion that the produce rule should be limited in scope to biological hazards.

- **Chemical Hazards:** The U.S. EPA currently regulates chemicals that can be used on specific crops while States regulate application. Public health effects are considered in the approval process for agricultural chemicals prior to introduction into the marketplace and use. If chemical hazards were to be included in the final produce rule it would represent a redundant regulatory burden on growers.
- **Radiological Hazards:** Growers have little to no control or influence over radiological hazards nor do they have experience in evaluating radiological hazards. Potential radiological contamination in the U.S. has not been a focal point in terms of food safety concerns. In fact, the FDA has not included radionuclide samples in the Total Dietary Study program since 2005. Unlike with microbiological and chemical hazards, there is little or no data relating to known cases of radionuclide contamination in the U.S. Even though events from outside the U.S., such as the 2011 Fukushima earthquake in Japan resulted in radiation levels exceeding acceptable limits in Japanese produce, the increased levels did not adversely affect U.S. produce as measured by detection levels in Washington and other states after the accident. Therefore, food safety plans covering catastrophic events that are not reasonably likely to occur should be outside of the proposed rule especially since growers would have no control over potential radiological contamination or even testing for contamination. While the FDA may have responsibility for national food safety in the event of a nuclear event that does affect
the safety of the U.S. food supply, delegating responsibility to individual growers falls outside the scope of this proposed rule and if implemented would only raise concerns from domestic producers and from import communities.

- **Physical Hazards:** Physical hazards can occur in covered produce; however they rarely if ever reach the threshold of causing severe adverse health consequences or death. Therefore, they should be excluded from provisions of the produce safety rule.

**PMA Comment:** PMA supports the use the term “biological hazards” in this rule as it provides clarity and it is concise.

*FDA tentatively concludes it would not be appropriate to exempt any farms from this proposed rule based on the speed of their deliveries to the consumer.*

**PMA Comment:** PMA agrees with FDA’s conclusion that it is not appropriate to exempt any farms from this proposed rule based on the speed of their deliveries to the consumer.

*FDA tentatively concludes that the risk posed to animals, and to humans from contact with animals or consumption of animals as food, by farm practices in producing and harvesting fruits and vegetables does not merit imposition of new regulatory requirements at this time. Therefore, this proposal is limited to produce for use as human food. Produce that is intended for use as animal food would not be subject to the requirements of this rule.*

**PMA Comment:** PMA agrees with FDA’s conclusion that the produce safety rule should be limited to produce for use as human food.

*Under proposed § 112.1(a), food that meets the definition of produce in § 112.3(c) and that is a raw agricultural commodity (RAC) as defined in section 201(r) of the FD&C act, would be covered by part 112, unless it is excluded by § 112.2. Section 201(r) defines “raw agricultural commodity” as any food in its raw or natural state, including all fruits that are washed, colored, or otherwise treated in their unpeeled natural form prior to marketing.*

**PMA Comment:** PMA agrees with FDA’s conclusion that food that meets the definition of produce in § 112.3(c) and that is a raw agricultural commodity (RAC) as defined in section 201(r) of the FD&C act, would be covered by part 112, unless it is excluded by § 112.2.

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**Subpart A. General Provisions - Exemptions**

**Produce Rarely Consumed Raw Exemption**
Subpart A—§ 112.2 What produce is not covered by this part? (Exemptions and Exclusions)

(1) Produce that is rarely consumed raw, specifically the produce on the following exhaustive list—arrowhead, arrowroot, artichokes, etc.....

PMA Comment: PMA opposes the use of a list of exempted commodities based on consumer preparation for consumption and recommends that this exemption be eliminated. PMA does not support the approach of using a commodity-specific list of exempt products based on current likely means of consumer preparation and consumption for produce commodities.

- Use of produce preparation and cooking methods to determine commodity-specific produce risks inappropriately shifts food safety responsibility from producers to consumers. Food safety begins with agricultural growing practices and continues through the supply chain to the consumer.

- Consumption patterns change over time and growers have no control over consumer behavior. Currently consumers on an ever more frequent basis are preparing and consuming raw vegetable drinks made from a variety of raw vegetables previously only eaten when cooked (e.g. kale, carrot greens and collard greens). Consumer preferences and how they consume certain produce items have and will continue to change over time. When consumer preparation and manners of consumption change so do the risks associated with consumption of produce items as the risk reduction provided by cooking are no longer applicable. To enhance produce safety, there needs to be an industry-wide commitment by all growers whether their commodity is cooked or not. Growers can and should focus on the areas where they have control; namely, during agricultural production, harvest and packing operations.

- Exemption of produce rarely consumed raw ignores the issue of potential cross-contamination at retail and during preparation in consumer’s homes. For example: it is not uncommon for some crops that are rarely consumed raw to be fertilized with raw manure in some parts of the country. The preventive controls of consumer cooking and segregation of covered and un-covered produce may not be sufficient to prevent consumer illnesses due to the potential of cross microbial contamination in consumers home or during distribution.

- If FDA is steadfast in retaining the proposed exemption for produce rarely consumed raw, then the agency should consider the following means of updating and amending the produce safety regulation to take into consideration the risk posed to consumers based on how they consume specific produce items:
o **Proposed Rule Making & Public Comment:** FDA may wish to consider routinely and on a regular basis proposing amendments via proposed rule and public comment process to amend the list of produce items set forth in §112.2 that are rarely consumed raw. FDA may open this portion of the produce rule for public comment on a regular basis, for example every 5 years, so as to seek public input and data as to the risk posed to consumers based on how they consume (cooked or uncooked) specific produce items. This strategy is routinely employed by other Federal Agency’s to keep Federal Regulations up-to-date and relevant.

o **Citizens Petition:** The FDA may wish to consider a citizens petition process whereby any citizen(s) could petition FDA and present data that provides evidence that a specific produce item or items meet the criteria for being rarely consumed raw and should hence be added to the inclusive list of produce exempted because it is rarely consumed raw. Conversely, citizen petitions may be filed that request that item be removed from the list of produce items that are rarely consumed raw, due to data which provides evidence that consumer preparation and eating habits (cooking or not cooking) have changed for a specific produce item(s).

o **Variance for Produce Rarely Consumed Raw:** The FDA may wish to consider including all produce as “covered produce” in the produce safety standard including produce which is “rarely consumed raw” but allowing states and foreign national governments to apply for variances which would exempt produce items that are “rarely consumed raw” from all produce safety standard provisions. This would provide a meaningful, science and risk-based mechanism to review available data and allow for revocation of the variance if new evidence that consumer preparation and eating habits (cooking or not cooking) have changed for a specific produce item(s).

o **Discretionary Enforcement by FDA:** The FDA may wish to consider including all produce as “covered produce” in the produce safety standard including produce which is “rarely consumed raw” but explicitly stating that the Agency will use discretionary and limited resources to enforce the regulation for produce that is “rarely consumed raw”.

o **NLEA Approach:** The FDA may wish to consider the approach taken in the Nutrition Labeling and Education Act of 1990 (NLEA) which requires FDA to update and publish nutritional information for the 20 most commonly consumed fruit and the 20 most commonly consumed vegetables for nutritional labeling requirements. FDA could take a similar approach of
simply publishing a list of the produce items which are rarely consumed raw based on data which is submitted and available to the agency.

- If the FDA intends to offer a list of exempted commodities because they are rarely consumed raw in the final rule, the list should be created on a case-by-case basis after completion of a science-based commodity specific risk assessment. If a risk-based approach is applied to agricultural production processes, regardless of the product, the ultimate product the consumer purchases will have been produced using food safety programs addressing known risks. The likelihood of illness arising from the production process from either directly contaminated products or through cross-contamination should be minimized.

**Commercial Processing Exemption**

*Subpart A—§ 112.2 What produce is not covered by this part? (Exemptions and Exclusions)*

**Commercial Processing Exemption**

(b)(1) *The covered produce receives commercial processing that adequately reduces the presence of microorganisms of public health significance. Examples of commercial processing that adequately reduces the presence of microorganisms of public health significance are processing in accordance with the requirements of parts 113, 114, or 120 of this chapter, treating with a validated process to eliminate spore-forming microorganisms (such as processing to produce tomato paste or shelf-stable tomatoes), and processing such as refining or distilling produce into products such as sugar, oil, spirits, or similar products;*

(b)(2) *You must establish and keep documentation in accordance with the requirements of subpart O of this part, of the identity of the recipient of the covered produce that performs the commercial processing described in paragraph (b)(1) of this section; and*

(b)(3) *The requirements of this subpart and subpart Q of this part apply to such produce.*
Preamble: It is important to note that any of the exemptions in proposed § 112.2 are only applicable to the produce specified in the exemption. In other words, a covered farm may not rely on these exemptions for all of its covered produce simply because a subset of that produce is rarely consumed raw; is for personal or on-farm consumption; is not a RAC; or will receive the requisite commercial processing; in those instances, only the subset that meets the relevant exemption criteria would be exempt from this proposed rule.

For example, if you own or operate a farm that produces both tomatoes that will be processed into tomato paste, and tomatoes that will not receive any commercial processing to adequately reduce pathogens, and you do not qualify for any other exemption, you would be subject to the rule when you grow, harvest, pack or hold those tomatoes that will not be processed to adequately reduce pathogens. Likewise, if you produce both artichokes and lettuce, you would be subject to the rule when you grow, harvest, pack or hold lettuce, but you would not be subject to the rule when you grow, harvest, pack, or hold artichokes.

We request comment on proposed §§ 112.1 and 112.2, including the specific examples of produce that would be covered by the rule; the list of produce that would not be covered by the rule because it is rarely consumed raw; and the proposed exemption for produce that receives commercial processing, including the types of processing that should qualify for this exemption.

PMA Comment: PMA is supportive of the FDA produce safety regulation exempting commodities destined to receive commercial processing that adequately reduces the presence of pathogenic microorganisms (should they be present). It should be noted that fresh-cut processing, e.g. salads, sliced tomatoes, fruit cups, etc., does not have a “kill” step so that raw products intended for these types of operations should not be exempt.

- Growers need to minimize the potential for microorganisms of public health significance on produce regardless of whether the product is intended for further processing or not. However, produce intended for commercial processing need not be grown under the same rules and requirements as produce intended for consumption as a RAC.
- Produce destined for commercial processing that adequately reduces the presence of microorganisms of public health significance may often end up in the fresh produce supply. FDA and State regulatory agencies must have sufficient regulatory enforcement oversight capabilities to detect and take action against such violations, or else this will create an uneven economic playing field for those whom must follow the FDA produce standards.
Qualified Exemption

§ 112.5 Who is eligible for a qualified exemption and associated modified requirements based on average monetary value of all food sold and direct farm marketing?

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

- **Qualified exemptions not science or risk based**: 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.

- **Documentation**: PMA does support the requirement that qualified farms must maintain and provide adequate documentation (e.g. food safety records) as needed to demonstrate the basis for their qualified exemption.

- **Consumer safety regulations predicated on business size based on revenue is not science based**: As per FDA statistics (Regulatory Impact Analysis), farm entities which are eligible for the “qualified exemption” are a small percent of the overall fresh produce supply available to consumers. However, FDA has a statutory obligation to promote and protect the public health of all consumers whom receive food products from all market channels, not just for certain market channels. Minimum food safety requirements implemented across all market channels would ensure consistency as opposed to two-tiered food safety requirements depending on farm business size based on revenue.

- **Impact of illness outbreaks**: Foodborne illness outbreaks associated with produce adversely impact public health and diminish consumer confidence for a specific produce commodity. These adverse effects are not proportional to business size, as all produce farms large and small in size are adversely economically affected by a foodborne illness outbreak associated with a particular produce commodity. These widespread adverse effects of a foodborne illness outbreak associated with a particular produce item on growers whom are not the responsible party are particularly devastating as losses are not covered by insurance and may result in a grower losing their business. These adverse economic consequences to growers whom are not the responsible party for a foodborne illness outbreak are
likely greater than the costs of implementing a food safety program irrespective of business size.

- **Unfunded Mandate for States:** This exemption may place undue economic burden on state, local and tribal governments, as they will now be the agency’s which by default will be tasked with on-farm food safety regulatory enforcement on this economic class of entities.

- **Un-Equivalent Risk Associated with “Qualified Exempt” Produce:** The total food sales revenues and distances from the farm associated with the “qualified exemption” are an arbitrary means of measuring risk. Farms outside the United States but within 275 miles of the farm may meet criteria for the “qualified exemption”. Additionally, the total product volume (or number of exposure dosages) for up to $500,000 worth of exempted produce in the USA is very different from the volume of product of the same exempted produce when it is produced in an emerging economy. Since the volume of product represented by $500,000 is different, the number of exposures represented is different and therefore so is the risk to public health.

- **Qualified Exemption Total Food Sales Companies:** The “qualified exemption” total food sales exemption may permit a mechanism for some companies to work around food safety requirements by creating new and separate business entities with total food sales of less than $500,000 in order to qualify for an exemption. This creates an uneven business marketplace for those whom do not engage in such practices and potentially increases public health risk for the whole produce commodity category, thus endangering the livelihood and business viability of companies whom are conforming to the FDA produce safety standard.

- **Market Access:** Exempting farms with less than $500,000 in total food sales potentially reduces the economic viability of these entities as they will likely no longer be able to sell into mainstream retail and foodservice markets due to the perception that the products that they produce are less safe because they are not regulated by the FDA produce safety standard. Counter intuitively this $500,000 total food sales exemption, while intending to relieve these small entities of the potential economic burden associated with the produce safety standard may in fact unintentionally harm this class of farms in the marketplace by undermining the perceived safety of products from these farms.

- **Farm Animal Value:** PMA seeks clarification as to whether or not and how the value of on-farm live domesticated animals would be used in the calculation of “total food sales”.
Less Than $25K Total Food Sales Exemption

§ 112.4 Who is subject to the requirements of this part?

(a) Except as provided in paragraph (b) of this section, if you are a farm or farm mixed-type facility with an average annual monetary value of food (as “food” defined in § 112.3(c)) sold during the previous 3-year period of more than $25,000 (on a rolling basis), you are a “covered farm” subject to this part. If you are a covered farm subject to this part, you must comply with all applicable requirements of this part when you conduct a covered activity on covered produce.

PMA Comment: PMA opposes qualified exemption based solely on revenue (<$25K annual food sales) and recommends that this exemption be eliminated.

- **Food safety is not limited by business size:** Food safety risks are not limited to a particular business size based on revenue and for this reason PMA cannot support exemptions based solely on business revenue. High risk processes and practices can exist in any operation. Human pathogens know no boundaries based on the economic size of a farm.

- **Revenues are not a science-based measure:** Consumer safety regulations predicated on business size based on revenue is not science based. As per FDA statistics (Regulatory Impact Analysis), farm entities which market less than $25,000 worth of food per year provide a small percent of the overall fresh produce supply available to consumers. However, FDA has a statutory obligation to promote and protect the public health of all consumers whom receive food products from all market channels, not just for certain market channels. This exemption goes beyond what has been mandated in the Food Safety Modernization Act. Minimum food safety requirements implemented across all market channels and sizes of farms would ensure consistency as opposed to two-tiered food safety requirements depending on farm business size based on revenue.

- **Produce related outbreaks impact everyone:** Foodborne illness outbreaks associated with produce adversely impact public health and diminish consumer confidence for a specific produce commodity. These adverse effects are not proportional to business size, as all produce farms large and small in size are adversely economically affected. These widespread adverse effects of a foodborne illness outbreak associated with a particular produce item on the growers whom are not the responsible party are particularly devastating as losses are not covered by insurance and may result in a grower losing their business. These adverse economic consequences to growers whom are not the responsible party to a
foodborne illness outbreak are likely greater than the costs of implementing food safety programs irrespective of business size.

- **Unfunded Mandate for States:** This exemption places undue economic burden on state, local and tribal governments, as they will now be the agency’s which by default will be tasked with on-farm food safety regulatory enforcement on this economic class of entities.

- **Un-Equivalent Risk Associated with $25K worth of produce:** The $25,000 total food sales exemption is arbitrary and not science-based as a means of measuring exposure to risk. For example, the total volume or product (or number of exposure dosages) that represents $25,000 worth of exempted produce in the USA is very different from the volume of product off the same exempted produce when it is grown in an emerging economy. Since the volume of product represented by $25,000 is different, the number of exposures represented is different and hence so is the risk.

- **<$25,000 Total Food Sales Companies:** The $25,000 total food sales exemption may permit companies to create new or separate business entities with total food sales of less than $25,000 in order to qualify for an exemption. This creates an uneven business environment for those whom do not engage in such practices and potentially increases public health risk for the whole produce commodity category, thus endangering the livelihood and business viability of companies whom are conforming to the FDA produce safety standard.

- **Market Access:** Exempting farms with less than $25,000 in total food sales potentially reduces the economic viability of these entities as they will likely no longer be able to sell into desirable retail and foodservice markets due to the perception that the products they produce are less safe because they are not regulated by the FDA produce safety standard. Counter intuitively this $25,000 total food sales exemption, while intending to relieve these entities of the economic burden associated with the produce safety standard, may in fact unintentionally harm this class of farms in the marketplace by undermining the perceived safety of products from these farms.

- **Farm Animal Value:** PMA seeks clarification as to whether or not and how the value of on-farm live domesticated animals would be used in the calculation of “total food sales”.

