

FSMA Facts

I Have a Farm - Does the Proposed Preventive Controls Rule Affect Me?

The answer to this question begins with determining if you have a farm, which is exempt from FDA's food facility registration, or a farm mixed-type facility, which is required to register. Facilities that do not have to register with FDA, such as farms, retail food establishments, and restaurants, are not subject to the requirements for Hazard Analysis and Risk-based Preventive Controls (HA/PC) in the Proposed Preventive Controls Rule for Human Food.

Definition of a Farm

A farm is defined as a facility in one general location devoted to the growing and harvesting of crops, the raising of animals (including seafood) or both. The term "farm" includes:

- 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
- 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.

Definition of a Farm Mixed-Type Facility

A farm mixed-type facility is an establishment that grows and harvests crops or raises animals and may conduct other activities within the farm definition, but also conducts activities that require the establishment to be registered. Because of a number of exemptions, some farm-mixed type facilities are subject to the HA/PC requirements, and some are not.

Farm Mixed-Type Facilities – Some are covered, some are not

Farm mixed-type facilities may be covered by the Proposed Rule on Preventive Controls for Human Food.

How do I know if my farm mixed-type facility is covered? You fit this definition if:

- Your farm manufactures, processes, packs or holds food that is not grown, raised or consumed on any farm you own
- Your farm manufactures or processes any food produced on your farm (or another farm that you own), and that food is not consumed on any farm you own.

Exemptions and Limitations

This does not mean you are automatically subject to the preventive controls rule. There are a number of limitations and exemptions that are likely to apply to many farm mixed-type facilities are included in the Proposed Rule on Preventive Controls for Human Food.

First, activities within the definition of "farm," including farm activities that are covered by the proposed rule on produce safety, are not subject to the Proposed Rule on Preventive Controls for Human Food. Activities within the farm definition are as follows:

- Growing/raising crops/animals
- Harvesting raw agricultural commodities grown/raised on one of your farms
- Packing or holding food grown, raised, or consumed on one of your farms
- Manufacturing/processing food that is consumed on one of your farms.

So even though a farm mixed-type facility must register, the activities it conducts within the farm definition would not be subject to the HA/PC requirements even if other activities are.

Next, there is a proposed exemption if you are a small/very small business and the only activities your

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farm mixed-type facility conducts that would be covered by HA/PC are certain on-farm low-risk manufacturing/processing activities on specific foods. Some examples are making jams, jellies and preserves from acidic fruits, making maple syrup, and shelling peanuts and tree nuts. (We are proposing to define a small business as one employing fewer than 500 persons. We are proposing three options for a very small business—less than \$250,000, less than \$500,000 or less than \$1 million in total annual food sales.)

There is also a proposed exemption for you if the only activity your farm mixed-type facility does that is covered by HA/PC is storage of non-fruit or vegetable raw agricultural commodities that are intended for further distribution or processing. Examples would be storage of grain or unpasteurized milk.

If your farm mixed-type facility is a “qualified facility,” then you would be subject to modified requirements. A qualified facility is one of the following:

- A very small business (FDA is proposing three options: less than \$250,000, less than \$500,000, or less than \$1 million in total annual sales of food)
- A facility that on average over the previous three years has less than \$500,000 in annual value of food sold AND the majority of the food is sold directly to “qualified end users.” (These are consumers in any location or a restaurant or retail food establishment in the same state or within 275 miles of your farm mixed-type facility.)

“Qualified facilities” would be required to submit certain documentation and, in certain instances, may need to provide notification to consumers of their complete business address.

Your Farm Mixed-type Facility is Covered if...

Here are some examples of activities carried out by mixed-type facilities that would be subject to the Preventive Controls requirements, unless your facility is subject to an exemption mentioned above:

- Manufacturing/processing activities such as:
 - Cutting/ chopping/slicing produce
 - Freezing produce
 - Drying that creates a distinct commodity, such as drying grapes to make raisins

Farmer’s Markets and Community Supported Agriculture Programs: Does the Preventive Controls Rule Apply?

