

# Understanding the Food Safety Modernization Act (FSMA) and Its Potential Impact on New England Farms

## FSMA Proposed Rules

The Food Safety Modernization Act (FSMA) is the federal food safety law that applies to farms growing fruits and vegetables that may be eaten raw. FSMA is intended to reduce the risk of microbial contamination of fresh produce. It will be administered by the federal Food & Drug Administration (FDA).

The law was passed two years ago, but proposed regulations were released in January 2013, for public comment up to September 16, 2013. Please take the time to understand what impact these rules could have on your farm business and share your comments with FDA (see page 2).

## Two Parts

1). **The Produce Safety Rule** applies to “farms” or those who grow, harvest, pack or hold covered produce. The rules apply to produce generally eaten raw, i.e. greens, melons, tomatoes, apples, etc. (aka “covered produce” or raw agricultural commodities “RAC’s”). They do NOT apply to produce not eaten raw, i.e. sweet corn, potatoes, pumpkins, etc. Also NOT covered is produce grown for personal consumption, on farm consumption, or on another farm under the same ownership.

2). **The Preventive Controls Rule** applies to “facilities” that manufacture, process, pack or hold human food and to operations that buy and resell products grown on other farms. These facilities will need to register with the federal government and comply with regulations outlined

in the preventive controls portion of the rule. Facilities are defined in the rules and cover operations that modify or process produce from its original state.

## Exemptions

### Produce Rule Exemptions:

- If you sell less than \$25,000 of food per year averaged over three years, you are exempt, and therefore not covered under these rules.
- If you sell more than \$25,000 but less than \$500,000 of food averaged over three years, AND more than half of your sales are to [qualified end users](#) within 275 miles of your farm, you will receive a qualified exemption. Qualified end users include selling directly to consumers, to restaurants and to grocery stores.
- If you sell more than \$500,000 of food per year OR less than half of your sales are to qualified end users, you are not exempt, and therefore need to comply with these rules.

**Be aware that those you sell to may request that you meet stricter standards than what is required of you by law. Also, if you are implicated in an outbreak of foodborne illness, your exemption can be taken away.**

### Preventive Controls Exemptions:

- If you are a farm, and you only grow, wash and trim off outer leaves, and if you only sell products you grow, preventive controls does not apply to you.

- If you peel, chop, combine ingredients or buy and resell products from another farm you are a facility or a farm-mixed type facility and likely will be subject to some requirements under this law. Additionally, food facilities must register with the Federal government. Exemptions do apply based on type and size of the operation.

### Requirements

**Produce Rule**-Adhere to the science-based minimum standards established by the FDA for the safe growing, harvesting, packing, and holding of produce on farms. The standards are for the following routes of microbial contamination of produce: agricultural water, biological soil amendments of animal origin, domesticated and wild animals, equipment, tools and buildings, and staff.

**Preventive Controls**-Write a food safety plan that: a) identifies hazards, b) specifies the steps (preventive controls) that will be put in place to minimize or prevent those hazards, c) identifies monitoring procedures, d) records monitoring results and e) specifies what actions will be taken to correct problems that arise. Facilities would also need to comply with the updated Good Manufacturing Practices.

### To Comment

To include your comments on the proposed rules, mail comments (deadline September 16, 2013) to:

Division of Dockets Management (HFA-305)  
 Food and Drug Administration  
 5630 Fishers Lane, Rm. 1061  
 Rockville, MD 20852

### Comments must include:

#### Produce Rule

1. Agency name and Docket No. FDA-2011-N-09212.
2. Regulatory Information Number RIN 0910-AG35

#### Preventive Controls

1. Agency name and Docket No. FDA-2011-N-0920
2. Regulatory Information Number RIN 0910-AG36

### Submit comments online:

#### Produce Rule

<http://www.regulations.gov/#!submitComment;D=FDA-2011-N-0921-0028>

#### Preventive Controls

<http://www.regulations.gov/#submitComment;D=FDA-2011-N-0920-0013>

### For More Information

The New Hampshire FSMA Task Force, led by UNH Cooperative Extension has been collecting information about the proposed FSMA rules and making it available to the New Hampshire agriculture community. Visit any of the websites listed below for more information.

<http://extension.unh.edu/Food-Safety-Modernization-Act-FSMA>

<http://www.farmtalkfsma.org/>

<http://www.fda.gov/food/guidanceregulation/fsma/default.htm>