§ 112.3 What definitions apply to this part?
(a) The definitions and interpretations of terms in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321) apply to such terms when used in this part.

(b) For the purpose of this part, the following definitions of very small business and small business also apply:

**Agricultural water** means water used in covered activities on covered produce where water is intended to, or is likely to, contact covered produce or food contact surfaces, including water used in growing activities (including irrigation water applied using direct water application methods, water used for preparing crop sprays, and water used for growing sprouts) and in harvesting, packing, and holding activities (including water used for washing or cooling harvested produce and water used for preventing dehydration of covered produce).

**PMA Comment:** PMA is supportive of the FDA proposed produce safety regulation definition of agricultural water.

- The proposed definition of agricultural water narrowly defines and places food safety regulatory requirements on only a specific subset of water used in on-farm operations.
- FDA needs to provide guidance as to whether or not water used to irrigate crops where the edible portion is grown underground such as carrots and onions would be considered agricultural water. PMA believes that water used to irrigate such crops should fall within the definition of agricultural water.

**Composting** means a process to produce humus in which organic material is decomposed by the actions of microorganisms under thermophilic conditions for a designated period of time (for example, 3 days) at a designated temperature (for example, 131°F (55 °C)), followed by a curing stage under cooler conditions.

**PMA Comment:** PMA is supportive of the FDA proposed produce safety regulation definition of composting.

**Covered activity** means growing, harvesting, packing, or holding covered produce, provided that all covered produce used in covered packing or holding activities is grown, raised, or consumed on that farm or another farm under the same ownership. Covered activity does not include manufacturing/processing within the meaning defined in this chapter.
PMA Comment: PMA is supportive of the FDA definition of covered activity except we would request FDA consider covered produce grown on another farm under different ownership and transferred to a second farm be considered a RAC and not a processed/manufactured product.

Covered produce means produce that is subject to the requirements of this part in accordance with §§ 112.1 and 112.2. The term “covered produce” refers to the harvestable or harvested part of the crop.

PMA Comment: PMA is supportive of the FDA proposed produce safety regulation definition of covered produce.

- FDA needs to provide guidance as to whether or not produce flowers or blooms which mature into the harvestable part of the crop would be considered “covered produce” and be subject for example to agricultural water quality standards. This is important in that water is often applied, for example, to strawberry and apple blooms for protection from frost damage.
- PMA believes that in most cases blooms should be considered the harvestable part of the crop and be considered “covered produce” as numerous scientific studies have demonstrated that, for example, tomato blooms artificially contaminated with Salmonella will result in mature fruits that are contaminated with Salmonella.
  - More research is needed to determine if pathogen contamination of blooms leads to contaminated fruit with other crops like strawberry, apples and citrus.

Direct water application method means using agricultural water in a manner whereby the water is intended to, or is likely to, contact covered produce or food-contact surfaces during use of the water.
**PMA Comment:** PMA is supportive of the FDA proposed produce safety regulation definition of direct application method for agricultural water.

- The proposed definition for direct application of agricultural water narrowly defines and places food safety regulatory requirements on only a specific subset of water used for on-farm operations.
- FDA needs to provide guidance as to whether or not water used to furrow irrigate crops where the harvestable portion of the crop is likely to contact soil exposed to irrigation water including underground crops (e.g. carrots, potatoes, onions, etc.) would be considered a direct application method of agricultural water and hence subject to the proposed numerical agricultural water microbial water quality standards. Examples of such crops where the harvestable portion might contact furrow water would be bush style fresh market tomatoes, melons, carrots and onions. PMA believes that water used to irrigate such crops should fall within the definition direct application method for agricultural water and hence, subject to numerical agricultural water microbial water quality standards.

Farm means a facility (as defined in §1.227 of this chapter) in one general physical location devoted to the growing and harvesting of crops, the raising of animals (including seafood) or both. Farm includes:

(i) Facilities that pack or hold food, provided that all food used in such activities is grown, raised, or consumed on that farm or another farm under the same ownership; and

(ii) Facilities that manufacture/process food, provided that all food used in such activities is consumed on that farm or another farm under same ownership.

**PMA Comment:** PMA recommends that the definition of “farm” be amended as follows:

- **Farm means** an individual tract or tracts of land where crops are grown, harvested, packed and held, animals are raised (including seafood), or both and have a similar farm/ranch manager, operator or landowner(s) and are operated under a common on-farm food safety management scheme. The term “farm” includes:
  (i) Facilities that perform harvesting activities on RACs and do not transform a raw agricultural commodity, as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act [FFDCA], into a processed food as defined in section 201(gg) of the FFDCA.
(ii) Facilities that receive RACs from other “farms”, that perform harvesting activities on RACs and do not transform a raw agricultural commodity, as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act [FFDCA], into a processed food as defined in section 201(gg) of the FFDCA.

(iii) Facilities that manufacture/process food, provided that all food used in such activities is consumed on that farm or another farm under same ownership.

- By redefining farm to include pack and hold activities performed on select RACs not grown on the farm, provides uniform and effective regulation of all farm pack and hold activities solely under the produce safety regulation. This means that some packhouses may have to register as FDA Food Facilities as per the Bioterrorism Act but they would not be subject to the Preventive Controls for Human Food Regulation but instead they would be “farms” for the purposes of coverage under the Produce Safety Regulation.
- “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.

**Harvesting** applies to farms and farm mixed-type facilities and means activities that are traditionally performed by farms for the purpose of removing raw agricultural commodities from the place they were grown or raised and preparing them for use as food. Harvesting is limited to activities performed on raw agricultural commodities on the farm on which they were grown or raised, or another farm under the same ownership. 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 [FFDCA], into a processed food as defined in section 201(gg) of the FFDCA. Gathering, washing, trimming of outer leaves of, removing stems and husks from, sifting, filtering, threshing, shelling, and cooling raw agricultural commodities grown on a farm or another farm under the same ownership are examples of harvesting.

**PMA Comment:** PMA recommends that the definition of “harvesting” be amended as follows:

- Harvesting/Postharvest Handling is defined as activities on farms and off farms that are traditionally performed to remove raw agricultural commodities from the place they were grown or raised and preparing them for use as food. Harvesting is not limited to activities performed on raw agricultural commodities on the farms on which they were grown or raised. Harvesting activities performed on or off farms include; gathering, washing, trimming of outer leaves, removing stems and husks.
from, sifting, filtering, threshing, shelling, coring, waxing, artificial ripening, cutting, labeling, packing, packaging, fumigation, cooling, holding and storing of raw agricultural commodities. 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 [FFDCA], into a processed food as defined in section 201(gg) of the FFDCA.

- The definition of harvesting must include postharvest handling activities that have been associated with the preparation for use of fresh produce for food. Advanced farming practices, unique crop harvesting methods, and the incredible expenses of such systems make the sole ownership of postharvest handling equipment not possible in all situations. As a result, it is common to perform job-sharing and equipment sharing for harvesting activities including postharvest handling activities. While the farmers each operate independent businesses, their cooperation and resource sharing is an important part of cost efficiency.

- “Harvesting” activities are harvesting activities wherever performed and by whomever performs them and should be covered by the same regulation. By redefining harvesting to include postharvest activities routinely performed on RACs not grown on the farm where postharvest handling/harvest activities occur, provides uniform and effective regulation of all “harvesting” activities solely under the produce safety regulation. This means that some packhouses may have to register as FDA Food Facilities as per the Bioterrorism Act but they would not be subject to the Preventive Controls for Human Food Regulation but instead they would be covered “harvesting” activities for the purposes of coverage under the Produce Safety Regulation.

**PMA Comment:** PMA strongly urges that “coring”, “waxing”, “artificial ripening”, “cutting”, “labeling and stickering”, “packaging” and “fumigation” to be included in the definition of harvesting.

- “Coring” - PMA also strongly urges FDA to include “coring” in the definition of harvesting. Field cleaning (trimming of outer leaves) and coring of lettuce is routinely done to harvest only the usable portion of various types of lettuce, thus reducing waste and wasteful transport of outer leaves that are not used in salad processing to processing plants.
  - Field cleaning and coring of lettuce has been 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.
Field cleaning and coring of lettuce does NOT transform a raw agricultural commodity, as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act [FFDCA], into a processed food as defined in section 201(gg) of the FFDCA.

Proposed produce rule provisions regarding safe growing and harvesting of produce provide sufficient preventive controls to significantly reduce the likelihood of produce contamination posed by the practice of field cleaning and coring of lettuce.

- “Waxing”, “artificial ripening”, “cutting”, “labeling/stickering”, “packaging” and “fumigation” does NOT transform a raw agricultural commodity, as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act [FFDCA], into a processed food as defined in section 201(gg) of the FFDCA.
- “Waxing”, “artificial ripening”, “cutting”, “labeling/stickering”, “packaging” and “fumigation” have been traditionally performed by farms for the purpose preserving the quality of raw agricultural commodities immediately after they have been removed from the place where they were grown or raised and during preparing them for use as food. For example, brussel sprouts and broccoli florets may be harvested and marketed on the whole stalks or individual edible bud or florets. They are routinely on the farm cut away from the stalk in preparation for marketing. This is not processing/manufacturing.

FDA should not limit “harvesting” activities “to activities performed on raw agricultural commodities on the farm on which they were grown, raised, or another farm under the same ownership”. Eliminating this limitation will allow “harvesting” activities on produce not under the same ownership to remain part of “farm” activities.

Hazard means any biological agent that is reasonably likely to cause illness or injury in the absence of its control.

Reasonably foreseeable hazard means a potential hazard that may be associated with the farm or the food.

PMA Comment: PMA seeks guidance and clarification from FDA regarding criteria and situations in which a farmer could reasonably conclude that there was no foreseeable hazard.

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

**PMA Comment:** PMA recommends that the definition of “holding” be amended as follows:

- Holding means storage of food. Holding facilities include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks. For farms and during postharvest handling of raw agricultural commodities, holding also includes activities traditionally performed for the safe or effective storage of raw agricultural commodities, grown or raised on the same farm or from other farms, 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.

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

**PMA Comment:** PMA is generally supportive of the FDA proposed produce safety regulation definition of manufacturing/processing. However, FDA should not classify the following activities, whether they occur on or off farm, as part of harvesting/postharvest handling operations, as there is no substantial transformation of the produce item into different product in commerce: cutting, trimming, washing, waxing, cooling, mixing, labeling, or packaging of fresh produce raw agricultural commodities. These actions are simply “harvesting”/postharvest handling activities and not manufacturing/processing operations and should not be considered manufacturing/processing.

PMA strongly urges that “coring”, “waxing”, “artificial ripening”, “cutting”, “labeling and stickering”, “packaging” and “fumigation” to be included in the definition of harvesting and not manufacturing/processing.
“Coring” - Field cleaning (trimming of outer leaves) and coring of lettuce is routinely done to harvest only the usable portion of various types of lettuce, thus reducing waste and wasteful transport of outer leaves that are not used in salad processing to processing plants.

- Field cleaning and coring of lettuce has been 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.
- Field cleaning and coring of lettuce does not transform a raw agricultural commodity, as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act [FFDCA], into a processed food as defined in section 201(gg) of the FFDCA.

Waxing", “artificial ripening”, “cutting”, “labeling/stickering”, “packaging” and “fumigation” does not transform a raw agricultural commodity, as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act [FFDCA], into a processed food as defined in section 201(gg) of the FFDCA.

“Waxing”, “artificial ripening”, “cutting”, “labeling/stickering”, “packaging” and “fumigation” have been traditionally performed by farms for the purpose preserving the quality of raw agricultural commodities immediately after they have been removed from the place where they were grown or raised and during preparing them for use as food. For example, brussel sprouts and broccoli florets may be harvested and marketed on the whole stalks or individual edible bud or florets. They are routinely (on the farm) cut away from the stalk in preparation for marketing. This is not processing/manufacturing.

Microorganisms mean yeasts, molds, bacteria, viruses, protozoa, and microscopic parasites and includes species having public health significance. The term “undesirable microorganisms” includes those microorganisms that are of public health significance, that subject food to decomposition, that indicate that food is contaminated with filth, or that otherwise may cause food to be adulterated.

PMA Comment: PMA is supportive of the FDA proposed produce safety regulation definition of microorganisms but strongly urges the removal from the definition “undesirable microorganisms” including “those that subject food to decomposition”.

- Microorganisms that subject covered produce to decomposition are naturally occurring unavoidable plant pathogens; none of which have any public health significance or would be capable of causing severe adverse health consequences or death.
The proposed FDA definition of “undesirable microorganisms” should not include those that subject food to decomposition.

**Mixed-type facility** means an establishment that engages in both activities that are exempt from registration under section 415 of the FFDCA and activities that require the establishment to be registered. An example of such a facility is a “farm mixed-type facility,” which is an establishment that grows and harvests crops or raises animals and may conduct other activities within the farm definition, but also conducts activities that require the establishment to be registered.

**Table 2. Summary of Organizing Principles Regarding Classification of Activities On-Farm and Off-Farm Number Organizing Principles**

1. The basic purpose of farms is to produce RACs, and RACs are the essential products of farms.
2. Activities that involve RACs and that farms traditionally do for the purposes of growing their own RACs, removing them from the growing areas, and preparing them for use as a food RAC, and for packing, holding and transporting them, should all be within the definition of “farm.”
3. Activities should be classified based in part on whether the food operated on is a RAC or a processed food, and on whether the activity transforms a RAC into a processed food.
4. Activities farms may perform on others’ RACs should appropriately be classified as manufacturing/processing, packing, or holding in the same manner as these activities are classified off-farm when the RACs are to be distributed into commerce.
5. Manufacturing/processing, packing, or holding food—whether RACs or processed foods, from any source—for consumption on the farm should remain within the farm definition.

**PMA Comment:** PMA is generally supportive of the FDA proposed produce safety regulation definition of mixed-type facility however, PMA cannot support organizing principal 4: “activities farms may perform on other’s RACs should appropriately be classified as manufacturing/processing, packing, or holding in the same manner as these activities are classified off-farm when RACs are to be distributed into commerce”. PMA has already provided arguments here arguing that RACs brought to another farm under different operational management from the producing operation should not be thought of as manufactured or processed products. The simple act of transporting the RAC to
another farm operation like a packing house does not materially transform the RAC into a processed or RTE product. As long as the packing house does not perform processing or manufacturing activities as defined by FDA, the product remains a RAC and as such should be regulated under the Produce Rule.

**Non-fecal animal byproduct** means solid waste (other than excreta) that is animal in origin (such as meat, fat, dairy products, eggs, carcasses, blood meal, bone meal, fish meal, shellfish waste (such as crab, shrimp, and lobster waste), fish emulsions, and offal) and is generated by commercial, institutional, or agricultural operations.

**PMA Comment:** PMA is generally supportive of the FDA proposed produce safety regulation definition of non-fecal animal byproduct.

**Packaging** (when used as a verb) means placing food into a container that directly contacts the food and that the consumer receives.

**PMA Comment:** PMA is generally supportive of the FDA proposed produce safety regulation definition of packaging. However, PMA recommends that the definition of “packaging” be amended as follows:

- “Packaging (when used as a verb) means placing food into a container that directly contacts the food and that the consumer receives. Packaging of a raw agricultural commodity does not 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.”

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

**PMA Comment:** PMA is generally supportive of the FDA proposed produce safety regulation definition of packing. However, PMA recommends that the definition of “packing” be amended as follows:

- Packing means placing food into a container other than packaging the food. Packing of a raw agricultural commodity does not 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.

**Sanitize** means to adequately treat cleaned food-contact surfaces by a process that is effective in destroying vegetative cells of microorganisms of public health significance, and in substantially reducing numbers of other undesirable microorganisms, but without adversely affecting the product or its safety for the consumer.

**PMA Comment:** PMA is generally supportive of the FDA proposed produce safety regulation definition of sanitize.

**Soil amendment** means any chemical, biological, or physical material (such as elemental fertilizers, humus, manure, non-fecal animal byproducts, peat moss, perlite, pre-consumer vegetative waste, sewage sludge biosolids, table waste, agricultural tea and yard trimmings) intentionally added to the soil to improve the chemical or physical condition of soil in relation to plant growth or to improve the capacity of the soil to hold water. The term soil amendment also includes growth media that serve as the entire substrate during the growth of covered produce (such as mushrooms and some sprouts).

**PMA Comment:** PMA is generally supportive of the FDA proposed produce safety regulation definition of soil amendment.

**Surface water** means all water which is open to the atmosphere and subject to surface runoff, including water obtained from an underground aquifer that is held or conveyed in a manner that is open to the atmosphere, such as in canals, ponds, other surface containment or open conveyances.

**PMA Comment:** PMA is generally supportive of the FDA proposed produce safety regulation definition of surface water.

**Water distribution system** means a system to carry water from its primary source to its point of use, including pipes, sprinklers, irrigation canals, pumps, valves, storage tanks, reservoirs, meters, and fittings.