Retail food establishments do not have to register and, thus, would be exempt from the Hazard Analysis/Preventive Controls (HA/PC) requirements. As directed by FSMA, FDA intends to amend the definition of “retail food establishment” to clarify that, in determining the primary function of an establishment, the sale of food products directly to consumers includes:

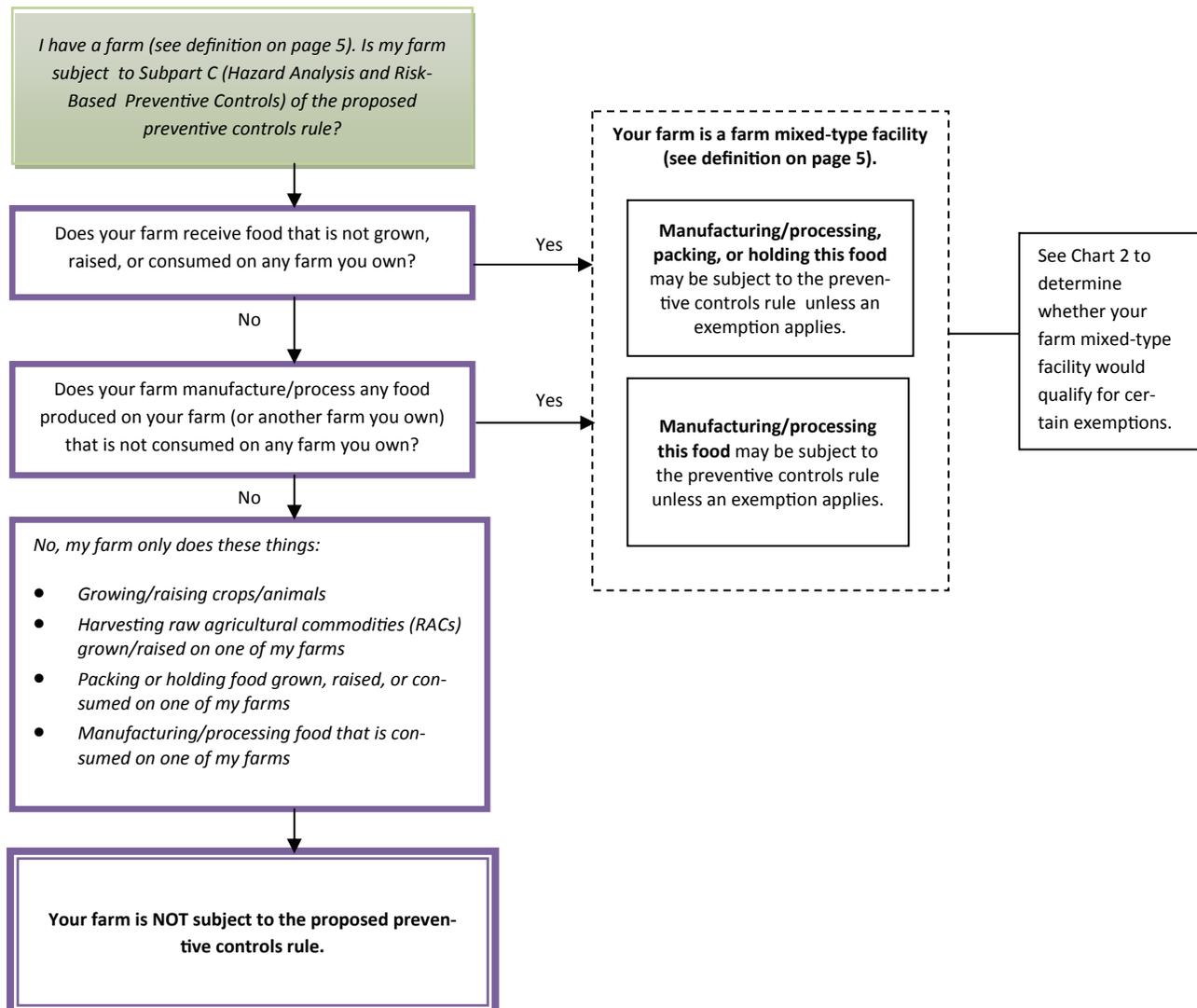
- Sale of food to consumers at a roadside stand or farmer’s market and
- Sale and distribution of food through a community-supported agriculture program.

