DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 16 and 112

[Docket No. FDA–2011–N–0921]

RIN 0910–AG35

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: To minimize the risk of serious adverse health consequences or death from consumption of contaminated produce, the Food and Drug Administration (FDA) is proposing to establish science-based minimum standards for the safe growing, harvesting, packing, and holding of produce, meaning fruits and vegetables grown for human consumption. FDA is proposing these standards as part of our implementation of the FDA Food Safety Modernization Act (FSMA). These standards would not apply to produce that is rarely consumed raw, produce for personal or on-farm consumption, or produce that is not a raw agricultural commodity. In addition, produce that receives commercial processing that adequately reduces the presence of microorganisms of public health significance would be eligible for exemption from the requirements of this rule. The proposed rule would set forth procedures, processes, and practices that minimize the risk of serious adverse health consequences or death, including those reasonably necessary to prevent the introduction of known or reasonably foreseeable biological hazards into or onto produce and to provide reasonable assurances that the produce is not adulterated on account of such hazards. We expect that the proposed rule, if finalized as proposed, would reduce foodborne illness associated with the consumption of contaminated produce.

DATES: Submit either electronic or written comments on the proposed rule by May 16, 2013. Submit comments on information collection issues under the Paperwork Reduction Act of 1995 by February 15, 2013 (see the ''Paperwork Reduction Act of 1995'' section of this document).

ADDRESSES: You may submit comments, identified by Docket No. FDA–2011–N–0921 and/or Regulatory Information Number RIN 0910–AG35, by any of the following methods, except that comments on information collection issues under the Paperwork Reduction Act of 1995 must be submitted to the Office of Regulatory Affairs, Office of Management and Budget (OMB) (see the ''Paperwork Reduction Act of 1995'' section of this document).

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- Mail/Hand delivery/Courier (for paper or CD–ROM submissions): Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name and Docket No. FDA–2011–N–0921 and Regulatory Information Number RIN 0910–AG35 for this rulemaking. All comments received may be posted without change to *http://www.regulations.gov*, including any personal information provided. For additional information on submitting comments, see the ''Comments'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* and insert the docket number(s), found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Samir Assar, Center for Food Safety and Applied Nutrition (HFS–317), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–1636.

SUPPLEMENTARY INFORMATION:

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Executive Summary

The FDA Food Safety Modernization Act (FSMA) (Pub. L. 111–353) requires FDA to publish a notice of proposed rulemaking to establish science-based

minimum standards for the safe production and harvesting of those types of fruits and vegetables that are raw agricultural commodities for which we have determined such standards minimize the risk of serious adverse health consequences or death. Further, new section 419 also requires FDA to adopt a final regulation based on known safety risks, setting forth procedures, processes, and practices that we determine to minimize the risk of serious adverse health consequences or death, including those that are reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into produce and to provide reasonable assurances that produce is not adulterated under section 402 of the FD&C Act.

This proposed rule focuses on microbiological hazards related to produce growing, harvesting, packing, and holding. We conducted a ''Draft Qualitative Assessment of Risk to Public Health from On-Farm Contamination of Produce'' and considered the findings of this assessment in developing this proposed rule. While we acknowledge the potential for chemical, physical or radiological contamination of produce, for reasons discussed in this proposed rule, we are not proposing specific standards for these hazards in this rulemaking.

Scope of Coverage of the Proposed Rule

The proposed rule would apply to both domestic and imported produce. However, as explained in the remainder of this document, the proposed rule contains several exemptions:

- The proposed rule would not apply to certain specified produce commodities that are rarely consumed raw.
- The proposed rule also would not apply to produce that is used for personal or on-farm consumption, or that is not a raw agricultural commodity.
- The proposed rule would provide an exemption for produce that receives commercial processing that adequately reduces the presence of microorganisms (*e.g.* a ''kill step'') as long as certain documentation is kept.
- The proposed rule would not cover farms that have an average annual value of food sold during the previous three-year period of $25,000 or less.
- The proposed rule would provide a qualified exemption and modified requirements for farms that meet two requirements: (1) The farm must have food sales averaging less than $500,000 per year during the last three years; and (2) the farm's sales to qualified end-users must exceed sales to others. A qualified end-user is either (a) the consumer of the food or (b) a restaurant or retail food establishment that is located in the same State as the farm or not more than 275 miles away. Instead, these farms would be required to include their name and complete business address either on the label of the produce that would otherwise be covered (if a label is required under the FD&C Act and its implementing regulations) or at the point-of-purchase. This exemption may be withdrawn in the event of an active investigation of an outbreak that is directly linked to the farm, or if it is necessary to protect the public health and prevent or mitigate an outbreak based on conduct or conditions on the farm that are material to the safety of the produce. As explained in the Preamble, these entities are either exempt from all the requirements of the rule or are subject to a narrower set of requirements.

Summary of the Major Provisions of the Regulatory Action

The proposed rule would establish science-based minimum standards for the safe growing, harvesting, packing, and holding of produce on farms. We propose new standards in the following major areas:

- Worker Training and Heath and Hygiene
  - Establish qualification and training requirements for all personnel who handle (contact) covered produce or food-contact surfaces and their supervisors (proposed §§ 112.21, 112.22, and 112.23);
  - Require documentation of required training (proposed § 112.30); and
  - Establish hygienic practices and other measures needed to prevent persons, including visitors, from contaminating produce with microorganisms of public health significance (proposed §§ 112.31, 112.32, and 112.33).
- Agricultural Water
  - Require that all agricultural water must be of safe and sanitary quality for its intended use (proposed § 112.41). Agricultural water is defined in part as water that is intended to, or likely to, contact the harvestable portion of covered produce or food-contact surfaces (proposed § 112.3(c));
  - Establish requirements for inspection, maintenance, and follow-up actions related to the use of agricultural water, water sources, and water distribution systems associated with growing, harvesting, packing, and holding of covered produce (proposed §§ 112.42 and 112.46);
  - Require treatment of agricultural water if you know or have reason to believe that the water is not safe and of adequate sanitary quality for its intended use, including requirements for treating such water and monitoring its treatment (proposed § 112.43);
  - Establish specific requirements for the quality of agricultural water that is used for certain specified purposes, including provisions requiring periodic analytical testing of such water (with exemptions provided for use of public water supplies under certain specified conditions or treated water), and requiring certain actions to be taken when such water does not meet the quality standards (proposed §§ 112.44 and 112.45); and provide for alternative requirements for certain provisions under certain conditions (proposed § 112.12); and
  - Require certain records, including documentation of inspection findings, scientific data or information relied on to support the adequacy of water treatment methods, treatment monitoring results, water testing results, and scientific data or information relied on to support any permitted alternatives to requirements (proposed § 112.50).
- Biological Soil Amendments
  - Establish requirements for determining the status of a biological soil amendment of animal origin as treated or untreated, and for their handling, conveying, and storing (proposed §§ 112.51, 112.52)
  - Prohibit the use of human waste for growing covered produce except in compliance with EPA regulations for such uses or equivalent regulatory requirements (proposed § 112.53);
  - Establish requirements for treatment of biological soil amendments of animal origin with scientifically valid, controlled, physical and/or chemical processes or composting processes that satisfy certain specific microbial standards (proposed §§ 112.54 and 112.55); and provide for alternative requirements for certain provisions under certain conditions (proposed § 112.12);
  - Establish application requirements and minimum application intervals for untreated and treated biological soil amendments of animal origin (proposed § 112.56); and provide for alternative requirements for certain provisions under certain conditions (proposed § 112.12); and
  - Require certain records, including documentation of application and harvest dates relevant to application intervals; documentation from suppliers of treated biological soil amendments of animal origin, periodic test results, and scientific data or information relied on to support any permitted alternatives to requirements (proposed § 112.60).

- Domesticated and Wild Animals
  - If animals are allowed to graze or are used 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, require, at a minimum, an adequate waiting period between grazing and harvesting for covered produce in any growing area that was grazed, and measures to prevent the introduction of known or reasonably foreseeable hazards into or onto covered produce (proposed § 112.82); and
  - If under the circumstances there is a reasonable probability that animal intrusion will contaminate covered produce, require monitoring of those areas that are used for a covered activity for evidence of animal intrusion immediately prior to harvest and, as needed, during the growing season (proposed § 112.83).
- Equipment, Tools, and Buildings
  - Establish requirements related to equipment and tools that contact covered produce and instruments and controls (including equipment used in transport), buildings, domesticated animals in and around fully-enclosed buildings, pest control, hand-washing and toilet facilities, sewage, trash, plumbing, and animal excreta (proposed §§ 112.121–134); and
  - Require certain records related to the date and method of cleaning and sanitizing equipment used in growing operations for sprouts, and in covered harvesting, packing, or holding activities (proposed § 112.140).
- Sprouts
  - Establish measures that must be taken related to seeds or beans for sprouting (proposed § 112.141);
  - Establish measures that must be taken for the growing, harvesting, packing, and holding of sprouts (proposed § 112.142);
  - Require that you test the growing environment for *Listeria* spp. or *L. monocytogenes* and that you test each production batch of spent irrigation water or sprouts for *E. coli* O157:H7 and *Salmonella* species and take appropriate follow-up actions (proposed §§ 112.143, 112.144, 112.145, 112.146); and
  - Require certain records, including documentation of your treatment of seeds or beans for sprouting, a written environmental monitoring plan and sampling plan, test results, and certain methods used (proposed § 112.150).

As proposed, the effective date is 60 days after a final rule is published, however, we are providing for a longer timeline for farms to come into compliance. Small businesses (*i.e.,* those subject to proposed part 112 and, on a rolling basis, the average annual monetary value of food sold during the previous three-year period is no more than $500,000) would have three years after the effective date to comply; for some of the water requirements, they would have five years. In addition, very small businesses (*i.e.,* those subject to proposed part 112 and, on a rolling basis, the average annual monetary value of food sold during the previous three-year period is no more than $250,000) would have four years after the effective date to comply; for some of the water requirements, they would have six years. All other farms would have two years after the effective date to comply; for some of the water requirements, they would have four years to comply.

Costs and Benefits

The baseline estimate for preventing all illnesses associated with microbial contamination of produce covered by this proposed regulation is $1.6 billion; however, we do not expect that we will eliminate all illnesses associated with covered produce. Instead, we expect that the proposed produce safety regulation will prevent some portion of this illness burden from recurring. We estimate the number of foodborne illness prevented by this regulation to be 1.75 million, with an associated benefit of $1.04 billion, annually. As described in the Preliminary Regulatory Impact Analysis (PRIA), making a precise estimate of the rule's likely effectiveness is extremely difficult, because FDA has only limited data that would establish a clear baseline estimate of how contamination occurs and the likely impact of the proposed provisions on that baseline, with respect to causing human illness. We estimate the costs of the proposed rule to be $459.56 million annually for domestic farms, $170.62 million annually for foreign farms covered by the rule (for a grand total of $630.18 million annually), resulting in $406.22 million annually in estimated potential net benefits.

Summary of Costs and Benefits of the Proposed Rule [1]	Prevented foodborne Illnesses (in millions)	Total benefits (in millions)	Total domestic costs (in millions)	Total foreign costs (in millions)	Total costs (domestic + foreign)	Net benefits (in millions)
Total	1.75	$1,036.40	$459.56	$170.62	$630.18	$406.22

	Very small	Small	Large
Average Annual Cost per Farm	$4,697	$12,972	$30,566

[1] As described in detail in the PRIA, data to estimate the costs and benefits of this rule are limited. Best estimates were made for both the costs and the benefits of the rule, given the data available. We request comment on these estimations, and request, in particular, data related to the amount of contamination attributable to each potential pathway of contamination, the relative effectiveness of each provision at reducing contamination, and data related to current industry food safety practices.

Proposed Rule

I. Introduction

Each year, about 48 million Americans (1 in 6) get sick, 128,000 are hospitalized, and 3,000 die from foodborne diseases, according to estimates from the Centers for Disease Control and Prevention. The FDA Food Safety Modernization Act (FSMA) (Pub. L. 111–353), signed into law by President Obama on January 4, 2011, enables FDA to better protect public health by helping to ensure the safety and security of the food supply. FSMA enables us to focus more on preventing food safety problems rather than primarily reacting to problems after they occur. The law also provides us with new enforcement authorities to help us achieve higher rates of compliance with prevention- and risk-based safety standards and to better respond to and contain problems when they do occur. In addition, the law gives us important new tools to better ensure the safety of imported foods and directs us to build an integrated national food safety system in partnership with State and local authorities.

Section 105 of FSMA adds section 419 to the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 350h) requiring FDA to publish a notice of proposed rulemaking to establish science-based minimum standards for

the safe production and harvesting of those types of fruits and vegetables that are raw agricultural commodities for which we have determined such standards are necessary to minimize the risk of serious adverse health consequences or death. Further, new section 419 also requires FDA to adopt a final regulation based on known safety risks, setting forth procedures, processes, and practices that we determine to minimize the risk of serious adverse health consequences or death, including those that are reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into produce and to provide reasonable assurances that produce is not adulterated under section 402 of the FD&C Act. This proposed rule sets forth such standards, as well as certain exemptions from the standards, consistent with section 419 of the FD&C Act.

Two additional proposed rules, with the produce safety proposed rule, will be the foundation of, and central framework for, a new food safety system in the United States. In an accompanying notice in this issue of the **Federal Register**, FDA is publishing the preventive controls proposed rule that would apply to human food and require domestic and foreign facilities that are required to register under the FD&C Act to have written plans that identify hazards, specify the steps that will be put in place to minimize or prevent those hazards, monitor results, and act to correct problems that arise.

FDA also intends to publish the foreign supplier verification program (FSVP) proposed rule, which would help ensure the safety of foods imported into the U.S. by making importers accountable for verifying that the food they import is produced using processes and procedures that achieve the same level of public health protection for imported food as required of domestic growers and processors under FSMA's new standards for produce safety and preventive controls.

Eating fruits and vegetables is an important part of a healthy diet (Ref. 1). FDA is responsible for ensuring the safety of all domestic and imported fruits and vegetables consumed in the United States. We place a high priority on identifying and implementing measures that can reduce the incidence of foodborne illness associated with produce and maintain a high level of consumer confidence in this important food category. Produce is vulnerable to contamination with microorganisms of public health significance (*e.g.,* bacteria and viruses that can cause disease), as well as chemical, physical, and radiological contaminants. Contamination of produce can occur on-farm during growing (either in an open environment or in a fully- or partially-enclosed building), harvesting, packing, or holding; or elsewhere along the farm-to-table continuum.

A. Contamination With Microbiological Hazards

American consumers enjoy one of the safest supplies of produce in the world. Over the last few decades, however, problems linked to produce, including the associated public health implications, have been reported in a number of countries worldwide. Many factors affect the occurrence of microbial contamination of fresh produce, including worker health and hygiene, the quality of agricultural water, the use of animal manure and other materials of animal origin as fertilizer, the presence of wild or domestic animals in or near fields or packing areas, growing and harvesting operations, and equipment and building sanitation. As discussed in more detail below, FDA has taken several steps to help reduce the likelihood of microbial contamination; significant advances have been made. However, in spite of these efforts, produce-associated foodborne illnesses continue.

FDA has looked specifically at outbreaks where the point of contamination is likely to have happened early in the production chain, during growing, harvesting, manufacturing, processing, packing, holding, or transportation (Ref. 2). Of the total reported outbreaks and outbreak-related illnesses linked to FDA-regulated foods between 1996 and 2010, in the FDA database, produce accounted for 23.3% and 42.3%, respectively. Both domestic produce and imported produce were identified as vehicles in these outbreaks. From 1996 to 2010, approximately 131 produce-related reported outbreaks occurred, resulting in 14,132 outbreak-related illnesses, 1,360 hospitalizations and 27 deaths. These outbreaks were associated with approximately 20 different fresh produce commodities (Ref. 3). Commodities associated with outbreaks during this time period included sprouts; leafy greens such as lettuce and spinach; tomatoes; melons such as cantaloupe and honeydew; berries such as raspberries, blueberries, blackberries, and strawberries; fresh herbs such as basil and parsley; and green onions as well as fresh-cut fruits and vegetables. FDA also has evidence that contamination occurs on some produce crops at least intermittently based on sampling performed as part of investigation, inspections, and FDA Domestic and Import Field Assignments and data from United States Department of Agriculture (USDA)'s Agricultural Marketing Service (AMS) Microbiological Database program (MDP) (Ref. 4 Ref. 5). For instance, in 2009, AMS tested eight types of produce for E. coli O157:H7, non-O157 E. coli carrying shiga toxin and enterotoxin genes, and Salmonella. MDP identified 51 samples with E. coli carrying shiga toxin genes; however only 24 of these were determined to be pathogenic. MDP identified 32 samples with Salmonella confirmed by culture. The USDA AMS MDP was discontinued in 2012 and FDA is evaluating options for any future collection of similar microbiological data.

The following commodities accounted for 88.5% of the total produce-associated outbreaks:

- 34 outbreaks associated with sprouts,
- 30 outbreaks associated with leafy greens such as lettuce and spinach
- 17 outbreaks associated with tomatoes
- 14 outbreaks associated with melons such as cantaloupe and honeydew
- 10 outbreaks associated with berries, such as raspberries, blueberries, blackberries and strawberries
- 6 outbreaks associated with fresh herbs such as basil and parsley
- 3 outbreaks associated with green onions.

(Ref. 2)

In the FDA database, fresh-cut fruits and vegetables accounted for 16.8% of the total produce-related outbreaks. Generally, the most likely point of original contamination for the fresh-cut-related outbreaks, as determined by FDA and its federal and state partners during the outbreak investigations, appears to be during growing, harvest, packing or holding, while the commodity is still in its raw agricultural commodity (RAC) form, rather than during manufacturing/processing of the fresh-cut product (Ref. 2). In a few instances, such as unwashed, field packed tomatoes being removed from a warm ripening room and placed in cold water to firm for slicing (which may have promoted infiltration of pathogens) (Ref. 6), it is possible that practices or conditions at the fresh-cut facility contributed to the contamination event. It is possible that the way product is handled during processing, including mixing large batches of fresh-cut product, may spread contamination across a larger volume of product, impacting the size and scope of an outbreak associated with fresh-cut

produce. However, there have also been a number of very large outbreaks associated with RACs.

Pathogens associated with the produce outbreaks include bacteria, viruses and parasites. Between 1996 and 2010, the majority of fresh produce-related outbreaks and illnesses in the FDA database were associated with bacterial agents (86.5%), followed by parasites (11.6%) and viruses (1.9%). These outbreaks involved a number of pathogens, including *E. coli* O157:H7, *E. coli* O157, *Salmonella* species (*Salmonella* spp.), *Listeria monocytogenes (L. monocytogenes), Cyclospora, Shigella sonnei,* and Hepatitis A.

In an accompanying document titled ''Draft Qualitative Assessment of Risk to Public Health from On-Farm Contamination of Produce,'' FDA has conducted a qualitative assessment of risk associated with growing, harvesting, packing, and holding of produce (hereafter referred to as the Qualitative Assessment of Risk (QAR)). In particular, the QAR is intended to address various risk management questions related to biological hazards of concern in fresh produce that can lead to serious adverse health consequences or death; potential routes of contamination; and the likelihood of contamination and likelihood of illness attributable to consumption among various types of produce commodities. The findings of this qualitative assessment of risk informed our regulatory approach and several proposed provisions. We provide a summary of the findings in section IV; additionally, we refer to the QAR throughout this proposed rule, including the discussion of proposed provisions in section V of this document.

B. Contamination With Chemical, Physical or Radiological Hazards

Chemical contaminants of produce can originate from a variety of sources. Most common among these include soil (through previous chemical exposure), equipment (*e.g.,* lubricants, fuels, and refrigerants), pesticides, insecticides and related agents, and cleaning compounds (*e.g.,* sanitizers) normally used in the course of maintaining buildings and equipment. FDA monitors chemical and pesticide residues in foods through its regulatory monitoring programs with emphasis on raw agricultural commodities (RACs) and foods consumed by infants and children. Illnesses attributable to chemical hazards are rare (Ref. 7). In fact, between 1997 and 2011, there have been no Class I recalls of produce associated with a chemical hazard for which there is a reasonable probability of causing serious health problems or death (Ref. 8). Current monitoring, regulations, and industry practice have been sufficient to keep these hazards under control.

Similarly, the potential public health consequences of physical hazard contamination (*e.g.* glass or metal fragments) in produce appear to be relatively (Ref. 7). Rarely do the physical hazards associated with produce suggest a risk of serious adverse health consequences or death for individuals that would consume the product. In fact, between 1997 and 2011, there have been no Class I recalls of produce associated with a physical hazard for which there is a reasonable probability of causing serious health problems or death (Ref. 8).

The presence of radiological hazards in foods is a rare event and consumer exposure to harmful levels of radionuclide hazards, outside of catastrophic events, is very low (Ref. 7. Ref. 9).

While we acknowledge the potential for chemical, physical or radiological contamination of produce, based on our analysis (Ref. 7), and for the reasons discussed in section IV.B of this document, we are not proposing specific standards for these hazards in this rulemaking.

II. Efforts to Address Produce Safety

FDA and others have taken a number of actions to address produce safety in the last two decades. This section describes several of these activities up to and including FSMA.

A. Inspections and Investigations

We have conducted a number of inspections and investigations that have provided useful information about the routes of contamination. Investigations involved visiting multiple field locations and packing operations. Observations during the investigations revealed several areas of farm practices that seem most likely to have been possible routes of contamination for produce involved in the outbreaks. Our inspections, investigations, and surveillance sampling activities are described in more detail in accompanying documents.

B. Guidance Documents and Letters to Industry

1. GAPs Guide

On October 2, 1997, President Clinton announced the ''Initiative to Ensure the Safety of Imported and Domestic Fruits and Vegetables'' (Produce and Imported Food Safety Initiative or PIFSI). As part of this initiative, the President directed the Secretary of the Department of Health and Human Services (HHS) and the Secretary of the U.S. Department of Agriculture (USDA), in cooperation with the agricultural community, to issue guidance on good agricultural practices (GAPs) for fresh fruits and vegetables. In October, 1998, we issued final guidance to industry entitled ''Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables'' (GAPs Guide) (Ref. 10). This guide contains voluntary recommendations for good agricultural practices (GAPs) that growers and packers can undertake to address common factors contributing to contamination in their operations. The GAPs Guide is a broad scope guidance that takes into account the diversity of conditions and practices associated with the growing, harvesting, packing and holding of fresh produce. We noted that firms should use the general recommendations in the GAPs Guide to tailor practices to their individual operations. As the GAPs Guide notes, current technologies cannot eliminate all potential food safety hazards associated with fresh produce that will be eaten raw. Therefore, the focus of the GAPs Guide is on implementing measures to minimize the potential for introduction of such hazards.

On September 2, 2008, we issued a notice in the **Federal Register** (73 FR 51306) requesting comments and scientific data and information to assist us in improving the GAPs Guide. We specifically asked for information about (1) current agricultural practices and conditions used to produce, harvest, pack, cool, and transport fresh produce; (2) risk factors for contamination of fresh produce associated with these practices; and (3) possible recommendations or additional measures that would enhance the safety of fresh produce. We also requested information about the estimated costs and benefits of current practices and/or the cost and benefits of any recommendations. We received approximately two dozen submissions from organizations and individuals, including: Industry, government, universities, environmental groups, consumers, and consumer groups. A number of comments discussed the value of performing operational assessments, developing food safety plans and record keeping but suggested that any updated guidance acknowledge that these activities should be commensurate with the complexity of an operation and associated risks. Other

comments requested additional information on microbial testing to ensure that when testing is done it is meaningful and cost effective.

2. Letters to Lettuce, Tomato, and Cilantro Industries

On February 5, 2004, we issued a letter to firms that grow, harvest, pack or hold fresh lettuce and fresh tomatoes, expressing concern regarding outbreaks of foodborne illness associated with the consumption of these products, and recommending actions to enhance the safety of these products (Ref. 11). On November 4, 2005, we issued a second letter to firms that grow, harvest, pack, hold or manufacture/process fresh and fresh-cut lettuce, reiterating concerns about continuing outbreaks (Ref. 12). In the November 2005 letter, we strongly encouraged applicable firms to review their current operations in light of the GAPs Guide, as well as other available information regarding the reduction or elimination of pathogens on fresh produce. We encouraged firms to consider modifying their operations to ensure that they were taking the appropriate measures to provide a safe product to the consumer. We recommended that firms from the farm level through the distribution level undertake these steps.

In March, 2011, we issued a letter to firms that grow, harvest, pack or hold fresh cilantro, expressing concern about positive sample findings and recommending actions to enhance the safety of these products (Ref. 13). Between 2004 and March, 2011, there had been 28 confirmed *Salmonella* positive sample results in fresh cilantro in, or entering into, commerce. Samples were of both U.S. and imported origin. As with earlier letters to the industry, we strongly encouraged applicable firms to review their current operations in light of the GAPs Guide, as well as other available information regarding the reduction or elimination of pathogens on fresh produce. We encouraged firms to consider modifying their operations to ensure that they were taking the appropriate measures to provide a safe product to the consumer. In addition, we encouraged these firms to assess hazards unique to the production of cilantro and to develop commodity-specific preventive control strategies. We recommended that firms from the farm level through the distribution level undertake these steps.

3. Guidances and Letters Regarding Sprouts

On October 27, 1999, we published a notice of availability (64 FR 57893) for two guidance documents to inform all parties involved in the production of sprouts (*i.e.,* producers, conditioners, and distributors of seeds and beans used for sprouting, sprout producers) that sprouts have been recognized as an important cause of foodborne illness and to provide recommendations for preventive controls that we believed should be taken immediately to reduce the likelihood of sprouts serving as a vehicle for foodborne illness (Ref. 14).(Ref. 15) The first guidance document, ''Reducing Microbial Food Safety Hazards for Sprouted Seeds'' (the Sprout Guide), provides recommendations based on the recommendations of the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) (Ref. 16). We also released a second guidance, ''Sampling and Microbial Testing of Spent Irrigation Water During Sprout Production'' (the Sprout Testing Guide), to assist sprouters in implementing one of the principal recommendations in the broader Sprout Guide, *i.e.,* that producers test spent irrigation water for two pathogens (*Salmonella* spp. and *E coli* O157:H7) before product enters commerce. We refer to these guidances collectively as the Sprout Guides.

On April 22, 2005, we announced in the **Federal Register** (70 FR 20852) a public meeting to elicit information on current science related to foodborne illness associated with the consumption of sprouts. The meeting notice contained a series of questions to help focus comments, including questions regarding: (1) Practices that may contribute to contamination of seeds used for sprouting and intervention strategies that could help prevent, reduce, or control contamination of seeds used for sprouting; (2) Whether the preventive controls recommended in our Sprout Guides could be improved and, if so, how this might be done; (3) What can or should be done to increase the involvement of producers of seeds for sprouting and seed distributors to ensure the safety of sprouts; (4) How, if at all, should the actions to improve the safety of seeds for sprouting be structured to take into account variation within the seed and sprout industry, including variations in size of establishments, the types of seeds and sprouts produced and the practices used in production; and (5) Existing food safety systems or standards (such as international standards) that we should consider as part of our efforts to minimize foodborne illness associated with the consumption of sprouts.

In general, comments expressed a need to include the seed industry, as well as the sprout industry, in efforts to improve the safety of sprouts. Several comments stated that any recommendations should be scientifically sound, based on appropriate (and feasible) expectations for risk reduction, and be easy to understand and implement. Comments expressed concern about the effect on worker health of treating seed with 20,000 ppm calcium hypochlorite. Comments were generally supportive of recommendations in the Sprout Guides to test spent irrigation water; several comments supported expanded testing, including seed testing by seed producers and distributors. All but one comment maintained that seeds were the primary source of contamination in sprout-associated outbreaks. Several comments discussed practices and conditions, such as animal grazing, which could contaminate seed in the field. One comment suggested the industry develop a GAPs guidance specific to the production of seed for use in sprouts. Several comments supported applying Current Good Manufacturing Practices (CGMPs) (21 CFR Part 110) to sprout facilities. A number of comments cited the diversity of sprout types currently being produced and noted this diversity of products is likely to continue to grow. These comments maintained it was therefore appropriate to provide flexibility for individual operations to select mitigations appropriate for the products they produce. Comments to the 2005 Sprout Public Meeting were considered in this rulemaking and will be further described when we discuss proposed provisions specific to sprouts in section V.M. of this document.

On May 1, 2009, we issued a letter to suppliers and distributors of seeds and beans used for sprouting, and sprouters, to make firms aware of our serious concerns with continuing outbreaks associated with the consumption of raw and lightly cooked sprouts and to urge firms to review their operations in light of our Sprout Guides and other available information (Ref. 17), and to modify their operations accordingly to ensure they are taking appropriate measures to provide a safe product to consumers. We also shared a May 1, 2008, letter from the California Department of Public Health (CDPH) to the California sprout industry outlining several critical areas of concern identified in recent investigations and CDPH recommendations for controlling hazards associated with those observations (Ref. 18).

4. Draft Commodity Specific Guidances

On August 3, 2009, we published a notice in the **Federal Register** announcing the availability for public

comment of draft commodity specific guidances (CSGs) for melons (74 FR 38437), tomatoes (74 FR 38438) and leafy greens (74 FR 38439). The draft CSGs are intended for growers, packers, processors, transporters, retailers, and others throughout the supply chain. The draft CSGs, if finalized, would provide a framework for identifying and implementing appropriate measures to minimize the likelihood of microbial contamination of tomatoes, leafy greens, and melons. The draft CSGs reflect both commodity specific information, such as recommendations for tomato repacking, and advances in collective thinking in broader areas, such as assessing potential hazards in and near the field before beginning production and immediately before harvest, and protecting and maintaining water quality at its source and during distribution and use. The draft CSGs are designed to complement our GAPs Guide and Fresh-cut Guide. On November 4, 2009, we published a notice in the **Federal Register**, extending to January 4, 2010, the comment period on the draft CSGs. We have not yet issued these guidances in final form.

In developing the draft CSGs, we relied heavily on existing industry commodity specific guidelines, our produce safety initiatives and programs, lessons learned from outbreak investigations, and other public and private programs. We have since received several dozen written comments, from industry, States, and individuals. Comments were generally supportive of the scope and objectives of the draft CSGs. Comments provided their views on both commodity specific issues (*e.g.,* recommendations for field packing tomatoes, water quality for rehydrating leafy greens after harvest) and cross-cutting issues (*e.g.,* management of wild animal intrusion, quality of water used in postharvest operations). A number of comments requested that we recognize different risks may be associated with different commodities within the commodity groups covered by the CSGs, noting, for example, that cantaloupe (not watermelon) have been identified as the vehicle in the majority of foodborne illness outbreaks associated with melons. A number of comments expressed concern about potential bias of the CSG approach (*i.e.,* separate recommendations for different commodities) against small farms growing a diversity of crops, especially the concern that the CSG approach could require such farms to have multiple food safety plans to cover each of the commodities they grow. Additional comments will be discussed when we describe proposed provisions relevant to those comments.

5. Guidances Regarding Nuts

On March 11, 2009, we published a notice in the **Federal Register** (74 FR 10598) announcing the availability for public comment of draft guidance for industry: Measures to Address the Risk for Contamination by *Salmonella* Species in Food Containing a Peanut-Derived Product as an Ingredient. Additionally, on June 29, 2009, we published a notice in the **Federal Register** (74 FR 310308) announcing the availability for public comment of draft guidance for industry: Measures to Address the Risk for Contamination by *Salmonella* Species in Food Containing a Pistachio-Derived Product As An Ingredient. These draft guidance documents were intended for manufacturers who use a peanut-derived product or pistachio-derived product as an ingredient in a food product. These draft guidances provide recommendations for evaluating the effectiveness of certain *Salmonella* control measures. We have not yet issued these guidances in final form.

6. Fresh-cut Guide

On March 6, 2006, we published a notice in the **Federal Register** (71 FR 11209) announcing the availability on our Web site of a draft Guidance for Industry entitled ''Guide to Minimize Microbial Food Safety Hazards of Fresh-cut Fruits and Vegetables'' (the Fresh-cut Guide). We received a number of comments from trade associations, consumer groups, and industry. Comments were generally supportive of the draft Guide. A few comments included questions about our draft definition of fresh-cut produce and whether the recommendations in the draft guidance were mandatory or voluntary, in light of the mandatory requirements in existing CGMPs.

On February 25, 2008, we published a notice (73 FR 10037) announcing our finalization and the availability of our ''Guide to Minimize Microbial Food Safety Hazards of Fresh-cut Fruits and Vegetables'' (the Fresh-cut Guide). The Fresh-cut Guidance complements the CGMPs in 21 CFR, Part 110 and provides recommendations for a framework for identifying and implementing appropriate measures to minimize the likelihood of microbial contamination during the processing of fresh-cut produce. Examples of recommendations for fresh-cut processors in the Fresh-cut Guidance include: (1) Know your suppliers and have a mechanism to verify that your suppliers use good agricultural practices, good manufacturing practices, and other appropriate food safety practices; and (2) ensure equipment is designed to prevent water collection. While fresh-cut produce is not covered under the scope of this proposed rule, we include a reference to our guidance on fresh-cut produce as some of the measures recommended in that document are relevant to the requirements proposed for covered produce in this rule.

B. Produce Safety Action Plan

On June 15, 2004, we published a **Federal Register** notice (69 FR 33393) announcing a public meeting to elicit information from stakeholders concerning key elements of a draft produce safety action plan entitled ''Produce Safety From Production to Consumption: An Action Plan to Minimize Foodborne Illness Associated With Fresh Produce'' (the Produce Safety Action Plan or PSAP). We posted the draft PSAP on June 18, 2004 (Ref. 19). The draft PSAP continued the 1997 Produce and Imported Food Safety Initiative, building on experience from earlier efforts such as the development and implementation of the GAPs Guide, inspections of farms and produce packing facilities, surveillance sampling assignments, and investigations of foodborne illness outbreaks. The draft PSAP addressed all principal points between the farm and table where contamination of produce could occur. It covered fresh fruit and vegetables in their native (RAC) form and raw, minimally processed products (*i.e.,* fresh-cut produce) that have received some processing to alter their form but have not been subject to a thermal process that would eliminate microbial hazards. The draft PSAP was not intended to cover processed products such as juice, or agricultural products other than fruits and vegetables.

After considering comments received from various stakeholders, in October 2004, we issued the final PSAP. In recognition that contamination of produce can happen at any point in the supply chain, the PSAP expands on the areas covered by the GAPs Guide (*i.e.,* farms and packing houses) to extend to all parts of the food supply chain from farm through retail or consumer preparation and consumption. The PSAP does not cover frozen fruits and vegetables, fruit and vegetable juices, or nuts. The PSAP has four main objectives: (1) Prevent contamination of fresh produce with pathogens; (2) minimize the public health impact when contamination of fresh produce

occurs; (3) improve communication with producers, packers, processors, transporters, distributors, preparers, consumers, and other government entities about the safety of fresh produce; and (4) facilitate and support research relevant to the contamination of fresh produce. For each objective, the PSAP identifies steps or actions that could contribute to the achievement of that objective. The PSAP has measurable goals and outcomes, and several steps outlined in the PSAP are already in progress or have been completed. For example, we issued the Fresh-cut Guide and provided technical assistance to industry efforts to develop commodity specific supply chain guidance as part of the PSAP objective regarding prevention of contamination.

C. Public Hearings

On February, 27, 2007, we published a notice (72 FR 8750) of two public hearings, and request for comment, on the safety of fresh produce. In that notice, we stated that we believe that the measures outlined in the PSAP, the GAPs Guide, and other public and private sector actions, when implemented, can be effective in reducing the likelihood of microbial contamination of fresh produce. However, the fact that outbreaks of foodborne illness associated with fresh produce continue to occur supports the need for a close examination of: The extent to which these measures have been implemented; whether they have been effective when implemented properly; and, what additional or different interventions might be appropriate to reduce the likelihood of future outbreaks.

We held the public hearings to share information about recent outbreaks of foodborne illness associated with microbial contamination of fresh produce, and to invite comments, data, and other scientific information about: Current practices used to grow, harvest, pack, hold, manufacture/process, and transport fresh produce; risk factors for contamination of fresh produce associated with these practices; and measures FDA could take to enhance the safety of fresh produce. The notice of hearings included a list of issues and questions to help focus comments and asked for scientific information and data. We received approximately 48 submissions from industry, government, universities, environmental groups, consumers, and consumer groups. Recurring comments included: The importance of activities to promote or enhance rapid, accurate traceback; strengthened coordination and communication between all sectors (*i.e.,* researchers, regulators, and industry) on available science and current unpublished data; and an integrated, multidisciplinary approach to identify best practices not currently incorporated by industry. A number of comments expressed concerns about the cost of third party audits and lack of standardization of such audits. Comments also indicated a desire for training. Comments were divided on whether we should continue to promote adoption of voluntary GAPs guidance or pursue rulemaking to establish mandatory requirements. Comments supporting mandatory requirements differed on what these requirements should look like; suggestions ranged from mandatory GAPs to a Hazard Analysis and Critical Control Point (HACCP)-like approach, or a combination of the two. Comments were in general agreement that, whatever regulatory approach was chosen, it should be consistent across the United States, based on sound science, and cover a broad range of commodities while being flexible enough to accommodate the needs of specific commodities, regions, operations, practices, and different sizes of operations.

D. Partnerships and Collaborations

1. Public and Private Standards

Because the GAPs Guide is voluntary, FDA and food safety partners in the public and private sectors have emphasized education and outreach to industry to promote adoption of the guidance. Buyer requirements that producers and other suppliers provide self- or third party audit verification that they are following the GAPs Guide have further promoted adoption of the guidance. We have worked with the fresh produce industry since the release of the GAPs Guide to promote its recommendations and to advance the scientific knowledge applicable to enhancing the safety of fresh produce. For example, in conjunction with the PSAP, we have provided technical assistance to industry in developing several industry commodity specific guidelines that cover the entire supply chain, including commodity-specific guidelines for melons, leafy greens, tomatoes, and green onions; these commodities together accounted for 70 percent of the foodborne outbreaks associated with produce between 1998 and 2009 (Ref. 3). These industry guidelines were in turn helpful to us in developing FDA's draft commodity specific guidances for the same commodities (see section II.B.4 of this document). Additional industry guidelines have been developed or are in progress for a broad range of commodities, including: strawberries, mushrooms, watermelon, potatoes, storage onions, and citrus.

We provided technical assistance to the Association of Food and Drug Officials (AFDO) to formulate a Model Code of Practice for the Production of Fresh Fruits and Vegetables (the Model Code) (Ref. 20). This work grew out of a request from the tomato industry in late 2006 to address outbreaks of foodborne illness attributed to fresh tomatoes. However, the AFDO Board believed that it was also important to address GAPs in the production of a broader range of fresh fruits and vegetables. Thus, AFDO convened a working group to develop a Model Code for produce safety during growing, harvesting, packing and holding that could be considered as a model for guidance and/or regulation by Federal and State regulatory bodies, and for collaboration among such parties and the industry. The Model Code does not address the additional processing steps that may occur at a fresh-cut or other processing facility, which is covered by the CGMPs in 21 CFR part 110. The Model Code focuses on minimizing the potential for contamination of fresh produce with pathogens.

Through cooperative agreement with Cornell University, FDA has, together with USDA AMS, established a jointly funded Produce Safety Alliance (PSA), based on the successful Seafood HACCP Alliance for Training and Education. The PSA is a public-private partnership that will develop and disseminate science- and risk-based training and education programs to provide produce farms with fundamental food safety knowledge, starting in advance of this proposed rule and continuing after the final rule is promulgated. The PSA includes active participation from the produce industry and academic institutions nationwide. The curriculum development process has already started, through establishment of topic-specific working committees charged with identifying challenges to understanding and implementing GAPs on farms. This first phase of work, in advance of a final rule, is intended to assist farms, especially small farms, in establishing appropriate food safety measures, consistent with the GAPs Guide and other existing guidances, so that they will be better positioned when we issue a final rule establishing produce safety standards under section 419 of the FD&C Act. As this rulemaking progresses, the PSA materials will be modified, as needed, to be consistent with the requirements in the rule.

2. Foodborne Illness Investigations—Environmental Assessment Model

An ''environmental assessment,'' in the foodborne illness outbreak or food contamination setting, means an investigation that is triggered by an outbreak of foodborne illness or food contamination incident with the purpose of determining how the environment may have contributed to the introduction or transmission of pathogens or other hazards that caused illness or contamination. In addition to our more traditional investigational team approach, during this process we work collaboratively with a number of experts from CDC, State and local agencies, and industry.

In 2010, we conducted an environmental assessment in response to a foodborne illness outbreak involving 33 cases of STEC O145 infection in 5 States. While we have not made a definitive determination regarding how or at what point in the supply chain *E. coli* O145 contamination occurred, this assessment was important in a number of respects. As mentioned above, we worked collaboratively with a number of experts from CDC, State and local agencies, and industry. Working with this team, we assessed potential sources of *E. coli* O145 not just in the field of interest, but in the larger growing area surrounding the field of interest, along with the potential for *E. coli* O145 to be transported from a source in the surrounding area to the field where implicated lettuce was grown. This highly collaborative, systems-based approach allowed for the discovery of important environmental risk factors that would not typically be explored by conventional investigation methods (Ref. 21). On December 29, 2010, we posted a report, entitled ''Environmental Assessment: Non-O157 Shiga Toxin-Producing *E. coli* (STEC): Findings and Potential Preventive Control Strategies'' (Ref. 21), outlining the environmental assessment approach used in this investigation, our observations and tentative conclusions.

In 2011, we conducted an environmental assessment in response to a foodborne illness outbreak involving a total of 139 persons infected with any of four outbreak-associated strains of *L. monocytogenes,* including 29 deaths, in 28 States (as of November 1, 2011). On October 19, 2011, we posted a report, entitled ''Environmental Assessment: Factors Potentially Contributing to the Contamination of Fresh Whole Cantaloupe Implicated in a Multi-State Outbreak of Listeriosis,'' providing an overview of the assessment process, potential contributing factors in this outbreak, and recommended measures firms should employ to prevent similar contamination (*http://www.fda.gov/Food/FoodSafety/FoodborneIllness/ucm276247.htm*). As discussed further in sections III.F and V.A.2.b.i of this document, this proposed rule would not apply to off-farm packing facilities such as the packing facility associated with this cantaloupe outbreak—such facilities would instead be subject to existing part 110 and section 418 of the FD&C Act. However, we include the findings of this environmental assessment here because the contributing factors are relevant to both on-farm and off-farm produce packing practices.

3. Produce Safety Initiative Assessments

In August 2006 we launched the Leafy Greens Safety Initiative (LGSI), a multi-year initiative which involved assessments of practices and conditions at select leafy greens farms and facilities in California (Ref. 22). In the summer of 2007, we began a multi-year Tomato Safety Initiative (TSI) to assess practices and conditions associated with growing and packing tomatoes on the Eastern Shore of Virginia, followed by assessments in three tomato growing areas in Florida (Ref. 23).

The initiatives were conducted as part of a strategy to reduce foodborne illness by focusing food safety efforts on specific products, practices, and growing areas that have been identified in past outbreak investigations. The initiatives were a collaborative effort between FDA and the State health and agriculture departments in California, Virginia, and Florida, in cooperation with several universities and members of the produce industry. Both initiatives contained several important components, the most visible of which was a series of assignments to the field to assess conditions and practices at farms and packing houses that could lead to contamination and to observe actions taken by growers and packers in response to these conditions. Other important components of the initiatives included continuing communication and outreach with the industry at all points along the supply chain, facilitating and promoting research to enhance leafy green and tomato safety, and strengthening collaboration between Federal, State, and local public health officials in disease detection and response.

Assessments of tomato packing facilities covered dump tank water quality parameters, employee hygiene, and facility cleaning and sanitation practices. Assessments of the farms addressed irrigation water sources (such as ponds and wells), source water and procedures for mixing crop chemicals, the potential impacts of weather events, such as drought and flooding, and animal proximity to growing fields. Assessments were scheduled to coincide with tomato production and harvest seasons on the Eastern Shore of Virginia and in three tomato producing regions in Florida.

Where the teams observed conditions or practices at one or more locations that might be improved, they shared those observations directly with the individual firm and also shared observations in general terms at a post-assessment meeting so that all interested parties could apply the findings to their operations. For example, we identified issues related to proximity of portable toilets to irrigating ponds and harvesting of drops at one or more locations. The teams recommended that portable toilets should be distanced from the irrigation pond and policies that forbid the harvesting of drops should be strictly enforced. We also shared preliminary observations through other venues, including a tomato research priorities meeting in College Park (hosted by Joint Institute for Food Safety and Applied Nutrition (JIFSAN) and the University of Florida's Institute of Food and Agricultural Sciences) (JIFSAN 2010 (update)), a Leafy Greens Research Needs workshop hosted by United Fresh in Herndon, VA (United Fresh 2008), and as technical assistance to public and private efforts to develop new or enhanced guidances.

4. Research

FDA researchers have focused on refining or developing methods to detect, isolate and subtype pathogens of concern in produce, to enhance our ability to analyze samples in support of our compliance activities. As resources permit, FDA scientists also directly investigate questions about factors contributing to produce contamination. We also supported extramural research and collaborations with other Federal agencies, academic institutions, and industry-supported entities to leverage research efforts, expertise, and resources (such as experimental stations for field research). This includes successful collaborations with USDA on research of mutual interest. To fill knowledge gaps, thus facilitating implementation of any new policies, we have initiated new agreements with USDA to conduct research in key areas such as agricultural water and soil amendments (Ref. 24). Specifically, FDA has provided approximately one million dollars to sponsor research at USDA

ARS and to develop a produce safety rule research network at the Western Center for Food Safety at University of California Davis. We intend these collaborative efforts to result in the collection of data that may help resolve questions about the necessary time between application of raw manure or contaminated water and safe harvest of produce in key agro-ecological growing conditions and for key crops. Our goal is for this research to result in suggested protocols that farms could follow in compliance with a final produce rule, and for this process to be duplicated for other crops and regions as further funding is secured. This FDA sponsored research was initiated to demonstrate the commitment of federal agencies to address the needs of farmers, to provide initial data to finalize study protocols for further research, and to attract matching funds from industry.

In partnership with academic institutions across the country, FDA has also created four Centers of Excellence (CoE), each housed at a university and charged with specific food-safety tasks (Ref. 25). In 2008, a 5-year cooperative agreement was awarded to the University of California, Davis (UC Davis) to establish the most recent of these CoEs, the Western Center for Food Safety (WCFS). Through this agreement, FDA has been able to leverage the resources and expertise of UC Davis to study the impact of the unique geography and ecology of the growing regions of the Western United States.

5. Engagement With Other Federal Agencies

FDA regularly consults and coordinates with other Federal agencies in the area of produce safety. Examples of these efforts can be found throughout this document and include collecting samples, sharing data, providing training and technical assistance to industry, and research. Our partnerships with USDA and CDC have been particularly valuable to our efforts.

6. Engagement with Industry and Academia

We regularly engage with experts in the produce industry and in academia. These engagements serve to both educate the industry about our thinking, activities, and expectations, and to educate us about current industry practices and academic efforts to enhance the safety of produce.

In addition to the collaborations mentioned above, we initiated multiple produce industry listening sessions across the country prior to the passage of FSMA. At these sessions, we provided local industry and academia an opportunity to ask questions and voice concerns about the potential for legislation impacting the produce industry. We visited a total of 13 States with significant produce production in 2010. FDA and USDA technical experts, scientists and managers participated in these meetings, and we were able to tour large and smaller scale farms, and talk to people with practical experience in production and implementing food safety programs on farms.

We also were involved with the Produce Safety Project (PSP), a research and advocacy organization based at Georgetown University and funded by the Pew Charitable Trust. The PSP provided four issue briefs (Ref. 26.Ref. 27.Ref. 28.Ref. 29) each focused on specific aspects of produce production, the risks they may represent, prevention and mitigation strategies to address these risks, and further research needs in the area. Further, PSP held 6 regional stakeholder discussion sessions to elicit comment and reaction from the produce industry, and to offer an avenue to speak directly to the documents' authors. A common message from the industry during these discussions was concern about food safety and a desire to know how to reduce risks. Small growers and packers in particular conveyed a need for information and technical support that would assist them in implementing food safety practices.

E. Current Industry Practices

In response to foodborne illnesses associated with produce in the mid 1990s, the produce industry developed produce safety guidance, engaged in outreach regarding produce safety best practices, developed compliance auditing programs, and funded produce safety research.

1. Industry Produce Safety Best Practices Guidance

In 1997, the International Fresh-cut Produce Association and the Western Growers Association published Voluntary Food Safety Guidelines for Fresh Produce, which provided generalized voluntary industry guidelines to minimize the potential for contamination for fresh produce in growing, packing, shipping and processing operations. After FDA issued our GAPs Guide, industry developed commodity specific guidances for various produce industry segments including: Commodity Specific Food Safety Guidelines for the Melon Supply Chain (2005), Commodity Specific Food Safety Guidelines for the Lettuce and Leafy Greens Supply Chain (2006), Commodity Specific Food Safety Guidelines for the Fresh Tomato Supply Chain (2006 1st Edition, 2008 2nd edition) and Commodity Specific Food Safety Guidelines for the Production, Harvest, Post-Harvest, and Valued-Added Unit Operations of Green Onions (2010). In addition, other industry segments including, but not limited to mushrooms, strawberries, watermelons, citrus, avocados, almonds, and dry bulb onions developed commodity specific guidances. The fresh-cut produce industry, via the International Fresh Produce Association, published in 1992 Food Safety Guidelines for the Fresh-cut Produce Industry and updated this publication periodically, with the 4th edition being published most recently in 2001.

2. Produce Industry Food Safety Compliance Auditing

Shortly after the FDA GAPs Guide was finalized, a number of retail produce buyers informed suppliers that as a condition of sale, their produce suppliers must follow, and be third party audited for conformance with, the FDA GAPs guide (Ref. 30). In 1999 USDA AMS began developing a GAPs and Good Handling Practices (GAP & GHP) Audit Verification Program, in response to requests from growers and the Association of Fruit and Vegetable Inspection and Standardization Agencies. The program, based on the GAPs Guide, was piloted in 2000 and fully available later that same year. In September 2001 the United Fresh Fruit and Vegetable Association published guidance entitled Food Safety Auditing Guidelines: Core Elements of Good Agricultural Practices for Fresh Fruits and Vegetables to provide the basis for GAPs audits in the produce industry. In 2011 the United Fresh Produce Association published a Harmonized GAPs Standard for use by producers and third party auditors in the fresh produce industry.

In 2007 leafy greens growers in California, with the assistance of the USDA AMS and CDFA, developed and implemented the California Leafy Greens Marketing Agreement (CA LGMA) (Ref. 31). The objective of the CA LGMA is to protect public health via compliance with the food safety practices accepted by the LGMA board, verified through mandatory government audits of members and signatories to the agreement by CDFA auditors trained and licensed by USDA AMS (Ref. 31). In 2007 leafy greens growers in Arizona also adopted a similar marketing agreement and audit structure for their growers (Ref. 32). At the request of industry, the USDA AMS in 2009 held seven hearings throughout the United

States to solicit input from the leafy greens industries across the U.S. regarding their desire to develop a proposed national marketing agreement for leafy greens (74 FR 45565). A decision regarding the proposed USDA AMS national marketing agreement for leafy greens is currently pending.

In 2007, the Florida Legislature passed a law that provided the Department of Agriculture and Consumer Services with the authority to address safety concerns related to fresh tomatoes. Implementing regulations which became effective on July 1, 2008 (Florida Tomato Inspection Regulation 5G–6, 2007) adopted and incorporated by reference almost all of the recommendations in the Commodity Specific Food Safety Guidelines for the Fresh Tomato Supply Chain, 2nd Edition (July 2008).

GAPs implementation and GAPs audits have now become common components of purchase specifications for produce in some market segments, and have been a significant force in increasing awareness of GAPs and promoting their implementation (Ref. 33). However, growers and packers who sell product through direct marketing channels, or to buyers who do not include GAPs as a condition of sale, may be less familiar with GAPs.

3. Produce Industry Produce Safety Education Outreach

In addition to participation in the PSA housed at Cornell University (discussed above in section II.D. of this document), the produce industry promoted adoption and implementation of the recommendations in the FDA GAPs Guide through education and outreach efforts in cooperation with the land grant universities. The National GAPs Program at Cornell University, with collaborators at other land grant universities, developed a series of publications to train domestic growers and packers on the key principles of produce safety, including: Food Safety Begins on the Farm: A Grower's Guide (2000); Food Safety Begins on the Farm: A Grower Self Assessment of Food Safety Risks (2003); and, Fruits, Vegetables, and Food Safety: Health and Hygiene on the Farm (2004). These publications and others developed by land grant universities throughout the United States have been used to train the produce industry on produce safety best practices.

F. 2010 Federal Register Notice and Preliminary Stakeholder Comments

On February 23, 2010, we published in the **Federal Register** (75 FR 8086; 2010 FR notice) a notice opening a docket to obtain information about current practices and conditions for the production and packing of fresh produce. On May 20, 2010, we extended the original 90-day comment period for the docket until July 23, 2010 (75 FR 28263). We established this docket to provide an opportunity for interested parties to provide information and share views that would inform the development of (1) safety standards for fresh produce at the farm and packing house and (2) strategies and cooperative efforts to ensure compliance.

In particular, we welcomed input on these general categories: (1) Role of the good agricultural practice recommendations in the GAPs Guide; (2) Standards for domestic and foreign growers and packers; (3) Identification and prioritization of risk factors; (4) Environmental assessment of hazards and possible pathways of contamination; (5) The impact of scale/size of growing operations on the nature and degree of possible food safety hazards; (6) Methods to tailor preventive controls to particular hazards and conditions affecting an operation; (7) Possible approaches to tailoring preventive controls to the scale of an operation so that the controls achieve an appropriate level of food safety protection and are feasible for a wide range of large and small operations; (8) Coordination of produce food safety practices and sustainable and/or organic production methods; (9) Coordination of produce food safety practices and environmental and/or conservation goals or practices; (10) Coordination of produce food safety practices and Federal, state, local and tribal government statutes and regulations; (11) Microbial testing; (12) Postharvest operations and the role of the CGMPs in 21 CFR part 110; (13) Records and other documentation that would be useful to industry and regulators in ensuring the safety of fresh produce; and (14) Strategies to enhance compliance.

We further advised that information previously submitted to the dockets requesting comments on the draft commodity-specific guidances (CSGs), or to the docket requesting comments and scientific data and information to update the GAPs Guide, would be considered in this rulemaking and need not be resubmitted. Comments submitted to these dockets, *i.e.,* dockets on the GAPs Guide update and draft CSGs, as well as comments at the Sprouts Public Meeting and Produce Safety Hearings, are discussed in sections II.B. and II.D. of this document.

In response to the 2010 FR notice, we received about 880 comments from consumers, farmers and producers, industry groups and trade associations, consumer groups, environmental groups, academia, retail establishments, packers and handlers, food markets and coops, laboratories and public health facilities, and federal, state, local and foreign governments. The USDA Agricultural Marketing Service (AMS) submitted a record of their public hearings related to their proposed voluntary national marketing agreement for leafy green vegetables (NLGMA) (74 FR 45565, September 3, 2009 and 74 FR 48423, September 23, 2009), and requested that we consider the contents of that record (which included testimony, exhibits, and written arguments or briefs based on evidence received at the public hearing) in our deliberations to develop safety standards for fresh produce. A summary of general comments received is presented in this section while specific comments relevant to the issues addressed in this proposed rule are discussed in sections V.C through V.R of this document.

1. Comments on Impact, Flexibility and Transparency

Overall, a majority of stakeholders, including farmers, producers, consumers and industry, expressed concern about the scope and impact of regulation on the livelihoods of those who produce food and on their ability to produce food in an economically-feasible manner. Most comments supported a food safety system, grounded in science, for the production of produce in a fair and equitable manner for both domestic and imports. Comments noted that regulations developed should be science-based and provide for producers to manage risks in a manner appropriate to their operations. Several comments maintained that risk assessments, hazard assessments, operational assessments and development of food safety plans are vital tools for farmers to be able to demonstrate that the food safety practices they employ are effective. Conversely, others questioned the need for some industry segments, such as small farms or growers of ''low risk'' commodities to establish food safety plans. A majority of comments also stated that research is needed on various issues relevant to produce safety, including water quality, soil amendments, animals (both wildlife and domesticated), and worker health and hygiene. Comments urged the agency to tailor regulations to reflect variables such as farm size, markets served, growing conditions, and risk. In addition, comments highlighted the importance of transparency in the

development and implementation of food safety standards, and expressed that transparency provides regulators, buyers, and the public with the confidence they need to ensure that all reasonable and required practices have been put in place and that any specific producer or packer of produce is in compliance with required food safety practices. 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. As discussed in section IV below, 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. We recognize the need to incorporate appropriate flexibility within regulations to reflect the diversity of commodities and associated processes, practices, and conditions covered within the scope of this rule. For example, exemptions based on monetary value of food sold by the farm and direct farm marketing, commercial processing of commodities, and other criteria are reflected in proposed subpart A. Under certain specified conditions, qualified exemptions and associated modified requirements in a calendar year are also provided under proposed subpart A. In addition, proposed § 112.12 would establish a framework for alternatives to certain requirements of the rule. We realize that numerous differences exist among practices based on risk or agro-ecological conditions and therefore alternatives to certain requirements would be permitted when adequate and documented scientific data or information support such alternatives. Similarly, proposed subpart P sets procedures for a State or foreign country to request a variance from one or more requirements of this part when certain conditions are met, as required by Section 419(c)(2) of the FD&C Act. For example, a State or foreign country may consider that the historical performance of an industry within their jurisdiction (*e.g.,* as indicated by the epidemiological record) and the combination of measures taken by that industry merits requesting a variance from some or all provisions of this proposed rule. In requesting a variance, among other things, the State or foreign country would submit information that, while the procedures, processes and practices to be followed under the variance would be different from those prescribed in this proposed rule, the requested variance is reasonably likely to ensure that the produce is not adulterated under section 402 of the FD&C Act and provide the same level of public health protection as the requirements of the final regulations (see proposed 112.173). FDA would encourage consideration of these kinds of submissions.

Furthermore, in addition to soliciting comments on the proposed regulation through this notice, we will be holding public meetings in diverse geographic areas of the United States to provide persons in different regions an opportunity to comment, as required under Section 419(a)(2) of the FD&C Act.

2. Comments on Environmental Considerations

Several comments pointed out that there are a number of state and federal laws and programs that relate to environmental stewardship, and noted that environmental conservation and food safety are not necessarily cross-competing goals. Comments favored a uniform regulatory approach among Federal, State, local and tribal governments' statutes and regulations, and recommended that we consider the work of other Federal agencies, including the Environmental Protection Agency, the Department of Agriculture, and the Department of the Interior in developing proposed requirements for produce to ensure such requirements do not unnecessarily inhibit co-management of food safety and environmental concerns. In this regard, a few comments stated that while co-management of food safety and sustainability may be considered, ultimately, food safety has to be top priority and it is unacceptable to sell unsafe food to customers.

Section 419(a)(3)(D) of the FD&C Act directs that this proposed rule take into consideration, consistent with ensuring enforceable public health protection, conservation and environmental practice standards and policies established by Federal natural resource conservation, wildlife conservation, and environmental agencies. As discussed further in Sections III.A.8 and V.I, we consulted with several Federal agencies in order to take into consideration conservation and environmental practice standards and policies established by those agencies. FDA also plans to work closely with Federal, State, and local agencies in implementing the final rule.

3. Comments on Guidance and Education

A majority of comments also expressed the need for guidance to assist stakeholders in implementing the requirements established in final regulations. Moreover, several comments stressed the importance of educational programs and incentives in any effective food safety system.

Section 419(e) of the FD&C Act requires FDA to publish updated good agricultural practices and guidance for the safe production and harvesting of specific types of fresh produce, in consultation with the Secretary of Agriculture, representatives of State departments of agriculture, farmer representatives, and various types of entities engaged in the production and harvesting or importing of fruits and vegetables that are raw agricultural commodities, including small businesses. In addition, section 419(e) of the FD&C Act requires FDA to conduct education and outreach regarding this guidance through public meetings in diverse geographical regions. FDA intends to provide ample opportunity for public consultation and input and will strive to develop stronger partnerships with the private sector to ensure optimal use of resources.

4. Comments Related to Foreign Producers

A number of foreign governments expressed concerns with the foreign producers' ability to comply with and FDA's enforcement of the regulation, stressing the need for transparency. Some comments requested we consider convergence with existing private schemes, such as the Global Food Safety Initiative and Global G.A.P to avoid duplication of efforts while others urged us to consider recognition of foreign governments' produce safety initiatives.

In implementing a final rule based on this proposed rule, we intend to provide equal treatment in the application, compliance, and enforcement of the proposed standards for foreign and domestic facilities. Recognizing that foreign farms in some countries may have difficulty in understanding the rule's applicability to them, we will partner with stakeholders to identify areas for outreach and technical cooperation to achieve greater understanding of the proposed provisions.

Furthermore, consistent with section 419(c)(2) of the FD&C Act, in proposed subpart P, we establish a procedure

whereby a State or foreign country could request a variance from one or more requirements proposed in the rule, where the State or foreign country determines that (1) the variance is necessary in light of local growing conditions; and (2) 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 FD&C Act, and to provide the same level of public health protection as the requirements of this rule (see section V.P. of this document).

G. White House Food Safety Working Group

In 2009, President Obama established a White House Food Safety Working Group to identify measures needed to upgrade our food safety laws for the 21st Century, coordinate Federal efforts, and develop short- and long-term agendas to make food safer. Specific objectives of this workgroup included: Fostering coordination of food safety efforts throughout the government and ensuring laws are being adequately enforced to keep the American people safe from foodborne illness. The workgroup was co-chaired by the Secretaries of the HHS and USDA. Participating agencies included FDA, USDA's Food Safety and Inspection Service (FSIS), CDC, the Department of Homeland Security, the Department of Commerce, the Department of State, EPA, and several offices of the White House.

On July 7, 2009, the workgroup released its report ''Implementing a National Public Health Approach to Food Safety: Report to the President.'' This report included recommendations for a new public health-focused approach to the safety of all food based on three core principles: (1) Prioritizing prevention, (2) strengthening surveillance and enforcement, and (3) improving response and recovery. Workgroup recommendations and White House directives specific to produce included (1) issuing commodity-specific guidances to reduce the likelihood of microbial contamination in the production and distribution of tomatoes, melons, and leafy greens; and (2) taking steps (including seeking public comment) to establish required practices through regulation. The numerous steps we have taken in response to these directives are described throughout this section.

H. Other Related Issues

1. Tracking and Tracing of Produce

Our regulations in 21 CFR part 1, subpart J require that persons who manufacture, process, pack, transport, distribute, receive, hold, or import food in the United States establish and maintain records identifying the immediate previous sources and immediate subsequent recipients of food. During an outbreak of foodborne illness, these records can help determine the source of the food implicated in the outbreak. Farms are excluded from the requirements of part 1, subpart J. We recently held public meetings to stimulate and focus a discussion about mechanisms to enhance product tracing systems for food in general (74 FR 56843; November 3, 2009) and for produce in particular (73 FR 55115; September 24, 2008). Section 204 of FSMA now directs us to take a variety of different actions that will enhance our ability to track and trace foods, including to establish pilot projects to explore and evaluate methods to rapidly and effectively identify recipients of food to prevent or control a foodborne illness outbreak. Further efforts to enhance the tracking and tracing of food are outside of the scope of this proposed rule.

2. Transportation of Food

On April 30, 2010 (75 FR 22713), we published in the **Federal Register** an Advance Notice of Proposed Rulemaking (ANPRM) as a first step in implementing the Sanitary Food Transportation Act of 2005 (SFTA). SFTA requires the Secretary of HHS to issue regulations setting forth sanitary transportation practices to be followed by shippers, carriers by motor vehicle or rail vehicle, receivers, and others engaged in food transport. Section 111 of FSMA directs us to promulgate regulations to implement SFTA. We intend to focus our efforts directed to sanitary transportation practices as a separate rulemaking, already underway under the ANPRM. However, such efforts are outside of the scope of this proposed rule.

III. Legal Authority

FDA is proposing this regulation under the FD&C Act as amended by FSMA, and the Public Health Service Act (PHS Act).

A. Section 105 of FSMA and Section 419 of the FD&C Act

On January 4, 2011, the FDA Food Safety Modernization Act (FSMA) (Pub. L. 111–353) was signed into law. Section 105 of FSMA, Standards for Produce Safety, among other things, amends the FD&C Act to create a new section 419 with the same name.

Section 419(a)(1)(A) of the FD&C Act directs the Secretary of HHS, ''in coordination with the Secretary of Agriculture and representatives of State departments of agriculture (including with regard to the national organic program established under the Organic Foods Production Act of 1990), and in consultation with the Secretary of Homeland Security,'' to ''publish a notice of proposed rulemaking to establish science-based minimum standards for the safe production and harvesting of those types of fruits and vegetables, including specific mixes or categories of fruits and vegetables, that are raw agricultural commodities for which the Secretary has determined that such standards minimize the risk of serious adverse health consequences or death.'' In addition to this broad direction in section 419(a)(1)(A), section 419(a)(3) establishes more specific requirements for the content of the proposed rule, including that the proposed rule:

- ''[P]rovide sufficient flexibility to be applicable to various types of entities engaged in the production and harvesting of fruits and vegetables that are raw agricultural commodities, including small businesses and entities that sell directly to consumers, and be appropriate to the scale and diversity of the production and harvesting of such commodities'' (section 419(a)(3)(A));
- ''[I]nclude, with respect to growing, harvesting, sorting, packing, and storage operations, science-based minimum standards related to soil amendments, hygiene, packaging, temperature controls, animals in the growing area, and water'' (section 419(a)(3)(B));
- ''[C]onsider hazards that occur naturally, may be unintentionally introduced, or may be intentionally introduced, including by acts of terrorism'' (section 419(a)(3)(C));
- ''[T]ake into consideration, consistent with ensuring enforceable public health protection, conservation and environmental practice standards and policies established by Federal natural resource conservation, wildlife conservation, and environmental agencies'' (section 419(a)(3)(D));
- ''[I]n the case of production that is certified organic, not include any requirements that conflict with or duplicate the requirements of the national organic program established under the Organic Foods Production Act of 1990, while providing the same level of public health protection as the requirements under guidance documents, including guidance

documents regarding action levels, and regulations under the FDA Food Safety Modernization Act'' (section 419(a)(3)(E)); and

- ''[D]efine, for purposes of [section 419], the terms 'small business' and 'very small business'' (section 419(a)(3)(F)).

Furthermore, section 419(b) of the FD&C Act establishes additional requirements that the final regulation:

- ''[P]rovide for minimum science-based standards for those types of fruits and vegetables, including specific mixes or categories of fruits and vegetables, that are raw agricultural commodities, based on known safety risks, which may include a history of foodborne illness outbreaks'' (section 419(b)(1));
- ''[P]rovide for coordination of education and enforcement activities by State and local officials, as designated by the Governors of the respective States or the appropriate elected State official as recognized by State statute'' (section 419(b)(2)(A)); and
- ''[I]nclude a description of the variance process under [section 419(c)] and the types of permissible variances the Secretary may grant'' (section 419(b)(2)(B)).

In section 419(c), the FD&C Act establishes criteria for the final regulation, including that the final regulation:

- ''[S]et forth those procedures, processes, and practices that the Secretary determines to minimize the risk of serious adverse health consequences or death, including procedures, processes, and practices that the Secretary determines to be reasonably necessary to prevent the introduction of known or reasonably foreseeable biological, chemical, and physical hazards, including hazards that occur naturally, may be unintentionally introduced, or may be intentionally introduced, including by acts of terrorism, into fruits and vegetables, including specific mixes or categories of fruits and vegetables, that are raw agricultural commodities and to provide reasonable assurances that the produce is not adulterated under section 402'' (section 419(c)(1)(A));
- ''[P]rovide sufficient flexibility to be practicable for all sizes and types of businesses, including small businesses such as a small food processing facility co-located on a farm'' (section 419(c)(1)(B));
- ''[C]omply with chapter 35 of title 44, United States Code (commonly known as the 'Paperwork Reduction Act'), with special attention to minimizing the burden (as defined in section 3502(2) of such Act) on the business, and collection of information (as defined in section 3502(3) of such Act), associated with such regulations'' (section 419(c)(1)(C));
- ''[A]cknowledge differences in risk and minimize, as appropriate, the number of separate standards that apply to separate foods'' (section 419(c)(1)(D));
- ''[N]ot require a business to hire a consultant or other third party to identify, implement, certify, compliance with these procedures, processes, and practices, except in the case of negotiated enforcement resolutions that may require such a consultant or third party'' (section 419(c)(1)(E);
- ''[P]ermit States and foreign countries from which food is imported into the United States to request from the Secretary variances from the requirements of the regulations, subject to [section 419(c)(2) of the FD&C Act], where the State or foreign country determines that the variance is necessary in light of local growing conditions and that 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 FD&C Act] and to provide the same level of public health protection as the requirements of the regulations adopted under [section 419(b) of the FD&C Act]'' (section 419(c)(1)(F)); and
- Establish requirements relating to variances, including that:
  - ''A State or foreign country from which food is imported into the United States may in writing request a variance from the Secretary. Such request shall describe the variance requested and present information demonstrating that the variance does not increase the likelihood that the food for which the variance is requested will be adulterated under section 402, and that the variance provides the same level of public health protection as the requirements of the regulations adopted under [section 419(b) of the FD&C Act]. The Secretary shall review such requests in a reasonable timeframe'' (section 419(c)(2)(A)).
  - ''The Secretary may approve a variance in whole or in part, as appropriate, and may specify the scope of applicability of a variance to other similarly situated persons'' (section 419(c)(2)(B)).
  - ''The Secretary may deny a variance request if the Secretary determines that such variance is not reasonably likely to ensure that the food is not adulterated under section 402 and is not reasonably likely to provide the same level of public health protection as the requirements of the regulation adopted under [section 419(b) of the FD&C Act]. The Secretary shall notify the person requesting such variance of the reasons for the denial'' (section 419(c)(2)(C)).
  - ''The Secretary, after notice and an opportunity for a hearing, may modify or revoke a variance if the Secretary determines that such variance is not reasonably likely to ensure that the food is not adulterated under section 402 and is not reasonably likely to provide the same level of public health protection as the requirements of the regulations adopted under [section 419(b) of the FD&C Act]'' (section 419(c)(2)(D)).

In addition, section 105(c) of FSMA creates a new section 301(vv) in the FD&C Act (21 U.S.C. 331(vv)) to prohibit ''[t]he failure to comply with the requirements under section 419 [of the FD&C Act].''

1. Coordination and Consultation Requirements

Consistent with section 419(a)(1)(A) of the FD&C Act, FDA has coordinated with the Secretary of Agriculture and representatives of State departments of agriculture (Ref. 34. Ref. 35) and consulted with the Secretary of Homeland Security regarding this proposed rule.

2. Definitions of Small and Very Small Businesses

Section 419(a)(3)(F) of the FD&C Act requires that the regulations define the terms ''small business'' and ''very small business.'' These terms are significant because section 419 of FSMA contains provisions specific to such entities.

- ''With respect to small and very small businesses* * * that produce and harvest those types of fruits and vegetables that are raw agricultural commodities that the Secretary has determined are low risk and do not present a risk of serious adverse health consequences or death, the Secretary may determine not to include production and harvesting of such fruits and vegetables in such rulemaking, or may modify the applicable requirements of regulations promulgated pursuant to [section 419]'' (section 419(a)(1)(B) of the FD&C Act).
- ''[T]he regulations promulgated under [section 419 of the FD&C Act] shall apply to a small business* * * after the date that is 1 year after the effective date of the final regulation* * * [and] to a very small business* * * after the date that is 2 years after the effective date of the final regulation'' (section 419(b)(3) of the FD&C Act).

In section V.A. of this document, we discuss our proposed definitions of small and very small business. In section IV.K. of this document, we discuss our proposal to establish compliance dates for small and very small businesses that are three and four years, respectively, after the effective

date of the final regulation, with additional, more extended compliance dates for certain proposed provisions related to water. FDA has tentatively decided not to exempt or modify the requirements of the proposed rule with respect to small and very small businesses that produce and harvest certain types of produce based on a determination that such types of produce are low risk and do not present a risk of serious adverse health consequences or death using the discretionary authority provided by section 419(a)(1)(B). It is not necessary to use this discretionary authority in part because, as discussed in section V.A. of this document, FDA proposes in § 112.2 to exclude certain types of low risk produce from the coverage of this rule without regard to the business size of the farm producing and harvesting such produce. As discussed in section IV.C.2. of this document, these exclusions are based on our tentative conclusion that science-based minimum standards to minimize the risk of serious adverse health consequences or death from biological hazards in these commodities are not warranted. Another reason it is not necessary to use the discretionary authority in section 419(a)(1)(B) is because, as discussed in section V.A. of this document, FDA proposes in § 112.4 to apply this regulation only to businesses with an average annual monetary value of food sold during the previous three-year period of more than $25,000 on a rolling basis, based on a tentative conclusion that businesses with $25,000 or less in sales do not contribute significantly to the produce market (1.5% of covered produce acres) and, therefore, to the volume of production that could become contaminated. Accordingly, we tentatively conclude that imposing the proposed requirements on these businesses is not warranted because it would have little measurable public health impact. We note that such farms would continue to be subject to the applicable requirements of the FD&C Act.

3. Exemptions and Exceptions

Section 419(f)(1) of the FD&C Act establishes an exemption from the requirements under section 419 based on average annual monetary value of the food sold directly to ''qualified end-users'' (as defined in section 419(f)(4)) as compared to all other buyers and average annual monetary value of all food sold. Section 419(f)(2) establishes requirements for consumer notifications with respect to food from exempt farms, and section 419(f)(3) provides that the Secretary may withdraw the exemption in specified circumstances. In sections V.A and V.R of this document, we discuss proposed §§ 112.5 and 112.6, and subpart R, respectively, which would implement these provisions of the FD&C Act.

Section 419(g) of the FD&C Act states ''[t]his section shall not apply to produce that is produced by an individual for personal consumption.'' In section V.A. of this document, we discuss proposed § 112.2(a)(2), which would implement this provision.

Section 419(h) of the FD&C Act states ''[t]his section shall not apply to activities of a facility that are subject to section 418.'' In sections III.F and V.A.2.b.i of this document we discuss proposed § 112.4(a), which would implement this provision.

4. Intentional Adulteration

FDA proposes to implement section 105 of FSMA in two regulations, rather than a single regulation that covers all hazards relevant to produce. This rulemaking is not intended to address hazards ''that may be intentionally introduced, including by acts of terrorism.'' (§ 419(a)(3)(C) and (c)(1)(A) of the FD&C Act). FDA plans to implement section 105 of FSMA regarding such hazards in a separate rulemaking in the future, and intends to consult with the Secretary of Homeland Security in that rulemaking, as required by § 419(a)(1)(A) of the FD&C Act. FDA tentatively concludes that intentional hazards likely will require different kinds of controls and would be best addressed in a separate rulemaking.

5. Science-Based Minimum Standards Related to Specific Topics

Consistent with the provisions in Section 419(a)(3)(B) of the FD&C Act that requires us to establish ''science-based minimum standards related to soil amendments, hygiene, packaging, temperature controls, animals in the growing area, and water,'' this proposed rule addresses specific topics relevant to production and harvesting of produce on farms. We address standards related to soil amendments in subpart F; standards for hygiene in subpart D, standards for animals in the growing area in subpart I; and standards for water in subpart E. We address packaging as part of our proposed standards for harvest, packing, and holding activities in subpart K; and temperature controls as part of our proposed standards for agricultural water in subpart E.

6. Providing Sufficient Flexibility To Be Practicable

As required by section 419(a)(3)(A) and (c)(1)(B), this proposed rule would provide sufficient flexibility to be practicable for all sizes and types of entities engaged in the production and harvesting of fruits and vegetables that are raw agricultural commodities, including small businesses and entities that sell directly to consumers, and is appropriate to the scale and diversity of the production and harvesting of such commodities.

As discussed in section IV of this document, we have chosen a regulatory approach that provides significant flexibility. We propose a variety of different types of measures (including GMP-type measures, numerical standards, requirements to monitor and take action under certain circumstances, and written plans) to tailor the requirements of the proposed rule appropriately and to be practical for the diversity of farms and commodities that would be covered by the proposed rule.

Wherever possible, we have also attempted to fashion this regulation to be as flexible as possible to accommodate future changes in science and technology and the particularities of local growing conditions and commodities. As discussed in section V.B of this document, in proposed § 112.12, we list the specific requirements established in this rule for which we would allow alternatives to be established and used in appropriate circumstances. This provision would provide significant flexibility by allowing individual farms to develop alternative standards suitable to their operations with appropriate scientific support. In addition, consistent with sections 419(c)(1)(F) and (c)(2) of the FD&C Act, in proposed subpart P, we provide for a mechanism by which a State or a foreign country from which food is imported into the United States may request a variance from one or more requirements proposed in 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 Act and to provide the same level of public health protection as the requirements of this part. Proposed subpart P would provide additional flexibility for alternative practices to be used where appropriate to specific local growing conditions and commodities.

7. Use of Third Parties

In accordance with section 419(c)(1)(E) of the FD&C Act, we are not proposing to require a farm to hire a consultant or third party to identify, implement, certify, or comply with these produce safety standards. These standards are intended to be capable of implementation by those who engage in routine activities on the farm. As discussed in section II.D.1 and V.Q., FDA has, together with USDA AMS, established a jointly funded Produce Safety Alliance (PSA), a public-private partnership that will develop and disseminate science- and risk-based training and education programs to provide produce farms with fundamental food safety knowledge. Education and outreach through mechanisms like PSA and other sources of information that are familiar to the produce farming community (such as Cooperative Extension, land grant universities and trade associations) is the foundation of our intended compliance strategy. Through these mechanisms, FDA aims to assist farmers in gaining the food safety knowledge they will need to comply with the provisions of a final produce safety rule.

8. Consideration of Environmental Standards

As required by section 419(a)(3)(D), in developing these produce safety standards and consistent with ensuring enforceable public health protection, we took into consideration conservation and environmental practice standards and policies established by Federal natural resource conservation, wildlife conservation, and environmental agencies. In developing this rule, we consulted with USDA's National Organic Program and Natural Resources Conservation Service, U.S. Fish and Wildlife Service, and the EPA to take into consideration conservation and environmental practice standards and policies established by those agencies (Ref. 34). Our proposed requirements encourage the application of practices that can enhance food safety, including sustainable conservation practices. Additionally, as discussed in section V.E of this document, this proposed rule is designed to be compatible with existing conservation practices in the management of agricultural water systems. Moreover, as discussed in section V.I of this document, this proposed rule would not require the destruction of habitat or the clearing of farm borders around outdoor growing areas or drainages.

9. Consistency With National Organic Program

In accordance with section 419(a)(3)(E), this proposed rule does not include any requirements that conflict with or duplicate the requirements of the National Organic Program. In developing this proposed rule, we consulted with technical experts and representatives from the National Organic Program (Ref. 34). 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, proposed § 112.54(c) would establish multiple options for composting processes used to treat biological soil amendments of animal origin used to grow covered produce, including two options (§ 112.54(c)(1) and (2)) that are consistent with the options available to USDA-certified organic farms under the National Organic Program regulations in 7 CFR 205.203(c)(2).

As another 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. Proposed § 112.56(a)(1)(ii) would not require an 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 or after application. For certified organic farms growing produce that would be subject to this rule, the National Organic Program application intervals would run concurrently with the proposed application interval in this proposed rule, rather than consecutively. Organic farms (like other farms) using raw manure would either need to wait 9 months between application and harvest and use application methods meeting the proposed requirements for avoiding and minimizing contact between covered produce and raw manure, or apply the raw manure in a manner that does not contact covered produce during or after application. Doing so would not jeopardize their compliance with the requirements of the National Organic Program.

