Frequently Asked Questions and Answers

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

March, 2013

A: General

A.1 What does the proposed produce safety rule establish?

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

- Worker Training and Health and Hygiene
- Agricultural Water
- Biological Soil Amendments of Animal Origin
- Domesticated and Wild Animals
- Equipment, Tools, and Buildings
- Sprouts

A.2 What kind of produce does the proposed produce safety rule apply to?

The proposed rule covers most fruits and vegetables while they are in their raw or natural (unprocessed) state. It would not apply to raw agricultural commodities that are rarely consumed raw, those produced for personal or on-farm consumption, and (with certain documentation) those destined for commercial processing, such as canning, that will adequately reduce microorganisms of public health concern.

A.3 How would the proposed rule define "farm"?

The proposed rule would 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. "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.

A.4 How would the proposed rule define "mixed-type facility" and "farm mixed-type facility?

The proposed rule would define "mixed-type facility" to mean an establishment that engages in both activities that are exempt from registration under section 415 of the Federal Food, Drug, and Cosmetic Act (FD&C Act), and activities that require the establishment to be registered. An example of such a facility is a "farm mixed-type facility" which is an establishment that grows and harvests crops or raises animals and may conduct other activities within the farm definition, but also conducts activities that require the establishment to register with FDA under section 415 of the FD&C Act.

A.5 Where can I find out more about what activities are within the definition of "farm" and what activities are outside that definition?

Table 3 in the proposed produce rule preamble (in section V.A.2.b.i, at 78 FR 3543-4) provides examples of activities and their classification. For more information, we

encourage you to read section V.A.2.b.i of the proposed produce rule preamble (starting at 78 FR 3539), and section VIII of the proposed preventive controls rule preamble (starting at 78 FR 3674), which includes the most detail on this topic.

A.6 When would packing produce be subject to the rule and when would it not be subject to the rule? What is the reason for the difference?

Produce packing that does not occur on a farm would not be subject to the proposed rule because the proposed rule would only apply to covered farms as defined in the rule (see proposed § 112.4).

Packing produce for consumption on the farm would not be covered by the rule because the rule would not apply to produce for on-farm consumption (see proposed § 112.2(a)(2)).

When a covered farm packs produce grown on that farm (or another farm under the same ownership) for distribution into commerce, that activity would be covered by the rule because the activity is within the definition of "farm" in the rule (see proposed §112.3(c) definition of farm: "'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").

When a covered farm packs produce that was not grown on that farm (or another farm under the same ownership) for distribution into commerce, that activity would not be subject to the proposed rule because it would not be within the definition of "farm" in the rule (see proposed §112.3(c) definition of farm: "'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").

The definition of "farm" and related definitions in the proposed rule are based in part on FDA's tentative conclusions that:

- the basic purpose of farms is to produce raw agricultural commodities (RACs) and RACs are the essential products of farms;
- 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"; and
- 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.

A.7 Who would be a "covered farm" under the proposed rule?

The proposed rule would define "farm" and "mixed-type facility" (see above). Farms and farm mixed-type facilities that have an average annual monetary value of food sold

during the previous 3-year period of more than $25,000 (on a rolling basis) would be "covered farms" under the proposed rule, unless they are eligible for the qualified exemption (see below) and FDA has not withdrawn their qualified exemption.
The proposed rule would not apply to farms that have an average annual value of food sold during the previous 3-year period of $25,000 or less. FDA notes, however, that these farms are and will continue to be covered under the adulteration provisions and other applicable provisions of the FD&C Act, whether or not they are included within the scope of this proposed rule.

A.8 What food would count in calculating the average annual monetary value of food sold during the previous three-year period (for the purposes of proposed §§ 112.4, 112.5, and the definitions of small and very small business in proposed § 112.3(b))? For example, would the value of peaches I sold to a commercial cannery be calculated when determining the average monetary value of food sold during the previous 3-year period?

In the term "average annual monetary value of food sold," the word "food" means "food as defined in section 201(f) of the FD&C Act and includes seeds and beans used to grow sprouts" (see proposed § 112.3(c)). In section 201(f) of the FD&C Act, "food" means (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article. Thus, all food would count in calculating the average annual value of food sold, even if that food is not covered produce. In the example, the value of peaches sold to a commercial cannery would be included in the calculation to determine the average monetary value of food sold during the previous 3-year period.