The following flow chart provides additional information that may help you understand how the Preventive Controls Rule for Human Food relates to your farm.

Updated: 8/15/13

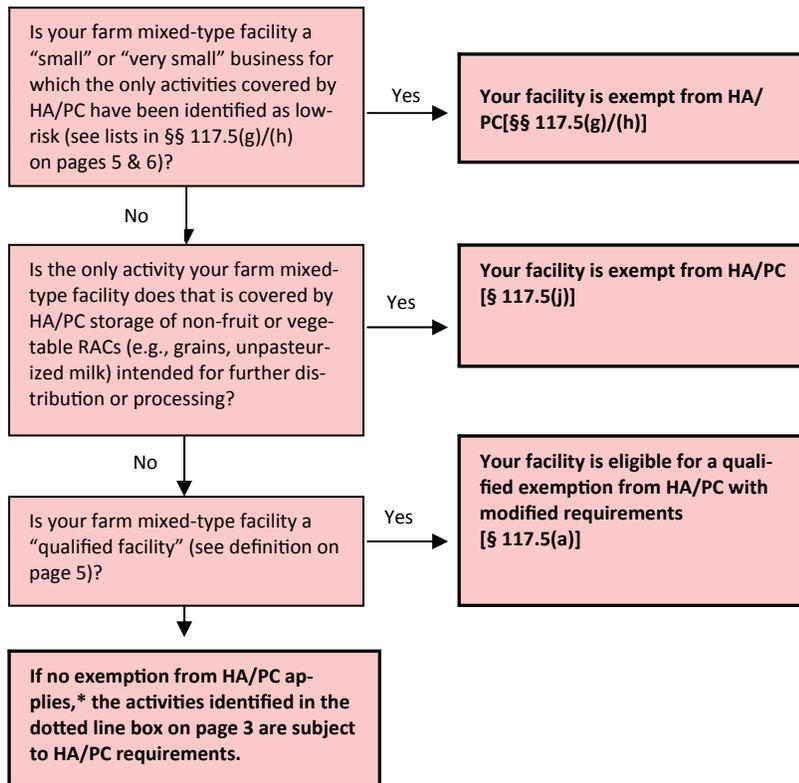
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Chart 1: Is my farm subject to Hazard Analysis and Risk-Based Preventive Controls (HA/PC)?



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Chart 2: Exemptions* for Farm Mixed-type Facilities from Subpart C- Hazard Analysis and Risk-Based Preventive Controls (HA/PC)



* There are other exemptions not discussed here. This chart only covers the exemptions most likely to apply to farm mixed-type facilities.

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Definitions Used for Purposes of the Proposed Preventive Controls Rule for Human Food

Farm means 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:

(1) 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

(2) 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.

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

Qualified end-user, with respect to a food, means the consumer of the food (where the term consumer does not include a business); or a restaurant or retail food establishment (as those terms are defined in 21 CFR § 1.227) that:

- (1) Is located;
 - (i) In the same State as the qualified facility that sold the food to such restaurant or establishment; **or**
 - (ii) Not more than 275 miles from such facility; **and**
- (2) Is purchasing the food for sale directly to consumers at such restaurant or retail food establishment.

