CAFF Discussion of FDA Produce Rule—Exemptions

Produce that is NOT covered by the Produce Rule includes:

- Produce grown for personal or on-farm consumption
- Produce that is rarely consumed raw (e.g, potatoes, turnips, winter squash)
- Produce that is not in its raw or natural state (i.e., produce that receives additional processing and that would be subject to the Preventive Controls rule)

You are NOT covered by the Produce Rule if the average annual monetary value of ALL food you sold during the previous 3-year period is no more than $25,000 (in inflation adjusted 2011 dollars).

Tester-Hagan "qualified exemption"

In its proposed Produce Rule, FDA outlines the modified requirements for qualified exempt farms. A farm is eligible for modified requirements through a qualified exemption if the farm:

1. Has less than $500,000 in annual gross sales (2011 dollars adjusted for inflation) over a previous three-year period, AND
2. Sells the majority of the food directly to a "qualified end-user," i.e., a consumer, or a restaurant, or a retail food establishment (e.g., a grocery store) that is located in the same state as the farm or not more than 275 miles from the farm.

The $500,000 threshold applies to the value of *all* food sales from a farm, not just sales of covered produce. This includes sales of processed foods, hay, commodities like corn and soybeans, dairy, livestock, and produce.

- *Consider telling the FDA that their interpretation of "food" as "all food sold from the farm" is too broad and that they should limit the food counting toward the $500,000 as just the food covered by FSMA. This would allow farms to diversify into produce without being immediately subject to all aspects of the Produce Rule.*

[Inflation has been running at 2% or less in recent years. At 2% per year, $500,000 in 2011 becomes $510,000 in 2012 and $520,200 in 2013.]

If you meet these requirements, then you must:

- Provide the name and complete address of the farm where the produce was grown on either a food packaging label or on a sign at the point of purchase (such as a farmers' market or farm stand, or on the internet);
- Comply with the compliance and enforcement requirements of the Produce Rule (see below); and
- Be subject to the provisions regarding the withdrawal of your status as a partially covered ("qualified exempt") operation (see below).

If the produce will undergo additional commercial processing that kills harmful microorganisms (e.g. processing tomatoes), then the produce is not covered but you are subject to the recordkeeping requirements and the compliance and enforcement requirements of the Produce Rule (see below).

Compliance and Enforcement Requirements of the Produce Rule

Regardless of their status under FSMA, all farms – including qualified exempt farms – are prohibited through pre-existing law from selling adulterated food. Food is considered to be adulterated under a number of circumstances, including if it:

- "consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is unfit for food; or

- if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health."

The proposed standards also state that failing to comply with the Produce Rule is a "prohibited act" subject to penalties and enforcement actions laid out in pre-existing law, the Federal Food, Drug, and Cosmetic Act.

This gives the FDA the right to inspect all "qualified exempt" farms to make sure that you are doing whatever the FDA ends up saying you need to do plus to check that you are not handling food in "filthy" conditions.

Withdrawal of Qualified Exemption

FDA outlines the circumstances and process under which a farm's qualified exempt status could be withdrawn.

There are two broad circumstances under which that status could be withdrawn:

1. In the event of an active investigation of a foodborne illness outbreak that is directly linked to a qualified exempt farm; or
2. 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 the farm that are material to the safety of the covered produce grown, harvested, pack, or held on the farm. (Also known as the "material conditions" clause.)

Though the rule outlines a process that FDA would pursue to withdraw such an exemption, it does not explain how a farm might get back its exemption. This "one strike and you are out" approach has been championed by certain consumer organizations but seems potentially unfair to farmers.

You can read more and find links to the rule at: http://sustainableagriculture.net/fsma/learn-about-the-issues/qualified-exemptions-and-modified-requirements/ .

FARFA has suggested the following comments to FDA on withdrawing exemptions:

1. The FDA should be held to specific, evidentiary standards before it can revoke a farmer's or food facility's Tester-Hagan exemption.

2. A farm or facility that is exempt under the Tester-Hagan amendment should be given at least 90 days to submit evidence and defend its exemption if FDA seeks to revoke it.

3. If the exemption is revoked, the farm or facility should have at least two years to come into compliance with the FSMA rules. The FDA has other mechanisms it can use if there is an immediate threat of foodborne illness.