In addition, this proposed rule would establish in proposed § 112.163 that records kept for other purposes could be used to satisfy the recordkeeping requirements in this proposed rule. Accordingly, 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.

Further, while not critical to our conclusion regarding compliance with section 419(a)(3)(E) of the FD&C Act, we note that the provisions of the proposed rule are not in conflict with or duplicative of the non-binding recommendations of the National Organic Standards Board's Compost Tea Task Force (Ref. 36). Certified organic farms would be able to comply with the provisions of this proposed rule with respect to their use of agricultural teas while simultaneously meeting or exceeding the non-binding recommendations in the NOSB Compost Tea Task Force Report.

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.

10. Minimizing PRA burden

In implementing section 419 of the FD&C Act through this proposed rule, FDA has complied with chapter 35 of title 44, United States code (commonly known as the ''Paperwork Reduction Act'' (PRA)), with special attention to minimizing the burden (as defined in section 3502(2) of such Act (44 U.S.C. 3502(2)) on the facility, and collection of information (as defined in section 3502(3) of such Act (44 U.S.C. 3502(3)), associated with the proposed rule. Under section 3502(2) of the PRA, ''burden'' means the ''time, effort, or financial resources expended by persons to generate, maintain, or provide information to or for a Federal agency.'' Under section 3502(3) of the PRA, ''collection of information'' means, in relevant part, ''the obtaining, causing to be obtained, soliciting, or requiring the disclosure to third parties or the public, of facts or opinions by or for an agency, regardless of form or format, calling for * * * answers to identical questions

posed to, or identical reporting or recordkeeping requirements imposed on, ten or more persons.* * *'' In section X of this document, we discuss how this proposed rule complies with the requirements of the PRA. In addition, in implementing section 419 of the FD&C Act, we have paid special attention to minimizing burden and collection of information associated with this proposed rule.

As discussed above, we are proposing requirements that provide significant flexibility for different sizes and types of farms. By making these requirements flexible enough to be practicable for different sizes and types of farms, the proposed rule also avoids creating unnecessary information collection burden for entities, because farms should be able to tailor their recordkeeping to their specific circumstances while still complying with the requirements of the proposed rule.

In addition, as discussed in section IV.E. of this document, the only requirements we are proposing that constitute collections of information are those that are necessary to implement section 419 of the FD&C Act and for the efficient enforcement of the FD&C Act. We propose to require records under this rule only in instances where maintenance of detailed information is needed to keep track of measures directed at minimizing the risk of a known or reasonably foreseeable hazards, where identification of a pattern of problems is important to minimizing the risk of such hazards, or where they are important to facilitate verification and compliance with standards and this cannot be effectively done by means other than a review of records. These instances are discussed in more detail in section IV.E. of this document and throughout section V of this document. In addition, 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.

B. Other Provisions of the Federal Food, Drug, and Cosmetic Act

FDA's authority for this proposed rule also derives from sections 402(a)(3), 402(a)(4), and 701(a) of the FD&C Act. Section 402(a)(3) of the FD&C Act provides that a food is adulterated if it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food. Section 402(a)(4) of the FD&C Act provides that a food is adulterated if it 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. Under section 701(a) of the FD&C Act, FDA is authorized to issue regulations for the efficient enforcement of the FD&C Act. The proposed rule includes many requirements that are necessary to prevent food from being adulterated (either because it consists in whole or in part of a filthy, putrid, or decomposed substance, because it is otherwise unfit for food, or because it has been held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health). A regulation that requires measures to prevent food from being held under insanitary conditions whereby either of the proscribed results may occur allows for the efficient enforcement of the FD&C Act. See, *e.g.,* regulations to require HACCP systems for fish and fishery products (21 CFR Part 123) and juice (part 120), regulations to require a safe handling statement on cartons of shell eggs that have not been treated to destroy Salmonella organisms and to require refrigeration of shell eggs held for retail distribution (parts 101 and 115), and regulations for the production, storage, and transportation of shell eggs (part 118).

C. The Public Health Service Act

In addition to the FD&C Act, FDA's legal authority for the proposed rule derives from the PHS Act. Authority under the PHS Act for the proposed regulations is derived from the provisions of sections 311, 361, and 368 (42 U.S.C. 243, 264, and 271) that relate to communicable disease. The PHS Act authorizes the Secretary to make and enforce such regulations as ''are necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States * * * or from one State * * * into any other State'' (section 361(a) of the PHS Act). (See sec. 1, Reorg. Plan No. 3 of 1966 at 42 U.S.C. 202 for transfer of authority from the Surgeon General to the Secretary; see 21 CFR 5.10(a)(4) for delegation from the Secretary to FDA.) The provisions in the proposed rule are necessary to prevent food from being contaminated with human pathogens such as Salmonella, L. monocytogenes, and E. coli O157, and therefore to prevent the introduction, transmission, or spread of communicable disease from foreign countries into the United States, or from one state in the United States to another. As discussed in section II of this document, without appropriate prevention steps, certain practices on farms can lead to the contamination of food with pathogens, increasing the likelihood of foodborne illness. We tentatively conclude that the proposed provisions in this document are necessary to prevent the spread of communicable disease and to prevent food from containing filthy, putrid, or decomposed substances; being otherwise unfit for food, or being 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.

D. Legal Authority for Records Requirements

We are proposing to use our authority under the FD&C Act and the PHS Act to institute certain records requirements as follows:

- For covered produce that is exempted from the requirements of the proposed rule because it receives commercial processing that adequately reduces the presence of microorganisms of public health significance, the identity of the recipient that receives this produce (§ 112.2);
- For alternatives that farms may establish and use for certain requirements of the proposed rule, the scientific data and information used to support such alternatives (§ 112.12);
- Documentation of compliance with certain requirements related to training of personnel (§ 112.30); water monitoring and testing (§ 112.50); biological soil amendments of animal origin (§ 112.60); sanitizing of equipment used in growing operations for sprouts, or for covered harvest, packing, or holding activities (§ 112.140), and sprouts (§ 112.150); and
- General requirements in subpart O that apply to records required to be established and maintained.

As discussed further in sections V.A., V.B., V.C., V.E., V.F., V.L., V.M., and V.O. of this document, the proposed recordkeeping requirements are necessary for covered farms to ensure their own compliance with these aspects of the proposed rule and for FDA to ensure that covered farms are complying with the same aspects of the proposed rule. Therefore, these proposed requirements are necessary for the efficient enforcement of the FD&C Act because they will aid both farms and FDA in ensuring that food is not adulterated, and are necessary to prevent the spread of communicable disease because they will aid both farms and FDA in ensuring that food does not

become contaminated with human pathogens.

In addition to having the authority under the FD&C Act and the PHS Act to require this recordkeeping, we also have the authority to require access to the records. Because the underlying requirements are necessary to minimize the likelihood of adulteration and the spread of communicable disease, access to records that demonstrate that a farm has followed those requirements is essential to confirm compliance and achieve the full benefits of the rule. We also have the authority to copy the records when necessary. We may consider it necessary to copy records when, for example, our investigator may need assistance in reviewing a certain record from relevant experts in headquarters. If we are unable to copy the records, we would have to rely solely on our investigators' notes and reports when drawing conclusions. In addition, copying records will facilitate follow up regulatory actions. Therefore, we have tentatively concluded that the ability to access and copy records is necessary to enforce the rule and prevent adulteration and the spread of communicable disease. In other relevant sections of this document, we explain in more detail the recordkeeping provisions that we believe are necessary and, because they are limited to what is necessary, that we believe do not create an unreasonable recordkeeping burden.

F. Intrastate Activities

FDA tentatively concludes that the provisions in the proposed rule should be applicable to activities that are intrastate in character. The plain language of section 419 of the FD&C Act directs FDA to establish science-based minimum standards for the safe production and harvesting of fruit and vegetable RACs to minimize the risk of serious adverse health consequences or death. Section 419 does not include a limitation to interstate commerce. In addition, the exemption provided in section 419(f) of the FD&C Act, based in part on the proportion of a farm's sales made to restaurants or retail food establishments intrastate or within 275 miles, suggests that Congress intended the rule issued under section 419 to apply to intrastate commerce because otherwise there would be no need to provide an exemption for farms whose sales are intrastate in character. In addition, section 301(vv) of the FD&C Act provides that ''[t]he failure to comply with the requirements under section 419'', or the causing thereof, is a prohibited act. Section 301(vv) does not require an interstate commerce nexus. Notably, other subsections in section 301 of the FD&C Act, and section 304 of the FD&C Act (21 U.S.C. 334) demonstrate that Congress has included a specific interstate commerce nexus in the provisions of the FD&C Act when that is its intent. Accordingly, it is reasonable to interpret sections 419 and 301(vv) of the FD&C Act as not limiting the application of the proposed rule only to those farms with a direct connection to interstate commerce.

FDA is mindful that its interpretation of FSMA and the FD&C Act should not cast doubt on the constitutionality of those statutes. (See *Solid Waste Agency of Northern Cook County* v. *U.S.,* 531 U.S. 159 (2001)). FDA has considered the relevant provisions of FSMA and the FD&C Act, FDA's responsibilities in implementing those statutes, and the law interpreting the commerce clause of the Constitution (Article I, section 8). Congress's power to legislate under the commerce clause is very broad. However, such power is not without limits, see *United States v. Lopez,* 514 U.S. 549, 567 (1995); *U.S.* v. *Morrison,* 529 U.S. 598, 618 (2000), and these limits have been construed in light of relevant and enduring precedents. In particular, in *Lopez,* supra, the Supreme Court acknowledged the continuing vitality of *Wickard* v. *Filburn,* 317 U.S. 111 (1942), noting that ''although Filburn's own contribution to the demand for wheat may have been trivial by itself, that was not 'enough to remove him from the scope of Federal regulation where, as here, his contribution, taken together with that of many others similarly situated, is far from trivial.''' (514 U.S. at 556.) See also *Gonzales* v. *Raich,* 545 U.S. 1, 17–25 (2005). This principle applies to the application of sections 419 and 301(vv) of the FD&C Act, as added by section 105 of FSMA. Accordingly, given the collective impact on commerce of farms that grow, harvest, pack, or hold food that is sold in ''intrastate'' commerce, FDA tentatively concludes that such farms should be subject to the proposed rule unless an exemption from the rule applies (for example, if the farm is eligible for the qualified exemption in proposed § 112.5, or if the farm only grows produce exempt from the regulation under one of the exemptions in proposed § 112.2). This outcome is consistent with section 709 of the FD&C Act (21 U.S.C. 379a), which states that in any action to enforce the act's requirements respecting foods, drugs, devices, and cosmetics, any necessary connection with interstate commerce is presumed. Likewise, this outcome is consistent with FSMA's risk-based, preventive approach to food safety because the risk presented by unsafe food can be great, whether or not the food moves from one state to another. FDA seeks comment on the number of so-called ''intrastate'' farms that would not be exempt from the proposed rule either under the proposed exemption in § 112.5 or as a result of growing only produce that would be exempt under proposed § 112.2.

E. Relevance of Section 415 of the FD&C Act to ''Farm'' Definition and Related Definitions

Section 419 directs FDA to issue a proposed rule ''for the safe production and harvesting'' of certain produce. Section 419 does not affirmatively identify the businesses to which the proposed rule must apply, but requires FDA to address ''with respect to growing, harvesting, sorting, packing, and storage operations * * * soil amendments, hygiene, packaging, temperature controls, animals in the growing area, and water'' (419(a)(3)(B)); frequently uses the term ''farm'' (*e.g.,* section 419(f)); and clarifies that section 419 does not apply to produce produced by an individual for personal consumption (section 419(g)) or activities of facilities subject to section 418 (section 419(h)). FDA intends to issue a notice of proposed rulemaking implementing section 418 of the FD&C Act (section 103 of FSMA) in the near future. FDA tentatively concludes that ''activities of facilities subject to section 418'' are those activities triggering the requirement to register with FDA under section 415 of the FD&C Act (21 U.S.C. 350d), ''Registration of Food Facilities.'' FDA therefore tentatively concludes that it is reasonable to apply this proposed rule to farms and activities of farm mixed-type facilities that are within a definition of ''farm'' consistent with that utilized in FDA's implementation of section 415 of the FD&C Act, except to the extent that such entities are producing fruits and vegetables for their own consumption. In the near future, we plan to address how we will coordinate the definitions in the section 415 registration regulations with the definitions we are proposing for the purpose of the produce safety proposed rule. Ultimately, FDA intends that the activities to be regulated under this proposed rule will not trigger the requirement to register under section 415 of the FD&C Act and as a result will not be ''activities of a facility subject to section 418,'' consistent with the requirement in section 419(h). Moreover, the activities within the definition of ''farm'' we propose as part of this rulemaking closely track those identified in section 419(a)(3)(B), and

this interpretation is consistent with section 419(f)'s use of the term ''farm.''

Because section 418(o)(2) of the FD&C Act defines the term ''facility'' for the purposes of section 418 to mean only those facilities required to register under section 415 of the FD&C Act, FDA tentatively concludes that Congress intended the exemptions from the registration requirement set forth in section 415 and FDA's implementing regulations in part 1, subpart H (including the farm exemption in § 1.226(b)) to be meaningful for the purposes of defining section 418's applicability (and in turn, section 419's applicability). Thus, we tentatively conclude that activities within a definition of ''farm'' consistent with the definition utilized to implement the section 415 registration requirement are not subject to section 418 of the FD&C Act, but activities outside such a definition of ''farm'' are subject to section 418 when they cause a facility to be required to register with FDA under section 415. We discuss the proposed definition of ''farm'' and related definitions in section V.A.2.b.i of this document. We seek comment on these interpretations.

IV. Regulatory Approach

A. Qualitative Assessment of Risk

As discussed below, we are proposing to adopt an approach that focuses on the likelihood of contamination of produce posed by the agricultural practices applied to the crop, while exempting only the lowest-risk produce. We conducted a qualitative assessment of risk (QAR) of hazards related to produce production and harvesting. The QAR indicated that produce commodities are potentially subject to similar microbiological hazard pathways: Commodities can potentially become contaminated from, for example, direct exposure to contaminated water or soil amendment. Therefore, we propose to adopt a regulatory approach for minimizing the risks associated with those hazards and, as appropriate, provide flexibility for the use of alternative measures that would provide the same level of public health protection as the proposed standard.

The QAR addressed various questions related to produce safety, including: (1) What are the biological hazards of concern in produce that can lead to serious adverse health consequences or death? (2) How does produce become contaminated (*i.e.,* routes of contamination) during on-farm growth, harvesting, and postharvest operations? (3) Does the likelihood of contamination vary among produce commodity types? (4) Does the likelihood of illness attributable to produce consumption vary among produce commodity types? (5) What is the impact of postharvest practices on the level of contamination at consumption? (6) What on-farm interventions are available to reduce the likelihood of contamination? (Ref. 2). The qualitative assessment of risk document is currently being peer reviewed and changes can be reasonably anticipated based on the peer review. The peer review plan is available online at *http://www.fda.gov/ScienceResearch/SpecialTopics/PeerReviewofScientificInformationandAssessments/ucm079120.htm*. We will consider peer reviewers' and public comments in finalizing the qualitative assessment and this proposed rule.

While data and information available to us at this time permitted us to conduct only a qualitative (not quantitative) assessment, some important conclusions can be drawn, which provide a basis for our proposed science-based minimum standards for the safe production and harvesting of produce commodities. We provide below a brief summary of conclusions of the QAR.

Key conclusions from this assessment are:

- Produce can be contaminated with biological hazards, and the vast majority of produce-related illnesses are associated with biological hazards.
- The most likely routes of contamination from growing, harvesting, and on-farm postharvest activities are associated with seed (for sprouts), water, soil amendments, animals, worker health and hygiene, and buildings/equipment.
- Although some types of produce have been repeatedly associated with outbreaks, all types of produce commodities have the potential to become contaminated through one or more of these potential routes of contamination.
- The specific growing, harvesting, and on-farm postharvest conditions and practices associated with a produce commodity influence the potential routes of contamination and the likelihood that the given route could lead to contamination and illness. Use of poor agricultural practices could lead to contamination and illness, even where the potential for contamination is relatively low.
- Postharvest practices such as cooking (and, possibly certain peeling) before consumption may have an impact on the likelihood of contamination of the edible portion and the likelihood of illness.

Hazards of concern in produce—The scientific evidence from outbreaks, surveys and published literature establish that human pathogens (*e.g.,* Salmonella, pathogenic E.coli, Shigella, Cyclospora) constitute a biological hazard with the potential to cause serious adverse health consequences or death and result in the vast majority of foodborne illness known to be associated with produce consumption.

Potential routes of contamination—Based on our observations during inspections, investigations, and surveillance activities and other available information, we have grouped the possible routes of contamination into five major pathways: Water, Soil amendments, Animals, Worker health and hygiene, and Equipment and buildings. Seed is an additional route of contamination for sprouts.

Likelihood of contamination—All produce commodities can be contaminated before, during, and/or after harvest through one or more of the potential routes of contamination. Although the likelihood of contamination varies by commodity, it appears to be dependent on the practices employed and, to a lesser extent, on the characteristics of the commodity. There appears to be greater variability in the likelihood of contamination among commodities during growing than during harvest or after harvest.

Likelihood of exposure—Subsequent to any contamination on-farm, consumer and retail handling practices and produce consumption rates affect the likelihood that consumers will be exposed to contamination. Postharvest practices such as cooking (and possibly certain peeling) before consumption may have an impact on the likelihood of exposure if indeed the produce is contaminated.

Risk of illness—Contaminated produce has the potential to cause illness. However, there are differences among commodities in the risk of illness primarily based on the routes of contamination associated with the commodity.

Produce commodities that are ranked as ''higher'' risk of illness and those ranked as ''lower'' risk of illness share some of the same characteristics. Both categories include:

- Crops where the harvestable portion grows in the ground;
- Row crops where the harvestable portion grows on or near the ground;
- Crops where the harvestable portion grows above the ground;
- Crops where the harvestable portion grows on trees, high above the ground; and

• Crops that are generally grown without soil.

Such diversity suggests that sorting commodities for risk based only on the manner in which commodities grow would be inappropriate. This diversity also characterizes commodities associated with outbreaks. Even within a commodity group, physical characteristics (such as texture of the fruit) of the commodity that could alter the potential for contamination and, therefore, association with an outbreak, do not always appear to do so.

In summary, some produce types are repeatedly associated with reported foodborne illness whereas other produce types are only intermittently associated with foodborne illness. Still other produce commodities have not been associated with reported foodborne illness. Likely factors contributing to the likelihood of contamination, exposure, and illness include: Agricultural practices used during growing, harvesting, and postharvest; physical characteristics of the crop; consumer and retail handling practices (such as cooking and peeling); and rates of consumption. However, use of poor agricultural practices could lead to contamination and illness, even where the potential for contamination is relatively low.

With regard to water as a route of contamination:—

• Agricultural water can be a source of contamination of produce.

• Public Drinking Water Systems (domestically regulated by the EPA) have the lowest relative likelihood of contamination due to existing standards and routine analytical testing.

• Groundwater has the potential to pose a public health risk, despite the regulation of many U.S. public wells being subject to regulation under the Ground Water Regulation.

• There is a significant likelihood that U.S. surface waters will contain human pathogens, and surface waters pose the highest potential for contamination and the greatest variability in quality of the agricultural water sources.

• Susceptibility to runoff significantly increases the variability of surface water quality.

• Water that is applied directly to the harvestable portion of the plant is more likely to contaminate produce than water applied by indirect methods that are not intended to, or not likely to, contact produce.

• Proximity of the harvestable portion of produce to water is a factor in the likelihood of contamination during indirect application.

• Timing of water application in produce production before consumption is an important factor in determining likelihood of contamination.

• Commodity type (growth characteristics, *e.g.* near to ground) and surface properties (*e.g.,* porosity) affect the probability and degree of contamination.

• Microbial quality of source waters, method of application, and timing of application are key determinants in assessing relative likelihood of contamination attributable to agricultural water use practices.

With regard to soil amendments as a route of contamination—

• Soil amendments can be a source of contamination to produce

• Biological soil amendments of animal origin have a greater likelihood of containing human pathogens than do chemical or physical soil amendments or those that do not contain animal waste (*e.g.,* plant-based soil amendments).

• Human waste is the most likely waste to contain human pathogens.

• Animal waste subject to treatments, such as chemical and physical treatments and composting, has relatively lower levels of human pathogens than untreated animal waste.

• Composting is less likely than controlled chemical or physical treatments to fully eliminate human pathogens from animal waste.

• Incompletely treated, or re-contaminated, biological soil amendments of animal origin may also contain human pathogens.

• Human pathogens in untreated or composted biological soil amendments, once introduced to the growing environment, will eventually die off, but the rate of die-off is dependent upon a number of environmental, regional, and other agro-ecological factors.

• Treatments, such as chemical and physical treatments and composting, can effectively reduce the levels of human pathogens in animal waste.

• Among application methods, application of soil amendments in a manner in which they contact the harvestable portion of the crop presents the greatest likelihood of contamination, especially when applied close to harvest.

With regard to animals as a route of contamination—

• Animals can be a source of contamination to produce.

• Animal excreta poses a high likelihood of contamination of produce.

• Excreta from domesticated animals poses a greater likelihood of contamination of produce than does excreta of wild animals. However, domesticated animals can be expected to be more readily controlled (*i.e.,* kept apart from produce growing, harvesting, and postharvest areas).

• Excreta from wild animals that rarely associate with human activities poses the least likelihood of contamination of produce.

• Human pathogens from animal excreta, once introduced to the growing environment, can be expected to eventually die off; but the rate of die-off is dependent upon a number of environmental, regional, and other agro-ecological factors.

With regard to worker health and hygiene as a route of contamination—

• Humans (*i.e.,* workers and visitors) are potential carriers of foodborne pathogens and can be a source of contamination of produce.

• Individuals with communicable diseases that can be spread via food who are engaged in activities in which they contact produce or food contact surfaces can result in contamination of the produce or food-contact surfaces with human pathogens.

• Hand-washing reduces the potential for contamination of produce. Its efficacy varies depending upon the use of soap, the quality of the water, and whether or not hands are dried after washing.

• Dirty and damaged gloves may contaminate produce.

• Workers or visitors that touch animals can contaminate produce or food contact surfaces.

• Poor hygienic practices, *e.g.* lack of hand washing, can lead to contamination of produce.

• The presence of adequate toilet facilities in reasonable proximity to growing areas can reduce produce contamination.

With regard to equipment and buildings as a route of contamination—

• Food contact surfaces are potential routes of contamination of produce.

• Food contact surfaces such as equipment that are designed and constructed to be cleanable minimize the potential for contamination of produce.

• Pests in buildings used to grow or pack produce can be a source of contamination of produce.

• Waste material can be a source of contamination, or may become an attractant for pests and thereby act as a source of contamination to produce, if not properly contained, stored, and conveyed.

The provisions proposed in section V of this document reflect the above conclusions drawn from our qualitative assessment of risk. We seek public comment on the QAR, conclusions drawn from that assessment, and our consideration of those conclusions in

developing the proposed requirements. We also request you to submit any data or factual information that may help the agency to conduct, as warranted, a thorough and robust quantitative assessment of risk associated with produce production and harvesting practices.

B. Focus on Biological Hazards

Section 419 of the FD&C Act directs us to establish science-based minimum standards for the safe production and harvesting of those types of fruit and vegetable raw agricultural commodities (RACs) for which we determine that such standards minimize the risk of serious adverse health consequences or death (section 419(a)(1)(A) of the FD&C Act). These standards are to be based on known safety risks and 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 fruit and vegetable RACs and to provide reasonable assurances that produce will not be adulterated under section 402 of the FD&C Act (sections 419(b)(1) and 419(c)(1)(A) of the FD&C Act).

As discussed in the QAR, available data and information clearly establish that human pathogens constitute a biological hazard with the potential to cause serious adverse health consequences or death and result in the vast majority of foodborne illness known to be associated with produce consumption. By contrast, chemical, physical, and radiological hazards associated with produce rarely pose a risk of serious adverse health consequences or death for individuals that would consume the product (Ref. 7). Section 419(c)(1)(A) of the FD&C Act requires FDA to ''set forth those procedures, processes, and practices that the Secretary determines to minimize the risk of serious adverse health consequences or death, including procedures, processes, and practices that the Secretary determines to be reasonably necessary to prevent the introduction of known or reasonably foreseeable biological, chemical, and physical hazards * * * and to provide reasonable assurances that the produce is not adulterated under section 402 [of the FD&C Act].'' The frequency and nature of chemical, physical, and radiological hazards in produce are such that promulgation of a new regulatory regime for their control does not, at this time, appear to be reasonably necessary to prevent their introduction into produce or to provide reasonable assurances that produce will not be adulterated under section 402 of the Act. FDA tentatively concludes that existing programs, such as EPA registration of pesticides, and State and industry efforts to control the presence of pesticides and mycotoxins in produce, are sufficient to keep these hazards under control. In addition, under its broader food safety regulatory framework, FDA monitors natural toxins (*e.g.,* mycotoxins), pesticides, industrial chemicals (such as dioxins; cooking or heating related chemicals, such as acrylamide), and other chemical contaminants, and radionuclides in foods.

For these reasons, we tentatively conclude 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. Because of the proposed rule's focus on biological hazards, and because of the effectiveness of cooking and similar processes on the reduction of the likelihood of contamination of such hazards, as described in the Qualitative Assessment of Risk, we also propose to exempt produce that is rarely consumed raw or that receives commercial processing that adequately reduces the presence of microorganisms of public health significance (see section V.A. of this document).

We request comment on this approach, and specifically on whether there are practices that are reasonably necessary to prevent the introduction of known or reasonably foreseeable chemical, physical or radiological hazards into produce or otherwise to provide reasonable assurances that produce is not adulterated under section 402 of the FD&C Act because of chemical, physical, or radiological hazards. For example, proposed § 112.11 would require covered farms to take appropriate measures to minimize risks of serious adverse health consequences or death from the use of, or exposure to, covered produce attributable to biological hazards that may arise unexpectedly and therefore not be reflected in a specific standard set forth in proposed subparts C to O of this rule, or when there are biological hazards specific to a covered farm's location or circumstances for which such measures would be appropriate. Should § 112.11 also apply, for example, in the event of an accident or other unexpected event, such as a likelihood of radiological contamination relevant to a covered farm's location, to require that the covered farm take appropriate measures to prevent the introduction of radiological hazards into or onto the produce or by taking measures to provide reasonable assurances that the produce is not adulterated under section 402 of the FD&C Act? Such measures might include, for example, preventing covered produce from entering commerce if it may have been contaminated with radiological hazards that may render it injurious to health. As another example, if a covered farm's land was previously used for another activity that may have contaminated the soil with chemical hazards such that using the land to grow covered produce may cause introduction of those hazards into or onto the covered produce, should proposed § 112.11 require the covered farm to take appropriate measures to prevent the introduction of the chemical hazards into or onto the produce or by taking measures to provide reasonable assurances that the produce is not adulterated under section 402 of the FD&C Act? Such measures might include, for example, collecting and analyzing soil samples for residues of pesticides that are typically used in the production of cotton, if you intend to use a former cotton field for produce production. We seek comment on whether, and to what extent, chemical, physical, or radiological hazards should be covered within the scope of this rule.

C. Consideration of Differing Risk of Different Commodities and Practices

Section 419 of the FD&C Act also directs us to establish requirements that would provide sufficient flexibility to be applicable to various types of entities engaged in the production and harvesting of fruit and vegetable RACs, including small businesses and entities that sell directly to consumers, and to be appropriate to the scale and diversity of the production and harvesting of such commodities (section 419(a)(3)(A) of the FD&C Act). Section 419 further directs us to acknowledge differences in risk while minimizing, as appropriate, the number of separate standards we apply to separate foods (section 419(c)(1)(D) of the FD&C Act). We considered different approaches to determine how we might most appropriately respond to these directives, informed by the information contained in the Qualitative Assessment of Risk. These primarily included:

- Commodity-specific approach—covering only those produce commodities or commodity groups that might be described as posing a relatively higher risk of foodborne illness or applying different requirements to commodity categories based on relative risk of foodborne illness represented by the commodity category (such as higher, moderate and lower risk). A benefit of opting to pursue a commodity specific

approach would be a reduction in the costs of the proposed rule. Some commodities have little or no history of links to foodborne illness and, thus, exempting them from coverage could reduce costs to farmers with little or no reduction in calculated benefits from the rule. However, because foodborne illness outbreaks have regularly been associated with commodities that have previously not been linked to outbreaks, this approach carries the risk of failing to prevent future outbreaks.

• Integrated approach—covering all produce commodities except those that pose little or no risk of foodborne illness and then applying the most stringent requirements to agricultural practices that pose the greatest likelihood of contamination of the produce, regardless of the covered produce commodity. A benefit of selecting this option is that we would cover all commodities except those that pose little or no risk of foodborne illness, an approach that takes into account the sporadic and unpredictable nature of illness outbreaks, while still being sensitive to risk.

As discussed below, we explored both approaches thoroughly using information available to us at this time, and propose to use an integrated approach. Based on available data, we have not been able to fully develop a commodity-specific approach that we believe would adequately minimize risk of serious adverse health consequences or death from biological hazards in produce. However, as discussed in section IV.C.1.b., we have tentatively identified an approach based on outbreak data, and we further explore that option in that section. We welcome comment on this approach and ask that you provide data and factual information that would help us to further consider developing this or another appropriate commodity-specific approach.

1. Commodity-Specific Approaches

As noted above, there are multiple possible approaches that we could take with respect to produce. One of them is what we refer to as a ''commodity-specific approach'' in which this rule would apply only to those produce commodities or commodity groups that pose a relatively higher risk of foodborne illness. (We could also simply apply different or less stringent requirements to the relatively lower-risk commodities.) In theory, commodities might also be grouped into higher, moderate, or lower levels of risk with different levels of stringency applied to each. As discussed in section IV.A. above, we attempted to categorize commodities and commodity groups by risk in our Qualitative Assessment of Risk.

a. Relative Risk Considerations

To fully explore the viability of a commodity-specific approach, we reviewed the relative risk of different commodities using four such data sources: Outbreak data; Pathogen surveillance data; Commodity characteristics; and Market channels. Our analysis shows that each data source presents certain gaps that make it challenging to develop a commodity-specific approach that would adequately minimize risk of serious adverse health consequences or death. We explain our analysis below and request data and factual information on how we might address these gaps and further develop and consider a commodity-specific approach.

i. Outbreak Data and Commodity Risk: We reviewed FDA's data on produce-related outbreaks and considered categorizing commodities or commodity groups by risk based on documented association of specific produce commodities with specific outbreaks of human illness (Ref. 2). Using this approach, we could exempt certain commodities or commodity groups that had never been linked to human illnesses or were only rarely linked to human illness; this would allow us to reduce the costs of the rule with little or no reduction in calculated benefits. However, our QAR also leads us to tentatively conclude that past patterns of outbreaks by commodity have limitations which make it challenging to use as a key determining factor in establishing the scope of this proposed rule or how its provisions apply. We briefly discuss the reasons here (please refer to the QAR for more information).

Our QAR concluded that some produce types are repeatedly associated with reported foodborne illness, whereas other produce types are intermittently associated with reported foodborne illness. Still other produce commodities have not been associated with reported foodborne illness. As such, five commodity groups (leafy greens, tomatoes, herbs, melons, and sprouts) together account for 77 percent of all produce-related outbreaks from 1996–2010 (Ref. 3). These commodity groups also account for 54 percent of produce-related illnesses and 56 percent of produce-related hospitalizations. Sprouts account for a quarter of the produce related outbreaks (26%), 15 percent of the illnesses, 9 percent of the hospitalizations, and one death.

As discussed in the QAR, because only a small percentage of outbreaks are both reported and assigned to a food vehicle, outbreak data may not provide a complete picture of the commodities upon which we need to focus to minimize current and future risk of illness. The food vehicle responsible for an outbreak is not identified in about half of all outbreaks. Identifying the vehicle of an outbreak in which the vehicle is contained in a multi-ingredient food (*e.g.,* salsa, salads) is particularly challenging. As our abilities to detect outbreaks and to identify food vehicles responsible for an outbreak improve, including refining our approach to outbreaks associated with multi-ingredient foods, it is likely that previously unrecognized outbreak vehicles will be identified. A further complication to use of outbreak data as an indication of commodity risk is that, until a food is identified as a vehicle in an outbreak, public health officials may not be likely to include questions about that commodity when investigating an outbreak, making the attribution of outbreaks to commodities with no outbreak history more difficult.

In addition, as discussed in the QAR, our data show that the patterns of outbreaks associated with produce commodities change over time. Some commodities have a continuing and repeated pattern of association with outbreaks, over multiple years, such as tomatoes and leafy greens (Ref. 2). On the other hand, occasionally a produce commodity is associated with an outbreak that had not been previously linked to foodborne illness. For example, prior to the 2008 Salmonella Saintpaul outbreak (Ref. 37), jalapeno and serrano peppers had not been identified as vehicles in a foodborne illness outbreak. Papayas had also not been associated with outbreaks, prior to an outbreak that occurred in 2011. Therefore, a regulatory approach that relied on a static list of commodities prepared solely from a history of outbreaks would not be able to prevent future outbreaks in commodities not previously associated with an outbreak.

If we adopted an approach that exempted commodities without a history of outbreaks, we would likely need to add commodities as future outbreaks occur. For example, we could adopt a ''moving window'' approach that would consider only outbreaks over a given time period. For example, we could consider only the outbreaks over the most recent five years at any given time. Using such an approach, produce commodities or commodity groups might move onto and off of the higher risk list over time based on changes in outbreak data. The advantage of such an approach could potentially be to

recognize and reward efforts by industry segments that implement changes in practices contributing to reduced outbreaks associated with their commodities, and provide an incentive for other industry segments to enhance the safety of their practices. However, the adoption of such practices by an industry segment does not change the risk posed by the commodity in the absence of such practices, such as when practices are not universally adopted or they are discontinued. In the absence of those practices, illness outbreaks may resume. For example, sprout associated outbreaks appeared to decline after release of our Sprout Guides in 1999 and, for three years (2005–2007), there were no reported outbreaks associated with sprouts, presumably because of improved practices during the production of sprouts (Ref. 3). However, outbreaks have recurred since that time period, possibly because practices have regressed to some extent or possibly because of the entry of new sprout growers who were not familiar with the voluntary recommendations in the Sprout Guides and had not adopted them. In late 2008, there was one sprout-associated Salmonella outbreak; in 2009, a Salmonella outbreak associated with sprouts resulted in more than 200 illnesses; and in 2010, there were 3 outbreaks associated with sprouts (Ref. 3). Further, as discussed in the QAR, some commodities (*e.g.,* leafy greens) are consistently associated with outbreaks while others (*e.g.,* grapes, jalapeno peppers) are only rarely associated with outbreaks. With a moving window approach those commodities that only intermittently are associated with outbreaks may cycle on and off the higher risk list, even though their risk may not have actually changed. For these reasons, we have tentatively concluded that a ''moving window'' approach for determining risk based on outbreak history is not viable.

Grouping commodities based on outbreak history also has challenges. Within a commodity group, contamination may have been associated with relatively few types of produce, such as cantaloupe and honeydew melons within the melon group, which includes multiple species, or more broadly, such as roma, red round, plum, and grape tomatoes within the tomato group, which consists of multiple varieties within a single species (Ref. 3).

Having considered that making exemptions solely based on outbreak data could significantly reduce the costs of the proposed rule with little or no reduction in calculated benefits, we have not selected this alternative, because we do not believe that the past history of outbreaks can be fully predictive of future outbreaks. Historically, outbreaks are sometimes linked to commodities that had no previous associated illnesses. If we were to develop a commodity-specific list of covered produce, we could add commodities to the list as more data became available. We request comment on whether this option would adequately minimize the risk of serious adverse health consequences or death and whether it would sufficiently move toward a prevention-based food safety system. We request comment on this determination and on the specific approaches we have outlined here. We are particularly interested in the marginal effects of adopting this approach: If we exempted commodities based on a 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.

ii. Pathogen Surveillance Data and Commodity Risk: As an alternative to categorizing and regulating commodities based on outbreak history, we considered using data on levels and frequency of pathogen detection, such as by surveillance sampling assignments in specific produce commodities. As demonstrated in the QAR, this approach would also present a number of challenges. Of most importance, our contamination data are limited in that most sampling programs have focused on produce commodities that have an existing history of known outbreaks, providing little additional information about the risk presented by commodities that do not have such a history. Given the potential for system failure and sporadic contamination, it is probable that testing of other produce commodities may eventually lead to positive identification of contamination. For example, when we added cucumbers to our surveillance sampling program in 2009, we found a significant number of positive samples for Salmonella spp. although, in previous years, cucumbers had not been identified as the vehicle of a foodborne outbreak in FDA's database. We also found pathogens in and on produce commodities such as broccoli, culantro, rapini, and radicchio that have not been currently identified in outbreaks (Ref. 3). For this reason, we do not believe that pathogen surveillance data alone can provide sufficient information for a risk-based exemption from the proposed rule's provisions. We request comment on this determination.

iii. Commodity Characteristics and Commodity Risk: As an alternative to categorizing and regulating commodities based on outbreak history or surveillance data, we also considered using characteristics of produce commodities themselves, such as growth habit. In other words, if, for example, the risk of illnesses associated with tree fruit, were consistently lower than the risk of illness from commodities grown in the soil, such a distinction might provide the basis of an exemption. However, as demonstrated in the QAR, we found that it would be extremely difficult to make conclusions across commodity groups that are consistent with outbreak and surveillance data, in light of the diversity of commodities, practices, and conditions across operations.

Attempts to categorize produce by commodity characteristics is confounded by the outbreak data, which show no consistent pattern that can be matched to commodity characteristics such as growth habit. As discussed in the QAR, the characteristics of approximately 20 produce commodities associated with outbreaks are diverse and include:

- Crops generally grown without soil, such as sprouts;
- Crops where the harvestable portion grows in the ground, such as green onions;
- Row crops where the harvestable portion grows on or near the ground, such as lettuce, spinach, basil, parsley and cantaloupe;
- Crops where the harvestable portion grows above the ground, such as tomatoes and chili peppers, raspberries and blueberries; and
- Crops where the harvestable portion grows on trees, high above the ground, such as mangoes and almonds.

Moreover, as discussed in the QAR, even within what may be a reasonable set of commodities to group together, physical characteristics of the produce that could alter the potential for contamination do not always appear to do so. For example, within the melon group, cantaloupe has a netted rind, whereas honeydew has a smooth rind, seemingly making it less likely to harbor pathogens. However, both have been associated with outbreaks (Ref. 3).

In addition, multiple characteristics would have to be considered to create commodity groupings, making such an approach very complicated. For example, while growth characteristics, such as distance between the edible portion of the plant and the ground, may make a commodity less likely to become contaminated through certain routes, (*e.g.,* tree fruit may be less vulnerable to contamination from grazing animals), distance from the

ground does not necessarily provide an increased level of protection against other sources of contamination (*e.g.,* direct contact with a crop protection spray if the spray mix were made using contaminated water). Furthermore, once the produce commodity is removed from the growing area, it may lose any safety advantage it had in the field based on growth characteristics if it is exposed to routes of contamination such as poor worker hygiene practices, contaminated water, or insanitary food contact surfaces. As another example, mangoes are an example of a produce commodity that may be thought to present relatively low risk of foodborne illness, but for which poor water quality management during insect disinfestation hot water treatment and cooling as part of harvest, packing, and holding resulted in an outbreak (Ref. 38). Some physical characteristics of produce commodities (*e.g.,* netted rind of cantaloupe or large, rough surface area of some leafy greens) may increase the likelihood of contaminants being trapped and surviving long enough to cause illness, but as noted earlier, these characteristics do not necessarily determine whether contamination occurs or persists.

For the reasons described here, we have tentatively determined that such an approach cannot serve as the sole basis for a risk-based exemption from the proposed rule. We request comment on this determination and on whether there are known produce characteristics that could serve as a reliable and practicable indicator of contamination and illness risk. We seek comment on this issue and data to inform commodity categorization.

iv. Market Channel and Risk: We also considered whether different market channels might have an impact on the likelihood of contamination of produce and therefore whether use of certain market channels should be a factor in covering or regulating produce in this proposed rule. In particular, we considered whether there is a difference in the likelihood of contamination of produce that is sold directly to the consumer or end user (''direct market channels'') as compared to that of produce that is sold into other commercial channels. We are not aware of any data that would enable us to compare the likelihood of contamination in these two situations. We tentatively conclude that produce in both direct market channels and other commercial channels are subject to the same routes of contamination, although the number of opportunities for contamination during packing and holding may be greater for produce in other commercial channels as compared to produce in direct market channels if there are greater numbers of touch points and handlers in these channels than there are in direct market channels. We seek comment on this tentative conclusion.

Section 419(f) of the FD&C Act provides a qualified exemption from this proposed rule for many farms selling directly to consumers or other ''qualified end users,'' and as a result, many farms that primarily use direct market channels will not be subject to the requirements of this proposed rule (with qualifications provided by the statute). Because the statutory qualified exemption addresses market channels as a possible risk factor, and because we identified no data that would allow us to otherwise use market channels as a factor in covering and regulating produce under this proposed rule, we tentatively conclude that we should not otherwise use market channels as a basis of risk categorization in this proposed rule. We seek comment on this tentative conclusion.

b. Considering an Appropriate Commodity-Specific Approach

In the previous section, IV.C.1.a, we discuss four different relative risk considerations that might be used to develop an appropriate commodity-specific approach. Each has a set of challenges, as discussed above. Of the four, outbreak data provide the most direct representation of public health burden, even considering the confines associated with these data. In this section we further explore how outbreak data might be used to identify commodity groups or specific commodities to cover in this proposed rule.

One possible commodity-specific approach would be to cover those commodity groups that have been associated with outbreaks. Commodity groups ''associated with outbreaks'' could be identified as, for example, commodity groups associated with one or more outbreaks during a set period of time. The remaining commodity groups could then either not be subject to the proposed rule, or be subject to the proposed rule but with less stringent requirements. A commodity-specific approach that covers the commodity groups associated with outbreaks would target the commodity groups that present the greatest public health burden. However, as discussed above in section IV.C.1.a., there are various drawbacks with using outbreak data in this way. For example, because only a small percentage of outbreaks are both reported and assigned to a food vehicle, outbreak data may not provide a complete picture of the commodities upon which we need to focus to minimize current and future risk of illness.

Another possible commodity-specific approach that attempts to account for the drawbacks of the above approach would be to cover *all* of the commodities that have been identified as associated with an outbreak at any time. Produce commodities that have not been identified as associated with an outbreak could then either not be subject to the proposed rule, or be subject to the proposed rule but with less stringent requirements. This option would address more than the percent of known outbreaks addressed by the above approach in that it would address all known outbreaks. This approach would also significantly reduce the costs of the proposed rule by exempting produce categories that have never been associated with human illness. As discussed above, however, outbreaks have been associated with commodities without an illness history. Although we would expect to use additional data to update any list we might develop of commodities subject to the provisions of the rule, we would expect that this approach would not minimize the risk of occurrence of some number of additional outbreaks and illnesses.

We have discussed limitations with each of the above methods of creating a risk-based exemption from the rule. We could also combine two or more of the approaches used above to create a more holistic picture of risk. For example, we might combine a history of outbreak data with the growing characteristics of a commodity or class of commodity. Such an approach could potentially exempt additional commodities that pose minimal or no risk (in addition to those we already considered in the proposed approach: Those specified as rarely consumed raw, and those that are receive commercial processing that adequately reduces the presence of microorganisms of public health significance). If there were individual commodities or classes of commodities that have not been linked to human illness and we had reason to believe that they were unlikely to be linked to human illness in the future, we would consider exempting these commodities or classes of commodities from some or all provisions of the rule. This would reduce the cost of the rule without significantly reducing the calculated benefits of the rule. However, we have not been able to fully develop an approach that might combine a history of outbreak data with the growing characteristics of a commodity or class

of commodities to create risk-based exemptions from the rule and, thus, minimize the risk of serious adverse health consequences or death. We seek comment on this issue. Is there information in the QAR that could be used to develop such a system of risk-based exemptions? Are there commodity characteristics or growth conditions that could be used as a basis to develop such a system? Do the proposed provisions for variances (see section V.P. below) adequately address this issue?

We ask for comment on all of the above approaches, and we especially ask for comment on the likely marginal effects of the different risk-based exemptions. If we adopted one of the approaches above, what would the likely reductions in the costs of the proposed rule be, and what would the likely increases in human illnesses be (using our proposed rule as a baseline). We also ask for comment on whether any of the above approaches would be sufficiently protective of the public health.

c. Need for additional data and information

We seek comment on our analysis and considerations related to considering an appropriate commodity-specific approach that would adequately minimize risk of serious adverse health consequences or death from biological hazards associated with produce. We also request comment on whether and how different relative risk considerations, including outbreak data, pathogen surveillance data, commodity characteristics and/or market channels, could be used to develop a commodity-specific approach, and data and factual information that would address the drawbacks that are discussed in this section IV.C. that may be accounted for in such an approach. Specifically,

- Are there specific commodities or categories of commodities that should be excluded from the scope of the rule, based on data related to their relative risk considerations? (Note that under our proposed integrated approach, we propose to exempt certain commodities, including a specified list of produce that is rarely consumed raw, and produce that receives commercial processing that adequately reduces the presence of microorganisms of public health significance; see section V.A.2.a. of this rule.)
  - For example, the QAR ranked certain produce commodities, such as bananas and coconuts, as lower risk for illness, in part because such commodities are peeled or shelled before consumption in a manner that can be expected not to transfer contamination onto the interior, edible portion of the commodity. Should such commodities be covered by the rule? Is coverage of these commodities unnecessary? Should they be covered but subject to a less stringent set of requirements?
  - Certain commodities are ranked in the QAR as presenting a relatively lower likelihood of exposure, in part because such commodities have fewer potential routes of contamination and/or lower potential for contamination. In addition, some commodities are not known to have been associated with outbreaks. Some commodities (for example, pears, grapefruit, oranges, and lemons) meet both of these criteria, considering the rankings and outbreak data used in the QAR. Should commodities that meet both of these criteria be covered by the rule? Is coverage of these commodities unnecessary? 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?
  - How should the agency account for uncovered commodities in considering a commodity-specific approach that relies on outbreak data?
- Are there pathogen surveillance data from sampling programs focusing on produce commodities that have no history of known outbreaks that would be useful in considering a commodity-specific approach?
- Can commodity characteristics be used as a basis to consider a commodity-specific approach? While the outbreak data show no consistent pattern that can be matched to commodity characteristics such as growth habit, our QAR shows that produce commodities that are ranked as higher risk of illness and those ranked as lower risk of illness do share some of the same characteristics. A further refinement of our assessment might be helpful in developing a commodity-specific approach based on commodity characteristics. Considering the qualitative nature of our assessment, are there quantitative data sets available that would enable a further refinement of our assessment?
- Are produce in both direct market channels and other commercial channels subject to the same routes of contamination? Is the number of opportunities for contamination during packing and holding greater for produce in other commercial channels as compared to produce in direct market channels? If yes, is this due to greater numbers of touch points and handlers in these channels than there are in direct market channels, or to other factors?
- Should market channels be used as a basis for risk categorization? If so, how? Is there a need to consider market channels in risk categorization, considering that the statutory qualified exemption already addresses market channels as a possible risk factor?
- Are other data or information available that would otherwise be useful in considering a commodity-specific approach?

2. Integrated Approach, as Proposed

As discussed in section IV.A. above, our QAR indicates that some produce types are repeatedly associated with reported foodborne illness whereas other produce types are intermittently associated with foodborne illness. Still other produce commodities have not been associated with reported foodborne illness. Likely factors contributing to the likelihood of contamination, exposure, and illness include: Agricultural practices used during growing, harvesting, and postharvest; physical characteristics of the crop; consumer and retail handling practices (such as cooking and peeling); and rates of consumption. However, use of poor agricultural practices could lead to contamination and illness, even where the potential for contamination is relatively low.

Therefore, we tentatively conclude that an integrated approach that focuses on the likelihood of contamination of produce posed by the agricultural practices applied to the crop, while exempting the lowest-risk produce, would provide the most appropriate balance between public health protection, flexibility, and appropriate management of different levels of risk. We tentatively conclude that controls should be tailored, taking into account the analysis done by the farm in certain areas, to the potential routes of contamination that each commodity presents based on the agricultural practices employed, and the characteristics of the commodity and the environmental conditions under which it is grown.

Based on our QAR, we are able to identify certain conditions under which produce commodities constitute very low to no risk with respect to biological hazards. We tentatively conclude that, under these conditions, science-based minimum standards to minimize the risk of serious adverse health consequences or death from biological hazards in produce are not warranted. As described in the QAR, such conditions include produce that receives commercial processing that

adequately reduces the presence of microorganisms of public health significance (proposed § 112.2(b)); and produce commodities that are rarely consumed raw (proposed § 112.2(a)(1)). In each of these cases the produce can be expected to receive commercial processing or other treatments that significantly minimize the risk of serious adverse health consequences or death from biological hazards associated with such produce.

In addition, as discussed in section V.A. of this document, FDA proposes in § 112.4 to apply this regulation only to businesses with an average annual monetary value of food sold during the previous three-year period of more than $25,000 on a rolling basis, based on a tentative conclusion that businesses with $25,000 or less in sales do not contribute significantly to the produce market and, therefore, to the volume of production that could become contaminated. Accordingly, imposing the proposed requirements on these businesses would have little measurable public health impact. In addition to these exclusions proposed by FDA, section 419(f) of the FD&C Act provides a qualified exemption for certain farms, which FDA proposes to implement in proposed §§ 112.5 and 112.6, and subpart R, as discussed in sections V.A. and V.R. of this document.

For produce commodities that would be covered within the scope of this rule (*i.e.,* ''covered produce'' as defined in proposed § 112.3), we are proposing to establish science-based minimum standards to minimize the risk of serious adverse health consequences or death. Given our current understanding of existing microbiological hazards and current data limitations, as described in our QAR, we have determined that a regulatory approach that addresses the potential likelihood of contamination posed by procedures, processes, and practices employed in the growing, harvesting, packing, and holding of produce commodities will be more effective and appropriate than an approach based on the individual commodities' physical characteristics, known record of contamination, or known outbreak history. The only commodity-specific requirements proposed in this rule are those designated for sprouts, which have unique growing procedures (*i.e.,* warm, moist nutrient-rich environment for an extended period of time that supports pathogen growth in addition to sprouting) and, therefore, present a unique risk profile (Ref. 16.Ref. 2). For this reason, and as discussed in section V.M. of this document, we tentatively conclude that a specific set of safety standards (proposed subpart M) for this produce commodity is warranted.

The requirements of the proposed regulation would be based on identified routes of contamination and the associated practices that affect the likelihood that produce becomes contaminated: Agricultural practices that are more likely to contaminate produce would require more stringent measures to ensure that the likelihood of contamination is sufficiently minimized. For example, as discussed in section V.E. of this document, we are proposing the most stringent standards for water that is used in direct contact with the harvestable portion of covered produce during or after harvest activities (when there is little further opportunity for pathogen die off) and in certain other uses that present significant safety risk for the safety of the produce (such as irrigation of sprouts); less stringent standards for water that directly contacts the harvestable portion of covered produce (other than sprouts) during growing activities (when the opportunity for pathogen die off is greater); and no requirements when water is used during growing, but does not contact the harvestable portion of covered produce (other than sprouts). Similarly, we are proposing to prohibit the use on covered produce of biological soil amendments that present the greatest likelihood of pathogen contamination, *i.e.,* untreated human waste (Ref. 39). Untreated manure or other untreated biological soil amendments of animal origin, which are less likely to be contaminated with human pathogens than human waste, but are relatively likely to be contaminated (Ref. 35. Ref. 36. Ref. 37), would be allowed, subject to stringent requirements; manure or other biological soil amendments of animal origin that have been properly composted to reduce the level of pathogens contained therein would be subject to less stringent requirements; and certain chemically or physically treated biological soil amendments of animal origin that receive more robust treatments to eliminate pathogens would be subject to the least stringent requirements.

In addition, we are proposing to include other measures that would be broadly applicable (*e.g.,* personnel qualifications and training requirements in proposed subpart C, health and hygiene requirements in proposed subpart D; requirements for equipment, tools, buildings, and sanitation in proposed subpart L) and the proposed standards for these are consistent for all covered growing, harvesting, packing, and holding operations.

We tentatively conclude that the appropriate way to minimize the risk of serious adverse health consequences or death is to require all covered farms to comply with the standards in this proposed rule with regard to all but the lowest risk produce. Identifying the higher-risk agricultural practices and setting standards in which the stringency of the requirement tracks the risk of the chosen practices is appropriate from a public health risk mitigation standpoint and would also provide an incentive for farmers to move to lower-risk practices where such options are available. We also expect that our proposed approach is more workable for row crop farmers who may grow multiple produce commodities than it would be if we were to assign different requirements to specific commodities based on the risk of foodborne illness associated with those commodities. In these types of operations, many agricultural practices and agricultural inputs (such as water sources and distribution systems, soil amendments and their application methods) tend to be farm-specific and, thus, relatively consistent across produce commodities on a given farm. Requiring different measures from row to row based on the produce commodity in that row would likely pose a considerable burden on such farms. Setting standards that enable such farms to apply consistent measures to multiple crops is consistent with the statutory provision in section 418(c)(1)(D) of the FD&C Act that directs the agency to ''acknowledge differences in risk and minimize, as appropriate, the number of separate standards that apply to separate foods.''

D. Framework of the Rule

In developing a framework for this proposed rule we considered various models used in proposed and final FDA regulations, including those applied in: (1) The existing Current Good Manufacturing Practice in Manufacturing, Packing or Holding Human Food regulation (current 21 CFR part 110; ''Food CGMP regulation''); (2) the Production, Storage, and Transportation of Shell Eggs regulation (21 CFR part 118; ''Shell Egg Regulation''); (3) the Hazard Analysis and Critical Control Point (HACCP) Systems (''juice HACCP'') regulation (21 CFR part 120); and (4) the Fish and Fishery Products (''seafood HACCP'') regulation (21 CFR part 123). None of these regulations applies to fruits and vegetables at the point at which we propose to regulate such food by this regulation (during growing, harvesting,

packing, and holding on farms), but as models they are instructive.

Generally, the Food CGMP Regulation sets out mandatory, broad, generally-applicable practices and conditions that are required to be met, and the criteria and definitions in that part are applicable in determining whether the food is adulterated (1) within the meaning of section 402(a)(3) of the act, in that the food has been manufactured under such conditions that it is unfit for food, or (2) within the meaning of section 402(a)(4) of the 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 that part are also applicable in determining whether a food violates section 361 of the Public Health Service Act. In some instances where the appropriate measures are universal and well recognized, the cGMP requirements are prescriptive (*e.g.,* the requirement to remove unsecured jewelry at § 110.10(a)(4), the requirement that each freezer and cold storage compartment be fitted with a temperature indicating thermometer, temperature measuring device or temperature recording device at § 110.40(e)). However, more commonly, because of the diversity of operations subject to the regulation and the desire to provide flexibility for operators to put in place measures that are best suited to the specifics of their operation, the cGMP rule sets out more general requirements (*e.g.,* the requirement that persons working in direct contact with food conform to hygienic practices to the extent necessary to protect against contamination of the food at § 110.10(b), the requirement that food that can support the rapid growth of undesirable microorganisms be held in a manner that prevents the food from becoming adulterated at § 110.80(b)(3)). Many provisions of the Shell Egg Regulation also take a similar approach to the Food CGMP Regulation.

The Juice HACCP and Seafood HACCP Regulations set out mandatory frameworks through which entities subject to those regulations assess the hazards that are reasonably likely to occur in their products and processes and design tailored controls to prevent or eliminate them or reduce them to an acceptable level. These regulations require the development of a plan, based on the assessment of hazards, which includes monitoring procedures, corrective action procedures, verification procedures, and recordkeeping procedures. The plan also includes the identification of the critical control points (CCPs) where the controls must be applied and critical limits, which are the set points for the process that must be met to ensure product safety.

The Food CGMP Regulation and the Shell Egg Regulation do not use the structure applied in the other regulations identified here to ensure that the conditions and practices are keeping hazards in check as anticipated (through hazard analysis, establishment of critical control points, monitoring, corrective actions, verification, and recordkeeping in all applicable contexts). The Food CGMP Regulation preceded the HACCP regulations and is generally thought of as a pre-requisite or foundation to those regulations. That is, it is generally recognized that HACCP-type regulations must build on the foundation of a good manufacturing practice (GMP)-type regulation in order to further reduce the risk of illness or injury to consumers associated with contaminated produce (Ref. 40 Ref. 41).

In developing the framework for this proposed rule, we considered the following: (1) The produce farming community is very diverse, including very small and large farms, some with significant expertise in the area of food safety and others with minimal knowledge in the area, some located in the U.S. and some abroad; (2) there is a broad range of crops and agricultural practices employed by the produce farming community, such that a measure for addressing an on-farm route of contamination for one produce commodity in one region may not be practical or effective for another on-farm route of contamination, produce commodity or region; (3) this proposed rule is the first effort by FDA to regulate the produce farming community—the produce farming community does not have the history of regulatory interaction with FDA and the same experience with food safety regulations as does the food manufacturing industry; (4) the adequacy of some measures to control specific known or reasonably foreseeable hazards affecting produce is well established, while others are poorly studied, suggesting that future research may identify alternative measures that may be more effective and/or efficient; and (5) some on-farm routes of contamination occur in a relatively controlled environment (*e.g.,* a fully or partially enclosed building), while others occur in an outdoor environment that may be beyond the control of the farm (*e.g.,* an open field), affecting the ability of the farm to take measures that minimize the likelihood of contamination.

Given these considerations, and the need to tailor the proposed requirements to specific on-farm routes of contamination (as discussed in section IV.C of this document), we propose an integrated approach that draws on our past experiences in the regulations discussed above. In some cases, we propose standards that are very similar to those contained in the Food CGMP Regulation, especially where the routes of contamination are well-understood and appropriate measures are well-established and generally applicable across covered produce commodities (*e.g.,* personnel qualifications, training, health, and hygiene; harvesting, packing, and holding activities; equipment, tools, buildings, and sanitation). We rely on this approach where possible, in part, because we tentatively conclude that compliance would be more suitable with this regulatory framework (given the diversity of the industry with respect to size, agricultural practices, and knowledge of food safety) than would be the case with a more complex framework such as one that also required an individual written plan.

In other cases, we have proposed specific numerical standards against which the effectiveness of a farm's measures would be compared and actions taken to bring the operation into conformance with the standards, as necessary (*e.g.,* proposed standards for agricultural water in subpart E; biological soil amendments of animal origin in subpart F; sprout environmental testing and spent sprout irrigation water testing in subpart M). We rely on such a numerical standards approach where the effectiveness of individual measures (*e.g.,* protection of agricultural water sources from contamination, establishment of application intervals for certain soil amendments, and chemical disinfection treatment of seeds before sprouting) is not complete or fully known and/or because much of what affects the on-farm route of contamination is outside the control of the farm (*e.g.,* the quality of a particular surface water source). In some of these cases (*e.g.,* composting of biological soil amendments of animal origin in proposed § 112.54) we have provided measures that are well established to meet the numerical standard under a wide range of conditions, while also recognizing that other measures, if properly validated, may also be suitable (see proposed § 112.12, discussed in section V.B. of this document). Our proposed use of numerical standards is similar to the

requirement for egg testing in the Shell Egg Regulation.

In still other cases, we have proposed a standard that requires the farm to inspect or monitor an on-farm route of contamination and take appropriate measures if conditions warrant. We rely on such a monitoring approach where the diversity of conditions that can be expected relative to an on-farm route of contamination is very high and it would be impractical and unduly restrictive to set out a standard that specifies the appropriate measures for each possible circumstance (*e.g.,* requirements for monitoring for animal intrusion in proposed § 112.83, requirement for inspection of agricultural water system in proposed § 112.42). In addition, we propose this approach in instances where further research is needed to fully understand the effectiveness of measures to mitigate the risk of serious adverse health consequences or death. Our proposed use of inspection and monitoring followed by appropriate corrective action is similar to the requirement to monitor for rodent activity and take corrective action on egg farms in the Shell Egg Regulation (§ 118.4).

Finally, in still other cases, we propose a standard that requires the farm to develop a written plan, committing itself to specific measures (*e.g.,* sprout environmental testing and spent sprout irrigation water testing). We propose the use of written plans where the details of the measures to be taken are more than can be reasonably expected to be retained in memory, especially where the details may change over time and a historical record of the evolution of the measures is important for the operator to assess whether further changes to the measures are needed (*e.g.,* changes or rotation in the sampling sites for sprout environmental testing). Such plans are also important for the efficient enforcement of the standard as they serve as a clear commitment on the part of the operator of the farm to a particular course of action, against which their actual performance can be judged by the regulator. Our proposed use of written plans in these specific instances is similar to the requirement for a written Salmonella Enteritidis prevention plan on egg farms in the Shell Egg Regulation (§ 118.4).

We performed a quantitative risk assessment to estimate the predicted effectiveness of some of the provisions of the proposed regulation with respect to one example commodity and one example pathogen (Ref. 42). This quantitative risk assessment evaluated the combination of fresh-cut lettuce, enterohemorrhagic *E. coli* (EHEC), and irrigation water (with and without proposed measures in place), and concluded that a number of variables may influence the predicted EHEC illnesses associated with fresh-cut lettuce, as defined by the model scenarios that included contamination from irrigation water and other environmental sources on the farm, and changes in the contamination during the product life cycle from farm to consumption. The quantitative risk assessment document is currently being peer reviewed and changes can be reasonably anticipated based on the peer review. The peer review plan is available online at *http://www.fda.gov/ScienceResearch/SpecialTopics/PeerReviewofScientificInformationandAssessments/ucm079120.htm.* We will consider peer reviewers' and public comments in finalizing the quantitative risk assessment and this proposed rule.

This rulemaking is not intended to address ''hazards that may be intentionally introduced, including by acts of terrorism.'' (§ 418(b)(2) of the FD&C Act). FDA plans to implement section 103 of FSMA regarding such hazards in a separate rulemaking in the future. FDA tentatively concludes that intentional hazards likely will require different kinds of controls and would be best addressed in a separate rulemaking. However, we request comment on whether we should include standards related to preventing economically motivated intentional adulteration of produce in this rule. Is economically motivated adulteration of produce reasonably likely to occur and, if so, by what mechanisms may potential hazards be intentionally introduced in produce for economic reasons? If such adulteration is reasonably likely to occur, what standards should FDA consider for preventing such adulteration?

E. Records

We are proposing to require that farms keep records as a component of the above described standards, under certain, limited circumstances. In determining those circumstances in which records are necessary, we considered the statutory direction in section 419(c)(1)(C) of the FD&C Act to comply with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*) ''with special attention to minimizing'' the recordkeeping burden on the business and collection of information as defined in that act.

Records are useful for keeping track of detailed information over a period of time. Records can identify patterns of problems and, thus, enable a farm to find and correct the source of problems. Records are also useful for investigators during inspections to determine compliance with requirements (*e.g.,* by FDA investigators to determine compliance with requirements that would be established by this rule, or by a third party auditor that a farm or retailer may voluntarily engage under a business arrangement between the farm and the retailer). We propose to require records in instances where they are important to facilitate verification and compliance with standards and this cannot be effectively done by means other than a review of records; where identification of a pattern of problems is important to minimizing the likelihood of contamination; and where maintenance of detailed information is needed by the operator in order to minimize the risk of contamination and demonstrate their compliance.

F. Farm-Specific Food Safety Plans

Each farm has a unique combination of size, climate, crops grown, current and previous use of its own land and nearby land, sources of agricultural water, growing, harvesting, packing, and holding practices, animal grazing, potential for domestic and wild animals to enter growing or packing areas, and sewage or septic system. Relevant documents on produce safety, such as our GAPs Guide (Ref. 10), industry CSGs for melons, tomatoes, leafy greens, and green onions (Ref. 43. Ref. 44. Ref. 45. Ref. 46), the CA and AZ LGMA (Ref. 31. Ref. 32), the AFDO Model Code of Produce Safety (Ref. 20), the Codex Guide (Ref. 47), and Industry Harmonized GAPs (Ref. 48. Ref. 49) recommend that a farm tailor its food safety practices to the practices and conditions at its individual operation. In addition, many of these documents explicitly recommend that a farm conduct an assessment of its growing environment and may specify when assessments should be done (*e.g.,* before planting, during production, and immediately prior to harvest) to identify potential food safety hazards in light of its particular commodities, practices and conditions (Ref. 43. Ref. 44. Ref. 45. Ref. 46. Ref. 40. Ref. 47).

Several of these documents further recommend that a farm use the findings of its assessment to help establish a plan to control potential hazards (Ref. 43. Ref. 46. Ref. 48. Ref. 45. Ref. 49. Ref. 28. Ref. 18)(Ref. 50. Ref. 51). For example, the introduction to the AFDO Model Code notes that a food safety plan should be commensurate with the size and complexity of an operation and the inherent risks of the commodities

grown, along with site specific practices and conditions. The purpose of a food safety plan is to establish measures designed to prevent the introduction of known or reasonably foreseeable food safety hazards into or onto produce in light of the crops, practices, and conditions at the physical location of the farm and would include, for example, measures applicable to an individual farm for agricultural water, animal grazing, and any specific hazards identified in the recommended operational assessment. The FDA draft CSGs recommend developing and maintaining written food safety plans and SOPs for areas such as handling and storage practices, field, facility, and vehicle cleaning and sanitation, and employee training programs. A number of comments to the 2010 FR notice maintained that the most effective approach to produce safety would be one that incorporates food safety plans developed at the operational level. Conversely, another group of comments questioned the need for some industry segments, such as small farms or growers of ''low risk'' commodities to develop or implement food safety plans. The above-mentioned documents provide guidance or recommendations for operators to consider and, as such, do not represent requirements that must be met. We recognize that requiring covered farms to conduct a hazard analysis and develop a food safety plan at the level required in our juice and seafood HACCP regulations, or prescribed by section 418 of FSMA for food manufacturing/processing facilities, may not be feasible. We also recognize that, at this time, only limited tools are available to help with the development of on-farm food safety plans.

Also as noted above, this proposed rule is the first effort by FDA to regulate the produce farming community. We have tentatively concluded, in part based on the statutory direction in section 419 to establish ''minimum science-based standards,'' and in recognition of the direction to pay special attention to minimizing recordkeeping burden and collection of information, that the most appropriate approach for this proposed rule is to establish standards of the type described in section D above. We are not proposing to require farms to conduct operational assessments or to develop food safety plans akin to similar requirements for facilities subject to section 418 of FSMA or our juice HACCP or seafood HACCP regulations. We acknowledge that operational assessments and food safety plans have a prominent place in many public and private produce guidance documents, as discussed above.

The importance of tailoring what you do at an individual operation to your commodities, practices and conditions is commonly accepted, and an operational assessment and food safety plan could be valuable tools for farms to select and implement those recommendations which are appropriate for their circumstances. While we are not proposing to require farms to conduct an operational assessment or develop a food safety plan, we do recommend that farms do so, because this could help farms be more effective in protecting the safety of their produce.

Further, we request comment on whether we should require that some or all covered farms perform operational assessments and/or develop a food safety plan, and if only some, what criteria should be used to separate those to whom the requirement would apply from those to whom it would not.

G. Foreign Farms

The proposed rule would apply to foreign farms that meet the criteria to be covered farms and that grow, harvest, pack, or hold covered produce for import into the United States. This is protective of public health, as foreign farms have been implicated in foodborne illness outbreaks associated with contaminated produce consumed in the United States (Ref. 3). This is also consistent with the requirements of section 419 of the FD&C Act, which clearly contemplates that the rule issued under that authority will apply to foreign farms. This is apparent in sections 419(c)(1)(F) and (c)(2), which provide for a variance process in which states or foreign countries from which food is imported into the US may request variances from FDA. Foreign countries would not be eligible to request variances from this rule if Congress did not intend the rule to apply to farms in foreign countries.

H. Consistency With Codex Guidelines

In developing our proposed approach, we considered the recommendations of relevant Codex guidelines, specifically, the Codex Code of Hygienic Practice for Fresh Fruits and Vegetables (CAC/RCP 53–2003) (the Codex Code). Many of the provisions proposed in this rule are parallel to or consistent with the recommendations in the Codex Code. For example, like our proposed approach of focusing on biological hazards, the Codex Code (while intended to help control microbial, chemical and physical hazards associated with production of fresh fruits and vegetables) pays particular attention to minimizing microbial hazards. It concentrates on microbial hazards and addresses physical and chemical hazards only in so far as they relate to good agricultural and manufacturing practices. The Codex Code recommends measures applicable to all stages of the production of fresh fruits and vegetables, from primary production to packing, with a particular emphasis on those intended to be consumed raw (Section 2.1 of the Codex Code). In proposed § 112.2(a)(1), we propose to exempt a specified list of produce that is rarely consumed raw from the scope of this rule. Similarly, for those commodities not cooked before consumption, the Codex Code recommends a set of broadly applicable minimum standards, with risk-based adjustments.

With respect to agricultural water, the Codex Code recommends the assessment of agricultural water for suitability for use; special attention to irrigation water that is directly applied to edible portion, especially close to harvest; and use of clean water for initial stages followed by potable water for later stages during and after harvest, including cooling (Section 3.2.1.1 of the Codex Code). Many of the proposed provisions described in section V.E. of this document are consistent with these recommendations.

As another example, the Codex Code recommends that personnel follow health and hygiene requirements and that toilet and hand washing and drying facilities be provided during and after harvest, which are reflected in the proposed provisions described in section V.D. of this document. In addition, the proposed provisions described in section V.L. of this document and the Codex Code both recognize the importance of proper design, construction, maintenance and cleaning of buildings and equipment in ensuring produce safety.

Moreover, the Codex Code recommends that ''manure, biosolids and other natural fertilizers which are untreated or partially treated may be used only if appropriate corrective actions are being adopted to reduce microbial contaminants, such as maximizing the time between application and harvest of fresh fruits and vegetables'' (Section 3.2.1.2 of the Codex Code). The recommendation to consider maximizing time between application of untreated amendments and harvest is reflected in proposed provisions described in section V.F. of this document, in particular proposed § 112.56, which stipulates application

intervals for different biological soil amendments of animal origin.

The Codex Code also recommends that ''existing practices should be reviewed to assess the prevalence and likelihood of uncontrolled deposits of animal faeces coming into contact with crops. Considering this potential source of contamination, efforts should be made to protect fresh produce growing areas from animals. As far as possible, domestic and wild animal should be excluded from the area'' (Section 3.1 of the Codex Code). We believe that the proposed provisions in § 112.82, which requires an adequate waiting period between grazing by working animals and harvesting when under the circumstances there is a reasonable probability that grazing or working animals will contaminate covered produce, and § 112.83, which requires monitoring for wild animal intrusion and assessment of safety of harvest where significant intrusion is evident if under the circumstances there is a reasonable probability that animal intrusion will contaminate covered produce, are consistent with (though not identical to) these Codex recommendations.

Furthermore, the proposed requirements related to the maintenance of records (described in section V.O. of this document) are in concert with the Codex documentation and records recommendations for growers and packers, which states: ''Growers should keep current all relevant information on agricultural activities such as the site of production, suppliers' information on agricultural inputs, lot numbers of agricultural inputs, irrigation practices, use of agricultural chemicals, water quality data, pest control and cleaning schedules for indoor establishments, premises, facilities, equipment and containers. Packers should keep current all information concerning each lot such as information on incoming materials (*e.g.* information from growers, lot numbers), data on the quality of processing water, pest control programmes, cooling and storage temperatures, chemicals used in postharvest treatments, and cleaning schedules for premises, facilities, equipment and containers, etc.'' (Section 5.7 of the Codex Code). In the discussion throughout section V of this document, we point out where the proposed provisions are consistent with these and other recommendations of the Codex Code.

I. Product Testing as a Strategy To Control Pathogens

We considered requiring microbiological product testing either routinely or under specific conditions as a strategy to minimize known or reasonably foreseeable hazards. While not widely adopted, product testing is being used by some in the produce industry. Some produce buyers for retail distributors require routine microbial testing of product as a condition of sale in their purchasing specifications (Ref. 52). Individual fresh-cut produce companies began product testing in response to the 2006 *E. coli* O157:H7 outbreak associated with bagged fresh spinach (Ref. 53). At least one company is reported to use product testing to verify the efficacy of good agricultural practices programs and to prevent contaminated product lots from entering commerce (Ref. 52). The California Leafy Greens Marketing Agreement requires crop testing for *E. coli* O157:H7 and *Salmonella* spp. whenever a crop has been directly contacted with water that exceeds the agreements' acceptance criteria for generic *E. coli* (Ref. 31).

Product testing, especially microbiological testing, for process control purposes presents several challenges. Pathogen prevalence in produce as a result of contamination events that occur during growing, harvesting, packing, or holding on farms are generally temporally intermittent, non-homogeneous in a lot or a field, and at low concentrations (Ref. 54). Therefore, unlike some processed foods that may consist of batches of homogeneous material (*e.g.,* bulk flour, milk, juice), produce are best thought of as individual units, and while a positive test result for one unit does raise concern about the rest of the lot or the field subject to the same conditions, procedures, processes, and practices, any contamination present in one unit may not have necessarily spread to other units. In addition, it is generally recognized that negative product test results do not necessarily indicate the absence of a hazard, particularly when the hazard is present at very low levels and is not uniformly distributed (Ref. 55. Ref. 56). Sampling plans intended to ensure detection of contamination with a reasonable assurance of success in produce lots or fields can be cost-prohibitive, and may not be effective for use in produce. For example, for any given contamination rate, the probability of detecting *Salmonella* increases with the number of samples tested and it is not feasible to identify low levels of contamination in an individual lot. For example, when 30 samples in a lot are tested, the probability of detecting *Salmonella* is 1 percent when the contamination rate is 1 in 3000, 26 percent when the contamination rate is 1 in 100, and 96 percent when the contamination rate is 1 in 10 (Ref. 57). Both industry and FDA survey data indicate that contamination rates in produce (melons, greens, tomatoes), while variable, are typically very low (Ref. 58. Ref. 59). In addition, microbial testing can only detect the pathogens that the analytical procedures are designed to detect. Testing instead for indicator organisms may be a viable option, but is not without challenges, as discussed in section V.E.2. of this document.

Another factor affecting the utility of product testing for pathogens as a control measure is that FDA recommends, and it is generally industry practice, to hold any batch of product from which samples are taken for testing to prevent the need for a recall should the test results demonstrate the presence of a pathogen. With a highly perishable product as is the case for most produce, storing product during such analyses would significantly reduce the shelf-life of the product. For these reasons, we tentatively conclude that product testing would be impracticable as a component of science-based minimum standards proposed in this rule except as set forth in proposed subpart M under certain circumstances for sprouts.

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. The effective date is the date that provisions in the rule affect the current CFR.

An effective date of 60 days after date of publication of the final rule in the **Federal Register** would be consistent with the effective dates in recent FDA rules directed to food safety. See, *e.g.,* **Federal Register** of July 9, 2009 (74 FR 33029 at 33030), establishing an effective date of September 8, 2009, for a final rule for the prevention of Salmonella Enteritidis in shell eggs during production, storage, and transportation; and **Federal Register** of June 25, 2007 (72 FR 34751 at 34752), establishing an effective date of August 24, 2007, for a final rule for current good manufacturing practice in manufacturing, packaging, labeling, or holding operations for dietary supplements.

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 (those subject to proposed part 112 and, on a rolling basis, the average annual monetary value of food sold during the previous three-year period is no more than $250,000, as defined in proposed § 112.3(b)(1)) would be four years from the effective date (with the exception of compliance with §§ 112.44, 112.45, 112.50(b)(5), 112.50(b)(6), and 112.50(b)(7), as discussed below). The compliance date for very small businesses would not be in conflict with the requirement in section 419(b)(3)(B) of the FD&C Act for the regulations promulgated under section 419 to apply to very small businesses ''after the date that is 2 years after the effective date of the final regulation. * * *'' because this requirement specifies that the regulations shall apply after, not on, the date that is 2 years after the effective date. To provide additional flexibility to small businesses, we would provide two more years for very small businesses to comply with the rule than is required under section 419(b)(3)(B). 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.)

The compliance date for small businesses (those subject to proposed part 112 and, on a rolling basis, the average annual monetary value of food sold during the previous three-year period is no more than $500,000, as defined in proposed § 112.3(b)(2)) would be three years from the effective date (with the exception of compliance with §§ 112.44, 112.45, 112.50(b)(5), 112.50(b)(6), and 112.50(b)(7), as discussed below). The compliance date for small businesses would not be in conflict with the requirement in section 419(b)(3)(A) of the FD&C Act for the regulations promulgated under section 419 to apply to small businesses ''after the date that is 1 year after the effective date of the final regulation. * * *'' because this requirement specifies that the regulations shall apply after, not on, the date that is 1 year after the effective date. To provide additional flexibility to small businesses, we would provide two more years than is required under section 419(b)(3)(A). Providing an extended compliance period to 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.)

The compliance date for all other farms subject to the rule would be two years from the effective date (with the exception of compliance with §§ 112.44, 112.45, 112.50(b)(5), 112.50(b)(6), and 112.50(b)(7), as discussed below).

The compliance dates for water quality requirements in proposed § 112.44 and related provisions in §§ 112.45, 112.50(b)(5), 112.50(b)(6), and 112.50(b)(7) would be two years beyond the compliance date for the rest of the final rule applicable to the farm based on its size. We recognize that farms may need additional time to cope with implementation of the water quality testing, monitoring, and related record-keeping provisions. This additional compliance period would also be expected to permit farms to consider identifying alternatives to the standard in proposed § 112.44(b) and developing adequate scientific data or information necessary to support a conclusion that the alternative would provide the same level of public health protection as the standard that would be established in this part, and would not increase the likelihood that the covered produce will be adulterated under section 402 of the FD&C Act, in light of the farm's covered produce, practices, and conditions. The extended compliance dates for the water quality testing, monitoring, and related record keeping requirements in proposed §§ 112.44, 112.45, 112.50(b)(5), 112.50(b)(6), and 112.50(b)(7) would then be six years from the effective date for very small businesses, five years from the effective date for small businesses, and four years from the effective date for all other farms subject to the rule.

The compliance dates would apply to all farms subject to the rule, including those farms that satisfy the requirements in proposed § 112.5 for an exemption from most requirements of the rule, because such farms have modified requirements (proposed § 112.6) to which they would be subject on the relevant compliance date.

We seek comment on these proposed implementation periods. In addition, given that activities related to produce production, harvesting, packing, and holding may be affected by the produce growing season, we seek comment on whether these compliance dates sufficiently address any issues related to the seasonal nature of produce-related activities.

V. The Proposal

A. Subpart A—General Provisions

As proposed, subpart A contains provisions that establish the scope of, and definitions applicable to, this regulation, and identifies who is subject to the requirements of this part. This subpart also describes the proposed modified requirements and procedures governing qualified exemptions from this rule.

1. Comments Related to Proposed Provisions

We received several comments in response to the 2010 FR notice that addressed issues relevant to the general scope of this proposed rule. Some comments requested that tree crops be exempt from this regulation. For example, an apple grower asserted that apples are not as susceptible to *E. coli* and other pathogens as are lettuce and tomatoes, and therefore they should not be subject to the same controls and restrictions. Additionally, one grower stated that citrus fruits should be exempt because citrus fruits have not been identified to be the source of an incident of food-borne illness, a majority of such produce does not touch the ground, citrus fruit are washed during the packing process, and the peel is rarely consumed raw. Several comments from produce associations requested removal of watermelons from the ''melon'' category, stating that they should have their own category since they have a different risk profile from other melons. In addition, comments from several tree nut growers stated that some tree nut commodities should have less rigorous requirements or be exempt.