B. Qualified exemption and modified requirements

B.1 What qualified exemption is being proposed for certain farms under the proposed rule?

As required by FSMA, certain farms would be exempt from most of the requirements of the proposed rule and would instead be subject to modified requirements. This qualified exemption could be withdrawn under certain circumstances. The following farms would be eligible for the qualified exemption:

Farms for which, during the previous 3-year period preceding the applicable calendar year:

The average annual monetary value of the food sold directly to qualified end-users during such period exceeded the average annual value of the food sold to all other buyers during that period; AND

The average annual monetary value of all food sold during such period was less than $500,000, adjusted for inflation.

B.2 What modified requirements would the proposed rule establish for farms eligible for the qualified exemption? (proposed § 112.6)

Farms eligible for the qualified exemption would be subject to proposed subparts A, Q, and R. The proposed rule would also require a farm eligible for the qualified exemption to do the following:

- When a food packaging label **is required** on food that would otherwise be covered produce under the FD&C Act or its implementing regulations, the farm must include prominently and conspicuously on the food packaging label the name and the complete business address of the farm where the covered produce was grown;
- When a food packaging label **is not required** on food that would otherwise be covered produce under the FD&C Act or its implementing regulations, the farm must prominently and conspicuously display, at the point of purchase, the name and complete business address of the farm where the produce was grown on a label, poster, sign, placard, or documents delivered contemporaneously with the produce in the normal course of business, or, in the case of Internet sales, in an electronic notice.

The complete business address would be required to include the street address or post office box, city, state, and zip code for domestic farms, and comparable full address information for foreign farms.

B.3 If some of the produce that I grow is not covered by the proposed rule or is eligible for exemption from most requirements under certain conditions, could my farm still be covered by this rule?

Yes. 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 the 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.

B.4 Are there circumstances in which FDA could withdraw a qualified exemption?

Yes. The proposed rule would allow FDA to withdraw a qualified exemption:

- In the event of an active investigation of a foodborne illness outbreak that is directly linked to your farm; or
- If FDA determines that it is necessary to protect the public health and prevent or mitigate a foodborne illness outbreak based on conduct or conditions associated with your farm that are material to the safety of the food that would otherwise be covered produce grown, harvested, packed or held at your farm (see proposed § 112.201).

B.5 What are examples of the types of conduct or conditions that could trigger the withdrawal of a qualified exemption?

As an example, we may receive reports to the Reportable Food Registry under section 417 of the FD&C Act about contamination of a food, and the reports may lead us to investigate a farm that grew, harvested, packed or held the food. If our investigation finds conduct or conditions associated with the farm that are material to the safety of the food that would otherwise be covered produce subject to proposed subparts B through O of the proposed rule (for example, conduct or conditions that likely led to the contamination of the food), we would consider withdrawing the qualified exemption applicable to the farm if doing so would be necessary to protect the public health and prevent or mitigate a foodborne illness outbreak. Likewise, if during a routine inspection of a farm to which the qualified exemption applies, we discover conditions and practices that are likely to lead to contamination of food that would otherwise be covered produce with microorganisms of public health significance, we would consider withdrawing the

qualified exemption provided to the facility if doing so would be necessary to protect the public health and prevent or mitigate a foodborne illness outbreak.

B.6 How would the proposed rule define "qualified end-user"?

The proposed rule would define "qualified end-user" to mean, with respect to a food:
The consumer of the food; OR
A restaurant or retail food establishment that is located in the same state as the farm that produced the food, or not more than 275 miles from such farm.

B.7 Would establishments like community sponsored agriculture (CSA) farms, "U-pick" farms, or farms that sell at farmers markets be covered by the proposed rule?

CSA farms, U-pick farms, and farms that sell at farmers markets, like all farms, would need to analyze their individual situations to determine if they would be covered by the proposed rule. In particular, these operations would need to analyze their sales under the terms of proposed § 112.5 to determine their eligibility for the qualified exemption and modified requirements.

For example, if a U-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 U-pick farm would be eligible for the qualified exemption and modified requirements.

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 directly 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 and modified requirements. 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.

C. Alternate Approaches for Requirements

C.1 Would the proposed rule allow the use of alternative practices?