**PMA Comment:** PMA is generally supportive of the FDA proposed produce safety regulation definition of water distribution system.
Subpart B. General Requirements

Produce Rule and the National Organic Program (NOP)

As per Section 419(a)(3)(E) of the Food Safety Modernization Act, FDA Produce Safety Standards are precluded from having any requirements that conflict with or duplicate the requirements of the National Organic Program. Compliance with the provisions of this proposed rule would not preclude compliance with the requirements for organic certification in 7 CFR part 205. Moreover, where this proposed rule and the National Organic Program would include similar or related requirements, we propose that our requirements may be satisfied concurrently with those of the National Organic Program (i.e., to the extent the requirements are the same, compliance with this proposed rule could be achieved without duplication). For example, the National Organic Program application intervals for the use of raw manure as a soil amendment in 7 CFR 205.203(c)(1) are 90 days and 120 days before harvest, depending on whether the edible portion of the crop contacts the soil. Proposed § 112.56(a)(1)(i) would require a 9 month application interval for use of raw manure in the growing of covered produce when application is performed in a manner that does not contact covered produce during application and minimizes the potential for contact with covered produce after application. Records kept under 7 CFR 205.103 for the purposes of the National Organic Program that contain information that would be required in records under this proposed rule would not need to be duplicated. We seek comment on our approach to ensuring that this proposed rule does not conflict with or duplicate the requirements of the National Organic Program while providing the same level of public health protection as required under FSMA.

PMA Comment: PMA is not aware of any provisions of the proposed FDA Produce Safety Standards that conflict with or duplicate the requirements of the National Organic Program. It is also important for the Agency to affirm that the USDA NOP program assures the organic integrity of produce and USDA NOP is not a food safety program.

Alternative approaches that provide the same level of protection of public health.

§ 112.12 Are there any alternatives to the requirements established in this part?

(a) You may establish alternatives to the following specific requirements of this part, provided that you satisfy the requirements of paragraphs (b) and (c) of this section:

(1) The requirements in § 112.44(c) for testing water, and taking action based on test results, when agricultural water is used during growing operations for covered produce (other than sprouts) using a direct water application method;

(2) Composting treatment processes established in § 112.54(c)(1) and (c)(2);
(3) The minimum application interval established in § 112.56(a)(1)(i) for an untreated biological soil amendment of animal origin that is reasonably likely to contact covered produce after application or for a compost agricultural tea that contains compost agricultural tea additives; and

(4) The minimum application interval established in § 112.56(a)(4)(i) for a biological soil amendment of animal origin treated by a composting process that is reasonably likely to contact covered produce after application.

(b) You may establish and use an alternative to any of the requirements listed in paragraph (a) of this section, provided you have adequate scientific data or information to support a conclusion that the alternative would provide the same level of public health protection as the applicable requirement established in this part (including meeting the same microbiological standards, where applicable), and would not increase the likelihood that your covered produce will be adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act, in light of your covered produce, practices, and conditions, including agro-ecological conditions and application interval.

(c) Scientific data and information used to support an alternative to a requirement listed in paragraph (a) of this section may be developed by you, available in the scientific literature, or available to you through a third party. You must establish and maintain documentation of the scientific data and information on which you rely in accordance with the requirements of Subpart O of this part.

PMA Comment: PMA is supportive of the FDA produce safety regulation allowing growers to make on-farm food safety decisions based on their specific operational risks and for them to have the flexibility to use alternatives to the required provisions.

PMA Comment: PMA agrees with FDA’s proposed use of alternatives to the draft rules provided here on Agricultural Water and Biological Soil Amendments of Animal Origin provisions, as the alternative approach permits the timely implementation of new scientific and technical information regarding the safe growing, harvesting, packing and holding of produce.
• **Limited Use of Alternative Approaches**: It is unclear why the FDA limited the use of alternative approaches to only the specific sections listed. For example, alternative approaches are allowed for only in §112.44(c) of the Agricultural water provisions and may not, as currently proposed, be allowed for § 112.45 “How often must I test Agricultural water...”. It is strongly recommended that alternative approaches be permitted for all produce safety standard provision areas and specifically for agricultural water (Subpart E) and biological soil amendments of animal origin (Subpart F), as these are areas of current, active and intense research efforts. It is unclear as to why FDA believes that alternative approaches should be limited to only specific provisions of the produce safety standard.

• **“Same level of public health protection”**: It is unclear as to the means and quantitative measure that FDA would use to evaluate whether or not an alternative practice used by a grower provided the same level of public health protection. Detailed guidance to growers is needed from the FDA to make this alternative approach work. The FDA must define a clear end point and means of assessing that the “same level of public health protection” has in fact been achieved. If the endpoint and means of assessing that the endpoint has been achieved is not defined by the FDA, it is likely that few research efforts will be funded to develop alternative methods. Growers must have a specific target to focus limited research funds toward or the program will fail because of uncertainty about achieving the “same level of public health protection” and being out of compliance with the FDA regulation upon inspection by the Agency.
• **Research Needs:** There are significant data and research gaps which will impede the use of alternative approaches to the provisions of the FDA produce safety standards, and a significant investment in on-farm food safety research will be required. While there is currently ongoing industry sponsored research from institutions like the Center for Produce Safety in Davis, California regarding the means to ensure the safe use of biological soil amendments of animal origin and agricultural water, there needs to be a mechanism for formal dialogue among industry, academia and FDA to assure that research and implementation of viable alternatives may come to fruition. Establishing a process for peer review in which FDA would participate and provide opinion as to whether or not research results indicate that the “same level of public health protection” has been achieved by a new alternative approach to be in compliance with FDA produce safety standards will be crucial to the successful development and use of alternative approaches. Without such a peer review mechanism, it is unlikely that alternative approaches will be pursued by the agricultural community, as there is a significant risk that a promising research finding and potentially new alternative practices will not be implemented unless they receive some type of assurances from the FDA that they meet the standard of providing the “same level of public health protection”. It is recommended that joint industry/academia and government peer review panels be formed around specific produce safety regulation provision areas to provide critical review and determine if a specific alternative provides the “same level of public health protection”.

**Produce Safety Rule Update/Amendment Process**

FDA is limited in its ability to quickly and routinely update or amend the produce safety standards as it must use of the lengthy and laborious public rule making and public comment process. On-farm produce safety preventive controls are nascent, with more research and development needed as to both the causes and the means of preventing on-farm contamination of fresh produce. While FDA’s alternative approaches and variances provide a good start, many of the produce safety standard provision areas require the ability to apply new science and to facilitate the adoption of new practices which promote produce safety by the fresh produce industry. On-farm, science-based preventive control solutions should be derived from sound research. Improved mechanisms for dialogue among, academia, industry and government are needed to systematically identify, fund, complete and communicate high priority and high impact on-farm preventive controls research. Once research is completed the science-based produce safety standards must be able to incorporate this new knowledge and allow for its use. FDA must develop an expedited public rule making and public comment process to provide a means to amend
the produce safety standard in a timely manner, so that the best available science may be incorporated in the FDA produce safety standards.

**Subpart C. Personnel Qualifications and Training**

**Qualification & Training Requirements**

§ 112.21 What requirements apply regarding qualifications and training for personnel who handle (contact) covered produce or food-contact surfaces?

All of the following requirements apply regarding qualifications and training for personnel who handle (contact) covered produce or food contact surfaces:

(a) All personnel (including temporary, part time, seasonal, and contracted personnel) who handle covered produce or food-contact surfaces, or who are engaged in the supervision thereof, must receive adequate training, as appropriate to the person’s duties, upon hiring, at the beginning of each growing season (if applicable), and periodically thereafter.

(b) All personnel (including temporary, part time, seasonal, and contracted personnel) who handle covered produce or food-contact surfaces, or who are engaged in the supervision thereof, must have the training, in combination with education or experience to perform the person’s assigned duties in a manner that ensures compliance with this part.

(c) Training must be conducted in a manner that is easily understood by personnel being trained.

(d) Training must be repeated as necessary and appropriate in light of observations or information indicating that personnel are not meeting standards established by FDA in Subparts C through O of this part.

**PMA Comment:** PMA supports and agrees with the need for training employees on food safety appropriate to his/her duties, at the time of hiring and at the beginning of the growing season.

- The scope of the proposed training requirements is consistent with many of the commodity specific guidelines already in use by the produce industry and the USDA GAP audit criteria.

**Minimum Training Requirements**
§ 112.22 What minimum requirements apply for training personnel who conduct a covered activity?

(a) At a minimum, all personnel who handle (contact) covered produce during covered activities or supervise the conduct of such activities must receive training that includes all of the following:

(1) Principles of food hygiene and food safety;

(2) The importance of health and personal hygiene for all personnel and visitors, including recognizing symptoms of a health condition that is reasonably likely to result in contamination of covered produce or food-contact surfaces with microorganisms of public health significance; and

(3) The standards established by FDA in Subparts C through O of this part that are applicable to the employee’s job responsibilities.

(b) Persons who conduct harvest activities for covered produce must also receive training that includes all of the following:

(1) Recognizing covered produce that should not be harvested, including covered produce that may be contaminated with known or reasonably foreseeable hazards;

(2) Inspecting harvest containers and equipment to ensure that they are functioning properly, clean, and maintained so as not to become a source of contamination of covered produce with known or reasonably foreseeable hazards; and

(3) Correcting problems with harvest containers or equipment, or reporting such problems to the supervisor (or other responsible party), as appropriate to the person’s job responsibilities.

(c) At least one supervisor or responsible party for your farm must have successfully completed food safety training at least equivalent to that received under standardized curriculum recognized as adequate by the Food and Drug Administration.

Training Record keeping
§ 112.30 Under this Subpart, what requirements apply regarding records?
(a) You must establish and keep records required under this Subpart C in accordance with the requirements of Subpart O of this part.

(b) You must establish and keep records of training, that document required training of personnel, including the date of training, topics covered, and the persons(s) trained.

Subpart D. Standards Directed to Health and Hygiene

§ 112.31 What measures must I take to prevent ill or infected persons from contaminating covered produce with microorganisms of public health significance?

§ 112.32 What hygienic practices must personnel use?

§ 112.33 What measures must I take to prevent visitors from contaminating covered produce and food-contact surfaces with microorganisms of public health significance?

§ 112.32 What hygienic practices must personnel use?

(a) Personnel who work in an operation in which covered produce or food-contact surfaces are at risk of contamination with known or reasonably foreseeable hazards must use hygienic practices while on duty to the extent necessary to protect against such contamination.

(b) The hygienic practices that personnel use to satisfy the requirements of paragraph (a) of this section when handling (contacting) covered produce or food-contact surfaces during a covered activity must include all of the following practices:

(1) Maintaining adequate personal cleanliness to protect against contamination of covered produce and food-contact surfaces;

(2) Avoiding contact with animals other than working animals, and taking appropriate steps to minimize the likelihood of contamination of covered produce when in direct contact with working animals;

(3) Washing hands thoroughly, including scrubbing with soap and running water that satisfies the requirements of § 112.44(a) (as applicable) for water used to wash hands, and drying hands thoroughly using single-service towels, clean cloth towels, sanitary towel service or other adequate hand drying devices:

   (i) Before starting work;
(ii) Before putting on gloves;

(iii) After using the toilet;

(iv) Upon return to the work station after any break or other absence from the work station;

(v) As soon as practical after touching animals (including livestock and working animals), or any waste of animal origin; and

(vi) At any other time when the hands may have become contaminated in a manner that is reasonably likely to lead to contamination of covered produce with known or reasonably foreseeable hazards.

(4) If you choose to use gloves in handling covered produce or food-contact surfaces, maintaining gloves in an intact and sanitary condition and replacing such gloves when no longer able to do so.

PMA Comment: PMA supports and agrees with the need for employee training in the subject areas specified in section §112.22.

- It is unclear what FDA means by “food safety training at least equivalent to that received under standardized curriculum recognized as adequate by the Food and Drug Administration”? Does this mean that all “supervisors” will be required to have Produce Safety Alliance accredited training certificates available for FDA inspections? If FDA does require that all supervisors be required to have Produce Safety Alliance accredited training this may be problematic as there will likely be insufficient capacity to provide such accredited training in a timely manner.

- Worker health and hygiene training is already a widely accepted food safety practice in the produce industry. Worker health and hygiene training programs are necessary for the effective implementation of individual company food safety plans.

- Many of the training requirements proposed by FDA are already incorporated into worker health and hygiene Standard Operating Procedures (SOPs). For example, the USDA GAPs audit criteria and numerous commodity specific food safety best practices guidance have requirements for: recognizing health conditions reasonably likely to result in the contamination of produce, exclusion of any person thought to show symptoms of a health condition that might lead to product contamination, training personnel to notify supervisors or the responsible party of any applicable health conditions, hand washing procedures and facilities, and the appropriate use of gloves, if applicable.

- Many growers today train workers at the time of hire and at the beginning of each season. Additionally, given the transitory nature of the produce workforce, frequent training is an important component of an overall food safety program.
PMA is in agreement with FDA on the provisions for recordkeeping (§112.30) and on hygienic practices (§112.32).

**Personnel Training Strategies**

**PMA Comment:** Currently produce industry worker health and hygiene training strategies and procedures are based on a specific company’s operations, commodities, growing environment, etc. and are typically part of any overall produce safety plan. The produce industry will need continued technical assistance to aid in implementation of the FDA produce safety standards particularly in the area of worker health and hygiene training. This is because of the many languages that will need to be used in training and the need for print, poster and other training materials.

The Produce Safety Alliance (PSA) is an excellent example of academic, industry and government collaboration to translate on-farm food safety best practices into training program content and materials for the entire industry. These training materials are routinely used by industry trainers, associations, extension groups, and universities to deliver training courses. It is anticipated that the PSA curriculum which will aid growers to be in compliance with the final produce safety regulations will be customized for particular commodity group use as appropriate. Additionally, there are numerous trade organizations, commodity boards and marketing agreements and orders already involved in commodity specific on-farm food safety training. These organizations offer regional and commodity specific customized training programs. Successful implementation of the final produce safety standard will require cooperation and a coordinated effort among the PSA, land grant university cooperative extension trainers, associations, and community colleges to deliver relevant, customized training for needs of specific growing regions and commodities.

**Subpart E. Agricultural Water**

**Agricultural Water Proposed Definition**

§ 112.3 Agricultural water means water used in covered activities on covered produce where water is intended to, or is likely to, contact covered produce or food contact surfaces, including water used in growing activities (including irrigation water applied using direct water application methods, water used for preparing crop sprays, and water used for growing sprouts) and in harvesting, packing, and holding activities (including water used for washing or cooling harvested produce and water used for preventing dehydration of covered produce).
**PMA Comment:** PMA recommends adding all irrigation water, water used for dust abatement and water applied for cooling prior to harvest to the definition of “agricultural water”.

- The distinction between water that is likely to contact the covered produce or food contact surfaces and water that is not intended to contact the crop or food contact surfaces does not address the risk of water unintended for contact that does in fact contact produce. Based on the proposed definitions of agricultural water and covered produce, water used to irrigate an orchard through drip or furrow irrigation would not be considered agricultural water because the water is unlikely to contact the harvestable portion of the crop. Nor is water used for dust abatement considered in FDA’s proposed definition of agricultural water.
- FDA needs to clarify as to whether or not water used for dust abatement would or would not be deemed likely to contact covered produce or food contact surfaces and what agricultural water numerical standards would apply to its microbial quality.

§ 112.41 What requirements apply to the quality of agricultural water? All agricultural water must be safe and of adequate sanitary quality for its intended use.

**Measures to Reduce the Potential for Contamination In On-farm Agricultural Water Systems**

§ 112.42 What measures must I take with respect to my agricultural water sources, water distribution system, and pooling of water?

(a) At the beginning of a growing season, you must inspect the entire agricultural water system under your control (including water source, water distribution system, facilities, and equipment), to identify conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food-contact surfaces in light of your covered produce, practices, and conditions, including consideration of the following:

(1) The nature of each agricultural water source (for example, ground water or surface water);

(2) The extent of your control over each agricultural water source;

(3) The degree of protection of each agricultural water source;

(4) Use of adjacent or nearby land; and
(5) The likelihood of introduction of known or reasonably foreseeable hazards to agricultural water by another user of agricultural water before the water reaches your covered farm.

(b) You must adequately maintain all agricultural water sources that are under your control (such as wells) by regularly inspecting each source and keeping the source free of debris, trash, domesticated animals, and other possible sources of contamination of covered produce to the extent practicable and appropriate under the circumstances.

(c) You must adequately maintain all agricultural water distribution systems as necessary and appropriate to prevent the water distribution system from being a source of contamination to covered produce, food-contact surfaces, areas used for a covered activity, or water sources, including by regularly inspecting and adequately storing all equipment used in the system.

(d) You must immediately discontinue use of a source of agricultural water and/or its distribution system, and not use the water source and/or its distribution system when you have determined or have reason to believe that your agricultural water is not safe and of adequate sanitary quality.

(1) Re-inspect the entire agricultural water system under your control, identify any conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food-contact surfaces, make necessary changes, and test the water to determine if your changes were effective to ensure that your agricultural water is safe and of adequate sanitary quality for its intended use; or

(2) Treat the water in accordance with the requirements of § 112.43.

(e) As necessary and appropriate, you must implement measures reasonably necessary to reduce the potential for contamination of covered produce with known or reasonably foreseeable hazards as a result of pooling of water. For example, such measures may include using protective barriers or staking to keep covered produce from touching the ground or using an alternative irrigation method.

**PMA Comment:** PMA supports the proposed provisions in §112.42 (a)(1)-(5) for inclusion in the final rule.

- The grower requirements the FDA is proposing relating to on-farm agricultural water systems under a grower's control (§112.42(a)(1)-(5)) are already integral
components of commodity specific guidelines and some regional food safety programs, e.g. the California and Arizona leafy greens marketing agreements. These measures together protect agricultural water quality and ensure it is safe for its intended use.