As we explained in Section IV.C, we tentatively concluded that an approach that considers both the risk associated with the commodity and that associated with the agricultural practices applied to the crop under the conditions in which it is grown, would provide the most appropriate balance between public health protection, flexibility, and appropriate management of different levels of risk. Under this approach, we considered available information on outbreaks and contamination as well as existing evidence on characteristics of the commodity (such as whether the commodity grows on trees or has a smooth rind). This evidence informed the proposed requirements, but we have tentatively concluded that limiting the scope of this rule based on outbreak data or on the levels of frequency of pathogen detection alone would not adequately address the risk of serious adverse health consequences or death. Therefore, as discussed in section

V.A.2.a. of this document, we are proposing to cover apples, citrus fruits, watermelons, and tree nuts in this proposed rule. Because the scope and stringency of the regulatory requirements depends in several cases on the types of practices employed within operations, producers of different commodities who use different practices will not be subject to all of the same controls and restrictions. We seek comment on our proposed approach. Because our regulatory approach does not depend on categorizing commodities based on risk profiles, we do not see the need to distinguish among fruits, including watermelons, on this basis. We do note, however, that in proposed § 112.1(b)(1) we have listed watermelons separately from other melons. While we propose to cover tree nuts that do not meet the criteria we propose for ''rarely consumed raw'' (see section V.A.2.a) in this proposed rule, such as walnuts and almonds, we recognize that many of these tree nuts receive commercial processing to adequately reduce pathogens and, thus, may be eligible for an exemption under proposed § 112.2(b) (discussed in section V.A.2.a. of this document). Our main food safety concerns relevant to on-farm growing, harvesting, packing, and holding of tree nuts pertain to those tree nuts that would be sold raw and untreated. We request comments on our treatment of tree nuts in this proposal.

We also received comments regarding various activities performed on produce in relation to the scope of this proposed rule. One comment stated that ''processing'' should not refer to rinsing heads of lettuce or bunches of greens before they are packed for market, but rather should be defined specifically to include other processes that appear to involve additional risk to the consumer. Some comments suggested that no grower should be exempt from these food safety regulations, whereas another stakeholder stated that the produce safety standards must be very clear as to what constitutes produce processing versus produce preparation for market acceptance and that Part 110 should be reserved for situations where extensive commingling, cutting, washing and bagging of produce are practiced. Finally, a comment suggested that growers who deliver produce to the consumer within 24–30 hours should be exempt from this regulation. As discussed in section III.F. of this document and further in section V.A.2.b.i below, this proposed rule would apply to activities of farms and farm mixed-type facilities that are within the definition of ''farm'' proposed here. A farm or farm mixed-type facility that washes its own covered produce would be harvesting within the farm definition and therefore that activity would be covered by this proposed rule unless another exemption applied. However, a farm mixed-type facility that washes covered produce not grown on that farm or another farm under the same ownership for distribution into commerce would be engaging in an activity outside the farm definition (*i.e.,* a manufacturing/processing activity). Such activities would not be subject to this rule but instead would be subject to section 418 of the FD&C Act.

As discussed in section I of this document and the QAR, produce is vulnerable to contamination by pathogens, which can occur at various points during growing, harvesting, packing, and holding. Although contamination usually occurs in low doses, even low doses of some of these harmful pathogens can result in human illness or death (Ref. 60). Thus, if produce is contaminated with a pathogen, there is a reasonable possibility that the amount of the pathogen present will be enough to cause serious adverse health consequences or death to a consumer even without an extended time period before consumption for the pathogen to grow and multiply. In addition, even in cases where the delivery time may not exceed 24–30 hours, consumers and other recipients may store produce (in a refrigerator or otherwise) thereafter and not consume it immediately, allowing additional time for pathogen growth. Therefore, 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.

2. Proposed Requirements

a. Food Covered by This Rule

This proposal is applicable to certain farm activities performed on certain produce for use as human food. Section 105 of FSMA does not specify whether the rulemaking conducted under that section should apply to human food, animal food, or both. The general rulemaking requirements in 419(a)(1)(A), (b)(1), and (c)(1)(A) authorize FDA to establish standards for the safe production and harvesting of fruits and vegetables that are raw agricultural commodities for which the Secretary has determined that such standards minimize the risk of serious adverse health consequences or death. 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. This is reflected in the title of the proposed rule (''Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption'') and its proposed location in Chapter I, Subchapter B of Title 21, Code of Federal Regulations (''Food for Human Consumption'').

As 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. 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.'' 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. As discussed in section III and IV of this document, FDA tentatively concludes that proposed § 112.1(a) is consistent with section 419(a)(1)(A) of the FD&C Act, which directs us to establish science-based minimum standards for the safe production and harvesting of those types of fruits and vegetables that are raw agricultural commodities for which the Secretary has determined that such standards minimize the risk of serious adverse health consequences or death.

We propose to establish a definition of ''produce'' in proposed § 112.3(c) (see section V.A.2.b.iii. of this document) that would be relevant to the use of that term in proposed § 112.1. ''Produce'' would mean any fruit or vegetable (including specific mixes or categories of fruits and vegetables) grown for human consumption, and would include mushrooms, sprouts (irrespective of seed source), peanuts, tree nuts and herbs. Within the definition of ''produce,'' we would further define ''fruit'' and ''vegetable'' to reflect the common meanings of those terms.

We would define a fruit as the edible reproductive body of a seed plant or tree

nut (such as apple, orange and almond), such that fruit would mean the harvestable or harvested part of a plant developed from a flower. This is consistent with the common meaning of the term ''fruit,'' as demonstrated by the Merriam-Webster Dictionary definition of ''fruit'' to mean, in relevant part ''the usually edible reproductive body of a seed plant; especially: One having a sweet pulp associated with the seed * * * a succulent plant part (as the petioles of a rhubarb plant) used chiefly in a dessert or sweet course * * * a product of fertilization in a plant with its modified envelopes or appendages; specifically: The ripened ovary of a seed plant and its contents * * *'' (Ref. 61).

We would define a vegetable as the edible part of an herbaceous plant (such as cabbage and potato) or fleshy fruiting body of a fungus (such as white button and shiitake) grown for an edible part, such that vegetable would mean 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 and cilantro).

This is consistent with the common meaning of the term ''vegetable,'' as demonstrated by the Merriam-Webster Dictionary definition of ''vegetable'' to mean, in relevant part, ''a usually herbaceous plant (as the cabbage, bean, or potato) grown for an edible part that is usually eaten as part of a meal; also: Such an edible part * * *'' (Ref. 61).

We are proposing to specify in the definition of produce that it includes mushrooms, sprouts, peanuts, tree nuts and herbs, to leave no doubt about the status of these foods. Taxonomically, a mushroom is a fungus (Ref. 62). For regulatory purposes in the United States, however, mushrooms have generally been treated as vegetables. Mushrooms are classified as vegetables by USDA AMS under the Perishable Agricultural Commodities Act (7 U.S.C. 499a–499t) (PACA) (Ref. 63), using a definition stating in relevant part that ''fresh fruits and fresh vegetables'' means ''all produce in fresh form generally considered as perishable fruits and vegetables * * *'' (21 CFR 46.2(u)). The USDA 2010 Dietary Guidelines for Americans also include mushrooms in the ''vegetable'' food group (Ref. 64). In addition, the produce industry appears to recognize mushrooms as vegetables, as demonstrated by various industry documents (Ref. 65. Ref. 66). Moreover, the hazards and controls relevant to minimizing serious adverse health consequences or death during the growing, harvesting, packing, and holding of mushrooms are generally similar to those for other produce (Ref. 67). Accordingly, we tentatively conclude that it is reasonable to include mushrooms in the proposed definition of ''vegetable.''

Sprouts meet the definition of ''vegetable'' above from the Merriam-Webster Dictionary (Ref. 61). In addition, sprouts are classified as vegetables by USDA AMS under PACA (Ref. 63). The USDA 2010 Dietary Guidelines for Americans also include ''bean sprouts'' in the ''vegetable'' food group (Ref. 64). In addition, the produce industry appears to recognize sprouts as vegetables, as demonstrated by various industry documents (Ref. 68). Moreover, the hazards and controls relevant to minimizing serious adverse health consequences or death during the growing, harvesting, packing, and holding of sprouts are generally similar to those for other produce, but with additional controls necessary due to the unique risks presented by sprouts (Ref. 160. Ref. 161) (see section V.M of this document). Accordingly, we tentatively conclude that it is reasonable to include sprouts in the proposed definition of ''vegetable.'' Herbs meet the definition of ''vegetable'' above from the Merriam-Webster Dictionary (Ref. 61). Herbs are generally consumed in combination with other foods (for example, in salads or as garnishes) rather than consumed as distinct servings, but they nonetheless satisfy the dictionary definition of ''vegetable.'' In addition, USDA considers herbs to be covered commodities under PACA, such that they are classified as ''herbs'' but fall within the broader category of ''fresh fruits and fresh vegetables'' (Ref. 63). In addition, the produce industry appears to recognize herbs as vegetables, as demonstrated by various industry documents (Ref. 66). Moreover, the hazards and controls relevant to minimizing serious adverse health consequences or death during the growing, harvesting, packing, and holding of herbs are generally similar to those for other produce(Ref. 13. Ref. 50). Accordingly, we tentatively conclude that it is reasonable to include herbs in the proposed definition of ''vegetable.''

Peanuts and tree nuts both meet the definition of ''fruit'' above from the Merriam-Webster Dictionary (Ref. 61). The Merriam-Webster Dictionary defines ''peanut,'' in relevant part, as ''a low-branching widely cultivated annual herb * * * of the legume family with showy yellow flowers having a peduncle which elongates and bends into the soil where the ovary ripens into a pod containing one to three oily edible seeds * * *,'' and ''nut,'' in relevant part, as ''a hard-shelled dry fruit or seed with a separable rind or shell and interior kernel * * *'' (Ref. 61). In addition, the produce industry appears to recognize peanuts and tree nuts as produce, as demonstrated by various industry documents (Ref. 65. Ref. 66). Moreover, the hazards and controls relevant to minimizing serious adverse health consequences or death during the growing, harvesting, packing, and holding of peanuts and tree nuts are generally similar to those for other produce (Ref. 69. Ref. 70). Specifically, peanuts and tree nuts share the significant hazard of pathogens with other covered produce. To a significant extent, this hazard is eliminated during manufacturing/processing operations, such as roasting, by facilities subject to section 418 of the FD&C Act, rather than through measures taken by farms subject to this regulation. However, as discussed in section V.A.2.a below, peanuts meet our proposed criteria for ''rarely consumed raw'' and therefore would be exempt from this proposed rule. Tree nuts that do not meet the criteria for ''rarely consumed raw'' would also be exempt from this proposed regulation if you establish and keep documentation that demonstrates that the recipient of the produce performs commercial processing in accordance with proposed § 112.2(b)(1). For tree nuts that remain subject to the proposed rule, the kinds of measures necessary to minimize the risk of known or reasonably foreseeable biological hazards are the same as those in subparts A through O of this proposed rule (*e.g.,* control of soil amendments, agricultural water, worker hygiene). Accordingly, we conclude it is reasonable to include peanuts and tree nuts in the proposed definition of produce as a ''fruit.'' We recognize that peanuts and tree nuts are not covered commodities under PACA ((Ref. 63. Ref. 71) and that the USDA 2010 Dietary Guidelines for Americans consider nuts a ''protein food'' rather than as part of the ''fruits and vegetables'' group for the purpose of providing dietary advice (Ref. 72); however, in light of the treatment of peanuts and tree nuts as produce in common usage and in the produce industry, and the commonality of on-farm hazards and controls for peanuts, tree nuts, and other produce (Ref. 70. Ref. 69), we tentatively conclude that it is reasonable to include peanuts and tree nuts in the proposed definition of produce as ''fruits.''

We propose to specify in the definition of ''produce'' that the term would 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 would include barley, dent- or flint-corn, sorghum, oats, rice, rye, wheat, amaranth, quinoa, buckwheat, cotton seed, and soybean. Our proposed definition of ''food grains'' is consistent with the common meaning of the term ''grain'' when used in the context of food, as demonstrated by the Merriam-Webster Dictionary definition of ''grain'' to mean, in relevant part, ''a seed or fruit of a cereal grass * * * the seeds or fruits of various food plants including the cereal grasses and in commercial and statutory usage other plants (as the soybean) * * * plants producing grain * * *'' (Ref. 61). In addition, the industry appears to recognize grains as a separate commodity group from produce, as demonstrated by various industry documents regarding ''produce'' and ''fruits and vegetables'' that do not include grains (Ref. 65. Ref. 66). Grains are not covered commodities under PACA (Ref. 63). The USDA 2010 Dietary Guidelines for Americans treat grains as a separate food group from the ''fruits and vegetables'' food group (Ref. 73). In addition, the hazards and controls relevant to minimizing serious adverse health consequences or death during the growing, harvesting, packing, and holding of grains are significantly different from those relevant to fruits and vegetables (Ref. 74). Specifically, the hazards of concern in grains are primarily chemical hazards such as mycotoxins and pesticides, rather than biological hazards (which, as discussed in section IV.B. of this document, are the only hazards we currently propose to address in this rule, as they are the most significant hazards affecting covered produce), because grains are milled and/or cooked such that pathogens that may be present are reduced to a level where they are unlikely to present a risk to public health for most products. Accordingly, we tentatively conclude that it is reasonable to exclude grains from the definition of ''produce.''

Proposed § 112.1(b)(1) lists specific examples of produce covered by this rule. Such covered produce would include almonds, apples, apricots, aprium, asian pear, avocados, babaco, bamboo shoots, bananas, Belgian endive, blackberries, blueberries, broccoli, cabbage, cantaloupe, carambola, carrots, cauliflower, celery, cherries, citrus (such as clementine, grapefruit, lemons, limes, mandarin, oranges, tangerines, tangors, and uniq fruit), cucumbers, curly endive, garlic, grapes, green beans, guava, herbs (such as basil, chives, cilantro, mint, oregano, and parsley), honeydew, kiwifruit, lettuce, mangos, other melons (such as canary, crenshaw and persian), mushrooms, nectarine, onions, papaya, passion fruit, peaches, pears, peas, peppers (such as bell and hot), pineapple, plums, plumcot, radish, raspberries, red currant, scallions, snow peas, spinach, sprouts (such as alfalfa and mung bean), strawberries, summer squash (such as patty pan, yellow and zucchini), tomatoes, walnuts, watercress and watermelon.

The list of fruits and vegetables provided in proposed § 112.1(b)(1) is not an exhaustive list of produce covered by this rule. This section is intended simply to provide examples of produce commonly consumed in the United States that would be included within the scope of this regulation. The absence of a specific fruit or vegetable from this list does not indicate that it is not covered, except where the specific fruit or vegetable is exempted from the regulation by § 112.2(a)(1). We request comment on the examples of fruits and vegetables listed in 112.1(b)(1).

Proposed § 112.1(b)(2) would clarify that mixes of intact fruits and vegetables (such as fruit baskets) are also covered by this rule. Proposed § 112.1(b)(2) is consistent with section 419(a)(1)(A) of the FD&C Act, which includes mixes or categories of fruits and vegetable RACs as part of the rulemaking requirement we are implementing through this proposed rule.

As proposed, § 112.2(a) identifies three types of produce not covered by this rule. First, proposed § 112.2(a)(1) provides an exclusion for produce that is rarely consumed raw. FDA proposes to establish the following exhaustive list of specific fruits and vegetables that would be exempt under this provision: arrowhead, arrowroot, artichokes, asparagus, beets, black-eyed peas, bok choy, brussels sprouts, chick-peas, collard greens, crabapples, cranberries, eggplant, figs, ginger root, kale, kidney beans, lentils, lima beans, okra, parsnips, peanuts, pinto beans, plantains, potatoes, pumpkin, rhubarb, rutabaga, sugarbeet, sweet corn, sweet potatoes, taro, turnips, water chestnuts, winter squash (acorn and butternut squash), and yams. Because these listed fruits and vegetables are almost always consumed only after being cooked, which is a kill-step that adequately reduces the presence of microorganisms of public health significance, we propose that these listed produce be excluded from the requirements of this rule. Studies have shown that the numbers of microorganisms of public health significance (such as *Listeria monocytogenes, Salmonella,* shiga toxin-producing *E. coli*) are significantly reduced in produce by a variety of relatively moderate heat treatments (Ref. 75. Ref. 76. Ref. 77. Ref. 78). Therefore, we tentatively conclude that the cooking that the produce listed in § 112.2(a)(1) receive before they are consumed, whether commercially or by the consumer, would be sufficient to minimize the risk of serious adverse health consequences or death.

We note that all produce commodities are and will continue to be covered under the adulteration provisions and other applicable provisions of the Federal Food, Drug, and Cosmetic Act and applicable implementing regulations, irrespective of whether they are included within the scope of this proposed rule.

We developed this list in proposed § 112.2(a)(1) of produce that rarely is consumed raw by analyzing consumption data on selected produce commodities using data available from the National Health and Nutrition Examination Survey (NHANES) and other resources (Ref. 79). We looked at the percentage of the population consuming the produce commodity in fresh form as well as the percentage of eating occasions on which the produce commodity is eaten uncooked (Ref. 79. Ref. 80). As explained further in a memo to the record, we found that artichokes, asparagus, beets, bok choy, brussels sprouts, cranberries, eggplant, figs, ginger root, lima beans, okra, plantains, potatoes, rhubarb, sweet corn, sweet potatoes, turnips, and yams are eaten uncooked by less than 0.1% of the U.S. population and are consumed uncooked on less than 0.1% of eating occasions (Ref. 79). Other commodities, including black-eyed peas, chick-peas, collard greens, crabapples, kale, kidney beans, lentils, parsnips, peanuts, pinto beans, pumpkin, rutabaga, sugarbeet, taro, water chestnut, and winter squash (which includes both acorn and butternut squash) are included in the NHANES data set but their categories of reported consumption do not include ''uncooked,'' indicating that they are not consumed uncooked in any measurable quantity (Ref. 79). Still other commodities on the list, namely, arrowhead and arrowroot, are not identified in the NHANES data set as being eaten in the United States in any form, uncooked or otherwise (Ref. 79). Other references indicated that those commodities are typically consumed

cooked (Ref. 63. Ref. 82). We request comment on the proposed criteria used for identifying the commodities that are rarely consumed raw. Further, we request comment on additional commodities that should be considered for inclusion in the list in 112.2(a)(1). As noted above, we analyzed consumption data on selected produce commodities to generate this list. We acknowledge that there may be additional commodities that would meet these criteria that we did not analyze. Also, we anticipate that, in the case of some commodities, the consumption rates in the United States may be too low for the NHANES data and other data sources used in our analysis to support a conclusion that the commodity is rarely consumed raw using our proposed criteria. We request comment on additional sources of information and/or criteria that should be applied in such cases.

We also request comment on the inclusion of commodities that our analysis indicates are rarely consumed raw, but may not be prepared in a manner that would kill microbial contaminants, should they be present on the food. For example, we have included asparagus, bok choy, and cranberries in the list of commodities that will be exempt from the requirements of this rule in proposed § 112.2(a)(1) because the NHANES data indicated that these commodities are consumed uncooked by less than 0.1% of the U.S. population and are consumed uncooked on less than 0.1% of eating occasions (Ref. 79). However, we are concerned that the method of food preparation that these commodities may be subjected (for example, stir frying bok choy) to prior to consumption may not constitute a kill-step that adequately reduces the presence of microorganisms of public health significance. We request comment on our tentative conclusions about these commodities and others proposed for exclusion in § 112.2(a)(1).

Second, § 112.2(a)(2) proposes to exempt produce that is produced by an individual for personal consumption or produced for consumption on the farm or another farm under the same ownership. With respect to the exemption for personal consumption, section 419(g) of the FD&C Act specifically exempts food produced by an individual for personal consumption from this rulemaking, and proposed § 112.2(a)(2) implements this exclusion. With respect to the exclusion for produce for consumption on the farm or another farm under the same ownership, such activities are within the definition of farm that we propose here, and would therefore be subject to this rule without an exemption. To the extent that there is any difference between produce ''for personal consumption'' and produce ''consumed on the farm or another farm under the same ownership,'' FDA proposes to exclude produce for either type of consumption from this proposed rule.

Third, § 112.2(a)(3) proposes to exclude produce that is not a raw agricultural commodity from this proposed rule. For example, this would exclude ''fresh-cut'' produce, which is subject to current part 110 and to section 418 of the FD&C Act as applicable (Ref. 83). This is consistent with section 419(a)(1)(A) of the FD&C Act, which directs FDA to ''establish science-based minimum standards for the safe production and harvesting of those types of fruits and vegetables * * * that are raw agricultural commodities * * *.'' This is also consistent with the application of this rule to activities within the farm definition. In section V.A.2.b.i of this document, we discuss how we considered how the activities of farms relate to the concept of a RAC and tentatively concluded that the farm definition and related definitions in this proposed rule should be revised based on the concept that RACs are the essential products of farms. Accordingly, the definitions proposed here (for the terms farm, mixed-type facility, harvesting, manufacturing/processing, packing, and holding) reflect the tentative conclusion that activities involving RACs 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.'' This is the case even if the same activities off-farm would be considered to be ''manufacturing/processing'' because those activities involve ''making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food.'' This special classification of on-farm activities, however, should only apply to RACs because only RACs, not processed foods, are the essential products of farms. For all of these reasons, RACs are a logical and appropriate focus for these produce safety standards.

In addition to these three exemptions mentioned above, under the conditions specified in § 112.2(b), we propose to allow covered produce which receives commercial processing that adequately reduces the presence of microorganisms of public health significance to be eligible for an exemption from the requirements of this part (except for subparts A, Q, and O). Examples of commercial processing that adequately reduces the presence of microorganisms of public health significance are processing in accordance with the requirements of part 113, part 114, or part 120; 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. As discussed in section IV.C. of this document, FDA tentatively concludes that such commercial processing significantly minimizes the risk of serious adverse health consequences or death associated with biological hazards for such produce, such that the produce can be considered to be low risk and the imposition of the requirements in this proposed rule is not warranted. We note that such produce is and will continue to be covered under the adulteration provisions and other applicable provisions of the Federal Food, Drug, and Cosmetic Act and applicable implementing regulations, irrespective of whether it is included within the scope of this proposed rule.

As proposed, to qualify for the § 112.2(b) exemption, proposed § 112.2(b)(2) would require you to establish and keep documentation of the identity of the recipient of the covered produce that performs the commercial processing in accordance with the requirements of proposed subpart O. FDA tentatively concludes that such records are necessary for the efficient enforcement of the FD&C Act. Without such records, FDA would have no way to assess whether farms are complying with the terms of this exemption. In addition, proposed § 112.2(b)(3) would clarify that the requirements of subparts A and Q apply to such produce because subpart A includes relevant provisions such as the scope of this rule and definitions, and Q contains provisions relating to compliance and enforcement.

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.

b. Definitions

Proposed § 112.3 would establish the definitions of terms for purposes of part 112. To the extent possible, the new definitions proposed in § 112.3 are consistent with the common meanings of these terms as well as the definitions of the terms in other food safety regulations (see, *e.g.,* current § 110.3 and § 111.3) and other applicable sources. As proposed in § 112.3(a), to provide clarity and consistency, the definitions and interpretations of terms in section 201 of the FD&C Act will apply to such terms when used in part 112.

i. Definitions of ''Farm,'' ''Mixed-Type Facility,'' and Related Activities

We are proposing to establish an inter-related series of definitions in this proposed rule that, collectively, would address several issues related to the scope of establishments (namely, ''farms'') that would be subject to the rule. These inter-related definitions include two definitions for types of establishments (*i.e.,* ''farm'' and ''mixed-type facility'') and five definitions for types of activities (*i.e.,* ''harvesting,'' ''holding,'' ''manufacturing/processing,'' ''packaging,'' and ''packing'') conducted on farms and mixed-type facilities.

These proposed definitions are based on definitions already established in our regulations (*e.g.,* in § 1.227 in the regulations for Registration of Food Facilities, established under section 415 of the FD&C Act; hereinafter the section 415 registration regulations). However, the definitions that we are proposing for the purpose of the produce safety rule have some differences relative to the current definitions established in the section 415 registration regulations. In the near future, we plan to address how we will coordinate the definitions in the section 415 registration regulations with the definitions we are proposing for the purpose of the produce safety proposed rule.

In developing these proposed definitions, we considered how the activities of farms relate to the statutory concepts of ''raw agricultural commodity'' and ''processed food.'' The FD&C Act defines ''raw agricultural commodity'' and ''processed food'' in relation to each other, and identifies certain activities that transform a raw agricultural commodity (RAC) into a processed food and others that do not. Section 201(r) of the FD&C Act (21 U.S.C. 321(r)) defines ''raw agricultural commodity'' to mean ''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.'' Section 201(gg) of the FD&C Act (21 U.S.C. 321(gg)) defines ''processed food'' to mean ''any food other than a raw agricultural commodity and includes any raw agricultural commodity that has been subject to processing, such as canning, cooking, freezing, dehydration, or milling.'' In addition, section 201(q)(1)(B)(i)(II) of the FD&C Act (which defines pesticide chemicals) contains the following language regarding activities that do not transform a RAC into a processed food: ''the treatment [with pesticide chemicals] is in a manner that does not change the status of the food as a raw agricultural commodity (including treatment through washing, waxing, fumigating, and packing such commodities in such manner).''

The status of a food as a RAC or processed food is relevant for many different purposes under the FD&C Act, including section 419(a)(1)(A) of the FD&C Act, which authorizes FDA to establish minimum science-based standards applicable to certain fruits and vegetables that are RACs. For example, under 403(w) of the FD&C Act (21 U.S.C. 343(w)), labeling requirements related to major food allergens apply to processed foods but do not apply to RACs. Under sections 201(q), 403(k), 403(l), and 408 of the FD&C Act (21 U.S.C. 321(q), 343(k), 343(l), and 346a), the status of a food as a RAC has an impact on the manner in which pesticide chemicals and their residues are regulated. FSMA created more provisions in the FD&C Act and elsewhere that take status as a RAC or processed food into account, including section 417(f) of the FD&C Act (21 U.S.C. 350f(f)), establishing notification requirements for reportable foods that do not apply to fruits and vegetables that are RACs; section 418(m) of the FD&C Act, which authorizes FDA to exempt or modify the requirements for compliance under section 418 with respect to facilities that are solely engaged in the storage of RACs other than fruits and vegetables intended for further distribution or processing; and section 204(d)(6)(D) of FSMA (21 U.S.C. 2223(d)(6)(D)), which contains special provisions for commingled RACs applicable to FDA's authority under section 204 of FSMA to establish additional recordkeeping requirements for high risk foods.

The term ''raw agricultural commodity'' and similar terms also appear in other Federal statutes. While these statutes are not implemented or enforced by FDA and do not directly impact the interpretation of the definitions in sections 201(r) and 201(gg) of the FD&C Act, they do provide some suggestions about what ''raw agricultural commodity'' and related concepts can mean in various circumstances. For example, the Secretary of Transportation may prescribe commercial motor vehicle safety standards under 49 U.S.C. 31136, but the Motor Carrier Safety Improvement Act of 1999 (Pub. L. 106–159, title II, Sec. 229, Dec. 9, 1999), as added and amended by the Safe, Accountable, Flexible, Efficient Transportation Equity Act: A Legacy for Users (Pub. L. 109–59, title IV, Sec. 4115, 4130, Aug. 10, 2005), provided an exemption from maximum driving or on-duty times for drivers transporting ''agricultural commodities'' or farm supplies within specific areas during planting and harvest periods. In that circumstance, ''agricultural commodity'' is defined as ''any agricultural commodity, non-processed food, feed, fiber, or livestock * * * and insects'' (49 U.S.C. 31136 note). Another example is 19 U.S.C. 1677(4)(E), which provides for certain circumstances in which producers or growers of raw agricultural products may be considered part of the industry producing processed foods made from the raw agricultural product for the purposes of customs duties and tariffs related to such processed foods. In that circumstance, ''raw agricultural product'' is defined as ''any farm or fishery product'' (19 U.S.C. 1677(4)(E)). These statutes are informative in that they suggest that the ''raw agricultural commodity'' concept describes and

signifies the products of farms in their natural states, or, in other words, that which a farm exists to produce on a basic level.

Because the status of a food as a RAC or processed food is of great importance in defining the jurisdiction of FDA and the U.S. Environmental Protection Agency (EPA) over antimicrobial substances, FDA and EPA have developed guidance regarding whether or not various activities transform RACs into processed foods. FDA and EPA jointly issued a legal and policy interpretation of the agencies' jurisdiction under the FD&C Act over antimicrobial substances used in or on food (hereinafter the ''1998 Joint EPA/FDA Policy Interpretation'') (63 FR 54532, October 9, 1998). In 1999, FDA issued guidance addressing several of the issues discussed in the 1998 Joint EPA/FDA Policy Interpretation. (See Guidance for Industry: Antimicrobial Food Additives, July 1999 (hereinafter ''Antimicrobial Guidance'') (Ref. 84)). Table 1 summarizes activities that cause food RACs to become processed foods and activities that do not change the status of a food RAC, as set out in the 1998 Joint EPA/FDA Policy Interpretation and the Antimicrobial Guidance.

TABLE 1—THE EFFECT OF ACTIVITIES ON RACS THAT ARE FOODS

Activities that change a RAC into a processed food	Activities that do not change the status of a RAC
Canning	Application of pesticides (including by washing, waxing, fumigation, or packing).
Chopping	Coloring.
Cooking	Drying for the purpose of storage or transportation.
Cutting	Hydro-cooling.
Drying that creates a distinct commodity	Otherwise treating fruits in their unpeeled natural form.
Freezing	Packing.
Grinding	Refrigeration.
Homogenization	Removal of leaves, stems, and husks.
Irradiation	Shelling of nuts.
Milling	Washing.
Pasteurization	Waxing.
Peeling	Activities designed only to isolate or separate the commodity from foreign objects or other parts of the plant.
Slaughtering animals for food and activities done to carcasses post-slaughter, including skinning, eviscerating, and quartering.	
Slicing.	
Activities that alter the general state of the commodity.	

In developing the proposed definitions, we also considered the definition of ''manufacturing/processing'' that FDA established in § 1.227. Under § 1.227(b)(6), ''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. The summary in Table 1 demonstrates that the activities that transform a RAC into a processed food (and are sometimes therefore referred to as ''processing'' in the context of a food's status as a RAC or processed food) are not coextensive with the definition of ''manufacturing/processing'' that FDA established in § 1.227(b)(6) for the purposes of the section 415 registration regulations. The definition of ''Manufacturing/processing'' in that regulation includes most food-handling activities because it is satisfied by any degree of ''making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food.'' In contrast, transforming a RAC into a processed food seems to require meeting a threshold of altering the general state of the commodity (Ref. 3, section 7 and 63 FR 54532 at 54541), sometimes referred to as transformation of the RAC into a new or distinct commodity (61 FR 2386 at 2388). Because the activities that transform a RAC into a processed food are not coextensive with the definition of ''manufacturing/processing'' in § 1.227(b)(6), a given activity may be manufacturing/processing under the current definition in § 1.227(b)(6) without transforming a RAC into a processed food. Examples of such activities include coloring, washing, and waxing.

The current section 415 registration regulations demonstrate that some activities may be classified differently on farms and off farms. For example, ''washing'' is an example of manufacturing/processing under the definition of that term in § 1.227(b)(6). However, ''washing'' produce is identified as part of harvesting under the farm definition in § 1.227(b)(3), so washing on farms is harvesting rather than manufacturing/processing under the Section 415 registration regulations. To date, we have not articulated organizing principles explaining these differences.

In this document, we are tentatively articulating five organizing principles (summarized in Table 2 below) to explain the basis for the proposed definitions that would classify activities on-farm and off-farm for the purpose of this proposed rule. In the near future, we plan to address how we will coordinate the definitions in the section 415 registration regulations with the definitions we are proposing for the purpose of this proposed rule.

First Organizing Principle. The statutes we describe above, and previous interpretations of the concepts of RACs and processed food as set forth in the 1998 Joint EPA/FDA Policy Interpretation and the Antimicrobial Guidance, lead FDA to tentatively conclude that the basic purpose of farms is to produce RACs and that RACs are the essential products of farms.

Second Organizing Principle. Our second organizing principle is that 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.'' This is because

the basic purpose of farms is to produce RACs (principle 1). This is the case even if the same activities off-farm would be considered to be manufacturing/processing, because those activities involve ''making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food.''

Third Organizing Principle. 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. This is because principle 2 (*i.e.,* the special classification of on-farm activities) should only apply to RACs. A farm that chooses to transform its RACs into processed foods should be considered to have chosen to expand its business beyond the traditional business of a farm.

Fourth Organizing Principle. Principle 2 (*i.e.,* the special classification of on-farm activities) should only apply to RACs grown or raised on the farm itself or on other farms under the same ownership because the essential purpose of a farm is to produce its own RACs, not to handle RACs grown on unrelated farms for distribution into commerce. (For the purposes of this discussion, we refer to RACs grown or raised on a farm or another farm under the same ownership as a farm's ''own RACs,'' in contrast to RACs grown on a farm under different ownership, which we refer to as ''others' RACs.'') Activities that 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. In general, when a farm opts to perform activities outside the farm definition, the establishment's activities that are within the farm definition should be classified as manufacturing/processing, packing, or holding in the same manner as for a farm that does not perform activities outside the farm definition, but the activities that are outside the farm definition should be classified in the same manner as for an off-farm food establishment.

Fifth Organizing Principle. 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 because otherwise farms could not feed people and animals on the farm without being considered to have engaged in activities outside the farm definition.

TABLE 2—SUMMARY OF ORGANIZING PRINCIPLES REGARDING CLASSIFICATION OF ACTIVITIES ON-FARM AND OFF-FARM

Number	Organizing principle
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.

We are proposing to include definitions for two types of establishments (*i.e.,* ''farm'' and ''mixed-type facility'') and five types of activities (*i.e.,* ''harvesting,'' ''holding,'' ''manufacturing/processing,'' ''packaging,'' and ''packing''), to reflect the organizing principles articulated immediately above and to clarify how those definitions apply to specific activities depending on where the activities take place, the food used in the activities, where the food comes from, and where the food is consumed. We discuss these proposed definitions in this section because they are interrelated; however, we propose that they appear in § 112.3(c) in alphabetical order with the other definitions discussed in section V.A.2.b.iii of this document below.

We are proposing to define ''farm'' to mean a facility in one general physical location devoted to the growing and harvesting of crops, the raising of animals (including seafood), or both. The term ''farm'' includes: (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 the same ownership. The proposed definition of ''farm'' is based on the definition already established in § 1.227(b) in the section 415 registration regulations, except that it does not include the statement ''Washing, trimming of outer leaves of, and cooling produce are considered part of harvesting.'' The description of harvesting activities is included in a separate proposed definition of ''harvesting'' and thus would be redundant in the proposed definition of ''farm.''

We are proposing to define ''Mixed-type facility'' to mean an establishment that engages in both activities that are exempt from registration under section 415 of the FD&C Act and activities that require the establishment to be registered. This term and its definition were initially developed in the preamble to the proposed rule on food facility registration (68 FR 5378 at 5381) and in the interim final rule on food facility registration (68 FR 58894 at 58906–7, 58914, 58934–8). The proposed definition would also provide, as an example of such a facility, a definition of a ''farm mixed-type facility.'' A ''farm mixed-type facility'' would be defined as 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. This definition is important to include in this rule because the activities of farm mixed-type facilities that are within the definition of ''farm'' are potentially subject to this rule, as provided in proposed § 112.4. FDA would apply this proposed rule only to the ''farm'' portion of these establishments' activities, and not to the ''non-farm'' portion of their activities (which would be subject to section 418 of the FD&C Act and therefore not subject to this proposed rule, consistent with section 419(h) of the FD&C Act). Put another way, farms and the ''farm'' portion of

the activities of farm mixed-type facilities would be subject to this proposed rule as applicable. For simplicity, FDA proposes to reference these activities collectively in proposed § 112.4(a) as one aspect of what makes an entity a ''covered farm'' and then to refer only to ''covered farms'' throughout the proposed rule. Thus, references to ''farms'' and ''covered farms'' throughout this proposed rule should be understood to include the portion of a farm mixed-type facility's activities that are within the farm definition.

We are proposing to define the term ''Harvesting'' to apply to farms and farm mixed-type facilities and be defined as 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 would be 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 would not include activities that transform a raw agricultural commodity, as defined in section 201(r) of the FD&C Act, into a processed food as defined in section 201(gg) of the FD&C Act. Gathering, washing, trimming of outer leaves of, removing stems and husks from, sifting, filtering, threshing, shelling, and cooling raw agricultural commodities grown on a farm or another farm under the same ownership would be listed as examples of harvesting. This proposed definition would include the same examples of ''harvesting'' that are currently part of the farm definition in § 1.227(b)(3) (washing, trimming of outer leaves, and cooling) and would add other examples to help clarify the scope of the definition of harvesting. ''Harvesting'' is a category of activities that is only applicable to farms and farm mixed-type facilities. Activities that would be ''harvesting'' when performed on a farm on the farm's own RACs would be classified differently under other circumstances, such as at a processing facility that is not on a farm, or when performed by a farm on others' RACs. For example, at an off-farm facility that packs tomatoes, washing the tomatoes after they are received would not be ''harvesting'' because it is not being performed on the farm that produced the tomatoes (or another farm under the same ownership). Instead, washing tomatoes at the off-farm packing facility would be ''manufacturing,'' because it involves preparing, treating, modifying, or manipulating food.

We are proposing to define ''Holding'' to mean the storage of food. The proposed definition would state that, for farms and farm mixed-type facilities, holding would also include activities traditionally performed by farms for the safe or effective storage of RACs grown or raised on the same farm or another farm under the same ownership, but would not include activities that transform a RAC, as defined in section 201(r) of the FD&C Act, into a processed food as defined in section 201(gg) of the FD&C Act. This would mean that more activities than just storage of food would be classified as ''holding'' when a farm or farm mixed-type facility performs those activities on its own RACs. For example, fumigating or otherwise treating a farm's own RACs against pests for the purpose of safe and effective storage would be ''holding'' under this proposed definition. However, fumigating or otherwise treating food against pests under other circumstances (such as off-farm or by a farm handling others' RACs) would not be ''holding'' food because it is not storage of food, which would remain the definition of holding applicable to most circumstances.

We are proposing to define ''Manufacturing/processing'' to mean making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients. The proposed definition would also state that, for farms and farm mixed-type facilities, manufacturing/processing would not include activities that are part of harvesting, packing, or holding. Under this proposed definition, the expanded definitions of ''packing'' and ''holding,'' and the extra category ''harvesting,'' would apply to activities performed by farms and farm mixed-type facilities on their own RACs. These expanded and extra categories would not apply off-farm or to foods other than a farm's own RACs or a farm mixed-type facility's own RACs. Thus, some activities that would otherwise be manufacturing/processing would instead be defined as packing, holding, or harvesting by virtue of being performed by a farm or farm mixed-type facility on its own RACs. Accordingly, these activities would not be manufacturing/processing because they would already be classified into the expanded definitions of packing or holding, or into the extra category of harvesting.

We are proposing to define ''Packaging'' to mean (when used as a verb) placing food into a container that directly contacts the food and that the consumer receives. We are proposing to use the same definition of ''packaging'' as is currently established in § 1.227.

We are proposing to define ''Packing'' to mean placing food into a container other than packaging the food. The proposed definition would also state that, for farms and farm mixed-type facilities, packing would also include activities (which may include packaging) traditionally performed by farms to prepare RACs grown or raised on the same farm or another farm under the same ownership for storage and transport, but would not include activities that transform a RAC, as defined in section 201(r) of the FD&C Act, into a processed food as defined in section 201(gg) of the FD&C Act. This would mean that more activities than just placing food into a container other than packaging would be classified as ''packing'' when a farm or farm mixed-type facility performs those activities on its own RACs. For example, packaging (placing food into a container that directly contacts the food and that the consumer receives) a farm's own RACs would be ''packing'' under this definition because farms traditionally do this to provide greater protection for fragile RACs than would be possible if the RACs were placed in containers other than the consumer container, and because this activity does not transform a RAC into a processed food. However, packaging food under other circumstances would not be ''packing'' food because packaging is explicitly excluded from the definition of packing applicable to most circumstances (placing food into a container other than packaging). Other examples of activities that could be packing when performed by a farm or a farm mixed-type facility on its own RACs include packaging or packing a mix of RACs together (*e.g.,* in a bag containing three different colored bell peppers, or a box of mixed produce for a community sponsored agriculture program farm share); coating RACs with wax, oil, or resin coatings used for the purposes of storage or transport; placing stickers on RACs; labeling packages containing RACs; sorting, grading, or culling RACs; and drying RACs for the purpose of storage or transport.

Table 3 provides examples of how we would classify activities conducted off-farm and on-farm (including farm mixed-type facilities) using these proposed definitions.

TABLE 3—CLASSIFICATION OF ACTIVITIES CONDUCTED OFF-FARM AND ON-FARM

[including farm mixed-type facilities]

Classification	Off farm	On farm (including farm mixed-type facilities)
Harvesting	**Notes:** Not applicable. Harvesting is a classification that only applies on farms and farm mixed-type facilities.	**Notes:** Activities traditionally performed by farms for the purpose of removing RACs from growing areas and preparing them for use as food. Harvesting is limited to activities performed on RACs on the farm on which they were grown or raised, or another farm under the same ownership. Harvesting does not include activities that change a RAC into processed food. Activities that are harvesting are within the farm definition.
	Examples: Not applicable	**Examples:** activities that fit this definition when performed on a farm's "own RACs" (a term we use to include RACs grown or raised on that farm or another farm under the same ownership) include gathering, washing, trimming of outer leaves, removing stems and husks, sifting, filtering, threshing, shelling, and cooling. These activities, performed on a farm's own RACs, are inside the farm definition.
Packing	**Notes:** Placing food in a container other than packaging the food (where packaging means placing food into a container that directly contacts the food and that the consumer receives).	**Notes:** Placing food in a container other than packaging the food (using the same definition of packaging), or activities (which may include packaging) traditionally performed by farms to prepare RACs grown or raised on that farm or another farm under the same ownership for storage or transport. Packing does not include activities that change RAC into a processed food. Activities that are packing are within the farm definition when they are performed on food grown, raised, or consumed on that farm or another farm under the same ownership; under any other circumstances they are outside the farm definition.
	Examples: putting individual unit cartons into a larger box used for shipping, and putting articles of produce in non-consumer containers (such as shipping crates).	**Examples:** activities that fit the definition of packing when performed on a farm's own RACs include packaging, mixing, coating with wax/oil/resin for the purpose of storage or transport, stickering/labeling, drying for the purpose of storage or transport, and sorting/grading/culling. These activities, performed on a farm's own RACs, are inside the farm definition. Activities that fit the definition of packing when performed on a farm on any other foods, including RACs grown or raised on a farm not under the same ownership, include putting individual unit cartons into a larger box used for shipping, and putting articles of produce in non-consumer containers (such as shipping crates)—the same activities that fit the definition of packing off farm. These activities, performed on food other than a farm's own RACs, are outside the farm definition unless done on food for consumption on the farm.
Holding	**Notes:** Storage of food	**Notes:** Storage of food, or activities traditionally performed by farms for the safe or effective storage of RACs grown or raised on that farm or another farm under the same ownership. Holding does not include activities that change a RAC into a processed food. Activities that are holding are within the farm definition when they are performed on food grown, raised, or consumed on that farm or another farm under the same ownership; under any other circumstances they are outside the farm definition.
	Example: storing food, such as in a warehouse	**Examples:** activities that fit the definition of holding when performed on a farm's own RACs include fumigating during storage, and storing food, such as in a warehouse. These activities, performed on a farm's own RACs, are inside the farm definition.

TABLE 3—CLASSIFICATION OF ACTIVITIES CONDUCTED OFF-FARM AND ON-FARM—Continued

[including farm mixed-type facilities]

Classification	Off farm	On farm (including farm mixed-type facilities)
		An activity that fit the definition of holding when performed on a farm on any other foods, including RACs grown or raised on a farm not under the same ownership, is storing food, such as in a warehouse—the same activity that fits the definition of holding off farm. This activity, performed on food other than a farm's own RACs, is outside the farm definition unless done on food for consumption on the farm.
Manufacturing/Processing	**Notes:** Making food from 1 or more ingredients, or synthesizing, preparing, treating, modifying, or manipulating food. Includes packaging (putting food in a container that directly contacts food and that consumer receives).	**Notes:** Making food from 1 or more ingredients, or synthesizing, preparing, treating, modifying, or manipulating food; except for things that fall into the categories of harvesting, packing, or holding (see rows above). Activities that are manufacturing/processing are outside the farm definition unless done on food for consumption on the farm.
	Examples: activities that fit this definition include washing, trimming of outer leaves, removing stems and husks, sifting, filtering, threshing, shelling, cooling, packaging, mixing, coating, stickering/labeling, drying, sorting/grading/culling not incidental to packing or holding, fumigating, slaughtering animals or post-slaughter operations, irradiation, cutting/coring/chopping/slicing, canning, artificial ripening, cooking, pasteurizing/homogenizing, infusing, distilling, salting, smoking, grinding/milling, and freezing.	**Examples:** activities that fit the definition of manufacturing/processing when performed on a farm's own RACs include slaughtering animals or post-slaughter operations, irradiation, cutting/coring/chopping/slicing, canning, coating with things other than wax/oil/resin, drying that creates a distinct commodity, artificial ripening, cooking, pasteurizing/homogenizing, infusing, distilling, salting, smoking, grinding/milling, and freezing. These activities, performed on a farm's own RACs, are outside the farm definition unless done on food for consumption on the farm.
		Activities that fit the definition of manufacturing/processing when performed on a farm on any other foods, including RACs grown or raised on a farm not under the same ownership include washing, trimming of outer leaves, removing stems and husks, sifting, filtering, threshing, shelling, cooling, packaging, mixing, coating, stickering/labeling, drying, sorting/grading/culling not incidental to packing or holding, fumigating, slaughtering animals or post-slaughter operations, irradiation, cutting/coring/chopping/slicing, canning, artificial ripening, cooking, pasteurizing/homogenizing, infusing, distilling, salting, smoking, grinding/milling, and freezing—the same activities that fit the definition of manufacturing/processing off farm. These activities, performed on food other than a farm's own RACs, are outside the farm definition unless done on food for consumption on the farm.

ii. Proposed Definitions of ''Very Small Business'' and ''Small Business''

SUMMARY OF PROPOSED QUALIFICATIONS

[on a rolling basis, average annual monetary value of food sold during the previous three-year period]

Above $250,000 and no more than $500,000	Small Business.
Above $25,000 and no more than $250,000	Very Small Business.
$25,000 or less	Excluded from coverage.

As required by section 419(a)(3)(F) of the FD&C Act, proposed § 112.3(b) defines the terms ''very small business'' and ''small business'' for purposes of this proposed rule only. FDA uses a measure of the average annual monetary value of food sold to determine farm size. This measure should serve as a valid proxy for both the volume and value of production within size category and commodities. The USDA National Commission on Small Farms recommended a definition for a small farm as a family farm with less than $250,000 annual monetary value of all commodities sold (Ref. 85). The Commission's recommendation was based on the reasoning that these farms are the likeliest to exit the industry, and have the greatest need to improve net farm incomes Ref. 85). The Commission states that although 94% of all U.S. farms generate less than $250,000 annual monetary value of all commodities sold, their revenue constitutes only 41% of total gross revenue from all farms (Ref. 85). We propose to use the $250,000 annual monetary value of food sold threshold for our cutoff of a very small farm since the revenue of covered produce farms below this threshold constitutes only 12% of total gross revenue from food

sales by produce farms and make up 83% of all produce farms. We propose to use the statutory cutoff of $500,000 annual monetary value of food sold as one part of the criteria for the qualified exemption in section 419(f) of the FD&C Act (implemented in proposed § 112.5) as the threshold for a small farm. Farms below the $500,000 annual value of food sold cutoff make up 89% of covered farms, and their revenue constitutes 18% of total gross revenue from food sales by produce farms. We developed this proposed definition using sales class breaks found in generally available information from USDA (Ref. 86).

Proposed § 112.3(b)(1) would define your farm to be a very small business if it is subject to proposed part 112 and, on a rolling basis, the average annual monetary value of food you sold during the previous three-year period is no more than $250,000.

Proposed § 112.3(b)(2) would define your farm to be a small business if it is subject to proposed part 112 and, on a rolling basis, the average annual monetary value of food you sold during the previous three-year period is no more than $500,000; and your farm is not a very small business as provided in proposed § 112.3(b)(1).

For clarity, in both proposed § 112.3(b)(1) and (2), the limitation ''if it is subject to this part'' is intended to exclude farms not subject to the proposed rule per proposed § 112.4(a), that is, farms with $25,000 or less of annual value of food sold. As discussed in section V.A.2.c of this document, we propose to exclude such farms from the coverage of this proposed rule such that there would be no reason for them to be classified as small or very small businesses.

iii. Additional Proposed Definitions

Proposed § 112.3(c) would establish the following additional definitions that would apply for the purposes of part 112.

We propose to define ''adequate'' to mean that which is needed to accomplish the intended purpose in keeping with good public health practice. This proposed definition is the same as the definition we have established in § 110.3 with respect to current good manufacturing practice in manufacturing, packing, or holding human food. We have been applying this definition for the purpose of enforcing the regulations in part 110 for more than 40 years and tentatively conclude that it would be an appropriate definition to apply to part 112 as well. Throughout this document, we provide examples of what we mean by ''adequate'' for purposes of complying with specific proposed provisions.

We propose to define ''adequately reduce microorganisms of public health significance'' to mean reduce the presence of such microorganisms to an extent sufficient to prevent illness. This proposed definition would establish in part 112 a definition that we have used in guidance associated with the risk of foodborne illness from pathogens (Ref. 87. Ref. 88). As discussed in those documents, the extent of reduction sufficient to prevent illness is usually determined by the estimated extent to which a pathogen may be present in the food combined with a safety factor to account for uncertainty in that estimate. For example, if it is estimated that there would be no more than 1,000 (*i.e.,* 3 logs) Salmonella organisms per gram of food, and a safety factor of 100 (*i.e.,* 2 logs) is employed, a process that adequately reduces Salmonella spp. would be a process capable of reducing *Salmonella* spp. by 5 logs per gram of food.

We propose to define ''agricultural tea'' to mean a water extract of biological materials (such as humus, manure, non-fecal animal byproducts, peat moss, pre-consumer vegetative waste, table waste, or yard trimmings), excluding any form of human waste, produced to transfer microbial biomass, fine particulate organic matter, and soluble chemical components into an aqueous phase. Agricultural teas are held for longer than one hour before application. We developed this term to cover a wide range of ''teas'' used in production of fresh produce, but not to include ''tea'' served as a beverage. The term ''agricultural tea'' was based in part on the definition of ''compost tea'' developed by the National Organic Standards Board (Ref. 89). Human waste would be excluded for consistency with proposed § 112.53 regarding the use of human waste as a soil amendment. The one hour limitation is intended to distinguish between agricultural teas and other liquids such as leachate and runoff and is consistent with the recommendations of the recommendations of the National Organic Standards Board (Ref. 36).

We propose to define ''agricultural tea additive'' to mean a nutrient source (such as molasses, yeast extract, or algal powder) added to agricultural tea to increase microbial biomass. The term ''agricultural tea additive'' was based in part on the definition of ''compost tea additive'' developed by the National Organic Standards Board (Ref. 89).

We propose to define ''agricultural water'' to mean 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). This proposed definition is different from our definition of agricultural water in our Good Agricultural Practices guide (Ref. 10) both because it is not limited to water in the growing environment, and because we have excluded water that does not contact covered produce from this definition based on the information in our QAR.

We propose to define ''animal excreta'' to mean solid or liquid animal waste. By contrast, we are proposing to define ''manure'' to mean animal excreta, alone or in combination with litter (such as straw and feathers used for animal bedding) for use as a soil amendment. We are proposing definitions to distinguish ''animal excreta'' from ''manure'' based on whether the animal excreta is used as a soil amendment because some proposed requirements make such a distinction. For example, the proposed requirements in §§ 112.54 and 112.56 are directed to the treatment and safe application of biological soil amendments of animal origin, including manure intentionally used as a soil amendment, and the proposed requirements in §§ 112.82 and 112.83 would be directed to preventing contamination of covered produce with animal excreta deposited by wild or domestic animals that intrude in an area where a covered activity is conducted on covered produce. The proposed definition of ''manure'' also accounts for the potential inclusion of animal litter that is collected with animal excreta, *e.g.,* from barns.

We propose to define ''application interval'' to mean the time interval between application of an agricultural input (such as a biological soil amendment of animal origin) to a growing area and harvest of covered produce from the growing area where the agricultural input was applied. The proposed definition would provide a simple term to use when describing such a time interval. The proposed application intervals for biological soil amendments in proposed § 112.56 would establish requirements regarding such time intervals.

We propose to define ''biological soil amendment'' to mean any soil

amendment containing biological materials such as humus, manure, non-fecal animal byproducts, peat moss, pre-consumer vegetative waste, sewage sludge biosolids, table waste, agricultural tea, or yard trimmings, alone or in combination. We are proposing this definition as a means to distinguish soil amendments that contain biological components from those that do not (like chemical fertilizers). In addition, we propose to define ''biological soil amendment of animal origin'' to mean a biological soil amendment which consists, in whole or in part, of materials of animal origin, such as manure or non-fecal animal byproducts, or table waste, alone or in combination. The term ''biological soil amendment of animal origin'' does not include any form of human waste. We are proposing this definition as a means to distinguish these biological soil amendments from soil amendments that are wholly plant-based (such as yard trimmings).

We propose to define ''composting'' to mean 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. The proposed definition is consistent with definitions or explanations of ''compost'' and ''composting'' in documents such as a State regulation (Ref. 90), Appendix B to 40 CFR part 503 (Ref. 91), documents prepared by the U.S. EPA (Ref. 92), and the Produce Safety Project Issue Brief on Composting of Animal Manures (Ref. 27).

We propose to define ''covered activity'' to mean 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 activities would not include manufacturing/processing within the definition elsewhere in proposed § 112.3(c). As discussed in sections III.F and V.A.2.b.i of this document, manufacturing/processing on a farm is potentially subject to the coverage of Section 418 of the FD&C Act, unless all of the food used in such activities is consumed on that farm or another farm under the same ownership. Where all of the manufactured/processed food is consumed on that farm or another farm under the same ownership, the activity would be potentially within the scope of Section 419 of the FD&C Act and this proposed rule, except that Section 419(g) of the FD&C Act specifies that ''[t]his section shall not apply to produce that is produced by an individual for personal consumption,'' and section 419(c)(1)(B) of the FD&C Act also requires that FDA ensure that the final rule is practicable for ''a small food processing facility co-located on a farm.''

FDA tentatively concludes that on-farm manufacturing/processing activities for on-farm consumption (like produce for individual consumption) should not be subject to this rule, either because it is automatically excluded by Section 419(g) or because, to the extent there may be any difference between produce ''for personal consumption'' and produce ''consumed on the farm or another farm under the same ownership,'' it is appropriate to exclude on-farm manufacturing/processing for on-farm consumption from the rule. The definition of covered activity would also specify, for clarity, that this part does not apply to activities of a facility that are subject to part 110 of this chapter .

We propose to define ''covered produce'' to mean 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. We are proposing to define ''covered produce'' to provide a simple term to use when describing food that would be within the scope of the rule under proposed § 112.1 and not exempt from the rule under proposed § 112.2.

We propose to define ''curing'' to mean the maturation stage of composting, which is conducted after much of the readily metabolized biological material has been decomposed, at cooler temperatures than those in the thermophilic phase of composting, to further reduce pathogens, promote further decomposition of cellulose and lignin, and stabilize composition. This proposed definition is consistent with definitions of ''curing'' in a State regulation (Ref. 93), documents prepared by the U.S. EPA (Ref. 92), and a glossary of composting terms prepared by the Cornell Waste Management Institute (Ref. 94).

We propose to define ''direct water application method'' to mean 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. This proposed definition would provide a simple term to use when describing such water within regulations such as proposed § 112.44(c). By cross-reference to the definitions of ''covered produce'' and ''produce'', this term only applies to methods in which the water is intended to, or is likely to, contact the harvestable part of the covered produce.

We propose to define ''food'' to mean food as defined in section 201(f) of the FD&C Act and to include seeds and beans used to grow sprouts. We have long considered seeds and beans used to grow sprouts to be ''food'' within the meaning of section 201(f) of the FD&C Act (Ref. 95). Seeds and beans used to grow sprouts are both articles used for food and articles used for components of articles used for food. We are proposing to include them specifically in the definition of food for purposes of this rule for clarity because sprouts are covered by this rule.

We propose to define ''food-contact surfaces'' to mean those surfaces that contact human food and those surfaces from which drainage or other transfer onto the food or onto surfaces that contact the food ordinarily occurs during the normal course of operations. ''Food-contact surfaces'' includes food-contact surfaces of equipment and tools used during harvest, packing, and holding. This proposed definition of ''food-contact surfaces'' is consistent with the definition of this term in § 110.3 except that we propose to add the phrase ''or other transfer'' after ''drainage'' definition of ''food-contact surfaces'' to clarify that surfaces from which any transfer involving liquids or non-liquids onto the food or onto surfaces that contact the food are food-contact surfaces.

We propose to define ''hazard'' to mean any biological agent that is reasonably likely to cause illness or injury in the absence of its control. The proposed definition is consistent with the NACMCF HACCP guidelines, the Codex HACCP Annex, Federal HACCP regulations for seafood, juice, and meat and poultry, except that for the purposes of this rule the term would be limited to biological hazards because, as discussed in section IV.A. of this document, this proposed rule is only addressing biological hazards. The NACMCF HACCP guidelines (Ref. 41) and our HACCP regulation for juice (§ 120.3(g)) define ''hazard'' and ''food hazard,'' respectively as a biological, chemical, or physical agent that is reasonably likely to cause illness or injury in the absence of its control. The Codex HACCP Annex defines ''hazard'' as a biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect (Ref. 96). Our HACCP regulation for seafood (§ 123.3(f)) and the FSIS HACCP regulation for meat and poultry (9 CFR 417.1) define ''food safety hazard'' as any biological, chemical, or physical property that may cause a food

to be unsafe for human consumption. We recognize that there are other hazards relevant to produce safety on farm that would not be addressed in this proposed rule such as chemical, physical, and radiological hazards (see section IV.B. of this document) and do not intend to suggest by this definition that such hazards are not hazards. We request comment on whether we should instead use the term ''biological hazards'' in this rule.

We propose to define ''humus'' to mean a stabilized (*i.e.,* finished) biological soil amendment produced through a controlled composting process. We are proposing to use ''humus'' as the term to identify the final, mature product of composting for the purpose of this rule. Our proposed definition derives from our proposed definitions for ''composting'' and ''curing'' and the Cornell Waste Management Institute's glossary of composting terms (Ref. 94), which defines humus as a complex aggregate made during the decomposition of plant and animal residues; mainly derivatives of lignin, proteins, and cellulose combined with inorganic soil parts. However, other relevant documents (Ref. 27. Ref. 92. Ref. 97) refer to the production of ''humus-like material'' through composting, and humus can be produced by mechanisms other than the action of microorganisms (Ref. 98). We request comment on whether our proposed definition and use of the term ''humus'' for the final product of composting is appropriate for the purpose of this rule, or whether we should use a term other than ''humus,'' such as ''mature compost.''

We propose to define ''manure'' to mean animal excreta, alone or in combination with litter (such as straw and feathers used for animal bedding) for use as a soil amendment. As discussed above in the definition of animal excreta, this definition is intended to make a distinction between the terms ''manure'' and ''animal excreta.''

We propose to define ''microorganisms'' to mean yeasts, molds, bacteria, viruses, protozoa, and microscopic parasites and to include species having public health significance. As proposed, 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. The substantive difference between this proposed definition and that in current § 110.3 is the addition of protozoa (*e.g., Giardia lamblia*) and microscopic parasites (*e.g., Cyclospora cayetanensis*). Because such microorganisms are relevant to produce safety, we tentatively conclude that it is reasonable to include them.

We propose to define ''monitor'' to mean to conduct a planned sequence of observations or measurements to assess whether a process, point, or procedure is under control, and, when applicable, to produce an accurate record of the observation or measurement.

We propose to define ''non-fecal animal byproduct'' to mean solid waste (other than manure) 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. This proposed definition reflects the use of a similar term in sources such as the State of Florida's regulations (Ref. 90). However, we are proposing to include more examples of these byproducts than are included in Florida's regulations to clearly communicate what we mean by the term. We propose to define ''pest'' to mean any objectionable animals or insects including birds, rodents, flies, and larvae. This proposed definition is consistent with the definition of ''pest'' in current § 110.3.

We propose to define ''pre-consumer vegetative waste'' to mean solid waste that is purely vegetative in origin, not considered yard trash, and derived from commercial, institutional, or agricultural operations without coming in contact with animal products, byproducts or manure or with an end user (consumer). As proposed, pre-consumer vegetative waste includes material generated by farms, packing houses, canning operations, wholesale distribution centers and grocery stores; products that have been removed from their packaging (such as out-of-date juice, vegetables, condiments, and bread); and associated packaging that is vegetative in origin (such as paper or corn-starch based products). As proposed, pre-consumer vegetative waste does not include table waste, packaging that has come in contact with materials (such as meat) that are not vegetative in origin, or any waste generated by restaurants. This proposed definition is consistent with a State regulation (Ref. 90).

For the purpose of this rule, we propose to define the term ''produce'' to mean any fruit or vegetable (including mixes of intact fruits and vegetables) and includes mushrooms, sprouts (irrespective of seed source), peanuts, tree nuts and herbs. For the purposes of this rule, we propose to define ''fruit'' as 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; and ''vegetable'' as 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).

For the purposes of this rule, 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. With this definition, we are proposing to specifically include mushrooms, sprouts (irrespective of seed source), peanuts, tree nuts and herbs, and specifically exclude food grains. We explain our proposed definition of ''produce'' in detail above, in section V.A.2.a of this document. We request comments on our proposed definition of ''produce.''

We propose to define ''production batch of sprouts'' to mean all sprouts that are started at the same time in a single growing unit (*e.g.,* a single drum or bin, or a single rack of trays that are connected to each other), whether or not the sprouts are grown from a single lot of seed (including, for example, when multiple types of seeds are grown within a single growing unit). Through this definition, we intend to treat as a production batch product that would be exposed to the same conditions during sprouting, such as multiple seed types grown in a common drum or multiple trays in a single rack that may be exposed to water that has contacted other product in the same growing unit. This term is used in proposed subpart M. Limiting the definition of ''production lot'' to a single growing unit would prevent sprout growers from ''pooling'' samples from multiple growing units within an operation whereby contamination in spent water in one unit could be diluted by non-contaminated water from other units to

the point where pathogens might not be detected. This proposed definition is consistent with our 1999 guidance for industry on sampling and microbial testing of spent irrigation water during sprout production (Ref. 15). We recognize that there are a diversity of growing practices and a variety of growing units that may represent different product volumes, so we request comment on this proposed definition.

We propose to define ''qualified end-user,'' with respect to a food, to mean the consumer of the food; or a restaurant or retail food establishment (as those terms are defined in § 1.227) that is located (i) in the same State as the farm that produced the food; or (ii) not more than 275 miles from such farm. The definition would also state that the term ''consumer'' does not include a business. This definition implements section 419(f)(4) of the FD&C Act. We note that section 419(f)(4)(A) of the FD&C Act does not provide for a different analysis for when an international border falls within the 275 miles; thus, we tentatively conclude that international borders should not affect the distance calculation. Thus, for example, a farm in Mexico selling food to a restaurant or retail food establishment in the U.S. that is within 275 miles of the farm could count that sale as a sale to a qualified end user. As another example, the same would also be true for a U.S. farm selling food to a restaurant or retail food establishment in Mexico that is within 275 miles of the farm. Finally, we also note that the requirements related to distance (in the same state or within 275 miles of the farm) only apply to restaurants and retail food establishment customers, and not to consumers. Thus, a farm may count any sale directly to a consumer as a sale to a qualified end-user.

We propose to define ''raw agricultural commodity (RAC)'' to mean ''raw agricultural commodity'' as defined in section 201(r) of the FD&C Act. We propose to include this reference to the FD&C Act definition to provide additional clarity regarding the meaning of this term.

We propose to define ''reasonably foreseeable hazard'' to mean a potential hazard that may be associated with the farm or the food. We provide a proposed definition for this term as it is used in section 419(c)(1)(A) of the FD&C Act and reflected in several requirements proposed in this rule. As noted in the discussion of the proposed definition of ''hazard'' in this section, this definition would be limited to biological hazards because those are the only hazards we are currently proposing to address in this rule. We recognize that there are other reasonably foreseeable hazards relevant to produce safety on farm that would not be addressed in this proposed rule such as chemical, physical, and radiological hazards (see section IV.B of this document) and do not intend to suggest by this definition that such hazards are not reasonably foreseeable. We request comment on whether we should instead use the term ''reasonably foreseeable biological hazards'' in this rule.

We propose to define ''sanitize'' to mean 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. This proposed definition is consistent with the existing § 110.3 definition for ''sanitize'' except that we propose to include the term ''cleaned'' before ''food-contact surfaces.'' It is well established that sanitizers can be inactivated by organic material and, thus, are not effective unless used on clean surfaces (Ref. 99). This proposed definition is consistent with the definition of ''sanitize'' in § 111.3.

We propose to define ''sewage sludge biosolids'' to mean the solid or semi-solid residue generated during the treatment of domestic sewage in a treatment works within the meaning of the definition of 'sewage sludge' in 40 CFR 503.9(w). This proposed definition is consistent with that of the U.S. Environmental Protection Agency (EPA), which has regulatory jurisdiction over treated domestic sewage and has established terms to describe specific types of treated waste.

We propose to define ''soil amendment'' to mean 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. This proposed definition is consistent with commonly used definitions in industry guidelines and marketing agreements (Ref. 46. Ref. 31). We also propose to include within the meaning of ''soil amendment'' growth media that serve as the entire substrate during the growth of covered produce (such as mushrooms and some sprouts). While this inclusion is not consistent with the common usage of the term, it provides convenience since it is addressing the identical standards that we are proposing for identical hazards that exist for such growth media and soil amendments.

We propose to define ''spent sprout irrigation water'' to mean water that has been used in the growing of sprouts. This definition is intended to minimize the potential for confusion between spent sprout irrigation water and water used for irrigation of other types of covered produce.We are proposing to define ''static composting'' to mean a process to produce humus in which air is introduced into biological material (in a pile (or row) covered with at least 6 inches of insulating material, or in an enclosed vessel) by a mechanism that does not include turning. As proposed, examples of structural features for introducing air would include embedded perforated pipes and a constructed permanent base that includes aeration slots. As proposed, examples of mechanisms for introducing air include passive diffusion and mechanical means (such as blowers that suction air from the composting material or blow air into the composting material using positive pressure). The proposed definition derives from definitions and explanations of ''static composting'' in documents such as prepared by the U.S. EPA (Ref. 92), the Produce Safety Project Issue Brief on Composting of Animal Manures (Ref. 27), and a report from the Food and Agriculture Organization of the United Nations (Ref. 100).

We propose to define ''surface water'' to mean 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. This proposed definition is consistent with EPA's definition and with common usage of the term ''surface water'' (Ref. 101). We propose to define this term to distinguish ''surface water'' from other water, such as water from an underground aquifer that has not been held or conveyed in a manner open to the environment (''ground water'') because there is a greater likelihood that surface water could become contaminated, for example, by surface runoff.

We propose to define ''table waste'' to mean any post-consumer food waste, irrespective of whether the source material is animal or vegetative in origin, derived from individuals, institutions, restaurants, retail

operations, or other sources where the food has been served to a consumer. This definition is intended to distinguish post-consumer food waste from pre-consumer vegetative waste.

We propose to define ''turned composting'' to mean a process to produce humus in which air is introduced into biological material (in a pile, row, or enclosed vessel) by turning on a regular basis. Turning is the process of mechanically mixing biological material that is undergoing a composting process with the specific intention of moving the outer, cooler sections of the material being composted to the inner, hotter sections. The proposed definition is consistent with definitions or explanations of ''windrow composting'' in documents prepared by the U.S. EPA (Ref. 92. Ref. 91), the Produce Safety Project Issue Brief on Composting of Animal Manures (Ref. 27), and a report from the Food and Agriculture Organization of the United Nations (Ref. 100). We are proposing to use the term ''turned composting'' rather than ''windrow composting'' so that the term describing this method would not be limited to use in ''rows.''

We propose to define ''water distribution system'' to mean 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. The proposed definition would provide a simple term to use when describing such systems.

We propose to define ''we'' to mean the U.S. Food and Drug Administration.

We propose to define ''yard trimmings'' to mean purely vegetative matter resulting from landscaping maintenance or land clearing operations, including materials such as tree and shrub trimmings, grass clippings, palm fronds, trees, tree stumps, untreated lumber, untreated wooden pallets, and associated rocks and soils. This proposed definition is consistent with a definition in State composting regulations (Ref. 90), except that we are proposing to use the term ''yard trimmings'' rather than ''yard trash.'' We are proposing to use the term ''yard trimmings'' to avoid potentially negative connotations associated with the word ''trash,'' even though some components of our proposed definition (*e.g.,* untreated wooden pallets) arguably are not ''trimmings.'' We request comment on whether our proposed use of the term ''yard trimmings'' is appropriate for the purpose of this rule, or whether we should propose to use a term other than ''yard trimmings,'' such as ''yard trash'' or ''yard waste.''

We propose to define ''you'' to mean a person who is subject to some or all of the requirements in this part.

c. Persons Subject to This Rule

Proposed § 112.4(a) states that, except as provided in paragraph (b) of that section, if you are a farm or farm mixed-type facility with an average annual monetary value of food (as ''food'' is defined in § 112.3(c)) sold during the previous three-year period of more than $25,000 (on a rolling basis), you are a ''covered farm'' subject to this part; however, specific exemptions and partial exemptions apply. 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. We are proposing to apply this proposed rule only to farms and farm mixed-type facilities with an average annual monetary value of food (as ''food'' is defined in § 112.3(c)) sold during the previous three-year period of more than $25,000 (on a rolling basis) because we have tentatively concluded that farms with $25,000 or less in sales do not contribute significantly to the produce market. Farms below the $25,000 limit collectively account for only 1.5% of covered produce acres, suggesting that they contribute little exposure to the overall produce consumption. We note that such farms are and will continue to be covered under the adulteration provisions and other applicable provisions of the Federal Food, Drug, and Cosmetic Act and applicable implementing regulations, irrespective of whether they are included within the scope of this proposed rule.

As proposed, § 112.4(a) would make clear that the rule applies to both farms and farm mixed-type facilities, and that such entities would be subject to the rule when they conduct a covered activity on covered produce, as those terms are defined in proposed § 112.3(c). This would mean that, for example, a farm mixed-type facility that is a covered farm and that grows, harvests, packs, and holds its own lettuce would be subject to the proposed rule when conducting those activities (unless an exemption applies, such as that in proposed § 112.4(b)). However, the covered farm would not be subject to the rule when conducting other activities that are not covered activities, or when conducting operations on food other than covered produce. For example, if the farm mixed-type facility applied a manufacturing/processing step (such as chopping) to its lettuce for distribution into commerce (*i.e.,* not for consumption on the farm or another farm under the same ownership, or for personal consumption), this would not be a ''covered activity'' as that term is defined in proposed § 112.3(c) and would therefore not be subject to this rule. In proposed § 112.4(b), we propose to state that you are not a covered farm if you satisfy the requirements in § 112.5 and we have not withdrawn your exemption in accordance with the requirements of subpart R of this part. This implements section 419(f) of the FD&C Act and is discussed further immediately below.

d. Qualified Exemptions

i. Criteria for Eligibility for a Qualified Exemption

Proposed § 112.5(a) establishes the criteria for eligibility for a qualified exemption and associated special requirements based on average monetary value of all food sold and direct farm marketing. This exemption is mandated by Section 419(f) of the FD&C Act. Except as provided in § 112.6, you would be exempt from all of the requirements of this part, except proposed subparts except A, Q, and R, in a calendar year if:

- During the previous 3-year period preceding the applicable calendar year, the average annual monetary value of the food you sold directly to qualified end-users during such period exceeded the average annual monetary value of the food you sold to all other buyers during that period (§ 112.5(a)(1)); and
- The average annual monetary value of all food you sold during the 3-year period preceding the applicable calendar year was less than $500,000, adjusted for inflation (§ 112.5(a)(2)).

Proposed § 112.5(b) provides that, for the purpose of determining whether the average annual monetary value of all food sold during the 3-year period preceding the applicable calendar year was less than $500,000, adjusted for inflation, the baseline year for calculating the adjustment for inflation is 2011. The conditions related to average annual monetary value established in section 419(f)(1)(B) of the FD&C Act allow adjustment for inflation. To establish a level playing field for all farms that may satisfy the criteria for the qualified exemption, we are proposing to establish the baseline year for the calculation in proposed § 112.5(a)(2). We are proposing to establish 2011 as the baseline year for inflation because 2011 is the year that FSMA was enacted into law.

Section 419(f) of the FD&C Act does not specifically target arrangements such as community-sponsored agriculture (CSA), you-pick operations,

or farmers markets. It does seem likely that many such operations will meet the criteria for qualified exemption. Each such operation would need to analyze its sales under the terms of § 112.5 to determine its eligibility for the qualified exemption. For example, if a you-pick operation has an average annual monetary value of food sold during the relevant 3-year period of less than $500,000, and all of its sales were to individuals who come to the farm to pick their own produce, all of its sales would be sales to consumers (who are qualified end-users, regardless of location) for the purpose of determining the proportion of the sales that are to qualified end-users. In this example, the you-pick farm would be eligible for the qualified exemption. As another example, if a CSA farm has an average annual monetary value of food sold during the relevant 3-year period of less than $500,000; and 25% of the monetary value of its sales comes from sales to individual consumers enrolled in the CSA, 50% of the monetary value of its sales comes from sales to restaurants in the same state as the farm, and 25% of the monetary value of its sales comes from sales to other buyers who are not qualified end-users; the CSA farm would be eligible for the qualified exemption. In this example, the CSA farm's sales to qualified end-users (consumers and in-state restaurants) make up 75% of the average annual monetary value of food sold, so the value of the farm's sales to qualified end-users exceed the value of its sales to all other buyers during the relevant time period.

ii. Applicable Requirements for Qualified Exemptions

Proposed § 112.6 establishes the requirements that apply to you if you are eligible for a qualified exemption in accordance with § 112.5. Proposed § 112.6(a) explains that subparts A, Q, and R remain applicable to those who qualify for a qualified exemption under § 112.5. This is because subpart A contains this provision and other general provisions such as definitions, Subpart Q contains provisions related to compliance and enforcement, and subpart R contains provisions necessary to implement section 419(f)(3) of the FD&C Act, as discussed further in section V.R. of this document. Consistent with section 419(f)(2) of the FD&C Act, proposed § 112.6(b) establishes the modified requirements (label or point of purchase display) applicable to those who meet the requirements under § 112.5 for a qualified exemption.

Specifically, proposed § 112.6(b)(1) would require that, when a food packaging label is required on food that would otherwise be covered produce under the FD&C Act or its implementing regulations, you include prominently and conspicuously on the food packaging label the name and complete business address of the farm where the produce was grown. Proposed § 112.6(b)(2) requires that, when a food packaging label is not required on food that would otherwise be covered produce under the FD&C Act, you prominently and conspicuously display, at the point of purchase, the name and complete business address of the farm where the produce was grown. As proposed, the name and address of the farm must be displayed on a label, poster, sign, placard, or documents delivered contemporaneously with the produce in the normal course of business, or, in the case of Internet sales, in an electronic notice. That is, if a label is otherwise required on the produce that would otherwise be covered (for example, tomatoes in a ''clam shell'' package) then the label must include the name and business address of the farm where the produce was grown. If a label is not required (for example, unpackaged tomatoes) then the name and business address of the farm where the produce was grown must be displayed at the point of purchase (such as on a poster, for example). These proposed provisions reflect our interpretation of section 419(f)(2)(A)(i) and (ii) as applying only to food that would otherwise be covered produce but for the qualified exemption. We tentatively conclude that this interpretation is reasonable because applying these consumer notification requirements to food that would not otherwise be covered produce would mean applying requirements to food that bears no relationship to the subject of this rulemaking (*e.g.,* to milk from a farm that also grows and harvests produce and that meets the criteria for the qualified exemption from this proposed rule).

Proposed 112.6(b)(3) states that the complete business address that you must include in accordance with the requirements of paragraph (b)(1) or (2) of this section must include the street address or post office box, city, state, and zip code for domestic farms, and comparable full address information for foreign farms. Proposed § 112.6(b)(3) would enable consumers to contact the farm where the food that would otherwise be covered produce was grown (*e.g.,* if the consumer identifies or suspects a food safety problem with a the produce) irrespective of whether the produce bears a label. The use of the term ''business address'' in section 419(f)(2)(A) of the FD&C Act contrasts with Congress' use of a different term, ''place of business,'' in section 403(e) of the FD&C Act (21 U.S.C. 343(e)). Section 403(e) provides that foods in package form are misbranded unless the product label bears the name and place of business of the manufacturer, packer, or distributor of the food. Our regulations interpret ''place of business'' as requiring only the firm's city, state, and zip code to appear on the product label, as long as the firm's street address is listed in a current telephone directory or other city directory (21 CFR 101.5(d)). We tentatively conclude that the use of the term ''business address'' in section 419(f)(2)(A) demonstrates Congress' intent to require the farm's full address, including the street address or P.O. box, to appear on labels or other required notifications when the farm qualifies for the exemption in section 419(f) of the FD&C Act. If Congress had considered the less complete address already required under section 403(e)(1) of the FD&C Act and the ''place of business'' labeling regulation (§ 101.5(d)) to be adequate for notification to consumers for foods required to bear labels, there would have been no need to impose a new, more specific requirement in section 419(f)(2)(A)(1) for the farm's ''business address'' to appear on the food label. Requiring the complete business address for this purpose is consistent with our guidance to industry on the labeling of dietary supplements as required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act (Ref. 103). When proposed § 112.5(b) would apply to a food for which a food packaging label is required under any other provision of the FD&C Act, the complete business address would substitute for the ''place of business'' required under section 403(e)(1) of the FD&C Act and 21 CFR 101.5(d) and would not impose any requirement for a label that would be in addition to any label required under any other provision of the FD&C Act. We seek comment on the feasibility of the labeling provisions in proposed 112.6(b), particularly in the case of consolidating produce from several farm locations.

Section 419 of the FD&C Act does not explicitly require farms that meet the criteria for the qualified exemption to establish and maintain documentation of the basis for their exemption. FDA considers that it may be necessary for farms to maintain such records, and to allow FDA access to such records upon

request, in order to efficiently enforce section 419 of the FD&C Act. Otherwise we would have no way to determine whether a farm claiming the qualified exemption actually met the criteria for that exemption. This could be important, for example, if a farm claiming the qualified exemption is directly linked to a foodborne illness outbreak during an active investigation or if FDA determines, based on conduct or conditions associated with the farm that are material to the safety of the food produced or harvested at such farm, that it is necessary to protect the public health and prevent or mitigate a foodborne illness outbreak to withdraw the farm's qualified exemption (see section V.R. of this document discussing proposed subpart R). Because the withdrawal procedure in proposed subpart R would only apply to farms that are eligible for the qualified exemption, we would need to know whether the farm is indeed eligible for the exemption in order to select the appropriate and efficient enforcement strategy. We request comment on whether we should require farms to be able to provide adequate documentation, as needed, to demonstrate the basis for the qualified exemption. Specifically, we request comment on whether we should do this by requiring records to be established and maintained in accordance with the requirements of proposed subpart O, or if there is an alternative strategy by which we could require retention of and access to such records (such as by requiring farms only to retain records kept in the normal course of their business bearing on the criteria for the qualified exemption that they use to determine their eligibility and requiring FDA access to such records upon request).