We are proposing to allow for the use of alternatives to certain requirements of part 112 under certain specified conditions. Under proposed § 112.12, you may establish and use an alternative to certain specified requirements, 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 requirement 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. The specific requirements for which alternatives may be established and used are:

- Requirements 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 (see proposed § 112.44(c));
- Composting treatment processes (see proposed § 112.54(c)(1) and (2));
- Minimum application interval for an untreated biological soil amendment of animal origin that is reasonably likely to contact covered produce after application (including compost agricultural teas that contain compost agricultural tea additives) (see proposed § 112.56(a)(1)(i)); and
- Minimum application interval for a biological soil amendment of animal origin treated by a composting process that is reasonably likely to contact covered produce after application (see proposed § 112.56(a)(4)(i));

C.2 Where could I find scientific data and information that I would need to support the establishment and use of an alternative?

Scientific data and information used to support an alternative to a requirement for which alternatives are permitted may be:

- Developed by you;
- Available in the scientific literature; or
- Available to you through a third party (see proposed § 112.12(c)).

C.3 Would I be required to have documentation to support the use of an alternative, and would I be required to submit that documentation to FDA?

We do not propose to require you to submit scientific data or information in support of an alternative to us for review or approval prior to marketing. However, we would require that you establish and 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 (see proposed §§ 112.12(c) and 112.166).

D. Agricultural Water

D.1 How would the proposed rule define "agricultural water"?

The proposed rule would 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 (i.e., the harvestable or harvested part of the crop) or food-contact surfaces, including water used in growing, harvesting, packing, and holding activities. Agricultural water includes:

- Irrigation water applied using direct water application methods;
- Water used for preparing crop sprays;
- Water used for growing sprouts;
- Water used for washing or cooling harvested produce; and
- Water used to prevent dehydration of produce (see proposed § 112.3(c)).

D.2 Would the proposed rule establish requirements for indirect water application (for example, drip irrigation)?

The standards proposed in subpart E of the rule are directed to agricultural water only (see also A.19 above for proposed definition of agricultural water). Indirect water application methods where water is not intended to, and is not likely to, contact the harvestable or harvested part of the crop would not be subject to the requirements of proposed subpart E of the rule. As proposed, "agricultural water" would not include indirect water application methods used during growing. For example, generally, the water used for drip or furrow irrigation in apple orchards would not be considered agricultural water because the water is unlikely to contact the harvestable portion of the crop. FDA is proposing to distinguish between water that is intended to, or is likely to, contact produce or food-contact surfaces and water that is not intended to, and is not likely to, contact produce or food-contact surfaces based on the relative likelihood of contamination from water that contacts produce and the need for measures to minimize such likelihood.

While indirectly applied water is unlikely to contact produce or food-contact surfaces, we recognize that it presents the possibility of produce contamination. For example, use of contaminated water in drip or furrow irrigation may still serve as a vehicle for bringing contaminants into the growing environment which may potentially be transferred to produce by rain splash, workers, or equipment; use of contaminated water for dust abatement on farm roads may also be transferred to produce by run-off, rain splash, workers, or equipment.

Indirect water application methods would remain subject to Section 402(a)(4) of the FD&C Act. That is, indirect water application may adulterate produce if, considering the water quality and the manner of its application, the use of the water causes produce to be prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth or rendered injurious to health. Moreover, if a pathogen is

detected in or on produce, such produce would be considered adulterated under Section 402(a)(1) of the FD&C Act, in that it contains a poisonous or deleterious substance which may render it injurious to health. Therefore, we have tentatively concluded that indirect water application methods do not need to be covered within the scope of "agricultural water" for the purposes of the proposed rule. We are seeking public comment on our proposed limited scope of "agricultural water."

D.3 When the proposed rule would require me to treat my agricultural water, what requirements would it establish with respect to my treatment method?

The proposed rule does not specify a specific water treatment or method for treating agricultural water when treatment would be required. The proposed rule would require you to use a treatment method that is effective to make the water safe and of adequate sanitary quality for its intended use (see proposed § 112.43(b)). The proposed rule would also require you to deliver the treatment in a manner to ensure that the treated water consistently meets that standard, and to monitor the treatment at a frequency adequate to ensure that the treated water consistently meets that standard (see proposed § 112.43(c)).