**PMA Comment:** It is unclear as to exactly what FDA is intending in the provisions set forth in §112.42 (e) associated with pooled water.

- Water pooling in produce fields often occurs and it is impractical to expect that all pooling water can or should be eliminated.
- What microbial hazards would be associated with pooled water in a produce field if the water used to irrigate the crop met all provision of this 21CFR112? If agricultural water and soil amendments with only a rare probability to contain human pathogens are used as per provisions of the proposed produce safety rule, it is unclear as to how pooled water increases the likelihood of produce microbial contamination. The two references for this provision are two guidance documents which do not provide any scientific support for this provision.
- The agency needs to cite/reference incidents where pooled water in fields have been a potential contributing factor in a produce associated foodborne illness outbreak, sample positives or adulterated produce being introduced into commerce.

§ 112.43 What treatment of agricultural water is required, and what requirements apply to treating agricultural water?

(a) You must treat any agricultural water that you use (such as with an EPA-registered antimicrobial pesticide product) if you know or have reason to believe that the water is not safe and of adequate sanitary quality for its intended use.

(b) Any method you use to treat agricultural water to satisfy the requirement in paragraph (a) of this section must be effective to make the water safe and of adequate sanitary quality for its intended use.

(1) You must deliver any treatment of agricultural water required by paragraph (a) of this section in a manner to ensure that the treated water is consistently safe and of adequate sanitary quality for its intended use.

(2) You must monitor any treatment of agricultural water at a frequency adequate to ensure that the treated water is consistently safe and of adequate sanitary quality for its intended use.
PMA Comment: FDA states on page 3567 of the proposed produce safety standard as published in the Federal Register the following: “Any chemicals used in the treatment of water would require EPA registration under the Federal Insecticide, Fungicide and Rodenticide Act before they can be lawfully used.” We note, however, that at the present time, no such registration for chemical treatment of irrigation water exists. This is not correct as the EPA master label for PPG Calcium Hypochlorite Tablets EPA Reg. No. 748-295 has the following optional marketing claims and symbols that may be added to this product label:

- For use in all types of irrigation water systems; and
- Approved for use in USDA-inspected fresh fruit and vegetable wash water operations.

Agricultural Water Criteria
§ 112.44 What testing is required for agricultural water, and what must I do based on the test results?

(a) You must test the quality of agricultural water according to the requirements in § 112.45 using a quantitative, or presence-absence method of analysis provided in Subpart N of this part to ensure there is no detectable generic Escherichia coli (E. coli) in 100 milliliters (mL) of agricultural water when it is:

(1) Used as sprout irrigation water;

(2) Applied in any manner that directly contacts covered produce during or after harvest activities (for example, water that is applied to covered produce for washing or cooling activities, and water that is applied to harvested crops to prevent dehydration before cooling), including when used to make ice that directly contacts covered produce during or after harvest activities;

(3) Used to make a treated agricultural tea;

(4) Used to contact food-contact surfaces, or to make ice that will contact food-contact surfaces; or

(5) Used for washing hands during and after harvest activities.

(b) If you find that there is any detectable generic E. coli in 100 mL of water, you must immediately discontinue use of that source of agricultural water and/or its distribution system for the uses described in paragraph (a) of this section. Before you may use the water source and/or distribution system again for the uses...
described in paragraph (a) of this section, you must either re-inspect the entire agricultural water system under your control, identify any conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food-contact surfaces, make necessary changes, and retest the water to determine if your changes were effective and to ensure that the water meets the requirements of paragraph (a) of this section; or treat the water in accordance with the requirements of § 112.43.

(c) When agricultural water is used during growing activities for covered produce (other than sprouts) using a direct water application method you must test the quality of water in accordance with one of the appropriate analytical methods in Subpart N. If you find that there is more than 235 colony forming units (CFU) (or most probable number (MPN), as appropriate) generic E. coli per 100 mL for any single sample or a rolling geometric mean (n=5) of more than 126 CFU (or MPN, as appropriate) per 100 mL of water, you must immediately discontinue use of that source of agricultural water and/or its distribution system for the uses described in this paragraph. Before you may use the water source and/or distribution system again for the uses described in this paragraph, you must either re-inspect the entire agricultural water system under your control, identify any conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food-contact surfaces, make necessary changes, and retest the water to determine if your changes were effective; or treat the water in accordance with the requirements of § 112.43.

(d) You may establish and use alternatives to the requirements established in paragraph (c) of this section, provided you satisfy the requirements of § 112.12.

PMA Comment: PMA supports FDA’s tentative decision to use a microbial indicator, generic *E. coli*, to characterize the variability in agricultural water microbial quality. However, PMA does not support the use of quantitative generic *E. coli* levels as the criteria in the regulation to determine when agricultural water is not of safe and of adequate sanitary quality and would require the discontinuation of use. Monitoring for generic *E. coli* may provide information regarding the potential for overt fecal contamination but it is not a definitive indicator of pathogens in agricultural water. Nor does agricultural water with generic *E. coli* levels below the proposed quantitative criteria mean that the agricultural water is definitively free of human pathogens. Hence, PMA contends that the body of scientific knowledge is currently inadequate to establish quantitative metrics based solely on the use of generic *E. coli* as an indicator organism. Additionally, as new scientific knowledge becomes available, growers must be able to utilize updated
and improved testing and sampling methodologies which can better assess the safety of the agricultural water that they will use. PMA is concerned that as more information about generic *E. coli* and other indicators become available the quantitative criteria set forth in the proposed produce rule will be obsolete and not protective of public health or overly protective of public health. Use of the U.S. Environmental Protection Agency (EPA) recreational water standard may be appropriate for some crops such as lettuce and leafy greens but this quantitative criteria is likely overly protective for many other crops and may be not protective enough in other instances.

The risk of produce contamination by agricultural water is determined by the microbial quality of water at its source, the ability of the user to control the introduction of microbial contaminants into the water source, the variability of microbial quality, the manner in which water is applied and the time between water application and consumption.

PMA supports the concept of routine water testing based on an individual entities operational assessment of risk. It should however, not be tied to a specific quantitative standard in the regulation that requires cessation of use. Information derived from risk based agricultural water sampling should be used by growers to allow them to characterize and understand the variability in microbial quality of agricultural water that they use and for monitoring for deviations from an established baseline which would trigger consideration by growers for the need to implement a preventive control. Due to differences among commodities, agro-ecological growing conditions and production practices, agricultural water testing cannot use rote, prescribed, one size fits all testing criteria and sampling frequency.

Additionally, generic *E. coli* and other indicator organisms are not optimal indicators for the presence of pathogenic *E. coli* taken as single testing events. We have seen the research of Velledis and Wright that demonstrate clearly that *Salmonella spp.* contamination in the Suwanee River basin is not correlated with generic *E. coli* levels. Similarly, Atwill’s research in California and Arizona that focused on industry water testing data indicated that generic *E. coli* tests were not indicative of *Salmonella* or pathogenic *E. coli* contamination. However, in some production areas, e.g. Salinas Valley, San Joaquin Valley and Imperial Valley in California and the Yuma region of Arizona, where intensive irrigation water testing for generic *E. coli* has been underway since 2007, generic *E. coli* testing has become a reasonable predictive tool to indicate potential variances in water quality. As growers establish “baselines” for irrigation water sources over multiple growing seasons, the use of generic *E. coli* as an indicator for a potential contamination event becomes apparent. For example, if a grower uses a deep well in Salinas, CA and the test results are routinely a “non-detect”, a single test result of 100 MPN/100 ml would certainly
alert the grower that something had changed in the water source and/or the irrigation delivery system and further attention is needed to ascertain what might have occurred. Similarly, if a grower in Yuma, AZ receives a generic E. coli result of 10,000 MPN/100 ml on an open canal source when a typical reading of 150 MPN/100 ml was expected, the grower would know to check the canal system and speak with the water authority in the area to see if an event had occurred that may have compromised the quality of the water delivered to the farm. So while generic E. coli might not be a direct measure of pathogenic E. coli or Salmonella, it can be used as an indicator to provide trend analysis that growers can act on and use to alert them of potential contamination issues. Order of magnitude variations from expected results can trigger a water system inspection and evaluation as to food safety status and permit growers to conduct a risk assessment and make proactive decisions on corrective actions if needed.

The Produce Rule requires that “all agricultural water must be safe and of adequate sanitary quality for its intended use” and requires testing any water that directly contacts produce or food contact surfaces during and after harvest activities for generic E. coli (non-detect). Therefore, as currently proposed, any packing operation that packs only products from company-owned farms will be required to test accordingly. However, the Preventive Controls Rule states that “any water that contacts food, food-contact surfaces, or food-packaging materials must be safe and of adequate sanitary quality,” and does not include provisions for testing, target organisms, or numeric limits as part of their standards related to water used in packing operations. If the final Rules remain as proposed in these areas, many packing operations that pack product from other companies will be subject to the Preventive Controls Rule, which does not require water used in operations to be tested to demonstrate that it is “safe and of adequate sanitary quality.” The U.S. EPA’s public drinking water systems standard is currently used by commodity-specific guidelines, USDA GAP and GHP, and several states for water applied during and after harvest. The U.S. EPA standard of no detectible generic E. coli per 100 mL of water is a science-based and protective of human health for high risk uses of agricultural water.

**Agricultural Water Testing Frequency**

§ 112.45 How often must I test agricultural water that is subject to the requirements of § 112.44?

(a) You must test any agricultural water that is subject to the requirements of § 112.44 at the beginning of each growing season, and every three months thereafter during the growing season, except that there is no requirement to test water when:
(1) You receive water from a Public Water System, as defined under the Safe Drinking Water Act (SDWA) regulations, 40 CFR part 141, that furnishes water that meets the microbial requirements under those regulations or under the regulations of a State approved to administer the SDWA public water supply program, and you have Public Water System results or certificates of compliance that demonstrate that the water meets that requirement;

(2) You receive water from a public water supply that furnishes water that meets the microbial requirement described in § 112.44(a), and you have public water system results or certificates of compliance that demonstrate that the water meets that requirement; or

(3) You treat water in accordance with the requirements of § 112.43.

(b) If you use untreated surface water for purposes that are subject to the requirements of § 112.44, you must test the water as specified in the table in this paragraph.

If the untreated surface water is:

(1) From any source where a significant quantity of runoff is likely to drain into the source (for example, a river or natural lake). Then you must test the untreated surface water—At least every 7 days during the growing season.

(2) From any source where underground aquifer water is transferred to a surface water containment constructed and maintained in a manner that minimizes runoff drainage into the containment (for example, an on-farm man-made water reservoir). Then you must test the untreated surface water—At least once each month during the growing season.

PMA Comment: PMA concurs that there is a need for testing of agricultural water sources. However, agricultural testing frequently should be commensurate with the potential for contamination risk from that water source and the inherent characteristics of the water source/delivery system and be based on the growers’ operational assessment of risk. Water sources that have greater variability in microbial quality should be tested more frequently; and less variable water sources should be tested at a lower frequency. Obviously, more frequent testing would be more informative and useful in modeling, and continuous monitoring, if cost effective, would be most informative for growers. However, constant agricultural water microbial quality monitoring is simply not possible. Establishment of quantitatively risk-based sampling intervals is needed and will require further research.
PMA supports FDA’s tentative decision that the frequency for testing agricultural water sources (ground water and untreated surface water) and distribution systems needs to be commensurate with risk and water source variability and be based on the grower’s operational assessment of risk.

The adequacy of an agricultural water source may be determined by measuring the baseline of the prevalence and quantity of generic *E. coli* in that water source. In doing so, a grower might perform monthly tests for one or more seasons (to understand the variability due to seasonality) to quantify the prevalence and quantity of generic *E. coli* in a particular water source. If the test results are consistently below the microbial limit for generic *E. coli*, it is reasonable to assume the potential risk of contamination from the source is low. Additional monthly testing would not provide any greater level of food safety protection. However, even when a source is considered low risk, if there is an event such as heavy rain, runoff, or a broken pipe that could trigger changes in baseline levels, additional testing will be needed and the need for event-based testing should be included in a company’s SOPs. If post-event testing produces generic *E. coli* readings exceeding the microbial limit, source water testing verification would be needed to determine the need and frequency of further testing as well as inform the need for corrective actions (e.g. re-inspection of the entire agricultural system to identify the root cause and stop use of water until further testing indicates it is again safe to use).

For those water sources which demonstrate repeated microbial limit exceedances, appropriate testing frequencies need to be established. However, setting these testing frequencies must be done by the individual grower based on the water source (testing strategies for closed water sources may be more clearly elucidated that those for open, flowing water sources), application method for the irrigation water, time interval until harvest, temperature, climate, etc. In other words, the grower must do an assessment of risk and set testing frequencies and corrective actions as dictated by the assessment. A one size fits all approach would not be satisfactory and would unnecessarily limit a grower’s options to manage contamination risks.

PMA recommends that operators be allowed to design a sampling program for their operations based on level of control of the water source and how the water is used. Growers using information gathered from their inspection (proposed § 112.42) should then be allowed to tailor operation-specific sampling frequency and start/stop acceptance criteria based on the working knowledge and characterization of their agricultural water system.

**Harvest and Packing Water**

§ 112.46 What measures must I take for water that I use during harvest, packing, and holding activities for covered produce?

(a) You must manage the water as necessary, including by establishing and following water-change schedules for recirculated water, to maintain adequate sanitary
quality and minimize the potential for contamination of covered produce and food-contact surfaces with known or reasonably foreseeable hazards (for example, hazards that may be introduced into the water from soil adhering to the covered produce).

(b) You must visually monitor the quality of water that you use during harvest, packing, and holding activities for covered produce (for example, water used for washing covered produce in dump tanks, flumes, or wash tanks, and water used for cooling covered produce in hydrocoolers) for build-up of organic material (such as soil and plant debris).

(c) You must maintain and monitor the temperature of water at a temperature that is appropriate for the commodity and operation (considering the time and depth of submersion) and is adequate to minimize the potential for infiltration of microorganisms of public health significance into covered produce.

PMA Comment: PMA is supportive of the FDA proposed produce safety regulation in sections § 112.46 (a) and (b). However, § 112.46 (c) should be deleted.

- Use of a positive temperature differential between produce and water with the water being warmer than the produce is a weak preventive at best. While this positive water temperature differential may reduce internalization of human pathogens, it does not prevent the contamination of the exterior surfaces of fresh produce contacted by this water. Proper use and management of water disinfectants is the appropriate and effective preventive control in this situation.
- Use of a positive temperature differential between produce and water, with the water being warmer than the produce, is often not practicable as hydro-cooling is routinely used to remove field heat from fresh produce and re-hydrate the produce after harvest. It is indeterminate as to when an operator would be required to “maintain and monitor the temperature of water at a temperature that is appropriate for the commodity and operation”. It is also unclear as to what commodities and operations this provision would be applied to. Recent research by Xia et al. 2012 (Xia, et al. 2012. Effects of Tomato Variety, Temperature Differential, and Post-Stem Removal Time on Internalization of Salmonella enterica Serovar Thompson in Tomatoes. Journal of Food Protection 75(2): 297-303) has clearly demonstrated that internalization of Salmonella by stem scar infiltration is a complex phenomenon and not solely due to a temperature differential between tomatoes and wash water. Hence, this simplistic approach of providing a temperature differential is an ineffective preventive control and should be deleted in favor of a more effective
preventive control such as proper use and management of water disinfectants to prevent or reduce the likelihood of produce-to-water-to-produce cross contamination.

**Recordkeeping**
§ 112.50 Under this Subpart, what requirements apply regarding records?

(a) You must establish and keep records required under this Subpart E in accordance with the requirements of Subpart O of this part.

(b) You must establish and keep the following records:

(1) The findings of the inspection of your agricultural water system in accordance with the requirements of § 112.42(a);

(2) Documentation of the results of any analytical tests conducted to determine whether agricultural water is safe and of adequate sanitary quality for its intended use;

(3) Scientific data or information you rely on to support the adequacy of a method used to satisfy the requirements of § 112.43(b) and (c)(1);

(4) Documentation of the results of water treatment monitoring under § 112.43(c)(2);

(5) Documentation of the results of water testing you perform to satisfy the requirements of § 112.44;

(6) Scientific data or information you rely on to support any alternative to the requirements established in § 112.44(c) for agricultural water used during growing activities using a direct water application method in accordance with the requirements of § 112.44(d); and

(7) Annual documentation of the results or certificates of compliance from a public water system under 112.45(a)(1) or (a)(2), if applicable.

**PMA Comment:** PMA supports the proposed agricultural water recordkeeping provisions as set forth in §112.50.
Current practice in the produce industry for those commodities grown under commodity-specific guidelines and using USDA GAP and GHP practices call for recordkeeping consistent with the proposed FDA requirements for:

- Agricultural water system inspection findings;
- Results of any analytical tests;
- Specific data or information to support the adequacy of a method for testing;
- Results of any water treatments; and
- Annual documentation regarding water obtained from a public water source.