B. Subpart B—General Requirements

As proposed, subpart B discusses the general requirements applicable to persons who are subject to this part and alternatives from the requirements established in this part that would be permitted, under specified conditions.

1. Comments Relevant to Proposed Provisions

We received several comments in response to the 2010 FR notice that addressed issues relevant to the general requirements established in this subpart of the rule. A consumer organization urged FDA to take additional steps to ensure the safety of bagged salads and all leafy greens. Some comments recommended that FDA include in this rule an amendment mechanism that can expeditiously accommodate new scientific knowledge.

Section 402 of the FD&C Act specifies conditions under which a food is deemed adulterated, including if the food bears or contains any added poisonous or deleterious substance which may render it injurious to health (402(a)(1)); if it is unfit for food (402(a)(3)); or if it 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 (402(a)(4)). In proposed § 112.11, we would specifically require that covered farms take appropriate measures to minimize the risk of serious adverse health consequences or death from the use of, or exposure to, covered produce, including those measures reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into covered produce as well as to provide reasonable assurances that the produce is not adulterated under section 402 of the FD&C Act on account of such hazards. Such hazards would include all pathogens to the extent that they pose a risk of serious adverse health consequences or death, including *Salmonella* and *E. coli* O157:H7, in all covered produce raw agricultural commodities, including leafy greens. With respect to bagged salads, we note that such salads are manufactured in facilities that are required to register with us and, therefore, would be covered under section 418 of the FD&C Act and any regulations promulgated pursuant to that authority, rather than by this proposed rulemaking.

We recognize the value in making this regulation flexible, where appropriate, to accommodate future changes in science and technology. In proposed § 112.12, we list the specific requirements established in this rule for which we believe alternatives may be appropriate and the circumstances under which such alternatives could be used. In addition, consistent with section 419(c)(2) of the FD&C Act, in proposed subpart P, we provide for a mechanism by which a State or a foreign country from which food is imported into the United States may request a variance from one or more requirements proposed in 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 Act and to provide the same level of public health protection as the requirements of this part (see section V.P. of this document). We also intend to publish guidance, as appropriate, to provide updates on current thinking with respect to best practices in produce safety.

2. Proposed Requirements

a. General Requirements Applicable to Persons Subject to This Part

As proposed, § 112.11 establishes the general requirements applicable to persons who are subject to this rule. Proposed § 112.11 requires that you take appropriate measures to minimize the risk of serious adverse health consequences or death from the use of, or exposure to, covered produce, including those measures reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into covered produce, and to provide reasonable assurances that the produce is not adulterated under section 402 of the FD&C Act on account of such hazards.

This provision is consistent with the requirements of section 419(c)(1)(a) of the FD&C Act, which mandates, in relevant part, that we publish regulations that ''set forth those procedures, processes, and practices that the Secretary determines to minimize the risk of serious adverse health consequences or death, including procedures, processes, and practices that the Secretary determines to be reasonably necessary to prevent the introduction of known or reasonably foreseeable biological, chemical, and physical hazards, including hazards that occur naturally, may be unintentionally introduced, * * * into fruits and vegetables, * * * and to provide reasonable assurances that the produce is not adulterated under section 402.'' As discussed in section IV.B. of this document, we have tentatively concluded that this rule should focus solely on biological hazards.

In subparts C to O, we propose science-based minimum standards related to the growing, harvesting, packing, and holding of covered produce that we believe are necessary to minimize the risk of serious adverse health consequences or death by preventing the introduction of hazards and providing reasonable assurances that the covered produce is not adulterated.

Proposed § 112.11 would require, for example, that whenever a standard specified in this part is not met, you would take those steps reasonably necessary to identify and evaluate the cause of the problem and ensure that it is rectified. Accurate identification of

the cause of the failure is critical to the success of any potential corrective actions. For example, if your employees are having difficulty identifying covered produce that should not be harvested due to potential contamination, you might initially think the answer is to provide more frequent training; however upon investigation, you may discover that the actual cause of the problem is that your employee training program is providing inaccurate information. In this case, to correct the problem, you would need to fix your training program. Promptly taking such follow-up actions once the cause of the problem has been identified is necessary to minimize the risk of serious adverse health consequences or death from the use of, or exposure to, your covered produce and to provide reasonable assurances that the product is not adulterated under section 402 of the FD&C Act.

In addition, proposed § 112.11 would require you to take appropriate measures to minimize risks of serious adverse health consequences or death from the use of, or exposure to, covered produce that may arise unexpectedly and therefore not be reflected in a specific standard set forth in proposed subparts C to O of this rule. For example, in the event of an unexpected event, such as receipt of information suggesting that your covered produce from a particular field is adulterated because it bears or contains a pathogen that may render the produce injurious to health, proposed § 112.11 would require you to take appropriate measures to minimize the risk of serious adverse health consequences or death from the use of, or exposure to, your covered produce by preventing the introduction of biological hazards into or onto your produce or by taking measures to provide reasonable assurances that the produce is not adulterated under section 402 of the FD&C Act. Such measures might include, for example, conducting a root cause investigation to try to determine the source of the contamination, making appropriate changes to your conditions and practices suggested by the root cause investigation, including to produce in other fields, as appropriate, determining the extent of the impact of the root cause (*i.e.,* within the suspect field and in other fields), and excluding adulterated produce from commerce. We note, however, that we do not intend for proposed § 112.11 to suggest that you would need to take measures to exclude animals from outdoor growing areas, to destroy animal habitats near your outdoor growing areas, to clear farm borders around outdoor growing areas or drainages, or to take any action that would violate applicable environmental laws or regulations.

We propose to include proposed § 112.11 in order to account for the variety of possible circumstances that might arise in which an unexpected circumstance or unique farm characteristics would justify preventive measures to prevent introduction of hazards or provide assurances against adulteration in order to minimize the risk of serious adverse health consequences or death. We request comment on this approach, and on whether we should instead establish specific standards for any types of hazards that would be covered in proposed § 112.11 but for which we have not proposed specific standards in proposed subparts C through O.

b. Alternatives to Certain Requirements

As proposed, § 112.12 allows for the use of alternatives to certain requirements of this part. Subparagraph (a) lists the specific requirements for which alternatives may be considered provided you are in compliance with subparagraphs (b) and (c), which describe the conditions for use of an alternative. Proposed § 112.12(b) states that you may establish and use an alternative to any of the requirements listed in paragraph (a), 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 FD&C Act, in light of your covered produce, practices, and conditions, including agro-ecological conditions and application interval. We do not propose to require you to submit such scientific data or information to us for review or approval prior to marketing. However, we would require that you maintain a record of any such scientific data or information, including any analytical information, and make such data and information available to us to evaluate upon request.

Proposed § 112.12(c) clarifies that the scientific data and information used to support an alternative to a requirement may be developed by you, available in the scientific literature, or available to you through a third party, and further provides that documentation of such data and information must be established and maintained in accordance with the requirements of subpart O of this part. As discussed in section II.E.4. of this document, FDA is collaborating with partners on research that may provide scientific support for specific alternatives to certain of these requirements. FDA intends to issue guidance on specific alternatives that it may identify as meeting the requirements of the rule in order to assist farms in complying with the final rule. For example, a farm that applies crop protection sprays to the harvestable portion of crops (*i.e.,* application of water containing crop protection substances using a direct water application method) several days before the crop is harvested using a water source that does not meet the requirements of § 112.44(c) (i.e, EPA generic *E. coli* ''recreational water'' standard), may use an alternative measure provided by their Cooperative Extension agent, for example, as long as the measure is based on scientifically sound data and meets the conditions described above (*i.e.,* provides the same level of public health protection as the applicable requirement and does not increase the likelihood that covered produce will be adulterated). For example, the study might demonstrate that the quality of water used for direct application method irrigation is not important as long as there are at least two days between application and harvest, or that water of some lesser standard than that in § 112.44(c) could safely be applied immediately before harvest. The farm operator would maintain a copy of the information provided by the agent as documentation that the alternative measure was based on sound science. When FDA becomes aware of such information, it is our intention to include it in guidance, so that farm operators can also rely on FDA guidance for such alternative measures.

As proposed in § 112.12(a), you may establish alternatives to the following requirements:

(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) The composting treatment processes required in § 112.54(c)(1) and (2);

(3) The minimum application interval established in § 112.56(a)(1)(i) for an untreated biological soil amendment of animal origin; 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.

Under proposed § 112.12(a)(1), you may establish an alternative to the requirements, established in proposed § 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. Under proposed § 112.44(c), you must test the quality of water you use during growing activities for covered produce (other than sprouts) in accordance with one of the appropriate analytical methods in proposed subpart N. If you find that there is more than 235 CFU (or 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 that paragraph and before you may use the water source and/or its distribution system again for those uses, you must either: (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 retest the water to determine if your changes were effective, or (2) treat the water in accordance with the requirements of § 112.43. As discussed in section V.E. of this document, we considered several factors and ultimately determined that the microbial standard in proposed § 112.44(c), which is based on certain aspects of U.S. EPA's recreational water standards is appropriate for the uses of agricultural water covered by proposed § 112.44(c). We seek comment on this approach.

However, we acknowledge that in specific circumstances an alternative standard (*e.g.,* a standard that applies an application interval (time between application and harvest) in place of the 112.44(c) water standard, but is limited to a specific commodity or commodity group and region) may be appropriate if the alternative standard is shown to provide the same level of public health protection as the standard in proposed § 112.44(c) and not to increase the likelihood that the covered produce will be adulterated. For example, we are working with USDA and other stakeholders to facilitate research into application intervals that would be commodity- and region-specific, such that water not meeting the proposed § 112.44(c) standard could be used in a direct water application method for growing covered produce other than sprouts as long as it was applied before the start of the scientifically established application interval (*i.e.,* at a certain number of days before harvest or earlier). Therefore, we tentatively conclude that it would be appropriate to allow for alternatives to the requirements in proposed § 112.44(c).

Under proposed § 112.12(a)(2), you may establish an alternative to the treatment processes, established in proposed § 112.54(c)(1) and (2), for composting, provided you comply with § 112.54(c)(3). The processes established in § 112.54(c)(1) and (2) as scientifically valid controlled composting processes demonstrated to satisfy the microbial standard in § 112.55(b) for Salmonella and for fecal coliforms are: (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; and (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. We tentatively conclude that it would be appropriate to allow for the use of other static or turned composting protocols that maintain conditions for a combination of temperatures and time other than the temperature and times specified in proposed §§ 112.54(c)(1) and (2), and is followed by adequate curing, which includes proper insulation, if they achieve the same level of pathogen reduction (*i.e.,* meet the microbial standard in § 112.55(b)). In this sense, the microbial standards would provide a performance standard; practices that meet this objective measure would be acceptable. It would be your responsibility to consider the moisture content, pH, carbon to nitrogen ratio (C:N), feedstock, and any other appropriate consideration needed during composting to adequately achieve the microbial standards of proposed § 112.55(b).

Under proposed § 112.12(a)(3), you may establish an alternative to the minimum application interval of nine (9) months, established in proposed § 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. As discussed in section V.F of this document, we have tentatively concluded that, under certain circumstances, the application interval in § 112.56(a)(1)(i) may be more than what is necessary for minimizing the likelihood that covered produce that is grown in soils amended with an untreated biological soil amendment, and is reasonably likely to contact the soil after application, pose to the public health. These circumstances could include differences in likelihood of contamination posed by the specific feedstock, application method or treatment method, especially given the potential for new innovations in such methods.

Under proposed § 112.12(a)(4), you may establish an alternative to the minimum application interval of 45 days, established in proposed § 112.56(a)(4)(i), for a biological soil amendment of animal origin treated by a composting process in accordance with the requirements of proposed § 112.54(c) that satisfies the microbial standard in proposed § 112.55(b), and that is reasonably likely to contact covered produce after application. As discussed in section V.F. of this document, we are proposing a multiple-hurdle approach to minimizing the likelihood of contamination by addition of an application interval of 45 days to any biological soil amendment of animal origin treated by composting that is reasonably likely to contact covered produce after application. This time period has been shown to be effective when the population of the pathogen is minimal (Ref. 104) as can be expected of a fully composted biological soil amendment of animal origin. This multiple hurdle approach and time interval has also been utilized in current industry standards for leafy greens (Ref. 31). We seek comments on this proposal. We have also tentatively concluded that, under certain circumstances, the application interval in § 112.56(a)(4)(i) may be more than what is necessary for minimizing the likelihood of contamination of covered produce that is grown in soils amended with a treated biological soil amendment, and that is reasonably likely to contact the soil after application. These circumstances could include differences in likelihood of contamination posed by the specific feedstock, application method or treatment method, especially given the potential for new innovations in such methods.

As noted above, in any use of alternatives permitted in § 112.12(a)(1) through § 112.12(a)(4), in accordance with proposed § 112.12(b), you would be required to have adequate scientific data or information to support a conclusion that the alternative would provide the same level of public health protection as the requirement specified

in the proposed rule and would not increase the likelihood that your covered produce will be adulterated under section 402 of the FD&C Act. Further, in accordance with proposed § 112.12(c), you must establish and maintain documentation of such scientific data or information, which may be developed by you, available in the scientific literature, or available to you through a third party. We are working with USDA and other stakeholders to conduct research on relevant alternative practices and intend to make the results of that research available in the future. We seek comment on whether we should require you to notify FDA of your conclusion to establish or use an alternative that is permitted under §§ 112.12(a)(1) through (a)(4), and whether we should require you to submit relevant scientific data or information to FDA as part of such a notification.

C. Subpart C—Standards Directed to Personnel Qualifications and Training

As proposed, subpart C discusses minimum standards directed to personnel qualifications and training that are reasonably necessary to minimize the risk of serious adverse health consequences or death from the use of, or exposure to, covered produce, including those reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into covered produce, and to provide reasonable assurances that the covered produce is not adulterated under section 402 of the FD&C Act.

1. Comments Related to Proposed Provisions

We received several comments in response to the 2010 FR notice that addressed issues relevant to personnel qualifications and training. Several comments expressed concern over language and educational barriers greatly impeding the farm's ability to effectively fulfill the training requirements for their field workers. They also stressed the need for far reaching, accurate, consistent, and well-rounded training programs with skilled trainers providing the same information to growers, processors and distributors. Comments further suggested that training materials should have addendums to reflect the differences among the varied growing regions, commodities, and production practices and processes, as well as train-the-trainer programs for individuals responsible for training farm workers. Many firms also urged organizations, universities, and extension agencies to share experiences and to provide resources for worker training. Several comments pointed out difficulties in training due to the transient or short term nature of farm workers and due to the seasonal relocation of their operations. In addition, comments expressed concern over the cost of implementation, including regular refresher courses and training materials, and the reliability of third-party training materials. One comment requested that individuals responsible for the training program and materials should ensure that curricula are updated to reflect any new scientific information.

We believe that adequate and appropriate training of personnel who handle covered produce or food-contact surfaces, or who are engaged in the supervision thereof, is an essential component of standards for produce safety. Regardless of the nature of the farm workers, we propose that they must receive training upon hiring, at the beginning of each growing season, and with periodic updates as necessary in order to prevent contamination of covered produce. Farm workers need to know how to recognize potential contamination problems (*e.g.,* a leafy green vegetable contaminated with manure) and to be trained to know what to do when those situations present themselves. The farm worker is a key component in the food chain for ensuring the safety of covered produce. No matter the transient nature, any worker can be a potential pathway for contamination of produce during growing, harvesting, packing, and holding (*e.g.,* because of hygiene issues or illness) or fail to identify a situation that may result in contamination of the covered produce being grown, harvested, packed, or held if they are not cognizant of proper food safety procedures and standards. It is not uncommon for workers to change based on season and location and, therefore, proposed § 112.21(a) would require personnel to receive training upon hiring and at the beginning of each growing season (if applicable). Proposed § 112.21(a) would also require that personnel receive periodic updates as a way of reminding them of the proper procedures including any changes in those procedures. Such updates may not require full training sessions, but only short descriptive sessions to ensure that all personnel remain aware of all procedures necessary to maintain the safety of produce.

Together with the USDA, Cornell University's National GAPs program, the Association of Food and Drug Officials (AFDO), and the National Association of State Departments of Agriculture (NASDA), we have formed the Produce Safety Alliance (PSA), which is a public-private partnership established to provide educational outreach assistance to fresh produce growers and packers. This program is in the process of creating training materials that will be both region- and commodity-specific. We expect these materials to be standardized, multi-formatted, and multi-lingual, and available in pictorial format to help overcome literacy issues. Specific focus areas for the PSA include GAPs and co-management education and outreach efforts for produce farmers and packers, with special emphasis on small-scale operations. This alliance will also include a train-the-trainer lesson plan and an education outreach program delivery for farmers, trainers, and regulators. We intend to explore the need for additional such partnerships, as appropriate, to address any commodity-specific needs for outreach and assistance. We welcome comments and suggestions for training development strategies.

2. Proposed Requirements

Proposed § 112.21 would establish requirements for the qualifications and training for personnel who handle (contact) covered produce or food-contact surfaces, or who are engaged in the supervision thereof. Having personnel follow proper food hygiene practices, including personal health and hygiene, can reduce the potential for on-farm contamination of covered produce. Educating personnel who conduct covered activities in which they contact covered produce and supervisors about food hygiene, food safety, and the risks to produce safety associated with illnesses and inadequate personal hygiene is a simple step that can be taken to reduce the likelihood of pathogens being spread from or by personnel to covered produce.

Most current FDA, private and international guidelines for the produce industry include provisions related to training food handlers in the importance of personal health and hygiene to food safety (Ref. 10. Ref. 20. Ref. 50. Ref. 48. Ref. 96. Ref. 26). As described in the QAR, FDA's follow-up farm investigations in response to outbreaks and contamination events identified poor worker health and hygiene, unsafe produce handling and storage practices, and specifically poor training in these areas, as likely contributing factors to these events. This information reinforces the importance of training farm personnel, including supervisors, in food hygiene, food safety, employee health and personal hygiene.

Proposed § 112.21(a) would require that all personnel (including temporary, part time, seasonal and contracted personnel) who handle (contact) covered produce or food-contact surfaces and their supervisors receive training that is appropriate to the person's duties, upon hiring, at the beginning of each growing season (if applicable), and periodically thereafter. Because ensuring that covered produce is not contaminated is dependent on personnel following proper food safety and hygiene practices, all personnel who contact covered produce and food-contact surfaces must receive training when hired, before they participate in the growing, harvest, packing or holding of covered produce in which they contact covered produce, and must be periodically reminded about the need to follow these practices through refresher training. When a farm hires workers after the beginning of a growing season, these workers would need to be trained upon hiring. Because the farm does not employ these workers at the beginning of the first growing season, the requirement for training at the beginning of each growing season would not be applicable to those workers until the beginning of the next growing season, if they are still employed by the farm at that time. Managers and supervisors must have the necessary knowledge of food safety and hygiene principles and practices to be able to assess whether their staff are following appropriate practices, and take the necessary action to remedy any deficiencies, which could include on-the-spot training for their staff.

Periodic refresher training for all relevant personnel, including managers and supervisors, is necessary to ensure continual awareness of important food safety and hygiene principles. It is also important when new information is available about practices that may contribute to foodborne illness or when, for that reason or other reasons, changes in the farm's procedures are put in place. For example, during the past decade several segments of the produce industry reviewed and revised their industry guidelines or developed new guidelines to address current food safety concerns relative their specific commodity (*i.e.,* lettuce, tomatoes, sprouts, and cilantro).

Proposed § 112.21(b) would require that all personnel (including temporary, part time, seasonal and contracted personnel) who handle (contact) covered produce or food-contact surfaces and their supervisors 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. Proposed § 112.21(b) would provide flexibility for how personnel become qualified to perform their assigned duties by recognizing multiple pathways to obtain the necessary qualifications: Training (such as training provided on-the-job), in combination with education, or experience (*e.g.,* work experience related to an employee's current assigned duties). The standards in subparts C through O often involve action by farm personnel (*e.g.,* monitoring of animal intrusion, inspecting agricultural water system) that require specific knowledge, skills and abilities, without which the standard could not be properly achieved. Proposed § 112.21(b) requires that those farm personnel have the training so that they will have the necessary knowledge, skills, and abilities to perform their duties.

Proposed § 112.21(c) would establish requirements for training to be conducted in a manner that is easily understood by personnel being trained. The goals of training cannot be achieved if the person receiving the training cannot understand it. Training could be understood by personnel being trained if, for example, it was conducted in the language that employees customarily speak and at the appropriate level of education. In some cases in may be necessary to use easily understood pictorials or graphics of important concepts (Ref. 105).

Proposed § 112.21(d) would establish requirements for training to be repeated as necessary and appropriate in light of observations or information indicating that personnel are not adequately meeting standards established by FDA in subparts C through O of the rule. The goals of training are not achieved if the persons receiving the training do not correctly implement those standards taught. Moreover, repeated training as proposed in § 112.21(d) is necessary when an employee that does not follow the correct food safety protocol, because such behavior may increase the likelihood of introducing a food safety hazard to covered produce. When an employee requires additional training, it may consist of informal on-the-spot instruction to focus on those measures not being adequately implemented as opposed to more comprehensive training. For example, if you observe an employee commit a minor error, such as an inappropriate method for recording monitoring information in a log, an appropriate action could be to show the employee the correct method of recording the information and contrast this with the inappropriate method the employee had been using. However, if an employee displays repeated mistakes or a fundamental misunderstanding of the correct procedures for handling covered produce, an appropriate action may be to have the employee repeat relevant training, or to attend a comprehensive training course. If you conclude that the employee may not have the skills to conduct certain covered activities, an appropriate action may be to train the employee for new responsibilities that are more suitable to his or her skills.

Proposed § 112.22(a) would require that, at a minimum, all personnel who handle (contact) covered produce during covered activities must receive training that would include: (1) Principles of food hygiene and food safety (proposed § 112.22(a)(1)); (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 (proposed § 112.22(a)(2)); and (3) the standards as applicable to the employee's job responsibilities, including those established by FDA in subparts C through O of this part (proposed § 112.22(a)(3)).

We tentatively conclude that the broad topic areas addressed in proposed § 112.22(a) are those minimum topic areas necessary to be covered during training for all employees who handle (contact) covered produce. Training in the principles of food hygiene and food safety are necessary to provide an overall framework for job performance. Training in health, hygiene, and disease control can teach workers how to minimize the likelihood of transferring pathogens to covered produce. These topics are covered in several currently used guidance documents (Ref. 10. Ref. 20. Ref. 50. Ref. 48. Ref. 96). In addition, training in the specific standards established in subparts C through O of this part which are necessary for the employee to use during the course of their duties will increase the likelihood that those standards will be implemented correctly and effectively. We seek comments on the scope, frequency, and methods outlined in the proposed training sections of the proposed rule.

Proposed § 112.22(b) would require that persons who conduct covered harvest activities for covered produce 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 food safety hazards (proposed § 112.22(b)(1)); (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 food safety hazards (proposed § 112.22(b)(2)); 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 (proposed § 112.23(b)(3)).

We tentatively conclude that the topic areas addressed in proposed § 112.22(b), in addition to § 112.22(a), are those minimum topic areas necessary to be covered during training for persons who conduct harvest activities. Harvest workers need to learn how to recognize produce that should not be harvested (such as rotten or decayed fruit, ''drops,'' or harvestable items that have been contaminated with feces), because not harvesting such covered produce would be the first opportunity to prevent that produce from entering commerce, and as a practical matter may be the only such opportunity (for example, during a field-pack operation with no subsequent culling stage). Proposed § 112.112 would require that farms take all measures reasonably necessary to identify and not harvest covered produce that is visibly contaminated with animal excreta.

Harvest workers must be trained to both recognize this condition and to avoid harvesting covered produce that exhibits the condition. Harvest workers also need to know how to inspect harvest containers and equipment to ensure that they are functioning properly, clean, and maintained so that they will not act as a source of contamination or lead to damage of covered produce (damaged produce is more likely to harbor pathogens, and at a greater population, than is sound produce (Ref. 59. Ref. 106)). Harvest workers also need to know how to correct problems with harvest equipment or containers when they encounter them, or need to know that they should report such problems to someone who would be responsible for ensuring that the problem is corrected. These topics are covered in several currently used relevant documents (Ref. 8. Ref. 33. Ref. 18. Ref. 89. Ref. 84). We acknowledge the challenge these training requirements may pose to farms that employ contracted harvest crews. In such cases, we expect that the harvest crew company could provide the required training to workers, who move from farm to farm under the employment of the harvest crew company. Farms on which such harvest crews work could request certification from the harvest crew company that their workers have received the required training. We seek comment on the feasibility of the proposed training requirements, particularly with respect to harvest activities.

Proposed § 112.22(c) would require that at least one supervisor or responsible party for your farm successfully complete food safety training at least equivalent to that received under standardized curriculum recognized as adequate by the Food and Drug Administration. Experience at farming does not necessarily convey knowledge of food safety, particularly that of microbial food safety hazards, and therefore specialized training is needed to address the specific concerns of on-farm food safety. The purpose of training a supervisor or other responsible party is so that person can help train other employees, recognize conditions that could lead to contamination of covered produce, and take action to correct those conditions. As discussed in section II.D. of this document, FDA has, together with USDA AMS, established the jointly funded PSA, a public-private partnership that will develop and disseminate science- and risk-based training and education programs to provide produce growers and packers with fundamental, on-farm food safety knowledge, starting in advance of this proposed rule and continuing after the final regulation is promulgated. A first phase of PSA's work is intended to assist growers, especially small growers, in establishing food safety programs consistent with the GAPs Guide and other existing guidances and requirements so that they will be better positioned to comply with a final produce rule. As this rulemaking progresses, FDA will work to ensure that the PSA materials are modified, as needed, to be consistent with the requirements of this rule. Included in that material will be the standardized curriculum against which FDA intends to compare other training programs. After reviewing the final draft of the PSA training materials, FDA intends to publish a notice of availability of the documents in the **Federal Register**. We would encourage trainers outside the PSA to evaluate their courses, past, present, and future, against the PSA materials when they become available and to modify or adapt curricula, where necessary, to ensure that they are consistent with, and provide at least an equivalent level of instruction to, the Alliance course. We have no plans to publish a list of ''approved'' courses other than the Alliance course materials. Proposed § 112.23 would require that you assign or identify personnel to supervise (or otherwise be responsible for) your operations to ensure compliance with the requirements of the rule. Oversight by a qualified individual is essential to the effective implementation of the rule. Under proposed § 112.23, the personnel that you assign or identify to supervise (or otherwise be responsible for) your operations may be a single person (including yourself), or may be a team of individuals, each with specific areas of responsibility (*e.g.,* you may assign or identify separate persons to be responsible for your water distribution system, your harvest activities, your sanitary accommodations, and your packing activities).

Proposed § 112.30(a) would require that you establish and keep records required under subpart C in accordance with the requirements of subpart O of the rule. Proposed § 112.30(b) would require that you establish and keep records that document required training of personnel, including the date of the training, the topics covered, and the person(s) trained. An example of records that would comply with proposed § 112.30(b) is an attendance sheet with the date, list of those in attendance, and the particular topics covered (such as proper hand washing or how to collect samples for water testing). The records required by proposed § 112.30(b) would enable you to track the training personnel receive, thereby enabling you to identify personnel and training topics for periodic updates and personnel that have the prerequisite training for assignment to certain responsibilities. Such records would enable you to document that a person has, as would be required under proposed §§ 112.21(a) and (b), successfully completed training as appropriate to the person's duties, upon hiring and periodically thereafter, including the principles of food hygiene and food safety and also the training that would be specific to a person's tasks and responsibilities.

D. Subpart D—Standards Directed to Health and Hygiene

As proposed, subpart D discusses science-based minimum standards directed to health and hygiene that are reasonably necessary to minimize the risk of serious adverse health consequences or death from the use of, or exposure to, covered produce, including those reasonably necessary to prevent the introduction of known or

reasonably foreseeable hazards into covered produce, and to provide reasonable assurances that the produce is not adulterated under section 402 of the FD&C Act.

1. Comments Relevant to Proposed Provisions

We received some comments in response to the 2010 FR notice that addressed issues relevant to health and hygiene. Several comments noted the challenges of enforcing use of gloves and clean clothes. Others expressed concerns related to identifying sick employees who could contaminate covered produce or food-contact surfaces, while another comment asked about potential requirements on hygienic practices and questioned whether hand jewelry could contaminate produce such as leafy greens.

We recognize the importance of taking appropriate measures to prevent sick or infected persons from contaminating covered produce or food-contact surfaces. In proposed § 112.22(a)(2), we propose to require training of personnel to recognize 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. The proposed requirements for standards directed to health and hygiene focus on maintaining adequate personal cleanliness. Gloves can provide a barrier to reduce the potential for contamination; however, gloves themselves can transfer pathogens to covered produce if they become contaminated. Therefore, while we are not proposing to require the use of gloves, we are proposing to require the proper use of gloves when workers wear them (proposed § 112.32(b)(4)). Clothes should be adequately clean if by virtue of type of operation the workers are performing, the clothes could potentially contaminate covered produce with pathogens.

2. Proposed Requirements

Proposed subpart D would require that you take those measures that we tentatively conclude are reasonably necessary to prevent personnel and visitors from introducing known or reasonably foreseeable hazards into or onto covered produce or food-contact surfaces. As discussed above (see sections I.A. of this document, and QAR), people can carry a wide variety of pathogens (including hepatitis A virus, *Salmonella, E. coli* O157:H7, *Shigella, Cyclospora,* and *Cryptosporidium* (Ref. 93) (Ref. 107). Bacteria, viruses, and parasites are frequently transmitted from person to person and from person to food, particularly through the fecal-oral route (Ref. 95. Ref. 96. Ref. 97. Ref. 98. Ref. 93). Several of the provisions of proposed subpart D are similar to requirements in our Current Good Manufacturing Practice regulations for food and for dietary supplements (§ 110.10 and 111.10, respectively), and to provisions in our GAPs Guide (Ref. 10), the AFDO Model Code (Ref. 20), various produce industry guidelines (Ref. 46. Ref. 44), a marketing agreement (Ref. 31), and international guidelines (Ref. 96).

Proposed § 112.31 would require that you take measures necessary to prevent ill or infected persons from contaminating covered produce with microorganisms of public health significance. Proposed § 112.31(a) would require that you take measures to prevent contamination of covered produce and food-contact surfaces with microorganisms of public health significance from any person with an applicable health condition (such as communicable illnesses that present a public health risk in the context of normal work duties, infection, open lesion, vomiting, or diarrhea).

Proposed § 112.31(b)(1) would require that you exclude any person from working in any operations that may result in contamination of covered produce or food-contact surfaces with microorganisms of public health significance when the person (by medical examination, the person's acknowledgement, or observation (for example, by a supervisor or responsible party)) is shown to have, or appears to have, an applicable health condition, until the person's health condition no longer presents a risk to public health. Applicable health conditions would not include non-communicable diseases such as cancer, diabetes, or high blood pressure, or non-communicable conditions such as pregnancy, which would not present a likelihood of contamination to covered produce or food contact surfaces. For example, if an employee tells you that his or her physician has diagnosed that the employee has a fever, and the employee normally handles your covered produce, you must take steps to ensure that the employee does not come into contact with your covered produce because the fever may suggest that the employee has an infection and there is a reasonable possibility of contamination. Likewise, if you see that an employee has an open wound or sore, and the employee normally handles covered produce, you must take steps to ensure that he or she is excluded from handling covered produce if the wound could be a source of microbial contamination. Proposed § 112.31(b)(1) is similar to requirements in current §§ 110.10(a) and 111.10(a) and to provisions in our GAPs Guide (Ref. 10), the AFDO Model Code, various produce industry guidelines (Ref. 89. Ref. 84. Ref. 99), and a marketing agreement (Ref. 31), and the Codex Code (Ref. 96).

Proposed § 112.31(b)(2) would require that you instruct your personnel to notify their supervisor(s) (or a responsible party) if they have, or if there is a reasonable possibility that they have, an applicable health condition. Consistent with the training requirement proposed in § 112.22(a)(2), we are proposing this requirement as a measure specifically directed at preventing sick or infected persons from contaminating covered produce or food-contact surfaces and to emphasize that individual workers have a responsibility—every day—to take action to prevent contamination due to their own illness or infection. In a small or very small business, such as a farm largely operated by a husband and wife, the impact of proposed § 112.31(b)(2) would, in essence, be for a sick worker to take appropriate steps to exclude himself or herself from working in any operations that may result in contamination of covered produce or food-contact surfaces with pathogens. Proposed § 112.31(b)(2) is similar to requirements in current §§ 110.10(a) and 111.10(a) and to provisions in the AFDO Model Code (Ref. 20), and a produce industry guideline ((Ref. 46). We seek comments on the notification and other proposed requirements related to workers health.

Proposed § 112.32 would require that personnel use certain hygienic practices. Proposed § 112.32(a) would require that personnel who work in an operation in which covered produce or food-contact surfaces are at likelihood of contamination with known or reasonably foreseeable hazards use hygienic practices while on duty to the extent necessary to protect against such contamination. Hygienic practices can prevent introduction of microbial (such as bacteria and viruses that could be present in saliva or on skin) contamination of covered produce (Ref. 108). Inadequate hygienic practices among workers have been associated with outbreaks transmitted by various produce commodities, including strawberries, green onions, mamey, leaf lettuce, and basil (Ref. 107). Proposed § 112.32(a) is similar to requirements in current §§ 110.10(b) and 111.10(b) and to provisions in our GAPs Guide (Ref.

44), the AFDO Model Code (Ref. 20), various produce industry guidelines (Ref. 46. Ref. 44), a marketing agreement (Ref. 31), and the Codex Code (Ref. 96).

Proposed § 112.32(b) would require that personnel who handle (contact) covered produce use specific hygienic practices to satisfy the requirements of proposed § 112.32(a). Proposed § 112.32(b)(1) would require the specific practice of maintaining adequate personal cleanliness to protect against contamination of covered produce and food-contact surfaces. Requiring that workers maintain adequate personal cleanliness is similar to requirements in current §§ 110.10(b) and 111.10(b) and to provisions in the Codex Code (Ref. 96). We would expect that maintaining adequate personal cleanliness would include wearing adequate outer garments as necessary and appropriate to protect against contamination of covered produce and food-contact surfaces. Outer garments (*e.g.,* smocks, aprons, or coveralls worn over a worker's personal clothing) may be necessary and appropriate when a worker conducts an activity that has increased potential to contaminate the worker's personal garments with hazards that could be transferred to covered produce or food-contact surfaces during subsequent activities in which the worker may contact covered produce. For example, a worker's personal clothing could become contaminated with pathogens while a worker shovels manure, and such contamination could be transferred from the clothing to covered produce if the worker subsequently harvests covered produce wearing the same clothes. An apron, smock, or coverall worn over the worker's personal clothing while shoveling the manure could simply be removed before the worker moves on to a harvest activity, which would reduce the likelihood of contaminating covered produce during the subsequent harvest activity. We intend to provide further information about adequate worker personal cleanliness in guidance.

Proposed § 112.32(b)(2) would require that personnel avoid contact with animals other than working animals, and that personnel in direct contact with working animals take appropriate steps to minimize the likelihood of contamination of covered produce. Pathogens can be directly transmitted from animals to people when persons touch, pet, feed, or are licked by animals because animal hair, fur, saliva and skin can harbor pathogens (Ref. 98. Ref. 99. Ref. 100). For example, transmission of the pathogen *Giardia lamblia* from animals to humans was linked to an outbreak of foodborne illness associated with consumption of contaminated produce (Ref. 109).

Proposed § 112.32(b)(3) would require that personnel wash 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 that personnel dry hands thoroughly using single-service towels, clean cloth towels, sanitary towel service or other adequate hand drying devices on specified occasions. Those specified occasions include before starting work; before putting on gloves; after using the toilet; upon return to the work station after any break or other absence from the work station; as soon as practical after touching animals (including livestock and working animals) or any waste of animal origin; and 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. Under proposed § 112.32(b)(3), we would not expect workers to immediately stop work and wash their hands each time hands become soiled during the usual course of farm work with dirt or plant litter. However, we would expect workers to have sufficient training to recognize potential sources of hazards and to wash their hands when appropriate. We tentatively conclude that proposed § 112.32(b)(3) provides sufficient flexibility for operations to provide running water in a manner best suited to the conditions of use. For example, water can be supplied by a Public Water System, private well, or other source satisfying the requirements of § 112.44(a) through plumbed connections to building faucets (*e.g.,* inside a packing house) to supply running water throughout the facility. Alternatively, water supplied from sources above and used to fill clean, portable water containers suited to field use (such as a carboy, tank, water buffalo, or similar container) fitted with a valve, spout, or spigot such that water released passes over the hands also can provide adequate running water for washing hands. Under proposed § 112.44(a), with certain exceptions set forth in proposed § 112.45, you must test the quality of water used for hand washing during and after harvest to ensure that there is no detectable generic *E. coli* (see section V.E. of this document).

Workers often touch produce with their bare hands, and the produce covered by this rule would not necessarily have a ''kill step'' to adequately reduce pathogens that could be transmitted through bare-hand contact. Hand-washing, when done effectively, can eliminate both resident bacterial contamination (such as on the hands of a worker who may not realize he is ill or infected) and transient microbial contamination (such as bacteria, viruses, and parasites that gets onto hands through contact with the environment) (Ref. 110). As a result, hand-washing is a key control measure in preventing contamination of covered produce and food-contact surfaces (Ref. 26). The effectiveness of hand-washing is determined by multiple factors, including whether or not soap is used, the quality of water used, the duration of scrubbing and rinsing, and whether hands are dried. Soap serves as an emulsifier that enables dirt and oil to be suspended and washed off (Ref. 110). Rinsing hands without using soap, and not drying hands after washing, can promote the spread of microorganisms. For example, rinsing hands without using soap can loosen microorganisms without removing them, leaving the microorganisms more readily transferable to the next surface touched (Ref. 110). An investigation in follow-up to an outbreak of foodborne illness caused by *E. coli* O157:H7 in Florida found an association between illness and visits to fairs where visitors came in contact with animals, and found that persons who washed their hands with soap and water had a decreased likelihood of illness (Ref. 111). Drying hands is important because wet skin is more likely to transmit microorganisms than dry skin (Ref. 110). In addition, hand-drying has been demonstrated to remove bacteria from the hands and decrease ''touch-contact-associated bacterial transfer'' after hand-washing (Ref. 112). Proposed § 112.32(b)(3) does not prohibit use of hand sanitizers as a part of the hand washing process. However, our review of hand washing indicates that soap and water are far more effective than sanitizers in removing pathogens. The effectiveness of hand sanitizers has been shown to be highly dependent upon the removal of organic material from the hands prior to their use, as the presence of dirt, grease, or soil significantly reduces their effectiveness in eliminating bacteria on hands (Ref. 107).

Proposed § 112.32(b)(3) is similar to provisions in our GAPs Guide (Ref. 10), the AFDO Model Code (Ref. 20), various produce industry guidelines (Ref. 89. Ref. 84. Ref. 99), a marketing agreement (Ref. 31), and the Codex Code (Ref. 96). Several differences exist between proposed § 112.32(b)(3) and analogous provisions in current §§ 110.10(b) and 111.10(b). For example, proposed

§ 112.32(b) would not specify, in addition to the requirements for hand washing, that hands also be sanitized if necessary to protect against microbial contamination, while both §§ 111.10(b) and 111.10(b) have such a requirement. We tentatively conclude that the circumstances where use of a hand sanitizer as an additional measure to reduce likelihood of contamination with pathogens would be limited on a farm. Hand sanitizers are less likely to be effective on a farm than in a processing plant, since growers' hands are more likely to get dirty during production on a farm and the resulting presence of organic material on the hands would impede the effectiveness of hand sanitizers (Ref. 113).

In addition, proposed § 112.32(b)(3)(v) would specifically require washing hands after touching animals, a requirement that is not included in current § 110. We are proposing this requirement here because contact with animals is more likely to happen on a farm. In addition, the National Association of State Public Health Veterinarians has recommend washing hands after touching animals as a protection against outbreaks of *E. coli* O157:H7, *Salmonella Enteritidis, Cryptosporidium parvum,* non-O157 STEC, *Salmonella typhimurium,* and *Campylobacter jejuni* (Ref. 111).

Proposed § 112.32(b)(3) also would repeat some of the characteristics of an adequate hand-washing facility specified in proposed § 112.130 (*i.e.,* soap, running water of specified microbial quality, and adequate drying devices). Currently, in our CGMP regulation for food facilities, § 110.37(e) identifies examples of how to achieve compliance with the requirements for an adequate hand-washing facility, but it does not repeat them in the requirement in § 110.10(b) regarding workers washing their hands. In proposed § 112.32(b)(3) (and in proposed § 112.130), we are proposing to identify specific characteristics of an adequate hand-washing facility because many of these facilities are likely to be in outdoor growing areas and be portable. Standard features that we have come to expect as a matter of course in a hand-washing facility in a building used for manufacturing/processing food may not be standard in a portable hand-washing facility. Moreover, the outdoor nature of many areas where covered activities take place naturally presents workers with situations where they will get dirt on their hands, and workers may be routinely handling food, with their bare hands, that will not be cooked to adequately reduce pathogens. Therefore, we believe it is appropriate to repeat these requirements in the proposed provisions for workers to wash their hands as well as in the proposed provisions directed to hand-washing facilities. We seek comment on the hand-washing proposals described above.

Proposed § 112.32(b)(4) would require that, if you choose to use gloves in handling covered produce or food-contact surfaces, you maintain gloves in an intact and sanitary condition, and that you replace such gloves when you are no longer able to do so. We are not proposing to require the use of gloves, but gloves are used in many operations to protect workers' hands. While gloves also provide a barrier that can reduce the potential for pathogens on workers' hands to contaminate covered produce, gloves themselves, whether re-usable or disposable, can transfer pathogens to covered produce if the gloves become contaminated (Ref. 26). If gloves are used in handling covered produce or food contact surfaces, requiring that such gloves be either in an intact and sanitary condition, or else be replaced, reduces the potential for the gloves to be a source of contamination for covered produce. Proposed § 112.32(b)(4) is similar to requirements in current §§ 110.10(b) and 111.10(b). Our GAPs Guide (Ref. 10), various produce industry guidelines (Ref. 89. Ref. 84. Ref. 99) and the Codex Code (Ref. 96) include specific provisions directed to the use of gloves. The AFDO Model Code (Ref. 20) and a marketing agreement (Ref. 31) direct farms to establish policies to ensure proper use of gloves. It has been reported that glove use can foster a ''false sense of security'' that can lead to less sanitary practices such as wearing the same pair of gloves for extended periods of time without cleaning them, or washing hands infrequently (Ref. 114). If your workers wear gloves, you should ensure that they know that wearing gloves in no way diminishes the importance of washing hands, and that gloves must be maintained and replaced, when necessary and appropriate.

Proposed § 112.33 would require that you take measures to prevent visitors from contaminating covered produce and food-contact surfaces with microorganisms of public health significance. Proposed § 112.33(a) would define a visitor as any person (other than personnel) who enters your covered farm with your permission. Proposed § 112.33(b) would require that you make visitors aware of policies and procedures to protect covered produce and food-contact surfaces from contamination by people, and that you take all steps reasonably necessary to ensure that visitors comply with such policies and procedures. Proposed § 112.33(c) would require that you make toilet and hand-washing facilities accessible to visitors. In contrast to food processing facilities, on-farm visitors often enter areas where covered produce is grown and harvested, particularly on farms that offer consumers an opportunity to pick their own fruits and vegetables. As with workers, visitors can transmit pathogens to covered produce and food-contact surfaces. Thus, we are proposing to require that farms address the potential for visitors to contaminate covered produce, even though we have no similar requirements in regulations such as parts 110 and 111. Proposed § 112.33 is similar to provisions in our GAPS Guide (Ref. 10), the AFDO Model Code (Ref. 20), various produce industry guidelines (Ref. 89. Ref. 84. Ref. 99), a marketing agreement (Ref. 31), and the Codex Code (Ref. 96). A farm could comply with these proposed requirements by, for example, indicating the location of restrooms and hand-washing facilities accessible to visitors and clearly posting rules applicable to visitors where they are likely to be seen and read at the beginning of a visitor's visit, such as near the entrance or cash register at a ''pick-your-own'' farm operation.

E. Subpart E—Standards Directed to Agricultural Water

As proposed, subpart E discusses science-based minimum standards directed to agricultural water that are reasonably necessary to minimize the risk of serious adverse health consequences or death from the use of, or exposure to, covered produce, including those reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into covered produce, and to provide reasonable assurances that the produce is not adulterated under section 402 of the FD&C Act.

1. Comments Relevant to Proposed Provisions

We received some comments in response to the 2010 FR notice that addressed issues relevant to agricultural water. Several comments expressed concern that our proposed regulations could have an adverse effect upon or be in conflict with on-farm conservation or land management practices efforts; or that they could set standards for limiting all animal access to surface waters (*e.g.,* by fencing or other barrier) or prohibit vegetation (normally used to stabilize soil or for use as a natural water filter) surrounding surface water sources.

In developing the provisions in proposed part 112, we consulted with USDA's National Organic Program and Natural Resources Conservation Service, U.S. Fish and Wildlife Service, and the EPA (Ref. 115) to take into consideration conservation and environmental practice standards and policies established by those agencies. We recognize the importance of ensuring, to the extent possible, that our proposed provisions are compatible with existing conservation practices in the management of agricultural water systems. In proposed § 112.42(a)(1)–(5), we would require that you inspect your entire agricultural water system at the beginning of every growing season, focused on identifying conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food-contact surfaces. A similar (re)inspection would be required in proposed §§ 112.44(b) and (c) if the water you use for certain purposes does not meet the microbiological criteria described in those provisions. In each of these provisions, however, we do not describe specific inspection findings likely to adversely affect microbial water quality and relate them to specific required actions. For example, we do not propose that vegetation surrounding an on-farm pond be cut back and/or removed or that fencing must be used to prevent access to a pond by wildlife and domestic animals. We recognize that each farm, State, region, or produce commodity group may approach water management differently with respect to the likelihood of contamination of agricultural water and the use of specific conservation practices that may be appropriate or consistent with measures used to mitigate the likelihood of contamination. Practices used for one region or commodity may not be appropriate for others based upon historical experience. Under this proposed subpart, we would require that you address such issues only if they are reasonably likely to contribute to contamination of covered produce, and we would provide flexibility in the way in which you address any identified hazards, such that measures you implement to mitigate such hazards can be consistent with your current conservation practices. This approach allows you to put in place measures you deem most effective in addressing the potential for water contamination and to assess the effectiveness of those measures as they may be reflected in your microbial water quality data.

We also received a number of comments expressing concern about costs and associated burden related to testing of agricultural water, including pathogen testing, indicators, and frequency of testing. As described in section in the QAR, pathogen presence and distributions in the environment and water systems can be expected to be sporadic, with survival dependent on a multitude of factors. Thus, broad generalizations concerning their presence or persistence in water or on produce are problematic, and their detection difficult. Therefore, rather than testing for the presence or levels of various pathogenic microorganisms, we propose to use a microbial indicator as a monitoring measure to assess the potential for contamination. After considering various microbial indicators of water quality (see section V.E.2. of this document), we tentatively conclude that generic *Escherichia coli* (*E. coli*) is best suited for this purpose. It can be found in at least 90 percent of all human and animal feces (Ref. 116) and is most closely associated with incidents of fecal contamination (Ref. 107. Ref. 108. Ref. 109. Ref. 110. Ref. 108. Ref. 111. Ref. 112). There are multiple test methods, commercial kits, and formats available at relatively low cost, and the accuracy, precision, and sensitivity of these analytical testing options would meet the requirements in this proposed rule. Although the correlation between generic *E. coli* and fecal contamination is strong, as discussed in section V.E.2. of this document, generic *E. coli* does not always reliably predict the presence of pathogens despite fecal pollution being a known source of pathogenic microorganisms. This is explainable, however, considering the current understanding of pathogen occurrence and distribution described in the QAR and the taxonomic diversity of waterborne pathogens (*e.g.,* bacteria, viruses, and protists). Thus, generic *E. coli* monitoring serves as a measure to assess the potential for fecal contamination, not to directly predict the presence of pathogens.

Comments also emphasized that microbial testing should be performed at a frequency dependent upon the results of an assessment of the risks posed by your agricultural water system. We agree that the frequency should reflect the risk. In proposed § 112.45(a), with certain exceptions, we propose to require you to test water used for certain purposes at the beginning of each growing season, and every three months thereafter during the growing season. We tentatively conclude that this frequency would provide sufficient information regarding the microbial quality of your agricultural water. We are proposing in addition in § 112.45(b) that untreated surface waters must be tested more frequently than ground water sources because surface watersheds are subject to a greater number of external forces that shape their overall composition, chemistry, and microbial water quality (*e.g.,* erosion, run-off, dust, suspended sediments). We seek comment on our proposed approach.

A number of comments related to quantifying risks associated with the use of agricultural water as a function of water source, time of application, irrigation method, and commodity type. Our research shows that this is an extremely difficult task. In the QAR, we considered various factors relevant to produce production and harvesting, including water sources and use (See the QAR document). Some conclusions related to likelihood of produce contamination associated with water use can be drawn, although the relevance of these findings and whether they can be generalized across commodities, regions, and climates is not known. For example, Stine et al (2005) (Ref. 109) and Song *et al.* (2006) (Ref. 117) provide strong evidence that subsurface drip irrigation lowers the likelihood of waterborne contamination compared to furrow or overhead irrigation. These authors also suggest that proximity of the edible portion relative to water applied and surface texture of the edible portion play key roles in likelihood of contamination.

In addition, according to a WHO risk assessment (Ref. 118) of wastewater use in agriculture, pathogen (bacteria, protists, and viruses) die-off during the interval between last irrigation and consumption is approximately 1 log per day, although the rate varies with climatic conditions. Other measures that can be protective include cessation of watering, choice of irrigation method (localized irrigation—bubbler, drip, trickle is more protective than flood, furrow, or spray/sprinkler), and food preparation measures (washing) (Ref. 118). It is difficult to determine to what extent this assessment can be applied to water systems that are not based on wastewater use where high pathogen loads can be expected. Produce grown with water of significantly higher water quality continues to be implicated in disease outbreaks (Ref. 119). These outbreaks not only illustrate the challenge in assigning absolute risk reduction values to measures used in the mitigation of risk, but also the sporadic nature of pathogen occurrence and localized conditions leading to the persistence of pathogens in the environment.

A few comments recommended that equipment used to hold or convey water should be inspected to ensure that it is clean.

We agree that equipment used to hold or convey water should be maintained in a manner necessary to protect against contamination. In proposed 112.42(c), we propose to require that all agricultural water distribution systems must be adequately maintained 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. In addition, in proposed 112.42(b), we propose to require that all agricultural water sources that are under the control of a covered farm (such as wells) must be adequately maintained 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.

We seek comment on our proposals and approach related to agricultural water.

2. Water Quality Testing, Indicators, and Standards

In this subsection, we present a technical discussion of issues related to water quality such as testing samples, microbial quality indicators, and microbial quality standards. We discuss these issues in greater detail in this subsection to further support the provisions proposed below related to water quality testing and microbial indicators.

A fundamental component in assessing the adequacy of water for its intended use is a routine sampling and microbial testing program (Ref. 120. Ref. 29). Water sampling and testing allows for informed decisions regarding the management of water use, such as choosing a water source and combining that selection with, for example, the irrigation method for a specific commodity or time period prior to harvest. Testing for microbial quality of water can identify possible fecal contamination at the water source or in a section of its distribution system (*e.g.,* line break). Additionally, regular testing data may be used to identify seasonal (or other) trends and highlight areas of the system that may require attention. For example, regular testing results may show that periodic increases in indicator organisms are correlated with precipitation levels or suspended sediments in surface waters, providing useful information about when and how that water source can be safely used.

Microbial water quality testing can be performed using a variety of methods that have been validated for water testing. A key element of any testing program is determining the indicator organism or specific pathogen(s) and the frequency of testing. The sensitivity of the method is also important, although most test methods available today have sensitivities that match or exceed requirements for EPA drinking water and FDA bottled water standards.

Surface water quality and pathogen monitoring studies reported in the literature often quantify indicator organisms or pathogens on a monthly basis. However, most studies do not specifically address the impact of water quality on produce safety (Ref. 115. Ref. 116. Ref. 117. Ref. 118). A lack of consensus among the different recommendations and approaches underscores the complexity and uncertainty in water quality sampling and testing strategies. Nevertheless, a vast majority of studies that address frequency of testing recommend that surface water sources should be sampled more frequently than ground water sources (Ref. 121).

Two key determinants of an appropriate testing frequency emerge from this information: (1) Variability of the water source and (2) the extent to which it can be protected. The discussion above suggests that water obtained from a public water source is least likely to be a vehicle for pathogen contamination of produce, followed by water obtained from deep underground aquifers, shallow wells, and surface waters, in that order. This is consistent with findings reported in the literature (Ref. 122. Ref. 29). For purposes of defining likelihood of contamination, we further divide surface water into two types, based on the potential for contamination (through runoff), and the degree to which potential contamination can be recognized and controlled (*i.e.,* (1) surface waters where runoff is difficult to recognize and control because of the size of the watershed (*e.g.,* river or lake) and (2) surface waters where runoff can be easily detected and which can be managed so as to protect them from runoff (*e.g.,* on-farm reservoir or pond)). Runoff is used here in differentiating the likelihood of contamination of surface water because it has the potential to carry pathogens and is known to mobilize pathogens from sediment reservoirs to the water column (Ref. 117. Ref. 120. Ref. 121. Ref. 122. Ref. 123) as well as carry pathogens to the surface water system from sources such as failing septic systems and deposited animal feces (Ref. 123. Ref. 124).

a. Microbiological Indicators of Water Quality

A primary consideration in establishing a microbiological water quality testing program is the choice of target organism(s). Two general approaches are commonly used: Test for the presence of an indicator organism(s) that may signal the presence of pathogens or test for pathogens themselves. In the United States, bacterial indicators have a long history of being used to demonstrate the safety of drinking water and adequacy of its treatment at the source. They have also been used to monitor the status of drinking water in distribution systems and determine if surface waters are microbiologically safe for recreational use (*e.g.,* swimming) and shellfish harvest (Ref. 123).

Bacterial fecal indicators are non-pathogenic microorganisms that are commonly found in the intestines of warm-blooded animals that are easily isolated and quantified as a measure of fecal contamination and potential for enteric pathogens. Desired characteristics for effective indicator organisms include: Ease of detection; being present only when fecal contamination or pathogens are present; and, being in numbers that correlate with the amount of contamination, numbers of pathogens and risk of illness. Survival times of indicator organisms in sediments and in water should be equal (or greater) to those for pathogens and their detection should be accomplished by simple, rapid methods at low cost. Indicator microorganisms are widely used in water quality testing because of their broad utility across many types of water but no single indicator that is universally accepted (Ref. 123).

Pathogen detection has the obvious advantage of directly targeting microorganisms in water that are a risk to public health. However, sampling water for pathogens may present additional challenges, including larger sample sizes to facilitate detection, inherently higher costs, and the wide array of potential target pathogens (*i.e.,* the presence or absence of one pathogen may not predict for the presence or absence of other pathogens).

A number of indicator microorganisms have been used to predict the presence of pathogens in water, with varying degrees of success. These include total coliforms, fecal coliforms, enterococci, generic *E. coli,*

and coliphages. However, their presence does not always signal the presence of pathogens and the absence in their detection is not assurance that pathogens are absent (Ref. 126. Ref. 127. Ref. 128. Ref. 129. Ref. 130).

Consequently, Gerba (2009) (Ref. 120) suggested indicators be defined by a purpose for which they are better suited instead as an indicator for pathogens. For example, efficacy of treatment (*e.g.,* public water systems) or integrity in manufacturing processes (*e.g.,* bottled water) can be effectively monitored by total coliforms because these environmental bacteria are not expected to survive the treatment conditions or be introduced during the manufacturing process. Their presence in treated municipal water or in bottled water may signal an inadequate treatment or deficient manufacturing step meriting investigation and subsequent corrective action to resolve the problems identified. Another example is using fecal indicator bacteria (*e.g.,* enterococci or generic *E. coli*) to assess the risk of gastrointestinal illness (or other adverse health conditions) in marine and freshwater swimmers, because their presence is statistically correlated to adverse health outcomes in these groups (Ref. 119. Ref. 120). Generic *E. coli* alone, as an easily distinguishable member of the fecal coliform group, is more likely than the fecal coliform group as a whole to indicate fecal pollution (Ref. 120). Used in this way, indicator organisms are not used specifically to predict the presence of pathogens, but are useful predictors of undesirable conditions (*e.g.,* ineffective treatment, defective manufacturing process, presence of fecal material).

Total coliforms have frequently been used to assess water quality of several different types of natural waters (*e.g.,* freshwater and marine) but their use for this purpose has decreased recently as they have been found to be present in natural water both because of fecal contamination and as natural environmental inhabitants. They are regularly isolated from soil, plants, vegetables, and effluents from agricultural and food industries but their presence does not reliably signal a fecal contamination event (Ref. 131. Ref. 112). Fecal coliforms share a similar problem. Fecal coliforms are coliforms that are capable of growth at higher temperatures, conditions similar to those which can be found in the mammalian gut. However, some of its members (*e.g.,* Klebsiella, Citrobacter, Enterobacter spp.) can normally be found outside the intestine including soil, water, vegetation, fresh vegetables, silage, insects, and many others (Ref. 124) and there is ample evidence that they can grow and multiply there (Ref. 132. Ref. 133. Ref. 114. Ref. 123). This makes using fecal coliforms as indicators for fecal contamination problematic, as it would be difficult to separate increases in their numbers due to natural forces (*e.g.,* precipitation, erosion, wind, temperature) from increases due to fecal contamination events.

Generic *E. coli* is a member of both the coliform and fecal coliform groups but has been shown to more consistently be associated with fecal contamination than other indicators (Ref. 134. Ref. 135. Ref. 133. Ref. 136. Ref. 137. Ref. 138. Ref. 112). It can be found in at least 90 percent of all human and animal feces (Ref. 108) (Ref. 116) where it persists, more than other transient fecal *coli*forms (Ref. 125. Ref. 124). While its association with fecal contamination is very strong, it has also been isolated from environments with no apparent fecal contamination, including tropical watersheds (Ref. 126) and paper mill effluents (Ref. 127). Outside of these findings, reports of generic *E. coli* growth and proliferation outside the gut (*e.g.,* in water) are generally rare. Generic *E. coli* demonstrates variable survival times in water but may only persist from 4 to 12 weeks at 15–18 degrees Celsius (Ref. 116).

Generic *E. coli* has an extensive history of use as an indicator of fecal contamination and is considered the best indicator for monitoring water quality (Ref. 119). Its detection and enumeration can be performed using a variety of commercial products at relatively low cost. However, its ability to signal fecal contamination events is dependent upon sampling frequency and location relative to the source of contamination. Thus, instances of non-detection are not considered confirmation of the absence of fecal contamination because sampling frequency may not be adequate to detect events occurring over short periods of time. Sampling results can only be considered snapshots of water quality over time. Moreover, the fate and transport of generic *E. coli* in watersheds may be different than other fecal constituents in response to localized conditions (*e.g.,* sunlight, temperature) (Ref. 128. Ref. 129. Ref. 130).

One challenge in using indicator organisms to predict water quality is correlating information concerning their numbers to the presence or absence of pathogens (as compared to the presence or absence of fecal material). Although generic *E. coli* is recognized as a good indicator of fecal contamination, pathogens are not always present in that fecal material because their distribution and persistence is sporadic. As a consequence, the record of generic *E. coli* as a predictor of pathogens is mixed. The Canadian Federal-Provincial-Territorial Committee on Drinking Water states generic *E. coli* is unsatisfactory in predicting the presence of *Giardia, Cryptosporidium,* and enteric viruses (Ref. 119. Ref. 124) and Horman *et al.* 2004 (Ref. 131) found poor correlation between generic *E. coli* and the presence of pathogens (*Campylobacter* spp., *Giardia* spp., *Cryptosporidium* spp., and noroviruses) in Finnish surface waters. However, they did conclude that the absence of generic *E. coli* was a very strong predictor for the absence of pathogens. Duris et al (2009) (Ref. 132) found generic *E. coli* inconsistently correlated to genetic markers for generic *E. coli* O157 in Michigan and Indiana river water but suggested the relationship could be strengthened by increased sample size. Alternately, Wilkes *et al.,* 2009 (Ref. 133) reported generic *E. coli* concentrations were the best indicator of pathogens (*E. coli* O157:H7, *Salmonella* spp., *Campylobacter* spp, *Giardia* and *Cryptosporidium*) presence/absence in Canadian watersheds. Others have noted that generic *E. coli* has a better record as an indicator for *Salmonella* than for *E. coli* O157:H7 (Ref. 134). Review of these studies illustrates the complexity of possible interactions between indicators and pathogens in water, and their potential for separate fates within those systems.

Studies relating indicators, pathogens, and the risks associated with produce consumption are few and are complicated by the relationships described above. Different survival profiles between indicators and pathogens on produce may also affect risk. The World Heath Organization (Ref. 118) proposed a set of pathogen reduction measures that can be used alone or in combination to achieve a 6–7 log pathogen reduction they determined necessary to meet health-based targets. To verify the effectiveness of the measures, they recommend monitoring generic *E. coli* levels in treatment effluents and in crops at harvest. They noted that field pathogen die-off is variable (0.5–2 log per day), dependent on temperature, sunlight, crop type, time, and other factors.

Produce contamination events that occur during growing, harvesting, packing, or holding on farm are generally thought to occur intermittently and at low doses. As a result, the detection of human

pathogens in contaminated produce using available testing methodologies remains an arduous process. It is impractical to test 100% of the product; therefore sampling plans to collect a statistically significant subset must be devised. Unfortunately, although such testing has in the past prevented some contaminated product from entering the market when pathogens are found, it is also very possible that testing can entirely miss a point contamination, thus it cannot provide a litmus test for food safety because the sample size needed to detect low dose, low frequency, and non-uniformly distributed contamination is impractically large (Ref. 135). In addition, microbial testing can only detect the pathogens the analytical procedures are designed to detect, and we tend to only test for pathogens known to be of concern. Considering the range of potential pathogens, these are significant limitations.

b. Microbial Water Quality Standards

The lack of sufficient information to support a pathogen-based microbiological standard for water used in the production of produce has led to the adoption of the generic *E. coli* component of the U.S. EPA recreational water standards (for frequently used beaches) by some industry groups (Ref. 44. Ref. 31). The EPA recreational water standards were developed from epidemiological studies that correlated the risk of gastrointestinal illness to exposure to marine and freshwater by swimmers (Ref. 136). Generic *E. coli* was found to be a good predictor of swimming associated illness in freshwater and the EPA recommended criteria include a geometric mean of 126 CFU per 100 ml and a single sample maximum for designated beach areas of 235 CFU per 100 ml (Ref. 136). British Columbia, Canada has announced their intention to use a similar approach in setting generic *E. coli* criteria for irrigation water used on produce consumed raw. Their irrigation criteria (less than or equal to 77 CFU per 100 ml geometric mean) are the same as and were derived from those used for primary-contact recreation (Ref. 137). See section V.E. of this document for additional discussion of this issue.

The U.S. EPA criteria were developed from epidemiological studies of beach areas subject to point source fecal contamination rather than non-point source contamination (*e.g.,* birds, agricultural and livestock runoff). Non-point sources may also influence the quality of agricultural water. Further, adverse health outcomes as a consequence of immersion while swimming in contaminated water may be different from those as a result of eating produce irrigated with contaminated water. The routes of infection and pathogen mortality rates are different in each environment.

Based upon a WHO analysis of tolerable risk for irrigation water, the minimum microbial quality for water used on root crops that are eaten raw is 1,000 CFU generic E. coli per 100 ml (10,000 CFU generic E. coli per 100 ml in leaf crops) (Ref. 120. Ref. 118). According to the WHO analysis, using water of this microbial quality is dependent upon a 2 log reduction due to die-off between last irrigation and consumption (includes die-off in the field and during distribution) and a 1 log reduction attributed to washing prior to consumption. This analysis recognizes the variable nature of die-off values, ranging from 0.5–2.0 log per day (Ref. 118). The WHO analysis considers the need for a four log reduction through dilution, die-off, or treatment between the levels of generic E.coli in raw sewage (well represented in sewage by fecal coliform levels) and the levels in irrigation water used on root crops that are eaten raw (3 log for leaf crops), in addition to the 3 log reduction discussed above.

3. Proposed Requirements

a. General Requirement

Proposed § 112.41 would establish the requirement that all agricultural water must be safe and of adequate sanitary quality for its intended use. The principle of ''safe and of adequate sanitary quality for its intended use'' contains elements related both to the quality of the source water used and the activity, practice, or use of the water. Uses vary significantly, including: Crop irrigation (using various direct water application methods); crop protection sprays; produce cooling water; dump tank water; water used to clean packing materials, equipment, tools and buildings; and hand washing water. The way in which water is used for different commodities and agricultural practices can determine how effectively pathogens that may be present are transmitted to produce.

Comparing the probability of contamination of covered produce associated with key practices at different stages of production and across a range of commodities, the interrelatedness of these factors becomes apparent. The QAR shows that the likelihood of contamination associated with indirect water use for irrigation is relatively low compared to irrigation water that directly contacts produce (Ref. 2). Therefore, in Section V.A.2.b (Definitions), we propose to define ''agricultural water'' to mean 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). As we propose in § 112.3(c), ''covered produce'' refers to the harvestable or harvested portion of the crop. As proposed, ''agricultural water'' does not include indirect water application methods used during growing. For example, generally, the water used for drip or furrow irrigation in apple orchards would not be considered agricultural water because the water is unlikely to contact the harvestable portion of the crop. As another example, generally, the water used for overhead spray irrigation of romaine lettuce would be considered agricultural water because the water is likely to contact the harvestable portion of the crop. We are proposing to distinguish between water that is intended to, or is likely to, contact covered produce or food-contact surfaces (*e.g.,* direct water application method irrigation water) and water that is not intended to, or is not likely to, contact covered produce or food-contact surfaces based on the relative likelihood of contamination from water that contacts covered produce and the need for measures to minimize such likelihood.

If finalized as proposed, indirect water application methods would not be subject to the requirements of this rule. While indirectly applied water is unlikely to contact produce or food-contact surfaces, we recognize that it presents the possibility of produce contamination. For example, use of contaminated water in drip or furrow irrigation may still serve as a vehicle for bringing contaminants into the growing environment which may potentially be transferred to produce by rain splash, workers, or equipment; use of contaminated water for dust abatement on farm roads may also be transferred to produce by run-off, rain splash, workers, or equipment.

Indirect water application methods would remain subject to Section 402(a)(4) of the FD&C Act. That is, indirect water application may

adulterate produce if, considering the water quality and the manner of its application, the use of the water causes produce to be prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth or rendered injurious to health. Moreover, if a pathogen is detected in or on produce, such produce would be considered adulterated under Sections 402(a)(1) of the FD&C Act, in that it contains a poisonous or deleterious substance which may render it injurious to health. Therefore, we tentatively conclude that indirect water application methods do not need to be covered within the scope of ''agricultural water'' for the purposes of this rule.

We ask for comment on the limited scope of ''agricultural water'' to only water that is intended to, or likely to contact covered produce or food-contact surfaces. We also seek comment on its resulting effect on the applicability of the general requirement in proposed § 112.41 that agricultural water must be safe and of adequate sanitary quality for its intended use, to only water that is intended to, or likely to, contact covered produce or food-contact surfaces. Water that is not safe or of adequate sanitary quality for its intended use may lead to contamination of covered produce, even where the water use is indirect. We have previously recommended measures such as indirect water use when water quality is poor or unknown as a measure to minimize risk (Ref GAPs Guide). Considering the FD&C Act would still apply to such uses, and that there is a lower likelihood of contamination of produce by indirect water use, is there a need to subject indirect water use, including water used for dust abatement, to the general requirement in proposed § 112.41? We welcome comment on this approach, as well as other actions that have been found to be effective through practice and experience.

We also considered proposing some requirements for water that is used during growing, but which does not contact the harvestable portion of covered produce. For example, water that did not contact produce would not have been subject to any testing requirement, although we considered requiring this water and all agricultural water to be of safe and adequate sanitary quality for its intended use (proposed § 112.41). We also considered requiring indirect water to comply with proposed § 112.42(a) (sanitary survey) and § 112.42(b) through (d) (adequately maintaining water sources under your control). If we did include both direct and indirect water use in the definition of ''agricultural water'' in the final rule, which of the proposed requirements for agricultural water described in section V.E. of this document would (or would not) be appropriate for indirect water use? Are there other factors that we should consider? In every application of water, careful consideration should be given to what you know about the water's quality at its source, the impact your distribution system may have on the water quality, and when or how that water is to be used. For example, water that contains *Salmonella* would not be safe or of adequate sanitary quality for its intended use when used in a postharvest dump tank for tomatoes. *Salmonella* is a food safety hazard that is well-documented to present a risk of severe adverse health consequences or death, and tomatoes can become contaminated by water containing *Salmonella* (Ref. 138. Ref. 139. Ref. 140). As another example, when the surface water (*e.g.,* river) that you use for crop irrigation using a direct application method has a noticeable decrease in quality due to an upstream event like the failure of a waste water treatment plant, resulting in the accidental discharge of untreated municipal sewage into the river, your water source would not be safe or of adequate sanitary quality for its intended use until the discharge is over and the water has been tested because the incompletely treated sewage in the discharge is likely to contain pathogenic microorganisms that could compromise the safety of irrigated covered produce.

The most frequently used irrigation methods include overhead, surface and subsurface drip, furrow, flood, and seep irrigation (Ref. 29). These practices may be commodity-specific and choices may be limited by the availability of different water sources, crop needs, climate, precipitation levels, or regional practices. Each irrigation method presents a different likelihood of contamination, independent of the water source and its application to a particular commodity. For example, the likelihood of produce contamination may be reduced if irrigation water is delivered by subsurface drip irrigation compared to using the same water to irrigate by overhead spray (Ref. 141. Ref. 122). Researchers also concluded that both the physical properties of the edible portion of the crop, such as surface texture, and the location of the edible portion of the plant in relation to irrigation water played significant roles in contamination (Ref. 130). As discussed in the QAR, the timing of irrigation water application also plays a role in minimizing the persistence of contamination. For example, water containing elevated generic *E. coli* used in overhead irrigation shortly before harvest may increase the likelihood of covered produce being contaminated with the pathogen at harvest, but the same water could safely be used to establish a crop and throughout the majority of the growing season because, as discussed in the QAR, pathogens die-off over time on the surface of produce. Water used for washing hands during and after harvest, sprout irrigation, directly contacting produce during or after harvest (such as in washing and cooling, or to make ice that directly contacts produce), making treated agricultural tea, and water or ice that will contact food contact surfaces that contact covered produce presents an even greater likelihood of microbial contamination of covered produce (Ref. 131. Ref. 132). Waterborne pathogens can be transferred to covered produce with little opportunity for die-off if contaminated water is used for hand washing during or after harvest, or in harvest, packing or holding activities where it directly contacts produce or surfaces that contact produce and, therefore, it is important to ensure that the water is safe and of adequate sanitary quality for such uses. Moreover, the high nutrient, high moisture conditions inherent to sprout production and agricultural teas not only support pathogen survival but are also conducive to their amplification if present (Ref. 142. Ref. 16). Again, the selection of a water source for these uses must ensure that the water is safe and of adequate sanitary quality for that use.

b. Measures Regarding Agricultural Water Sources and Distribution Systems

Proposed § 112.42 would establish the measures that you must take with respect to agricultural water sources, water distribution systems, and pooling of water.

Proposed § 112.42(a) would establish that 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.

Human pathogens can enter an agricultural water system anywhere from its source to point of use. Central to the prevention of pathogen contamination of agricultural water is an inspection of water source and the components of the distribution system to identify potential routes of contamination. Inspections of water sources and components of its distribution system are recommended by government and industry references (Ref. 10. Ref. 20. Ref. 45. Ref. 44).

Generally, inspection of the agricultural water system under your control beginning at the water system source is the first opportunity for ensuring that it will deliver water that is safe and of adequate sanitary quality for its intended use. Inspection of your water source provides an opportunity to identify and characterize activities and situations that may lead to contamination of your agricultural water. Further, inspection results provide you with historical knowledge of your water sources, their quality, and factors that may affect their quality (Ref. 31). Inspection of the water source and any equipment used to obtain the water from the source (*e.g.,* well head, pumps, pipes) can ensure that the water that enters the distribution system is suitable for its intended use.

Proposed § 112.42(a)(1) requires you to consider the nature of your agricultural water sources to identify conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food-contact surfaces. As discussed in the QAR, ground water which is often believed to be pathogen free can be contaminated. Ground water can also be compromised and its water quality degraded if wells are improperly constructed, poorly maintained, or improperly located (*e.g.,* near areas of extensive livestock production or fields where manure is applied (Ref. 143. Ref. 144. Ref. 122). U.S. water systems using ground water as source waters for drinking must operate in compliance with the U.S. EPA Ground water Rule (GWR) (40 CFR parts 141 and 142) to protect against illness from waterborne pathogens in ground water. However, the GWR does not address private wells because they are not under the jurisdiction of the Safe Drinking Water Act and are therefore not subject to EPA regulation. Thus, water quality and survey data on ground water used for agriculture are not publicly available. By their nature, surface waters are open systems, subject to the influence of various environmental factors that can impact the safety of the water. For example, increased precipitation levels, storm events, or wind may result in a spike in water turbidity, due to redistribution of sediments. We tentatively conclude that there exists significant potential for contamination of ground and surface waters and, therefore, we propose to require you to include both ground and surface water sources in your inspection of your agricultural water systems. We seek comment on this tentative conclusion and associated proposals.

Proposed § 112.42(a)(2) requires you to consider the extent to which you have control over your agricultural water source to identify conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food-contact surfaces. You may have more control over your ground water source (well) if it draws water from an aquifer beneath your property and which you protect from the influence of surface activities. You would likely have less control if your well is located near a concentrated animal feeding operation or is influenced by surface water (*e.g.,* a shallow well). You may have greater access to and control of on-farm surface water sources such as impoundments, catches, and ponds, than you would for flowing surface waters that only course through but do not originate on your land.

Proposed § 112.42(a)(3) requires you to consider the degree of protection of each agricultural water source. Examples of protection for water sources include covers, containments, or fencing that exclude domesticated animals or other possible sources of contamination from the water source or earthen berms or other barriers that help minimize the influence of runoff on the water source.

Proposed § 112.42(a)(4) requires you to consider the use of adjacent or nearby land. Agricultural water may be affected by upstream agricultural practices and runoff from those operations into surface water sources that you use. For example, an upstream alfalfa grower may apply raw manure as a soil amendment, and irrigation water runoff from that field may flow into your agricultural surface water source. While you may have little or no control of other agricultural water user practices, this proposed requirement to consider those nearby uses of which you are aware will help you determine appropriate and safe use of that water source.

Proposed § 112.42(a)(5) requires you to consider 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. For example, if you use water from a river and are downstream from a waste water treatment plant that discharges into that river, this provision would require you to consider the likelihood that the wastewater treatment plant introduces hazards into the water before it reaches your farm. For example, you would consider the likelihood of accidental discharge of untreated municipal sewage into the river.

Proposed § 112.42(b) would require that you adequately maintain all agricultural water sources that are under your control (such as wells) by regularly inspecting each source and keeping the source free debris, trash, domesticated animals, and other possible sources of contamination of covered produce to the extent practicable and appropriate under the circumstances. Regular maintenance of your water sources is imperative to ensure the continued safety of your water. Maintenance of on-farm water sources may include upkeep and repair of berms, pipes, liners, or any structural elements, that are used to protect the source. Properly maintaining a well includes conducting wellhead inspections, during which time you check the condition of the well covering, casing, and cap to make sure all are in good repair, leaving no cracks or other entry points for potential contaminants. Properly maintaining a storage tank includes cleaning the interior surfaces of all rust scale, paint scale, dirt, and bio-film forming growths and inspecting exterior surfaces for corrosion which may become a route of contamination (Ref. 31). Properly maintaining a farm pond that is used for irrigation using a direct application method, with respect to keeping it free from domesticated animals, could mean fencing the pond if you keep domesticated animals in the area such that they would otherwise have access to the pond. On the other hand, if you treat the water before use in this way, you may not need to take steps to prevent access of the domesticated animals to the pond. This proposed provision should not be construed to require the ''taking'' of an endangered species, as the term is defined in the Endangered Species Act (16 U.S.C. 1532(19)) (*i.e.,* to harass, harm, pursue,

hunt, shoot, wound, kill, trap, capture, or collect, or to attempt to engage in any such conduct).

Proposed § 112.42(c) would require that you 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. Regular maintenance of your agricultural water distribution system can be performed in conjunction with inspections and cleaning, as applicable. If not regularly maintained, portions of a water distribution system may fail, corrode, collect debris, or otherwise become a source of contamination. For agricultural water distribution system components that are underground, it would be important to look for signs of erosion or wet soil areas, as they may indicate a damaged underground component requiring further inspection and maintenance (Ref. 145).

Proposed § 112.42(d) would establish that 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 for its intended use, until you either: (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 and 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. Using agricultural water that is not safe or of adequate sanitary quality for its intended use may lead to contamination of covered produce. Lapses in sanitary quality of water can occur in any segment of a water system, from source to point of use. For example, if you find that water contains *Salmonella* at the point where it would be used in a dump tank for tomatoes, it would not be safe or of adequate sanitary quality for that intended use. As another example, your water would not be considered safe or of adequate sanitary quality for its intended use if you found detectable generic *E. coli* in a 100 ml water sample you obtained at the point where the agricultural water is used for washing produce as described in proposed § 112.44(a). Similarly, your water would not be considered safe or of adequate sanitary quality if you found that test results exceeded 235 CFU per 100 ml generic *E. coli* in a water sample you obtained from water used to overhead irrigate lettuce (a direct application method) as provided in proposed § 112.44(c). We seek comment on these proposed thresholds.

Under this proposed provision in § 112.42(d)(1), for example, you would review your previous inspection results for the affected portion of your agricultural water system and compare those results to conditions you currently observe. You would identify changes likely to have an impact on the quality of water (*e.g.,* evidence of runoff, animal intrusion, suspended sedimentation, changes in adjacent land use) or any lapses in your procedures (*e.g.,* outdated well inspection, break in the water treatment schedule). You would test the water after you make changes you find necessary during your inspection. Under the proposed provision in § 112.42(d)(2), you could instead choose to treat your water in accordance with the requirements of § 112.43 to ensure its safety. We tentatively conclude that the measures proposed in § 112.42(d) are necessary and adequate to address deficiencies that may exist in your water management system and practices so that your agricultural water does not serve as a source of contamination to covered produce. We welcome comment on this approach, as well as other actions that have been found to be effective through practice and experience.