Treating agricultural water with antimicrobial compounds (such as with an EPA-registered antimicrobial pesticide product) can be an effective means to eliminate pathogens if done properly, including under conditions that ensure the effectiveness of the active ingredient. Any chemicals used in the treatment of water would require EPA registration under the Federal Insecticide, Fungicide and Rodenticide Act before they can lawfully be used. We note, however, that at the present time, no such registration for chemical treatment of irrigation water exists. We anticipate that the proposed delayed implementation period for water quality testing would provide industry adequate time to address such issues. We are seeking public comment on this issue.

E. Soil Amendments

E.1 How would the proposed rule define "biological soil amendment of animal origin"?

The proposed rule would define the term "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 (see proposed § 112.3(c)).

E.2 Does the proposed rule account for the differences between "manure" and "compost"?

Yes, we are proposing definitions that make the distinction clear. We are proposing to use the phrase "untreated biological soil amendments of animal origin" as a category that includes raw manure (see proposed §§ 112.3(c) and 112.51(a)). We use the term "treated biological soil amendments of animal origin" to include treatments that meet the requirements of the standards presented in subpart F of the proposed rule (see proposed § 112.51(a)). To further alleviate confusion, we use the term "compost" as a verb, to mean the act of composting, and do not use it as a noun to describe a soil amendment that was treated by a composting method. Instead, we use the term "humus" in its common agricultural meaning (see proposed § 112.3(c)).

E.3 How would the proposed rule categorize biological soil amendments of animal origin as treated or untreated?

The proposed rule would categorize a biological soil amendment of animal origin as treated if it has been processed to completion to adequately reduce microorganisms of public health significance in accordance with the proposed requirements of § 112.54, or in the case of an agricultural tea, if the biological materials used to make the tea have been so processed and the water used to make the tea satisfies the proposed requirements of § 112.44(a) (see proposed § 112.51(a)).

The proposed rule would categorize a biological soil amendment of animal origin as untreated if it:

- has not been processed to completion in accordance with the proposed requirements of § 112.54, or in the case of an agricultural tea, if the biological materials used to make the tea have not been so processed or the water used to make the tea does not satisfy the proposed requirements of § 112.44(a);
- has become contaminated after treatment;
- has been recombined with an untreated biological soil amendment of animal origin;

- is or contains a component that is untreated waste that you know or have reason to believe is contaminated with a hazard or has been associated with foodborne illness; or
- is an agricultural tea that contains an agricultural tea additive. (see proposed §112.51(b))

E.4 Does the proposed rule establish testing requirements for soil amendments?

No. The proposed microbial standards for treated biological soil amendments in § 112.55 are not meant as lot-by-lot microbial testing requirements. Rather, they are intended to provide the standard against which treatment processes would be required to be validated. A validated process, when properly implemented and monitored, would be expected to meet the listed microbial standards. The person applying the treatment process would need to monitor the physical parameters of the process (e.g., temperature of a compost pile) to ensure that they meet the conditions under which the process was validated. Farms would be able to use treatment processes that are validated to meet the relevant microbial standard without needing to test the end products of their treatments to confirm that the microbial standard was achieved.

E.5 How do the proposed application requirements and intervals for raw manure relate to those used in the National Organic Program?

The proposed rule does not include any requirements that conflict with or duplicate the requirements of the National Organic Program. Where the 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). Certified organic farms growing produce that would be subject to this rule and that use raw manure would need to follow the application requirements and intervals in the proposed rule for untreated biological soil amendments of animal origin. The National Organic Program application intervals for raw manure would run concurrently with FDA's proposed application interval, 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.

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.

F. Records

F.1 Would records maintained for the National Organic Program (NOP) meet the records requirements of the proposed rule?

The proposed rule would not require duplication of existing records if those records contain all of the information required by the proposed rule (see proposed § 112.163). USDA-certified organic growers who already maintain records of when biological soil amendments of animal origin are applied in compliance with 7 CFR 205.103 would not need to duplicate those records to meet the proposed requirements of § 112.60(b)(1).

F.2 Would the proposed rule permit me to use existing records to meet its requirements?

Yes. The proposed rule does not require duplication of existing records if those records contain all of the information required by proposed part 112 (see proposed § 112.163).

F.3 Does the proposed rule require that records be made available and accessible to FDA?

Yes. The proposed rule would require all records required by part 112 be readily available and accessible during the retention period for inspection and copying by FDA upon oral or written request (see proposed § 112.166).

F.4 How long will the public have to comment on the proposed rule?

The comment period is open for 120 days (until May 16, 2013) from the date the proposed rule is published in the Federal Register. See www.regulations.gov.