**FDA Aq Water Questions**

Proposed provisions directed to water, including those related to water quality, microbial indicators, and testing in §§ 112.41, 112.44, and 112.45; provision related to water sourced from public water systems in § 112.45(a); and recordkeeping in § 112.50; specifically:

1. Are the provisions in §§ 112.44–112.46 appropriately tailored to the risk posed by the manner in which the water is used?
2. Are the microbial standards specified in these provisions appropriate for the specified intended uses? For example, are the microbial standards appropriately tailored to uses such as direct application of irrigation water?
3. Are the provisions related to treatment of water sufficiently flexible to permit alternative safe uses of water that does not meet the specified microbial standard for its intended use?
4. Are there any alternative options not considered in the proposed rule?
5. Is there a need for a provision specifically related to disinfection treatment of re-circulated or single pass water used during and after harvest?

**PMA Comment:** PMA is supportive of the idea of a provision specifically related to disinfection treatment of re-circulated or single pass water used during and after harvest.

- The Listeriosis foodborne illness outbreak associated with consumption of cantaloupe from the Jensen Farms packing operation in 2011 clearly demonstrated that lack of a wash water disinfectant may spread microbial contamination ([Environmental Assessment: Factors Potentially Contributing to the Contamination of Fresh Whole Cantaloupe Implicated in a Multi-State Outbreak of Listeriosis, FDA 2011, www.fda.gov/Food/RecallsOutbreaksEmergencies/Outbreaks/ucm276247.htm](www.fda.gov/Food/RecallsOutbreaksEmergencies/Outbreaks/ucm276247.htm)).
- Use of re-circulated water in produce pack house operations has been identified as a potential route of produce cross contamination via produce-to-water-to-produce...
cross contamination in numerous industry commodity specific food safety best practices guidance documents (NATIONAL Commodity-Specific Food Safety Guidelines for Cantaloupes and Netted Melons, 2013; Commodity specific food safety guidelines for the production, harvest, postharvest and value-added unit operations of green onions, 2010; Commodity Specific Food Safety Guidelines for the Production and harvest of lettuce and leafy greens, 2010).

- Therefore, a provision specifically related to disinfection treatment of re-circulated or single pass water used during and after harvest should be developed.

Environmental Impact
Environmental issues: Consistent with § 25.50, FDA is involving the public in implementing its NEPA procedures applicable to this proposed rule. The agency will evaluate the information and input received in response to this proposed rule, including the specific questions below, to determine further actions, as appropriate.

AG WATER: Proposed Subpart E would establish standards for an indicator organism in agricultural water applied to covered produce, and establish requirements for waters that do not meet those standards. We are soliciting comments on potential means or mechanisms for meeting the proposed standards. In your responses, please distinguish, to the extent appropriate, between sprouts and other covered produce.

1. Do farms that would be covered by the proposed rule, if finalized, currently treat water used for irrigation directly applied to covered produce other than sprouts, or water used to irrigate sprouts (whether or not it is directly applied)? We are seeking comments on pesticides used to reduce concentration of organisms of concern in water used for such irrigation and not pesticides used to prevent biofouling (chemigation).

PMA Comment: Irrigation water is generally not treated with a disinfectant prior to use in a field. In very limited instances, some growers have experimented with sodium hypochlorite, ozone and copper sulfate treatments but these are relatively cost prohibitive given the volumes of water used in irrigation. There have also been concerns over the environmental impact and the quality of the treated soils when some of these treatments have been used. There are also some growers working with chlorine dioxide for large scale leafy greens production, but it is currently only an experimental program. Traditionally, growers will use sand filters to remove organic matter from open water sources to prevent clogging of pipes and pumps.
2. What actions are currently being taken by farmers, either on their own or at the request of produce handlers or sellers to control the bacterial loads in water? Please provide data to support the information provided.

**PMA Comment:** Some growers monitor open on-farm water sources used for irrigation. Growers look for potential instances of animal intrusion or other potential contaminating events and will design berms and other features to prevent run-off from entering an irrigation pond.

3. What water treatment methods do farmers use to clean their irrigation systems, how broadly are they used, and what are the effects on the environment? In what amounts or frequency are each of these methods applied? Please provide data to support the information provided.

**PMA Comment:** A small minority of growers actually clean and sanitize irrigation pipe; it just is not a practical activity given the linear length of pipe employed on a farm. Pipe is generally inspected at the beginning of a growing season and stored so as not to attract pests. The sheer volume of water that passes through these pipes makes it unlikely that any pipe could become harborage and dilution factors would seem to mitigate against buildup of bacteria (hundreds to thousands of gallons of water per minute).

### Subpart F. Biological Soil Amendments of Animal Origin and Human Waste

§ 112.51 What requirements apply for determining the status of a biological soil amendment of animal origin?

(a) A biological soil amendment of animal origin is treated if it has been processed to completion to adequately reduce microorganisms of public health significance in accordance with the requirements of § 112.54, or, in the case of an agricultural tea, the biological materials used to make the tea have been so processed and the water used to make the tea satisfies the requirements of 112.44(a).

(b) A biological soil amendment of animal origin is untreated if it:

(1) Has not been processed to completion in accordance with the requirements of § 112.54, or in the case of an agricultural tea, the biological materials used to make the tea have not been so processed or the water used to make the tea does not satisfy the requirements of 112.44(a);
(2) Has become contaminated after treatment;

(3) Has been recombined with an untreated biological soil amendment of animal origin;

(4) Is or contains a component that is untreated waste that you know or have reason to believe is contaminated with a hazard or has been associated with foodborne illness; or

(5) Is an agricultural tea that contains an agricultural tea additive.

§ 112.52 How must I handle, convey, and store biological soil amendments of animal origin?

(a) You must handle, convey and store any biological soil amendment of animal origin in a manner and location such that it does not become a potential source of contamination to covered produce, food-contact surfaces, areas used for a covered activity, water sources, and water distribution systems.

(b) You must handle, convey and store any treated biological soil amendment of animal origin in a manner and location that minimizes the risk of it becoming contaminated by an untreated or in-process biological soil amendment of animal origin.

(c) You must handle, convey, and store any biological soil amendment of animal origin that has become contaminated as if it was untreated.

§ 112.53 What prohibitions apply regarding use of human waste?

You may not use human waste for growing covered produce, except sewage sludge biosolids used in accordance with the requirements of 40 CFR part 503, Subpart D, or equivalent regulatory requirements.

§ 112.54 What treatment processes are acceptable for a biological soil amendment of animal origin that I apply in the growing of covered produce?

Each of the following treatment processes are acceptable for a biological soil amendment of animal origin that you apply in the growing of covered produce, provided that the
resulting biological soil amendments are applied in accordance with the applicable requirements of § 112.56:

(a) A scientifically valid controlled physical process (for example, thermal), chemical process (for example, high alkaline pH), or combination of scientifically valid controlled physical and chemical processes that has been demonstrated to satisfy the microbial standard in § 112.55(a) for Listeria monocytogenes (L. monocytogenes), Salmonella species, and E. coli O157:H7;

(b) A scientifically valid controlled physical process, chemical process, or combination of scientifically valid controlled physical and chemical processes, that have been demonstrated to satisfy the microbial standard in § 112.55(b) for Salmonella and fecal coliforms; or

(c) A scientifically valid controlled composting process that has been demonstrated to satisfy the microbial standard in § 112.55(b) for Salmonella and fecal coliforms. Scientifically valid controlled composting processes include:

1. Static composting that maintains aerobic (i.e., oxygenated) conditions at a minimum of 131°F (55°C) for 3 days and is followed by adequate curing, which includes proper insulation;

2. Turned composting that maintains aerobic conditions at a minimum of 131°F (55°C) for 15 days, with a minimum of five turnings, and is followed by adequate curing, which includes proper insulation; or

3. Other scientifically valid, controlled composting processes, provided you satisfy the requirements of § 112.12, including that the alternative process has been demonstrated to satisfy the microbial standard in § 112.55(b).

§ 112.55 What microbial standards apply to the treatment processes in § 112.54?

The following microbial standards apply to the treatment processes in § 112.54 as set forth in that section.

(a) For L. monocytogenes, Salmonella species, and E. coli O157:H7, the relevant standards in the table in this paragraph or;

For the microorganism—The microbial standard is—

1. L. monocytogenes Not detected using a method that can detect one colony forming unit (CFU) per 5 gram analytical portion.
(2) Salmonella species  
Less than three most probable numbers (MPN) per 4 grams of total solids (dry weight basis).

(3) E. coli O157:H7  
Less than 0.3 MPN per 1 gram analytical portion.

(b) Less than three MPN Salmonella species per 4 grams of total solids (dry weight basis); and less than 1,000 MPN fecal coliforms per gram of total solids (dry weight basis).

**Application Intervals**

§ 112.56 What application requirements and minimum application intervals apply to biological soil amendments of animal origin?

(a) Except as provided in paragraph (b) of this section, you must apply the biological soil amendments of animal origin specified in the first column of the table in this paragraph in accordance with the application requirements specified in the second column of the table in this paragraph and the minimum application intervals specified in the third column of the table in this paragraph.

<table>
<thead>
<tr>
<th>If the biological soil amendment of animal origin is—</th>
<th>Then the biological soil amendment of animal origin must be applied—</th>
<th>And then the minimum application interval is—</th>
</tr>
</thead>
<tbody>
<tr>
<td>(1)(i) Untreated .............................................</td>
<td>In a manner that does not contact covered produce during application and minimizes the potential for contact with covered produce after application</td>
<td>9 months.</td>
</tr>
<tr>
<td>(i) Untreated ..................................................</td>
<td>In a manner that does not contact covered produce during or after application</td>
<td>0 days.</td>
</tr>
<tr>
<td>(2) Treated by a scientifically valid controlled physical or chemical process, or combination of scientifically valid controlled physical and chemical processes, in accordance with the requirements of §112.54(a) to meet the microbial standard in §112.55(a).</td>
<td>In any manner (i.e., no restrictions)</td>
<td>0 days.</td>
</tr>
<tr>
<td>(3) Treated by a scientifically valid controlled physical or chemical process, or combination of scientifically valid controlled physical and chemical processes, in accordance with the requirements of §112.54(b) to meet the microbial standard in §112.55(b).</td>
<td>In a manner that minimizes the potential for contact with covered produce during and after application</td>
<td>0 days.</td>
</tr>
<tr>
<td>(4)(i) Treated by a composting process in accordance with the requirements of §112.54(c) to meet the microbial standard in §112.55(b).</td>
<td>In a manner that does not contact covered produce during or after application</td>
<td>45 days.</td>
</tr>
<tr>
<td>(i) Treated by a composting process in accordance with the requirements of §112.54(c) to meet the microbial standard in §112.55(b).</td>
<td>In a manner that does not contact covered produce during or after application</td>
<td>0 days.</td>
</tr>
</tbody>
</table>

(b) You may establish and use alternatives to the minimum application intervals established in paragraphs (a)(1)(i) and (a)(4)(i) of this section, provided you satisfy the requirements of §112.12.

**PMA Comment:** PMA supports the concept of an application-to-harvest interval for treated biological soil amendments of animal origin based on an individual entities
operational assessment of risk. The application-to-harvest interval for treated biological soil amendments of animal origin should not be tied to a specific quantitative standard in the regulation that prohibits use within shorter time intervals due to scientific uncertainty as to applicability of a static 45 day interval. PMA supports that growers should consider the application to harvest interval for treated soil amendments of animal origin, but the interval should be commensurate with risk of soil amendment-to-crop contamination based on the grower’s operational assessment of risk.

- The risk of soil amendment-to-crop contamination is determined by the inherent characteristics of the soil amendment, how it has been treated prior to application, the process validation and verification used, method of application (e.g. incorporation or side dress), days between application to harvest, potential for contact with the edible portion of the crop, temperature, weather, etc. There is an obvious need for consideration beyond just application-to-harvest interval and more research regarding the risk of specific practices, in various agro-ecological growing conditions and crops is needed. A minimum application interval of 45 days for treated biological soil amendments of animal origin is not supported by science and is probably not adequate for all crops under all production conditions and may be overly protective in other circumstances. Under certain agricultural production conditions, its known pathogens will survive for more than 45 days while in other cases pathogen persistence is much shorter than 45 days. Establishment of quantitatively risk-based application-to-harvest intervals for treated soil amendments is needed, but it will require further research that can customize the application-to-harvest interval based on the commodity, agro-ecological growing conditions and practices.

- Research, in general, has demonstrated that longer application to harvest intervals reduce the risk of soil amendment-to-crop contamination. However, it has clearly been demonstrated that the most significant reductions in pathogens occurs very quickly after treated soil amendment application to soils and extended application-to-harvest intervals have significantly diminished efficacy in reducing pathogen populations.
- Conversely, scientific data has demonstrated that under certain conditions, pathogens may persist for longer periods of time than 45 days in agricultural soils. (You et al. 2006. Survival of *Salmonella enterica* Serovar Newport in Manure and Manure-Amended Soils; Applied and Environmental Microbiology. 72(9): 5777–5783; Islam et al. 2004; Persistence of *Salmonella enterica* Serovar Typhimurium on Lettuce and Parsley and in Soils on Which
They Were Grown in Fields Treated with Contaminated Manure Composts or Irrigation Water; Foodborne Pathogens and diseases 1(1): 27-25; Islam et al. 2005; Survival of Escherichia coli O157:H7 in soil and on carrots and onions grown in fields treated with contaminated manure composts or irrigation water; Food Microbiology 22: 63–70).

- Under certain agricultural production conditions, pathogens derived from treated soil amendments of animal origin will survive for more than 45 days while in other cases pathogens persistence is much shorter than 45 days. This makes the use of a quantitative 45 day application-to-harvest interval for treated biological soil amendments of animal origin in the final produce safety rule unsupported by science in all cases and hence, it is arbitrary and capricious.

- Additionally, as new scientific knowledge becomes available, growers must be able to utilize updated and improved knowledge regarding safe application-to-harvest intervals for treated biological soil amendments of animal origin. PMA is concerned that as more information about application-to-harvest intervals for the use of treated biological soil amendment of animal origin becomes available, the quantitative criteria set forth in the proposed produce rule will be obsolete and not protective of public health or overly protective of public health and overly burdensome to produce growers.

PMA Comment: It is unclear from the codified and preamble discussion as to exactly what agricultural production scenario would qualify for the application to harvest interval set forth in §112.56 (a) (4) (ii).

- FDA needs to clarify as to exactly what agricultural production scenarios occur, whereby a biological soil amendment of animal origin could be applied; whereby it would not contact covered produce during or after application. Would use of plasticulture be sufficient to meet the criteria of “will not contact covered produce during or after application”? Covered produce may touch soil in the troughs of furrows where plastic may not cover the soil and plastic may develop rips exposing covered produce to soil, to which a composted biological soil amendment of animal origin had been added.

Recordkeeping
§ 112.60 Under this Subpart, what requirements apply regarding records?
(a) You must establish and keep records required under this Subpart F in accordance with the requirements of Subpart O of this part.

(b) For any biological soil amendment of animal origin you use, you must establish and keep the following records:

(1) Documentation of the date of application of any untreated biological soil amendment of animal origin (including raw manure) or any biological soil amendment of animal origin treated by composting to a growing area and the date of harvest of covered produce from that growing area, except when covered produce does not contact the soil after application of the soil amendment.

(2) For a treated biological soil amendment of animal origin you receive from a third party, documentation (such as a Certificate of Conformance) that:

(i) The process used to treat the biological soil amendment of animal origin is a scientifically valid process that has been carried out with appropriate process monitoring;

(ii) The applicable treatment process is periodically verified through testing using a scientifically valid analytical method on an adequately representative sample to demonstrate that the process satisfies the applicable microbial standard in § 112.55, including the results of such periodic testing; and

(iii) The biological soil amendment of animal origin has been handled, conveyed and stored in a manner and location to minimize the risk of contamination by an untreated or in process biological soil amendment of animal origin.

(3) For a treated biological soil amendment of animal origin you produce for your own covered farm(s), documentation that process controls (for example, time, temperature and turnings) were achieved.

(4) Scientific data or information you rely on to support any alternative composting process used to treat a biological soil amendment of animal origin in accordance with the requirements of § 112.54(c).

(5) Scientific data or information you rely on to support any alternative minimum application interval in accordance with the requirements of § 112.56(b).
PMA Comment: PMA generally supports the proposed biological soil amendment of animal origin recordkeeping provisions as set forth in §112.60. However, two areas might be problematic for growers:

- Certifications of conformance; and
- Documentation process controls were achieved.

Based on industry experience, assuring that a supplier has a “certificate of conformance” is necessary but not sufficient. An industry certification process to ensure a soil amendment company has validated treatment methods or that process controls were achieved is needed, particularly one based on agreed upon standards. Audit oversight would greatly assist growers in managing soil amendment suppliers with whom they may have little experience or control.

Subpart I. Domesticated and Wild Animals

Domesticated Animals in Fully-Enclosed Buildings
§ 112.81 How do the requirements of this Subpart apply to areas where covered activities take place?

(a) The requirements of this Subpart apply when a covered activity takes place in an outdoor area or a partially enclosed building and when, under the circumstances, there is a reasonable probability that animals will contaminate covered produce.

(b) The requirements of this Subpart do not apply when a covered activity takes place in a fully-enclosed building.

Animal Grazing Near Covered Produce
§ 112.82 What requirements apply regarding domesticated animals that I allow to graze in fields or use as working animals where I grow covered produce? At a minimum, if you allow animals to graze or use them as working animals in fields where covered produce is grown, and under the circumstances there is a reasonable probability that grazing or working animals will contaminate covered produce, you must take the following measures:

(a) An adequate waiting period between grazing and harvesting for covered produce in any growing area that was grazed to ensure the safety of the harvested crop; and
(b) If working animals are used in a growing area where a crop has been planted, measures to prevent the introduction of known or reasonably foreseeable hazards into or onto covered produce.