Proposed § 112.42(e) would establish that, 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. Pooling may occur if excessive water is applied to a crop, especially in areas of poor drainage. Pooled water that remains for extended periods of time has been shown to increase likelihood of contamination (Ref. 10. Ref. 45). Further, if pooled water is in close proximity to the crop, it may serve as an attractant for pests. Mounding soil, staking, subsoil drip irrigation, drip tape or plasticulture (use of agricultural plastics) are methods that are used to reduce the potential for pooling or to separate the pooled water from the covered produce. We acknowledge the potential for small pools of water to temporarily form in field areas or at the base of plants after irrigation. Small amounts of water of this nature, which are temporary and occur in the normal course of irrigation practices, are not reasonably likely to contribute to the contamination of covered produce. We are not suggesting that it will always be possible to eliminate pooling. Avoiding pooling by careful control of irrigation is ideal; however, events such as rainfall or irrigation malfunction may sometimes make pooling inevitable. In those cases, the proposed requirement would require farms to take steps to protect covered produce from contamination that may build in the pooled water.

c. Requirements for Treating Agricultural Water

Water treatment is an effective means of decreasing the number of waterborne outbreaks in sources of drinking water (Ref. 146). However, treatments that are inadequate or improperly applied, interrupted, or intermittent have been associated with waterborne disease outbreaks (Ref. 146). Failures in treatment systems are largely attributed to suboptimal particle removal and treatment malfunction (Ref. 147). For this reason, when treating water, it is important to monitor the treatment parameters to ensure the treatment is delivered in an efficacious manner. Monitoring treatment can be performed in lieu of microbial water quality monitoring, if under the intended conditions of the treatment, the water is rendered safe and of adequate sanitary quality for its intended use. Many operations choose to perform microbial water quality testing in addition to monitoring the water treatment as a further assurance of treatment effectiveness (Ref. 148).

Proposed § 112.43 would establish requirements related to treatment of agricultural water. Specifically, proposed § 112.43(a) would require that 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, whereas proposed § 112.43(b) would require that any method you use to treat agricultural water to satisfy this requirement in paragraph § 112.43(a) must be effective to make the water safe and of adequate sanitary quality for its intended use. In addition, proposed § 112.43(c) would require you to: (1) Deliver any treatment

of agricultural water required by § 112.43(a) in a manner to ensure that the treated water is consistently safe and of adequate sanitary quality for its intended use; and (2) 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.

If you choose to use water that is not safe or of adequate sanitary quality for its intended use, the water must be treated before it is put to such use to minimize the likelihood for contamination. For example, treating agricultural water with antimicrobial compounds can be an effective means to eliminate pathogens if done properly, including under conditions that ensure the effectiveness of the active ingredient (Ref. 149. Ref. 150). 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. We anticipate that the proposed delayed implementation period for water quality testing (see section IV.K. of the document) would provide industry adequate time to address such issues. We seek comment on this issue.

To ensure water treatment is delivered in an effective manner, monitoring the conditions of treatment is also essential. An effective monitoring program would measure the level of active compound as well as those factors that may affect its activity, such as pH, temperature, and contact time. For example, monitoring water treated with hypochlorite in an orange postharvest wash would include, at a minimum, monitoring the level of active antimicrobial (free available chlorine) and pH, since it is known that hypochlorite activity is reduced both by organic material (*e.g.,* soil, plant debris) and pH values outside its effective range (pH 6.0–7.5) (Ref. 149. Ref. 150). The concentration of active disinfectant and pH must be adjusted, as necessary, taking into account variations in water quality in order to maintain the effectiveness of the treatment. In addition, the frequency in which you monitor agricultural water treatment must be adequate to ensure that the conditions for proper treatment are consistently met and adjusted, as necessary, to result in water that is safe and adequate for its intended use. Research has shown that in other settings, monitoring of physical parameters, such as temperature, pH and disinfectant concentration, can be done in real-time and in an inexpensive, automated manner, facilitating good control of the process (Ref. 149). As a verification that the treatment process, monitored in accordance with the proposed requirements of § 112.43(c)(2), is effective in achieving a certain microbial standard (*e.g.,* no detectable generic *E. coli* in 100 ml of water), you may chose to perform periodic microbiological analysis of the treated agricultural water. We are not proposing at this time that treated water must be tested in this manner because we believe that the effectiveness of various treatment processes is well understood. However, we encourage farms to perform such testing to provide further assurance of the effectiveness of their treatment under the specific conditions that exist on their farm. We seek comment on this issue.

d. Testing and Frequency of Testing of Agricultural Water

Proposed § 112.44 would establish requirements related to testing of agricultural water and subsequent actions based on the test results. Specifically, proposed § 112.44(a) would require that you 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 to ensure there is no detectable generic *E. coli* in 100 ml 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.

We seek comment on the appropriateness of these proposed categories in which testing would be required.

Proposed § 112.44(b) would require that 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 § 112.44(a). Before you may use the water source and/or distribution system again for the uses described in § 112.44(a), 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 § 112.44(a); or treat the water in accordance with the requirements of § 112.43.

We reviewed the most widely used indicator(s) or indicator groups for their potential in assessing the microbial quality of water used for purposes described in proposed § 112.44(a) and all other uses of agricultural water as described in section V.E.2 of this document. We considered total coliforms and fecal coliforms as indicators of fecal contamination but determined that neither of them can serve as reliable indicators of a fecal contamination event (Ref. 124. Ref. 119. Ref. 151. Ref. 152). *Generic E. coli* is a member of both the coliform and fecal coliform groups but, unlike some members of those groups, it has been shown using various detection methods to be the only coliform consistently associated with fecal contamination (Ref. 132. Ref. 133. Ref. 134. Ref. 135. Ref. 136. Ref. 137. Ref. 108). Generic *E. coli* has an extensive history and support for use as an indicator of fecal contamination. Recently, it has emerged as the preferred indicator for monitoring water quality, not only because of the problems with other groups noted above, but also due to the development of superior methods of detection with greater accuracy, sensitivity, and simplicity over those previously used (Ref. 119). Despite widespread use and support for generic *E. coli* as an indicator of fecal contamination, its ability to signal contamination events is not without challenges. Sampling frequency and location relative to the source of contamination are reported to affect the performance of generic *E. coli* as an indicator of fecal contamination (Ref. 133. Ref. 143. Ref. 153. Ref. 131). Thus, non-detection cannot be considered absolute confirmation that fecal contamination has not occurred. Further, the fate and transport of generic *E. coli* takes different paths in different watersheds, and reservoirs have been identified, particularly sediments, where they may escape detection in the water column (Ref. 128. Ref. 129. Ref. 130. Ref. 154). Nevertheless, based on our review of the literature, we

tentatively conclude that generic *E. coli* serves as the most appropriate microbial indicator of fecal contamination of water at this time and, therefore, we propose to use a microbial standard of no detectable generic *E. coli* in 100 ml agricultural water when it is for the intended uses listed in § 112.44(a). We seek comment on our selection of this indicator.

As discussed in the QAR, water used for the purposes listed in proposed § 112.44(a) has the potential to serve as a vehicle of pathogen contamination by direct contact with covered produce. Water used in sprout production must be free of fecal contamination because the conditions under which sprouted seeds are produced (warm, moist, nutrient-rich environment for extended period of time) are conducive to pathogen multiplication (Ref. 14). As discussed in section I.A. of this document, outbreaks associated with sprouted seeds are well documented; *Salmonella* and *E. coli* O157:H7 have been the major causes of sprout-associated outbreaks (Ref. 14). Similarly, the conditions under which agricultural tea is produced (moist and nutrient-rich) are similar in that they support the multiplication of pathogens, if present (Ref. 142). Even a low number of pathogens introduced into or onto covered produce through contaminated water could rapidly increase to levels that could present risk of serious adverse health consequences or death to those who consume the covered produce for which the tea was used. Further, water that is used in direct contact with produce or food contact surfaces, or in making ice that directly contacts produce or food contact surfaces, must also be free of fecal contamination and pathogens. These water applications normally occur during or shortly after harvest, leaving only a relatively short period of time before consumption for the environmental factors that drive pathogen die-off to exercise a significant effect (see the QAR). In addition, we propose to apply the microbial standard in proposed § 112.44(a) to agricultural water that is intended for use in washing hands during harvesting, packing, and holding activities, where there is little opportunity for microbial die-off prior to consumption. Hands that contact produce during and after harvest must be free of microbial contaminants (Ref. 133). In the United States, the Occupational Safety and Health Administration (OSHA) of the U.S. Department of Labor has established requirements for water used for washing workers' hands. Under 29 CFR 1928.110(b), a hand-washing facility means ''a facility providing either a basin, container, or outlet with an adequate supply of potable water, soap and single-use towels;'' and potable water means ''water that meets the standards for drinking purposes of the State or local authority having jurisdiction, or water that meets the quality standards prescribed by the U.S. EPA's National Primary Drinking Water Regulations [NPDWR] (40 CFR part 141).'' The OSHA requirements in 29 CFR 1928.110 require that farms employing eleven or more employees engaged in hand-labor operations in the field for a period of more than three hours in a day provide water that satisfies the microbial maximum contaminant level (MCL) in the NPDWR, which states that any generic *E. coli*-positive repeat sample or generic *E. coli*-positive routine sample (which would include a finding of any detectable generic *E. coli* in 100 ml of water using the methods of analysis in proposed subpart N) constitutes a violation of the MCL for total coliforms. Therefore, the microbial standard for hand washing water during harvesting, packing, and holding activities that is specified in proposed § 112.44(a) would be consistent with the OSHA requirements.

We acknowledge the difficulty of associating specific indicator concentrations with specific produce related health risks. Even so, we have tentatively concluded that such difficulty does not negate the value of applying generic *E. coli* test results to the requirement to discontinue use of a water source until compliance with applicable generic *E. coli* standard is again achieved, because elevated indicator organism concentrations indicate increased levels of fecal contamination and elevated potential for the presence of human pathogens of fecal origin (Ref. 154). The uses listed in proposed § 112.44(a) are similar in that, if pathogens or fecal contamination are present, it is reasonably likely they could be transferred directly to covered produce through direct or indirect (via food-contact surfaces) contact with the water. Therefore, testing the agricultural water used for these purposes to ensure that it is absent of generic *E. coli* would provide reasonable assurances that the water does not contain pathogens, and therefore that the water is not likely to introduce pathogens into or onto covered produce and to provide reasonable assurances that the produce will not be adulterated under section 402 of the FD&C Act. Moreover, a requirement that there be no detectable generic *E. coli* per 100 mL of agricultural water used in these activities and practices would be consistent with EPA's MCLs for microbiological contaminants in public drinking water systems (40 CFR 141.63(b)) and with our standard of quality for bottled water (21 CFR 165.110(b)(2)(B)). We request comment on the need for, and appropriateness of, this proposed requirement and any other criteria that would ensure the safety of water for these intended uses.

We tentatively conclude that we should require that if the water you use for the purposes listed in § 112.44(a) does not meet the microbial standard of no detectible generic *E. coli* per 100 ml, you must immediately discontinue use of the water and/or distribution system for those purposes. Before you use the water source and/or distribution system again for those uses, you would need to either (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 retest the water to determine if your changes were effective and to ensure that the water meets the required microbial standard; or (2) treat the water in accordance with the requirements of § 112.43 (proposed § 112.44(b)). This proposed requirement is parallel to the requirement in proposed § 112.42(d), which is discussed above.

Proposed § 112.44(c) would require that 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 § 112.44(c). Before you may use the water source and/or distribution system again for the uses described in § 112.44(c), 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. We seek comment on this approach.

As discussed in section V.E.2 of this document, the WHO recommends monitoring generic *E. coli* numbers in treatment effluents as verification of wastewater treatment, and laboratory analysis of crop contamination levels with generic *E. coli* at harvest and in retail to verify pathogen mortality (die-off) (Ref. 118). However, they also noted the variability in pathogen die-off (0.5–2 log/day), dependent on temperature, sunlight intensity, crop type, time of water application, and other factors.

Some industry groups have adopted the generic *E. coli* component of the U.S. EPA recreational water standards (for beaches used frequently) for certain uses of agricultural water (Ref. 31. Ref. 44). In this regard, EPA recommends that criteria include a maximum steady state geometric mean of 126 CFU of generic *E. coli* per 100 ml and a single sample maximum allowable density of 235 CFU of generic *E. coli* per 100 ml (Ref. 136). British Columbia, Canada has announced their intention to use generic *E. coli* criteria for irrigation water used on produce consumed raw. Their irrigation criteria (less than or equal to 77 CFU per 100 ml geometric mean) are the same as and were derived from those used for primary-contact recreation (Ref. 137). Similarly, the generic *E. coli* component of EPA's recreational water standard (for beaches used frequently) serves as the basis for our proposed standard for microbial water quality for water used in direct application methods during growing (proposed § 112.44(c)).

It should be noted that EPA's recreational water standards for beaches used frequently also includes a recommendation for a maximum steady state geometric mean of 33 CFU of enterococci per 100 ml and a single sample maximum allowable density of 61 CFU of enterococci per 100 ml (Ref. 136). Similarly, the current British Columbia criteria for irrigation water used on produce consumed raw is a geometric mean of less than or equal to 200 CFU fecal coliform per 100 ml and they have announced their intention to use a geometric mean of less than or equal to 20 CFU enterococci per 100 ml (along with generic *E. coli,* as discussed above). We have tentatively concluded to not include enterococci or fecal coliform in our proposed standard at § 112.44(c) because we believe generic *E. coli* to be the superior indicator of fresh water quality and do not believe that the added cost of testing for both generic *E. coli* and enterococci is warranted. Wade et al (2003) (Ref. 155) performed a systematic review of 27 studies of water quality indicators used for the regulation of recreational waters. They compared the ability of enterococci, fecal coliform, generic *E. coli* and total coliform levels to predict for the occurrence of gastrointestinal illness. They concluded that for freshwater, generic *E. coli* was the more consistent predictor. Working under the framework of a WHO project for setting guidelines for quality of recreational waters and bathing beaches, Pruss (1998) (Ref. 156) reviewed 22 studies on uncontrolled waters (seas, lakes, and rivers) for dose-related relationships between GI illness and bacterial indicator (most commonly generic *E. coli,* enterococci, and fecal coliforms) counts. The author found the two indicator organisms which correlate best with health outcomes were enterococci for both marine and freshwater and generic *E. coli* for freshwater.

We considered proposing a drinking water standard for water used on covered produce other than sprouts during growing in a direct water application method, but tentatively conclude that such criteria would be unnecessarily restrictive as it would not sufficiently account for forces driving pathogen die-off (*e.g.,* sunlight, competing microorganisms) (see section V.E.2 of this document). We also considered proposing a second lower microbial quality criteria for water used in growing, but where the water used for irrigation is not reasonably likely to contact the edible portion of the covered produce (*e.g.,* surface irrigation of tree crops). However, we are not aware of another standard for which there is sufficient scientific support.

We acknowledge that the EPA recreational water standards were developed from epidemiological studies that correlated the risk of gastrointestinal illness to exposure to marine and freshwater by swimmers (Ref. 136), rather than to consumption of produce. These epidemiological studies were performed in beach areas subject to point source fecal contamination rather than non-point sources (*e.g.,* birds, agricultural and livestock runoff), which may impact agricultural water. Further, risks of adverse health outcomes resulting from full body contact in contaminated water may be different than risks associated with consuming produce irrigated with contaminated water, given the differences in the expected routes of infection and pathogen mortality rates in the different environments (bodies of water for the EPA recreational water standards; soil, plants, and produce for this proposed rule).

We also acknowledge that the proposed standard is more stringent than the WHO standard. Based upon an analysis of tolerable risk for irrigation water, WHO recommends that the minimum microbial quality for water used on root crops that are eaten raw is 1000 CFU generic *E. coli* per 100 ml (10,000 CFU generic *E. coli* per 100 ml in leaf crops) (Ref. 118. Ref. 120). According to the WHO analysis, using water of this microbial quality is dependent upon a 2 log reduction due to die-off between last irrigation and consumption (includes die-off in the field and during distribution) and a 1 log reduction attributed to washing prior to consumption. This analysis recognizes the variable nature of die-off values, ranging from 0.5–2.0 log per day (Ref. 118). The WHO analysis considers the need for a four log reduction through dilution, die-off, or treatment between the levels of generic *E.coli* in raw sewage (well represented in sewage by fecal coliform levels) and the levels in irrigation water used on root crops that are eaten raw (3 log for leaf crops), in addition to the 3 log reduction discussed above.

We tentatively conclude that the recreational water generic *E. coli* criteria would serve to minimize risk of known or reasonably foreseeable hazards when used as a standard for agricultural water used on produce other than sprouts during growing in a direct water application method. We recognize that is somewhat more protective than the WHO standard, which we believe is appropriate given the uncertainty in die-off values. We request comment on the need for, and appropriateness of, this requirement or other criteria that would ensure the quality of agricultural water used for this purpose.

We tentatively conclude that if agricultural water you use on produce other than sprouts during growing in a direct application method does not meet the microbial water quality described in § 112.44(c), you must immediately discontinue use of that source of agricultural water and/or its distribution system and either (1) re-inspect the agricultural water system components under your control, identify conditions that are reasonably likely to introduce hazards to the system, make necessary changes based upon your observations, and retest the water to determine if your changes were effective; or (2) treat the water in accordance with the requirements of § 112.43. This proposed requirement is parallel to the requirement proposed § 112.42(d), which is discussed above.

We tentatively conclude that violation of microbial water quality standards proposed in §§ 112.44(a) and (c) in and of itself would not necessarily establish evidence of adulteration of covered produce subjected to use of the water, nor would it necessarily mean that the food was contaminated. However, use of water that is shown to violate these standards would violate the requirement at proposed § 112.41 that all agricultural water must be safe and of adequate sanitary quality for its intended use. As described immediately above, these proposed standards are based on likelihood of fecal contamination (as indicated by the presence of generic *E. coli*), that we have tentatively concluded minimize the risk of serious adverse health consequences or death by preventing the introduction of hazards and providing reasonable assurances that produce is not adulterated under section 402 of the FD&C Act. Agricultural water in violation of these standards indicates increased likelihood of fecal contamination of the water and, consequently, increased likelihood of produce contamination with human pathogens, beyond that which is appropriate for the intended use. Therefore, we propose to require you to immediately discontinue use of that source of agricultural water and/or its distribution system until you have either followed certain prescribed steps to mitigate the problem or treated the water.

Under the provisions of proposed § 112.44, if covered farms choose to treat irrigation water in accordance with the requirements of proposed § 112.43, any chemicals used in such treatment would require registration under the Federal Insecticide, Fungicide and Rodenticide Act before they can be lawfully used. At the present time, no such registration for chemical treatment of irrigation water exists. As discussed in section IV.K. of this document, FDA is proposing to delay implementation of certain provisions, including the water quality testing requirements in proposed § 112.44, beyond the effective dates for other provisions of the rule. The proposed extended compliance dates for the water quality testing, monitoring, and related record keeping requirements in proposed §§ 112.44, 112.45, 112.50(b)(5), 112.50(b)(6), and 112.50(b)(7) are six years from the effective date for very small businesses, five years from the effective date for small businesses, and four years from the effective date for all other farms subject to the rule. We expect these extended compliance dates to provide adequate time for industry to address issues related to water quality testing. We seek comment on the adequacy of this timeline.

Proposed § 112.44(d) would also allow you to establish and use alternatives to the requirements established in proposed § 112.44(c) provided you satisfy the requirements of proposed § 112.12. As discussed in section V.B. of this document, under proposed § 112.12(a)(1), you may establish an alternative to the requirements, established in proposed § 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. We acknowledge that in specific circumstances an alternative standard (*e.g.,* a standard that applies an application interval (time between application and harvest) in place of the § 112.44(c) standard, but is specific to a specific commodity or commodity group and region) may be appropriate if the alternative standard is shown to provide the same level of public health protection as the standard in proposed § 112.44(c) and not to increase the likelihood that the covered produce will be adulterated. Therefore, we tentatively conclude that it would be appropriate to allow for alternatives to the requirements in proposed § 112.44(c).

We are working with USDA and other stakeholders to facilitate research into application intervals that would be commodity- and region-specific, such that water not meeting the proposed § 112.44(c) standard could be used in a direct water application method for growing covered produce other than sprouts as long as it was applied before the start of the scientifically established application interval (*i.e.,* at a certain number of days before harvest or earlier).

Proposed § 112.45 would establish requirements related to frequency of testing agricultural water that is subject to the requirements of § 112.44. Specifically, proposed § 112.45(a) would require that you 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 would be 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.

Water testing frequencies recommended by various industry documents vary widely, in part because there is a lack of publicly available information pertaining to the quality of irrigation waters. Recommendations range from monthly testing to once each year, for sources with a history of compliance with commodity specific recommendations (Ref. 31. Ref. 44). Even for sources considered reliable (*e.g.,* well water), a one year period between testing does not minimize the risk of known or reasonably foreseeable hazards because microbiological water quality, even when sourced from ground water sources, is too variable for this frequency of testing to be protective (*e.g.,* effects of flooding, runoff) (Ref. 29). Alternatively, we tentatively conclude testing more frequently (less than every 3 months) would not significantly improve the accuracy of your assessment of ground water quality and would therefore be unnecessary. We also considered proposing testing frequencies established as a function of commodity, irrigation method (*e.g.,* furrow, seep, subsurface dripfoliar), and timing of application (days prior to harvest), and concluded that the most effective approach is to test on a frequency related to the reliability of the agricultural water sources. We tentatively conclude that requiring testing as a function of time before harvest would be impractical for many farms as we have observed single sources (*e.g.,* a well) providing water for multiple crops in different phases of production. We request comment on whether we should allow for adjustment of ground water testing frequencies dependent upon historical test results. For example, we are considering requiring testing ground water sources every three months for one year and yearly after that if the ground water consistently met the standard. We also request public comments on our proposed approach to frequency of testing, each of the options described here, and any other alternative testing frequencies that can be supported by water quality data.

Proposed § 112.45(a)(1) provides an exception to testing required in § 112.45(a) when the water is sourced from a Public Water System or State authority approved to administer the SDWA public water supply program, and you have results of the water testing or certificates of compliance that demonstrate that the water meets the requirements of that program. These systems operate so that the water they deliver meets the microbial requirement in 112.44(a). In the U.S., Public Water Systems are required under U.S. EPA National Primary Drinking Water Regulations (NPDWR) in 40 CFR 141 to provide safe, clean water suitable for drinking and thus are at the lowest likelihood for pathogen contamination. Under the sampling, testing and reporting requirements of 40 CFR 141, we tentatively conclude that additional actions by the grower to assure its safety are unwarranted. Similarly, proposed § 112.45(a)(2) provides for an exception to testing when the water is furnished from a public water supply that furnishes water that meets the standards of § 112.44(a), and you have results of the water testing or certificates of compliance that demonstrate that the water meets that standard. The standard in § 112.44(a) is derived from the EPA drinking water standard, and this provision is included to accommodate foreign public water supplies that are not governed by the requirements of the EPA drinking water program, but provide water of a quality that meets the microbial requirement of proposed § 112.44(a). Where public water that meets or is comparable to (in other countries) EPA's drinking water standards is used in produce operations, we are not aware of anything suggesting a need for additional testing at its delivery point to the farm. We seek comments on this issue, including any practice(s) that could materially change the quality of public or municipal water between treatment and delivery to the farm, including changes in water quality during water distribution and holding. Finally, § 112.45(a)(3) exempts from testing water that you treat in accordance with proposed § 112.43, which is discussed above.

Proposed § 112.45(b)(1) would establish that if you use untreated surface water for purposes that are subject to the requirements of proposed § 112.44, and if the untreated surface water is 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 water at least every 7 days during the growing season. Proposed § 112.45(b)(2) would establish that if you use untreated surface water for purposes that are subject to the requirements of proposed § 112.44, and if the untreated surface water is 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 water at least once each month during the growing season.

Surface water is subject to a great number of environmental factors that may alter its microbial water quality as discussed in the QAR and, when untreated, presents a significant source of pathogen contamination of produce. We tentatively conclude that the most important among these is runoff, because it has the potential to increase the number of pathogens in the water column if its origins include human, livestock or wildlife feces and because it has the potential to increase the amount of suspended sediments, which are likely to harbor pathogens (Ref. 157. Ref. 154). In proposing these testing frequencies, we tentatively divided untreated surface water into two categories based upon their potential to be impacted by runoff and the degree to which you reasonably could be expected to exercise protection and control over them. Flowing surface waters (*e.g.,* river, stream, or creek) or sources that are not protected against runoff (*e.g.,* natural ponds, lakes) must be tested at a relatively higher frequently than surface waters for which you have direct control and which you can manage in a way so to minimize the effect of runoff and other sources of contamination (*e.g.,* on-farm reservoir or pond). Contamination events that can lead to surface water contamination can have profound effects on the quality of the water, but those effects can be fleeting, especially those involving runoff from rainfall (several days to several weeks). After the contamination event passes, water quality generally returns to background levels (Ref. 158). If sampling is less frequent than weekly from surface water sources subject to these kinds of contamination events, there is a good chance that some contamination events will go undetected. On the other hand, for surface water sources that are not subject to significant runoff, the water quality tends to remain stable, and the purpose of sampling is primarily to accurately characterize the background level. Monthly sampling provides 12 samples per year that give a good representation of the quality of water through the seasons. The sampling and testing frequencies proposed in § 112.45(b) are the minimum that we tentatively conclude provide sufficient information concerning your source surface water quality for you to use in determining method of application and its timing for which the water is safe and of adequate sanitary quality. We encourage additional sampling if you have reason to believe that its quality may have changed from the previous test. We welcome comments on the need for, and appropriateness of, our proposed testing frequencies, including any alternative approaches and examples where testing should be more or less frequent based upon your experience or observation.

The monitoring frequencies proposed in this rule are practical intervals that we tentatively conclude are reflective of the varying potential for changes in water quality between ground aquifers and surface watersheds. In proposing the monitoring frequencies for untreated surface waters, we considered factors that are most likely to impact water quality. Precipitation and its effects (*e.g.,* discharge and flow rate) along with temperature are common factors reported to affect the microbial quality of watersheds with agricultural land inputs (Ref. 159. Ref. 158). Precipitation levels have also been successfully used to manage openings and closings of molluscan shellfish harvest areas. These harvest areas are well characterized in terms of changes in the microbial water quality due to non-point source runoff as a consequence of rainfall. However, we have not proposed surface water testing frequency based upon precipitation because such an approach would require full characterization of its effects (Ref. 143) on the quality of surface water sources that are not likely to be generally useful across farms, States, or regions. Our approach to testing untreated surface water is to propose practical intervals of testing both because they are likely to capture transient events that may degrade quality and because they are useful regardless of geographic location. We welcome comments on this approach, including any alternate approaches, specifically if you believe that surface waters can be thoroughly characterized such that they require less frequent testing than proposed in § 112.45.

e. Requirements for Water Used in Harvesting, Packing, and Holding Activities

Proposed § 112.46 would establish the measures you must take for water that you use during harvest, packing, and

holding activities for covered produce. Specifically, proposed § 112.46(a) would require that you manage the water as necessary, including by establishing and following water-change schedules for re-circulated 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). The proposed language allows sufficient flexibility for you to establish measures that are best suited to your needs based on practice and experience. For example, you may establish a water-change schedule for water used in an apple flume based upon the rate of product flow, organic load, or other variables you determine best correlate with safety and sanitary quality of the flume water. Many commonly used wash water antimicrobials have decreased efficacy when organic matter is present in the water. For example, organic matter builds up in agricultural water flume systems from dirt and debris on the surface of fresh produce that are placed into the flume systems. Once the soluble and/or insoluble organic load builds up to sufficiently high levels, the addition of wash water antimicrobials becomes ineffective and inefficient. Changing the flume water on a regular basis, based on that system's unique operating conditions, can assure that wash water disinfection treatments are consistently effective (Ref. 149. Ref. 150). We point out that while water disinfection is one means to manage water quality, we are not specifically proposing to require disinfection treatment of re-circulated or single use water that is used in harvesting, packing, or holding activities. We are proposing that re-circulated or single pass water must be safe and of adequate sanitary quality for its intended use (§ 112.41) and that it contain no detectable *E. coli* (§ 112.44(a)). Further, if you have reason to believe that the water is not safe and of adequate sanitary quality for its intended use, proposed provisions in § 112.43 for water treatment can be applied. However, we are not proposing treatment of water as the only option. Other options for farms include making changes to the system and retesting the water successfully (§ 112.42(d)) and using the same water source for other uses for which it does qualify. For example, using water that does not meet the zero *E. coli* standard but does meet the 235 CFU per 100 ml standard for direct application method irrigation of produce other than sprouts; or for water that does not meet the 235 CFU per 100 ml standard, applying the water for irrigation in a different manner that is not a direct application method (§ 112.44). These provisions offer flexibility for farms to choose among different options to ensure that the water is safe and adequate for the purpose for which it is intended. Should farms choose to disinfect water as a measure to control waterborne hazards during handling during and after harvest, we tentatively conclude that an effective disinfection program would render such water safe and of adequate sanitary quality. However, we request public comment on the appropriateness of this tentative conclusion and on whether a provision specifically directed to disinfection of water used during and after harvest is needed. We also seek public input regarding practices or conditions when disinfection of re-circulated or single use water would be unnecessary, inappropriate, or impractical.

Proposed § 112.46(b) would require that you 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). Organic matter such as soil and plant debris has to the potential to adversely affect the quality of water; it may be a source of bacteria (including pathogens), support the growth of bacteria, and reduce the effectiveness of antimicrobial compounds (*e.g.,* chlorine compounds) (Ref. 150). Such monitoring allows you to recognize conditions that require action, such as a water change in a dump tank.

Proposed § 112.46(c) would require that you 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. Water temperature can influence processes leading to infiltration of microorganisms into many types of produce. As discussed in the QAR, infiltration of water containing pathogens into produce has been demonstrated in apples (Ref. 160), oranges (Ref. 161), tomatoes (Ref. 138. Ref. 139), and mangoes (Ref. 38) and was suggested to play a role in a 1999 *Salmonella* outbreak associated with mangos (Ref. 162). A recent study demonstrated that additional factors, such as tomato variety and the time delay between tomato stem removal and water immersion have a significant impact on the frequency and population of internalized *Salmonella* in tomatoes. (Ref 140). However, this study also demonstrated that *Salmonella* internalization of tomatoes via their stem scar can occur even under a zero temperature differential, and temperature differentials up to 10 °F have no effect on the internalization frequency and have limited impact on *Salmonella* cell populations internalized in tomatoes.

We considered proposing a single standard on temperature differential between water and product core temperature (*e.g.,* water must be at least 10 degrees F warmer than core) but tentatively conclude that there is insufficient scientific evidence supporting such a standard across all covered produce. However, we recognize the North American Tomato Trade Work Group and California Tomato Commission have recommended such a standard (Ref. 44). We seek public comment on the need for, and appropriateness of, the proposed provisions, including any alternative approaches that you found to be effective through experience or observation.

f. Records Requirements

Proposed § 112.50 would establish requirements about the records that you would need to establish and keep under this proposed subpart E. Specifically, proposed § 112.50(a) would require that you establish and keep records required under this proposed subpart E in accordance with the requirements of proposed subpart O. Proposed § 112.50(b) would require that you establish and keep the following records:

(1) The findings of the inspection of your agricultural water system in accordance with the requirements of proposed § 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 (2), if applicable.

Proposed § 112.50(b)(1) would require that you establish and keep records of agricultural water system inspection findings in order for FDA to verify compliance with the proposed requirement to inspect the agricultural water system. The records would also allow you to more effectively manage your agricultural water, to identify trends and changes in your agricultural water system over time, and to help identify potential sources of contamination of the water system and covered produce. In addition, these records may aid you in determining the most appropriate frequencies for maintenance of well and surface water sources, distribution and holding systems.

Proposed § 112.50(b)(2) would require that you establish and keep records of any analytical test results from any tests you may have conducted to determine if water meets the quality requirements proposed in § 112.41. We have tentatively concluded that these records are necessary because otherwise FDA would have no way to determine whether you were making appropriate decisions about whether your water is safe and of adequate sanitary quality for its intended use. When such tests are conducted, results of those tests are also fundamental in making informed decisions concerning your use of water.

We are proposing under § 112.50(b)(3) and (4) that you must establish and keep scientific information or data documenting the effectiveness of the treatment method that you use and records demonstrating that you deliver the treatment consistently to ensure the water is safe and of adequate sanitary quality. These records may include information provided by the antimicrobial product supplier, product labels with instructions for use, product material safety data sheets (MSDS), batch test results demonstrating correct active ingredient concentration, mixing proportions, and schedules or application rates you have developed to ensure water is treated effectively. They may also include results of testing you perform to confirm your treatment methods are being followed, such as records of active ingredient concentration, pH, temperature, flow rate, immersion time, or water changes, if they significantly impact the effectiveness of the treatment. Monitoring frequency may be affected by product flow, organic load on incoming product, temperature, UV exposure, and consumption rates or breakdown rate (expected and observed) for the active antimicrobial compound, among other factors. These records are necessary so that FDA can verify your compliance with those requirements. They will also allow you to ensure your own compliance with the requirements for water treatment in proposed § 112.43.

We are proposing in § 112.50(b)(5) that you must establish and keep records of the results of water testing you perform to satisfy the requirements of § 112.44. For example, records for water tests you perform to ensure input water used in sprout production meets the requirements in § 112.44(a) would include, at a minimum, the test date, specific water source (*e.g.,* municipal water or well number 3), method name (*e.g.,* multiple tube fermentation, membrane filter method, presence-absence test, and commercial product name, if applicable) and the test result (*e.g.,* not detected, generic *E. coli* MPN or CFU, as applicable). Records you maintain to demonstrate the microbial water quality meets the requirements of § 112.44(c) for foliar application of spinach would include, at a minimum, the test date, specific water source (*e.g.,* ranch X, well 3 or canal collection point 2), method name (*e.g.,* multiple tube fermentation, membrane filter method, and commercial product name, if applicable) and the test result (*e.g., E. coli* MPN or CFU, as applicable). We tentatively conclude that documentation of the results of water testing are necessary to demonstrate that the water you use meets the requirements of § 112.44 and to provide a history of the microbial quality of your water system, which will be useful in spotting problems before they occur, minimizing the potential for water to be a source of contamination to covered produce. These records are necessary so that FDA can verify your compliance with those requirements and so that you can ensure your own compliance with the requirements for water testing and responding to test results in proposed § 112.44. In proposed § 112.50(b)(6), we would require you to establish and keep that 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). Such documentation will enable us to verify, and you to ensure, that the alternative standard you use provides the same level of public health protection as the standard in proposed § 112.44(c) and does not increase the likelihood that the covered produce will be adulterated, in accordance with proposed § 112.12.

We are proposing in § 112.50(b)(7) that if you use water from a public water system, you must establish and keep annual documentation (*e.g.,* certificate of compliance, water quality testing results) demonstrating that system supplies water meeting the microbial requirements of § 112.45(a)(1) or (2), if applicable. We tentatively conclude that maintaining such annual documentation is necessary for FDA to verify that the water you use is not subject to the requirements for testing under proposed § 112.45 and to ensure that it meets the microbial requirements of proposed 112.44, and for you to demonstrate that those requirements have been met. We seek comment on the appropriateness of the proposed record-keeping requirements.

F. Subpart F—Standards Directed to Biological Soil Amendments of Animal Origin and Human Waste

Proposed subpart F establishes standards directed to treated and untreated biological soil amendments of animal origin and human waste. These standards include requirements applicable for determining the status of a biological soil amendment of animal origin; procedures for handling, conveying, and storing biological soil amendments of animal origin; provisions regarding the use of human waste in growing covered produce; acceptable treatment processes for biological soil amendments of animal origin applied in the growing of covered produce; microbial standards applicable to treatment processes; application requirements and minimum application intervals; requirements specific to agricultural teas; and records requirements. The proposed requirements in subpart F derive from current recommendations in our GAPs guidance (Ref. 10), commodity-specific guidances (Ref. 31) (Refs. LGMA), State regulations (Ref. 90. Ref. 163. Ref. 164), other Federal Regulations (40 CFR 503, 7 CFR 205), and international guidelines (Ref. 100. Ref. 51).

1. Comments Relevant to Proposed Requirements

We received several comments in response to the 2010 FR notice that addressed issues relevant to biological

soil amendments of animal origin and human waste.

a. Definitions

One comment stated that manure and compost are two different things, and the two words should not be used interchangeably as it causes confusion. We agree. As discussed in the QAR, and noted in the Produce Safety Project Issue Brief on Composting of Animal Manures there are documented differences in the populations and level of human pathogens in raw manure and animal feces and in properly composted manure (Ref. 27). We are proposing definitions that make the distinction clear. We are proposing to use the phrase ''untreated biological soil amendments of animal origin'' as a category that includes raw manure (see proposed § 112.3(c) and section V.A.2.b.iii of this document regarding ''biological soil amendment of animal origin,'' and proposed § 112.51(a) and section V.F.2.a of this document regarding ''untreated'' biological soil amendments of animal origin). We use the term ''treated biological soil amendments of animal origin'' to include treatments that meet the requirements of the standards presented in this subpart (see proposed § 112.51(a) and section V.F.2.a of this document). To further alleviate confusion, we use the term ''compost'' as a verb, to mean the act of composting, and do not use it as a noun to describe a soil amendment that was treated by a composting method. Instead, we use the term ''humus'' in its common agricultural meaning (see proposed § 112.3(c) and section V.A.2.b.iii of this document).

b. Consideration of Other Regulations and Guidances

Comments from growers whose operations are certified for organic produce requested us to ensure that our regulations do not interfere with existing organic certification systems or organic production practices. Another comment stated that the *California code of regulations for composting yards* (Cal. Code Regs. title. 14, ch. 3.1) would be an acceptable starting point in developing our regulations.

We consider that organic production practices and food safety are not cross-competing goals. In developing the provisions proposed in this rule, we consulted with technical experts and representatives from other Federal Agencies, including the Environmental Protection Agency, the Department of Agriculture (including both the National Organic Program and the Natural Resources Conservation Service), and the Department of the Interior (Fish & Wildlife Service) (Ref. 115). As discussed in section III.A.8. of this document, we tentatively conclude that compliance with the provisions of this proposed rule would not preclude compliance with the requirements for organic certification in 7 CFR part 205, and we seek comment on this tentative conclusion. Use of organic practices alone is not sufficient to ensure food safety. The use of raw manure at a time close to harvest, during organic or conventional production, presents a significant likelihood of contamination of covered produce if produce is reasonably likely to contact the soil. On this particular issue, and as discussed in sections II.E.4 and V.B of this document, we are working with USDA and other stakeholders to conduct research on application intervals necessary to ensure the safety of covered produce when raw manure is applied to a growing area and covered produce is reasonably likely to contact the soil. We also note that we considered several regulations, recommendations, and guidelines that address soil amendments, including those from State, federal, and international agencies, industry, and trade associations (including the California code of regulations for composting yards). In addition, we consulted with experts from multiple organizations and academia for scientific and technical input on the issues addressed in these provisions. The provisions proposed take into account information and input gathered through these consultations.

c. Treatments, Processes, and Practices

One comment suggested that many growers are accepting food waste compost, which has no manure in it but can often have a readily detectable level of *Salmonella,* and stated that ''green waste'' (or similar) does not necessarily equate to zero risk. Comments stated that if raw manure is used, there should be a science- and risk-based standard for determining the application-to-harvest waiting interval and that maximizing the time interval between soil amendment application and harvest is only logical if using fresh manure. Similarly, one comment stated that raw manure can be applied to soil if it is plowed and then given sufficient time before planting.

Our review of various composting methods suggests that, regardless of the source, if the process is properly conducted (including proper turning of feedstock) the expected pathogen load and subsequent likelihood of produce contamination can be minimized. We agree that certain sources, including plant material (Ref. 165) and animal sources (Ref. 166), have differing likelihood of containing human pathogens or higher population levels of human pathogens. To address this concern, we propose separate, but related, provisions. First, we do not propose treatment or timing restrictions for biological soil amendments that do not contain any animal waste product or human waste (such as would be the case with yard waste, purely vegetative matter, or shrub trimmings, or agricultural teas made from such materials). Such biological soil amendments would not be subject to the requirements in proposed subpart F because they would not fit the definition of ''biological soil amendments of animal origin'' and they do not contain human waste. Further, in § 112.51(b)(4) we propose that a biological soil amendment of animal origin 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, you must regard it as if it were an untreated biological soil amendment of animal origin for application and treatment purposes if you still wish to utilize it. In addition, we treat ''table waste'' as ''animal waste'' for the purposes of the definition of biological soil amendments of animal origin. As discussed in the QAR, post-consumer waste, or table waste (such as plate scrapings), has a greater likelihood of being contaminated, or contaminated at higher populations, with human pathogens due to its unknown content (*e.g.,* animal products, vegetable products, etc.) and its greater likelihood of containing human fluids or waste (*e.g.,* spittle, vomitus, etc) (Ref. 167).

Proposed § 112.56(a)(1)(i) would require that if you apply a biological soil amendment of animal origin that is untreated (such as raw manure), where covered produce is reasonably likely to contact the soil after application, the material must be applied in a manner that does not contact covered produce during application and minimizes the potential for contact with covered produce after application and the minimum application interval is nine (9) months. In section V.F.2.f. of this document we discuss the reasons for this proposed requirement in detail. Proposed § 112.56(b) would allow you to establish and use an alternative application interval under certain conditions (discussed further in section V.B. of this document). In situations where the covered produce will not contact the soil after application, proposed § 112.56(a)(1)(ii) would require that the biological soil

amendment of animal origin be applied in a manner that does not contact the produce at or after application, but would not require an application interval. Also, as discussed in section II.E.4. of this document, FDA is collaborating with partners on research that may provide scientific support for specific alternatives to this proposed application interval.

One comment stated that compost made with animal manure must meet temperature, mixing, and time requirements to ensure its safety, whereas another comment stated that biologically active soil suppresses pathogens and that *E. coli* pathogens decline more rapidly in soils with a large diversity of microorganisms rather than in sterile soils. One comment recommended that we require compost operations to have standard operating procedures, a quality assurance plan, compost testing within specified timeframes of sale, and a Hazard Analysis Critical Control Point (HACCP) program. According to this commenter, several growers are requesting testing prior to purchase, and are refusing compost that has not been recently tested.

Based on our review of the literature and as discussed in our QAR, we determined that improper composting will not have the desired pathogen reduction effect, and may enhance the survival of pathogenic organisms (Ref. 168). Therefore, we propose specific time and temperature controls for composting procedures in proposed § 112.54(c), and further recognize the need for composters to consider other factors that will impact the successful treatment of their particular composting situation (*e.g.,* feedstock, C:N ratios, pH). We consider that the potential effects of soil ecological diversity on pathogen populations are regionally specific, and may be highly effective under some circumstances, while potentially inert under other circumstances. We recognize the need for consistent treatment by suppliers of treated biological soil amendments of animal origin, and for assurance by those that use such amendments that the material has been produced under adequate conditions, to avoid it being a source of contamination. We have tentatively concluded that the most reliable and least burdensome proposal regarding the use of purchased treated biological soil amendments of animal origin is to require growers to obtain certain documentation (such as a Certificate of Conformance) from the treating operation that validated treatment methods were utilized, the treatment process is periodically verified through testing, and good handling practices were followed. This is proposed in subpart 112.60(b)(2) and we request comment on this proposed requirement, including periodic verification through testing.

d. Testing for Pathogens

Several comments suggested that variable minimum application-to-harvest waiting intervals should be applied using science-based knowledge about pathogen levels in and transfer from compost, and that if a compost tests pathogen-free, there should be no time limit between application, planting, and harvest. Another comment stated that pathogen testing has significant limitations, and that it would be more important to evaluate a treatment process to ensure that it is effective in inactivating pathogens.

We considered testing of individual lots of biological soil amendments of animal origin as a means to determine if they were suitable for application to a fresh produce growing area and tentatively conclude that such testing is not a reliable means of determining the safety or expected likelihood of contaminating produce by use of biological soil amendments of animal origin. We have multiple concerns that led us to this conclusion. First, we were unable to determine standardized testing methods, such as sample collection methods, sample collection times, or location of sample collection, which would yield repeatable and reliable results under different circumstances. Second, we were unable to determine the frequency and sample size that would reliably indicate the microbiological safety of a given manure lot. Third, we recognize that there are numerous pathogens which may be present in biological soil amendments of animal origin and that pathogen testing would be necessary for all such potential contaminants, which would be a significant economic burden. Therefore, we tentatively conclude that an approach that is the most reasonable and the most protective of public health would involve the use of treatments that have been validated to meet certain specified microbial standards as proposed in this subpart.

e. Research Needs

Some comments suggested that there is a need for research to identify means other than through heat to inactivate pathogens, and that such alternative approaches may be more practical for farmers. Comments opined on the use of chemical inactivation, and noted that the effectiveness of use of volatile acids or ammonia in the inactivation of pathogens is not fully established but that further research may help refine time and temperature parameters for chemical inactivation.

We agree that further research and innovation may lead to alternatives to heat treatments. Proposed § 112.54 addresses the use of physical processes, chemical processes, or combinations of physical and chemical processes, in addition to composting, that may be used as treatments for biological soil amendments of animal origin, provided that they meet the applicable requirements of § 112.55 and the treated biological soil amendment of animal origin is applied in accordance with the applicable requirements in § 112.56. We consider heat treatments to be physical processes within the meaning of that term in § 112.54, and we have purposefully chosen the broader term ''physical processes'' to allow for possibilities other than heat treatment. Thus, these proposed requirements would allow for the use of alternatives to heat treatment, and are intended to be flexible to foster innovation and development of new means of treating biological soil amendments of animal origin to ensure produce safety.

2. Proposed Requirements

As proposed in § 112.3, ''soil amendment'' would be defined to mean 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. Additionally, ''biological soil amendment'' would be defined in § 112.3 to mean any soil amendment containing biological materials such as humus, manure, non-fecal animal byproducts, peat moss, pre-consumer vegetative waste, sewage sludge biosolids, table waste, agricultural tea, or yard trimmings, alone or in combination. Finally, proposed § 112.3 would define ''biological soil amendment of animal origin'' to mean a biological soil amendment which consists, in whole or in part, of materials of animal origin, such as manure or non-fecal animal byproducts, or table waste, alone or in combination, and would specify that the term does not include any form of human waste. See section V.A.2.b.iii. of this document. Proposed subpart F is focused on biological soil amendments of animal origin, which include animal

manures and other materials of animal origin that you intentionally add to a growing area, and on human waste. Standards directed to animal feces deposited by domestic or wild animals that are not a part of your planned growing activities (*e.g.,* by working animals, by animals that graze or encroach into your growing areas) are proposed to be included in subpart I, as discussed in section V.I. of this document.

As discussed in the QAR, animal waste is likely to contain bacterial pathogens (*e.g., Campylobacter, Salmonella* spp., enterohemorrhagic *E. coli*) and various other pathogens such as parasites (*e.g., Cryptosporidium parvum, helminthes*), which may infect humans. The type of pathogen that may be present, and the extent to which it may be present, is dependent on the source of the manure (*e.g., E. coli* is more common from ruminants such as cattle, whereas *Salmonella* is more common from fowl such as chickens) and the rearing practices of the source animals (*e.g.,* animals from densely populated farms or farms with a high population of immature animals have an increased likelihood of harboring various pathogens) (Ref. 169). Enteric (or gastroinstestinal) pathogens are not generally considered to be environmental, and are more commonly expected to be derived (and in higher populations) from a human or animal source (*e.g.,* through feces, mortalities, blood, spittle, etc.) (Ref. 170). Material that does not contain any animal waste is far less likely to harbor these food safety hazards at microbial populations that can reasonably be expected to lead to severe adverse health consequences or death (Ref. 94). We have tentatively concluded that the likelihood of contaminating produce by use of biological soil amendments that do not contain animal waste or human waste (*e.g.,* yard trimmings, pre-consumer vegetative waste) carrying human pathogens is low. Similarly, we are unaware of a situation in which chemical and physical soil amendments, such as elemental fertilizers (*e.g.,* potash, aqueous nitrates), soil stabilizers (*e.g.,* sand or crushed rock) or others typically made of mined or synthetic materials, have served as sources of microbial contamination and, therefore, neither chemical nor physical soil amendments are a focus of provisions of this rule. Therefore, in this proposed subpart F, we are proposing to focus on biological soil amendments of animal origin and human waste, which present a reasonable likelihood of harboring human enteric pathogens. Unless otherwise specifically noted, chemical soil amendments, physical soil amendments, and biological soil amendments that are not of animal origin (other than those that contain human waste, which are covered by proposed § 112.53) are not covered by this rule. We encourage comment on our tentative decision not to provide requirements for the use of these kinds of soil amendments in this proposed rule.

a. Requirements for Determining Status

Proposed § 112.51 would establish requirements for determining the status of a biological soil amendment of animal origin for use in covered activities. Proposed § 112.51(a) would categorize a biological soil amendment of animal origin as 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). Section 112.51(b) would categorize a biological soil amendment of animal origin as untreated if: (1) It 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) it has become contaminated after treatment; (3) it has been recombined with an untreated biological soil amendment of animal origin; (4) it 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) it is an agricultural tea that contains an agricultural tea additive.

Proposed § 112.51(a) would provide a simple method of referring to biological soil amendments of animal origin as treated if they have received one of the treatment processes described in proposed § 112.54. We discuss those treatment process options in detail in section V.F.2.d of this document. Agricultural teas are mentioned separately for two reasons. First, treatments are typically applied to the biological materials used to make agricultural teas rather than to the teas themselves and our explicit mention of this fact is intended to aid in clarity. Second, we specify that the water used to make a treated agricultural tea must meet the standard in proposed § 112.44(a) to prevent the introduction of pathogens into treated agricultural teas, which can be applied with fewer application restrictions than untreated agricultural teas in accordance with proposed § 112.56. As discussed in section V.E.2.d of this document, the conditions under which agricultural tea is produced (moist and nutrient-rich) support the multiplication of pathogens, if present (Ref. 142). Even a low number of pathogens introduced into or onto covered produce through contaminated water could rapidly increase to levels that could present risk of serious adverse health consequences or death to those who consume the covered produce for which the tea was used (Ref. 142).

Proposed § 112.51(b) addresses the situations in which a biological soil amendment of animal origin should be regarded as untreated because they present a greater likelihood of contamination to covered produce than a treated biological soil amendment of animal origin. A treated biological soil amendment of animal origin can be expected to have a high content of available nutrients and minerals which can support rapid and prolific microbial population growth if sufficient moisture is available, possibly with limited competitive native microflora (Ref. 171) (depending on the specific treatment, treatment parameters, and handling used, (*e.g.,* heat treated poultry manure pellets would be expected to have limited microorganism content including competitive native microflora, and composted manure would be expected to have substantial competitive native microflora)) (Ref. 171. Ref. 172). Accordingly, pathogens could grow prolifically in a treated biological soil amendment of animal origin if it were to become contaminated through contact or partial mixing with an untreated biological soil amendment of animal origin, or other potential contaminant source, and if sufficient moisture were available (Ref. 171). Prolific microbial growth could also occur through premature termination of treatment, which could leave surviving microorganisms and a higher moisture content than after composting is completed. In addition, if a biological soil amendment of animal origin 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, we tentatively conclude that the increased likelihood of pathogen presence in such materials results in a need to apply the most stringent controls to their use in the growing of

covered produce. Prolific growth of a human pathogen in a nutrient-rich, possibly competition poor, biological soil amendment of animal origin could lead to the amendment acting as an inoculum that spreads microorganisms on any field or covered produce growing area to which the amendment may be applied, leading to a potential significant likelihood of produce contamination. To avoid such inoculation, we propose to require you to regard any biological soil amendment of animal origin that is partially or incompletely treated as an untreated biological soil amendment of animal origin. Finally, we tentatively conclude that agricultural teas that contain agricultural tea additives should be regarded as untreated biological soil amendments in light of their content and the likelihood that they contain human pathogens.

As discussed in section V.F.2.f. of this document, we tentatively conclude that the treatment process (including composting processes) can reduce the populations of pathogens significantly. However, it has been recently reported that while pathogens that are present in agricultural teas made from properly composted humus are reduced to undetectable levels within 8.5 days, such agricultural teas with added nutrient supplements (*i.e.,* agricultural tea additives) allow low populations of remaining *E. coli* O157:H7, *Salmonella,* and fecal coliforms to grow and multiply (Ref. 142). For this reason, we propose to impose the same application restrictions on agricultural teas that have been prepared with nutrient additives as those that we propose for the use of untreated biological soil amendments of animal origin, such as raw manure (proposed § 112.56(a)(1)(i)), and seek comment on this proposal. See section V.F.2.f. of this document for further discussion of the reasons for these restrictions.

b. Requirements for Handling, Conveying, and Storing

Proposed § 112.52 would establish requirements for handling, conveying and storing soil amendments of animal origin. Specifically, we propose in § 112.52(a) that you 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. As discussed immediately above, prolific growth of a human pathogen in a potentially competition-poor, nutrient-rich, biological soil amendment of animal origin could lead to the amendment acting as an inoculum that spreads microorganisms on any field or covered produce growing area to which the amendment may be applied, as well as to food-contact surfaces, areas used for covered activities, water sources, and water distribution systems. To fulfill the proposed requirement in § 112.52(a), we would expect you to take specific measures to ensure that untreated biological soil amendments of animal origin do not contaminate covered produce directly or indirectly through contact with food contact surfaces, areas in which covered activities are conducted, water sources, or distribution systems. Such measures may include, for example, separation of treated and untreated manure (or other biological soil amendments of animal origin) and preventing any leachate originating from untreated biological soil amendments of animal origin from becoming a source of contamination for source water or water distribution systems (Ref. 173).

As discussed in the QAR, any untreated biological soil amendment of animal origin that contaminates a food contact surface could be a source of further cross-contamination to covered produce. Moreover, a biological soil amendment of animal origin that has been treated by a composting process may still have a residual population of pathogens, since composting is not a complete kill step (Ref. 174); therefore, such biological soil amendments require a multiple hurdle approach to minimize the likelihood of introducing pathogens to a field on which they are applied. If composted material contaminates a food contact surface, the combined presence of available nutrients plus any pathogens that may have survived the composting process present a potential source of contamination for any covered produce that comes in contact with the contaminated food contact surface. Further, a fully heat-treated biological soil amendment of animal origin, while reasonably likely to be free of pathogens, may act as a source of nutrients for pathogens that might contaminate the food contact surface, thereby allowing them to multiply and pose a likelihood of contaminating any produce coming in contact with the food contact surface.

As proposed, § 112.52(b) requires that you handle, convey and store any treated biological soil amendment of animal origin in a manner and location that minimizes the likelihood of it becoming contaminated by an untreated or in-process biological soil amendment of animal origin. This proposed requirement is necessary because a biological soil amendment of animal origin previously treated to reduce pathogens can become re-contaminated by pathogens if not properly handled and stored (Ref. 175). For example, if you fully compost manure produced by your cows with the intent of using it to amend a field you use to grow covered produce, proposed § 112.52(b) would require that you handle, convey, and store the fully composted manure in a manner and location to prevent its contamination by raw manure, or by manure in the composting process. This requirement is critical because bacterial pathogens, such as *E. coli* O157:H7 or *Salmonella* spp., if allowed to re-contaminate finished compost, may grow and spread to populations that present a significant likelihood of contaminating any environment in which the soil amendment is used (Ref. 171). An example of cross-contamination may include turning a pile of manure that is in the process of composting with a front-end loader, and then proceeding to handle fully composted humus from a mature pile with the same equipment. To avoid such cross-contamination, you could clean the front-end loader between manipulating an incomplete pile and manipulating a mature pile; move ''downstream,'' beginning with sanitary equipment and manipulating the most mature piles first, then proceeding to less mature piles; or designate certain equipment to only be used on piles of a certain maturity; or adopt other strategies that meet the same goals.

Proposed § 112.52(c) would require you to handle, convey, and store any biological soil amendment of animal origin that has become contaminated (for example, by an untreated or in-process biological soil amendment of animal origin) as if it was untreated. In other words, a treated biological soil amendment of animal origin that has become contaminated would need to be applied in accordance with the application and interval restrictions of proposed § 112.56(a)(1) for untreated biological soil amendments of animal origin, or it would need to be treated in compliance with one of the options in proposed § 112.54 and then applied in accordance with the applicable requirements in § 112.56 for the treatment used. For example, if a treated or in-process biological soil amendment of animal origin becomes unintentionally contaminated (*e.g.,* from runoff from an untreated biological soil amendment of animal origin), you would either need to treat that material in accordance with an option in proposed § 112.54 and then apply it in

accordance with the applicable requirements in § 112.56 for the treatment used, or you would have to follow the application requirements for untreated biological soil amendments of animal origin in proposed § 112.56(a)(1) for the contaminated material.

c. Prohibition Regarding Use of Human Waste

Proposed § 112.53 would prohibit the use of 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. Human waste has a high probability of containing multiple diverse human pathogens, including bacteria, parasites and viruses, at potentially very large populations, thus presenting a significant likelihood of harboring and spreading these various microbiological hazards (Ref. 92). We recognize that an application of untreated human waste could occur outside of your control (for example, as a run-off event from adjacent land not under your control), or may have occurred as a previous use of land before you took possession. If you know or have reason to believe such an event has occurred, we would expect you to take measures reasonably necessary to minimize the risk of serious adverse health consequences or death based on your specific circumstances. Such measures may include crop diversion, reconditioning or destruction, and/or land remediation, or other comparable methods.

Under 40 CFR part 503 subpart D (§ 503.30, 31, 32 and 33), the U.S. EPA requires that the application of sewage sludge biosolids to fields in which food or feed crops are grown adhere to certain pathogen reduction requirements, and use certain vector attraction reduction options. Depending on which options are implemented, there are different ranges of wait periods between application of the soil amendment, and the harvest of the crop grown. For example, if an untreated human waste (*i.e.,* equivalent to domestic septage: ''Liquid or solid material removed from a septic tank, cesspool, portable toilet'') (40 CFR 503.9(f)), is applied to a field used to produce a food crop, then ''Food crops with harvested parts that touch the sewage sludge/soil mixture and are totally above the land surface shall not be harvested for 14 months after application of sewage sludge'' (40 CFR 503.32(c)(1), cross-referencing § (b)(5) of the same section). We agree these standards are appropriate for protecting public health and, therefore, we are not proposing to implement further restrictions. Our proposed definition of agricultural teas, discussed in section V.A.2.b.iii. of this document, would provide that agricultural teas are not made from any form of human waste because doing so would not be permissible under 40 CFR part 503 subpart B.

d. Acceptable Treatment Processes

Although there is great variability in available data on pathogen survival in animal manure depending on the type and source of manure in question, the location and environment under which the manure is stored, and numerous other factors (Ref. 176. Ref. 177. Ref. 178) there are data to suggest it is reasonable to expect that, given the proper conditions, pathogens in certain animal manures may survive for months (Ref. 179), years (Ref. 180), or even indefinitely (Ref. 174). Because the use of soil amendments that contain materials of animal origin poses a significant likelihood of contaminating the growing environment and covered produce with human pathogens, we have tentatively concluded that such materials used as a soil amendment require some level of treatment, or other risk-reducing steps (such as application restrictions), for use in the growing of covered produce. Proposed § 112.54(a)–(c) would establish acceptable treatment processes for a biological soil amendment of animal origin when applied in the growing of covered produce, along with associated microbial standards against which they must be validated in proposed § 112.55. A validated process, when properly implemented and monitored, would be expected to meet the listed microbial standards and thereby reduce the likelihood of hazards associated with biological soil amendments of animal origin from contaminating covered produce. The microbial standards in proposed § 112.55 are not meant as lot-by-lot microbial testing requirements. Instead, the person applying the treatment process would need to monitor the physical parameters of the process (*e.g.,* temperature of a compost pile) to ensure that they meet the conditions under which the process was validated. In addition, proposed § 112.54 would provide that the resulting biological soil amendments must be applied in accordance with the applicable application requirements in § 112.56. We seek comments on this approach.

The underlying framework for the provisions of §§ 112.54(a)–(c), 112.55, and 112.56 is that as the likelihood that a method of application of a biological soil amendment of animal origin will result in it contacting covered produce increases, the extent of measures taken to reduce the likelihood of known or reasonably foreseeable microbial hazards being present in the applied soil amendment must also increase. That is, for an application practice that is more likely to result in the amendment contacting covered produce (*e.g.,* broadcast application of a soil amendment vs. subsurface soil amendment injection for the same crop, or in-row application of a soil amendment for a row crop vs. in-row application for a tree crop), it is more important to have stricter controls for known or reasonably foreseeable microbial hazards in the applied soil amendment than for another amendment whose application practice is less likely to result in the amendment coming into contact with covered produce. Therefore, proposed § 112.54 consists of multiple acceptable options for the treatment of soil amendments and corresponding standards against which they are to be validated (as further described in § 112.55). These proposed treatment options were designed to be flexible to allow you to determine what your operation's needs are, and select the option that best fits those needs. In developing these proposed requirements, we have taken into account the wide variation presented by different feedstocks used in preparing biological soil amendments of animal origin, the diversity of commodities, and various growing regions. In addition, we considered the likelihood of contamination posed by biological soil amendments of animal origin subjected to each of these multiple treatment options when determining the appropriate application requirements, as proposed in § 112.56. We have tentatively concluded that the use of the physical, chemical, and composting treatments listed in proposed § 112.54(a)–(c), when applied in accordance with proposed § 112.56, are capable of adequately reducing pathogen levels in biological soil amendments of animal origin. We request comment on the appropriateness of each of the options considered, and discussion of any other options not listed in proposed § 112.54.

Physical treatments usually involve some form of high-heat treatment (cooking) of the biological soil amendment of animal origin to kill undesirable microorganisms. By contrast, chemical treatments usually involve greatly altering the pH of a biological soil amendment of animal origin, to the point that undesirable

microorganisms do not survive. In a study treating chicken manure with ammonia to reach high (alkaline) pH levels, a 3 to 4 log decrease of generic *E. coli* was observed over 6 days at 20°C, and drying manure to 10% moisture content and exposing it to ammonia gas (1% of manure wet weight) reduced pathogen load by 8 log (99.999999% reduction) (Ref. 181). To perform either physical or chemical treatments, the feedstock is generally placed in a large treatment container, and large amounts of energy are required in order to initiate the treatment. These factors alone make these forms of treatment impracticable for many farms. While such treatments can be expected to have a strong lethal impact on microorganisms present in the feedstock, they do not always result in complete elimination of pathogens. For example, chicken manure may be heat-treated to create a dried, pelleted material that is functionally sterile due to the high heat used during production; however, it has been observed that if the heat treatment is not uniform, the end product may still harbor human pathogens and pose a likelihood of the material being re-colonized by the microbial pathogen, leading to the possible contamination of any covered produce to which it is applied (Ref. 115).

Biological soil amendments of animal origin may also be prepared by combining multiple treatments, either alone or in combination. For example, a single feedstock may be heat-treated (physical) while also drenched in strong ammonia (chemical) to acidify the material (Ref. 182). Alternatively, feedstock may first be composted and then treated by heat to further reduce pathogens, effectively pasteurizing the material, as is common practice in the production of mushroom growth media (Ref. 183). These systems have been shown to be highly effective when proper controls are in place and monitored, but they also require significant inputs and capital investments.

Proposed § 112.54(a) would establish that a scientifically valid controlled physical process (*e.g.,* thermal), chemical process (*e.g.,* high alkaline pH), or combination of scientifically valid controlled physical and chemical processes that have been demonstrated to satisfy the microbial standard in § 112.55(a) for *Listeria monocytogenes, Salmonella* spp., and *E. coli* O157:H7 is a treatment option for biological soil amendments of animal origin. This standard is currently used by the mushroom industry, which utilizes a two-phase process consisting of a composting treatment that meets the composting standard proposed in § 112.54(c) followed by a subsequent heating process that meets the microbial standard of proposed § 112.55(a). Together, the treatment reduces over 7 log cfu/g of *Listeria, Salmonella,* and *E. coli* O157:H7 to undetectable levels (Ref. 183). It also eliminates much of the native microflora (Ref. 183). We have tentatively concluded that a treatment meeting this standard would significantly reduce or eliminate known or reasonably foreseeable microbial hazards in biological soil amendments of animal origin, and would constitute the lowest expected likelihood of any of the proposed treatment options. We have also tentatively concluded that a biological soil amendment of animal origin that has been treated to this standard would be appropriate for use when the likelihood for contamination of covered produce is the highest, such as the substrate (growth media) used for growing mushrooms and some sprouts. Therefore, as provided in proposed § 112.56(a)(2) and discussed further in section V.F.2 f of this document, any biological soil amendment of animal origin treated to this standard would have the fewest limitations on its application.

Proposed § 112.54(b) would establish that a scientifically valid controlled physical process, chemical process, or combination of scientifically valid controlled physical and chemical processes, that has been demonstrated to satisfy the microbial standard in § 112.55(b) for *Salmonella* and fecal coliforms is a treatment option for biological soil amendments of animal origin. We have tentatively concluded that a treatment meeting this standard would significantly reduce known or reasonably foreseeable microbial hazards in biological soil amendments of animal origin leading to minimal likelihood of contamination. A biological soil amendment of animal origin that has been treated to this standard would be appropriate for use when there is a high likelihood that the soil amendment will come into contact with covered produce. Moreover, as provided in proposed § 112.56 and discussed further in section V.F.2.f of this document, any biological soil amendment of animal origin treated to this standard would have minimal limitations on its application.

Proposed § 112.54(c) would establish that a scientifically valid controlled composting process that has been demonstrated to satisfy the microbial standard in § 112.55(b) for *Salmonella* and fecal coliforms is a treatment option for biological soil amendments of animal origin. Two specific scientifically valid controlled composting processes that could be used to meet the requirements of proposed § 112.54(c) are provided: (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; and (2) turned composting to maintain 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. These two composting processes are currently considered by the U.S. Environmental Protection Agency as Processes to Further Reduce Pathogens (Appendix B to 40 CFR part 503, part B.1). Both are recommended for use by the U.S. Department of Agriculture's Agricultural Research Service (Ref. 184), Natural Resources Conservation Service (Ref. 97), and National Organic Program (7 CFR part 205), and both are commonly accepted practices within the industry (Ref. 185). While there is robust discussion in the literature on times, temperatures, and other conditions (pH, moisture, oxygen levels, etc.) needed for significant reductions (albeit not elimination) of human pathogens in cattle, sheep and chicken manures, it is clear that composting cannot be considered as a pathogen-elimination step because of the many variables that can affect the efficacy of the composting process (*e.g.,* feedstock mixtures, climatic conditions, and various other physio-chemical parameters) (Ref. 174). These limits are currently used as composting endpoints by other federal agencies (40 CFR 503) States (Ref. 90. Ref. 164. Ref. 163), and industry (Ref. 31).

Composting is generally the least expensive method with the lowest capital investment requirement, and if properly managed, can be expected to significantly reduce pathogen populations in feedstock materials (Ref. 186). As noted in the Produce Safety Project Issue Brief on Composting of Animal Manures, composting has been shown to reduce the overall concentration of nitrogen in the soil amendment, which poses a concern for some farmers, but it also has been demonstrated that the remaining nitrogen is both in a more bio-available state (*i.e.,* more easily utilized by plants) and will persist in the environment for a longer time (therefore providing nutrients to plants for a longer time) (Ref. 27). Composting leaves much of the native microflora intact (Ref. 187).

Proper composting is not difficult for most operations, but it does require a labor commitment to ensure conditions are met and maintained to achieve the desired effect. Some of the most critical elements of composting include proper stacking of a pile, proper aeration and turning, and ensuring the pile attains the proper temperature and is allowed to cool (cure) for an adequate time (Ref. 27). There are currently no federally mandated composting standards for food safety. The USDA/NOP offers standards that are meant to maximize soil fertility in 7 CFR 205.203 (these are required to achieve ''USDA Certified Organic'' status, but otherwise are recommendations only), and EPA standards in 40 CFR part 503 are specific to sewage sludge, not animal manures. While these standards were not developed for food safety, several studies suggest that they would be appropriate for use as food safety measures (Ref. 27). Proper handling and storage during and after composting to avoid cross-contamination of cured product and in-process or raw product is critical, as discussed in section V.F.2.b of this document above regarding proposed § 112.52 of this rule. Other important factors in proper composting (such as the carbon to nitrogen ratio of the feedstock (C:N), the moisture content of the pile, the reaction to high cellulose-content material (*i.e.,* plant material such as straw or vegetative waste), and the specifics of the beneficial microbial content will vary depending on the feedstock (Ref. 187). The person who manages the composting process would also need to consider such factors as the moisture content, pH, carbon to nitrogen ratio (C:N), and feedstock to achieve the microbial standards set forth in proposed § 112.55. Many resources are available that discuss these details, such as the USDA NRCS handbook (Ref. 97). When composting processes are carried out in an incorrect manner, the organic matter in the finished product remains poorly stabilized and recontamination is more likely to occur, which can potentially result in the compost becoming a source of pathogens that could contaminate the field to which it is applied and any crops that are grown in the amended soil (Ref. 165).

As noted in the Produce Safety Project Issue Brief on Composting of Animal Manures, adequate curing, including proper insulation (usually consisting of around one foot thick of insulating material, *e.g.,* hay, straw, finished compost) is included as part of this proposed requirement, because curing is an important step in the composting process to further reduce the levels of pathogens, complete the chemical reactions of composting, and mitigate the impact that incomplete turning (creating temperature stratification within an active pile) would have on composting efficacy (Ref. 27). Proper insulation serves as a layer of protection from external influences (*e.g.,* temperature changes, wild animal encroachment).

The treatment processes proposed in § 112.54(c), paragraphs (1) and (2), may not be the only means of achieving adequate composting to meet the microbial standards in proposed § 112.55(b). Therefore, we have tentatively concluded that it would be appropriate to allow for the use of static or turned composting protocols other than those specified in § 112.54(c)(1) and (2), if they meet the microbial standards for validation for composting in proposed § 112.55(b). Proposed § 112.54(c)(3) allows for the use of other scientifically valid, controlled composting processes, provided you satisfy the requirements of § 112.12, including that the alternative has been demonstrated to satisfy the microbial standard in § 112.55(b). No such alternatives are provided for the treatment requirements of § 112.54(a) and 112.54(b), because those parts do not explicitly define the processes to be conducted to meet the microbial standards presented; therefore, any scientifically valid controlled physical, chemical, or combination of physical and chemical processes that has been demonstrated to satisfy the relevant microbial standard in either § 112.55(a), or § 112.55(b) will meet the requirements of those subparts.

e. Microbial Standards Applicable to Treatment Processes

Proposed § 112.55 establishes microbial standards applicable to the treatment processes in § 112.54. Proposed § 112.55(a) would provide microbial standards for the treatment process in proposed § 112.54(a). It would require: (1) *L. monocytogenes* to be not detectable using a method that can detect one colony forming unit (CFU) per five gram analytical portion; (2) *Salmonella* spp. to be less than 3 most probable number (MPN) per four grams of total solids (dry weight basis); and (3) *E. coli* O157:H7 to be less than 0.3 MPN per 1 gram analytical portion. As discussed immediately above regarding proposed § 112.54(a), these standards are the most stringent and meant for applications in which a biological soil amendment of animal origin would otherwise pose the greatest likelihood of transferring a known or reasonably foreseeable hazard to a covered produce commodity. These standards would also be useful if you wanted to use a biological soil amendment of animal origin with the least amount of application restrictions available under proposed § 112.56. As previously noted, these microbial standards are currently used by the mushroom industry for growth media and reduce over 7 log CFU/g of *Listeria, Salmonella,* and *E. coli* O157:H7 to undetectable levels (Ref. 183).

Proposed § 112.55(b) would provide two microbial standards, both of which must be satisfied for the treatment processes in proposed § 112.54(b) and (c). This section would require less than 3 MPN *Salmonella* spp. 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). These limits are currently used as composting validation endpoints by EPA (40 CFR 503), some States (Ref. 90. Ref. 164. Ref. 163), and industry (Ref. 31). Ohio and California (Ref. 163. Ref. 164), industry (Ref. 31) and other nations such as Canada and the United Kingdom (Ref. 27) use both of these criteria, while EPA and Florida (Ref. 92. Ref. 90) allow for either criteria to be used. As noted in the Produce Safety Project Issue Brief on Composting of Animal Manures, the EPA requirement of validation with either Salmonella spp. or fecal coliforms is based on the observation that reduction in fecal coliforms is well correlated to reduction in *Salmonella* spp. when biosolids are composted (Ref. 27). However, we tentatively conclude that satisfying both of these criteria is necessary to significantly minimize known or reasonably foreseeable hazards when combined with the applicable application requirements in proposed § 112.56. Monitoring the relative levels of indicator microbes such as fecal coliforms, which are predominantly *E. coli* in manures and freshly mixed compost, is advantageous in that they are abundant in manure. In the absence of a reliably present pathogen, fecal coliforms are useful to validate the efficiency of the thermophilic composting process (Ref. 27). Additionally, *E. coli,* the primary fecal coliform in manure, has been documented to be a good indicator of the inactivation of *E. coli* O157:H7 (Ref. 168). Validating solely with *Salmonella* spp. is not sufficiently protective or useful for validating the efficiency of a thermophilic composting process, since Salmonella spp. cannot be assumed to be present in all composting feedstock materials. On the other hand,

Salmonella spp. is the most common microbiological hazard associated with fresh produce (Ref. 3). As such, validating with fecal coliforms and *Salmonella* spp. not only assures the efficacy of the thermophilic composting process but also assures significant reduction of the pathogen *Salmonella* spp. when commonly used compost feedstocks are used that are likely sources of Salmonella spp. (*e.g.,* cattle and poultry manure) (Ref. 188). We seek comment on these proposed microbial standards and potential alternatives.

We do not intend this proposed provision to require that farms test their treated biological soil amendments for compliance with the microbial standards. Rather, we intend this provision to provide the standard against which treatment processes must be validated. Farms would be able to use treatment processes that are validated to meet the relevant microbial standard in this section without needing to test the end products of their treatments to confirm that the microbial standard was achieved.

f. Application Requirements and Minimum Application Intervals

Proposed § 112.56 establishes the application requirements and minimum application intervals applicable to biological soil amendments of animal origin. Proposed § 112.56(a) would establish a requirement that, except as provided in subparagraph (b), any biological soil amendment of animal origin that you use must be applied with the application method requirements and minimum application intervals specified in the table presenting proposed § 112.56(a)(1)–(4). The different application method requirements and intervals for biological soil amendments of animal origin are presented so that you may determine the amendment, application, and interval that is most appropriate for your situation, based on the expected likelihood of contaminating produce by use of the biological soil amendment of animal origin you plan to use.

In developing the application methods requirements of proposed § 112.56(a)(1)–(4), we first considered specifications of each type of biological soil amendment of animal origin, and then considered the likelihood that the soil amendment will come into contact with covered produce. For example, those biological soil amendments of animal origin treated with a process or processes capable of consistently and reliably reducing or eliminating pathogens as per § 112.54(a) do not have any application restrictions, and may come into contact with covered produce during harvest and growing (proposed § 112.56(a)(2)), such as in the growing of mushrooms and some sprouts. Conversely, those treatments that are expected to have some likelihood of harboring significant numbers of human pathogens, *i.e.,* those treated in accordance with the requirements of § 112.54(b) or (c), have proposed limitations on the method of application that minimize the potential for the treated biological soil amendment of animal origin to contact covered produce during and after application (proposed § 112.56(a)(3), (a)(4)(ii)) and also allow for pathogen die-off when it is reasonably likely that covered produce will contact soil after application of the soil amendment (proposed § 112.56(a)(4)(i)). Requirements would include the application of untreated biological soil amendments of animal origin in situations where it is reasonably likely that covered produce will contact the soil after application of the soil amendment (§ 112.56(a)(1)(i)), where the amendment would be permitted to be applied in a manner that minimizes the potential for contact with covered produce after application, but with an additional food safety measure that it can be applied only in a manner that does not contact covered produce during application and using a minimum application interval of 9 months. By contrast, in situations where covered produce will not contact the soil, (§ 112.56(a)(1)(ii)), the amendment would be permitted to be applied without an application interval. We explain each of these proposals in detail below.

Proposed § 112.56(a)(1)(i) requires that if you apply a biological soil amendment of animal origin that is untreated, then the material must be applied in a manner that does not contact covered produce during application and minimizes the potential for contact with covered produce after application and the minimum application interval is nine (9) months. This provision would apply to any situation in which the covered produce is reasonably likely to contact the soil after application of the soil amendment. Proposed § 112.56(a)(1)(ii) requires that if you apply a biological soil amendment of animal origin that is untreated, and the material is applied in a manner that does not contact covered produce during or after application, there is no minimum application interval. This provision would apply to any situation in which the covered produce will not contact the soil after application of the soil amendment. The specific microbial populations of raw manure are generally unknown, but can be expected to be very high, and are likely to include zoonotic microorganisms that pose a food safety hazard (such as *Salmonella* spp. up to 10^7 (Ref. 176) and *E. coli* O157:H7 up to 10^6 (Ref. 189)). Based on our QAR, we have determined that raw animal waste (manure, litter, mortalities, etc.) is likely to contain human pathogens and has the highest likelihood of contaminating covered produce. Therefore, we tentatively conclude that such material should only be used where, and in a manner, that such likelihood is minimized. As discussed above, the likelihood of produce contamination by an agricultural tea that contains agricultural tea additives is also high (Ref. 142). Given the desire to both allow for the continued use of raw manure, agricultural teas containing agricultural tea additives, and other untreated biological soil amendments of animal origin; and to minimize the risk of known and reasonably foreseeable hazards, we have tentatively concluded that we should require that untreated biological soil amendment of animal origin (including raw manure) applied in the growing of covered produce should either first be treated to reduce microbial food safety hazards; or if the covered produce is reasonably likely to contact the soil after application of the soil amendment, the untreated soil amendment should be applied in a manner that keeps it from coming into contact with covered produce during application, minimizes the potential for contact after application, and allows for the die-off of pathogens; and if the covered produce will not contact the soil after application of the soil amendment, the untreated soil amendment should be applied in a manner that keeps it from coming into contact with covered produce during and after application. In the case of agricultural teas containing agricultural tea additives, we tentatively conclude that because additional treatment is not an option they should be applied in the same manner as untreated biological soil amendments of animal origin. Proposed § 112.56(a)(1)(i) would therefore establish such restrictions on the manner of application for these materials when they are reasonably likely to come in contact with covered produce after application, as well as a minimum application interval (waiting period) of nine (9) months from the application of untreated biological soil amendments of animal origin to the harvest of covered produce. On the

other hand, under proposed § 112.56(a)(1)(ii), untreated biological soil amendments of animal origin would be permitted for use with no minimum waiting period when the soil amendment is applied in a manner that does not contact covered produce during or after application. We investigated the potential for survival of many enteric pathogens of public health concern (Ref. 190. Ref. 92) and determined that across various pathogens and their potential environments, pathogen survival and die-off time in soils amended with raw manures are extremely varied. One consistency across many trials was an observed rapid early die off of many pathogens, followed by a prolonged survival of the remaining low populations (Ref. 191. Ref. 104. Ref. 192). It is unclear in the existing literature at what point the population is low enough to minimize the potential for contamination of covered produce; it is reasonable to suggest that once pathogen populations fall below detection limits, their risks are minimized.

Some of the longest survival times involved organisms initially present at very high initial populations (*e.g., E. coli* O157:H7 in sheep manure (Ref. 177) surviving for 21 months) or involved certain pathogens such as encysting parasites (*Cryptosporidium parvum* cysts surviving for over a year (Ref. 193) or the eggs of parasitic flatworms (*Ascaris* ova surviving for over 15 years (Ref. 174)). Some enteric pathogens are reported to be more resilient to deleterious effects of the environment than others (most notably, *Salmonella* seems better attuned for survival outside of a host than does *E. coli* O157:H7 (Ref. 194)) and those microorganisms that produce spores are especially hardy. Basing all manure application standards on these extreme cases would be unnecessary. The majority of survival studies showed that most enteric pathogens of public health importance, under the most common conditions, would not survive in the soil past 1 year (Ref. 190). This includes organisms less commonly associated with fresh produce, such *Cryptosporidium, Giardia,* and *Ascaris* (parasitic flat worms). Organisms most commonly associated with fresh produce outbreaks (such as *E. coli, Salmonella* and *Listeria*) are unlikely to survive at detectable population levels in soil past 270 days (Ref. 181. Ref. 182. Ref. 183). Therefore, we tentatively conclude that utilizing a 9-month waiting period between the application of untreated biological soil amendment of animal origin and the harvest of covered produce would be protective for the preponderance of environments in situations where covered produce is reasonably likely to contact the soil after application of untreated biological soil amendments of animal origin. This is not inconsistent with the 12-month restriction used by some segments of the produce industry (Ref. 31). Where the soil amendment does not contact covered produce either during or after application, we do not believe that a minimum application interval is reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into covered produce. Therefore, proposed § 112.56(a)(1)(ii) provides for the option to use untreated biological soil amendments of animal origin with no minimum waiting period, provided the soil amendment is applied in a manner that does not contact covered produce during or after application. We seek comment on the proposed waiting period.

