

STANDARDS FOR PRODUCE SAFETY

Coverage and Exemptions/Exclusions for 21 PART 112

The Preventive Controls for Human Food rule clarified the definition of a farm to cover two types of farm operations, primary production farms and secondary activities farms. The same definition is used in the Produce Safety rule (section 112.3(c)). Below are basic criteria that determine whether an operation that meets the definition of “farm” is subject to the produce rule.

Does your farm grow, harvest, pack or hold produce?

Sections 112.1 and 112.3(c)
We define “produce” in section 112.3(c).

NO



Your farm is NOT covered by this rule.

YES

Does your farm on average (in the previous three years) have \$25k or less in annual produce sales?

Section 112.4(a)

YES



Your farm is NOT covered by this rule.

NO

Is your produce one of the commodities that FDA has identified as rarely consumed raw?

Section 112.2(a)(1)

If you grow, harvest, pack or hold more than one produce commodity, you must ask this question separately for each one to determine whether that particular produce commodity is covered by this rule.

YES



This product is NOT covered by this rule.

NO

Is your produce for personal/on-farm consumption?

Section 112.2(a)(2)

YES



This produce is NOT covered by this rule.

NO

Is your produce intended for commercial processing that adequately reduces pathogens (for example, commercial processing with a “kill step”)?

YES



This produce is eligible for exemption from the rule, provided you make certain statements in documents accompanying the produce, obtain certain written assurances, and keep certain documentation, as per Sections 112.2(b)(2) through (b)(6).

NO

Does your farm on average (in the previous three years) as per Section 112.5:

have < \$500k annual food sales,

AND

a majority of the food (by value) sold directly to “qualified end-users”?

Section 112.3(c)

“Qualified End-User” as defined in Section 112.3(c) means:

- the consumer of the food OR
- a restaurant or retail food establishment that is located—
 - (i) in the same State or the same Indian reservation as the farm that produced the food; OR
 - (ii) not more than 275 miles from such farm.

(The term “consumer” does not include a business.)

YES



Your farm is eligible for a qualified exemption from this rule, which means that you must comply with certain modified requirements and keep certain documentation, as per Sections 112.6 and 112.7.

NO

YOU ARE COVERED BY THIS RULE.