PMA Comment: PMA supports provisions put forth in § 112.83 with the following suggested amendments:

- If grazing occurs in an area where crops are subsequently grown, planting should not occur prior to nine months after grazing, consistent with the raw manure application interval.

Animal Intrusion

§ 112.83 What requirements apply regarding animal intrusion?

(a) If under the circumstances there is a reasonable probability that animal intrusion will contaminate covered produce, you must monitor those areas that are used for a covered activity for evidence of animal intrusion.

(1) As needed during the growing season based on:

   (i) Your covered produce; and

   (ii) Your observations and experience; and

(2) Immediately prior to harvest.

(b) If animal intrusion, as made evident by observation of significant quantities of animals, animal excreta or crop destruction via grazing occurs, you must evaluate whether the covered produce can be harvested in accordance with the requirements of § 112.112.

PMA Comment: PMA agrees with provisions put forth in § 112.83 and agrees with FDA’s tentative decision to not create a list of animals of concern for animal intrusion provisions.

- Wild or domestic animal intrusion into covered crops has been demonstrated to be means by which produce may be contaminated with human pathogens. Appropriate preventive controls to deter animals from entering growing areas should be taken after consulting with state and local wildlife officials to assure compliance with state
and local wildlife rules, regulations, ordinances and voluntary wildlife management initiatives.

- Currently many growers following commodity food safety programs or buyer requirements (e.g., CA LGMA and AZ LGMA) are required to monitor fields during the growing season and if evidence of animal intrusion exists (both wild and domestic animals), prior to or during harvest, then a preliminary examination takes place to determine if potential contamination is indeed present. If there is evidence of animal excreta or plant damage due to foraging, food safety personnel conduct an assessment of the risk posed by the evidence found to determine appropriate actions based on their standard operating procedures including whether or not the crop can be safely harvested.

- It is impracticable and impossible to completely prevent animal intrusion (e.g., birds in fields). As demonstrated by CPS research (Gordus and Atwill, 2011, Wildlife survey for _E. coli_ O157:H7 in the central coastal counties of California) preventive controls should focus actions by growers based on animal density, when animal intrusion occurs. For example, a single bird present in a field, is a much lower risk then a large number of birds feeding in the growing environment.

- The first version of CA and AZ LGMA guidelines included a list of “animals of concern” based on the available scientific literature at that time. The list was beneficial in that it enabled growers to focus on a small number of animals of concern. Current research (Gordus, 2013; Jay-Russell, 2013; Atwill 2013) indicates that more animals than appear on this original list warrant consideration when assessing on-farm routes of contamination. Hence, we have evolved to where a static list of animals of concern is of little utility to growers. Additionally, extrinsic environmental factors also have been demonstrated to significantly influence the prevalence of human pathogens in wildlife. As a result, commodity-specific guidelines are being modified to now focus on fecal matter as the risk factor regardless of the animal, and CA LGMA and AZ LGMA auditors now focus on fecal matter regardless of the animal of origin. The CA and AZ LGMA guidelines are also in the process of being amended to remove all references regarding animals of concern and focuses now on animal excreta in the field. Additionally, proposed amendments to the CA and AZ LGMA now focus on the density of animals in a pre-harvest environment and the presence of animal excreta.

- Are farms currently removing vegetation bordering growing areas? Vegetative buffers where wild animals or harborage for plant pest species may be removed from adjacent lands to produce growing fields to assure that animals or plant pest species are not inadvertently harvested along with the commercial crop, may be a condition of sale to buyers. Removal of vegetation bordering growing areas is not confined solely to being a food safety requirement.
Subpart K. Growing, Packing and Harvesting Activities

§ 112.111 What measures must I take if I grow, harvest, pack or hold both covered and excluded produce? If you grow, harvest, pack or hold produce that is not covered in this part (i.e., excluded produce in accordance with § 112.2) and also conduct such activities on covered produce, and the excluded produce is not grown, harvested, packed or held in accordance with this part, you must take measures during these covered activities, as applicable, to:

(a) Keep covered produce separate from excluded produce; and

(b) Adequately clean and sanitize, as necessary, any food-contact surfaces that contact excluded produce before using such food-contact surfaces for covered activities on covered produce.

§ 112.112 What measures must I take during harvest activities?

You must take all measures reasonably necessary to identify, and not harvest, covered produce that is reasonably likely to be contaminated with a known or reasonably foreseeable hazard, including steps to identify and not harvest covered produce that is visibly contaminated with animal excreta.

PMA Comment: It is unclear from preamble and codified discussion associated with § 112.112 as to exactly what FDA means or intends regarding "covered produce that is reasonably likely to be contaminated with a known or reasonably foreseeable hazard".

- This provision seems to focus almost exclusively on direct animal excreta contamination of covered produce.
- It is unclear if this provision requires growers to determine whether or not covered produce is reasonably likely to be contaminated with a known or reasonably foreseeable hazard from adjacent land operation such as concentrated animal feeding operations, sewage treatment plants, composting operations, irrigation canal dredge spoils, etc.
- If FDA intends for this provision to apply to adjacent land, use of further detailed information will be needed to enable growers to make such a determination that covered produce would be reasonably likely to be contaminated with a known or reasonably foreseeable hazard.

§ 112.113 How must I handle harvested covered produce during covered activities?
You must handle harvested covered produce in a manner that protects against contamination with known or reasonably foreseeable hazards. For example, by avoiding contact of cut surfaces of harvested produce with soil.

PMA Comments: PMA supports provisions put forward in Subpart K and strongly believes that operations need to engage in entity specific farm operational assessments of risk, as well as identification, development and implementation of appropriate preventive controls to control identified risks.

- Growing, harvesting, packing and holding practices, procedures and processes should be left to the discretion of individual farm entities and be based on the results of an individual farms' operational assessment of risk. For example, §112.111, if a company harvests and packs both covered and excluded produce, then one potential hazard may be cross contamination. To prevent cross contamination from occurring, a company's standard operating procedure for equipment cleaning and sanitation could include a requirement to clean and sanitize all food contact surfaces between handling excluded and covered products. The SOP could also call for verification tests to ensure the equipment is appropriately cleaned and sanitized.

- For some growers, as per § 112.112, one potential hazard might be product contamination from animal excreta. If so, the operational assessment of risk would result in standard operating procedures for pre-harvest and daily harvest field assessments. As part of the assessments, individual(s) would actively look for animal excreta on or near produce in fields. If animal excreta are found, there would be procedures for responding or mitigating the risk (e.g., cordon off and not harvesting the affected area). Appropriate operational assessments of risk should result in a farm operation taking “all measures reasonably necessary to identify and not harvest covered produce that is reasonably likely to be contaminated with a known or reasonably foreseeable hazard (e.g. animal excreta).

- PMA supports the provisions which require the handling of harvested covered produce in a manner that protects against contamination with known or reasonably foreseeable hazards. For example, by avoiding contact of cut surfaces of harvested produce with soil. This proposed provision is also included in the CA Leafy Greens Marketing Agreement which requires marketing agreement signatories to: “Evaluate appropriate measures that reduce and control the potential introduction of human pathogens through soil contact at the cut surface after harvest (e.g. frequency of knife sanitation, no placement of cut surfaces of harvested product on the soil, container sanitation, single use container lining, etc.).” Cut surfaces of some

**Dropped Produce**

§ 112.114 What requirements apply to dropped covered produce?

You must not distribute covered produce that drops to the ground before harvest (dropped covered produce) unless it is exempt under § 112.2(b). Dropped covered produce does not include root crops (such as carrots) that grow underground or crops (such as cantaloupe) that grow on the ground.

**PMA Comment:** PMA does not support provisions set forth in § 112.114, based on the lack of science data demonstrating the absolute certitude for pathogen transference to produce surfaces caused by contact with the ground. PMA supports the concept that growers should consider the risk of harvesting and distributing covered produce that drops to the ground before harvest (dropped covered produce) based on an individual entities operational assessment of risk. The absolute prohibition of harvesting dropped covered produce summarily ignores material facts that are applicable to the determination of risk, such as the exclusive use of chemical fertilizers and use of high quality well water for irrigation. PMA supports that growers should consider the risks of harvested dropped covered produce but the decision should be based on the grower’s operational assessment of risk, which takes into account the risk of contamination posed by the drop event to the specific commodity and the agricultural production practices used.

- There is little science supporting the need to discard produce dropped on the ground before harvest. If produce is dropped during harvest momentarily in an area not treated with soil amendments or otherwise contaminated, the likelihood of pathogens being at the exact spot where the produce drops is remote.
- For some commodities, it is not uncommon for produce dropped during harvest operations to be packed and shipped. This occurs even if product is not intended for processing as fruit may drop to the orchard floor after a wind storm. While it is true that damaged or bruised fruit provide an opportunity for pathogen intrusion into the edible portion and may liberate nutrients for pathogen growth, it is highly unlikely that very hard unripe fruit with thick outer skins would be damaged.
sufficiently to bruise or rupture the outer skin of the fruit. Risk of produce contamination from drops is much more complicated than bruising and contact with the ground and cannot be inferred universally for all produce crops. Additional factors such as the use of biological soil amendments of animal origin which may increase the likelihood of contamination of the orchard soil must also be taken into consideration. Prohibiting the harvest of all fresh produce drops will incur potentially unnecessary and costly changes in grower’s current windfall and harvesting practices. FDA should consider allowing the harvest of dropped fruit when fruit are not physically damaged or bruised.

§ 112.115 What measures must I take when packaging covered produce?

You must package covered produce in a manner that prevents the formation of Clostridium botulinum toxin if such toxin is a known or reasonably foreseeable hazard (such as for mushrooms).

Containers and the Potential for Produce Contamination

§ 112.116 What measures must I take when using food-packing (including food packaging) material?

(a) You must use food-packing material that is adequate for its intended use.

(b) If you reuse food-packing material, you must take steps to ensure that food contact surfaces are clean, such as by cleaning and sanitizing, when necessary, food-packing containers or using a clean liner.

PMA Comment: PMA supports provisions put forth in §112.116 (b).

- If produce containers are reused, they need to be clean. Data developed by research sponsored by the Center for Produce Safety from the University of Florida (Danyluk, 2013 Pathogen transfer risks associated with specific tomato harvest and packing operations) and from the University of Massachusetts (McLandsborough, 2013 Survival, transfer, and inactivation of Salmonella on plastic materials used in tomato harvest) demonstrated greater human pathogen (Salmonella) transference from damaged, dirty and wet cardboard boxes than from clean ones.
- Using soiled containers can also lead to pathogen transference from contaminated fruit to the cardboard and on to non-contaminated fruit.
Company specific assessment of likely routes of produce contamination should consider the potential for contamination from food contact surfaces including containers used to pack, hold and store fresh produce. If containers are reused, they should be examined to ensure cleanliness.

More research is needed regarding likelihood of commodity-specific contamination so as to determine the appropriate level of cleaning and sanitation care needed to control, reduce or eliminate the likelihood of produce contamination from these food contact surfaces.

Subpart L. Equipment, Tools and Buildings

§ 112.121 What equipment and tools are subject to the requirements of this Subpart?

Equipment and tools subject to the requirements of this Subpart are those that are intended to, or likely to, contact covered produce; and those instruments or controls used to measure, regulate, or record conditions to control or prevent the growth of undesirable microorganisms or other contamination. Examples include knives, implements, mechanical harvesters, waxing machinery, cooling equipment (including hydrocoolers), grading belts, sizing equipment, palletizing equipment, and equipment used to store or convey harvested covered produce (such as containers, bins, food-packing material, dump tanks, flumes, and vehicles or other equipment used for transport that are intended to, or likely to, contact covered produce).

§ 112.122 What buildings are subject to the requirements of this Subpart?

Buildings subject to the requirements of this Subpart include:

(a) Any fully- or partially-enclosed building used for covered activities, including minimal structures that have a roof but do not have any walls; and

(b) Storage sheds, buildings, or other structures used to store food-contact surfaces (such as harvest containers and food-packing materials).

Equipment and Tools

§ 112.123 What general requirements apply regarding equipment and tools subject to this Subpart?
All of the following requirements apply regarding equipment and tools subject to this Subpart:

(a) You must use equipment and tools that are of adequate design, construction, and workmanship to enable them to be adequately faced and properly maintained; and

(b) Equipment and tools must be:

(1) Installed and maintained as to facilitate cleaning of the equipment and of all adjacent spaces; and

(2) Stored and maintained to protect covered produce from being contaminated with known or reasonably foreseeable hazards and to prevent the equipment and tools from attracting and harboring pests.

(c) Seams on food-contact surfaces of equipment and tools that you use must be either smoothly bonded, or maintained to minimize accumulation of dirt, filth, food particles, and organic material and thus minimize the opportunity for harborage or growth of microorganisms.

(1) You must inspect, maintain, and clean and sanitize, when necessary and appropriate, all food-contact surfaces of equipment and tools used in covered activities as frequently as reasonably necessary to protect against contamination of covered produce.

(2) You must maintain and clean all non-food-contact surfaces of equipment and tools subject to this Subpart used during harvesting, packing, and holding as frequently as reasonably necessary to protect against contamination of covered produce.

(d) If you use equipment such as pallets, forklifts, tractors, and vehicles such that they are intended to, or likely to, contact covered produce, you must do so in a manner that minimizes the potential for contamination of covered produce or food-contact surfaces with known or reasonably foreseeable hazards.

PMA Comment: PMA supports the proposed provisions regarding equipment and tools set forth in § 112.123.

- The general requirements the FDA is proposing relating to the use of growing, harvesting and post-harvesting equipment and tools that might contact produce are
consistent with commodity-specific guidelines and current industry food safety audit standards.

- PMA supports provisions requiring that equipment and tools should be used for their intended purposes, designed and constructed to enable them to be cleaned and properly maintained, and cleaned and stored appropriately to avoid the risk of contamination. Since equipment and tool use differs by commodity, local environments, harvest and post-harvest practices, specific requirements relating to their use, sanitation, and storage should be determined after individual farm operations assess their risks and develop and implement preventive controls (i.e. sanitation program).

- Suslow, 2012 (Microbial Food Safety On-Farm Risk Assessment) demonstrated that produce contamination can occur when farm equipment has been in contact with contaminated soils or plant materials. Therefore, it is critical to ensure field equipment is cleaned, sanitized and tested to verify the sanitization was conducted properly.

- Yang, Y. et al, 2012. (Assessment of *Escherichia coli* O157:H7 transference from soil to iceberg lettuce via a contaminated field coring harvesting knife. Int J Food Microbiol. 153(3):345-50) clearly demonstrated that the welds and seams on food-contact surfaces tools such as lettuce harvest tools must be smoothly bonded to minimize accumulation of dirt, filth, food particles, and organic material and thus minimize the opportunity for harborage or growth of microorganisms.

**Instrumentation and Controls**

§ 112.124 What requirements apply to instruments and controls used to measure, regulate, or record?

Instruments or controls you use to measure, regulate, or record temperatures, hydrogen-ion concentration (pH), sanitizer efficacy or other conditions, in order to control or prevent the growth of undesirable microorganisms or other contamination, must be:

(a) Accurate and precise as necessary and appropriate in keeping with their purpose;

(b) Adequately maintained; and

(c) Adequate in number for their designated uses.

**PMA Comment:** PMA supports the proposed provisions regarding equipment and tools set forth in § 112.124.
• It is unclear as to what FDA means or intended by “undesirable microorganisms or other contamination” §112.124 as the proposed 21 CFR 112 only addresses undesirable microorganisms. What is meant or intended regarding “other contamination”?
• Guidance, as well as extensive training and outreach is needed to the produce industry regarding the level of accuracy or precision needed for some measurements such as free chlorine levels in agricultural water. For example, use of swimming pool chlorine test strips may or may not be as accurate and precise as what is needed to monitor and control the treatment of agricultural water.

**Transportation of Covered Produce**

§ 112.125 What requirements apply to equipment that is subject to this Subpart used in the transport of covered produce?

Equipment that is subject to this Subpart that you use to transport covered produce must be:

(a) Adequately clean before use in transporting covered produce; and

(b) Adequate for use in transporting covered produce.

**PMA Comment:** PMA supports the proposed provisions regarding transportation set forth in § 112.125.

**Buildings**

§ 112.126 What design and construction requirements apply to my buildings?

All of the following design and construction requirements apply regarding buildings.

(a) Buildings must be suitable in size, construction, and design to facilitate maintenance and sanitary operations for covered activities to reduce the potential for contamination of covered produce or food-contact surfaces with known or reasonably foreseeable hazards.

(b) Buildings must:

   (1) Provide sufficient space for placement of equipment and storage of materials;
(2) Permit proper precautions to be taken to reduce the potential for contamination of covered produce, food-contact surfaces, or packing materials with known or reasonably foreseeable hazards. The potential for contamination must be reduced by effective design including the separation of operations in which contamination is likely to occur, by one or more of the following means: location, time, partition, enclosed systems, or other effective means; and

(3) Be constructed in such a manner that floors, walls, ceilings, fixtures, ducts and pipes can be adequately cleaned and kept in good repair, and that drip or condensate does not contaminate covered produce, food contact surfaces, or packing materials.