One study, which specifically addressed considerations of microbial survival in soil and resulting transfer on to produce grown in the soil, suggested that, under ideal conditions for survival, organisms could survive for greater than 226 days (Ref. 191). The study was performed in the Southeastern U.S. (Georgia) and, therefore, is unlikely to reflect climatic conditions prevalent in other areas of the country, including the potential for the ground to freeze during winter. While microbes present on frozen ground can be expected to be reduced in population more rapidly (Ref. 195), those surviving are likely to persist for a longer time period in a state of dormancy (Ref. 196). The dormancy of microorganisms also means that they will pose a likelihood of contamination for greater periods of time, creating a wider window of opportunity for covered produce to become contaminated. We request comment on whether and how, as an additional requirement for the application of untreated biological soil amendments of animal origin, the time period when the soil is frozen should count toward the proposed application interval. Further, it has been noted that rapid freeze-thaw cycles of weather may cause more rapid die-off rates of pathogens present in soils (Ref. 197). We request comment on the impact that freeze-thaw cycles may have on use of biological soil amendments of animal origin.

Proposed § 112.56(a)(2) would establish that the use of a biological soil amendment of animal origin 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), would have no application method restrictions and no minimum application interval. At this level of microbial reduction, a treated biological soil amendment of animal origin can be expected to present negligible likelihood of contamination. Therefore, we have tentatively concluded that no further action is necessary for the safe use of such a product in conjunction with covered produce.

For example, unlike other biological soil amendments of animal origin, the nature of a growth medium that is a biological soil amendment of animal origin and is used for growing mushrooms, some sprouts and similarly grown produce, makes contact between the covered produce and the growth medium inevitable. This precludes the ability to utilize application restrictions as a meaningful measure to minimize the likelihood of pathogen contamination of covered produce through a multiple-hurdle approach, that would allow for the use of less robust treatment processes in combination with application manner restrictions. Therefore, we tentatively conclude that, such growth media must be 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).

As proposed, § 112.56(a)(3) would require that a biological soil amendment of animal origin treated by a scientifically valid controlled physical or chemical process, or a 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) be used in a manner that minimizes the potential for contact with covered produce during and after application, with no minimum application interval. We have tentatively concluded that treating a biological soil amendment of animal origin to meet the standards of § 112.54(b) would significantly decrease the population of any microorganisms of public health significance that may have previously been present. Further, the proposed application restriction of minimizing direct contact of the amendment with the edible portion of covered produce would further reduce the likelihood of any remaining microorganisms in a treated soil amendment contaminating covered produce, as well as reduce the

likelihood that the soil amendment would provide a nutrient source for any microorganisms of public health significance already present on covered produce. We have tentatively concluded that the treatment of the biological soil amendment of animal origin, combined with minimizing its contact with covered produce would adequately reduce the likelihood of contamination and subsequent severe adverse health consequences or death. We have also tentatively concluded that, with the likelihood already minimized, it is unnecessary to implement a further burden by proposing a minimum application interval for soil amendments treated by physical or chemical processes, or combinations of such processes, to the standards of § 112.54(b). For example, chicken manure pellets that have been treated by a controlled high-temperature process according to a protocol that has been validated to meet the standards in proposed § 112.54(b) could be used as an in-furrow side-dress for leafy greens immediately before harvest. However, in this same example, the application could not be conducted by overhead broadcast spreading, since this method would not minimize contact of the biological soil amendment with the covered produce.

Proposed § 112.56(a)(4)(i) would establish requirements for use of a biological soil amendment of animal origin treated by a composting process in accordance with the requirements of § 112.54(c) to meet the microbial standard in § 112.55(b) in a manner that minimizes the potential for contact with covered produce during and after application and with a minimum application interval of 45 days. This provision would apply to situations in which the covered produce is reasonably likely to contact the soil after application of the soil amendment.

Proposed § 112.56(a)(4)(ii) requires that if you apply a biological soil amendment of animal origin treated by a composting process in accordance with the requirements of § 112.54(c) to meet the microbial standard in § 112.55(b), and the material is applied in a manner that does not contact covered produce during or after application, there is no minimum application interval. This provision would apply to any situation in which the covered produce will not contact the soil after application of the soil amendment. Although the microbial standards and application restrictions for biological soil amendments of animal origin treated to meet the requirements of proposed § 112.56(a)(4) are the same as those described under proposed § 112.56(a)(3), there is an additional 45 day application interval for § 112.56(a)(4)(i) that would not be required in § 112.56(a)(3). We have tentatively concluded that process controls during chemical or physical treatments can be expected to be less prone to failure than process controls for composting. For example, heat treatments are often conducted in enclosed heat-treatment chambers (*i.e.,* ovens), often with various means of agitation (such as stirring rods, etc.), that can be accurately monitored and controlled to reach the required treatment conditions throughout the material being treated. Conversely, composting usually occurs outdoors, is exposed to fluctuating environmental pressures and wildlife activity, is not homogeneous in nature and prone to having ''cold-spots'' that are not completely treated (even with proper turning) (Ref. 174). In general, in composting, there is a higher likelihood of having a systems failure, which is also more likely to go undetected, should it occur. Composting may result in a treated biological soil amendment of animal origin that may continue to harbor human pathogens of food safety concern (Ref. 174), although any such hazards that may be present can be expected to be present at low populations and unlikely to survive for extended periods under normal environmental conditions after application. Examples of a system failure that may occur during composting, but would not be expected during a thermal or physical treatment, could include animal intrusion, incomplete turning, or reduced efficiency of composting due to environmental or climatic conditions (*e.g.,* heavy rainfall or excessive cloud cover reducing the temperature of the pile or portions of the pile). Therefore, we propose to impose an additional mitigation measure in situations where covered produce is reasonably likely to contact the soil after application of biological soil amendments of animal origin treated by composting by requiring a minimum application interval of 45 days. This time period has been shown to be effective when the population of the pathogen is minimal (Ref. 92. Ref. 91) (Ref. 198), as can be expected of a fully composted biological soil amendment of animal origin. This multiple hurdle approach and time interval has also been utilized in a current industry standard (Ref. 31). Where a biological soil amendment of animal origin does not contact covered produce either during or after application, we do not believe that a minimum application interval is reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into covered produce. Therefore, proposed § 112.56(a)(4)(ii) provides for the option to use a biological soil amendment of animal origin treated by composting with no minimum waiting period, provided the soil amendment is applied in a manner that does not contact covered produce during or after application. We seek comment on the appropriateness of the proposed application period intervals.

We have not proposed any provisions specific to the status of spent mushroom mulch (growth media already used in the production of mushrooms for subsequent use as a biological soil amendment of animal origin in the growing of other covered produce) and specifically request comment on how to classify its status. The practice of storing spent mushroom mulch for subsequent use in the growing of covered produce is not known to be a likely source of introduced contamination because the growth media would have been previously treated to eliminate pathogens (Ref. 62). Therefore, we tentatively conclude that spent mushroom mulch previously treated (in accordance with proposed § 112.54(a), to meet the microbial standards of § 112.55(a)) before use in the growing of mushrooms would still be considered as ''treated'' to meet the standards of § 112.54(c) after use for growing mushrooms, and for any possible subsequent use in the growing of fresh produce without any intervening treatment, unless you know or have reason to believe it has been otherwise contaminated with a hazard or has been associated with foodborne illness. We tentatively conclude that spent mushroom mulch should be considered, for the purpose of the application requirements in proposed § 112.56, as though it has been treated by composting, instead of considering it as though it has been treated in accordance with the most robust chemical/physical treatment process (§ 112.54(a)), though it would have received such a treatment in accordance with proposed § 112.54(a) before its use to grow mushrooms. This would have the effect of subjecting spent mushroom mulch used subsequently to grow other covered produce to the requirement to minimize the potential for contact with covered produce during and after application, and a minimum application interval of 45 days. We consider the weathering process (the common practice of spent mushroom mulch being placed in a field

in windrow for further composting over the course of several weeks to years) to be similar to composting in terms of likelihood of introduction of contaminants. We request comment on this tentative conclusion.

Under this proposal, you would, in most cases, maintain the flexibility to choose among a variety of treated and untreated soil amendments of animal origin based on the commodity being grown, growing conditions, and other factors relevant to your operation, but you would have to consider both the method of application (*e.g.,* whether it would result in contact between the amendment and the produce) and, for certain amendments, the interval before harvest. We would expect you to determine which application method is most appropriate for your situation by selecting the application method and interval restrictions that would coincide best with your operation, and then purchase or treat a biological soil amendment of animal origin that meets the corresponding specifications (*i.e.,* the first column in the table in § 112.56(a)). For example, if you intend to apply a side-dress of a biological soil amendment of animal origin close to harvest, you would find § 112.56(a)(1)(ii), (2), (3), and (4)(ii) have no minimum application interval. You would accordingly either use a controlled physical or chemical process that meets the requirements of § 112.54(a) and have no further restrictions, use a controlled physical or chemical process that meets the less stringent microbial standards of § 112.54(b) if you can apply the treated biological soil amendment of animal origin in a manner that minimizes potential for contact with the covered produce during and after application, or use composted or untreated biological soil amendments of animal origin if you can apply them in a manner that ensures they do not contact covered produce during or after application (for example, if you are growing tree crops such as oranges, you apply the untreated soil amendment without causing it to contact the oranges, and you do not harvest oranges that have been allowed to come into contact with the soil after application of the soil amendment). Conversely, you may determine which application method and interval is most appropriate by evaluating which specification your biological soil amendment of animal origin meets, and then apply it according to the coinciding application method and interval restrictions. If, for example, you wish to apply raw manure to your field, you would find the requirements that apply to raw manure in § 112.56(a)(1) and note that, if it is reasonably likely that your covered produce will come in contact with the soil (for example, where almonds are harvested by intentionally dropping to the ground) after application of the raw manure, the use of raw manure is restricted to application in a manner that does not contact covered produce during application and minimizes the potential for contact with covered produce after application, and may be applied no less than 9 months before harvest. On the other hand, if you can apply the raw manure in a manner that ensures it does not contact covered produce during or after application, you may use it without a minimum application interval. Any minimum application interval that you use can be concurrent with any application intervals that you are already required to, or voluntarily, apply. For example, if you are a USDA-certified organic grower, and utilize a 120-day application interval for the use of raw manure as part of participation in the National Organic Program, the proposed 9-month application interval requirement in § 112.56(a)(1)(i) would be concurrent, not consecutive, with the 120 days. Thus, your use of a 9-month application interval for raw manure would satisfy both this proposed rule and the requirements of the National Organic Program. As another example, if you plan to apply a biological soil amendment of animal origin to a field of spinach that is nearing harvest for fresh market consumption, assuming the spinach is reasonably likely to contact the soil after application of the soil amendment, you could select a biological soil amendment of animal origin that is heat-treated to meet the standards presented in § 112.54(b) (*e.g.,* chicken manure pellets), provided that you can apply it in a manner that minimizes the potential for contact with covered produce during and after application (*e.g.,* used as a side-dressing), because there would not be an application restriction interval with that type of biological soil amendment of animal origin. If you plan to use manure as a biological soil amendment of animal origin for the same crop and plan to apply the amendment before planting, and do not wish to utilize a treatment such as described by § 112.54(a) or (b), you would choose to compost the soil amendment to meet the requirements of § 112.54(c). Use of such a biological soil amendment of animal origin would only be restricted to application in a manner that minimizes the potential for contact with covered produce during and after application, and application at least 45 days prior to harvest.

Proposed § 112.56(b) would establish requirements for the use of alternatives to the minimum application intervals established in paragraphs (a)(1)(a) and (4)(a) of proposed § 112.56, provided you satisfy the requirements of § 112.12. We have tentatively concluded that, under certain circumstances, an alternative standard may be appropriate if it is shown to provide the same level of public health protection as the standard in proposed § 112.56(a)(1)(i) and (4)(a) and not to increase the likelihood that the covered produce will be adulterated. For example, alternatives to the proposed minimum application intervals could take into account specific characteristics of the locality, crop and the agro-ecological environment. Such alternatives could consider differences in feedstock; application methods; and treatment methods, especially given the potential for new innovations in such methods. In any such case, as discussed below, we propose in § 112.60(b)(5) that you establish and keep documentation of the scientific data and information you are relying on to support the use of an alternative minimum application interval. We do not propose that you would be required to submit such data and information to us for prior approval; we do, however, propose the requirement that you maintain a record of any such data and information for us to evaluate upon request.

h. Records Requirements

Proposed § 112.60(a) requires that you establish and keep records for subpart F in accordance with the requirements of subpart O of this part. Proposed § 112.60(b) would establish requirements for records you must establish and keep regarding biological soil amendments of animal origin that you use. Proposed § 112.60(b)(1) would require 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. These records would be required because the application of both raw manure and compost include minimum application intervals (§ 112.56(a)(1)(i) and (4)(i), respectively), so it would enable FDA to verify compliance with the application intervals associated with raw manure

and compost. These records would also allow you to keep track of the dates on which those biological soil amendments of animal origin were applied in order to determine when covered produce from those growing areas could be harvested in compliance with the rule. USDA-certified organic growers who already maintain records of when biological soil amendments of animal origin are applied in compliance with 7 CFR 205.103 would not need to duplicate those records to meet the requirements of § 112.60(b)(1).

Proposed § 112.60(b)(2) would require documentation (such as a Certificate of Conformance) for a treated biological soil amendment of animal origin that you receive from a third party. We have tentatively concluded that the information you will need both to verify that any biological soil amendment of animal origin you purchase for use in performing a covered activity is in compliance with this subpart F, and to inform your decisions on further handling, conveying, and storing of the purchased biological soil amendment of animal origin, includes the following: (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 likelihood of contamination by an untreated or in-process biological soil amendment of animal origin. Aspects (i) and (iii) of this proposed requirement reflect information that you would have if you treated the biological soil amendment of animal origin on your own farm in accordance with this proposed rule. Aspect (ii) of this requirement would provide you with reasonable assurances that your supplier is carrying out the applicable treatment process in an effective manner such that the biological soil amendment of animal origin that you purchase meets the applicable standards in proposed §§ 112.54 and 112.55. We tentatively conclude that it is appropriate to require this additional level of assurance from your suppliers in order to allow FDA to verify your compliance with these requirements. These requirements will also provide you with a comparable level of control over your supplier's process of treating a biological soil amendment of animal origin as you would have if you were to apply the treatment process on-farm, where you would be able to monitor the process controls yourself. You would not be required to perform any treatment processes on a biological soil amendment of animal origin that you purchase and for which you have the appropriate documentation showing it has already been treated by a validated process in accordance with § 112.55. These records would also allow you to ensure that a treated biological soil amendment that you purchase from a third party meets the requirements of this proposed rule and to determine the relevant application restrictions you must apply to such a soil amendment.

Proposed § 112.60(b)(3) would require documentation that process controls (for example, time, temperature and turnings) were achieved for any treated biological soil amendment of animal origin you produce for your own covered farms. This documentation is required to verify that the treatment or treatments you performed were properly carried out. For example, such records would inform you of any breakdown in the process or treatments, how they occurred or can be corrected, and create a history to help you predict and prevent any future breakdowns. Without such records, you would not be able to ensure, and we would not be able to verify, that the process or treatment you performed achieved the required parameters that are validated to meet the microbial standards of § 112.55 or that the alternatives that you are using (if applicable) satisfy the requirements of proposed § 112.12.

Proposed § 112.60(b)(4) would require documentation of 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)(3). Similarly, proposed § 112.60(b)(5) would require documentation of scientific data or information you rely on to support any alternative minimum application interval in accordance with the requirements of § 112.56(b). The records described in § 112.60(b)(4) and (5) would be required only if you choose to use alternatives to those processes presented in § 112.54(c)(1) and (c)(2) or application intervals in § 112.56(a)(1)(i) and (a)(4)(i), respectively. This documentation would be required so that, as necessary, we are able to verify that use of your alternative process achieves the required parameters of proposed subpart F and satisfies the requirements of proposed § 112.12.

Finally, we seek comment on an issue that is not explicitly addressed in our proposed provisions. Biological soil amendments (including agricultural teas derived from biological materials) are nutrient rich and may support rapid and prolific growth of human pathogens, if pathogens are present. Seeds used for sprouting have repeatedly been demonstrated to have the potential to be contaminated with human pathogens and cause human illnesses. We note that the National Organic Standards Board Compost Tea Task Force recommended not allowing for the use of ''compost tea'' for the production of edible seed sprouts (Ref. 36). We are concerned that using a biological soil amendment (including agricultural teas derived from biological materials) could increase the likelihood of rapid and prolific growth of human pathogens, if present, during sprout growing. We request comment on whether sprouters currently use biological soil amendments (including agricultural teas made from biological materials, such as ''compost teas'') in the growing of sprouts. In addition, we request comment on the likelihood of contamination presented by such a practice and whether the practice should be prohibited.

G. Subpart G—We Have Tentatively Reserved Subpart G of This Proposed Rule

H. Subpart H—We Have Tentatively Reserved Subpart H of This Proposed Rule

I. Subpart I—Standards Directed to Domesticated and Wild Animals

As proposed, subpart I provides science-based minimum standards that are directed to domesticated and wild animals and are reasonably necessary to minimize the risk of serious adverse health consequences or death from the use of, or exposure to, covered produce, including those reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into covered produce, and to provide reasonable assurances that the produce is not adulterated under section 402 of the FD&C Act.

1. Comments Related to Proposed Provisions

We received several comments in response to the 2010 FR notice that addressed issues relevant to standards directed to domesticated and wild animals. Some comments expressed concern about requiring measures that prohibit the use of domesticated work animals on farms. Some comments

asserted that monitoring wildlife in a farm environment is untenable, whereas other comments recommended that we prepare a list of ''animals of concern'' to enable farmers to know where to target preventive controls for domesticated and wild animals. Some comments recommended that sustainable conservation practices should be adopted and recognized as enhancing food safety. Several comments noted that farmers are subject to State and Federal laws regarding wildlife (*e.g.,* Endangered Species Act and Clean Water Act) and that there are programs that emphasize environmental stewardship (*e.g.,* National Organic Program and programs of the Natural Resources Conservation Service). Others expressed concern about any requirements that would lead to destruction of habitat or clearing of farm borders.

This proposed rule would not prohibit the use of on-farm domesticated working animals. Rather, this proposed rule would require you to take measures to prevent the introduction of known or reasonably foreseeable hazards into or onto covered produce, if you use working animals in a growing area where a crop has been planted and when, under the circumstances, there is a reasonable probability that animals will contaminate covered produce. We disagree with comments that asserted that monitoring for animal intrusion is untenable. Periodic monitoring for animal intrusion and deposition of their excreta is a necessary measure to prevent contamination of covered produce with biological food safety hazards when there is a reasonable probability that animals will contaminate covered produce. We consider that monitoring during the growing season and immediately prior to harvest is a practical and minimum necessary standard to sufficiently ensure that any potential hazards related to animal intrusion are identified for appropriate follow-up actions in these situations. Proposed § 112.83 is intended to provide you with information about animal movements on your farm, allow you to recognize significant intrusion, and facilitate your taking appropriate measures following significant animal intrusion.

While we recognize the value of establishing a list of ''animals of concern,'' we tentatively conclude that current scientific evidence on the extent to which specific animals present the greatest risk for pathogens is inadequate to develop such a list. Moreover, data on regional and seasonal variations in the prevalence of pathogens in different kinds of animals are scarce. We encourage the application of practices that can enhance food safety, including sustainable conservation practices. A set of examples of biodiversity and conservation practices that may enhance food safety is available from the Resource Conservation District of Monterey County, CA (Ref. 199). This proposed rule would not require the destruction of habitat or the clearing of farm borders. Instead, we propose to require you to monitor those areas that are used for a covered activity for evidence of animal intrusion when, under the circumstances, there is a reasonable probability that animals will contaminate covered produce.

2. Proposed Requirements

Proposed subpart I includes standards that would be directed to the potential for biological hazards from animal excreta to be deposited by your own domesticated animals (such as livestock, working animals, and pets), by domesticated animals from a nearby area (such as livestock from a nearby farm), or by wild animals (such as deer and wild swine) on covered produce or in an area where you conduct a covered activity on covered produce. Proposed subpart I would not be directed to the potential for biological hazards from manure that may be used as a soil amendment; such requirements directed to biological soil amendments of animal origin are discussed in section V.F of this document.

Consistent with sections 419(a)(1)(A), 419(a)(3)(E), and 419(a)(3)(D) of the Act, we consulted with USDA's National Organic Program and Natural Resources Conservation Service, U.S. Fish and Wildlife Service, and the EPA (Ref. 115) to ensure that environmental and conservation standards and policies established by those agencies are appropriately considered in developing the requirements proposed in this subpart. Based on these consultations, we tentatively conclude that the provisions of proposed subpart I do not conflict with or duplicate the requirements of the National Organic Program. In addition, also based on these consultations, we tentatively conclude that the provisions of proposed subpart I are consistent with existing conservation and environmental practice standards and policies while providing for enforceable public health protection measures. Furthermore, the provisions in proposed subpart I are consistent with current recommendations in our GAPs Guide (Ref. 10), the AFDO Model Code (Ref. 20), Commodity-specific industry guidances (Ref. 44. Ref. 46), and the LGMA (Ref. 31). We seek comment on the interactions of the proposed rule with the National Organic Program and opportunities to streamline compliance with both programs.

We acknowledge the longstanding co-location of animals and plant food production in agriculture. However, as discussed in the QAR, both wild and domestic animals may be a source of human pathogens. In fact, domesticated animals, due to their close proximity and interaction with humans, are generally more likely to harbor zoonotic pathogens than are wild animals (Ref. 200). Therefore we tentatively conclude that measures should be taken to minimize the likelihood of covered produce being contaminated by excreta from grazing and working animals. The likelihood of contaminating fresh produce with human pathogens from excreta from grazing and working animals is determined by numerous factors, including but not limited to the species of the animal, the number of animals per unit area of land, agro-ecological conditions, and the time period between animal grazing or working in fields and the harvest of fresh produce (Ref. 176. Ref. 169. Ref. 201. Ref. 202).

Proposed § 112.81(a) would establish that the requirements of proposed subpart I 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. We have tentatively concluded that measures directed to domesticated and wild animals (such as cows, swine, and deer) are necessary when a covered activity takes place in an outdoor area or a partially-enclosed building if, under the circumstances, there is a reasonable probability that animals will contaminate covered produce, because it is reasonably likely that such animals will encroach on such areas and deposit excreta on covered produce or food contact surfaces. Some human pathogens of public health concern (*e.g., E. coli* O157:H7) that have been associated with produce foodborne outbreaks are zoonotic, meaning that they may originate from animals as well as humans. Therefore, animals, both wild and domestic, may be a source of human pathogens during the growing, harvesting, packing and holding of covered produce. We expect this provision to provide flexibility for farmers to consider the nature of covered produce and covered activities (including characteristics of covered produce) in light of the potential for contamination, and determine whether

the proposed requirements of subpart I would be applicable under the circumstances. For example, in the case of covered produce that grows completely underground, we expect that there would not be a reasonable probability of contamination of covered produce by domesticated or wild animals that may graze on or encroach into fields. The proposed requirements in §§ 112.82 and 112.83, therefore, would not apply to covered activities taking place in an outdoor area or a partially-enclosed building when such activities relate to covered produce that grows completely underground. We note, however, that we do not intend the phrase ''under the circumstances'' in these proposed requirements to suggest that farms alter their surrounding environment in order to reduce the chances of animal intrusion, such as by clearing farm borders around outdoor growing areas or drainages. This proposed rule is not intended to require such actions. We intend the phrase ''under the circumstances'' to refer to the nature of the covered produce (such as its growth habit) and the nature of covered activities (such as the manner in which working animals are used in growing areas). We request comment on this issue.

Proposed § 112.81(b) would provide that the provisions of proposed subpart I would not apply to fully enclosed buildings. We tentatively conclude that the measures proposed in this section directed to domesticated and wild animals (such as cows, dogs, swine, and deer) are not necessary when a covered activity takes place in a fully-enclosed building. Rather, we propose measures directed at domesticated and wild animals (such as horses, dogs, and rodents) in a fully-enclosed building in proposed § 112.127 (see section V.L. of this document).

Proposed § 112.82 would establish requirements for measures that you must take, at a minimum, if you allow animals to graze or use them as working animals in fields where you grow covered produce and under the circumstances there is a reasonable probability that grazing or working animals will contaminate covered produce. Proposed § 112.82(a) would require you to implement an adequate waiting period between grazing and time of harvest for covered produce in any growing area that was grazed, to ensure the safety of the harvested crop. The potential likelihood of animals to act as vectors of human pathogens is determined by several factors, including but not limited to the type of commodity (as discussed above), and the species of the animal and its association with human or domesticated animal activity or waste (Ref. 199). A suitable time period based on these and other relevant factors must be established for the purpose of reducing, via die-off, pathogen levels in the excreta that may be transferred to covered produce. We would not expect it to be necessary for such time periods to exceed 9 months, which is the application interval we propose for use of raw manure as a soil amendment in proposed § 112.56(a)(1)(i).

Proposed § 112.82(b) would require that, if you use working animals in a growing area where a crop has been planted, you must take measures to prevent the introduction of known or reasonably foreseeable hazards into or onto covered produce. For example, if you use draft horses as working animals in your covered produce fields, you could establish and use horse paths which are segregated from covered produce plantings, and minimize entry of the horses into covered produce plantings, thus minimizing the opportunity for horse excreta to contact covered produce or food contact surfaces.

Proposed § 112.83 would establish requirements for measures related to animal intrusion in those areas that are used for covered activities for covered produce when under the circumstances there is a reasonable probability that animal intrusion will contaminate covered produce. We are proposing to require that you monitor these areas as needed throughout the growing season, based on the covered produce being grown and your observations and experiences (proposed § 112.83(a)(1)(i) and (ii)), and immediately prior to harvest (proposed § 112.83(a)(2)). In proposed § 112.83(b) we would also require that, if animal intrusion occurs, as evidenced by observation of significant quantities of animals, animal excreta or crop destruction via grazing, you must evaluate whether the covered produce can be harvested in accordance with the requirements of proposed § 112.112.

We acknowledge that when covered produce is grown in an outdoor environment, wild animals are likely to have access to production fields. The presence of animals in a production field of covered produce, in and of itself, is not a significant food safety risk. However, wild animals are known zoonotic disease reservoirs for human pathogens, and therefore their excreta may contaminate growing covered produce crops (Ref. 169. Ref. 203). Monitoring immediately prior to harvest will enable you to identify instances when covered produce cannot be safely harvested, such as when it is not possible to effectively avoid the harvest of covered produce that was directly exposed to animal excreta or that may be cross-contaminated during harvest (*e.g.,* contamination of covered produce by contact with a food-contact surface that contacted animal excreta), as provided for in proposed § 112.112.

Monitoring throughout the growing season may assist you in developing an understanding of when and the degree to which animal intrusion occurs throughout the production season from planting to harvest. This proposed provision should not be construed to require the ''taking'' of an endangered species, as the term is defined in the Endangered Species Act (16 U.S.C. 1532(19)) (*i.e.,* to harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or to attempt to engage in any such conduct), or to require farms to take measures to exclude animals from outdoor growing areas or destroy animal habitat or otherwise clear farm borders around outdoor growing areas or drainages.

J. Subpart J—We Have Tentatively Reserved Subpart J of This Proposed Rule

K. Subpart K—Standards Directed to Growing, Harvesting, Packing, and Holding Activities

As proposed, subpart K discusses science-based minimum standards directed to growing, harvesting, packing, and holding activities that are reasonably necessary to minimize the risk of serious adverse health consequences or death from the use of, or exposure to, covered produce, including those reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into covered produce, and to provide reasonable assurances that the produce is not adulterated under section 402 of the FD&C Act.

1. Comments Relevant to the Proposed Provisions

We received some comments in response to the 2010 FR notice that addressed the adequacy and cleanliness of food-packing material and requested that reusable containers be allowed in packing produce commodities.

It is important to ensure that food-packing material that is used in covered activities is adequate for its intended use, including that it is clean. In proposed § 112.116 below, we address the adequacy and cleanliness of food-packing material. Specifically, proposed § 112.116(b) would require that if you reuse food-packing material, you take

measures to ensure that food-contact surfaces are clean, such as by cleaning and sanitizing, when necessary, food-packing containers or using a clean liner.

2. Proposed Requirements

Proposed § 112.111 would establish that 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 (proposed § 112.111(a)); 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 (proposed § 112.111(b)). As discussed in the QAR, raw produce may have a variety of microorganisms in and on it, including, occasionally, human pathogens. The types of microorganisms, including human pathogens, detected on raw produce are diverse and may often be found in high numbers (Ref. 204. Ref. 205. Ref. 206). In addition, some human pathogens that are commonly isolated from the growing environment (*e.g., L. monocytogenes*) are reported to adapt and survive in the food production environment (*e.g.,* food contact surfaces, floors, walls, drains, sinks, standing water, and seals) and, thus, pose a potential source of contamination (Ref. 207). The proposed standards included in this part are designed to reduce the likelihood that human pathogens are present in or on covered produce. For this reason, excluded produce that is not grown, harvested, packed and stored in accordance with the standards proposed in this part is likely to present a greater likelihood of contamination with human pathogens than would covered produce that is grown, harvested, packed, and held in accordance with this part. We tentatively conclude that for operations handling both covered and excluded produce, cross-contamination is reasonably likely in the absence of measures directed toward its prevention. Such measures include separation of the two types of produce to avoid physical contact and any transfer of pathogens from one to the other; and cleaning and sanitizing, as necessary, food contact surfaces used on such excluded produce before those surfaces come in contact with covered produce so that any pathogens picked up by the food-contact surface from excluded produce are not transferred to covered produce.

Proposed § 112.112 would require you to 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. For example, you would comply with this provision by not harvesting a head of lettuce if you see evidence of bird excreta on the head of lettuce. As discussed in the QAR, it is well established that animal excreta is a source of pathogens. Transmission of pathogens from animal excreta to covered produce and, subsequently, to humans through consumption is reasonably likely in cases where the presence of animal excreta can be visually confirmed. Therefore, if the presence of animal excreta in a field of covered produce precludes your ability to safely harvest the covered produce, either because a significant portion of the covered produce has animal excreta on it or because the animal excreta that is present would be likely to contaminate food contact surfaces of harvest equipment, you must not harvest the relevant portions of that field.

Proposed § 112.113 would require that you handle harvested covered produce during covered activities 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. As discussed in the QAR, research demonstrates that soil microorganisms, including human pathogens, may effectively colonize produce when the produce has lost its protective covering (*e.g.* cuticle) in the course of harvest activities (*e.g.,* cutting or trimming) or when damaged during such operations (Ref. 208. Ref. 209). Once established, the high moisture content of produce provides a suitable environment for survival and growth of such pathogens. Pathogens, if present, may be transferred to cut surfaces of harvested produce from soil and, therefore, preventing unnecessary contact between such cut surfaces and soil will reduce the likelihood of such transfer. For example, you could take steps to temporarily place cut lettuce heads on clean cardboard or other clean surface during field packing, rather than placing them directly on the soil.

We considered washing as a requirement to reduce the likelihood of contamination. Washing is an attractive option because it effectively removes excess dirt, debris, and other organic matter and its use incurs a relatively low cost allowing it to be employed across a variety of equipment (water flumes, hydrocoolers, dips, scrubbers, sorters, etc.) or steps in combination, or in sequence before packaging. Despite these advantages, a number of studies have concluded that wash water, with or without an active antimicrobial agent, does not completely disinfect produce that may contain microorganisms of public health significance (Ref. 206. Ref. 210. Ref. 209). Wash water containing an antimicrobial such as chlorine is reported to reduce microbial populations by two or three log units (100 to 1000 fold), but does not eliminate microbes (Ref. 211. Ref. 210). Bacteria may find harborage and protection on plants through hydrophobic areas, stomata, lenticels, punctures, and bruises and where it is not readily washed off (Ref. 212. Ref. 213). Of special significance to bacterial survival on plants are circumstances that lead to bacterial cells being drawn in or internalized inside the edible portion of the plant where they may escape the action of water altogether. This phenomenon, termed internalization, may occur as a consequence of temperature differentials created when warm produce (from field heat or daytime high temperatures) is submerged in cooler water. Under these conditions, infiltration of water occurs because intercellular air spaces within fruits and vegetables contract, thereby creating a partial pressure differential that draws the water into the internal compartments of the plant. If the cooling water contains human pathogens the fresh produce item will now be internally contaminated. This phenomenon has been seen with Salmonella and E. coli O157:H7 in tomatoes, oranges, or mangoes (Ref. 138. Ref. 139. Ref. 214). As part of a post-outbreak study, Penteado *et al.* 2004 reported evidence that Salmonella spp. may have internalized in fresh mangoes during a postharvest cooling step involving a water bath (Ref. 38). We seek comment on whether we should consider washing, alone or in combination with other measures, as a requirement to reduce the likelihood of contamination.

Proposed § 112.114 would prohibit you from distributing covered produce that drops to the ground before harvest (dropped covered produce) unless it is exempt under § 112.2(b) (*i.e.* if it receives commercial processing to

adequately reduce the presence of microorganisms of public health significance). Dropped covered produce does not include root crops (such as carrots) that grow underground or crops (such as cantaloupe) that grow on the ground. However, produce that grows off the ground, such as tomatoes and apples, and that drop to the ground before harvest would be considered dropped covered produce. Evidence from studies of tree fruit (*e.g.,* apples and pears) indicates that dropped and damaged fruit contain coliform bacteria in significantly higher numbers than intact tree fruit (Ref. 215). Risk assessment models for apple contamination (Ref. 216) show that dropped apples are more likely to be contaminated with bacteria than tree-picked apples, and dropped fruit used in the production of apple products (*e.g.,* apple cider) are likely to increase rates of product contamination (Ref. 216). While data available to us is primarily derived from studies investigating apples, we tentatively conclude that all dropped covered produce is likely to present a potential likelihood for contamination, although to varying degrees. Studies have indicated that when produce drops to the ground, the produce can become structurally damaged, which is considered to be a factor for proliferation of human pathogens on such produce (Ref. 217. Ref. 218. Ref. 219). Excluding dropped fruit from harvest is also recommended in some existing guidance documents (Ref. 220. Ref. 221. Ref. 44). However, some produce is dropped to the ground as a part of the harvesting practice (*e.g.,* some tree nuts). We expect that such harvesting practices were developed because the fall does not damage the edible crop, because the crop is protected with a durable shell. Accordingly, we have defined ''dropped covered produce'' to exclude produce that is intentionally dropped as part of harvesting. Further, we do not propose to prohibit the use of dropped covered produce in a commercial process (*e.g.,* canning) that is designed to adequately reduce the presence of microorganisms of public health significance. Therefore, dropped covered produce that is exempt under proposed § 112.2(b) may be distributed for such commercial processing as described in proposed § 112.2 (see section V.A. of this document).

We seek comment on this provision and whether specific commodities should be exempted from this provision based on the harvesting practices associated with the commodity and/or the nature of the commodity itself. If specific commodities should be exempted from this provision, please explain the practices, processes, and conditions associated with that commodity that would justify such exemption. We expect that this proposed provision would prevent the marketing for fresh use of produce that may have been bruised as a result of the fall. As noted above, damaged or bruised fruit provide an opportunity for pathogen intrusion into the edible portion and may liberate nutrients for pathogen growth. We note that produce that is intentionally dropped to the ground as part of the harvesting method would not be considered ''dropped covered produce'' as defined in proposed § 112.114 (*i.e.,* produce that drops to the ground before harvest). We seek comment on whether proposed § 112.114 adequately takes into account produce that is intentionally dropped during harvesting and whether such harvesting practices do not cause damage to the produce. Proposed § 112.115 would establish measures that you must take when packaging covered produce. Specifically, proposed § 112.115 would require that you 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). The potential for toxin production by *C. botulinum* in mushrooms packaged under reduced oxygen conditions is well-known (Ref. 222). Mushrooms grow close to the ground, which is a source of *C. botulinum* spores. Mushrooms remain metabolically active after harvest, which may quickly reduce the amount of oxygen, particularly when mushrooms are packaged under conditions that limit the transfer of oxygen across the layer of packaging (Ref. 223). In such reduced oxygen or anoxic conditions, *C. botulinum* spores can germinate resulting in the formation of botulinum toxin, which can occur before any overt signs of mushroom spoilage (Ref. 222). Modified or reduced-oxygen packaging of other produce may present a similar risk for botulinum toxin formation (Ref. 224). Perforated packaging film allows free air access to mushrooms and is recommended as a means to reduce the potential for toxin formation in mushrooms (Ref. 225). Other means of preventing toxin formation in modified or reduced oxygen packaging may include use of time-temperature integrators on individual packages of produce to signal when a cumulative time-temperature combination has been reached that presents a risk for *C. botulinum* toxin formation or use of antimicrobial compounds (Ref. 224). We request comment on the need for this proposed provision and on the types or conditions of modified or reduced oxygen packaging methods that may or may not increase the risk of formation of botulinum toxin.

Proposed § 112.116 would establish measures that you must take when using food-packing (including food packaging) material. Specifically, proposed § 112.116(a) would require that food-packing material must be adequate for its intended use. For example, food-packing material that would be adequate for its intended use include plastic bins for holding fresh-picked fruit, wax-impregnated corrugated cardboard for broccoli to be hydrocooled or top-iced after packing, plastic clamshells used for packaging strawberries for retail sale, and single-use cardboard containers for packing tomatoes. Wooden bins or boxes, and canvas bags that may be used during harvest also would need to meet this requirement, and could be used if they are adequately clean and sanitary for their intended use. To implement this provision, you would have to use food-packing materials that are: (1) Cleanable or designed for single use and (2) unlikely to support growth or transfer of bacteria. In addition, proposed § 112.116(b) would require that if you reuse food-packing material, you take measures to ensure that food-contact surfaces are clean, such as by cleaning and sanitizing, when necessary, food-packing containers or using a clean liner. Evidence from scientific literature indicates that the number of microorganisms detected on the surface of fruits is directly correlated to the amount of contact time between the fruit commodity and its packing material (Ref. 226. Ref. 227). Although some food-packing material is sufficiently sturdy to be used multiple times, it may serve as a source of contamination in the absence of regular cleaning and sanitizing between each such use. Further, certain food-packing material may have a serviceable shelf life beyond which it may not possible to effectively clean and sanitize the material. It is reasonably likely that such packing material, if it continues to be used, may serve as harborage sites for pathogens, if they become established on its surface.

L. Subpart L—Standards Directed to Equipment, Tools, Buildings, and Sanitation

Proposed subpart L establishes science-based minimum standards that are reasonably necessary to prevent

equipment, tools, buildings, and inadequate sanitation from introducing known or reasonably foreseeable hazards into or onto covered produce or food-contact surfaces, and to provide reasonable assurances that the covered produce is not adulterated under section 402 of the FD&C Act.

A few comments recommended that equipment used to hold or convey water should be inspected to ensure that it is clean.

We agree that equipment used to hold or convey water should be maintained in a manner necessary to protect against contamination. In 112.42 (b), we would require that 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. In 112.42 (c), we would require that 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.

1. Comments Relevant to Proposed Provisions

We received some comments in response to the 2010 FR notice that expressed that the use of animals on a farm or their presence near farming operations should not be prohibited.

We address issues related to animals in and around farming operations in subpart I (see section V.I. of this document) of this rule. However, in this subpart, we address the presence of animals in fully-enclosed buildings. Specifically, proposed § 112.127 would require that you take reasonable precautions to prevent domesticated animals, including guard and guide dogs, in and around a fully-enclosed building from contaminating covered produce, food-contact surfaces, and food packing materials with known or reasonably foreseeable hazards.

2. Proposed Requirements

a. Equipment, Tools, and Buildings That Are Subject to the Requirements of This Subpart

Any equipment and tools used during covered activities that are intended to, or likely to, contact covered produce would be subject to proposed subpart L. In addition, instruments or controls used to measure, regulate, or record conditions to control or prevent the growth of undesirable microorganisms or other contamination would be subject to proposed subpart L. In proposed § 112.121, we provide examples of such equipment and tools, *i.e.,* 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).

Proposed § 112.122 would identify the types of buildings that are subject to the requirements of proposed subpart L. Such buildings would include any fully- or partially-enclosed buildings used for covered activities, including minimal structures that have a roof but do not have any walls (proposed § 112.122(a)). Fully-enclosed buildings are typically used to grow covered produce such as sprouts and mushrooms and may be used to grow a variety of covered produce indoors to create or extend the growing season in a particular geographic area. Partially-enclosed buildings can be used to grow covered produce such as tomatoes, and are often used to pack covered produce. Buildings that are subject to the requirements of the rule would also include storage sheds, buildings, or other structures used to store food-contact surfaces (such as harvest containers and food-packing materials) (proposed § 112.122(b)). We are proposing this requirement because contaminated food-contact surfaces can contaminate covered produce (Ref. 182) (Ref. 228) and, thus, present a potential hazard.

b. General Requirements Applicable to Equipment and Tools

As proposed, § 112.123 establishes general requirements applicable to equipment and tools subject to subpart L. Proposed § 112.123(a) would require you to use equipment and tools that are of adequate design, construction, and workmanship to enable them to be adequately cleaned and properly maintained. For example, some lettuce coring knives currently used in the industry are designed in a way that gives them the propensity to transfer microbial contaminants from soil to the lettuce (Ref. 229). Using a tool that is designed to minimize the potential for pathogen transfer from soil to the produce and/or that allows for mechanical polishing to facilitate cleaning and sanitizing the tool would enhance food safety (Ref. 230).

Proposed § 112.123(b)(1) would establish that equipment and tools you use must be installed and maintained in a manner that facilitates cleaning of the equipment and of all adjacent spaces. For example, equipment that is permanently installed in an on-farm packing operation would need to be installed in such a manner that both maintenance and cleaning crews are able to easily access any food contact surfaces, protective covering or barriers, and any movable parts or other potential sources of contamination. A conveyor belt system that is part of a grading line would be considered properly installed if there is easy access to the belt (a food-contact surface) for cleaning. The proposed provisions in § 112.123(b)(1) are consistent with the requirements in current § 110.40(a) and § 111.27(a).

Proposed § 112.123(b)(2) would establish that equipment and tools you use must be 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 or harboring pests. As discussed in the QAR, if farm equipment or tools are stored outside or in a partially-enclosed building, they may attract or harbor pests, which can carry human pathogens (Ref. 231). Appropriate practices for storing and maintaining equipment and tools can reduce the potential for these problems. For example, you would comply with this provision by storing equipment and tools indoors when practical, and when not practical, minimizing surrounding debris and checking periodically for pests.

Proposed § 112.123(c) would establish that 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. This provision is consistent with current § 110.40(a) and (b) and § 111.27(a).

Proposed § 112.123(d)(1) would require you to 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. This provision is intended to prevent transfer of contaminants on food-contact surfaces of equipment or tools (*e.g.,* harvest knives, grading belts, or harvest

bins) to covered produce. As discussed in the QAR, for example, it has been documented that *E. coli* O157:H7 can be transferred to Iceberg lettuce from contaminated coring devices used in a simulated field coring (Ref. 229). Even food contact surfaces made of stainless steel can transfer pathogens to covered produce, if not properly cleaned and sanitized. For example, transfer of pathogens from stainless steel tools to lettuce has been demonstrated to occur to various extents, depending on the amount of water on the leaf surface (Ref. 232).

Proposed § 112.123(d)(2) would require you to maintain and clean all non-food-contact surfaces of equipment and tools subject to subpart L used in covered activities during harvesting, packing, and holding as frequently as reasonably necessary to protect against contamination of covered produce. The potential for an equipment or tool to come into contact with covered produce varies with the type and intended use of the equipment or tool. Non-food-contact surfaces of tools and equipment used in contact with covered produce can be sources of contamination. Therefore, it is important to maintain such surfaces of covered equipment and tools in a clean and sanitary condition. However, such surfaces may not require cleaning as frequently as those that come into direct contact with produce, and may not require sanitizing. An example of such a surface is the handle of a tool used when working directly with covered produce, although depending on the use, such equipment or tool may be or consist of a food-contact surface. For example, a truck used to harvest produce may not need to be thoroughly cleaned or sanitized; however, the flatbed of the same truck if used to haul un-packed/loose produce would be considered a food-contact surface.

Proposed § 112.123(e) would establish that, if you use equipment such as pallets, forklifts, tractors, and vehicles such that they are intended to, or likely to, contact covered produce, you do so in a manner that minimizes the potential for contamination of covered produce or food-contact surfaces with known or reasonably foreseeable hazards. For example, you may consider the appropriate route for any equipment to move in, through, and out of production fields, and when there may be a need to visually inspect and clean such equipment to prevent contamination or cross-contamination of covered produce. The potential for transfer of contaminants from tractors to covered produce, for example, if the tractors drive through or otherwise come in contact with manure is also highlighted in our GAPs Guide (Ref. 10). We seek comment on the appropriateness of the proposed cleaning provisions related to equipment and tools.

c. General Requirements Applicable to Instruments and Controls

Proposed § 112.124 would establish that 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 pathogens 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. Proposed § 112.124 is consistent with current § 111.27(a)(6), and similar to requirements in current § 110.40(f). Accuracy addresses whether the recorded measurements are equal to the true value of that which is being measured, while precision addresses whether individual measurements are close to each other when made under the same conditions. Both accuracy and precision are necessary to ensure the validity and reliability of measurements. The appropriate degree of accuracy and precision, however, would need to be determined based on the nature of the instrument and its specific use for the covered activity. Instruments must also be adequately maintained to ensure that they are functioning properly for their intended use. For example, an in-line water oxidation-reduction potential meter that is used to determine the approximate sanitizer concentration in a water flume system must be appropriately maintained to ensure that there is no debris build-up that would interfere with its proper operation. In addition, you must have an adequate number of instruments as needed for the designated use. For example, if you are composting a small pile of manure and monitoring the temperature, one thermometer may be sufficient. However, if you are composting large windrows in excess of several hundred yards in length, and using an automated system to monitor the internal temperature of the pile, you would need multiple thermocouples placed throughout the pile to get a good reading of the overall temperature.

d. Transport of Covered Produce

Proposed § 112.125 would establish that equipment subject to subpart L that you use to transport covered produce during covered activities must be: (a) Adequately clean before use in transporting covered produce; and (b) adequate for use in transporting covered produce. Transport equipment that is intended to, or likely to, contact covered produce that is not clean, or that is not adequate for the covered produce it is being used to transport, can be a source of cross-contamination of covered produce. Equipment used to transport covered produce would not be adequately clean if, for example, there is dirt, filth, organic material, particles of food, remains of previous shipping loads, or any other extraneous materials or contaminants on surfaces that are likely to come into contact with the produce. Equipment used to transport covered produce would not be adequate if, for example, the same equipment is used to haul live animals or garbage that is not completely contained, and the equipment is either not designed in a manner that allows cleaning and sanitizing or it is not cleaned or sanitized, before it is used to transport covered produce. Proposed § 112.125 is consistent with recommendations in FDA's GAPs Guide (Ref. 10), the AFDO Model Code (Ref. 20), commodity-specific guidances (Ref. 85. Ref. 94. Ref. 27), and international guidelines (Ref. 96. Ref. 96).

e. Design and Construction Requirements Applicable to Buildings

Proposed § 112.126 would establish requirements applicable to the design and construction of buildings. As proposed, § 112.126(a) requires that your 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 foreseeable hazards. For buildings to be suitable in size, it should have enough room for covered activities to be conducted without cross-contact between covered produce or food-contact surfaces and building materials, non-food-contact surfaces, or clothing. Proposed § 112.126(a)(1) would establish requirements that your building provide sufficient space for placement of equipment and storage of materials. This is necessary for the maintenance of sanitary operations and the conduct of covered activities. The proposed provisions in § 112.126(a)(1) are consistent with requirements in current § 110.20(b)(1) and § 111.20. Proposed § 112.126(a)(2) would establish requirements that your buildings must permit proper precautions to be taken to reduce the potential for contamination of covered produce, food contact surfaces, or packing material 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. This provision provides flexibility in the precautions you take for your buildings and proposes separation of operations, such as by having sufficient space so that incompatible operations can be kept at a reasonable distance from each other, for example, so that spray coming off equipment being washed does not contact covered produce being packed. The proposed provisions in § 112.126(a) are similar to requirements in current § 110.20(b)(2) and § 111.20.

Proposed § 112.126(a)(3) would require buildings to be constructed in a manner such 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. Buildings where covered activities occur must be suitably constructed to allow adequate cleaning and sanitizing in order to minimize the presence or persistence of hazards and the potential for damage or contamination of covered produce. Buildings should be kept in good repair so as to prevent drip or condensate from pipes or ceilings to drop onto covered produce or food-contact surfaces, and holes in walls of enclosed buildings from permitting pests access to covered produce or areas of covered activities. The proposed provisions in § 112.126(a)(3) are consistent with requirements in current § 110.20(b)(4) and § 111.20.

Finally, proposed § 112.126(b) would establish requirements that you 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. Standing water can attract pests and support the growth of pathogens, such as *L. monocytogenes,* presenting potential for contamination of covered produce. The proposed provision in § 112.126(b) is similar to requirements in current § 110.37(b)(4) and § 111.15(f)(4).

f. Domesticated Animals in and Around Fully-Enclosed Buildings

Proposed § 112.127(a) would require you to 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. As discussed in the QAR, domesticated animals can carry pathogens, potentially resulting in contamination of covered produce or food contact surfaces. However, consistent with current § 110.35(c), we propose to permit guard or guide dogs 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 (proposed § 112.127(b)). You would need to take reasonable precautions to prevent contamination of covered produce, food-contact surfaces, and food-packing material with hazards from such dogs. We believe that animals such as guard or guide dogs, when kept under control and where the activities of the animal can be contained, are unlikely to result in contamination of produce, food-contact surfaces, or food-packing materials. We seek comment on the appropriateness of this provision and whether proposed provision § 112.127(b) should be extended to all working animals.

g. Pest Control

As discussed in the QAR, pests such as rodents, snakes, lizards, turtles, iguanas, and birds are known to carry human pathogens, such as *Salmonella* spp. and, if not controlled, can cause the contamination of covered produce, food contact surfaces or food-packing materials. Therefore, in proposed § 112.128(a), we propose to require you to take 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. Furthermore, we propose to require you to take measures to exclude pests from fully-enclosed buildings (proposed § 112.128(b)) and to prevent pests from becoming established in partially-enclosed buildings (such as by use of screens or by monitoring for the presence of pests and removing them, when present) (proposed § 112.128(c)). We recognize that it might be impossible to exclude pests, such as birds, from entering buildings that are not fully-enclosed. To comply with proposed § 112.128(c), you would need to take those steps reasonably necessary to prevent birds or other animals from building nests in partially-enclosed buildings and, if possible, to find and remove any nests that become established. Any measures or steps taken under these provisions would need to comply with applicable wildlife conservation regulations.

h. Toilet and Hand-Washing Facilities

Human feces may contain pathogens in relatively high concentrations (Ref. 233). The most basic measure to prevent the potential transfer of pathogens from human feces into or onto covered produce and food-contact surfaces is to provide toilet facilities that collect and contain human feces. Proposed § 112.129 would establish requirements related to toilet facilities, including that you must provide personnel with adequate, readily accessible toilet facilities, including facilities readily accessible to growing areas during harvesting activities (proposed § 112.129(a)). In proposed § 112.129(b), we propose to establish that 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 (proposed § 112.129(b)(1)); (2) be directly accessible for servicing, be serviced and kept clean on a schedule sufficient to ensure suitability of use, and be kept supplied with toilet paper (proposed § 112.129(b)(2)); and (3) provide for the sanitary disposal of waste and toilet paper (proposed § 112.129(b)(3)). These provisions are intended to contribute to an overall sanitary measure to help protect covered produce and areas where covered activities are conducted from contamination with pathogens. A portable toilet facility that leaks or a fixed toilet facility that lacks proper drainage or backflow devices would not be considered properly designed or maintained. As discussed in the QAR, runoff from such a toilet facility has the potential to directly contaminate covered produce, while contamination of soil and irrigation water from such runoff can have longer-lasting impact. To minimize the potential for contamination during events such as flooding or high winds, toilet facilities should be located away from water sources and water distribution systems, and at a reasonable distance from growing and packing areas. Sewage transport or other servicing trucks should have clear access to toilet facilities to ensure proper collection and disposal of wastes. In addition, workers are more likely to use toilet facilities that are clean, well-stocked, and in good condition (Ref. 234). We recognize that the growing area of a farm may spread

across several acres of land, and workers or visitors may be in growing areas for an extended period of time primarily during harvest activities. At times other than during harvest, we would consider toilet facilities to be readily accessible if, for example, the facility is available to workers at a farm building before and after they work in a growing area, or at a nearby public facility that is readily accessible to your workers. However, during harvest activities we consider it likely that workers and visitors will spend a significant amount of time in growing areas. We point out that the field sanitation requirements prescribed by the Occupational Safety and Health Administration (OSHA) under the Occupational Safety and Health Act, specifically 29 CFR 1928.110, describes the appropriate number of toilets to the number of workers, proper handwashing facilities, maximum worker-to-restroom distance, and frequency of cleaning facilities. Agricultural establishments subject to the requirements of 29 CFR 1928.110(c)(2), must provide one toilet facility for each 20 employees or fraction thereof (except that toilet facilities are not required for employees who perform field work for a period of three hours or less (including transportation time to and from the field) during the day).

As discussed in the QAR, the fecal-oral route for contamination of food with pathogens is well-established and proper washing and drying of hands are fundamental practices demonstrated to be effective in breaking the fecal-oral route of contamination. Therefore, in proposed 112.129(c), we would establish requirements that you provide a hand-washing station during growing activities that take place in a fully-enclosed building, and during covered harvesting, packing, or holding activities, that is in sufficiently close proximity to toilet facilities to make it practical for persons who use the toilet facility to wash their hands. We discuss the importance of hand-washing in presenting the proposed requirements for hygienic practices in section V.D. of this document.

The provisions in proposed § 112.129 are consistent with recommendations in our GAPs Guide (Ref. 10), the AFDO Model Code (Ref. 20), commodity-specific guidances (Ref. 85. Ref. 94. Ref. 194), and international guidelines (Ref. 96. Ref. 96). These provisions are also similar to requirements in current § 110.37(d) and § 111.15.

With respect to hand-washing facilities, we propose to require you to provide personnel with adequate, readily accessible hand-washing facilities during growing activities that take place in a fully-enclosed building, and during covered harvest, packing, or holding activities (proposed § 112.130(a)). In addition, in proposed § 112.130(b), we would establish requirements that your hand-washing facilities must be furnished with: Soap (or other effective surfactant) (proposed § 112.130(b)(1)); running water that satisfies the requirements of § 112.44(a) for water used to wash hands (proposed § 112.130(b)(2)); and adequate drying devices (such as single service towels, clean cloth towels or sanitary towel service) (proposed § 112.130(b)(3)). As discussed in the QAR, hand-washing is a key control measure in preventing the spread of pathogens from ill or infected workers to covered produce and food-contact surfaces. Workers often touch produce with their bare hands. Hand-washing, when done effectively, can significantly reduce the number of resident bacteria on the hands of a worker who may not be aware of being ill or infected, as well as transient microbial pathogens that get onto hands through contact with the environment or other ill workers. The effectiveness of hand-washing is determined by multiple factors, including whether or not soap is used, the quality of water used, the duration of scrubbing and rinsing, and whether and how hands are dried. The frequency of hand-washing, as well as the efficacy of a single hand-washing event, may also be important factors in the spread of microbial pathogens by ill or contaminated workers (Ref. 107).

Proposed subpart 112.130(c) would establish requirements that you 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 hand-washing 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. A hand-washing facility produces waste that can lead to contamination, and such waste needs to be controlled. For example, if the sink of a portable hand-washing station in field actively being harvested does not have a catch-basin or tank, but instead is open the ground, the waste-water from the sink can contaminate the soil. Finally, in proposed § 112.130(d), we would establish that you may not use hand antiseptic/sanitizer as a substitute for soap and water. As discussed in the QAR, hand sanitizers have not been found to be effective substitutes for washing hands with soap and water, because the presence of dirt, grease, or soil reduces their effectiveness in eliminating bacteria. However, we are not proposing to prohibit the use of sanitizers as they may be effective as an additional measure in reducing the number of bacteria on hands after proper washing with soap and water followed by drying

The hand-washing provisions in proposed § 112.130 are consistent with recommendations in our GAPs Guide (Ref. 10), the AFDO Model Code (Ref. 20), commodity-specific guidances (Ref. 85. Ref. 94. Ref. 194), and international guidelines (Ref. 96). They are also similar to the requirements in current § 110.37(e) and § 111.15(i).

i. Disposal of Sewage, Trash, Litter, and Other Waste

As discussed in the QAR, human feces may contain pathogens in relatively high concentrations and, therefore, sewage must be properly disposed and sewage and septic systems must be maintained to minimize the potential for failure, leakage, or spills (and any leakage or spill appropriately managed) to prevent contamination of covered produce. Events such as flooding or earthquakes also have the potential to damage sewage and septic systems and impair their function and, therefore, it would be appropriate to assess your sewage systems for damage or other failures, following such events. Proposed § 112.131 would establish requirements that apply to the control and disposal of sewage, including that you must dispose of sewage into an adequate sewage or septic system or through other adequate means (proposed § 112.131(a)), which is consistent with current § 110.37(c) and § 111.15(g); 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 (proposed § 112.131(b)); 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 (proposed § 112.131(c)); and that 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 (proposed § 112.131(d)). These provisions are consistent with recommendations in our GAPs Guide (Ref. 10), commodity-specific guidances (Ref. 44. Ref. 46), and the AFDO Model Code (Ref. 20).

Proposed subpart 112.132 would establish requirements that apply to the control and disposal of trash, litter, and other waste in areas used for covered activities. Proposed § 112.132(a) would establish requirements that you convey, store, and dispose of trash, litter and waste to: (1) Minimize the potential for trash, litter, or waste to attract or harbor pests (proposed § 112.132(a)(1)); 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 (proposed § 112.132(a)(2)). In addition, we propose to require that you 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 (proposed § 112.132(b)). The provisions proposed in § 112.132 are consistent with requirements in current §§ 111.15(a) and (g) and similar to requirements in current § 110.37(f). These provisions are also consistent with recommendations for packing areas in our GAPs Guide (Ref. 10), and commodity-specific guidance (Ref. 46).

j. Plumbing

Proposed § 112.133 would establish that plumbing must be of an adequate size and design and be adequately installed and maintained to (1) distribute water under pressure as needed, in sufficient quantities, in all areas where used for covered activities, for sanitary operations, or for hand-washing and toilet facilities (proposed § 112.133(a)); (2) properly convey sewage and liquid disposable waste (proposed § 112.133(b)); (3) avoid being a source of contamination to covered produce, food-contact surfaces, areas used for a covered activity, or agricultural water sources (proposed § 112.133(c)); and (4) 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 (proposed § 112.133(d)). An example of a problem that may result from inadequate plumbing is improper drainage of refrigeration drip pans. If drip pans do not drain properly, they may drip onto covered produce or allow moisture to accumulate providing an environment that can support the establishment of and growth of *L. monocytogenes*. Proposed § 112.133 is intended to ensure that your plumbing and water distribution systems do not adversely affect the water you use in covered activities on covered produce. If the plumbing and water distribution systems are not adequately installed and maintained, they may contaminate your water supply and, in turn, contaminate your covered produce through direct contact (such as when you use water in irrigation or harvest activities), or through indirect contact (such as when the contaminated water is used to wash a food-contact surface). Such cross-contamination of clean water and waste water has been implicated in outbreak investigations (Ref. 235). It would also be important to prevent contamination of water that must meet the requirements under subpart E by water that does not meet the relevant requirements. For example, water used for irrigation of covered produce other than sprouts using a direct water application method would need to meet the requirements of §§ 112.41 and 112.44(c) or (d), but would not necessarily meet the requirements of § 112.44(a) (see section V.E. of this document). These provisions are consistent with the requirements in current §§ 110.37(b) and 111.15(f), and with the recommendations in our GAPs Guide (Ref. 10), the AFDO Model Code (Ref. 20), and commodity-specific guidances (Ref. 46. Ref. 44).

k. Control of Animal Excreta and Litter From Domesticated Animals

In proposed § 112.134(a), we would require that, 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. For example, you would comply with this provision by not locating manure piles adjacent to packing sheds in which covered produce is exposed. As discussed in the QAR, pathogens inhabit the gut of a variety of warm-blooded animal species and are often shed in feces in high numbers. If not effectively controlled, such pathogens may persist in the environment for long periods of time (see the QAR) and may pose a threat to water quality from runoff and leaching (Ref. 236. Ref. 169), creating multiple opportunities for these pathogens to contaminate produce or food contact surfaces.

l. Record Keeping

Proposed § 112.140(a) would make clear that records required under this subpart L must be established and kept in accordance with the requirements of subpart O of this part. Records required to be established and kept under this subpart L include documentation of the date and method of cleaning and sanitizing of the equipment you use in growing operations for sprouts (proposed § 112.140(b)(1)) and in covered harvesting, packing, or holding activities (proposed § 112.140(b)(2)). These documentation requirements are intended to enable us to verify and you to ensure that requirements of this subpart are met.

M. Subpart M—Standards Directed to Sprouts

Proposed subpart M would establish science-based minimal standards for the growing, harvesting, packing and holding of sprouts that are reasonably necessary to minimize the risk of known or reasonably foreseeable hazards that are associated with serious adverse health consequences or death. As noted in section I of this document, sprouts have been frequently associated with foodborne illness outbreaks (Ref. 3). As a result, we issued our first commodity-specific guidance for sprouts. Likewise, the Codex Alimentarius Commission supplemented its Codex Fresh Fruits and Vegetables Code with a Sprout Annex (Ref. 50).

Sprouts present a special concern with respect to human pathogens than other covered produce because of the warm, moist, and nutrient-rich conditions required to produce sprouts, the same conditions that are also ideal for the proliferation of pathogens if present (Ref. 208. Ref. 16). Therefore, we believe it is necessary to incorporate this additional subpart establishing standards specific to sprouts. The provisions of proposed subpart M are consistent with recommendations in FDA's Sprout Guides (Ref. 14. Ref. 15), industry guidance (Ref. 237), and international regulations and guidelines (Ref. 38. Ref. 191. Ref. 192. Ref. 193).

We are also seeking comment on whether, or to what extent, the measures in this subpart should be applied to soil-grown sprouts. The NACMCF Sprout White paper and our Sprout Guides do not distinguish soil-grown sprouts and hydroponic sprouts (Ref. 14. Ref. 15.

Ref. 16). However, we are not aware of any outbreaks associated with sprouts grown in soil or media, which could be because of the lower percentage of sprouts grown in that manner, the nature of the species of sprouts grown in that manner, or a difference in likelihood of contamination posed by that method and hydroponics. This could be the case because of the relative ease of transfer of pathogens between sprouts in a water environment and, possibly, a greater amplification of pathogens during hydroponic sprout production compared to the more stressful environment for pathogen growth posed by exposure to air and sunlight when seeds are grown under conditions more typical of a natural setting (soil and media methods). On the other hand, we expect that seeds or beans would be a potential vehicle of contamination, regardless of sprouting method employed. Seeds or beans (in the form of seed leaves or cotyledons) could be part of the food consumed, regardless of the method used for sprouting. In addition, flats of soil or media grown sprouts may be placed on a growing rack, similar to hydroponic sprouts grown in clamshells (as opposed to large bins for bean sprouts or rotating drums used to start green sprouts), with overhead sprout irrigation water, providing an opportunity for pathogens, if present, to be spread within a flat of sprouts and to other flats on racks below. Alternatively, flats may be placed side-by-side in a growing area such as a greenhouse, where the likelihood of pathogen spread would presumably be lower than when a growing rack is used.

Finally, 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, in a final rule, a food safety plan and/or an operational assessment should be required for farms conducting covered activities related to sprouts, either in addition to or in place of the standards proposed in this subpart. We also request comment on whether a written plan similar to the type required under section 418 of the FD&C Act would be more appropriate for farms conducting covered activities related to sprouts.

1. Comments Relevant to the Proposed Provisions

We received very few comments related specifically to sprouts. Those that were submitted were generally supportive of our efforts to create policies to prevent illness and produce safer sprouts, citing the need for addressing residual agricultural chemicals and microbial contamination of seed, seed disinfection treatments, worker health and hygiene, and sanitation. One comment hoped that we understood the realities currently facing the sprout industry worldwide, and would take actions to ensure truly practical measures that would be accepted by the sprout industry, questioning, for example, the need for extensive record keeping or monitoring sprout facilities for *Listeria.* This comment maintained that we should consider current production methods and consumption practices in establishing standards for sprouts.

As discussed further in section V.M.3. of this document, our proposed rule carefully considers the various conditions under which sprouts are grown and consumed. The proposal provides flexibility to achieve the goal of minimizing the risk of known or reasonably foreseeable hazards that are associated with serious adverse health consequences or death. We consider that the proposed requirements for the growing, harvesting, packing and holding of sprouts, as well as for record keeping, are all practical and necessary to protect public health. With respect to consideration of the method of growth, as discussed above, we are seeking comment on whether soil-grown sprouts are subject to the same risk factors as hydroponic sprouts and to whether, or to what extent, the measures in this subpart should be applied to them.

One comment recommended that bean sprouts be subjected to less stringent requirements compared to others, *e.g.,* green sprouts, because bean sprouts are rarely consumed raw (less than 1% according to their estimates). This comment suggested that seed disinfection treatments might not be necessary (or argued for more disinfection method choices) for bean sprouts. Our 1999 Sprout Guides apply to all sprouted seeds and beans (Ref. 14. Ref. 15) and we are proposing in subpart M to cover all sprouts, including bean sprouts. Our earliest efforts to promote sprout safety, including consumer advisories, focused primarily on green sprouts, such as alfalfa and clover sprouts, where we were seeing sprout outbreaks and because we assumed bean sprouts were most often cooked before consumption (Ref. 238). However, in 2002, we updated our consumer advisories to include advice on the risks associated with eating all types of sprouts, including raw and lightly cooked bean sprouts based on four foodborne illness outbreaks associated with mung bean sprouts between 2000 and 2002 (Ref. 239). As noted in section V.A.2.a. of this document, we analyzed consumption of selected produce commodities to determine those that are rarely consumed raw. We included sprouts (alfalfa and mung bean) in our analysis, and based on data available from the NHANES, alfalfa and mung bean sprouts do not meet our criteria for rarely consumed raw commodities (Ref. 79).

2. Proposed Requirements

Proposed § 112.141 would establish measures directed to seeds or beans used to grow sprouts. Seeds and beans used for sprouting are believed to be the vehicle for contamination in most *E. coli* O157:H7 and *Salmonella* foodborne illness outbreaks associated with sprouts (Ref. 3. Ref. 16). Proposed § 112.141 is consistent with our Sprout Guide and other public and private programs (Ref. 50. Ref. 240).

Proposed § 112.141(a) would require that, if you grow seeds or beans for use to grow sprouts, you must take measures reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into or onto seeds or beans that you will use for sprouting. These measures would need to be taken during growing, harvesting, packing, and holding of seeds and beans, which include such activities as cleaning, conditioning, and blending.

Various crops may be grown to produce seeds and beans for sprouting with different production practices, growing seasons, conditions, and crop needs. Some of these plants set seeds or beans without intervention from growers, while others (such as alfalfa) may require steps, such as being cut-back, to encourage seed set. Harvesting, packing, and holding may also vary by seed type and by the conditions needed to maintain seed quality, such as germination. Because of the diversity of practices, processes, and procedures, the controls reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into or onto seeds or beans that you use for sprouting may vary. Therefore, we are not proposing to prescribe specific measures that are reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into or onto seeds or beans. However, you may refer to our recommendations in relevant guidances (Ref. 14. Ref. 10).

It is well-established that sprouts can become contaminated through the use of contaminated seeds for sprouting. Therefore, we considered proposing a supplier approval and verification program for seeds and beans received by sprouters for sprouting purposes. Such

a program would provide assurance that seeds or beans received from a third party for use to grow sprouts are grown, harvested, stored, and handled using measures reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into or onto seeds or beans used for sprouting.

However, a supplier approval and verification program may not be practical or effective for seeds and beans received by sprouters for sprouting purposes. For example, for most crops, only a small percentage of the harvested seeds or beans goes to sprout production (Ref. 16. Ref. 241). Several distributors sell seeds and beans primarily for agricultural use with little or no sales for sprouting (Ref. 16). Seeds and beans have a relatively long shelf-life, sometimes being stored for a year or longer, and they often pass through a number of business entities before their final sale. Therefore, the ultimate end use of seeds and beans will likely not be known by many growers, handlers, or distributors (Ref. 16. Ref. 196. Ref. 192. Ref. 197). We are also not aware of any regulatory standards that include a supplier approval and verification program for seeds and beans received by sprouters for sprouting purposes. For example, Food Standards Australia New Zealand (FSANZ) considered but did not require such a program (Ref. 242). We ask for comment on this approach and whether there are additional practical steps or practices that can be taken to ensure the safety of seeds and beans used for sprout production. Specifically, we request comments on whether a supplier approval and verification program for seeds and beans intended for sprout production is practical and effective.

We also considered whether to propose a requirement that you test incoming seeds and beans, and rejected this approach. Although epidemiological investigations often identify seeds and beans as the most likely source of contamination, contamination may be at very low levels (4 CFU/kg seed) (Ref. 16) and laboratory analyses have frequently been unable to isolate pathogens from implicated seeds or beans (Ref. 243). In a recent EFSA publication, the authors concluded that a 2-class sampling plan ''absence in 25g'', n=5; c=0, as specified in EC Regulation 2073/2005 for sprouted seeds, will not give sufficient confidence to demonstrate the absence of a target pathogen at these low levels in seeds. To increase the probability of rejection of a positive lot, the authors estimated that it would be necessary to analyze kilogram quantities of the sample (Ref. 244). Guidances from Canadian and Irish authorities include recommendations that seeds and beans be tested by the distributor, and that the sprouter obtain a Certificate of Analysis (CoA) for the seeds and beans (Ref. 240. Ref. 245), but recognize the limitations of testing seeds.

While a negative test result is not a guarantee of the absence of pathogens, a positive test result would facilitate detection of contaminated seeds and beans for destroying or diverting to non-food use. Thus, we would encourage seed suppliers and sprouters to test seed using statistically valid sampling and testing protocols. However, we tentatively conclude that testing seeds and beans is not sufficiently reliable to include as a measure necessary to prevent the introduction of known or reasonably foreseeable hazards. Instead, we propose to focus on seed treatment (proposed § 112.142) and testing spent irrigation water from each production batch of sprouts (or testing each production batch of sprouts at the in-process stage when testing spent irrigation water is not practicable) (proposed § 112.143).

When seeds or beans are used to produce sprouts, they are ''food,'' as defined in section 201(f) of the FD&C Act (Ref. 95). The definition of ''food'' in proposed § 112.3 is consistent with this interpretation. When you grow, harvest, pack, and store seeds and beans for sprouting at your operation, you know the end use of the seeds and beans, and proposed § 112.141(a) would require that you exercise control over that input into your sprout production. On the other hand, growers of seeds and beans may be unaware as to whether their crop will be used for sprout production. We seek comment on any provisions that would be effective in reducing the risk posed by contaminated seeds or beans in such cases, without also imposing an undue burden on the agricultural sector that produces seed used primarily for purposes of growing food or feed crops and not intended for use as food for human consumption as sprouts.

Proposed § 112.141(b) through (c) would establish additional requirements to ensure that seeds and beans do not serve as a vehicle for introducing contamination in sprouts. Proposed § 112.141(b) would require that if you know or have reason to believe that a lot of seeds or beans has been associated with foodborne illness, you must not use that lot of seeds or beans to produce sprouts. Contamination of seeds and beans is generally at a low level and not distributed homogeneously throughout a seed lot. Thus, a seed lot may be in distribution for some time and in use by multiple sprout farms before it is known or suspected to be contaminated. As discussed in the QAR, we are aware of outbreaks associated with multiple sprout farms using the same lot of seed. In addition, pathogens, such as *Salmonella* and *E. coli* O157:H7, can survive for an extended period of time on seeds and beans, as evidenced by outbreaks linked to seed that is a year or two old, so setting aside a potentially contaminated seed lot for later use does not reduce the likelihood of producing contaminated sprouts from that lot of seeds or beans (Ref. 16. Ref. 243). For these reasons, we have tentatively concluded that, once you know or have reason to believe that a lot of seeds or beans is contaminated, through microbial testing or implication as the vehicle in an outbreak, there is reason to believe that other parts of that lot may also be contaminated, you must not use that lot of seeds or beans to produce sprouts. This is consistent with existing guidances and standards (Ref. 16. Ref. 18. Ref. 192. Ref. 193).

Proposed § 112.141(c) would require that you visually examine seeds and beans, and packaging used to ship seeds or beans, for signs of potential contamination with known or reasonably foreseeable hazards. Visual examination of seeds and beans for sprouting, and the packaging used to ship them, provides an opportunity to see signs of potential contamination, such as rodent or bird feces or urine, which may introduce pathogens into or onto sprouts (Ref. 241. Ref. 246). Feces from rodents and birds are known to carry pathogens (Ref. 247). This proposed provision is consistent with recent FDA and international guidance (Ref. 38. Ref. 18. Ref. 192. Ref. 193).

Proposed § 112.142 would establish measures you must take for growing, harvesting, packing, and holding sprouts. Specifically, proposed § 112.142(a) would require that you grow, harvest, pack, and hold sprouts in a fully-enclosed building. Proposed § 112.142(b) would require that any food-contact surfaces you use to grow, harvest, pack, or hold sprouts must be sanitized after cleaning and before contact with sprouts or seeds or beans used to grow sprouts. As discussed in the QAR, although the source of contamination in outbreaks associated with sprouts has most often been incoming seeds or beans, pathogens can also be introduced during sprout growing, harvesting, packing, and holding.

Therefore, we are proposing these additional requirements for sprout farms (*i.e.,* conducting operations in a fully enclosed building, sanitizing food-

contact surfaces after cleaning) because we have tentatively concluded that the sprouting process represents a unique bacterial amplification step that requires a higher level of care compared to the growing, harvesting, packing, and holding of other covered produce. This proposed approach, a higher level of care compared to produce growing, harvesting, packing and holding generally, is consistent with Codex guidelines (Ref. 50).

Proposed § 112.142(c) would require you to treat seeds or beans that will be used to grow sprouts using a scientifically valid method immediately before sprouting to reduce microorganisms of public health significance. Consistent with our previous discussion of the term ''scientifically valid'' with respect to testing in the proposed rule to establish Current Good Manufacturing Practice requirements for dietary ingredients and dietary supplements (68 FR 12157 at 12198), we use the term ''scientifically valid'' to mean using an approach that is based on scientific information, data, or results published in, for example, scientific journals, references, text books, or proprietary research. Methods used for reducing microorganisms of public health significance in seeds or beans for sprouting must be scientifically valid if they are to provide assurance that they are effective.

Prior treatment conducted by a grower, handler, or distributor of seeds or beans, does not eliminate your responsibility to treat seeds or beans immediately before sprouting, at your covered farm. This proposed requirement is consistent with NACMCF recommendations and our Sprout Guide (Ref. 16. Ref. 14) and international guidance (Ref. 193. Ref. 191. Ref. 38). Specifically, NACMCF recommends that seed treatments that deliver less than a 5-log pathogen reduction be coupled with a microbial testing program. We did not cite any specific log reduction in our Sprout Guide as ''adequate to reduce pathogens.'' At that time, few if any seed treatments were thought to be capable of consistently delivering a 5-log pathogen reduction.

A number of treatments have been shown to reduce levels of, but not eliminate, pathogenic bacteria present on seeds. Such treatments are likely to reduce the level of contamination if present and, in turn, decrease the risk for foodborne disease with sprouted seeds (Ref. 16). We cited in the Sprout Guide a 20,000 ppm calcium hypochlorite treatment as an example of a treatment that has been shown to be effective for the reduction of pathogens on seed. Scientific literature indicates that the 20,000 ppm $Ca(OCl)_2$ treatment, widely adopted by sprouters who treat seed prior to sprouting, produces a 2.5 log reduction, with a range of 1.0–6.5 log reduction (Ref. 192. Ref. 201). Other chemical and physical seed disinfection treatments, alone and in combination, have been evaluated for efficacy but there is a high degree of variability in research results based on a number of factors (*e.g.,* seed type, whether seed was naturally or artificially contaminated, level of initial contamination). In their evaluation of the current state of microbiological safety of seeds and sprouts, Fett et al. (Ref. 243) present a comparison of the efficacy of select aqueous chemical disinfection treatments with $Ca(OCl)_2$ for sanitizing alfalfa seed from the literature. Canada recommends a lower level of calcium hypochlorite, 2,000 ppm (Ref. 245).

We acknowledge that several outbreaks have brought into question the effectiveness of seed disinfection treatments. For example, an outbreak of *Salmonella kottbus* in alfalfa sprouts was linked to seed that underwent a chlorine sanitization step, although records indicate the concentration of chlorine was probably lower than the recommended 20,000 ppm (Ref. 248). Conversely, in 1999, an outbreak of *Salmonella enterica* serotype Mbandaka occurred in Oregon, Washington, Idaho, and California. Based on epidemiologic and pulsed-field gel electrophoresis evidence from 87 confirmed cases, the outbreak was linked to contaminated alfalfa seeds grown in California's Imperial Valley. Trace-back and trace-forward investigations identified a single lot of seeds used by five sprout growers during the outbreak period. Cases of salmonellosis were linked with two sprout growers who had not employed chemical disinfection; no cases were linked to the three sprout growers who used seed disinfection (Ref. 249). In another outbreak of *Salmonella typhimurium* in clover sprouts linked to seed sold to multiple sprout operations, sprouters who had treated the seeds in 20,000 ppm chlorine had fewer cases attributed to their sprouts compared to those that did not (Ref. 250). This is consistent with modeling work by Montville and Schaffner, indicating that, while disinfection of seeds prior to sprouting did not guarantee pathogen free sprouts, disinfection reduced the percentage of contaminated batches. Seed disinfection was most effective when contamination was sporadic and at low levels; at a low prevalence (1 out of 10,000 25-g samples are positive), as would normally be expected, the percentage of contaminated batches was reduced from 13.7 to 0.1%. Where the initial contamination was high and uniform, the proportion of contaminated batches was reduced only from 100 to 87.7% (Ref. 251).

For these reasons we continue to believe that seed disinfection treatments are valuable as one of several measures necessary to ensure the safety of sprouts. We ask for comment on this approach.

Proposed § 112.143 would establish requirements for testing procedures you apply to the growing, harvesting, packing, and holding of sprouts. Specifically, proposed § 112.143(a) would require that you test the growing, harvesting, packing, and holding environment for *Listeria* spp. or *L. monocytogenes* (Lm) in accordance with the requirements of § 112.144. The proposed testing requirement in § 112.143(a) is in response to emerging concerns about positive sample findings and multiple recalls associated with *L. monocytogenes* in sprouts (Ref. 17. Ref. 252). Between 2002 and 2010, there have been 10 recalls involving multiple sprout types due to potential or confirmed contamination with *L. monocytogenes* (Ref. 253). In one of these recalls, the strain found in sprouts matched the strain isolated from 20 confirmed cases of listeriosis in 6 States and positive sample findings from an environmental investigation at the sprouting operation (Ref. 252).