Qualified facility means (when including the sales by any subsidiary; affiliate; or subsidiaries or affiliates, collectively, of any entity of which the facility is a subsidiary or affiliate) a facility that is a **very small business** as defined in the Proposed Preventive Controls Rule for Human Food (see below), **or** a facility to which both of the following apply:

(1) During the 3-year period preceding the applicable calendar year, the average annual monetary value of the food manufactured, processed, packed or held at such facility that is sold directly to qualified end-users (as defined in the Proposed Preventive Controls Rule for Human Food (see above)) during such period exceeded the average annual monetary value of the food sold by such facility to all other purchasers; and

(2) 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.

Small business means, for purposes of the Proposed Preventive Controls Rule for Human Food, a business employing fewer than 500 persons.

Very small business: FDA is asking for public comment on three different options for this definition

Option 1 for definition of "Very small business"

Very small business means, for purposes of the Proposed Preventive Controls Rule for Human Food, a business that has less than \$250,000 in total annual sales of food, adjusted for inflation.

Option 2 for definition of "Very small business"

Very small business means, for purposes of the Proposed Preventive Controls Rule for Human Food, a business that has less than \$500,000 in total annual sales of food, adjusted for inflation.

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Option 3 for definition of “Very small business”

Very small business means, for purposes of the Proposed Preventive Controls Rule for Human Food, a business that has less than \$1,000,000 in total annual sales of food, adjusted for inflation.

Relevant Sections of the Proposed Preventive Controls Rule for Human Food (proposed 21 CFR Part 117)

§117.5(a): Except as provided by subpart E of this part, subpart C of this part does not apply to a qualified facility. Qualified facilities are subject to the modified requirements in § 117.201.

§117.5(g): Subpart C of this part does not apply to on-farm packing or holding of food by a small or very small business if the only packing and holding activities subject to section 418 of the Federal Food, Drug, and Cosmetic Act that the business conducts are the following low-risk packing or holding activity/food combinations on food not grown, raised, or consumed on that farm mixed-type facility or another farm or farm mixed-type facility under the same ownership-- i.e., packing or re-packing (including weighing or conveying incidental to packing or re-packing); sorting, culling, or grading incidental to packing or storing; and storing (ambient, cold and controlled atmosphere) of:

- (1) Hard candy, fudge, taffy and toffee;
- (2) Cocoa beans and coffee beans (raw and roasted);
- (3) Cocoa products;
- (4) Grains and grain products;
- (5) Honey (raw and pasteurized);
- (6) Intact fruits and vegetables (for purposes of paragraph (g) and paragraph (h) of this section only, “intact fruits and vegetables” refers only to fruits and vegetables other than cocoa beans, coffee beans, peanuts, sugar beets, sugarcane, and tree nuts);
- (7) Jams, jellies and preserves;
- (8) Maple sap for syrup and maple syrup;

- (9) Peanuts and tree nuts;
- (10) Soft drinks and carbonated water;
- (11) Sugar beets, sugarcane, and sugar.

§117.5(h): Subpart C of this part does not apply to on-farm low-risk manufacturing/processing activities conducted by a small or very small business if the only manufacturing/processing activities subject to section 418 of the Federal Food, Drug, and Cosmetic Act that the business conducts are the following:

(1) When conducted on a farm mixed-type facility’s own raw agricultural commodities as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act (those grown or raised on that farm mixed-type facility or another farm/farm mixed-type facility under the same ownership) for distribution into commerce:

- (i) Artificial ripening of intact fruits and vegetables;
- (ii) Boiling/evaporation of maple sap to make maple syrup;
- (iii) Chopping raw peanuts and raw tree nuts;
- (iv) Coating (with coatings other than wax, oil, or resin used for the purpose of storage or transportation) intact fruits and vegetables (e.g., caramel apples) and coating raw peanuts and raw tree nuts (e.g., adding seasonings);
- (v) Drying/dehydrating intact fruits and vegetables (without the addition of sulfites) where the drying creates a distinct commodity (e.g., drying fruits or herbs);
- (vi) Extracting oil from grains (e.g., corn, oilseeds, soybeans);
- (vii) Grinding/milling/cracking/crushing grains (e.g., making grain products such as corn meal) and raw peanuts or raw tree nuts (e.g., making ground peanuts);
- (viii) Making jams, jellies and preserves from acid foods (e.g., acid fruits);

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(ix) Making sugar from sugar beets and sugarcane; and

(x) Salting raw peanuts and raw tree nuts.

