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Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption; Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food; Draft Qualitative Risk Assessment of Risk of Activity/Food Combinations for Activities (Outside the Farm Definition) Conducted in a Facility Co-Located on a Farm; Availability; Proposed Rules

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.

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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 Health 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 Value-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 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 uni 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. 350(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 inter-related; 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	<p>Notes: Not applicable. Harvesting is a classification that only applies on farms and farm mixed-type facilities.</p> <p>Examples: Not applicable</p>	<p>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.</p> <p>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.</p>
Packing	<p>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).</p> <p>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).</p>	<p>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.</p> <p>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, sticker/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.</p> <p>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.</p>
Holding	<p>Notes: Storage of food</p> <p>Example: storing food, such as in a warehouse</p>	<p>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.</p> <p>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.</p>

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)
Manufacturing/Processing ...	<p>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).</p> <p>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.</p>	<p>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.</p> <p>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.</p> <p>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.</p> <p>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.</p>

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 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 collocated 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 cayatanensis*). 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 and 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 it 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 coliforms (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 Health 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