Contamination from *L. monocytogenes* from the environment is common (Ref. 207) and, thus, targeted preventive controls to minimize *L. monocytogenes* in RTE foods are warranted. While appropriate sanitation measures can minimize the presence of environmental pathogens in a sprouting operation, we tentatively conclude that environmental monitoring is still necessary for sprouting operations as an added safety measure. Such monitoring can be conducted by testing for the specific pathogenic microorganism or by testing for an ''indicator organism,'' which can indicate conditions in which the environmental pathogen may be present. Typically, a firm that finds an indicator organism during environmental monitoring conducts microbial testing of surrounding surfaces and areas to determine the potential source of the contamination, cleans and sanitizes the contaminated surfaces and areas, and conducts additional microbial testing to determine whether the contamination has been eliminated. Further steps may be necessary if the indicator organism is

found on retest. Tests for the indicator organism *Listeria* spp. detect multiple species of *Listeria,* including the pathogen *L. monocytogenes.* For example, USDA's FSIS regulations and guidelines use *Listeria* spp. as an appropriate indicator organism for *L. monocytogenes* in for RTE meat or poultry products exposed to the processing environment after cooking to prevent product adulteration by *L. monocytogenes* (Ref. 254). FDA's current thinking is that *Listeria* spp. is an appropriate indicator organism for *L. monocytogenes,* because tests for *Listeria* spp. will detect multiple species of *Listeria,* including *L. monocytogenes,* and because the available information supports a conclusion that modern sanitation programs, which incorporate environmental monitoring for *Listeria* spp., have public health benefits. The taking of actions based on the presence of an appropriate indicator organism is protective of public health, since there will be times when steps are taken in the absence of the pathogen. Therefore, we tentatively conclude that testing the growing, harvesting, packing and holding environment for *Listeria* spp. or *L. monocytogenes* is a necessary measure to ensure the safety of sprouts.

Proposed § 112.143(b) would require that you either: (1) Test spent sprout irrigation water from each production batch of sprouts for *E. coli* O157:H7 and *Salmonella* spp. in accordance with the requirements of § 112.146; or (2) if testing spent sprout irrigation water is not practicable (for example, for soil-grown sprouts), that you test each production batch of sprouts at the in-process stage (*i.e.,* while sprouts are still growing) for *E. coli* O157:H7 and *Salmonella* spp. in accordance with the requirements of § 112.146. A production batch for which either of these pathogens is detected in the spent irrigation water for the sprouts would be considered adulterated under Section 402(a)(4) of the FD&C Act, in that it has been prepared, packed, or held under insanitary conditions whereby it may have been rendered injurious to health. A production batch for which either of these pathogens is detected in the sprouts would be considered adulterated under Sections 402(a)(1) of the FD&C Act, in that the sprouts contain a poisonous or deleterious substance which may render it injurious to health. Therefore, we tentatively conclude that microbiological testing of spent irrigation water from each production lot (or of each production batch of sprouts) is necessary to provide reasonable assurances that sprouts are not adulterated under Section 402 of the FD&C Act. The proposed testing requirement in § 112.143(b) to test spent sprout irrigation water (or sprouts) for *Salmonella* and *E. coli* O157:H7 would codify current recommendations in our Sprout Guides and is consistent with existing international guidelines and regulations (Ref. 38. Ref. 191. Ref. 193).

We are proposing these testing requirements in § 112.143(b) in addition to the proposed treatment requirements in § 112.142(c) because pathogens that are merely injured, but not killed, by seed treatment could potentially grow out again when subjected to enrichment conditions, as experienced during sprouting (Ref. 16. Ref. 74). Because seed disinfection treatments can reduce, but may not eliminate, pathogens on seed, we are proposing to require microbiological testing. Spent irrigation water that has flowed over and through sprouts is a good indicator of the types and quantities of microorganisms in the sprouts themselves (differing by only 1 log or less from the level in the sprouts) and the microflora in spent irrigation water is fairly homogeneous (Ref. 15. Ref. 198. Ref. 209). The optimal time for testing is when pathogen levels are highest (approximately 24–48 hours after the start of sprouting), but also when it is early enough in the sprouting process to obtain results before product is shipped.

We have emphasized testing irrigation water in proposed § 112.143(b) because testing sprouts has several significant disadvantages compared to testing spent irrigation water. First, contamination of sprouts is not likely to be as homogeneous as is the spent irrigation water (Ref. 243. Ref. 255). Second, multiple sprout samples must be taken from different locations in the drum or trays to ensure that the sample collected is representative of the batch. Furthermore, additional preparation (*e.g.,* selecting representative subsamples for analyses, blending or stomaching) is required when testing sprouts. Each additional step introduces a possibility for error. Consequently, testing of spent sprout irrigation water is generally preferred over testing sprouts unless production methods make it impractical to test spent sprout irrigation water. For example, spent irrigation water may not be available when sprouts are grown in soil.

We chose pathogen testing for *Salmonella* spp. and *E. coli* O157:H7 because these pathogens are the two most common agents in sprout-associated outbreaks in the U.S. (Ref. 3). Recently, EFSA concluded that there are currently no indicator organisms that can effectively substitute for the testing of pathogens in seeds, sprouted seeds or irrigation water (Ref. 244). We tentatively concur with this conclusion.

In developing our Sprout Guides in 1999 and in deliberations for this proposed rule, we also considered whether to include testing spent sprout irrigation water for *L. monocytogenes,* in addition to testing it for *Salmonella* spp. and *E. coli* O157:H7. However, we tentatively concluded that testing spent sprout irrigation water for *Listeria* has a number of potential challenges. The warm, moist, nutrient-rich conditions during sprouting encourage the proliferation of *Salmonella* and *E. coli* O157:H7 and this proliferation increases the probability of their detection, if present. In contrast, *Listeria* may be a poor competitor at the warmer temperatures and against the high level of native microflora present during the sprouting process. In addition, *Listeria* is ubiquitous. We would expect frequent positives using rapid tests for *Listeria* spp., which would not necessarily mean pathogens were present. Such testing would need to be followed by confirmatory testing to determine whether or not *L. monocytogenes* was present in order to determine appropriate actions with respect to the product. While rapid test kits are now available to screen for *L. monocytogenes,* their use on spent sprout irrigation water or sprouts would need to be validated (Ref. 14). We tentatively conclude that environmental monitoring for *Listeria* spp. or *L. monocytogenes* is the most practical approach for control of this pathogen. We request comments on this tentative conclusion.

We also considered the appropriateness of proposing provisions for testing spent sprout irrigation water for non *E. coli* O157:H7 shiga toxin-producing *E. coli* (STEC) which were involved in the recent large sprout associated *E. coli* O104 foodborne illness outbreak in Europe (Ref EU OB). The O104:H4 strain that caused the outbreak in Europe was an unusual strain that none of the tests that were being used to test for enterohaemorrhagic *E. coli* (EHEC) at that time would have picked it up. The challenge is that there are estimated to be 400 serotypes of *E. coli* that produces any one of the 3 Stx1 and/or 8 Stx2 subtypes and many of these are isolated from environmental and animal sources but have not been implicated in human illness. Many of the STEC strains entailed tedious plating and retesting to isolate and even longer to serotype (Ref. 256). For these reasons, we tentatively conclude that proposing to require testing spent sprout irrigation water for

non *E. coli* O157:H7 STECs would not be a practical approach at this time.

We request comments on this tentative conclusion, and on whether pathogens in addition to *E. coli* O157:H7 and *Salmonella* spp. should be included in testing of spent sprout irrigation water or in-process sprouts, either by specifically listing the additional pathogens or by set criteria (*e.g.,* association with one or more outbreaks linked to sprouts) for inclusion.

Proposed § 112.144 would establish requirements for how you test the growing, harvesting, packing, and holding environment for *Listeria* spp. or *L. monocytogenes.* Specifically, proposed § 112.144(a) would require that you establish and implement a written environmental monitoring plan that is designed to find *L. monocytogenes* if it is present in the growing, harvesting, packing or holding environment. Proposed § 112.144(b) would require that your written environmental monitoring plan be directed to sampling and testing for *Listeria* spp. or *L. monocytogenes.* Proposed § 112.144(c)(1) through (3) would require that your written environmental monitoring plan include a sampling plan that specifies: What you will test collected samples for (*i.e., Listeria* spp. or *L. monocytogenes*) (proposed § 112.144(c)(1)); How often you will collect environmental samples, which must be no less than monthly (proposed § 112.144(c)(2)); and Sample collection sites. The number and location of sampling sites must be sufficient to determine whether measures are effective and must include appropriate food-contact surfaces and non-food-contact surfaces of equipment, and other surfaces within the growing, harvesting, packing, and holding environment (proposed § 112.144(c)(3)). Proposed § 112.144(d) would require you to collect environmental samples and test them for *Listeria* spp. or *L. monocytogenes* according to the method in § 112.152.

Proposed § 112.144(c)(1) would require that you specify whether you will be testing for the pathogen *L. monocytogenes* or the indicator organism, *Listeria* spp. As discussed above, FDA's current thinking is that *Listeria* spp. may be an appropriate indicator organism for *L. monocytogenes,* because tests for *Listeria* spp. will detect multiple species of *Listeria,* including *L. monocytogenes.* FDA expects environmental monitoring to be conducted with sufficient frequency to detect the environmental pathogen or appropriate indicator organism if present. We tentatively conclude that monthly sampling and testing is a minimum requirement (proposed § 112.144(c)(2)). More frequent testing may be needed. For example, the frequency of monitoring for environmental pathogens should increase as a result of finding the environmental pathogen or an indicator of the environmental pathogen or as a result of situations that pose an increased likelihood of contamination, *e.g.,* construction (Ref. 211. Ref. 212). The frequency of taking environmental samples will vary depending on existing data on the presence of the environmental pathogen of concern in the environment where foods are exposed to the environment. In the absence of information, data should be generated to assist in determining the frequency of monitoring (Ref. 257). We request comment on whether the minimum frequency of at least monthly for environmental monitoring is adequate to assess whether the measures taken to minimize the risk associated with *L. monocytogenes* in sprouts are effective. We tentatively conclude that specifying the frequency of testing in the written environmental monitoring plan is necessary to enable assurance by the operator and verification by FDA that testing efforts are consistent with a carefully thought through effort to find the environmental pathogen if it is present in the environment.

The purpose of environmental monitoring is to verify the implementation and effectiveness of sanitation measures for controlling the presence of *L. monocytogenes* in the sprout production environment. The monitoring must be designed to find environmental pathogens that remain in the sprouting operation after routine cleaning and sanitizing procedures in order to prevent contamination of product that could lead to illness. To accomplish this purpose, there must be a scientific basis for the locations selected for sampling, the number of samples taken, the frequency of sampling, the sampling procedures used and the test methodology. The sampling must be biased—*i.e.,* the locations to be tested must be those in which the environmental pathogens can enter the environment where the food is exposed and those areas where harborage of the pathogen is likely (Ref. 258).

One approach to defining sampling locations is to divide the sprouting operation into zones based on the likelihood of contamination of the product. A common industry practice is to use four zones (Ref. 213. Ref. 212): Zone 1 consists of food-contact surfaces; Zone 2 consists of non-food-contact surfaces in close proximity to food and food-contact surfaces; Zone 3 consists of more remote non-food-contact surfaces that are in the area used for growing, harvesting, packing, and holding and could lead to contamination of zones 1 and 2; and Zone 4 consists of non-food-contact surfaces, outside of the area used for growing, harvesting, packing, and holding from which environmental pathogens can be introduced into the growing, harvesting, packing, and holding environment. Generally the number of samples and frequency of testing is higher in zones 1 and 2 because of the greater likelihood of food contamination if the environmental pathogen is present in these zones. Information on appropriate locations for sampling within these zones can be found in the literature (Ref. 175. Ref. 212). Operators should become familiar with locations in which environmental pathogens have been found in other sprout firms and use this information in selecting sites to sample.

L. monocytogenes frequently establishes itself in a harborage site on equipment and grows (increases in number) there, where both food and moisture are available. *L. monocytogenes* organisms work their way out of the harborage site during production and contaminate food. Testing food-contact surfaces for *Listeria* spp. is a commonly recommended verification measure for firms producing refrigerated RTE foods (Ref. 175. Ref. 211).

Examples of appropriate non-food-contact surfaces that could be monitored include exteriors of equipment, equipment supports, control panels, door handles, floors, drains, refrigeration units, ducts, overhead structures, cleaning tools, and motor housings. Standing water in growing, harvesting, and packing areas and areas that have become wet and then have dried are also appropriate places to monitor. Testing non-food-contact surfaces for *L. monocytogenes* or *Listeria* spp. is a commonly recommended verification measure for firms producing refrigerated or frozen RTE foods (Ref. 258. Ref. 259) and can detect *L. monocytogenes* that is brought into the plant by people or objects. Actions you then take can prevent transferring the organisms to a food-contact surface (where they can contaminate food) or from establishing a harborage that can serve as a source of contamination.

Proposed § 112.145 would establish requirements for actions you must take if you detect *Listeria* spp. or *L. monocytogenes* in the growing, harvesting, packing, or holding environment, *i.e.,* Conduct additional microbial testing of surfaces and areas surrounding the area where *Listeria* spp.

or *L. monocytogenes* was detected to evaluate the extent of the problem, including the potential for *Listeria* spp. or *L. monocytogenes* to have become established in a niche (proposed § 112.145(a); Clean and sanitize the affected surfaces and surrounding areas (proposed § 112.145(b)); Conduct additional microbial sampling and testing to determine whether the *Listeria* spp. or *L. monocytogenes* has been eliminated (proposed § 112.145(c)); Conduct finished product testing when appropriate (proposed § 112.145(d)); and Perform any other actions necessary to prevent reoccurrence of the problem (proposed § 112.145(e)). Testing the environment of a sprouting operation for *L. monocytogenes* (or for *Listeria* spp. as an indicator of potential contamination with *L. monocytogenes*), and taking actions to eliminate *L. monocytogenes* or *Listeria* spp. when found in the environment of a sprouting operation, is an important component of controlling microorganisms of public health significance (Ref. 175. Ref. 211). The actions we are proposing to require, including additional testing to determine the extent of contamination, ensuring contamination is eliminated and taking steps to prevent its recurrence, are consistent with recommendations in our *Listeria* Guide (Ref. 260).

If an environmental pathogen or an appropriate indicator organism (the test organism) is detected in the environment, steps must be taken to eliminate the organism, including finding a harborage site if one exists (Ref. 175. Ref. 211) (Ref. 257). Otherwise, the presence of the environmental pathogen could result in contamination of food-contact surfaces or food. The presence of the indicator organism suggests that conditions exist in which the environmental pathogen may be present and could result in contamination of food-contact surfaces or food. Actions must be taken for every finding of an environmental pathogen or indicator organism in the environment to prevent contamination of food-contact surfaces or food.

Sampling and microbial testing from surfaces surrounding the area where the test organism was found (proposed § 112.145(a)) are necessary to determine whether the test organism is more widely distributed than on the original surface where it was found and to help find the source of contamination if other sites are involved. Cleaning and sanitizing the contaminated surfaces and surrounding areas (proposed § 112.145(b)) are necessary to eliminate the test organism that was found there. Additional sampling and microbial testing (proposed § 112.145(c)) are necessary to determine the efficacy of cleaning and sanitizing. For example, detection of the test organism after cleaning and sanitizing indicates that the initial cleaning was not effective, and additional, more intensified cleaning and sanitizing, or other actions may be needed, including dismantling equipment, scrubbing surfaces, and heat-treating equipment parts (Ref. 207). The finding of a test organism on a food-contact surface usually represents transient contamination rather than a harborage site (Ref. 259). However, finding the test organism on multiple surfaces in the same area, or continuing to find the test organism after cleaning and sanitizing the surfaces where it was found, suggests a harborage site for the test organism. Mapping the location of contamination sites, whether the harborage site is on equipment or in the environment, can help locate the source of the harborage site or identify additional locations to sample (Ref. 257).

Proposed § 112.145 would not specify how certain actions must be performed, such as the number of sites to test when the test organism is found in a sprouting operation, or how to clean and sanitize the surfaces on which the test organism was detected. The number of sites appropriate for testing and the applicable cleaning and sanitizing procedures will depend on the sprouting operation and the equipment. We tentatively conclude that, when microbial testing is conducted as part of steps in light of the results of environmental monitoring, specifying such procedural requirements would not provide facilities with sufficient flexibility to develop and implement aggressive and appropriate actions to find and eliminate the source of the contamination in the environment. Such actions may involve investigative procedures when the initial measures have not been successful in eliminating the environmental pathogen or indicator organism. One example of an investigative procedure is taking samples from food-contact surfaces and/or produce at multiple times during the day while the equipment is operating and producing product (Ref. 207).

Proposed § 112.145(d) would require that if environmental monitoring identifies the presence of an environmental pathogen or indicator organism, the operator conduct finished product testing, when appropriate. As discussed in section IV.I. of this document, there are shortcomings for microbiological testing of food for process control purposes. Testing cannot ensure the absence of a hazard, particularly when the hazard is present at very low levels and is not uniformly distributed. If an environmental pathogen is detected on a food-contact surface, finished product testing would be appropriate only to confirm actual contamination or assess the extent of contamination, because negative findings from product testing could not adequately assure that the environmental pathogen is not present in food exposed to the food-contact surface. If you detect an environmental pathogen on a food-contact surface, the sprouting operation should presume that the produce is adulterated under Section 402(a)(4) of the FD&C Act.

Finished product testing could be appropriate if an environmental pathogen is detected on a non-food-contact surface, such as on the exterior of equipment, on a floor or in a drain. The potential for food to be contaminated directly from contamination in or on a non-food-contact surface is generally low, but transfer from non-food-contact surfaces to food contact surfaces can occur. Finished product testing can provide useful information on the overall risk of a food when pathogens have been detected in the environment.

Proposed § 112.145(e) would require that if environmental monitoring identifies the presence of an environmental pathogen or appropriate indicator organism, the operator perform any other steps necessary to prevent recurrence of the contamination. Actions taken as a result of monitoring for an environmental pathogen or an indicator organism for such pathogen must ensure these requirements are met. The measures for environmental monitoring specified in proposed § 112.145(a) through (d) are not all inclusive. Examples of measures that may be necessary include reinforcing employee hygiene practices and traffic patterns; repairing damaged floors; eliminating damp insulation, water leaks, and sources of standing water; replacing equipment parts that can become harborage sites (*e.g.,* hollow conveyor rollers and equipment framework), and repairing roof leaks (Ref. 180. Ref. 219). Additional information on measures for environmental monitoring can be found in the literature (Ref. 180. Ref. 221. Ref. 219). Proposed § 112.145 is consistent with the FSIS *Listeria* Guidelines (Ref. 254).

Proposed § 112.146 would establish requirements for how you collect and test samples of spent sprout irrigation water or sprouts. Specifically, proposed § 112.146(a) would require that you establish and implement a written

sampling plan that identifies the number and location of samples (of spent sprout irrigation water or sprouts) to be collected for each production batch of sprouts to ensure that the collected samples are representative of the production batch when testing for contamination. Additionally, proposed § 112.146(b) would require that, in accordance with the written sampling plan required under paragraph (a) of this section, you aseptically collect samples of spent sprout irrigation water or sprouts, and test the collected samples for *E. coli* O157:H7 and *Salmonella* spp. using a method that has been validated for its intended use (testing spent sprout irrigation water or sprouts) to ensure that the testing is accurate, precise, and sensitive in detecting these pathogens. This proposed provision is consistent with recommendations in our Sprout Testing Guide, the Canada and Irish Codes and the FSANZ standard (Ref. 15. Ref. 206. Ref. 201. Ref. 203).

One means to test for *E. coli* O157:H7 and *Salmonella* spp. as required under proposed § 112.146(b) is to follow our guidance on sampling and testing spent irrigation water or sprouts (Ref. 15). The methods described in our guidance have been validated to be effective on spent sprout irrigation water and sprouts (Ref. 15. Ref. 223. Ref. 224). The effectiveness of detection methods can vary depending on multiple factors, including but not limited to whether the sample tested is representative of the food, type of food, level of microflora present, the enrichment procedure and type of test used. Spent sprout irrigation water and sprouts have a high level of natural microflora that can interfere with detection (Ref. 15. Ref. 243). Therefore, other methods that have been validated to be effective for other foods may not work for spent sprout irrigation water and sprouts. Because the microflora in spent sprout irrigation water is more homogeneous compared to seeds or sprouts, sampling procedures described in our guidance for sprout irrigation water are relatively simple. In addition, spent sprout irrigation water can be used directly in the test procedures described in our guidance, thus reducing the possibility of error (Ref. 15. Ref. 243). Sampling spent sprout irrigation water or sprouts is an important testing procedure to ensure contaminated product does not enter commerce. The testing procedures described in our guidance give accurate results as quickly and simply as possible on the presence or absence of *E. coli* O157:H7 and *Salmonella* spp.

Proposed § 112.150 would establish requirements for records that you must establish and keep regarding sprouts. Under proposed § 112.150(a), you must establish and keep the required records in accordance with the requirements of proposed subpart O. As discussed in section V.O. of this document, proposed subpart O would establish general requirements applicable to all records.

Proposed § 112.150(b) would require you to establish and keep the following records: Documentation of your treatment of seeds or beans to reduce microorganisms of public health significance in the seeds or beans, at your farm (proposed § 112.150(b)(1)); your written environmental monitoring plan in accordance with the requirements of § 112.144 (proposed § 112.150(b)(2)); your written sampling and testing plan for each production batch of sprouts in accordance with the requirements of § 112.146(a) (proposed § 112.150(b)(3)); the results of any testing conducted in accordance with the requirements of §§ 112.143 and 112.144 (proposed § 112.150(b)(4)); any analytical methods you use in lieu of the methods that are incorporated by reference in § 112.152 (proposed § 112.150(b)(5)); and the testing method you use in accordance with the requirements of § 112.146(b) (proposed § 112.150(b)(6)). We are proposing to require you to keep the above records specific to sprout operations in order to help document your compliance with the provisions of this rule. We tentatively conclude that such records are needed for us to verify and you to ensure that appropriate measures are being followed consistently and correctly (*e.g.,* your sampling plan for spent sprout irrigation water from each production lot). The records would also allow FDA or you to identify trends that might signal a need to adjust the measures in your environmental monitoring plan to improve its effectiveness and reliability (*e.g.,* test results from your environmental monitoring program may signal the need to enhance sprouting operation cleaning and sanitation).

N. Subpart N—Analytical Methods

Proposed subpart N would specify methods of analysis for testing the quality of water and the growing environment for sprouts, as required under proposed subparts E and M (see sections V.E. and V.M., respectively, of this document).

Proposed § 112.151 would establish that you must test the quality of water to satisfy the requirements of § 112.45 by one of three methods: (1) Official methods of analysis published by the AOAC International; (2) standards methods for the examination of water and wastewater as published by the American Public Health Association; or (3) methods prescribed in the FDA Bacteriological Analytical Manual, or by another method that is at least equivalent to the above-mentioned three methods in accuracy, precision and sensitivity in detecting *E. coli.*

Proposed § 112.151(a)(1) provides for the use of official methods of analysis published by AOAC International in the latest edition of their publication ''Official Methods of Analysis of the Association of Official Analytical Chemists,'' 18th edition, revision 4 (published in 2011). The Official Methods of Analysis of AOAC International (18th Ed., revision 4, 2011) would be incorporated by reference with the approval of the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR Part 5.

Proposed § 112.151(a)(2) would establish that methods of analysis published in the Standard Methods for the Examination of Water and Wastewater (21st Edition, 2005), American Public Health Association would be acceptable for testing the quality of water. In addition, the Standards Methods for the Examination of Water and Wastewater, (21st Ed., 2005), would be incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 5.

Proposed § 112.151(a)(3) would establish that methods of analysis published in Chapter 4 of the FDA Bacteriological Analytical Manual (Edition 8, Revision A, 1998) (BAM), as updated in June 2011, would be acceptable for testing the quality of water. In addition, Chapter 4 of the BAM (Edition 8, Revision A, 1998), as updated in June 2011, would be incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 5. With advances in science and as appropriate, FDA periodically updates the BAM to add newer methods or revise existing ones. For the purposes of this proposed rule, we refer to Chapter 4 of the BAM (edition 8, revision A, published in 1988) as updated in June 2011. However, should FDA update or revise the methods and procedures currently listed in Chapter 4 of the June 2011 version, for the purpose of testing the quality of water, we encourage industry to use such relevant, updated methods and procedures.

Proposed § 112.151(a)(4) would provide for the use of a method that is at least equivalent in accuracy, precision, and sensitivity to the methods in § 112.151(a)(1), (a)(2) or (a)(3). Test kit methods are generally not published in the literature due to their proprietary nature. FDA is aware of

programs, such as the AOAC Research Institute's Performance Tested Methods Program that provides an independent third-party review of proprietary test method performance. Test methods demonstrated to meet acceptable performance criteria are granted Performance Test Methods (PTM) status. The PTM certification assures users that an independent assessment has found that the test method performance meets an appropriate standard for the claimed use. FDA would consider methods, particularly test kit methods, approved by the PTM program or other similar programs acceptable for testing the quality of water. FDA is also aware that there are numerous scientific testing and diagnostic development companies that have invented rapid tests and systems for pathogens and water quality. Many of these products undergo rigorous internal quality control and performance testing, as well as receive additional third-party and/or regulatory approvals. FDA is also aware that the Environmental Protection Agency (EPA) approves analytical methods that industrial and municipal facilities use to determine pollutants of wastewater (published in 40 CFR Part 136) and to meet federal requirements or to demonstrate compliance with drinking water and ground water regulations (40 CFR 141.402 and 40 CFR 141.403). For example, the EPA, has approved the use of E*Colite® Test, m-ColiBlue 24® Test, and Colitag® Test for compliance monitoring related to EPA's Ground Water Rule. FDA would consider these tests acceptable for testing the quality of water to satisfy the requirements of § 112.45.

Proposed § 112.152 establishes the methods you must use to test the growing environment for *Listeria* spp. or *L. monocytogenes* to satisfy the requirements of §§ 112.143(a) and 112.144. As proposed, you must test environmental samples using the methods and procedures described in Chapter 10 of the BAM, ''*Listeria monocytogenes,* Detection and Enumeration of *Listeria monocytogenes* in Foods.'' Chapter 10 of the BAM (Edition 8, Revision A, 1998), as updated in April 2011, would be incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 5. With advances in science and as appropriate, FDA periodically updates the BAM to add newer methods or revise existing ones. For the purposes of this proposed rule, we refer to Chapter 10 of the BAM (Edition 8, revision A, published in 1998) as updated in April 2011. However, should FDA update or revise the methods and procedures currently listed in Chapter 10 of the April 2011 version, for the purpose of testing the growing environment for *Listeria* spp. or *L. monocytogenes,* we encourage industry to use such relevant, updated methods and procedures.

Proposed § 112.152 would also provide for the use of a method at least equivalent in accuracy, precision, and sensitivity in detecting *Listeria* spp. or *L. monocytogenes* as is the method described in Chapter 10 of the BAM. For example, prescribed rapid detection kits with their respective enrichment media may be conditionally used to screen for presence of *Listeria* contaminants. Isolates may be rapidly positively or negatively confirmed as *L. monocytogenes* by using specific test kits. FDA is aware that there are numerous scientific testing and diagnostic development companies that have invented rapid tests and systems for *Listeria* spp. or *L. monocytogenes.* Many of these products undergo rigorous internal quality control and performance testing, as well as receive additional third-party and/or regulatory approvals. As discussed above in proposed § 112.151(a)(4), FDA would consider methods, particularly test kit methods, approved for example by the AOAC Research Institute's Performance Tested Methods Program PTM program or other similar, acceptable for testing *Listeria* spp. or *L. monocytogenes.*

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

As proposed, subpart O discusses the general requirements applicable to documentation and records that you must establish and maintain under proposed part 112.

1. Comments Relevant to the Proposed Requirements

We received several comments in response to the 2010 FR notice that addressed issues relevant to establishing and maintaining documents and records. Comments expressed concern over the costs of complying with record keeping requirements. Several comments also stated that there should not be a requirement for electronic record keeping for farmers, especially if they are small-scale. One comment requested that, to protect the confidentiality of individual farm businesses, any recordkeeping requirements be accompanied by assurance that information accessed by federal government authorities with respect to food safety protocols will remain confidential. Another comment requested that we consider pre-existing records kept by the produce industry for other purposes, so as to avoid duplication, while another farmer commented that records or documents would not ensure safety and, therefore, asked that records should be required for only annual activities, such as employee training and surveys of surrounding land activities. Finally, several comments indicated that the current legal liability system in the United States serves to discourage any grower or packing house from keeping additional detailed records related to food safety and that such records are subject to intrusive judicial subpoena power.

We believe that documentation of some practices is critical to ensure that science-based minimum produce safety standards proposed in this rule are adequately implemented on the farm. Records are useful for keeping track of detailed information over a period of time. Records can identify patterns of problems and, thus, enable a farm to find and correct the source of problems. Records are also useful for investigators during inspections to determine compliance with requirements (*e.g.,* by FDA investigators to determine compliance with requirements that would be established by this rule, or by a third party auditor that a farm or retailer may voluntarily engage under a business arrangement between the farm and the retailer). Therefore, we tentatively conclude that records of only annual activities are insufficient to ensure produce safety. However, in determining those circumstances in which records are necessary as part of science-based minimum standards that minimize the risk of serious adverse health consequences or death and provide reasonable assurances that produce is not adulterated under section 402 of the FD&C Act, we considered the statutory direction in section 419(c)(1)(C) of the FD&C Act to comply with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*) ''with special attention to minimizing'' the recordkeeping burden on the business and collection of information as defined in that act. We propose to require records in instances where maintenance of detailed information is needed to keep track of measures directed at minimizing the risk of known or reasonably foreseeable hazards, where identification of a pattern of problems is important to minimizing the risk of such hazards, or where they are important to facilitate verification and compliance with standards and this cannot be effectively done by means other than a review of records. See section IV.E of this document for further discussion.

We appreciate the concerns expressed by some commenters with respect to cost and burden to farms. To the extent possible, we attempted to propose documentation requirements that are risk-based and capable of being tailored to your individual farm, taking into account the unique characteristics of the operation, the commodities handled, and the operation's growing, harvesting, packing, and holding procedures. A large majority of growers, farmers, and producers indicated during listening sessions and other stakeholder discussions that they already practice good agricultural practices and keep adequate records. They agreed that such recordkeeping is necessary. Moreover, they indicated that the cost of a large scale recall event would have the potential to far exceed the cost of routine record keeping.

As proposed, the recordkeeping requirements allow the use of existing records and do not require duplication, provided such records satisfy all of the applicable requirements of this part (see proposed § 112.163). In addition, per proposed § 112.165, electronic records would be acceptable but would not be required by this subpart. Records would be acceptable under this subpart if kept in forms as diverse as hard copies of handwritten logs, invoices, and documents reporting laboratory results, provided that they are indelible and legible.

We understand the concerns regarding confidentiality. Our disclosure of information is subject to the Freedom of Information Act (FOIA) (5 U.S.C. 552), the Trade Secrets Act (18 U.S.C. 1905), the FD&C Act, and our implementing regulations under part 20, which include protection for confidential commercial information and trade secrets. We note that many segments of the food industry already are subject to food safety-related recordkeeping requirements similar to those proposed in this subpart. Other existing food safety regulations, such as the infant formula quality control procedures regulation (§ 106.100), the dietary supplement regulation (§ 111.605 and § 111.610), the acidified foods regulation (§ 114.100), the regulation on production, storage, and transportation of shell eggs (§ 118.10), the juice HACCP regulation (§ 120.12), and the seafood HACCP regulation (§ 123.9) require similar record keeping. In addition, many farmers that are part of the various programs such as National Organic Program and LGMA already have similar recordkeeping requirements (Ref. 45. Ref. 261). Recordkeeping has proven useful for the above-mentioned food industries and, thus far, we are not aware that any of these industries has been adversely affected by excessive judicial subpoenas resulting from their recordkeeping.

2. Proposed Requirements

Proposed subpart O would establish requirements that would be applicable to all records required by part 112. FDA tentatively concludes that the requirements in subpart O describing how records must be established and maintained, including the general requirements, record retention requirements, and requirements for official review and public disclosure, are applicable to all records that would be required under all subparts, because records that would be required under each of the subparts would aid farms in complying with the requirements of part 112; and allow farms to show, and FDA to determine, compliance with the requirements of part 112.

a. General Requirements

As proposed, § 112.161(a)(1) requires that your records include: (i) The name and location of your farm; (ii) actual values and observations obtained during monitoring; (iii) 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; (iv) 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 (v) the date and time of the activity documented.

The name and location of your farm and the date and time would allow the owner, operator, or agent in charge of a farm (and, during inspection, an FDA investigator) to assess whether the record is current and establish the relevance of the record to your farm, which is necessary for review by regulators. An adequate description of covered produce would allow the farm to more readily track measures, identify a pattern of problems, and verify compliance. Such a description will also allow the farm to identify specific produce for which the standards of this part have not been met, and to take appropriate measures as provided for under § 112.11.

Recording actual values and observations during monitoring are necessary to produce an accurate record. Notations that monitoring measurements are ''satisfactory'' or ''unsatisfactory,'' without recording the actual times and observations (*e.g.,* temperatures and turnings in treating biological soil amendments of animal origin) are vague and subject to varying interpretations and, thus, will not ensure that required measures have been taken or standards have been met. In addition, it is not possible to discern a trend without actual measurement values.

Proposed § 112.161(a)(1) is consistent with our HACCP regulations for seafood and juice. Our HACCP regulations for seafood and juice require that all records include the name and location of the processor; the date and time of the activity that the record reflects; the signature or initials of the person performing the operation; and where appropriate, the identity of the product and the production code, if any (§§ 123.9(a) and 120.12(b), respectively). Our HACCP regulations for seafood and juice also require that records contain the actual values (such as temperature) and observations obtained during monitoring (§§ 123.6(c)(7) and 120.12(b)(4), respectively).

Additional requirements in proposed § 112.161(a) include that records must be created at the time an activity is performed or observed (proposed § 112.161(a)(2)); be accurate, legible, and indelible (proposed § 112.161(a)(3)); and be dated, and signed or initialed by the person who performed the activity documented (proposed § 112.161(a)(4)).

These requirements would ensure that the records are useful to the owner, operator, or agent in charge of a farm in complying with the requirements of part 112, for example, in documenting compliance with monitoring requirements. These proposed requirements would also ensure that the records would be useful to FDA in determining compliance with the requirements of part 112. For example, the signature of the individual who made the observation would ensure responsibility and accountability. In addition, if there is a question about the record, a signature would ensure that the source of the record will be known. These proposed requirements are consistent with our HACCP regulations for seafood and juice. Our HACCP regulations for seafood and juice require that processing and other information be entered on records at the time that it is observed (§§ 123.9(a)(4) and 120.12(b)(4), respectively).

As proposed, under § 112.161(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. This documentation is necessary to show that you have taken the steps reasonably

necessary to minimize the risk of serious adverse health consequences or death from the use of, or exposure to, covered produce, including those measures reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into covered produce, and to provide reasonable assurances that the produce is not adulterated under section 402 of the FD&C Act. For example, if under § 112.44(b) you are required to discontinue the use of agricultural water and take corrective steps, this provision would require you to establish and keep a record of the corrective steps that you took.

As proposed, § 112.161(c) would require a supervisor or responsible party to review, date, and sign those records that are 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). These records relate to certain of your testing, monitoring, sanitizing, and corrective action activities. As described above, one of the primary purposes for establishing and maintaining records is so that you can review the records to see if the requirements of this part have been met. Requiring a signature from a supervisor or responsible party for these records emphasizes the importance of such a review.

b. Storage of Records

Proposed § 112.162 would establish the requirements regarding where your records must be stored. Proposed § 112.162(a) establishes that offsite storage of records is permitted after 6 months following the date the record was made if such record can be retrieved and provided onsite within 24 hours of request for official review. FDA realizes that the proposed requirements for recordkeeping could require some farms to store a significant quantity of records, and that there may not be adequate storage space in the farm for these records. Providing for offsite storage of most records after 6 months would enable a farm to comply with the proposed requirements for record retention while reducing the amount of space needed for onsite storage of the records without interfering with the purpose of record retention, because the records will be readily available. Proposed § 112.162(b) would clarify that electronic records are considered to be onsite at your farm if they are accessible from an onsite location at your farm. For example, we would consider electronic records to be onsite if they were available from your computer, including records transmitted to your computer via a network connection or accessed from either the Internet or electronic or digital storage applications.

Proposed § 112.162 is consistent with our HACCP regulations for seafood and juice. Our HACCP regulation for seafood provides for transfer of records if record storage capacity is limited on a processing vessel or at a remote processing site, if the records could be immediately returned for official review upon request (§ 123.9(b)(3)). Our HACCP regulation for juice permits offsite storage of processing records after 6 months following the date that the monitoring occurred, if such records can be retrieved and provided onsite within 24 hours of request for official review and considers electronic records to be onsite if they are accessible from an onsite location (§ 120.12(d)(2)). We seek comment on the appropriateness of the proposed recordkeeping requirements.

c. Use of Existing Records

As proposed, § 112.163 would clarify that the regulations in this part do not require duplication of existing records if those records contain all of the information required by this part. In this provision, we seek to minimize the burden of keeping records to that which is necessary to accomplish the intended purposes of this part.

For example, as proposed, you are not required to duplicate existing records, such as records kept to satisfy the requirements of the National Organic Program, if those records contain all of the information required by this part. Additionally, you are not required to keep all of the information required by this part in one set of records. Similarly, if you have records containing some but not all of the required information, this proposed regulation provides you the flexibility to keep any additional information required by this part either separately or combined with your existing records. While we propose this provision to give you the greatest degree of flexibility, we remind you that keeping records together in one place likely will expedite review of records in the event of a public health emergency or during an FDA inspection or investigation.

d. Length of Time for Records Storage

Proposed § 112.164(a) would require that you keep records required by this part for two years after the date the record was created. Retaining records for at least this length of time is necessary to ensure that the records are available for reference during verification activities as well as during FDA inspections. It is also critical for documentation and observation of trends of the food safety risks that may affect your operation over time. Multi-year retention of records allows an owner, operator, or agency to better understand and proactively respond to the risk factors affecting his or her farm. Since many weather events, such as drought or floods, which have an influence on the safety of fresh produce are relatively rare; maintaining historical records to inform the development of preventive controls specific to a given operation is invaluable. Similarly, proposed § 112.164(b) would establish that records that relate to the general adequacy of the equipment or processes being used by a farm, including the results of scientific studies and evaluations, must be retained at the farm for at least two years after the use of such equipment or processes is discontinued.

Certain growers and packers of covered produce currently retain records for at least two years. For example, produce operations certified by the National Organic Program must maintain their records relating to the production, harvesting, and handling of ''organic'' agricultural products for at least five years beyond the creation of the records (7 CFR 205.103). USDA's Agricultural Marketing Service requires that restricted use pesticide records be maintained for two years from the date of pesticide application (7 CFR 110.3). Under USDA's regulations implementing the Perishable Agricultural Commodities Act, 1930 (PACA), packers who pack and sell another firm's produce and growers and packers who voluntarily obtain a PACA license are required to preserve records for two years (7 CFR 46.14). Under the Florida Tomato Rule (''Tomato Good Agricultural Practices [T–GAP] & Tomato Best Management Practices'') (Ref. 262), firms must keep records documenting adherence to T–GAPs, ''including those addressing environmental review, water usage, record of completed education and training, pest control and crop production practices for the operation,'' for at least three calendar years (Ref. 44). Participants in the California Leafy Green Marketing Agreement (LGMA) must maintain their records kept under the LGMA agreement for two years (Ref. 45).

e. Acceptable Formats for Records

As proposed, § 112.165 would require that you keep records as either: (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. True copies of records should be of sufficient quality to detect whether the original record was changed or corrected in a manner that obscured the original entry (*e.g.,* through the use of white-out). Proposed § 112.165 would provide flexibility for mechanisms for keeping records while maintaining the integrity of the recordkeeping system. The proposed requirement allowing true copies is consistent with other regulations such as our Good Manufacturing Practices (GMPs) regulation for dietary supplements (§ 111.605(b)) and provides options that may be compatible with the way records are currently being kept in plants and facilities.

Proposed § 112.165 also would require that electronic records be kept in accordance with part 11 (21 CFR part 11). Part 11 provides criteria for acceptance by FDA, under certain circumstances, of electronic records, electronic signatures, and handwritten signatures executed to electronic records as equivalent to paper records and handwritten signatures executed on paper. The proposed requirement clarifies and acknowledges that records required by part 112 may be retained electronically, provided that they comply with part 11.

FDA tentatively concludes that it is appropriate to apply the requirements of part 11 to the records that would be required to be kept under part 112. However, we request comment on whether there are any circumstances that would warrant not applying part 11 to records that would be kept under part 112. For example, would a requirement that electronic records be kept according to part 11 mean that current electronic records and recordkeeping systems would have to be recreated and redesigned, which we determined to be the case in the regulation Establishment and Maintenance of Records Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (69 FR 71562; December 9, 2004 (the BT records regulation))? For the purposes of the records requirements in the BT records regulation, we concluded that it was not necessary for new recordkeeping systems to be established as long as current practices would satisfy the requirements of the Act and, therefore, we exempted the records from the requirements of part 11 (21 CFR 1.329(b)). We also exempted records related to certain cattle materials prohibited from use in human food and cosmetics from part 11 (21 CFR 189.5(c)(7) and 700.27(c)(7), respectively). We also seek comment on whether we should allow additional time for electronic records to be kept in accordance with part 11. Comments should provide the basis for any view that the requirements of part 11 are not warranted.

f. Making Records Available for Official Review

Proposed § 112.166(a) would require that you 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. Our access to records required under this part would expedite efforts to document and ensure that covered produce is not adulterated, as well as to quickly and accurately identify any adulterated covered produce and prevent it from reaching consumers. For example, during a foodborne illness outbreak or contamination investigation, records access would help enable you and us to pinpoint the source and cause of contamination in a timely manner. This provision is consistent with our HACCP regulations for juice (§ 120.12(e)) and seafood (§ 123.9(c)), and dietary supplement GMPs (§ 111.610(b)), which require that all records required under those rulemakings be available for review and copying at reasonable times. This provision also is similar to requirements in the infant formula quality control procedures regulation (§ 106.100(l)) stating that manufacturers make readily available for authorized inspection all records required under those regulations. In addition, this proposed provision is similar to provisions in the juice HACCP regulation (§ 123.9(f)) and in the regulation on production, storage, and transportation of shell eggs (§ 118.10(d)) that require that firms be able to retrieve and provide any records stored offsite within 24 hours of request for official review.

Proposed § 112.166(b) would require that 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, that you provide the records to us in a format in which they are accessible and legible. For example, you might provide us with an unencrypted copy of an electronic record or provide us with suitable equipment for viewing, printing, and copying a record. This provision would enable us to comprehend your records in a timely manner.

Consistent with proposed § 112.166(a), proposed § 112.166(c) would require that 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. Allowing for transfer of records will give practical storage relief to seasonal operations or those closed for other reasons for prolonged periods. Proposed § 112.166(c) is consistent with our HACCP regulations for seafood and juice, which provide for transfer of records for facilities closed for prolonged periods (between seasonal packs, in the case of juice) if the records could be immediately returned for official review upon request (§§ 123.9(b)(3) and 120.12(d)(3) for seafood and juice, respectively).

g. Disclosure Requirements

Proposed § 112.167 would specify that records required by this part are subject to the disclosure requirements under part 20 of this chapter. FDA's regulations in 21 CFR part 20, FOIA, the Trade Secrets Act [18 U.S.C. 1905], and the FD&C Act govern FDA's disclosures of information, including treatment of confidential commercial information and trade secret information. Our general policies, procedures, and practices relating to the protection of confidential information received from third parties would apply to information received under this rule. Proposed § 112.167 is consistent with, but framed differently than, the disclosure provisions of the HACCP regulations for seafood and juice (§§ 123.9(d) and 120.12(f), respectively). Proposed § 112.167 is framed similarly to the disclosure provisions for records that must be kept under part 118 (Prevention of *Salmonella Enteritidis* in Shell Eggs During Production); under § 118.10(f), records required by part 118 are subject to the disclosure requirements under part 20.

P. Subpart P—Variances

1. Relevant Provisions of Section 419 of the FD&C Act

In section 419(c), the FD&C Act establishes criteria for the final regulation, including that the final regulation ''permit States and foreign countries from which food is imported into the United States to request from the Secretary variances from the requirements of the regulations, subject to [section 419(c)(2) of the FD&C Act], where the State or foreign country determines that the variance is necessary in light of local growing conditions and that 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 FD&C Act] and to provide the same level of public health protection as the requirements of the regulations adopted under [section 419(b) of the FD&C Act]'' (section 419(c)(1)(F)). Section 419(c)(2) specifies the following:

''REQUESTS FOR VARIANCES.—A State or foreign country from which food is imported into the United States may in writing request a variance from the Secretary. Such request shall describe the variance requested and present information demonstrating that the variance does not increase the likelihood that the food for which the variance is requested will be adulterated under section 402, and that the variance provides the same level of public health protection as the requirements of the regulations adopted under [section 419(b) of the FD&C Act]. The Secretary shall review such requests in a reasonable timeframe'' (section 419(c)(2)(A)).

''APPROVAL OF VARIANCES.—The Secretary may approve a variance in whole or in part, as appropriate, and may specify the scope of applicability of a variance to other similarly situated persons'' (section 419(c)(2)(B)).

''DENIAL OF VARIANCES.—The Secretary may deny a variance request if the Secretary determines that such variance is not reasonably likely to ensure that the food is not adulterated under section 402 and is not reasonably likely to provide the same level of public health protection as the requirements of the regulation adopted under [section 419(b) of the FD&C Act]. The Secretary shall notify the person requesting such variance of the reasons for the denial'' (section 419(c)(2)(C)).

''MODIFICATION OR REVOCATION OF A VARIANCE.—The Secretary, after notice and an opportunity for a hearing, may modify or revoke a variance if the Secretary determines that such variance is not reasonably likely to ensure that the food is not adulterated under section 402 and is not reasonably likely to provide the same level of public health protection as the requirements of the regulations adopted under [section 419(b) of the FD&C Act]'' (section 419(c)(2)(D)).

2. Proposed Requirements

Consistent with the statutory provisions mentioned above, in this subpart, we propose a process by which variances from one or more requirements of part 112 may be requested by a State or foreign government, information that must accompany such requests, and the procedures and circumstances under which FDA may grant or deny such requests, and modify or revoke such variances. Variances approved by FDA would be limited to the requirements of part 112 specified by FDA, and have no effect on the application of other provisions of the FD&C Act.

Consistent with section 419(c)(2)(A) of the Act, proposed § 112.171 would establish that a State or foreign country from which food is imported into the U.S. may request a variance from one or more of the requirements proposed in part 112, where the State or foreign country determines that the variance is necessary in light of local growing conditions (proposed § 112.171(a)); and 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 Act and to provide the same level of public health protection as the requirements of proposed part 112 (proposed § 112.171(b)). Such a determination would likely be based on the particular crop, climate, soil, geographic, and environmental conditions of a particular region, as well as processes, procedures, or practices followed in that region. Given the diversity of covered produce commodities and covered activities subject to the requirements of part 112, we tentatively conclude that this provision provides sufficient flexibility while ensuring the same level of public health protection for covered produce. For example, a State or foreign country may consider that the historical performance of an industry within their jurisdiction (*e.g.,* as indicated by the epidemiological record) and the combination of measures taken by that industry merits requesting a variance from some or all provisions of this proposed rule. In requesting a variance, among other things, the State or foreign country would submit information that, while the procedures, processes and practices to be followed under the variance would be different from those prescribed in this proposed rule, the requested variance is reasonably likely to ensure that the produce is not adulterated under section 402 of the FD&C Act and provide the same level of public health protection as the requirements of the final regulations (see proposed 112.173). FDA would encourage consideration of these kinds of submissions, and welcomes requests for pre-petition consultations, including meetings, with interested States or foreign governments to facilitate the development of variance petitions, including data and information that would be needed to demonstrate that the variance is necessary in light of local growing conditions and that 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 Act and provide the same level of public health protection as the requirements in this rule, when finalized. As discussed in section IV.K, FDA is proposing extended compliance dates for this proposed rule. We expect that these compliance periods would allow sufficient time for variance petitions to be developed, submitted, and reviewed by FDA. We request comment on the compliance periods.

In proposed § 112.172, we propose to establish that a request for a variance, as described in proposed § 112.171, must be submitted by the competent authority (*e.g.,* the regulatory authority for food safety) for the state or foreign government to FDA in the form of a citizen petition in accordance with 21 CFR 10.30.

In proposed § 112.173, we propose that, in addition to the requirements set forth in § 10.30, the Statement of Grounds (which is specified under § 10.30(b)) such petition requesting a variance must include a statement that the applicable State or foreign country has determined that the variance is necessary in light of local growing conditions and that 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 Act and to provide the same level of public health protection as the requirements of this part (proposed § 112.173(a)). In addition, the Statement of Grounds would be required to describe with particularity the variance requested, including the persons to whom the variance would apply and the provision(s) of part 112 to which the variance would apply (proposed § 112.173(b)); and present information demonstrating that the procedures, processes, and practices to be followed under the variance requested are reasonably likely to ensure that the produce is not adulterated under Section 402 of the Act and to provide the same level of public health protection as the requirements of proposed part 112 (proposed § 112.173(c)). Under these provisions, a State or foreign country would be required to submit relevant and scientifically-valid information or materials specific to the covered produce or covered activity to support the petitioner's determination that the variance requested is reasonably likely

to ensure that the produce is not adulterated under Section 402 of the Act and to provide the same level of public health protection as the requirements of this part. This would include information about the crop, climate, soil, and geographical or environmental conditions of a particular region, as well as the processes, procedures, or practices followed in that region.

Proposed § 112.174 establishes our presumption that information submitted in a petition requesting a variance and comments submitted on such a petition, including a request that a variance be applied to its similarly situated persons, does not contain information exempt from public disclosure under part 20 of this chapter and would be made public as part of the docket associated with this request. We do not believe that information exempt from disclosure under part 20 of this chapter is the type of information that FDA is requiring to be submitted in such a petition or that would be relevant in any comments submitted on such a petition. We also believe that providing full public access to this information is important to ensuring transparency and for the opportunity for states and foreign governments to request similar variances for similarly situated persons. Therefore, we expect to make these submissions publicly available.

Proposed § 112.175 would establish the Director or Deputy Directors of the Center for Food Safety and Applied Nutrition (CFSAN), or the Director of the Office of Compliance, CFSAN as the responsible official for responding to a request for a variance from one or more requirements in proposed part 112.

Proposed § 112.176 would establish the general procedures applying to a petition requesting a variance from one or more requirements in proposed part 112. Proposed § 112.176(a) would provide that the procedures sets forth in § 10.30 govern the process by which FDA responds to a petition requesting a variance. Section 10.30 of this chapter specifies the requirements for any citizen petition submitted by a person (including a petitioner who is not a citizen of the United States) to FDA. Proposed § 112.176(b) would establish that, under § 10.30(h)(3) of this chapter, we will publish a notice in the **Federal Register**, requesting information and views on the filed petition, including information and views from persons who could be affected by the variance if the petition were to be granted (either because their farm is covered by the petition or as a person similarly situated to persons covered by the petition). For example, similarly situated persons may include those whose farm operates under similar circumstances with similar procedures, processes, and practices as those covered by the petition. Proposed § 112.176(c) would establish that, under § 10.30(e)(3), FDA will respond to the petitioner in writing and will publish a notice on our Web site announcing our decision to either grant or deny the petition. Proposed § 112.176(c)(1) would establish that, if we grant the petition, either in whole or in part, we will specify the persons to whom the variance would apply and the provision(s) of this part to which the variance would apply. Proposed § 112.176(c)(2) would establish that, if FDA denies the petition (including partial denials), FDA will explain the reason(s) for the denial in its written response to the petitioner and in the notice on our Web site announcing the decision to deny. Under proposed § 112.176(d), we propose to make readily accessible to the public, and periodically update, a list of filed petitions requesting variances, including the status of each petition (for example, pending, granted, or denied). The provisions in proposed § 112.176 would ensure transparency in FDA's activities and decision-making, which allows the public to better understand the agency's decisions, increasing credibility and promoting accountability.

Proposed § 112.177 would establish circumstances under which an approved variance could apply to any person other than those identified in the petition requesting the variance. Under proposed § 112.177(a), a State or a foreign country that believes that a variance requested by a petition submitted by another State or foreign country should also apply to similarly situated persons in its jurisdiction may request that the variance be applied to its similarly situated persons by submitting comments in accordance with § 10.30. These comments must include the information required in § 112.173. If FDA determines that these comments should instead be treated as a separate request for a variance, FDA will notify the State or foreign country that submitted these comments that a separate request must be submitted in accordance with §§ 112.172 and 112.173. Moreover, under proposed § 112.177(b), we propose that if we grant a petition requesting a variance, in whole or in part, we may specify that the variance also applies to persons in a specific location who are similarly situated to those identified in the petition. Consequently, under proposed § 112.177(c), if we specify that the variance also applies to persons in a specific location who are similarly situated to those identified in the petition, we will inform the applicable State or foreign country where the similarly situated persons are located of our decision in writing and will publish a notice on our Web site announcing our decision to apply the variance to similarly situated persons in that particular location. We tentatively conclude that the provisions in proposed § 112.177 ensure consideration of the application of variances to similarly situated persons to and provide for transparency and accountability in FDA's review of requests and decision-making.

Proposed § 112.178 would provide that we may deny a variance request if it does not provide the information required under proposed § 112.173 (including the requirements of § 10.30), or if we determine that the variance is not reasonably likely to ensure that the produce is not adulterated under Section 402 of the Act and to provide the same level of public health protection as the requirements of this part. For example, we would expect to deny a petition if the State or foreign government failed to submit scientifically-valid data, information, or materials to demonstrate that the procedures, processes, or practices to be followed under the requested variance are reasonably likely to ensure that the produce is not adulterated under Section 402 of the Act and to provide the same level of public health protection as the requirements of proposed part 112.

Proposed § 112.179 would specify that a variance approved by FDA becomes effective on the date of our written decision on the petition.

Under proposed § 112.180, we would be able to modify or revoke an approved variance if we determine that such variance is not reasonably likely to ensure that the produce is not adulterated under Section 402 of the Act and to provide the same level of public health protection as the requirements of proposed part 112. For example, we may deem it necessary to modify terms and conditions of the variance based on a review of updated scientific data or factual information that is applicable to the covered produce and procedures, processes, or practices followed under the variance.

Proposed § 112.181 would establish the procedures that apply if FDA determines that an approved variance should be modified or revoked. Under § 112.181(a), we would provide notice of such a determination as follows: (1) We will notify a State or a foreign country directly, in writing at the

address identified in its petition, if we determine that a variance granted in response to its petition should be modified or revoked. Our direct, written notification will provide the State or foreign country with an opportunity to request an informal hearing under part 16 of this chapter; (2) We will publish in the **Federal Register** a notice of our determination that a variance should be modified or revoked. This notice will establish a public docket so that interested parties may submit written submissions on our determination; and (3) When applicable, we will: (i) Notify in writing any States or foreign countries where a variance applies to similarly situated persons of our determination that the variance should be modified or revoked; (ii) Provide those States or foreign countries with an opportunity to request an informal hearing under part 16 of this chapter; and (iii) Include in the **Federal Register** notice described in paragraph (a)(2) of this section public notification of our decision to modify or revoke the variance granted to States or foreign countries in which similarly situated persons are located.

Under § 112.181(b), we would consider submissions from affected States or foreign countries and from other interested parties as follows: (1) We will consider requests for hearings by affected States or foreign countries under part 16 of this chapter. If FDA grants a hearing, we will provide the State or foreign country with an opportunity to make an oral submission. We will provide notice on our Web site of the hearing, including the time, date, and place of hearing. If more than one State or foreign country requests an informal hearing under part 16 of this chapter about our determination that a particular variance should be modified or revoked, we may consolidate such requests (for example, into a single hearing); and (2) We will consider written submissions submitted to the public docket from interested parties.

Under § 112.181(c), we would provide notice of our final decision as follows: (1) On the basis of the administrative record, FDA will issue a written decision, as provided for under part 16 of this chapter; and (2) We will publish a notice of our decision in the **Federal Register**. The effective date of the decision will be the date of publication of the notice.

We tentatively conclude that these provisions are necessary not only to ensure transparency and accountability in FDA's activities and decision-making, but also to provide relevant parties with an opportunity for due process.

Finally, in proposed § 112.182, we would provide examples of permissible types of variances. These examples of variances from certain requirements in proposed part 112 are consistent with our proposed provisions in subpart B for alternatives from requirements in proposed part 112. A State or foreign government may request a variance from other requirements in proposed part 112, provided the conditions described in proposed § 112.171 are met.

3. Conforming Amendment to 21 CFR Part 16

We propose to amend § 16.1(b)(1) to include Section 419(c)(2)(D) of the FD&C Act relating to the modification or revocation of a variance from the requirements of Section 419 of the FD&C Act, to the list of statutory and regulatory provisions under which regulatory hearings are available.

Q. Subpart Q—Compliance and Enforcement

1. Overall Strategy for Implementation and Compliance

FDA expects this proposed rule to improve produce safety to the extent the proposed requirements related to practices are actually implemented by farms. Many farms already follow some or all of the proposed practices, but we recognize that, when finalized, the proposed rule will be the first national standard for on-farm practices related to produce safety and that it will take time and a concerted, community-wide effort for the wide range of farms to come into full compliance. FDA is committed to working with the produce community and with partners in the U.S. Department of Agriculture, State agencies, and foreign governments to facilitate compliance through education, technical assistance and regulatory guidance.

We anticipate that compliance will be achieved primarily through the conscientious efforts of farmers, complemented by the efforts of State and local governments, extension services, private audits and certifications, and other private sector supply chain management efforts. We also recognize that the time needed to comply will vary, so we are proposing to phase in compliance dates based on farm size (see section IV.K of this document).

Under the FD&C Act, FDA has authority to inspect produce farms and can take enforcement action when needed to prevent significant hazards from entering the food supply or in response to produce safety problems, although FDA faces severe constraints in inspection and enforcement when it comes to foreign farms. FDA's inspection resources are very limited, however, in relation to the number of produce farms and the many other food production, processing and storage settings for which FDA has regulatory responsibility. Thus, as outlined below, FDA inspection will play an important but necessarily limited role in the overall compliance effort. FDA invites comment on all aspects of its compliance strategy.

2. Education, Technical Assistance and Regulatory Guidance

Education and technical assistance is the foundation of our intended compliance strategy. As discussed in section II.D. above, FDA has, together with USDA AMS, established a jointly-funded Produce Safety Alliance (PSA), a public-private partnership that will develop and disseminate science- and risk-based training and education programs to provide produce growers and packers with fundamental food safety knowledge. A first phase of PSA's work is intended to assist farms, especially small and very small farms, in establishing food safety programs consistent with the GAPs Guide and other existing guidances so that they will be better positioned to comply when we issue a final produce safety rule under section 419 of the FD&C Act. As this rulemaking progresses, FDA will work to ensure that the PSA materials are modified, as needed, to be consistent with the requirements of the produce safety rule. FDA intends to work with federal, State, and local officials, industry, and academia through the PSA to assist farmers to implement measures necessary to minimize the risk of serious adverse health consequences or death from consumption of covered produce.

We also will work to provide education and technical assistance through other sources of information that are familiar to the produce farming community (such as Cooperative Extension, land grant universities, trade associations, and foreign partners and JIFSAN to reach farmers exporting covered produce into the U.S. in their local languages). We plan to work with these and other stakeholders to develop a network of institutions that can provide technical assistance to the farming community, especially small and very small farms, as they endeavor to comply with the provisions of the final rule.

FDA intends to further facilitate compliance with a final produce safety rule through the development and dissemination of guidance, in multiple

languages, on procedures, conditions, and practices that farms can implement to reduce the risk of known or reasonably foreseeable hazards. Section 419(e) of the FD&C Act requires FDA to develop guidance ''for the safe production and harvesting of specific types of fresh produce under [section 419]'' and to hold at least three public meetings in diverse geographical areas of the U.S. as part of an effort to conduct education and outreach regarding the guidance. Consistent with this statutory provision, FDA plans to develop guidance materials, including additional guidances specific to commodities, practices, and conditions, as needed and informed, in part, by stakeholder input, including that received during public meetings.

Section 419(a)(4) of FSMA states that ''the Secretary shall prioritize the implementation of the regulations under this section for specific fruits and vegetables that are raw agricultural commodities based on known risks which may include a history and severity of foodborne illness outbreaks.'' As discussed immediately above, we intend to fulfill this mandate by (1) conducting extensive outreach and educational efforts focused on the known risks of specific types of produce and specific types of agricultural practices applied to such produce; (2) focusing our inspection and enforcement efforts on farms that present the greatest risk based, in part, on past association with outbreaks, contamination, or the known risks of their agricultural practices and conditions and/or their specific types of produce; and (3) developing guidance materials related to the rule (including commodity-specific guidances) focused on known risks. We request comment on this approach and on specific strategies we should employ in order to best prioritize our implementation of the rule in this manner.

3. Supply Chain Management

FDA anticipates that significant incentives and accountability for compliance with a final produce safety rule will come through non-regulatory audits and supply chain management initiated by private entities.

As discussed in section II.F.2. of this document, a number of retail produce buyers currently require, as a condition of sale, that their produce suppliers comply with and be audited by third parties for conformance with the FDA GAPs guide. USDA AMS also offers a GAPs and Good Handling Practices (GAP&GHP) Audit Verification Program. USDA AMS and the California Department of Food and Agriculture (CDFA) have developed and are implementing the California Leafy Greens Marketing Agreement (CA LGMA) to protect public health via compliance with the food safety practices that are accepted by the LGMA board (Ref. 45). Compliance with such practices is further verified for members and signatories to the agreement through mandatory government audits by CDFA auditors who are trained and licensed by USDA AMS (Ref. 263). Leafy greens growers in Arizona have adopted a similar marketing agreement and audit structure for their growers (Ref. 32).

At the request of industry, the USDA AMS in 2009 held seven hearings throughout the United States to solicit input from the leafy greens industries across the U.S. regarding their desire to develop a proposed national marketing agreement for leafy greens. A decision regarding the proposed USDA AMS national marketing agreement for leafy greens is currently pending, but FDA and USDA are committed to working together to harmonize the provisions of any national or regional marketing agreements for produce with the provisions of any final rule FDA issues under section 419 of the FD&C Act. Rigorous audits conducted under national or regional marketing agreements can be an important tool for fostering compliance with the produce safety rule.

FDA also intends to issue notices of proposed rulemaking implementing sections 418 and 805 of the FD&C Act (sections 103 and 301 of FSMA). FDA is aware of the diversity in quality of audits and the need to strengthen that system, but we anticipate that audits will be an important source of accountability for compliance with a final produce safety rule.

4. Inspections

With a community as large and diverse as the produce farming industry, it is not reasonable to expect that industry-wide compliance can be gained primarily through inspection and enforcement, though, of course, inspection and enforcement must be a component of our efforts. Inspections will, of necessity, be targeted to those farms that present the greatest risk based, in part, on their association with past outbreaks or contamination events and the risk associated with the agricultural practices they apply in the growing, harvesting, packing, and holding of covered produce.

FDA intends to work collaboratively with our federal and State regulatory partners to use available inspection resources to conduct risk-based inspections of farms for compliance with a final produce safety regulation. Section 702(a)(1)(A) of the FD&C Act [21 U.S.C. 372(a)(1)(A)] expressly authorizes FDA to conduct examinations and investigations for the purposes of the FD&C Act through any health, food, or drug officer or employee of any State, Territory, or political subdivision thereof (such as a locality), duly commissioned to act on behalf of FDA. Qualified State, Territorial, or local regulatory officials may be commissioned or serve under contract with FDA to conduct examinations, inspections, and investigations for purposes of the FD&C Act. In addition, section 702(a)(2) [21 U.S.C. 372(a)(2)] expressly authorizes FDA to conduct examinations and investigations for the purposes of the FD&C Act through officers and employees of another Federal department or agency, subject to certain conditions set forth in that section. We expect to continue to cooperatively leverage the resources of federal, State, and local government agencies in this way as we strive to obtain industry-wide compliance with a final produce safety rule.

Section 419(b)(2)(A) of the FD&C Act specifically instructs FDA to ''provide for coordination of education and enforcement activities by State and local officials, as designated by the Governors of the respective States or the appropriate elected State official as recognized by State statute.'' Consistent with this provision and with the direction to improve the training of State, local, territorial, and tribal food safety officials under Section 1011 of the FD&C Act (21 U.S.C. 399c, added to the FD&C Act by section 209 of FSMA), FDA intends to work closely with extension and education organizations and State, local, territorial, and tribal partners to develop the tools and training programs needed to facilitate consistent inspection and regulatory activities associated with the requirements of a final produce safety rule. We expect to build on our collaboration with State, local, territorial, and tribal officials in the development of tools and training for use by inspectors in farm investigations on issues specific to food safety during growing, harvest, packing and holding produce.

FDA anticipates that some States may choose to adopt requirements modeled after the provisions of a final federal produce safety rule and may choose to perform inspections under their own authorities to enforce those provisions of their state laws. Such actions would further drive compliance with a final federal produce safety rule.

5. Comments Related to the Proposed Provisions

We received many comments on strategies for compliance, including comments from farmers, consumers, retail, State, federal and foreign governments, academia, trade associations and industry groups, and a non-profit research and advocacy organization. These comments broadly expressed strategies for compliance that included specific suggestions on how to ensure that all covered produce is in compliance with a final rule. Several comments recognized the importance of partnerships with respect to bringing about compliance with, and ultimately enforcing, a final rule. Comments urged the agency to work in cooperation with other federal, State, Territorial, tribal and local agencies with jurisdiction and expertise to ensure a coordinated and uniform approach to enforcement and compliance that will improve efficiency and effectiveness. Several comments noted that governmental testing laboratories should be recognized and funding should be provided to States to hire and train auditors.

We agree that partnerships will play a crucial role in bringing the produce industry into compliance with a final rule. As discussed in our overall strategy above and reflected in proposed 112.193, FDA intends to work with State, Territorial, tribal, and local partners to develop the education and enforcement tools and training programs needed to facilitate consistent inspection and regulatory activities associated with the requirements of a final produce safety rule. Education and outreach through mechanisms like PSA and other sources of information that are familiar to the produce farming community (such as Cooperative Extension, land grant universities, and trade associations) are the foundation of our intended compliance strategy. We also plan to work with these and other stakeholders to develop a network of institutions that can provide technical assistance to the farming community, especially small and very small farms, as they endeavor to comply with the provisions of a final rule. Of course, although much of our initial effort will be focused on education and outreach, we will also inspect farms on a targeted basis for compliance with a final produce safety rule. Partnerships will play an important role with regard to inspections as well. FDA intends to work collaboratively with our federal, State, Territorial, tribal, and local regulatory partners to use available inspection resources to conduct risk-based inspections of farms for compliance with the final regulation. FDA intends to further facilitate compliance with our final regulation through the development and dissemination of guidance on procedures, conditions, and practices that farms can implement to reduce the risk of known or reasonably foreseeable hazards.

Several comments noted that foreign governments could also play an important role in verifying compliance. Some noted that global recognition of food safety and food defense efforts should be developed. One country specifically requested that we recognize foreign fresh produce initiatives as equivalent oversight of the industry.

We agree that foreign governments will play an important part in bringing about compliance with a final produce rule with respect to foreign products. We have already begun to reach out to foreign governments regarding the requirements of FSMA and will continue to provide technical assistance as we move closer to finalizing rules issued under FSMA authorities. There are several provisions of FSMA that directly relate to these partnerships. Section 305 of FSMA specifically directs us to develop a plan to build the capacity of foreign governments with respect to food safety that will include, among other things, training of foreign governments on our requirements, provisions for mutual recognition of inspection reports, and provisions for multilateral acceptance of laboratory methods and testing and detection techniques. Under section 307 of FSMA, which added section 808 to the FD&C Act [21 U.S.C. 384d], we are directed to establish a system for the recognition of accreditation bodies that accredit third-party auditors to certify that eligible entities meet certain requirements. Under that section, foreign governments or agencies of foreign governments, may be accredited as third party auditors who could help to ensure compliance with a final produce safety rule. Section 303 of FSMA amended section 801 of the FD&C Act to, among other things, allow us to designate an agency or representative of the foreign government of the country from which a food originated to provide certification or other assurances that certain foods are in compliance with the FD&C Act, if FDA chooses to require such certifications or assurances for certain foods. We are working to implement these provisions of FSMA. In addition, as set forth in subpart P of this proposed rule, foreign countries may request variances from requirements proposed in this rule, provided they meet certain conditions. See section V.P. of this document for further discussion of the process, conditions, and procedures related to a request for variance(s).

In addition to partnering with other U.S. agencies and foreign governments, several comments discussed the strength of industry programs imposed throughout the supply chain and urged us to leverage these private sector efforts. Some commented on the importance of verification of compliance by qualified and independent third parties and recognition of third party certification. These third parties could be those hired by industry, including retailers, to ensure the safety of produce from their suppliers. However, some comments identified duplicative audits and excessive documentation as problematic, particularly for small growers. Other comments recognized that importers can play an important role in verifying compliance with a final produce safety rule and safety of imported produce.

We agree that we should leverage the efforts of private supply chain management to further compliance with a final rule in this area. See discussion of our overall enforcement and compliance strategy immediately above. We also agree that importers will play an important role in ensuring the safety of produce grown in other countries and shipped to the United States. Under section 301 of FSMA, importers will have to verify that imported covered produce is produced in compliance with processes and procedures that provide the same level of public health protection as those required under section 419 of the FD&C Act.

Other comments noted that compliance with produce safety requirements should be tiered to reflect farm size, market requirements and risk. One comment noted that there should be dedicated inspectors for identified groups that may need additional assistance.

We agree that we should prioritize our compliance and enforcement efforts. As discussed above, we will be targeting our education efforts to the smaller businesses that may not be as familiar with our requirements as some of the larger farms. We also propose to give small and very small businesses extra time to comply with the final rule, as discussed in section IV.K of this document. With respect to inspections, they will, of necessity, be targeted to those farms that present the greatest risk based, in part, on their association with past outbreaks or contamination events and the risk associated with the agricultural practices they apply in the

growing, harvesting, packing, and holding of covered produce.

A few comments mentioned that research can play an important part in bringing about industry compliance. Some noted that foodborne illness outbreak investigations needed to be improved and used as educational opportunities to support food safety research. They noted that better investigative methods should be developed to help reveal possible sources of contamination. FDA agrees, as reflected in the recent establishment of the Coordinated Outbreak Response and Evaluation (CORE) Network, which is a permanent cadre of FDA experts whose full time responsibility is to enhance outbreak detection, response, and follow up investigations to inform future prevention efforts. CORE will work with CDC, state and local partners, and the food industry to investigate root causes of major outbreaks and share findings with the food safety community.

Comments also noted that a permanent institutional part of government should be developed to coordinate research, information, responses to, and control measures for, human pathogens and their evolution in the environment, including the farm environment, animal production, the industrial and commercial environment and the medical (healthcare) system. As discussed previously, we are pursuing regulatory science and research activities in collaboration with various partners. See section II.E. of this document for further information.

6. Proposed Requirements

Proposed § 112.191 states that the criteria and definitions in this part apply in determining whether a food is adulterated (1) within the meaning of section 402(a)(3) of the Federal Food, Drug, and Cosmetic Act in that the food has been grown, harvested, packed, or held under such conditions that it is unfit for food; or (2) 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).

As discussed in section III of this document, FDA proposes these regulations under the FD&C Act as amended by FSMA, and the Public Health Service Act (PHS Act). We note that section 419(c)(1)(A) of the FD&C Act provides that FDA shall establish in this rulemaking ''procedures, processes, and practices that the Secretary determines to be reasonably necessary * * * to provide reasonable assurances that the produce is not adulterated under section 402 [of the FD&C Act]'' and that similar references to preventing adulteration under section 402 of the FD&C Act also appear in section 419(c)(1)(F), (c)(2)(A), (c)(2)(C), and (c)(2)(D). In sections V.A. through V.O. of this document, we explain how the proposed provisions are necessary to protect against contamination with hazards that may adulterate food. We tentatively conclude that the link between the proposed provisions and the potential for adulteration provides a basis for applying the criteria and definitions in proposed part 112 in determining whether, under particular circumstances, a food is adulterated under section 402(a)(3) or (a)(4) or in violation of section 361 of the PHS Act. We also note 402(a)(4) of the FD&C Act provides that food is adulterated if it has been ''prepared, packed, or held under insanitary conditions'' whereby either of the proscribed results may occur. ''Prepared, packed, or held'' includes growing, harvesting, packing, and holding. The common meaning of ''prepare,'' as represented by the dictionary definition is, in relevant part, ''to make ready beforehand for some purpose, use, or activity * * * to put together'' (Ref. 264). Growing and harvesting are operations that make food ready for use as food. In addition, growing and harvesting at times involve holding of food.

Section 105(c) of FSMA amends section 301 of the FD&C Act (21 U.S.C. 331) by adding a new section—(vv)—to the list of acts and the causing thereof that are prohibited. Under section 301(vv), the following act, and the causing thereof, is prohibited: ''[t]he failure to comply with the requirements under section 419 [of the FD&C Act].'' To clearly communicate that failure to comply with regulations established under section 419 is a prohibited act, proposed § 112.192 would establish that the failure to comply with the requirements of part 112, issued under section 419 of the Federal Food, Drug, and Cosmetic Act, is a prohibited act under section 301(vv) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(vv)).

Proposed § 112.193 provides that under Section 419(b)(2)(A) of the FD&C Act, FDA coordinates education and enforcement activities by State, Territorial, tribal, and local officials. As described above, we plan to work closely with State, Territorial, tribal, and local partners to develop the education and enforcement tools and training programs needed to facilitate consistent inspection and regulatory activities associated with the requirements proposed in subparts A through O.

R. Subpart R—Withdrawal of Qualified Exemption

As proposed, subpart R establishes the procedures that would govern the circumstances and process whereby we may issue an order withdrawing a qualified exemption applicable to a farm in accordance with the requirements of § 112.5. Specifically, proposed § 112.201 lists the circumstances under which FDA can withdraw a qualified exemption applicable to a farm, while §§ 112.202 and 112.203 specify the procedure and information that FDA would include in an order to withdraw such qualified exemption. In addition, proposed §§ 112.204 through 112.207 provide for a process whereby you may submit a written appeal (which may include a request for a hearing) of an order to withdraw a qualified exemption applicable to your farm, and proposed §§ 112.208 through 112.211 provide a procedure for appeals, hearings, and decisions on appeals and hearings.

1. Requirements of Section 419 of the FD&C Act

Section 419(f)(3)(A) of the FD&C Act specifies that, ''[i]n the event of an active investigation of a foodborne illness outbreak that is directly linked to a farm subject to an exemption under [section 419(f) of the FD&C Act], or if the Secretary determines that it is necessary to protect the public health and prevent or mitigate a foodborne illness outbreak based on conduct or conditions associated with a farm that are material to the safety of the food produced or harvested at such farm, the Secretary may withdraw the exemption provided to such farm under [section 419(f) of the FD&C Act].'' Section 419 does not expressly prescribe the procedures for withdrawing a qualified exemption provided to a farm under section 419(f). We tentatively conclude that it is appropriate to be transparent about the process we would use to withdraw a qualified exemption and that we should include the process in the proposed rule.

2. Proposed Requirements

a. Circumstances for Withdrawal

Proposed § 112.201 would establish the circumstances under which FDA can withdraw an exemption applicable to a farm. Consistent with Section 419(f)(3)(A) of the FD&C Act, it states

that we may withdraw your qualified exemption under proposed § 112.5:

(1) In the event of an active investigation of a foodborne illness outbreak that is directly linked to your farm (proposed § 112.201(a)); or

(2) If we determine that it is necessary to protect the public health and prevent or mitigate a foodborne illness outbreak based on conduct or conditions associated with your farm that are material to the safety of the food that would otherwise be covered produce grown, harvested, packed or held at your farm (proposed § 112.201(b)).

Proposed § 112.201(a) would implement the statutory language of section 419(f)(3)(A) of the FD&C Act. An outbreak of foodborne illness is the occurrence of two or more cases of a similar illness resulting from the ingestion of a common food. Food can become contaminated at many different steps in the farm-to-table continuum: On the farm; in packing, manufacturing/processing, or distribution facilities; during storage or transit; at retail establishments; in restaurants; and in the home. When foodborne illness is associated with food, an investigation may enable us to directly link the illness to the farm that grew, harvested, packed, and/or held the food.

Proposed § 112.201(b) would also implement the statutory language of section 419(f)(3)(A) of the FD&C Act, which provides that FDA may withdraw a qualified exemption available to a farm under section 419(f) ''if the Secretary determines that it is necessary to protect the public health and prevent or mitigate a foodborne illness outbreak based on conduct or conditions associated with a farm that are material to the safety of the food produced or harvested at such farm.'' We tentatively conclude that the food to which this standard applies is food that would otherwise be covered produce, because that is the food that would be subject to this proposed rule if a qualified exemption is withdrawn. We also tentatively conclude that it is reasonable to interpret the word ''produced'' in this standard to refer to the activities within the farm definition other than harvesting, because this proposed rule would apply only to activities within the farm definition and the standard already uses the word ''harvested.'' Thus, proposed § 112.201(b) would provide that FDA may withdraw the qualified exemption applicable to a farm under proposed § 112.5 if FDA determines that it is necessary to protect the public health and prevent or mitigate a foodborne illness outbreak based on conduct or conditions associated with a farm that are material to the safety of the food that would otherwise be covered produce grown, harvested, packed, or held at such farm. As an example, we may receive reports to the Reportable Food Registry under section 417 of the FD&C Act about contamination of a food, and the reports may lead us to investigate a farm that grew, harvested, packed or held the food. If our investigation finds conduct or conditions associated with the farm that are material to the safety of the food that would otherwise be covered produce subject to proposed subparts B through O of this rule (for example, conduct or conditions that likely led to the contamination of the food), we would consider withdrawing the qualified exemption applicable to the farm under proposed § 112.5 if doing so would be necessary to protect the public health and prevent or mitigate a foodborne illness outbreak. Likewise, if during a routine inspection of a farm to which the qualified exemption in proposed § 112.5 applies, we discover conditions and practices that are likely to lead to contamination of food that would otherwise be covered produce with microorganisms of public health significance, we would consider withdrawing the qualified exemption provided to the facility under proposed § 112.5 if doing so would be necessary to protect the public health and prevent or mitigate a foodborne illness outbreak.

b. Procedure for Issuance of Withdrawal Order

Proposed § 112.202(a) would provide that, if FDA determines that a qualified exemption applicable to a farm under § 112.5 should be withdrawn, any officer or qualified employee of FDA may issue an order to withdraw the exemption. We intend to create and maintain a written record of a determination that the withdrawal of an exemption is warranted and to include the basis for the determination in the written record. Proposed § 112.202(b) would require that an FDA District Director in whose district the farm is located (or, in the case of a foreign farm, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition), or an FDA official senior to such Director, must approve an order to withdraw the exemption as part of the withdrawal determination procedure before the order is issued. A Regional Food and Drug Director is an example of an FDA official senior to a District Director. The Deputy Directors and Director of the Center for Food Safety and Applied Nutrition are examples of an FDA official senior to the Director of the Office of Compliance. Requiring prior approval of a withdrawal order by a District Director or an FDA official senior to a District Director is consistent with the approval requirement for a detention order in part 1, subpart K (Administrative Detention of Food for Human or Animal Consumption). Requiring prior approval of a withdrawal order by the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition is consistent with current FDA practices when dealing with foreign firms. Proposed § 112.202(c) would require that FDA issue an order to withdraw the exemption to the owner, operator, or agent in charge of the farm. We tentatively conclude that it would be appropriate for FDA to issue an exemption withdrawal order to any of these persons. Proposed § 112.202(d) would require that FDA issue an order to withdraw the exemption in writing, signed and dated by the officer or qualified employee of FDA who is issuing the order.

c. Information Included in FDA's Withdrawal Order

Proposed § 112.203(a) through (h) would require that an order to withdraw a qualified exemption applicable to a farm under § 112.5 include the following information:

(a) The date of the order (proposed § 112.203(a));

(b) The name, address and location of the covered farm (proposed § 112.203(b));

(c) A brief, general statement of the reasons for the order, including information relevant to:

(1) An active investigation of a foodborne illness outbreak that is directly linked to the farm; or

(2) Conduct or conditions associated with a farm that are material to the safety of the food that would otherwise be covered produce grown, harvested, packed and held at such farm (proposed § 112.203(c));

(d) A statement that the farm must comply with subpart B through subpart O of this part on the date that is 60 calendar days after the date of the order (proposed § 112.203(d));

(e) The text of section 419(f) of the Federal Food, Drug, and Cosmetic Act and of subpart R of the rule (proposed § 112.203(e));

(f) A statement that any informal hearing on an appeal of the order must be conducted as a regulatory hearing under part 16 (21 CFR Part 16), with certain exceptions described in proposed § 112.208 (proposed § 112.203(f));

(g) The mailing address, telephone number, email address, and facsimile number of the FDA district office and

the name of the FDA District Director in whose district the farm is located (or, in the case of a foreign farm, the same information for the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition); (proposed § 112.203(g)); and

(h) The name and the title of the FDA representative who approved the order (proposed § 112.203(h)).

