

FSMA FACT SHEET

If I Am a Farm That Engages in Certain Manufacturing Operations, When Am I Subject to the Preventive Controls for Human Food Rule?

Overview

If an operation engages in both activities that fall under the “farm” definition and activities that require the establishment to be registered (such as certain manufacturing and processing activities), it is considered a “farm mixed-type facility.” These facilities are required to comply with the obligations under both the Produce Safety and Preventive Controls for Human Food rules, as relevant to each part of the operation. However, certain manufacturing, processing, packing and holding activities are not subject to the requirements for hazard analysis and risk-based preventive controls when they are conducted on-farm by small or very small businesses, if these are the only activities the businesses conduct that would be subject to the requirements for hazard analysis and risk-based preventive controls. The exemption only applies to the low-risk activity/food combinations listed in the regulation.

Exemption Requirements

To be exempt from the hazard analysis and risk-based preventive controls requirements in the Preventive Controls for Human Food rule, your operation must:

- Meet the “farm” definition, except that you also engage in certain manufacturing/processing activities, such that your operation is a “farm mixed-type facility”;
- Be a small business (you have fewer than 500 full-time equivalent employees) or a very small business (your average sales of human food (plus the market value of human food held without sale) was less than \$1 million per year); and,
- The only activities you conduct that would subject you to the hazard analysis and risk-based preventive controls requirements are those on the following low-risk activity list.

Low-Risk Activity List

The following is an exclusive list of the activities involving almonds that can be performed within the on-farm low-risk exemption:

- Packing (or re-packing) and holding tree nut products (including weighing or conveying incidental to packing or re-packing, sorting, culling or grading incidental to packing or storing, and storing).
- Chopping, coring, cutting, peeling, pitting, shredding and slicing tree nuts, and tree nut products (e.g., chopping roasted almonds).
- Coating tree nuts (e.g., adding seasonings provided that the seasonings have been treated to significantly minimize pathogens), and tree nut products (e.g., adding seasonings provided that the seasonings have been treated to significantly minimize pathogens).
- Grinding/cracking/crushing/milling tree nuts, and tree nut products (e.g., roasted almonds).
- Labeling tree nut products, (provided that they are single-ingredient, or are in forms in which the consumer can reasonably be expected to recognize the food allergen(s) without label declaration, or both (e.g., roasted or seasoned whole almonds, single-ingredient almond flours).
- Making candy from tree nuts (e.g., almond brittles).
- Making trail mix and granola from tree nut products for direct consumption, provided that tree nuts are treated to significantly minimize pathogens.
- Mixing tree nut products.
- Packaging tree nut products.
- Salting tree nut products direct consumption.
- Sifting tree nut flour products (e.g., almond flour).

Note that “tree nut products” includes such products as roasted almonds, seasoned almonds and almond flour.

Additional Considerations

If you are a farm mixed-type facility and you pack or hold processed foods other than almond products or you manufacture/process other foods, you should consult the full text of the exemptions at 21 CFR §§ 117.5(g) and (h) to determine if these additional activities you conduct also are considered low risk and covered by the same exemption.

If you aren't sure whether your operation is a “farm mixed-type facility” you should consult:

- The ABC Fact sheet: Is My Operation a “Farm” Covered by the Produce Safety Rule?
- The definition of “farm” at 21 CFR § 1.227
- The FDA’s Draft Guidance: Classification of Activities as Harvesting, Packing, Holding, or Manufacturing/Processing for Farms and Facilities; Guidance for Industry



Keep in mind that farms can perform certain activities and remain within the farm definition (and thus exempt from hazard analysis and preventive controls requirements), including:

- Packing or holding raw agricultural commodities
- Packaging and labeling raw agricultural commodities (when these activities don't involve additional manufacturing/processing)
- Manufacturing/processing food, provided all the processed food used in such activities is consumed on the farm or another farm under the same management
- Packing or holding processed food, provided all the processed food used in such activities is consumed on the farm or another farm under the same management