(2) When conducted on food other than the farm mixed-type facility's own raw agricultural commodities for distribution into commerce:

(i) Artificial ripening of intact fruits and vegetables;

(ii) Chopping peanuts and tree nuts;

(iii) Coating (with coatings other than wax, oil, or resin used for the purpose of storage or transportation) intact fruits and vegetables (e.g., caramel apples) and coating peanuts and tree nuts (e.g., adding seasonings);

(iv) Cooling intact fruits and vegetables using cold air;

(v) Drying/dehydrating (whether for storage/transport or for creating a distinct commodity) intact fruits and vegetables (without sulfiting), cocoa beans, coffee beans, grains and grain products, and peanuts and tree nuts;

(vi) Extracting oils from grains (e.g., corn, oilseeds, and soybeans);

(vii) Fermenting cocoa beans and coffee beans;

(viii) Grinding/milling/cracking/crushing cocoa beans, coffee beans, grains (e.g., making grain products such as corn meal), and peanuts and tree nuts (e.g., making ground peanuts);

(ix) Labeling (including applying stickers to) hard candy, cocoa beans, cocoa products from roasted cocoa beans (other than milk chocolate), coffee beans, intact fruits and vegetables, grain and grain products (other than those containing wheat in a form that would not be recognized as containing wheat without a label declaration), honey, jams/jellies/preserves, maple sap, maple syrup, intact

single-ingredient peanuts or tree nuts (shelled and unshelled), soft drinks and carbonated beverages, sugar beets, sugarcane, and sugar;

(x) Making hard candy, fudge, taffy, and toffee;

(xi) Making cocoa products from roasted cocoa beans;

(xii) Making honey;

(xiii) Making jams, jellies and preserves from acid foods (e.g., acid fruits);

(xiv) Making maple syrup;

(xv) Making soft drinks and carbonated water;

(xvi) Making sugar from sugar beets and sugarcane;

(xvii) Mixing cocoa beans, coffee beans, intact fruits and vegetables, grain and grain products, honey, maple sap and maple syrup, and peanuts and tree nuts;

(xviii) Packaging hard candy, fudge, taffy, toffee; cocoa beans; cocoa products; coffee beans; intact fruits and vegetables (other than modified atmosphere or vacuum packaging); grain and grain products; honey; jams, jellies and preserves; maple syrup; peanuts and tree nuts (including modified atmosphere or vacuum packaging); soft drinks and carbonated water; and sugar beets, sugarcane, and sugar;

(xix) Salting peanuts and tree nuts;

(xx) Shelling/hulling cocoa beans (i.e., winnowing), intact fruits and vegetables (e.g., dried beans and peas), and peanuts and tree nuts;

(xxi) Sifting grains and grain products;

(xxii) Sorting, culling, and grading (other than when incidental to packing or storage) hard candy, fudge, taffy, and toffee; cocoa beans; cocoa products; coffee beans; intact fruits and vegetables; grain and grain products; honey; jams, jellies

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and preserves; maple sap; maple syrup; peanuts and tree nuts; soft drinks and carbonated water; and sugar beets, sugarcane, and sugar;

(xxiii) Treating cocoa beans, coffee beans, intact fruits and vegetables, grain and grain products, and peanuts and tree nuts against pests (other than during growing) (e.g., fumigation);

(xxiv) Waxing (wax, oil, or resin used for the purpose of storage or transportation) intact fruits and vegetables.

§117.5(j): Subpart C of this part does not apply to facilities that are solely engaged in the storage of raw agricultural commodities (other than fruits and vegetables) intended for further distribution or processing.