FDA tentatively concludes that the requirements that we propose in § 112.203 would provide the owner, operator, or agent in charge of a farm subject to a withdrawal with adequate notice of the basis for our determination to withdraw the exemption and of their opportunity to appeal our determination and to request an informal hearing. The proposed notification procedures are similar to and consistent with the notification requirements in other regulations involving administrative action, such as administrative detention of food under § 1.393, orders for diversion or destruction of shell eggs under the PHS Act under § 118.12(a)(i), and with procedures for an informal hearing in part 16. We seek comments on the proposed process for withdrawal of a qualified exemption.

d. Requirements When a Withdrawal Order Is Issued

Proposed § 112.204 would require that the owner, operator, or agent in charge of a farm that receives an order to withdraw an exemption applicable to that farm under § 112.5 either (a) comply with applicable requirements of this part within 60 calendar days of the date of the order or, if operations have ceased and will not resume within 60 calendar days, before the beginning of operations in the next growing season; or (b) appeal the order within 10 calendar days of the date of the order in accordance with the requirements of § 112.206. We tentatively conclude that either of the two circumstances that could result in our determination that an exemption should be withdrawn (as described in proposed § 112.201) warrant prompt compliance with the rule in the interest of public health. We tentatively conclude that ten calendar days for the submission of an appeal from the date of the receipt of a withdrawal order is appropriate for purposes of the efficient adjudication of the appeal of a withdrawal order and would provide reasonable due process that comes to closure sufficiently in advance of the effective date of the order to provide an opportunity for the farm to come into compliance if we deny the appeal.

e. Procedure for Appealing a Withdrawal Order (Including Requests for Informal Hearing)

Proposed § 112.205(a) would establish that submission of an appeal, including submission of a request for an informal hearing, will not delay or stay any administrative action, including enforcement action by FDA, unless the Commissioner of Food and Drugs, as a matter of discretion, determines that delay or a stay is in the public interest. For example, the submission of an appeal of a withdrawal order with a request for an informal hearing would not prevent FDA from simultaneously detaining food from the farm under section 304(h) of the FD&C Act, seeking seizure of food from the farm under section 304(a) of the FD&C Act, or seeking or enforcing an injunction under section 302 of the FD&C Act. Proposed § 112.205(b) would require that, if the owner, operator, or agent in charge of the farm appeals the order, and FDA confirms the order, the owner, operator, or agent in charge of the farm must comply with applicable requirements of this part within 60 calendar days of the date of the order or, if operations have ceased and will not resume within 60 calendar days, before the beginning of operations in the next growing season. Proposed § 112.205(b) would make clear that the 60 calendar day time frame for compliance applies regardless of whether the owner, operator, or agent in charge of a farm requests, and FDA grants, a hearing. As already discussed, FDA tentatively concludes that the circumstances that lead to a determination that an exemption should be withdrawn warrant prompt compliance in the interest of public health.

Proposed § 112.206(a) would require that, to appeal an order to withdraw a qualified exemption applicable to a farm under § 112.5, the owner, operator, or agent in charge of the farm must: (1) Submit the appeal in writing to the FDA District Director in whose district the farm is located (or, in the case of a foreign farm, to the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition), at the mailing address, email address, or facsimile number identified in the order within 10 calendar days of the date of the order; and (2) respond with particularity to the facts and issues contained in the order, including any supporting documentation upon which the owner, operator or agent in charge of the farm relies. Allowing the owner, operator, or agent in charge of the farm to submit an appeal in person, by mail, email, or fax would provide for flexibility as well as speed. For example, submitting in person would give the owner, operator, or agent in charge direct knowledge that the request for appeal had been delivered and received. Email and fax are instantaneous, and overnight mail delivery services are readily available to those who choose to use them; however, the ten day time frame for appeal of the order would not require the use of overnight mail delivery. For clarity, proposed § 112.206(a)(1) would repeat the 10 calendar day time frame that would be established in proposed § 112.204 and would not establish any new requirement. Any appeal would need to be written in order for FDA to evaluate the basis for the appeal. We are proposing that a written appeal would need to address with particularity all of the issues raised in the withdrawal order and include all supporting documentation so that we would be able to issue a final determination as to the disposition of the appeal solely on the basis of the materials submitted as part of the written appeal.

Proposed § 112.206(b) would provide that, in a written appeal of the order withdrawing an exemption provided under § 112.5, the owner, operator, or agent in charge of the farm may include a written request for an informal hearing as provided in § 112.207. Requesting an informal hearing does not mean that a hearing will be held, because we may deny the request (see discussion of proposed § 112.207(b) below). However, if the owner, operator, or agent in charge of the farm does not request an informal hearing at the time the written appeal is submitted, the owner, operator, or agent in charge of the farm will not be entitled to an informal hearing. Instead, FDA will make a final decision based on the written appeal and its supporting materials.

Proposed § 112.207(a)(1) would provide that, if the owner, operator, or agent in charge of the farm appeals the order, the owner, operator, or agent in charge of the farm may request an informal hearing. Proposed § 112.207(a)(1) would restate an option that would be included in proposed § 112.206(b) to highlight the opportunity to request an informal hearing. Proposed § 112.207(a)(2) would require that, if the owner, operator, or agent in charge of the farm appeals the order, the owner, operator, or agent in charge of the farm must submit any request for an informal hearing together with its written appeal submitted in accordance with § 112.206 within 10 calendar days of the date of the order. We tentatively conclude that requiring submission of a request for an informal hearing in writing at the time

that the owner, operator, or agent in charge of the farm would be required to submit a written appeal is appropriate for purposes of the efficient adjudication of the appeal of a withdrawal order and would provide reasonable due process that would come to closure sufficiently in advance of the effective date of the order to provide an opportunity for the farm to come into compliance if we deny the appeal.

Proposed § 112.207(b) would establish that a request for an informal hearing may be denied, in whole or in part, if the presiding officer determines that no genuine and substantial issue of material fact has been raised by the material submitted. Proposed § 112.207(b) would also provide that if the presiding officer determines that a hearing is not justified, written notice of the determination will be given to the owner, operator, or agent in charge of the farm explaining the reason for the denial. Under proposed § 112.206(a), a written appeal would be required to respond with particularity to the facts and issues contained in the withdrawal order, including any supporting documentation upon which the owner, operator or agent in charge of the farm relies. If the materials submitted do not directly address the facts and issues contained in the withdrawal order in a manner that suggests that there is a genuine dispute regarding the material facts contained in the order, the presiding officer may determine that an informal hearing is not warranted. The presiding officer may include written notice of the determination that a hearing is not justified as part of the final decision on the appeal.

f. Procedure for Appeals (Including Informal Hearings)

Proposed § 112.208(a) would establish that, if the owner, operator or agent in charge of the farm requests an informal hearing, and FDA grants the request, the hearing will be held within 10 calendar days after the date the appeal is filed or, if applicable, within a time frame agreed upon in writing by the owner, operator, or agent in charge of the farm and FDA. We tentatively conclude that, if we grant a request for an informal hearing, holding the hearing within 10 calendar days, or within an alternative time frame as agreed upon in writing, is appropriate for purposes of the efficient adjudication of the appeal of a withdrawal order and would provide reasonable due process that would come to closure sufficiently in advance of the effective date of the order to provide an opportunity for the farm to come into compliance if we deny the appeal.

Proposed 112.208(b) would establish that the presiding officer may require that a hearing conducted under this subpart be completed within 1 calendar day, as appropriate. We tentatively conclude that, if we grant a request for an informal hearing, limiting the time for the hearing itself to be completed within 1 calendar day is appropriate for purposes of the efficient adjudication of the appeal of a withdrawal order and would provide reasonable due process that would come to closure sufficiently in advance of the effective date of the order to provide an opportunity for the farm to come into compliance if we deny the appeal.

Proposed § 112.208(c)(1) through (7) would establish that, if the owner, operator or agent in charge of the farm requests an informal hearing, and FDA grants the request, FDA must conduct the hearing in accordance with part 16, except that:

(1) The order withdrawing an exemption under § 112.5, rather than the notice under § 16.22(a), provides notice of opportunity for a hearing under this section and is part of the administrative record of the regulatory hearing under § 16.80(a) of this chapter.

(2) A request for a hearing under this subpart must be addressed to the FDA District Director (or, in the case of a foreign farm, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition) as provided in the order withdrawing an exemption.

(3) Section 112.209, rather than § 16.42(a), describes the FDA employees who preside at hearings under this subpart.

(4) Section 16.60(e) and (f) of this chapter does not apply to a hearing under this subpart. The presiding officer must prepare a written report of the hearing. All written material presented at the hearing will be attached to the report. The presiding officer must include as part of the report of the hearing a finding on the credibility of witnesses (other than expert witnesses) whenever credibility is a material issue, and must include a proposed decision, with a statement of reasons. The hearing participant may review and comment on the presiding officer's report within 2 calendar days of issuance of the report. The presiding officer will then issue the final decision.

(5) Section 16.80(a)(4) of this chapter does not apply to a regulatory hearing under this subpart. The presiding officer's report of the hearing and any comments on the report by the hearing participant under § 112.208(c)(4) are part of the administrative record.

(6) No party shall have the right, under § 16.119 of this chapter to petition the Commissioner of Food and Drugs for reconsideration or a stay of the presiding officer's final decision.

(7) If FDA grants a request for an informal hearing on an appeal of an order withdrawing an exemption, the hearing must be conducted as a regulatory hearing pursuant to regulation in accordance with part 16, except that § 16.95(b) does not apply to a hearing under this subpart. With respect to a regulatory hearing under this subpart, the administrative record of the hearing specified in §§ 16.80(a)(1), (a)(2), (a)(3), and (a)(5), and 112.208(c)(5) constitutes the exclusive record for the presiding officer's final decision. For purposes of judicial review under § 10.45 of this chapter, the record of the administrative proceeding consists of the record of the hearing and the presiding officer's final decision.

Under § 16.1(b), the procedures in part 16 apply when a regulation provides a person with an opportunity for a hearing on a regulatory action under part 16. Section 419 of the FD&C Act does not expressly provide for a hearing if circumstances lead FDA to determine that a qualified exemption provided to a farm under proposed § 112.5 should be withdrawn. However, we tentatively conclude as a matter of agency discretion that providing an opportunity for a hearing by regulation in this subpart of the proposed rule would provide appropriate process to the owner, operator, or agent in charge of a farm subject to withdrawal of the farm's qualified exemption. We also tentatively conclude that the modified part 16 procedures contained in this proposed rule would provide the owner, operator, or agent in charge of a farm subject to a withdrawal order sufficient fairness and due process while enabling FDA to expeditiously adjudicate an appeal of a withdrawal order for which an informal hearing has been granted. We seek comment on this proposed process.

Section 16.119 provides that, after any final administrative action that is the subject of a hearing under part 16, any party may petition the Commissioner for reconsideration of any part or all of the decision or action under § 10.33 or may petition for a stay of the decision or action under § 10.35. Proposed § 112.208(c)(6) would specify that these procedures for reconsideration and stay would not apply to the process of withdrawing a qualified exemption provided under proposed § 112.5. The circumstances that may lead FDA to withdraw a qualified exemption include

an active investigation of a foodborne illness outbreak that is directly linked to a farm, or our determination that it is necessary to protect the public health and prevent or mitigate a foodborne illness outbreak based on conduct or conditions associated with a farm that are material to the safety of the food that would otherwise be covered produce grown, harvested, packed, or held at such farm. Such circumstances require prompt action. Under § 16.120, a farm that disagrees with FDA's decision to withdraw an exemption provided under § 112.5 has an opportunity for judicial review in accordance with § 10.45.

g. Presiding Officer

Proposed § 112.209 would require that the presiding officer for an appeal, and for an informal hearing, must be an FDA Regional Food and Drug Director or another FDA official senior to an FDA District Director. Under § 16.42(b), an officer presiding over an informal hearing is to be free from bias or prejudice and may not have participated in the investigation or action that is the subject of the hearing or be subordinate to a person, other than the Commissioner, who has participated in such investigation or action. An order for the withdrawal of a qualified exemption applicable to a farm must be approved by a District Director or an official senior to a District Director. It is, therefore, necessary that appeals of a decision to issue a withdrawal order should be handled by persons in positions senior to the District Directors. The Regional Food and Drug Director is such a person and could be from the same region where the farm is located, provided that the Regional Food and Drug Director did not participate in the determination that an exemption should be withdrawn and is otherwise free from bias or prejudice. Alternatively, the Regional Food and Drug Director could be from a different region than the region where the farm is located, for example in the event the Regional Food and Drug Director for the region in which the farm is located is the FDA official who approved the withdrawal order. Any Office Director of FDA's Office of Regulatory Affairs could preside at a hearing, provided that the Office Director did not participate in the determination that an exemption should be withdrawn and is otherwise free from bias or prejudice.

h. Decisions on Appeals (Including Informal Hearings)

Proposed § 112.210(a) would require that, if the owner, operator, or agent in charge of a farm appeals the order without requesting a hearing, the presiding officer must issue a written report that includes a final decision confirming or revoking the withdrawal by the tenth calendar day after the appeal is filed. Under proposed § 112.201, FDA would issue a withdrawal order either in the event of an active investigation of a foodborne illness outbreak that is directly linked to a farm or if we determine that an exemption withdrawal is necessary to protect the public health and prevent or mitigate a foodborne illness outbreak based on conduct or conditions associated with a farm that are material to the safety of the food that would otherwise be covered produce grown, harvested, packed, or held by the farm. We tentatively conclude that we will need 10 calendar days to review the written appeal and the materials submitted with the written appeal, and that a final decision confirming or revoking a withdrawal order should be issued as quickly as possible in the interest of the public health and to provide reasonable due process that would come to closure sufficiently in advance of the effective date of the order to provide an opportunity for the farm to come into compliance if we deny the appeal.

Proposed § 112.210(b)(1) would require that, if the owner, operator, or agent in charge of a farm appeals the order and requests an informal hearing and, if FDA grants the request for a hearing and the hearing is held, the presiding officer must provide a 2 calendar day opportunity for the hearing participants to review and submit comments on the report of the hearing under § 112.208(c)(4), and must issue a final decision within the 10-calendar day period after the hearing is held. We tentatively conclude that it is appropriate to grant the owner, operator, or agent in charge of a farm subject to a withdrawal order the opportunity to review and submit comments to the presiding officer's report because the report is part of the record of a final agency action (see discussion of proposed § 112.211(d)) that is not subject to further reconsideration by FDA. The presiding officer would have discretion to determine whether to revise the report of the hearing in light of any comments that might be submitted by any of the hearing participants.

Proposed § 112.210(b)(2) would require that, if the owner, operator, or agent in charge of a farm appeals the order and requests an informal hearing and if FDA denies the request for a hearing, the presiding officer must issue a final decision on the appeal confirming or revoking the withdrawal within 10 calendar days after the date the appeal is filed. We tentatively conclude that ten calendar days for the presiding officer to issue a final decision is appropriate for purposes of the efficient adjudication of the appeal of a withdrawal order, would provide reasonable due process that would come to closure sufficiently in advance of the effective date of the order to provide an opportunity for the farm to come into compliance if we deny the appeal, and is in the interest of public health.

i. Revocation of Withdrawal Order

Proposed § 112.211(a) through (c) would establish that an order to withdraw a qualified exemption applicable to a farm under § 112.5 is revoked if:

(a) The owner, operator, or agent in charge of the farm appeals the order and requests an informal hearing, FDA grants the request for an informal hearing, and the presiding officer does not confirm the order within the 10 calendar days after the hearing, or issues a decision revoking the order within that time (proposed § 112.211(a)); or

(b) The owner, operator, or agent in charge of the farm appeals the order and requests an informal hearing, FDA denies the request for an informal hearing, and FDA does not confirm the order within the 10 calendar days after the appeal is filed, or issues a decision revoking the order within that time (proposed § 112.211(b)); or

(c) The owner, operator, or agent in charge of the farm appeals the order without requesting an informal hearing, and FDA does not confirm the order within the 10 calendar days after the appeal is filed, or issues a decision revoking the order within that time (proposed § 112.211(c)).

We tentatively conclude that an order to withdraw an exemption may be revoked in one of two manners. First, we are proposing that the FDA officer responsible for adjudicating the appeal and presiding over a hearing, if one is granted, may expressly issue a written decision revoking the order within the specified 10 calendar day time frame. Second, we are proposing that the failure of the FDA officer responsible for adjudicating an appeal to issue a final decision expressly confirming the order within the specified time frames will also serve to revoke the order. We tentatively conclude that fairness would warrant the revocation of a withdrawal order if FDA is unable to meet the proposed deadlines for expressly confirming an order.

Proposed § 112.211(d) would establish that confirmation of a withdrawal order by the presiding

officer is considered a final agency action for purposes of section 702 of title 5 of the United States Code (5 U.S.C. 702). A confirmation of an order withdrawing an exemption therefore would be reviewable by the courts under section 702 of title 5 and in accordance with § 10.45 (21 CFR 10.45).

3. Conforming Amendment to 21 CFR Part 16

We propose to amend § 16.1(b)(2) to include part 112, subpart R, relating to the withdrawal of a qualified exemption applicable to a farm, to the list of regulatory provisions under which regulatory hearings are available.

VI. Preliminary Regulatory Impact Analysis

A. Overview

FDA has examined the impacts of this proposed rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L.104–4). Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). FDA has developed a preliminary regulatory impact analysis (PRIA) that presents the benefits and costs of this proposed rule (Ref. 265). FDA believes that the proposed rule will be an economically significant regulatory action as defined by Executive Order 12866. FDA requests comments on the PRIA.

B. Regulatory Flexibility Act

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because many small businesses will need to implement a number of new provisions, FDA acknowledges that the final rules resulting from this proposed rule will have a significant economic impact on a substantial number of small entities.

C. Small Business Regulatory Enforcement Fairness Act of 1996

The Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121) defines a major rule for the purpose of congressional review as having caused or being likely to cause one or more of the following: An annual effect on the economy of $100 million or more; a major increase in costs or prices; significant adverse effects on competition, employment, productivity, or innovation; or significant adverse effects on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets. In accordance with the Small Business Regulatory Enforcement Fairness Act, the Office of Management and Budget (OMB) has determined that this proposed rule is a major rule for the purpose of congressional review.

D. Unfunded Mandates Reform Act of 1995

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $136 million, using the most current (2010) Implicit Price Deflator for the Gross Domestic Product. FDA expects that the proposed rule will result in a 1-year expenditure that would exceed this amount.

E. Paperwork Reduction Act of 1995

This proposed rule contains information collection provisions that are subject to review by OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in the proposed rule have been submitted to OMB for review under Section 3507(d) of the Paperwork Reduction Act of 1995. FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

To ensure that comments on information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov*. All comments should be identified with the title ''Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption.'' In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3407(d)), the Agency has submitted the information collection provisions of this proposed rule to OMB for review. These requirements will not be effective until FDA obtains OMB approval. FDA will publish a notice concerning OMB approval of these requirements in the **Federal Register**.

F. Public Access to the Analyses

The analyses that FDA has performed in order to examine the impacts of this proposed rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), and the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) are available to the public in the docket for this proposed rule (Ref. 265).

VII. Analysis of Environmental Impact

The agency has prepared a categorical exclusion determination relying upon the categorical exclusion at 21 CFR 25.30(j) and the determination that there are no extraordinary circumstances which raise the potential for this rule to individually or cumulatively have a significant effect on the human environment (Ref. 266). FDA requests comment on its analysis and determination. As set out in more detail in Section IX of this document, to the extent there are any environmental effects that FDA should take into consideration as it prepares a final rule, FDA requests public comment and supporting data or other information (*e.g.,* studies, data, reports). The agency will evaluate the information and input received in response to this proposed rule, including the specific questions listed in section IX of this document. Although FDA finds that no EIS is necessary for this proposed rule, if in response to comment received, FDA prepares an EA or EIS, it will provide notice and an opportunity for public review and comment on any such document.

VIII. Federalism

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the proposed rule, if finalized, would not contain policies that would have substantial direct effects on the States, on the relationship between the National Government and

the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency tentatively concludes that the proposed rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

IX. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Comments on proposed provisions and related issues—We seek comment on the need for, and appropriateness of, the various provisions proposed in this rule and our accompanying rationale. Specifically, we seek comment on the following issues:

- Proposed provisions in subpart A, including:
  - proposed §§ 112.1 and 112.2, including the produce that would be covered or not covered by the rule; the list of produce that would not be covered by the rule because it is rarely consumed raw (including asparagus, bok choy, and cranberries); and the proposed exemption for produce that receives commercial processing, including the types of processing that should qualify for this exemption;
  - proposed definitions in § 112.3(c), including those of agricultural water, hazard, reasonably foreseeable hazard, produce, humus, production batch of sprouts, and yard trimmings;
  - proposed definitions of small and very small businesses in § 112.3(b); as well as the proposed exclusion of certain farms from the scope of this rule based sales in § 112.4(a);
  - whether and how we should require farms that meet the criteria for the qualified exemption to establish and maintain documentation of the basis for their exemption;
  - the feasibility of the labeling provisions in proposed 112.6(b), particularly in the case of consolidating produce from several farm locations.
- Proposed general requirements in § 112.11, including on whether we should establish specific standards for any types of hazards that would be covered in proposed § 112.11 but for which we have not proposed specific standards in proposed subparts C through O; and the proposed allowance in § 112.12 for alternatives to certain specified requirements, including appropriateness of the list of permitted alternatives. Are there other proposed provisions for which we should permit alternatives and, if so, under what, if any, additional or different criteria than those proposed in § 112.12(b) and (c)?
- Proposed provisions in subparts C and D directed to personnel training, and health and hygiene, including the proposed requirements for training on principles of food hygiene and food safety, and for the maintenance of adequate personal cleanliness and hygienic practices when handling covered produce or food-contact surfaces during covered activities, including the provisions relevant to use of gloves and hand sanitizers;
- 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:
  - Are the provisions in §§ 112.44–112.46 appropriately tailored to the risk posed by the manner in which the water is used?
  - 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?
  - 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?
  - Is there a need for a provision specifically related to disinfection treatment of re-circulated or single pass water used during and after harvest?
  - Are there any alternative options not considered in the proposed rule?
- Proposed provisions in subpart F directed to soil amendments, including those related to status, treatment, application restrictions, minimum application intervals, and recordkeeping (including the requirement related to documentation such as Certificates of Conformance); our focus on biological soil amendments of animal origin; any alternative options that we have not considered in this proposed rule; and the risk presented by the use of biological soil amendments in sprouting and whether that practice should be prohibited;
- Proposed provisions in subparts I, K, and L, including proposed § 112.81 related to the scope of applicability of subpart I, proposed § 112.114 related to dropped produce, and proposed § 112.115 related to measures to prevent formation of botulinum toxin; specifically:
  - Do you agree with our proposal to apply the proposed provisions in subpart I when covered activities take place in an outdoor area or a partially-enclosed building where there is a reasonable probability of contamination of covered produce, and our tentative conclusion that, accordingly, crops that grow completely underground would not be subject to the proposed provisions of subpart I?
  - With respect to dropped produce, should proposed § 112.114 apply to all commodities or should we provide for certain exceptions (and, if so, under what criteria)? Does proposed § 112.114 appropriately address produce (such as almonds) that is intentionally dropped to the ground during harvesting and where such harvesting does not cause bruising or damage to the produce? Should produce with peelable skin be excluded?
  - Is proposed § 112.115 a reasonably necessary measure to ensure the safety of packaged covered produce? Are there specific types or conditions of modified or reduced oxygen packaging methods that may or may not increase the risk of formation of botulinum toxin?
- Proposed provisions specific to sprouts in subpart M, including treatment of seeds and beans; microbial indicators and frequency of environmental monitoring; and requirement to establish and implement a written environmental monitoring plan (§ 112.144(a)) and sampling plan for each production batch of sprouts (§ 112.146(a)); as well as whether soil-grown sprouts should be subject to the proposed requirements, and whether and how to establish a supplier approval and verification program for seeds and beans used for sprouting;
- Proposed provisions in subpart N, including methods and allowance for alternative methods to be used provided they are at least equivalent to the proposed method in accuracy, precision, and sensitivity;
- Proposed requirements related to documentation and records in subpart O, including the requirement for a supervisor or responsible party to review certain records, and whether there are any circumstances that would warrant not applying part 11 to records that would be required to be kept under part 112;
- Proposed provisions in subpart P for variances, including related process and scientific data and information to

support a request for variance, and circumstances for approval or denial of a request for variance and for modification or revocation of an approved variance; Are there any specific concerns that we should consider in finalizing the procedures and processes for requests for variances, as applicable to foreign governments?

- Overall implementation and compliance strategy and proposed provisions in subpart Q, including specific strategies we should employ in order to best prioritize our implementation of the rule, and coordination of education and enforcement activities by relevant State, Territorial, tribal, and local authorities; and
- Proposed provisions in subpart R for withdrawal of a qualified exemption, including related process and timeframes for actions to be taken by FDA or farms.
- Regarding the scope of the recordkeeping requirements, are there alternative options that should be considered?
- Regarding the handwashing and toilet facility requirements, are our proposals reasonably consistent with current model practices or are there alternatives not considered in the proposed rule?

Regulatory approach—As discussed in section IV of this document, we have tentatively concluded that we should use a regulatory framework based on practices, procedures, and processes associated with growing, harvesting, packing, and holding of all covered produce. We considered and rejected the option to develop a framework that (based solely on a history of outbreaks or illnesses associated with the commodity) would be applicable to individual commodities or classes of commodities. Relevant references on the subject of produce safety, as well as the QAR, identify common on-farm routes of contamination, such as personnel training, health, and hygiene; domestic and wild animals; biological soil amendments of animal origin; agricultural water; and equipment and buildings. Procedures, processes and practices in each of these on-farm routes of contamination have the potential to introduce biological hazards into or onto any covered produce. Therefore, we are proposing an integrated approach to prescribe standards for each of these on-farm routes of contamination that we have tentatively determined are reasonably necessary to prevent the introduction of known or reasonably foreseeable biological hazards and to provide reasonable assurances that produce is not adulterated under section 402 of the FD&C Act. We also recognize the need for additional standards specifically tailored to the growing, harvesting, packing and holding of sprouts, and have proposed minimum necessary standards for sprouts. We seek comment on our tentative conclusions related to this issue and the proposed regulatory approach described in section IV of the document. In addition, we seek comment on the following:

- Are there any alternative approaches that we should consider in establishing science-based minimum standards for the safe production and harvesting of produce and to minimize the risk of serious adverse health consequences or death?
- Are there specific commodities or categories of commodities that should be excluded from the scope of the rule, based on data related to their relative risk considerations? (Note that under our proposed integrated approach, we propose to exempt certain commodities, including a specified list of produce that is rarely consumed raw, and produce that receives commercial processing that adequately reduces the presence of microorganisms of public health significance; see section V.A.2.a. of this rule.)
- For example, the QAR ranked certain produce commodities, such as bananas and coconuts, as lower risk for illness, in part because such commodities are peeled or shelled before consumption in a manner that can be expected not to transfer contamination onto the interior, edible portion of the commodity. Should such commodities be covered by the rule? Is coverage of these commodities unnecessary? Should they be covered but subject to a less stringent set of requirements?
- Certain commodities are ranked in the QAR as presenting a relatively lower likelihood of exposure, in part because such commodities have fewer potential routes of contamination and/or lower potential for contamination. In addition, some commodities are not known to have been associated with outbreaks. Some commodities (for example, pears, grapefruit, oranges, and lemons) meet both of these criteria, considering the rankings and outbreak data used in the QAR. Should commodities that meet both of these criteria be covered by the rule? Is coverage of these commodities unnecessary? 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?
- How should we account for uncovered commodities in considering a commodity-specific approach that relies on outbreak data?
- Are there pathogen surveillance data from sampling programs focusing on produce commodities that have no history of known outbreaks that would be useful in considering a commodity-specific approach?
- Can commodity characteristics be used as a basis to consider a commodity-specific approach? While the outbreak data show no consistent pattern that can be matched to commodity characteristics such as growth habit, our QAR shows that produce commodities that are ranked as higher risk of illness and those ranked as lower risk of illness do share some of the same characteristics. A further refinement of our assessment might be helpful in developing a commodity-specific approach based on commodity characteristics. Considering the qualitative nature of our assessment, are there quantitative data sets available that would enable a further refinement of our assessment?
- We seek comment on our tentative conclusion that produce in both direct market channels and other commercial channels are subject to the same routes of contamination, although the number of opportunities for contamination during packing and holding may be greater for produce in other commercial channels as compared to produce in direct market channels if there are greater numbers of touch points and handlers in these channels than there are in direct market channels.
- We seek comment on our tentative conclusion that because the statutory qualified exemption addresses market channels as a possible risk factor, and because we identified no data that would allow us to otherwise use market channels as a factor in covering and regulating produce under this proposed rule, we should not otherwise use market channels as a basis of risk categorization in this proposed rule.
- Are other data or information available that would be otherwise useful in considering a commodity-specific approach?
- We seek comment on the proposed effective and compliance dates.
- We seek comment on the appropriateness of the proposed exemptions and partial exemptions. Are there additional exemptions and relevant data to support such exemptions that we should consider?

Qualitative assessment of risk—We seek comment on the QAR, conclusions drawn from that assessment, and our consideration of those conclusions in developing the proposed requirements described in this rule. We also request

you to submit any data or factual information that may help the agency to conduct, as warranted, a thorough and robust quantitative assessment of risk associated with produce production and harvesting practices.

Chemical, physical or radiological hazards—We seek comment on our tentative conclusion that procedures, practices, and processes, which are proposed in this rule, are reasonably necessary to prevent the introduction of biological hazards only, and on whether, and to what extent, chemical, physical or radiological hazards should be covered within the scope of a final rule. Are there procedures, practices, or processes that minimize the risk of serious adverse health consequences or death and that are reasonably necessary to prevent the introduction of known or reasonably foreseeable chemical, physical or radiological hazards into produce or to provide reasonable assurances that produce is not adulterated under section 402 of the FD&C Act?

Environmental testing for L. monocytogenes or Listeria spp for covered produce other than sprouts—Proposed § 112.143(a) would require testing the growing, harvesting, packing, and holding environment for sprouts for *Listeria* species or *L. monocytogenes;* however, we have not proposed to require environmental testing for other covered produce. A recent outbreak of listeriosis from cantaloupes attributed to insanitary conditions at a facility that washed, packed, cooled and held intact cantaloupes (Ref. 267) raises the question as to whether specific measures are necessary to minimize the risk posed by *L. monocytogenes* as an environmental pathogen. As discussed in section V.A. of this document, this proposed rule would not apply to off-farm facilities such as the facility associated with this cantaloupe outbreak— such facilities would instead be subject to part 110 and may be subject to section 418 of the FD&C Act. However, the same risk factors and potential measures for minimizing risk are relevant to both on-farm and off-farm produce washing, packing, cooling, and holding practices. Such measures could include environmental testing for *L. monocytogenes* or *Listeria* spp. to verify the adequacy of a covered farm's sanitation measures. Because *L. monocytogenes* is a ubiquitous microorganism, an intact fruit or vegetable could reasonably be expected to occasionally be positive for *L. monocytogenes.* Many studies have shown the presence of *L. monocytogenes* on fresh, intact produce, but there is limited epidemiological evidence associating listeriosis with produce, especially with intact fruits and vegetables (Ref. 268. Ref. 269. Ref. 270. Ref. 271. Ref. 272. Ref. 267). However, this recent outbreak indicates that intact produce can be a vehicle for listeriosis. What is not known is the extent to which, and under what circumstances, whole produce contaminated with *L. monocytogenes* presents a risk to consumers. The outbreak of listeriosis due to contamination of intact cantaloupes appears to have occurred due to a combination of factors, including pooled water on the floor of the facility, which was also difficult to clean, poorly designed equipment that was previously used for other commodities, no pre-cool step, a truck parked near the packing area that had visited a cattle operation, and possible low level contamination from the growing/harvesting operation (Ref. 273). The contribution of internalization of the organism and growth within the fruit is not known. Moreover, it is not known whether all of these circumstances are needed for *L. monocytogenes* to present a risk on produce or whether any one or more would have been sufficient. We also do not know the prevalence of *L. monocytogenes* environmental contamination of fruit and vegetable packing facilities (both on- and off-farm), nor do we know the prevalence of *L. monocytogenes* on produce washed, packed, cooled and stored in such facilities. We encourage research to answer these questions. We request comment on whether we should require, in a final rule, any or all covered farms that wash and pack produce, or that only pack produce, to perform environmental testing for *L. monocytogenes* or *Listeria* spp., and any criteria that should be employed to determine which farms should be subjected to such a requirement.

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.

Registration—We are also requesting comment about whether we should require, in a final rule, that covered farms, as described in proposed § 112.4(a), register with FDA. We are not aware of a nationwide database of farms, nor an accumulation of statewide databases, that would enable us to identify the names and locations of all entities subject to this proposed regulation. This would enable us to better provide outreach and technical assistance to covered entities. In addition, while inspection is intended to be only a relatively minor part of our overall compliance effort (see section V.Q. of the document for more information on our overall strategy), we anticipate performing inspections for enforcement purposes. We would use the covered farm registration information to create a database that we would use to allocate inspection resources. We are also interested in the existence of databases that could help us identify covered farms in the absence of a registration system, and in the appropriate data elements that should be collected in a registration system, should we decide to set up such a system.

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.

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).

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.

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.

4. Do farms currently use municipal water sources to irrigate produce that would be covered by this proposed rule, if finalized? If so, please provide data on the use rate and prevalence of this practice, as well as data regarding effects on crop productivity of disinfection byproducts in municipal water used to irrigate produce that would be covered by the rule.

5. What sources of irrigation water (for example, municipal water, surface water and groundwater) are most frequently used? If more than one source is available, is there a preference for using one source over another? Please explain why.

In addition, we seek comment on potential effects of actions taken as a result of this rule on water rights/Tribal rights. Are water rights or Tribal rights likely to be affected by actions taken as a result of this rule? If so, how and to what extent?

Proposed subpart F would require the use of application method restrictions, application intervals, and/or treatment of biological soil amendments of animal origin to reduce exposure of covered produce to organisms of public health concern. We recognize that the requirements in this section may represent a departure from current practices.

1. How do farms that would be covered by the proposed rule, if finalized, currently manage solid animal waste? Manage liquid animal waste?

2. What is the prevalence of composting on farms using methods described in proposed subpart F? Please provide data or other available information on the frequency of such composting.

3. Are composting methods other than those described in proposed subpart F currently utilized on farms? To what extent? Please provide data or other available information on the frequency of such composting.

4. Are currently utilized methods of composting governed by state, county or local laws, ordinances or regulations? Please identify in your comments any relevant laws, ordinances, or regulations, and include copies if reasonably feasible.

5. What are the current laws, ordinances, or regulations in produce growing areas that govern manure handling and storage? How if at all do such laws, ordinances, or regulations address potential environmental effects from methane associated with manure? Ammonia? Nitrogen? Phosphorus?

Under proposed subpart F, manure may be chemically treated as an alternative to composting that would not require use of an application interval. We are also soliciting comments on available chemical treatment methods.

1. Do farms that would be covered by the proposed rule, if finalized, currently utilize chemical treatments to prevent or minimize pathogens in manure?

2. What types and quantities of chemicals are used for chemical treatment of manure? Please describe the treatment protocols, including application time, containment methods, and temperature requirements.

3. Please provide any data or other information relating to the effectiveness, and the relative effectiveness, of these chemical manure treatments, as well as any environmental effects of their use.

Proposed subpart I would apply when under the circumstances there is a reasonable probability that animal intrusion will contaminate covered produce. In such circumstances, proposed subpart I would require monitoring of those areas that are used for a covered activity for evidence of animal intrusion immediately prior to harvest and as needed during the growing season. If significant evidence of animal intrusion is found, these provisions would require farms to evaluate whether the covered produce can be harvested in accordance with proposed subpart K. Proposed subpart K would require taking reasonable measures to identify, and not harvest, covered produce that is reasonably likely to be contaminated, including steps to identify and not harvest covered produce that is visibly contaminated with animal excreta. We are soliciting comments on current practices relevant to these provisions.

1. What measures, if any, are currently being implemented to prevent harvest of produce contaminated by excreta deposited by wild animals? If there are preferred measures, please explain the rationale for such preference. Please provide data to support the information provided.

2. Are farms removing vegetation bordering outdoor produce growing areas or drainages in an effort to deter wildlife from entering growing areas? If so, what is the current rate at which vegetation bordering outdoor produce growing areas or drainages is currently being removed? Are sediment basins or other conservation practices currently being removed and at what rate? Please provide data or other information to support the information provided.

3. To what extent have farmers taken action to exclude wildlife from outdoor produce growing areas? What measures are being used for these purposes, *e.g.* construction of fences or other physical barriers, chemical deterrents, or other mechanisms around growing areas to exclude wildlife? Please provide data or other information to support the information provided.

4. Has the implementation of measures to prevent animal intrusion negatively impacted habitat for rare or declining aquatic or terrestrial wildlife species or migratory birds? Please provide examples.

X. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. (FDA has verified the Web site addresses, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

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List of Subjects

21 CFR Part 16

Administrative practice and procedure.

21 CFR Part 112

Foods, Fruits and vegetables, Incorporation by reference, Packaging and containers, Recordkeeping requirements, Safety.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR Chapter I be amended to read as follows:

PART 16—REGULATORY HEARING BEFORE THE FOOD AND DRUG ADMINISTRATION

■ 1. The authority citation for 21 CFR part 16 continues to read as follows:

Authority: 15 U.S.C. 1451–1461; 21 U.S.C. 141–149, 321–394, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201–262, 263b, 364.

■ 2. In § 16.1:

■ a. In paragraph (b)(1), add an entry in numerical order.

■ b. In paragraph (b)(2), add an entry in numerical order.

The additions read as follows:

§ 16.1 Scope.

* * * * *

(b) * * *

(1) * * *

Section 419(c)(2)(D) of the Federal Food, Drug, and Cosmetic Act relating to the modification or revocation of a variance from the requirements of section 419 of the Federal Food, Drug, and Cosmetic Act (see part 112, subpart P of this chapter).

* * * * *

(2) * * *

§§ 112.201 through 112.211, (part 112, subpart R), relating to withdrawal of a qualified exemption.

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■ 3. Add part 112 to read as follows:

PART 112—STANDARDS FOR THE GROWING, HARVESTING, PACKING, AND HOLDING OF PRODUCE FOR HUMAN CONSUMPTION

Subpart A—General Provisions

Sec.

Subpart B—General Requirements

Subpart C—Standards Directed to Personnel Qualifications and Training

Subpart D—Standards Directed to Health and Hygiene

Subpart E—Standards Directed to Agricultural Water

Subpart F—Standards Directed to Biological Soil Amendments of Animal Origin and Human Waste

Subpart G—[Reserved]

Subpart H—[Reserved]

Subpart I—Standards Directed to Domesticated and Wild Animals

Subpart J—[Reserved]

Subpart K—Standards Directed to Growing, Harvesting, Packing, and Holding Activities

Authority: 21 U.S.C. 321, 331, 342, 350h, 371; 42 U.S.C. 243, 264, 271.

Subpart A—General Provisions

§ 112.1 What food is covered by this part?

(a) Unless it is excluded from this part under § 112.2, food that is produce within the meaning of this part and that is a raw agricultural commodity (RAC) is covered by this part. This includes a produce RAC that is grown domestically and a produce RAC 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.

(b) For the purpose of this part and subject to the exemptions and qualified exemptions therein, covered produce includes all of the following:

(1) Fruits and vegetables such as almonds, apples, apricots, aprium, asian pear, avocados, babaco, bamboo shoots, bananas, Belgian endive, blackberries, blueberries, broccoli, cabbage, cantaloupe, carambola, carrots, cauliflower, celery, cherries, citrus (such as clementine, grapefruit, lemons, limes, mandarin, oranges, tangerines, tangors, and uniq fruit), cucumbers, curly endive, garlic, grapes, green beans, guava, herbs (such as basil, chives, cilantro, mint, oregano, and parsley), honeydew, kiwifruit, lettuce, mangos, other melons (such as canary, crenshaw and persian), mushrooms, nectarine, onions, papaya, passion fruit, peaches, pears, peas, peppers (such as bell and hot), pineapple, plums, plumcot, radish, raspberries, red currant, scallions, snow peas, spinach, sprouts (such as alfalfa and mung bean), strawberries, summer squash (such as patty pan, yellow and zucchini), tomatoes, walnuts, watercress, and watermelon; and

(2) Mixes of intact fruits and vegetables (such as fruit baskets).

§ 112.2 What produce is not covered by this part?

(a) The following produce is not covered by this part:

(1) Produce that is rarely consumed raw, specifically the produce on the following exhaustive list—arrowhead, arrowroot, artichokes, asparagus, beets, black-eyed peas, bok choy, brussels sprouts, chick-peas, collard greens, crabapples, cranberries, eggplant, figs, ginger root, kale, kidney beans, lentils, lima beans, okra, parsnips, peanuts, pinto beans, plantains, potatoes, pumpkin, rhubarb, rutabaga, sugarbeet, sweet corn, sweet potatoes, taro, turnips, water chestnuts, winter squash (acorn and butternut squash), and yams;

(2) Produce that is produced by an individual for personal consumption or produced for consumption on the farm or another farm under the same ownership; and

(3) Produce that is not a raw agricultural commodity.

(b) Covered produce is eligible for exemption from the requirements of this part (except as noted in paragraphs (b)(1), (b)(2), and (b)(3) of this section) under the following conditions:

(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;

(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

(3) The requirements of this subpart and subpart Q of this part apply to such produce.

§ 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:

(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.

(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.

(c) For the purpose of this part, the following definitions also apply:

Adequate means that which is needed to accomplish the intended purpose in keeping with good public health practice.

Adequately reduce microorganisms of public health significance means reduce the presence of such microorganisms to an extent sufficient to prevent illness.

Agricultural tea means a water extract of biological materials (such as humus, manure, non-fecal animal byproducts, peat moss, pre-consumer vegetative waste, table waste, or yard trimmings), excluding any form of human waste, produced to transfer microbial biomass, fine particulate organic matter, and soluble chemical components into an aqueous phase. Agricultural teas are held for longer than one hour before application.

Agricultural tea additive means a nutrient source (such as molasses, yeast extract, or algal powder) added to agricultural tea to increase microbial biomass.

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).

Animal excreta means solid or liquid animal waste.

Application interval means the time interval between application of an agricultural input (such as a biological soil amendment of animal origin) to a growing area and harvest of covered produce from the growing area where the agricultural input was applied.

Biological soil amendment means any soil amendment containing biological materials such as humus, manure, non-fecal animal byproducts, peat moss, pre-consumer vegetative waste, sewage sludge biosolids, table waste, agricultural tea, or yard trimmings, alone or in combination.

Biological soil amendment of animal origin means a biological soil amendment which consists, in whole or in part, of materials of animal origin, such as manure or non-fecal animal byproducts, or table waste, alone or in combination. The term ''biological soil amendment of animal origin'' does not include any form of human waste.

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.

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. This part does not apply to activities of a facility that are subject to part 110 of this chapter.

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.

Curing means the maturation stage of composting, which is conducted after much of the readily metabolized biological material has been decomposed, at cooler temperatures than those in the thermophilic phase of composting, to further reduce pathogens, promote further decomposition of cellulose and lignin, and stabilize composition.

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.

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.

Food means food as defined in section 201(f) of the Federal Food, Drug, and Cosmetic Act and includes seeds and beans used to grow sprouts.

Food-contact surfaces means those surfaces that contact human food and those surfaces from which drainage, or other transfer, onto the food or onto surfaces that contact the food ordinarily occurs during the normal course of operations. ''Food-contact surfaces'' includes food-contact surfaces of equipment and tools used during harvest, packing and holding.

Growth media means material that acts as a substrate during the growth of covered produce (such as mushrooms and some sprouts) that contains, may contain, or consists of components that may include any animal waste (such as humus, manure, non-fecal animal byproducts or table waste).

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, into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Gathering, washing, trimming of outer leaves of, removing stems and husks from, sifting, filtering, threshing, shelling, and cooling raw agricultural commodities grown on a farm or another farm under the same ownership are examples of harvesting.

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

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.

Humus means a stabilized (*i.e.,* finished) biological soil amendment produced through a controlled composting process.

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.

Manure means animal excreta, alone or in combination with litter (such as straw and feathers used for animal bedding) for use as a soil amendment.

Microorganisms means 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.

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

Monitor means to conduct a planned sequence of observations or measurements to assess whether a process, point or procedure is under control and, when applicable, to produce an accurate record of the observation or measurement.

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.

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

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.

Pest means any objectionable animals or insects including birds, rodents, flies, and larvae.

Pre-consumer vegetative waste means solid waste that is purely vegetative in origin, not considered yard trash, and derived from commercial, institutional, or agricultural operations without coming in contact with animal products, byproducts or manure or with an end user (consumer). Pre-consumer vegetative waste includes material generated by farms, packing houses, canning operations, wholesale distribution centers and grocery stores; products that have been removed from their packaging (such as out-of-date juice, vegetables, condiments, and bread); and associated packaging that is vegetative in origin (such as paper or corn-starch based products). Pre-consumer vegetative waste does not include table waste, packaging that has come in contact with materials (such as meat) that are not vegetative in origin, or any waste generated by restaurants.

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.

Production batch of sprouts means all sprouts that are started at the same time in a single growing unit (*e.g.,* a single drum or bin, or a single rack of trays that are connected to each other), whether or not the sprouts are grown from a single lot of seed (including, for example, when multiple types of seeds are grown in a single growing unit).

Qualified end-user with respect to a food means the consumer of the food; or a restaurant or retail food establishment (as those terms are defined in § 1.227) that is located:

(i) In the same State as the farm that produced the food; or

(ii) Not more than 275 miles from such farm. The term ''consumer'' does not include a business.

Raw agricultural commodity (RAC) means ''raw agricultural commodity'' as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act.

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

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.

Sewage sludge biosolids means the solid or semi-solid residue generated during the treatment of domestic sewage in a treatment works within the meaning of the definition of ''sewage sludge'' in 40 CFR 503.9(w).

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).

Spent sprout irrigation water means water that has been used in the growing of sprouts.

Static composting means a process to produce humus in which air is introduced into biological material (in a pile (or row) covered with at least 6 inches of insulating material, or in an enclosed vessel) by a mechanism that does not include turning. Examples of structural features for introducing air include embedded perforated pipes and a constructed permanent base that includes aeration slots. Examples of mechanisms for introducing air include passive diffusion and mechanical means (such as blowers that suction air from the composting material or blow air into the composting material using positive pressure).

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.

Table waste means any post-consumer food waste, irrespective of whether the source material is animal or vegetative in origin, derived from individuals, institutions, restaurants, retail operations, or other sources where the food has been served to a consumer.

Turned composting means a process to produce humus in which air is introduced into biological material (in a pile, row, or enclosed vessel) by turning on a regular basis. Turning is the process of mechanically mixing biological material that is undergoing a composting process with the specific intention of moving the outer, cooler sections of the material being composted to the inner, hotter sections.

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.

We means the U.S. Food and Drug Administration (FDA).

Yard trimmings means purely vegetative matter resulting from landscaping maintenance or land clearing operations, including materials such as tree and shrub trimmings, grass clippings, palm fronds, trees, tree stumps, untreated lumber, untreated wooden pallets, and associated rocks and soils.

You means a person who is subject to some or all of the requirements in this part.

§ 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.

(b) You are not a covered farm if you satisfy the requirements in § 112.5 and we have not withdrawn your exemption in accordance with the requirements of subpart R of this part.

§ 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?

(a) You are eligible for a qualified exemption and associated modified requirements in a calendar year if:

(1) During the previous 3-year period preceding the applicable calendar year, the average annual monetary value of the food (as defined in § 112.3(c)) you sold directly to qualified end-users (as defined in § 112.3(c)) during such period exceeded the average annual monetary value of the food you sold to all other buyers during that period; and

(2) The average annual monetary value of all food (as defined in § 112.3(c)) you sold during the 3-year period preceding the applicable calendar year was less than $500,000, adjusted for inflation.

(b) For the purpose of determining whether the average annual monetary value of all food sold during the 3-year period preceding the applicable calendar year was less than $500,000, adjusted for inflation, the baseline year for calculating the adjustment for inflation is 2011.

§ 112.6 What modified requirements apply to me if I am eligible for a qualified exemption in accordance with § 112.5?

(a) If you are eligible for a qualified exemption in accordance with § 112.5, you are subject to the requirements of:

(1) This subpart A; and

(2) Subparts Q and R of this part.

(b) In addition, you are subject to the following modified requirements:

(1) When a food packaging label is required on food that would otherwise

be covered produce under the Federal Food, Drug, and Cosmetic Act or its implementing regulations, you must include prominently and conspicuously on the food packaging label the name and the complete business address of the farm where the produce was grown.

(2) When a food packaging label is not required on food that would otherwise be covered produce under the Federal Food, Drug, and Cosmetic Act, you must prominently and conspicuously display, at the point of purchase, the name and complete business address of the farm where the produce was grown, on a label, poster, sign, placard, or documents delivered contemporaneously with the produce in the normal course of business, or, in the case of Internet sales, in an electronic notice.

(3) The complete business address that you must include in accordance with the requirements of paragraph (b)(1) or (b)(2) of this section must include the street address or post office box, city, state, and zip code for domestic farms, and comparable full address information for foreign farms.

Subpart B—General Requirements

§ 112.11 What general requirements apply to persons who are subject to this part?

You must take appropriate measures to minimize the risk of serious adverse health consequences or death from the use of, or exposure to, covered produce, including those measures reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into covered produce, and to provide reasonable assurances that the produce is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342) on account of such hazards.

§ 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.

Subpart C—Standards Directed to Personnel Qualifications and Training

§ 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.

§ 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.

§ 112.23 What requirements apply regarding supervisors?

You must assign or identify personnel to supervise (or otherwise be

responsible for) your operations to ensure compliance with the requirements of this part.

§ 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?

(a) You must take measures to prevent contamination of covered produce and food-contact surfaces with microorganisms of public health significance from any person with an applicable health condition (such as a communicable illnesses that present a public health risk in the context of normal work duties, infection, open lesion, vomiting, or diarrhea).

(b) The measures you must take to satisfy the requirements of paragraph (a) of this section must include all of the following measures:

(1) Excluding any person from working in any operations that may result in contamination of covered produce or food-contact surfaces with microorganisms of public health significance when the person (by medical examination, the person's acknowledgement, or observation) is shown to have, or appears to have, an applicable health condition, until the person's health condition no longer presents a risk to public health; and

(2) Instructing personnel to notify their supervisor(s) (or a responsible party) if they have, or if there is a reasonable possibility that they have an applicable health condition.

§ 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; and

(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.

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

(a) A visitor is any person (other than personnel) who enters your covered farm with your permission.

(b) You must make visitors aware of policies and procedures to protect covered produce and food-contact surfaces from contamination by people and take all steps reasonably necessary to ensure that visitors comply with such policies and procedures.

(c) You must make toilet and hand-washing facilities accessible to visitors.

Subpart E—Standards Directed to Agricultural Water

§ 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.

§ 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 for its intended use, until you either:

(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 and 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.

§ 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.

(c)(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.

§ 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.

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

If the untreated surface water is—	Then you must test the untreated surface water—
(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).	At least once each month during the growing season.

§ 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 re-circulated 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.

§ 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; and

(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).

(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.

Subpart F—Standards Directed to 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 has 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 four grams of total solids (dry weight basis); and less than 1,000 MPN fecal coliforms per gram of total solids (dry weight basis).

§ 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.

If the biological soil amendment of animal origin is—	Then the biological soil amendment of animal origin must be applied—	And then the minimum application interval is—
(1)(i) Untreated	In a manner that does not contact covered produce during application and minimizes the potential for contact with covered produce after application	9 months.
(ii) Untreated	In a manner that does not contact covered produce during or after application	0 days.
(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).	In any manner (*i.e.,* no restrictions)	0 days.
(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).	In a manner that minimizes the potential for contact with covered produce during and after application	0 days.
(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).	In a manner that minimizes the potential for contact with covered produce during and after application	45 days.
(ii) Treated by a composting process in accordance with the requirements of § 112.54(c) to meet the microbial standard in § 112.55(b).	In a manner that does not contact covered produce during or after application	0 days.

(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.

§ 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)(3); and

(5) Scientific data or information you rely on to support any alternative minimum application interval in accordance with the requirements of § 112.56(b).

Subpart G—[Reserved]

Subpart H—[Reserved]

Subpart I—Standards Directed to Domesticated and Wild Animals

§ 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.

§ 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.

§ 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.

Subpart J—[Reserved]

Subpart K—Standards Directed to Growing, Harvesting, Packing, and Holding 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.

§ 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.

§ 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.

§ 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).

§ 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.

Subpart L—Standards Directed to Equipment, Tools, Buildings, and Sanitation

§ 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).

§ 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 cleaned 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.

(d)(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.

(e) 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.

§ 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.

§ 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.

§ 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. 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.

(b) 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.

§ 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.

§ 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).

§ 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 hand-washing 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 hand-washing 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.

§ 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 hand-washing 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.

(b) [Reserved]

§ 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.

Subpart M—Standards Directed to Sprouts

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

In addition to the requirements of this part, all of the following requirements apply to seeds or beans used to grow sprouts.

(a) If your farm grows seeds or beans for use to grow sprouts, you must take measures reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into or onto seeds or beans that you will use for sprouting.

(b) If you know or have reason to believe that a lot of seeds or beans have been associated with foodborne illness, you must not use that lot of seeds or beans to produce sprouts.

(c) You must visually examine seeds and beans, and packaging used to ship seeds or beans, for signs of potential contamination with known or reasonably foreseeable hazards.

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

You must take all of the following measures for growing, harvesting, packing, and holding sprouts:

(a) You must grow, harvest, pack, and hold sprouts in a fully-enclosed building.

(b) Any food-contact surfaces you use to grow, harvest, pack, and hold sprouts must be cleaned and sanitized before contact with sprouts or seeds or beans used to grow sprouts.

(c) You must treat seeds or beans that will be used to grow sprouts using a scientifically valid method immediately before sprouting to reduce microorganisms of public health significance. Prior treatment conducted by a grower, handler, or distributor of seeds or beans does not eliminate your responsibility to treat seeds or beans immediately before sprouting at your covered farm.

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

All of the following testing must be done during growing, harvesting, packing, and holding sprouts:

(a) You must test the growing, harvesting, packing, and holding environment for *Listeria* species or *L. monocytogenes* in accordance with the requirements of § 112.144.

(b) You must either:

(1) Test spent sprout irrigation water from each production batch of sprouts for *E. coli* O157:H7 and *Salmonella* species in accordance with the requirements of § 112.146; or

(2) If testing spent sprout irrigation water is not practicable (for example, for soil-grown sprouts), test each production batch of sprouts at the in-process stage (*i.e.,* while sprouts are still growing) for *E. coli* O157:H7 and *Salmonella* species in accordance with the requirements of § 112.146.

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

All of the following testing requirements apply for the growing, harvesting, packing, and holding environment for *Listeria* species or *L. monocytogenes.*

(a) You must establish and implement a written environmental monitoring plan that is designed to identify *L. monocytogenes* if it is present in the growing, harvesting, packing, or holding environment.

(b) Your written environmental monitoring plan must be directed to sampling and testing for either *Listeria* species or *L. monocytogenes.*

(c) Your written environmental monitoring plan must include a sampling plan that specifies:

(1) What you will test collected samples for (*i.e., Listeria* species or *L. monocytogenes);*

(2) How often you will collect environmental samples, which must be no less than monthly; and

(3) Sample collection sites; the number and location of sampling sites must be sufficient to determine whether measures are effective and must include appropriate food-contact surfaces and non-food-contact surfaces of equipment, and other surfaces within the growing, harvesting, packing, and holding environment.

(d) You must collect environmental samples and test them for *Listeria* species or *L. monocytogenes* according to the method in § 112.152.

§ 112.145 What actions must I take if the growing, harvesting, packing, or holding environment tests positive for Listeria species or L. monocytogenes?

You must take the following actions if you detect *Listeria* species or *L. monocytogenes* in the growing, harvesting, packing, or holding environment:

(a) Conduct additional testing of surfaces and areas surrounding the area where *Listeria* species or *L. monocytogenes* was detected to evaluate the extent of the problem, including the potential for *Listeria* species or *L. monocytogenes* to have become established in a niche;

(b) Clean and sanitize the affected surfaces and surrounding areas;

(c) Conduct additional microbial sampling and testing to determine whether the *Listeria* species or *L. monocytogenes* has been eliminated;

(d) Conduct finished product testing when appropriate; and

(e) Perform any other actions necessary to prevent reoccurrence of the contamination.

§ 112.146 What must I do to collect and test samples of spent sprout irrigation water or sprouts?

All of the following requirements apply for collecting and testing samples of spent sprout irrigation water or sprouts:

(a) You must establish and implement a written sampling plan that identifies the number and location of samples (of spent sprout irrigation water or sprouts) to be collected for each production batch of sprouts to ensure that the collected samples are representative of the production batch when testing for contamination.

(b) In accordance with the written sampling plan required under paragraph (a) of this section, you must aseptically collect samples of spent sprout irrigation water or sprouts, and test the collected samples for *E. coli* O157:H7 and *Salmonella* species using a method that has been validated for its intended use (testing spent sprout irrigation water or sprouts) to ensure that the testing is accurate, precise, and sensitive in detecting these pathogens.

§ 112.150 Under this subpart, what requirements apply regarding records?

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

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

(1) Documentation of your treatment of seeds or beans to reduce microorganisms of public health significance in the seeds or beans, at your farm;

(2) Your written environmental monitoring plan in accordance with the requirements of § 112.144;

(3) Your written sampling plan for each production batch of sprouts in accordance with the requirements of § 112.146(a);

(4) The results of all testing conducted in accordance with the requirements of §§ 112.143 and 112.144;

(5) Any analytical methods you use in lieu of the methods that are incorporated by reference in § 112.152; and

(6) The testing method you use in accordance with the requirements of § 112.146(b).

Subpart N—Analytical Methods

§ 112.151 What methods must I use to test the quality of water to satisfy the requirements of § 112.45

(a) You must test the quality of water using a method of analysis:

(1) As published in the ''Official Methods of Analysis of the Association of Official Analytical Chemists (AOAC) International'' (18th ed., revision 4, 2011) which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the AOAC International, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*; or

(2) As published in the Standards Methods for the Examination of Water and Wastewater (21st ed., 2005), American Public Health Association (APHA), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain a copy from the APHA, 800 I St. NW., Washington, DC 20001, 202–777–2742. You may inspect a copy at the Center for Food Safety and Applied Nutrition's Library, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–2163, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*; or

(3) As prescribed in Chapter 4 of the FDA Bacteriological Analytical Manual (BAM) (Edition 8, Revision A, 1998), as updated in June 2011. The Director of the Federal Register approves the incorporation by reference of FDA's BAM, Chapter 4 (Edition 8, Revision A, 1998), as updated in June 2011, in accordance with 5 U.S.C. 552(a) and 1 CFR part 5. You may obtain a copy of the method from Office of Regulatory Science, Center for Food Safety and

Applied Nutrition (CFSAN), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–1990, or you may examine a copy at CFSAN's Library, 5100 Paint Branch Pkwy., College Park, MD, 240–402–2163, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulation/ibr_locations.html*; or

(4) That is at least equivalent to the appropriate method of analysis in §§ 112.151(a)(1), (a)(2) or (a)(3) in accuracy, precision, and sensitivity.

§ 112.152 What methods must I use to test the growing environment for Listeria species or L. monocytogenes to satisfy the requirements of § 112.143(a) and § 112.144?

You must test the growing environment by testing for the presence of *Listeria* species or *L. monocytogenes* in environmental samples using the methods and procedures described in Chapter 10 of FDA's Bacteriological Analytical Manual (BAM) April 2011, Edition (Edition 8, Revision A, 1998), or a method that is at least equivalent in accuracy, precision, and sensitivity. The Director of the Federal Register approves the incorporation by reference of FDA's BAM, Chapter 10—''*Listeria monocytogenes,* Detection and Enumeration of *Listeria monocytogenes* in Foods,'' April 2011, in accordance with 5 U.S.C. 552(a) and 1 CFR part 5. You may obtain a copy of the method from Office of Regulatory Science, Center for Food Safety and Applied Nutrition (CFSAN), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–1990, or you may examine a copy at CFSAN's Library, 5100 Paint Branch Pkwy., College Park, MD, 240–402–2163, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulation/ibr_locations.html*.

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

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

(a) All records required under this part must:

(1) Include, as applicable:

(i) The name and location of your farm;

(ii) Actual values and observations obtained during monitoring;

(iii) 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;

(iv) 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

(v) The date and time of the activity documented;

(2) Be created at the time an activity is performed or observed;

(3) Be accurate, legible, and indelible; and

(4) 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.

§ 112.162 Where must I store records?

(a) Offsite storage of records is permitted after 6 months following the date the record was made if such records can be retrieved and provided onsite within 24 hours of request for official review.

(b) Electronic records are considered to be onsite at your farm if they are accessible from an onsite location at your farm.

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

Yes. The regulations in this part do not require duplication of existing records if those records contain all of the information required by this part.

§ 112.164 How long must I keep records?

(a) You must keep records required by this part for 2 years past the date the record was created.

(b) Records that relate to the general adequacy of the equipment or processes being used by a farm, including the results of scientific studies and evaluations, must be retained at the farm for at least 2 years after the use of such equipment or processes is discontinued.

§ 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.

§ 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.

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

Records required by this part are subject to the disclosure requirements under part 20 of this chapter.

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.

§ 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.

§ 112.173 What must be included in the Statement of Grounds in a petition requesting a variance?

In addition to the requirements set forth in § 10.30 of this chapter, the Statement of Grounds in a petition requesting a variance must:

(a) Provide a statement that the applicable State or foreign country has determined that the variance is necessary in light of local growing conditions and that 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;

(b) Describe with particularity the variance requested, including the persons to whom the variance would apply and the provision(s) of this part to which the variance would apply;

(c) Present information demonstrating that the procedures, processes, and practices to be followed under 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.

§ 112.174 What information submitted in a petition requesting a variance or submitted in comments on such a petition are publicly available?

We will presume that information submitted in a petition requesting a variance and comments submitted on such a petition, including a request that a variance be applied to its similarly situated persons, does not contain information exempt from public disclosure under part 20 of this chapter and would be made public as part of the docket associated with this request.

§ 112.175 Who responds to a petition requesting a variance?

The Director or Deputy Directors of the Center for Food Safety and Applied Nutrition (CFSAN), or the Director, Office of Compliance, CFSAN, responds to a request for a variance.

§ 112.176 What process applies to a petition requesting a variance?

(a) In general, the procedures set forth in § 10.30 of this chapter govern our response to a petition requesting a variance.

(b) Under § 10.30(h)(3) of this chapter, we will publish a notice in the **Federal Register**, requesting information and views on a filed petition, including information and views from persons who could be affected by the variance if the petition were to be granted (either because their farm is covered by the petition or as a person similarly situated to persons covered by the petition).

(c) Under § 10.30(e)(3) of this chapter, we will respond to the petitioner in writing and will also make public a notice on FDA's Web site announcing our decision to either grant or deny the petition.

(1) If we grant the petition, either in whole or in part, we will specify the persons to whom the variance applies and the provision(s) of this part to which the variance applies.

(2) If we deny the petition (including partial denials), our written response to the petitioner and our public notice announcing our decision to deny the petition will explain the reason(s) for the denial.

(d) We will make readily accessible to the public, and periodically update, a list of filed petitions requesting variances, including the status of each petition (for example, pending, granted, or denied).

§ 112.177 Can an approved variance apply to any person other than those identified in the petition requesting that variance?

(a) A State or a foreign country that believes that a variance requested by a petition submitted by another State or foreign country should also apply to similarly situated persons in its jurisdiction may request that the variance be applied to its similarly situated persons by submitting comments in accordance with § 10.30 of this chapter. These comments must include the information required in § 112.173. If FDA determines that these comments should instead be treated as a separate request for a variance, FDA will notify the State or foreign country that submitted these comments that a separate request must be submitted in accordance with §§ 112.172 and § 112.173.

(b) If we grant a petition requesting a variance, in whole or in part, we may specify that the variance also applies to persons in a specific location who are similarly situated to those identified in the petition.

(c) If we specify that the variance also applies to persons in a specific location who are similarly situated to those identified in the petition, we will inform the applicable State or foreign country where the similarly situated persons are located of our decision in writing and will publish a notice on our Web site announcing our decision to apply the variance to similarly situated persons in that particular location.

§ 112.178 Under what circumstances may FDA deny a petition requesting a variance?

We may deny a variance request if it does not provide the information required under § 112.173 (including the requirements of § 10.30 of this chapter), or if we determine that the variance is not 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.

§ 112.179 When does a variance approved by FDA become effective?

A variance approved by FDA becomes effective the date of our written decision on the petition.

§ 112.180 Under what circumstances may FDA modify or revoke an approved variance?

We may modify or revoke a variance if we determine that such variance is not 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.

§ 112.181 What procedures apply if FDA determines that an approved variance should be modified or revoked?

(a) We will provide the following notifications:

(1) We will notify a State or a foreign country directly, in writing at the address identified in its petition, if we determine that a variance granted in response to its petition should be modified or revoked. Our direct, written notification will provide the State or foreign country with an opportunity to request an informal hearing under part 16 of this chapter.

(2) We will publish a notice of our determination that a variance should be modified or revoked in the **Federal Register**. This notice will establish a public docket so that interested parties may submit written submissions on our determination.

(3) When applicable, we will:

(i) Notify in writing any States or foreign countries where a variance applies to similarly situated persons of our determination that the variance should be modified or revoked;

(ii) Provide those States or foreign countries with an opportunity to request

an informal hearing under part 16 of this chapter; and

(iii) Include in the **Federal Register** notice described in paragraph (a)(2) of this section public notification of our decision to modify or revoke the variance granted to States or foreign countries in which similarly situated persons are located.

(b) We will consider submissions from affected States or foreign countries and from other interested parties as follows:

(1) We will consider requests for hearings by affected States or foreign countries under part 16 of this chapter.

(i) If FDA grants a hearing, we will provide the State or foreign country with an opportunity to make an oral submission. We will provide notice on our Web site of the hearing, including the time, date, and place of hearing.

(ii) If more than one State or foreign country requests an informal hearing under part 16 of this chapter about our determination that a particular variance should be modified or revoked, we may consolidate such requests (for example, into a single hearing).

(2) We will consider written submissions submitted to the public docket from interested parties.

(c) We will provide notice of our final decision as follows:

(1) On the basis of the administrative record, FDA will issue a written decision, as provided for under part 16 of this chapter.

(2) We will publish a notice of our decision in the **Federal Register**. The effective date of the decision will be the date of publication of the notice.

§ 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).

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)).

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

Under Section 419(b)(2)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350h(b)(2)(A)), FDA coordinates education and enforcement activities by State, Territorial, tribal, and local officials.

Subpart R—Withdrawal of Qualified Exemption

§ 112.201 Under what circumstances can FDA withdraw a qualified exemption in accordance with the requirements of § 112.5?

We may withdraw your qualified exemption under § 112.5:

(a) In the event of an active investigation of a foodborne illness outbreak that is directly linked to your farm; or

(b) If we determine that it is necessary to protect the public health and prevent or mitigate a foodborne illness outbreak based on conduct or conditions associated with your farm that are material to the safety of the food that would otherwise be covered produce grown, harvested, packed or held at your farm.

§ 112.202 What procedure will FDA use to withdraw an exemption?

(a) If FDA determines that a qualified exemption applicable to a farm under § 112.5 should be withdrawn, any officer or qualified employee of FDA may issue an order to withdraw the exemption.

(b) An FDA District Director in whose district the farm is located (or, in the case of a foreign farm, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition), or an FDA official senior to such Director, must approve an order to withdraw the exemption.

(c) FDA must issue an order to withdraw the exemption to the owner, operator, or agent in charge of the farm.

(d) FDA must issue an order to withdraw the exemption in writing, signed and dated by the officer or qualified employee of FDA who is issuing the order.

§ 112.203 What information must FDA include in an order to withdraw a qualified exemption?

An order to withdraw a qualified exemption applicable to a farm under § 112.5 must include the following information:

(a) The date of the order;

(b) The name, address and location of the farm;

(c) A brief, general statement of the reasons for the order, including information relevant to:

(1) An active investigation of a foodborne illness outbreak that is directly linked to the farm; or

(2) Conduct or conditions associated with a farm that are material to the safety of the food that would otherwise be covered produce grown, harvested, packed and held at such farm.

(d) A statement that the farm must comply with subparts B through O of this part on the date that is 60 calendar days after the date of the order;

(e) The text of section 419(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350(f)) and of this subpart;

(f) A statement that any informal hearing on an appeal of the order must be conducted as a regulatory hearing under part 16 of this chapter, with certain exceptions described in § 112.208;

(g) The mailing address, telephone number, email address, and facsimile number of the FDA district office and the name of the FDA District Director in whose district the farm is located (or for foreign farms, the same information for the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition); and

(h) The name and the title of the FDA representative who approved the order.

§ 112.204 What must I do if I receive an order to withdraw a qualified exemption applicable to my farm?

The owner, operator, or agent in charge of a farm that receives an order to withdraw a qualified exemption applicable to that farm under § 112.5 must either:

(a) Comply with applicable requirements of this part within 60 calendar days of the date of the order or, if operations have ceased and will not resume within 60 calendar days, before the beginning of operations in the next growing season; or

(b) Appeal the order within 10 calendar days of the date of the order in accordance with the requirements of § 112.206.

§ 112.205 Can I appeal or request a hearing on an order to withdraw a qualified exemption applicable to my farm?

(a) Submission of an appeal, including submission of a request for an informal hearing, will not operate to delay or stay any administrative action, including enforcement action by FDA, unless the Commissioner of Food and Drugs, as a matter of discretion, determines that delay or a stay is in the public interest.

(b) If the owner, operator, or agent in charge of the farm appeals the order, and FDA confirms the order, the owner, operator, or agent in charge of the farm must comply with applicable requirements of this part within 60 calendar days of the date of the order, or, if operations have ceased and will not resume within 60 calendar days, before the beginning of operations in the next growing season.

§ 112.206 What is the procedure for submitting an appeal?

(a) To appeal an order to withdraw a qualified exemption applicable to a farm under § 112.5, the owner, operator, or agent in charge of the farm must:

(1) Submit the appeal in writing to the FDA District Director in whose district the farm is located (or in the case of a foreign farm, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition), at the mailing address, email address, or facsimile number identified in the order within 10 calendar days of the date of the order; and

(2) Respond with particularity to the facts and issues contained in the order, including any supporting documentation upon which the owner, operator or agent in charge of the farm relies.

(b) In a written appeal of the order withdrawing an exemption provided under § 112.5, the owner, operator, or agent in charge of the farm may include a written request for an informal hearing as provided in § 112.207.

§ 112.207 What is the procedure for requesting an informal hearing?

(a) If the owner, operator, or agent in charge of the farm appeals the order, the owner, operator, or agent in charge of the farm:

(1) May request an informal hearing; and

(2) Must submit any request for an informal hearing together with its written appeal submitted in accordance with § 112.206 within 10 calendar days of the date of the order.

(b) A request for an informal hearing may be denied, in whole or in part, if the presiding officer determines that no genuine and substantial issue of material fact has been raised by the material submitted. If the presiding officer determines that a hearing is not justified, a written notice of the determination will be given to the owner, operator, or agent in charge of the farm explaining the reason for the denial.

§ 112.208 What requirements are applicable to an informal hearing?

If the owner, operator or agent in charge of the farm requests an informal hearing, and FDA grants the request:

(a) The hearing will be held within 10 calendar days after the date the appeal is filed or, if applicable, within a timeframe agreed upon in writing by the owner, operator, or agent in charge of the farm and FDA.

(b) The presiding officer may require that a hearing conducted under this subpart be completed within 1 calendar day, as appropriate.

(c) FDA must conduct the hearing in accordance with part 16 of this chapter, except that:

(1) The order withdrawing an exemption under § 112.5, rather than the notice under § 16.22(a) of this chapter, provides notice of opportunity for a hearing under this section and is part of the administrative record of the regulatory hearing under § 16.80(a) of this chapter.

(2) A request for a hearing under this subpart must be addressed to the FDA District Director (or, in the case of a foreign farm, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition) as provided in the order withdrawing an exemption.

(3) Section 112.209, rather than § 16.42(a) of this chapter, describes the FDA employees who preside at hearings under this subpart.

(4) Section 16.60(e) and (f) of this chapter does not apply to a hearing under this subpart. The presiding officer must prepare a written report of the hearing. All written material presented at the hearing will be attached to the report. The presiding officer must include as part of the report of the hearing a finding on the credibility of witnesses (other than expert witnesses) whenever credibility is a material issue, and must include a proposed decision, with a statement of reasons. The hearing participant may review and comment on the presiding officer's report within 2 calendar days of issuance of the report. The presiding officer will then issue the final decision.

(5) Section 16.80(a)(4) of this chapter does not apply to a regulatory hearing under this subpart. The presiding officer's report of the hearing and any comments on the report by the hearing participant under § 112.208(c)(4) are part of the administrative record.

(6) No party shall have the right, under § 16.119 of this chapter to petition the Commissioner of Food and Drugs for reconsideration or a stay of the presiding officer's final decision.

(7) If FDA grants a request for an informal hearing on an appeal of an order withdrawing an exemption, the hearing must be conducted as a regulatory hearing under regulation in accordance with part 16 of this chapter, except that § 16.95(b) does not apply to a hearing under this subpart. With respect to a regulatory hearing under this subpart, the administrative record of the hearing specified in §§ 16.80(a)(1), (a)(2), (a)(3), and (a)(5), and § 112.208(c)(5) constitutes the exclusive record for the presiding officer's final decision. For purposes of judicial review under § 10.45 of this chapter, the record of the administrative proceeding consists of the record of the hearing and the presiding officer's final decision.

§ 112.209 Who is the presiding officer for an appeal and for an informal hearing?

The presiding officer for an appeal, and for an informal hearing, must be an FDA Regional Food and Drug Director or another FDA official senior to an FDA District Director.

§ 112.210 What is the timeframe for issuing a decision on an appeal?

(a) If the owner, operator, or agent in charge of a farm appeals the order without requesting a hearing, the presiding officer must issue a written report that includes a final decision confirming or revoking the withdrawal by the 10th calendar day after the appeal is filed.

(b) If the owner, operator, or agent in charge of a farm appeals the order and requests an informal hearing:

(1) If FDA grants the request for a hearing and the hearing is held, the presiding officer must provide a 2 calendar day opportunity for the hearing participants to review and submit comments on the report of the hearing under § 112.208(c)(4), and must issue a final decision within 10 calendar days after the hearing is held; or

(2) If FDA denies the request for a hearing, the presiding officer must issue a final decision on the appeal confirming or revoking the withdrawal within 10 calendar days after the date the appeal is filed.

§ 112.211 When is an order to withdraw a qualified exemption applicable to a farm revoked?

An order to withdraw a qualified exemption applicable to a farm under § 112.5 is revoked if:

(a) The owner, operator, or agent in charge of the farm appeals the order and requests an informal hearing, FDA grants the request for an informal hearing, and the presiding officer does not confirm the order within the 10 calendar days after the hearing, or issues a decision revoking the order within that time; or

(b) The owner, operator, or agent in charge of the farm appeals the order and requests an informal hearing, FDA denies the request for an informal hearing, and FDA does not confirm the order within the 10 calendar days after the appeal is filed, or issues a decision revoking the order within that time; or

(c) The owner, operator, or agent in charge of the farm appeals the order without requesting an informal hearing, and FDA does not confirm the order within the 10 calendar days after the appeal is filed, or issues a decision revoking the order within that time.

(d) Confirmation of a withdrawal order by the presiding officer is considered a final Agency action for purposes of 5 U.S.C. 702.

Dated: January 3, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–00123 Filed 1–4–13; 11:15 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 1, 16, 106, 110, 114, 117, 120, 123, 129, 179, and 211

[Docket No. FDA–2011–N–0920]

RIN 0910–AG36

Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend its regulation for Current Good Manufacturing Practice In Manufacturing, Packing, or Holding Human Food (CGMPs) to modernize it and to add requirements for domestic and foreign facilities that are required to register under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to establish and implement hazard analysis and risk-based preventive controls for human food. FDA also is proposing to revise certain definitions in FDA's current regulation for Registration of Food Facilities to clarify the scope of the exemption from registration requirements provided by the FD&C Act for ''farms.'' FDA is taking this action as part of its announced initiative to revisit the CGMPs since they were last revised in 1986 and to implement new statutory provisions in the FD&C Act. The proposed rule is intended to build a food safety system for the future that makes modern, science-, and risk-based preventive controls the norm across all sectors of the food system.

DATES: Submit either electronic or written comments on the proposed rule by May 16, 2013. Submit comments on information collection issues under the Paperwork Reduction Act of 1995 by February 15, 2013, (see the ''Paperwork Reduction Act of 1995'' section of this document).

ADDRESSES: You may submit comments, identified by Docket No. FDA–2011–N–0920 and/or RIN 0910–AG36, by any of the following methods, except that comments on information collection issues under the Paperwork Reduction Act of 1995 must be submitted to the Office of Regulatory Affairs, Office of Management and Budget (OMB) (see the ''Paperwork Reduction Act of 1995'' section of this document).

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- FAX: 301–827–6870.
- Mail/Hand delivery/Courier (for paper or CD–ROM submissions): Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name and Docket No. for this rulemaking. All comments received may be posted without change to *http://www.regulations.gov*, including any personal information provided. For additional information on submitting comments, see the ''Comments'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: *With regard to the proposed rule:* Jenny Scott, Center for Food Safety and Applied Nutrition (HFS–300), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–2166.

With regard to the information collection: Domini Bean, Office of Information Management, Food and Drug Administration, 1350 Picard Dr., PI50–400T, Rockville, MD 20850, *domini.bean@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

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