(4) You must provide adequate drainage in all areas where normal operations release or discharge water or other liquid waste on the ground or floor of the building.

PMA Comment: PMA supports the proposed provisions regarding transportation set forth in § 112.126.

While there is no data available on the number and quality of on-farm buildings such as packing sheds and storage facilities, many of the existing on-farms structures will probably not meet the proposed building requirements.

- All on-farm produce building should meet requirements that reduce the potential for produce contamination.
- Growers should use mandated on-farm operational assessments of risk and develop and implement preventive controls that reduce, control or eliminate the potential for produce contamination based on their individual operations and as per their unique food safety plan.
- The on-farm operational risk assessment should provide an opportunity for an operator who handles a given to identify and develop preventive controls or make alterations to their physical operation/building to insure that contamination risks are eliminated or greatly diminished.
- On-farm operational risk assessments also provide operators with the ability to assess hazards associated with the specific RAC, the risks associated with their particular handling or packing procedures, and other practices and processes in their operations. For example, pooled water may provide a potential means to promote produce contamination. This issue can be managed by knowing that pooled water can lead to *L. monocytogenes* cross contamination risks and by evaluating
the facility for areas where water might pool and then taking action to eliminate or minimize pooled water by improving drainage or physically removing water on a routine basis (e.g. by using workers to push water to drains).

§ 112.127 What requirements apply regarding domesticated animals in and around a fully-enclosed building?

(a) You must take reasonable precautions to prevent contamination of covered produce, food-contact surfaces, and food-packing materials in fully enclosed buildings with known or reasonably foreseeable hazards from domesticated animals by:

(1) Excluding domesticated animals from fully-enclosed buildings where covered produce, food-contact surfaces, or food-packing material is exposed; or

(2) Separating domesticated animals in a fully enclosed building from an area where a covered activity is conducted on covered produce by location, time, or partition.

(b) Guard or guide dogs may be allowed in some areas of a fully enclosed building if the presence of the dogs is unlikely to result in contamination of produce, food-contact surfaces, or food-packing materials.

Pests

§ 112.128 What requirements apply regarding pest control in buildings?

(a) You must take those measures reasonably necessary to protect covered produce, food-contact surfaces, and food-packing materials from contamination by pests in buildings, including routine monitoring for pests as necessary and appropriate.

(b) For fully-enclosed buildings, you must take measures to exclude pests from your buildings.

(c) For partially-enclosed buildings, you must take measures to prevent pests from becoming established in your buildings (such as by use of screens or by monitoring for the presence of pests and removing them when present).

PMA Comment: PMA supports the proposed provisions regarding transportation set forth in § 112.128.
Some on-farm produce farm operations may not be completely enclosed and this may inadvertently allow for birds and their nests to create the potential risk of produce contamination via bird droppings. Some operators address this particular risk by locating seasonal packing areas in a protected area of the packing shed, away from overhead beams and likely bird nesting areas. Others might choose to fully inspect and clean and sanitize the area to be used for packing prior to the start of harvest and then use temporary bird nets or screens to keep birds and other pests away from the packing area.

§ 112.129 What requirements apply to toilet facilities?

All of the following requirements apply to toilet facilities:

(a) You must provide personnel with adequate, readily accessible toilet facilities, including toilet facilities readily accessible to growing areas during harvesting activities.

(b) Your toilet facilities must be designed, located, and maintained to:

(1) Prevent contamination of covered produce, food-contact surfaces, areas used for a covered activity, water sources, and water distribution systems with human waste;

(2) Be directly accessible for servicing, be serviced and cleaned on a schedule sufficient to ensure suitability of use, and be kept supplied with toilet paper; and

(3) Provide for the sanitary disposal of waste and toilet paper.

(c) During growing activities that take place in a fully-enclosed building, and during covered harvesting, packing, or holding activities, you must provide a hand-washing station in sufficiently close proximity to toilet facilities to make it practical for persons who use the toilet facility to wash their hands.

§ 112.130 What requirements apply for hand-washing facilities?

All of the following requirements apply to hand-washing facilities:
(a) You must provide personnel with adequate, readily accessible handwashing facilities during growing activities that take place in a fully enclosed building, and during covered harvest, packing, or holding activities.

(b) Your hand-washing facilities must be furnished with:

(1) Soap (or other effective surfactant);

(2) Running water that satisfies the requirements of § 112.44(a) for water used to wash hands; and

(3) Adequate drying devices (such as single service towels, clean cloth towels or sanitary towel service).

(c) You must provide for appropriate disposal of waste (for example, waste water and used single-service towels) associated with a hand-washing facility and take appropriate measures to prevent waste water from a handwashing facility from contaminating covered produce, food-contact surfaces, areas used for a covered activity, agricultural water sources, and agricultural water distribution systems with known or reasonably foreseeable hazards.

(d) You may not use hand antiseptic/sanitizer or wipes as a substitute for soap and water.

PMA Comment: PMA supports the proposed provisions regarding transportation set forth in § 112.130.

- PMA seeks clarification and guidance from FDA regarding the use of “clean cloth towels” for drying ones hands. PMA recommends that the use of “clean cloth towels” be limited to sole propriety operations where only one person would be using the “clean cloth towel” to dry only their hands. Use of a “clean cloth towel” to dry multiple persons hands should not be allowed as this is likely to facilitate the transference of pathogens (if present) from one towel user to the next.

§ 112.131 What must I do to control and dispose of sewage?

All of the following requirements apply for the control and disposal of sewage:

(a) You must dispose of sewage into an adequate sewage or septic system or through other adequate means.
(b) You must maintain sewage and septic systems in a manner that prevents contamination of covered produce, food-contact surfaces, areas used for a covered activity, agricultural water sources, and agricultural water distribution systems with known or reasonably foreseeable hazards.

(c) You must manage and dispose of leakages or spills of human waste in a manner that prevents contamination of covered produce, and prevents or minimizes contamination of food contact surfaces, areas used for a covered activity, agricultural water sources, or agricultural water distribution systems.

(d) After a significant event (such as flooding or an earthquake) that could negatively impact a sewage or septic system, you must take appropriate steps to ensure that sewage and septic systems continue to operate in a manner that does not contaminate covered produce, food-contact surfaces, areas used for a covered activity, agricultural water sources, or agricultural water distribution systems.

§ 112.132 What must I do to control and dispose of trash, litter, and waste in areas used for covered activities?

All of the following requirements apply to the control and disposal of trash, litter, and waste in areas used for covered activities:

(a) You must convey, store, and dispose of trash, litter and waste to:

   (1) Minimize the potential for trash, litter, or waste to attract or harbor pests; and

   (2) Protect against contamination of covered produce, food-contact surfaces, areas used for a covered activity, agricultural water sources, and agricultural water distribution systems with known or reasonably foreseeable hazards.

(b) You must adequately operate systems for waste treatment and disposal so that they do not constitute a potential source of contamination in areas used for a covered activity.

§ 112.133 What requirements apply to plumbing?

The plumbing must be of an adequate size and design, and be adequately installed and maintained to:
(a) Distribute water under pressure as needed, in sufficient quantities, in all areas where used for covered activities, for sanitary operations, or for handwashing and toilet facilities.

(b) Properly convey sewage and liquid disposable waste;

(c) Avoid being a source of contamination to covered produce, food-contact surfaces, areas used for a covered activity, or agricultural water sources; and

(d) Not allow backflow from, or cross connection between, piping systems that discharge waste water or sewage and piping systems that carry water used for a covered activity, for sanitary operations, or for use in hand-washing facilities.

§ 112.134 What must I do to control animal excreta and litter from domesticated animals that are under my control?

(a) If you have domesticated animals, to prevent contamination of covered produce, food-contact surfaces, areas used for a covered activity, agricultural water sources, or agricultural water distribution systems with animal waste, you must:

(1) Adequately control their excreta and litter; and

(2) Maintain a system for control of animal excreta and litter.

§ 112.140 Under this Subpart L, what requirements apply regarding records?

(a) You must establish and keep records required under this Subpart L in accordance with the requirements of Subpart O of this part.

(b) You must establish and keep documentation of the date and method of cleaning and sanitizing of equipment subject to this Subpart used in:

(1) Growing operations for sprouts; and

(2) Covered harvesting, packing, or holding activities.

PMA Comment: PMA supports the use of science- and risk-based environmental monitoring for Listeria spp to assist operators in identifying resident Listeria spp niches within produce packing operations, which may provide opportunities for Listeria
monocytogenes to reside and persist. Environmental monitoring assists operators in identifying opportunities for improvement in equipment and building sanitary design, as well as needed improvements in cleaning and sanitation programs, or improved implementation of cleaning and sanitation programs. However, FDA should not mandate that any Listeria spp monitoring finding be taken to the next level of identifying the Listeria species associated with the positive environmental monitoring test result. The objective of the testing as stated above is to assist pack house operators in identifying resident Listeria spp niches within produce packing operations, so as to enable the operator to implement appropriate preventive controls to reduce, control or eliminate the risk of produce contamination with Listeria monocytogenes.

Additionally, Salmonella spp and E. coli should not be used for purpose of environmental monitoring in packing house operations as these human pathogens are typically not environmental pathogens.

Environmental monitoring should be risk based with more frequent environmental monitoring occurring if Listeria spp positive test results occur. Additionally, the produce handling practices employed by an operation, particularly when agricultural water may serve as a vehicle to cross contaminate produce or food contact surfaces, needs to be carefully considered when developing an environmental monitoring program. For example, wet pack operations should test more frequently than dry pack produce operations. The age, condition and cleanability of food contact surfaces and equipment should be taken into consideration when development of an environmental monitoring system occurs.

Subpart M. Standards Directed to Sprouts

112.141 What requirements apply to seeds or beans used to grow sprouts?

112.142 What measures must I take for growing, harvesting, packing, and holding sprouts?

112.143 What testing must I do during growing, harvesting, packing, and holding sprouts?

112.144 What requirements apply to testing the environment for Listeria species or L. monocytogenes?

112.145 What actions must I take if the growing, harvesting, packing, or holding environment tests positive for Listeria species or L. monocytogenes?
112.146 What must I do to collect and test samples of spent sprout irrigation water or sprouts?

112.150 Under this Subpart, what requirements apply regarding records?

PMA Comment: PMA requests that FDA provide guidance and clarification as to whether or not micro-greens would be covered in proposed Subpart M for sprouts or the general provisions for covered produce.

- Micro-greens (or micro greens) are whole plantlets harvested at a young seedling stage after a few true leaves have begun to develop beyond the cotyledons. They are distinct and separate and distinguished from sprouts, which are younger and grown typically in water in dark conditions. Sprouts are germinating seeds where just the cotyledons have opened up, or have not opened, with roots still attached (like bean sprouts), or sprouted grains, etc.

- Micro-greens are a plantlet form of young edible greens produced from various kinds of vegetables, herbs or other plants. They range in size from 1” to 1½” including the stem and leaves. A micro-green has a single central stem which has been cut just above the soil line during harvesting. It has two fully developed cotyledon leaves and usually one pair of very small, partially developed true leaves. The typical stem and leaf configuration for micro-greens is at about 1” to 1½” (25 to 38 mm) in height, and ½” to 1” (13 to 25 mm) in width across the top and includes the stem, cotyledon leaves and one set of very small, partially developed true leaves. The average crop-time for most micro-greens is 7–10 days from seeding to harvest.

- PMA advocates that micro-greens (or micro-greens) should not be subject to Subpart M of the proposed produce safety standard as they are not produce in manner that is most typical for sprouts and micro-greens have true leaves, which distinguish them from sprouts.

PMA Comment: PMA requests that FDA appropriately regulate seeds used to produce sprouts to assure that they will not cause severe adverse health consequences or death when eaten by consumers.

- Seed contaminated during growing, harvest and in postharvest operations have consistently been shown to be a significant contributing factor associated with foodborne illnesses associated with sprouts.
• There is no 100% reliable treatment of seeds to eliminate human pathogens before sprouting and pathogens may grow rapidly and prolifically under moist warm sprouting conditions.
• Because human pathogens cannot be eliminated from seeds before sprouting, appropriate and effective preventive controls should be required for the production, harvest and postharvest handling operations for seeds which will be used for sprouting and human consumption. Many seeds, such as alfalfa seeds, are intended to be used to animal feed not human food and are hence, not grown or handled in a sanitary manner. Until seeds used for growing sprouts for human consumption are grown and handled in a sanitary manner to prevent their contamination, foodborne illnesses associated with sprout contamination will continue to occur. The provisions set forth in Subpart M simply do not address the major and significant route of contamination of seeds which are used to produce sprouts for human consumption.

Subpart O. Requirements Applying to Records That You Must Establish and Keep

112.161 What general requirements apply to records required under this part?

112.162 Where must I store records?

112.163 May I use existing records to satisfy the requirements of this part?

112.164 How long must I keep records?

112.165 What formats are acceptable for the records I keep?

112.166 What requirements apply for making records available and accessible to FDA?

112.167 Can records that I provide to FDA be disclosed to persons outside of FDA?

§ 112.161 What general requirements apply to records required under this part?

(a) All records required under this part must include, as applicable:

(1) The name and location of your farm;

(2) Actual values and observations obtained during monitoring;
(3) An adequate description (such as the commodity name, or the specific variety or brand name of a commodity, and, when available, any lot number or other identifier) of covered produce applicable to the record;

(4) The location of a growing area (for example, a specific field) or other area (for example, a specific packing shed) applicable to the record; and

(5) The date and time of the activity documented:
   (i) Be created at the time an activity is performed or observed;
   (ii) Be accurate, legible, and indelible; and
   (iii) Be dated, and signed or initialed by the person who performed the activity documented.

(b) When records are required to be established and kept in Subparts C, E, F, L, and M of this part (§§ 112.30, 112.50, 112.60, 112.140, and 112.150), you must establish and keep documentation of actions you take when a standard in those Subparts is not met.

(c) Records required under §§ 112.50(b)(4), 112.50(b)(5), 112.60(b)(1), 112.60(b)(3), 112.140, 112.150(b)(1), 112.150(b)(4), and 112.161(b), must be reviewed, dated, and signed, within a reasonable time after the records are made, by a supervisor or responsible party.

§ 112.165 What formats are acceptable for the records I keep?

You must keep records as:

(a) Original records;

(b) True copies (such as photocopies, pictures, scanned copies, microfilm, microfiche, or other accurate reproductions of the original records); or

(c) Electronic records, in compliance with part 11 of this chapter.

PMA Comment: PMA generally supports the proposed provisions set forth in § 112.165 with the exception of § 112.165(c) which requires compliance with 21 CFR part 11 for electronic records.
On-farm operations will find compliance with 21 CFR 11 for recordkeeping onerous and burdensome.

For example the following provisions of 21 CFR 11 should not apply to on-farm produce operations.

- Use of secure, computer-generated, time-stamped audit trails to independently record the date and time of operator entries and actions that create, modify, or delete electronic records. Record changes shall not obscure previously recorded information. Such audit trail documentation shall be retained for a period at least as long as that required for the subject electronic records and shall be available for agency review and copying.
- Use of operational system checks to enforce permitted sequencing of steps and events, as appropriate.
- Use of authority checks to ensure that only authorized individuals can use the system, electronically sign a record, access the operation or computer system input or output device, alter a record, or perform the operation at hand.
- Use of device (e.g., terminal) checks to determine, as appropriate, the validity of the source of data input or operational instruction.
- Determination that persons who develop, maintain, or use electronic record/electronic signature systems have the education, training, and experience to perform their assigned tasks.
- Electronic signatures and handwritten signatures executed to electronic records shall be linked to their respective electronic records to ensure that the signatures cannot be excised, copied, or otherwise transferred to falsify an electronic record by ordinary means.
- Before an organization establishes, assigns, certifies, or otherwise sanctions an individual’s electronic signature, or any element of such electronic signature, the organization shall verify the identity of the individual.
- Electronic signatures that are not based upon biometrics shall:
  - Employ at least two distinct identification components such as an identification code and password.
  - When an individual executes a series of signings during a single, continuous period of controlled system access, the first signing shall be executed using all electronic signature components; subsequent signings shall be executed using at least one electronic signature component that is only executable by, and designed to be used only by, the individual.
When an individual executes one or more signings not performed during a single, continuous period of controlled system access, each signing shall be executed using all of the electronic signature components.

Persons who use electronic signatures based upon use of identification codes in combination with passwords shall employ controls to ensure their security and integrity. Such controls shall include:

- Maintaining the uniqueness of each combined identification code and password, such that no two individuals have the same combination of identification code and password.
- Ensuring that identification code and password issuances are periodically checked, recalled, or revised (e.g., to cover such events as password aging).
- Following loss management procedures to electronically deauthorize lost, stolen, missing, or otherwise potentially compromised tokens, cards, and other devices that bear or generate identification code or password information, and to issue temporary or permanent replacements using suitable, rigorous controls.
- Use of transaction safeguards to prevent unauthorized use of passwords and/or identification codes, and to detect and report in an immediate and urgent manner any attempts at their unauthorized use to the system security unit, and, as appropriate, to organizational management.
- Initial and periodic testing of devices, such as tokens or cards, that bear or generate identification code or password information to ensure that they function properly and have not been altered in an unauthorized manner.

§ 112.166 What requirements apply for making records available and accessible to FDA?

