

## FSMA FACT SHEET

# Is My Operation a “Farm” Covered By the Produce Safety Rule?

### Overview

Whether your operation is a “farm” or a “facility” affects which FSMA rules you’re required to comply with. There are two ways that an operation can be considered a farm:

- **Primary Production Farm:** These are more “traditional” farming operations, such as where almonds are grown.
- **Secondary Activities Farm:** These are certain operations with a connection to a farm, but that do not grow almonds themselves.

An operation also can be a “farm mixed-type facility,” which means it’s both a farm and a facility and therefore needs to comply with both the Produce Safety (21 CFR Part 112) and Preventive Controls for Human Food (PCHF) (21 CFR Part 117) rules.

### Primary Production Farm

When considering whether your operation is a “farm,” the first issue to think about is whether the operation could be a primary production farm. If your operation is devoted to growing and harvesting almonds, it’s a primary production farm.

Based on draft guidance from the FDA, the following types of operations also can be primary production farms:

- An operation that grows, harvests, hulls and shells almonds on the same farm (i.e., in the same general physical location) where almonds are grown. The almonds that are hulled and shelled by this operation can be grown on the same farm or elsewhere.
- An operation that grows, harvests, hulls and shells, and handles (i.e., sizes, sorts, grades, cleans and packs) almonds on the same farm (i.e., in the same general physical location) where the almonds were grown. The almonds that are hulled, shelled, and handled by this operation can be grown on the same farm or elsewhere.
- A huller and sheller that is located in the “same general physical location” where the almonds it hulls and shells were grown.
- An operation that hulls and shells almonds and also handles almonds that is located in the “same general physical location” where the almonds it hulls, shells and harvests were grown.

### Secondary Activities Farm

If your operation is not a primary production farm, you could still fall under the “farm” definition as a secondary activities farm. A secondary activities farm is an operation, not located on a primary production farm, but that is devoted to harvesting (such as hulling or shelling), packing, and/or holding almonds and that has certain ties to the farm(s) that grew the almonds that are harvested, packed and/or held.

The rule is that the primary production farm(s) that grows the majority of the almonds harvested, packed and/or held by the secondary activities farm, must own or jointly own a majority interest in the secondary activities farm.

#### For Example:

- A huller and sheller does not grow almonds, but receives almonds from multiple farms under separate management and hulls and shells them. The operation is a secondary activities farm if it is majority owned by the primary production farms that grow the majority of the almonds it hulls and shells. This is the case regardless of where the operation is located.
- An operation that handles (i.e., sizes, sorts, grades, cleans, and packs) almonds is majority owned by the primary production farms that grow the majority of the almonds it handles. The operation is a secondary activities farm, regardless of where it is located.

### Farm Mixed-type Facility

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 PCHF rules, as relevant to each part of the operation

#### For Example:

- An operation grows, hulls and shells, handles (i.e., sizes, sorts, grades, cleans and packs) and roasts almonds. These activities all are separate operations, but occur on the same farm and in the same general physical location where the almonds were grown. This operation is a farm mixed-type facility. The growing, hulling and shelling, and handling operations are performed by a primary production farm. The roasting operation is performed by a facility. The operation must comply with both the Produce Safety and PCHF regulations.
- An operation hulls and shells, handles (i.e., sizes, sorts, grades, cleans and packs) and roasts almonds. These activities all occur in the same general physical location, but separate from where almonds are grown. If the operation is majority owned by the primary production farms that grow the majority of the almonds it hulls and shells, handles and roasts, it is a farm mixed-type facility. The hulling/shelling and handling operations are performed by a secondary activities farm. The roasting operation is performed by a facility. The operation must comply with both the Produce Safety and PCHF regulations.

## Facilities

An almond operation that is not a farm will be classified as a “facility.” Facilities are required to register with the FDA and generally are covered by the PCHF regulation.

## Compliance Obligations

If an operation is a farm, it is required to comply with the Produce Safety rule. See the fact sheet entitled *What Do “Farms” Need to Do to Comply With FSMA?* to understand your compliance obligations.

If an operation is a facility, it is required to comply with the PCHF regulation. See the fact sheet entitled *What Do “Facilities” Need to Do to Comply With FSMA?* to understand your compliance obligations.