(a) You must have all records required under this part readily available and accessible during the retention period for inspection and copying by FDA upon oral or written request, except that you have 24 hours to obtain records you keep offsite and make them available and accessible to FDA for inspection and copying.

(b) If you use electronic techniques to keep records, or to keep true copies of records, or if you use reduction techniques such as microfilm to keep true copies of records, you must provide the records to FDA in a format in which they are accessible and legible.
(c) If your farm is closed for a prolonged period, the records may be transferred to some other reasonably accessible location but must be returned to your farm within 24 hours for official review upon request.

**FDA Questions**

Proposed requirements related to documentation and records in Subpart O,

- Including the requirement for a supervisor or responsible party to review certain records.

**PMA Comment:** PMA generally would support provisions requiring supervisor or responsible party to review certain records on a regular basis as part of verification activities.

- Regarding the scope of the recordkeeping requirements, are there alternative options that should be considered?

**PMA Comment:** PMA is concerned that all records would have to be recorded in ink as on-farm records are often currently recorded in pencil. Pencils are used because they are inexpensive, readily available and outdoor on-farm environmental conditions often dictate the use of pencils instead of pens because rain results in smeared ink recorded paperwork.

**Subpart P. Variances**

§ 112.171 Who may request a variance from the requirements of this part?

A State or a foreign country from which food is imported into the United States may request a variance from one or more requirements of this part, where the State or foreign country determines that:

(a) The variance is necessary in light of local growing conditions; and

(b) The procedures, processes, and practices to be followed under the variance are reasonably likely to ensure that the produce is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342) and to provide the same level of public health protection as the requirements of this part.
PMA Comment: PMA agrees with FDA’s proposed use of produce safety standard variances as prescribed by the Food Safety Modernization Act. However, PMA seeks clarification and guidance on the following issues:

- **“Same level of public health protection”:** It is unclear as to the means and quantitative measure that FDA would use to evaluate whether or not a variance request provided the same level of public health protection. Detailed guidance to growers, academia, state, and foreign national governments is needed from the FDA to make the variance process work appropriately.

- **Research Needs:** There are significant data and research gaps which will impede the use of variances to the provisions of the FDA produce safety standards and a significant investment in on-farm food safety research will be required. While there is currently ongoing industry sponsored research from institutions like the Center for Produce Safety at the University of California Davis, regarding the means to ensure the safe use of biological soil amendments of animal origin and agricultural water, there needs to be mechanisms for formal dialogue among industry, academia and FDA to assure that research and implementation of viable variances may come to fruition. Establishing a process for peer review in which FDA would participate and provide opinion as to whether or not research results indicate that the “same level of public health protection” has been achieved by a new approach to be in compliance with FDA produce safety standards will be crucial to the successful use of alternative approaches. Without such a peer review mechanism, it is unlikely that variances will be pursued by the agricultural community, as there is a significant risk that promising research findings and new variance practices will not be implemented unless they receive some type of assurances from the FDA that they meet the standard of providing the “same level of public health protection”. It is recommended that joint industry/academia and government peer review panels by produce safety regulation provision area be convened to provide review and determine if a specific alternative provides the “same level of public health protection”. Use of the National Academy of Science for peer review and policy development should also be considered for use.

§ 112.172 How may a State or foreign country request a variance from one or more requirements of this part? To request a variance from one or more requirements of this part, the competent authority (e.g., the regulatory authority for food safety) for a State or a foreign country must submit a petition under § 10.30 of this chapter.
**PMA Comment:** PMA generally supports the proposed provisions set forth in § 112.172. However, PMA request clarification and guidance from FDA as to whom would constitute a State or a foreign country “competent authority” as in many states and countries, the regulatory authority regarding food safety may be multi-jurisdictional.

- For example the California and Arizona Leafy Greens Marketing Agreements are quasi-government authorities operating under the auspices and authority of their respective state governments, hence would they be allowed to request variances?
- PMA supports the role of state governments as the entity that would be required to request a variance from FDA because state governments are best positioned and have in-depth working knowledge about how alternative food safety practices may increase or decrease risk for the entire produce commodity community within their state. Requisite use of state government allows the competent authority in each state to knowledgeably determine which alternative food safety practices a variance is being requested as it will affect numerous growers, not just the ones whom have requested a variance.

§ 112.182 What are the permissible types of variances that may be granted?

Examples of permissible types of variances include:

(a) Variance from the requirements, established in § 112.44(c), when agricultural water is used during growing operations for covered produce (other than sprouts) using a direct water application method;

(b) Variance from the process conditions, established in § 112.54(c)(1), for static composting;

(c) Variance from the process conditions, established in § 112.54(c)(2), for turned composting;

(d) Variance from the minimum application interval, established in § 112.56(a)(1), for an untreated biological soil amendment of animal origin; and

(e) Variance from the minimum application interval, established in § 112.56(a)(4), for a biological soil amendment of animal origin treated by a composting process in accordance with the requirements of § 112.54(c).

**PMA Comment:** PMA in general agrees with FDA’s proposed use of variances, however:
- **Limited Use of Variance Approaches:** It is unclear why the FDA limited the use of variances to only specific sections listed. For example, variances are allowed for only in §112.44(c) of the Agricultural water provisions and may not, as currently proposed, be allowed for § 112.45 How often must I test Agricultural water. It is strongly recommended that variance approaches be allowed for all produce safety standard provision areas and specifically for agricultural water (Subpart E) and biological soil amendments of animal origin (Subpart F) provision areas, as these are areas of current, active and intense research efforts. It is unclear as to why FDA believes that variance should be limited to only specific provisions of the produce safety standard.

**Subpart Q. Compliance and Enforcement**

§ 112.191 How do the criteria and definitions in this part apply?

The criteria and definitions in this part apply in determining whether a food is adulterated:

(a) Within the meaning of section 402(a)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342(a)(3)) in that the food has been grown, harvested, packed, or held under such conditions that it is unfit for food; or

(b) Within the meaning of section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act in that the food has been prepared, packed, or held under insanitary conditions, whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. The criteria and definitions in this part also apply in determining whether a food is in violation of section 361 of the Public Health Service Act (42 U.S.C. 264).

§ 112.192 What is the result of a failure to comply with this part?

The failure to comply with the requirements of this part, issued under section 419 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350h), is a prohibited act under section 301(vv) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(vv)).

**PMA Comment:** PMA strongly recommends that FDA strongly develop administrative procedures and processes to rapidly adjudicate issues that are noted during either “routine” or “for cause” inspection.
Produce growers, due to the perishability of their crops, must be able to rapidly rebut and offer evidence on their behalf to an FDA review panel when they disagree with evidence of violative conditions or practices are noted by an FDA inspector or an agent acting on behalf of the Agency.

Numerous factors affect the safety of produce where it is grown, harvested, packed and held and there are multitude of produce commodities, practices, procedures and agro-ecological growing conditions. It is unclear how FDA will sufficiently train FDA inspectors or agents acting on the Agency’s behalf in the intricacies of all produce production, packing and handling practices and procedures. Therefore, sufficient oversight by use of an FDA review panel consisting of subject matter experts from the appropriate FDA District Office and FDA CFSAN should be considered, to rapidly adjudicate any issues contested by the farm operator.

§ 112.193 What are the provisions for coordination of education and enforcement?


PMA Comment: PMA recommends that FDA strongly consider contracting with State Departments of Agriculture to perform education outreach and on-farm routine inspections for compliance to the FSMA produce safety standards. Produce associated “for cause” and outbreak investigations should be delegated to State Departments of Public Health.

- FSMA rules must take into account the numerous factors associated with the multitude of produce commodities, practices, procedures and agro-ecological growing conditions that affect the safety of produce; where it is grown, harvested, packed and held. State Departments of Agriculture have intimate working knowledge of the commodities, practices, procedures and agro-ecological growing conditions within their states.
- State Departments of Agriculture have more in-depth knowledge of agriculture in their state and they have a better holistic understanding of agricultural issues than either FDA or State Departments of Public Health. It will be much more efficient and effective to teach personnel with in-depth knowledge of agriculture at a State Departments of Agriculture about food safety than to train public health officers everything there is to know about agriculture operations.
State Departments of Agriculture are best suited to identify farms which are covered by the produce safety rule and would be subject to compliance inspections.

Produce farms to date have not been pervasively regulated regarding produce safety practices and procedures. FDA needs State Department of Agriculture input and assistance to make sure that the final produce safety and preventive controls rules are both effective and practicable to implement. There is also significant need to provide sufficient time and resources to train growers so that they can comply with final rules, as well as training FDA and state regulatory officials regarding agricultural practices and the various means by which growers may comply with this new set of food safety regulations.

The use of on-farm routine inspections by State Department of Agriculture officials for compliance to the FSMA produce safety standards is similar in approach to the California and Arizona Leafy Green Marketing Agreements which have been found to be very effective at promoting the implementation of farm food safety best practices.

Appropriate level Federal funding for education outreach and implementation of the produce rule is a must. Education outreach and implementation funding should be formula funded with each state getting baseline funding plus additional funds based on produce acreage.

Effective and Compliance Dates for Very Small, Small and All Other Businesses

§ 112.3 What definitions apply to this part?

(b)(1) Very small business. For the purpose of this part, your farm is a very small business if it is subject to this part and, on a rolling basis, the average annual monetary value of food (as defined in paragraph (c) of this section) you sold during the previous 3-year period is no more than $250,000.

(b)(2) Small business. For the purpose of this part, your farm is a small business if it is subject to this part and, on a rolling basis, the average annual monetary value of food (as defined in paragraph (c) of this section) you sold during the previous 3-year period is no more than $500,000; and your farm is not a very small business as provided in paragraph (b)(1) of this section.

Preamble Section IV
**J. Effective Dates:** We are proposing that the effective date of this rule would be 60 days after the date of publication of the final rule in the Federal Register with staggered compliance dates.

**K. Compliance Dates:** We are proposing that the compliance dates for entities subject to the rule would be based on the size of a farm and the effective date of the requirement, with additional flexibility for compliance with proposed provisions for water quality in §112.44 and related provisions in §§112.45 and 112.50 (specifically, 112.50(b)(5), 112.50(b)(6), and 112.50(b)(7)).

- The compliance date for very small businesses…would be **four years from the effective date** and compliance with §§112.44, 112.45, 112.50(b)(5), 112.50(b)(6), and 112.50(b)(7), **six years** from the effective date.
- The compliance date for small businesses would be **three years from the effective date** and compliance with §§112.44, 112.45, 112.50(b)(5) 112.50(b)(6), and 112.50(b)(7), **five years** from the effective date.
- The compliance date for all other farms subject to the rule would be **two years from the effective date** and compliance with §§112.44, 112.45, 112.50(b)(5), 112.50(b)(6), and 112.50(b)(7), **four years** from the effective date.

Providing an extended compliance period to very small businesses as a means of providing additional flexibility is consistent with our approach to compliance dates in recent rules directed to food safety. (See, e.g., 74 FR 33029 at 33034 and 72 FR 34751 at 34752).

**PMA Comment:** PMA recommends that upon publication of the final rule in the Federal Register all growers should start adopting the FDA produce safety standards as soon as possible.

- There are numerous training programs and educational outreach services available from university extension that can be utilized by small and very small farmers to understand, implement and be in compliance with the FDA produce safety standards.
- Additionally, after publication of the final rule in the Federal Register, market forces (i.e. produce buyers) will likely require all growers implement and be in conformance with the FDA produce safety standards, as quickly as possible.
• Adoption of all provisions including those pertaining to agricultural water as set forth in Subpart E should be implemented as soon as practicable by all growers irrespective of enterprise size.

• Based on the CA and AZ Leafy Greens Marketing Agreement experience in developing and implementing food safety standards after the spinach outbreak in 2006, the FDA compliance timeframe is very ambitious.

Additional Requirements for Consideration

Operational Assessment, Food Safety Plans

“As discussed in section IV of this document, while we recommend that farms conduct an operational assessment and develop a food safety plan, at this time, we are not proposing to require them to do so. We request comment on whether we should require, in a final rule, some or all covered farms to perform operational assessments and/or develop a food safety plan, and any criteria that should be employed to determine which farms should be subjected to such a requirement.”

PMA Comment: All farms, irrespective of commodity, should perform an operational assessment of risk for their operations and develop and implement a food safety plan with specific preventive controls to address the identified likely microbial hazards and routes of contamination. From a quality and food safety perspective, requirements need to be documented. Without written plans, a food safety program becomes an informal process and is, therefore, more open to interpretation and less consistent throughout an organization. A written food safety plan, whether it is a basic plan for small growers growing one crop or a sophisticated plan(s) for large, diversified growers, is an essential component of any food safety program. Being committed to food safety does not need to be an expensive undertaking but it is necessary for public health. Produce food safety needs to be enhanced among growers in the supply chain and not simply focus on requiring food safety programs at large companies, but at the small ones as well. There must be at least a minimum level of commitment to food safety at every company in order to enhance the safety of produce, as per the intent of FSMA.

The food safety plan should include an operational assessment of risk that assesses probable risks, identifies hazards and provides a course of action to minimize those hazards. The problem is there is no standardized risk assessment methodology. Therefore, we encourage the FDA to work collaboratively with the industry and industry associations to develop guidance documents to assess risk on a grower level that in turn becomes part of every written food safety plan.
More aggressive standards to insure safety

FDA proposes (112.11) that you take appropriate measures to minimize the risk of serious adverse health consequences or death from use of, or exposure to, covered produce (p3551). FDA wants producers to include those measures reasonably necessary to prevent introduction of known or reasonably foreseeable hazards into covered produce and to provide reasonable assurances that the produce is not adulterated. The measures might include conducting root cause analysis if produce is suspected of being adulterated, making changes to practices or conditions and/or excluding affected produce from entering commerce. FDA requests comments on this approach (p3552) and whether they should instead establish specific standards for any types of hazard that would be covered in proposed 112.11 but for which FDA has not proposed specific standards in proposed standards Subparts C through O.

PMA Comment: Because it is impossible to foresee every hazard that might occur on a farm, of any size, and then to set specific standards, we encourage the FDA to support the requirement for farm level written food safety plans that include hazard analyses and appropriate measures to minimize the risks of the hazards and hence, the potential for adverse health effects. Every effort should be made to understand the most likely route of produce contamination, so as to inform the growers as to what actions may be taken in the future to prevent produce contamination. However, root cause analysis should not be required if produce is only “suspected of being adulterated”. Additionally, produce may be contaminated at any place along the produce supply chain and it would not be useful or efficient for growers to perform a root cause analysis every time produce is “suspected of being adulterated”. Currently, when a produce item is found to be adulterated in commerce, prudent and responsible companies review their hazard analysis, operational assessment of risks and implementation of their food safety program to assure that their food safety systems are adequate and functioning appropriately.
Written Food Safety Plans

In FSMA, section 408 (h), “an owner, operator or agent in charge of a facility shall prepare a written plan that documents and describes the processes and procedures used by the facility to comply with the requirements of this section, including analyzing the hazards of sub-section (b) and identifying the preventive controls adopted under sub-section (c) to address those hazards.” However, in the proposed produce rule, there is no requirement for a written plan. “The FDA goes on to say, “although we recognize their value and encourage their use, we are not proposing to require farms to conduct operational assessments or to develop written food safety plans akin to similar requirements for facilities subject to section 418 of the FD&C Act or our juice HACCP or seafood HACCP regulations.”

PMA Comment: All farms, irrespective of commodity, should perform an operational assessment of risk for their operations and develop and implement a food safety plan with specific preventive controls to address the identified likely microbial hazards and routes of contamination. From a quality and food safety perspective, requirements need to be documented. Without written plans, a food safety program becomes an informal process and is therefore more open to interpretation and less consistent throughout an organization. A written food safety plan, whether it is a basic plan for small growers growing one crop or a sophisticated plan(s) for large, diversified growers, is an essential component of any food safety program. Being committed to food safety does not need to be an expensive undertaking but it is necessary for public health. Produce food safety needs to be enhanced among growers in the supply chain and not simply focus on requiring food safety programs at large companies but at the small ones as well. There must be at least a minimum level of commitment to food safety at every company in order to enhance the safety of produce, as per the intent of FSMA.

The food safety plan should include an operational assessment of risk that assesses probable risks, identifies hazards and provides a course of action to minimize those hazards. One issue is that there is no standardized operational assessment of risk methodology. Therefore, we encourage the FDA to work collaboratively with the industry and industry associations to develop guidance documents to assess risk on a grower level that, in turn, becomes part of every written food safety plan.
**Product Testing**
With the exception of sprouts, the FDA concludes testing is not useful. PMA agrees that raw and final product testing should not be included in the produce rule and has commented previously to the FDA that there is no science to support testing. Furthermore, there are several technical, operational and product quality challenges surrounding product testing, including: the challenges of testing fresh produce items because of their highly perishable nature and complex composition; the selectivity and sensitivity of the pathogen tests commercially available; the question of whether to test raw or finished products; and, the challenges surrounding effective and significant product sampling. In developing a food safety plan, growers will assess the hazards and develop controls to manage the risks. Testing should focus on evaluating the success of the controls in managing the risk. Product testing may identify an issue at a point in time but it will not identify the cause or contributing factors. Preventive controls and critical control points are more effective and informative of product safety on a regular basis. Limited food safety resources available to a grower are best utilized and most effective at reducing produce safety risk by implementing preventive controls not testing products. Testing takes valuable resources away from implementing food safety programs and may offer a false sense of security.