

# COMMENTS ON THE FSMA PROPOSED PREVENTIVE CONTROLS RULE

Docket Number : FDA-2011-N-0922

**From:**

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## INTRODUCTION

The Amagansett Food Institute (AFI) is a 501 (c) (3) recognized non-profit organization which has as its mission the support of farmers and food producers on the East End of Long Island, New York. Our business members and supporters will be greatly affected by these regulations and we have some significant objections to the regulations as currently proposed. Our farmer business members are all what would be commonly thought of as small farms. Many of them farm on land which has been preserved from development by the sale of development rights and which is rented from the local town or land trust. Most farm using organic methods. All of our farmer members have diversified farms on which they grow a variety of produce for harvest throughout the growing season. They sell that produce through a variety of means, including Community Supported Agriculture (CSA) memberships, directly to the public at farm stands and wholesale to restaurants and the local food bank. While their business models may differ, all share certain characteristics including a passionate commitment to a different way of feeding ourselves, one which involves knowing your farmer and where your food comes from, a respect for the land and the soil and openness to farming methods which improve the health of the soil.

Farming on the East End of Long Island presents both problems and opportunities for small farmers. It is a very expensive place to live and to do business. The Peconic Land Trust, a local land preservation organization, estimates the current cost of farm land without development rights at upwards of \$100,000 per acre. It is almost impossible to buy a home in our area for less than \$400,000. As a result, most small farms are operating on relatively small parcels of rented land, often piecing together many non-

contiguous parcels to form their farm. Many of these farms are relatively new and are struggling to build businesses which provide a living wage. On the positive side, many people in our community, particularly the summer and part-time residents, have the means to pay what it costs for these farms to produce the fresh organic produce they sell. AFI and its members believe strongly in good food and thus in food safety. Our concern, however is that the rules will treat many of our small local farms the same as big agricultural operations with resulting costs and reporting requirements that will seriously undermine the profitability of those small farms.

AFI also represents many small food producers including bakers, candy makers, and other small scale producers. Most of these producers are currently working in restaurant kitchens under a certification program administered by the New York State Department of Agriculture and Markets. As with farms in our area, the costs of doing business as a food producer on the East End of Long Island are very high and our members have a direct interest in the definitions of small business and very small business being proposed. Additionally, AFI itself is planning to open a food business incubator which will include a commercial kitchen and may act as a Food Hub for local food related businesses. We have concerns about how these regulations may apply to those activities.

## **FARM MIXED TYPE FACILITIES**

### **DEFINITION OF ON-FARM**

Many AFI member farms process items grown on the farm for added value and season extension. Most of these farms are made up of several non-contiguous parcels of land which are rented from the Town or local land trust. This is land which has been preserved from development and thus is restricted in its use. Because the farmers do not own or fully control the land and because of restrictions on building, most farmers processing food for added value do so at rented locations which are not located on the farm land itself. The Proposed regulations exempt on-farm low -risk manufacturing activities conducted on produce grown on that farm. AFI requests that FDA clarify the meaning of on-farm in this context and proposes that on-farm processing should include processing done by farm personnel under the direction of the farm wherever that takes place. In

other words, a rented kitchen facility would qualify as on-farm as long as the food processing is done under the direction and control of the farm.

### **EXPANSION OF LOW RISK ACTIVITIES**

Section 117.5(h) of the proposed rules contains a list of low risk activities which are exempt from Subpart C. The list includes preserving acid foods, but does not include other types of preserves or pickles. Currently, many of our farm members preserve cucumbers, garlic scapes, peppers and other low acid foods in kitchens certified by the New York State Department of Agriculture and Markets. This State process adds a layer of oversight which reduces the risk of improper handling. AFI proposes that this exemption include any type of food processing which is conducted in compliance with relevant State regulation.

### **COMMUNITY SUPPORTED AGRICULTURE (CSA)**

FDA has indicated in the FSMA Facts that the sale and distribution of food through a CSA qualifies as retail activity and thus is exempt from the requirements of the Rule. We are concerned, however that this provision may be in conflict with the definition of facility as it relates to the rules on packing and holding. It seems clear that a farm that prepares its own produce for its CSA members by cleaning and packing it into a CSA box is not considered a facility. There is some question, however as to whether that exemption is lost if the farm includes produce from another farm in its box. We do not believe that Congress intended to reach this sort of activity in the definition of facility and AFI proposes that FDA clarify that the occasional inclusion of produce from another farm in a CSA offering would not constitute "packing" or "holding" so as to make the CSA farm a facility.

### **DEFINITION OF VERY SMALL BUSINESS AND FOOD SOLD**

AFI proposes that FDA adopt the \$1,000,000 definition of very small business. We believe that businesses at or below this level are small enough that they are likely still selling their product locally or regionally. Compliance with the rules would be burdensome for businesses at this level.

Whatever level FDA ultimately adopts as the definition, it is important that the definition of food sold be limited to food which would be covered by the Rule. For Farm Mixed Facilities, this would mean that only the value of processed food sold would be considered in determining the size of the business. To do otherwise could discourage diversification and the production of added value products which enhance the farm's ability to create sustainable business models.

## **APPLICATION OF THE RULES TO FOOD HUBS**

Although not currently operating, AFI intends to create a food business incubator which will include a commercial kitchen to be rented to small food producers in hourly shifts and a food hub. The food hub will allow the aggregation of produce from member farms for sale to institutional end users such as hospitals and universities. This provides access to markets by small farmers whose volume of production would be insufficient to be attractive to the institutional buyer without aggregation and can be an important way of supporting small farmers. It is not clear to us how these Proposed Rules would apply to these activities.

With respect to food hubs, for example, does any aggregation of produce, for no matter how short a period of time constitute "holding"? Would an operation in which farmers dropped off boxed produce in a central location for sale on a same day basis make that location a "facility"? And if so, how would the size of the facility's business be judged? By the total volume of produce sold? Would it make a difference if the buyer paid each farm directly rather than paying the food hub operator? Given the low risk associated with these activities, AFI proposes that the Rules make clear that food hub activities are not "holding of produce" unless the holding routinely exceeds 24 hours.

With respect to the kitchen incubator, we assume that a rental kitchen which does not have its own staff engaged in food production would not be required to create a HARPC plan, although the businesses which use the kitchen might, depending upon the size of their business and their eligibility for an exemption. We also assume that if the kitchen hired its own staff to produce food, it might come under the rule. Here we also propose that the size of the business for the purpose of determining an exemption be

determined by the cost of processed food sold by the incubator, but not include the revenue earned by renting the kitchen. Please provide clarification on these issues in the final Rule.

## CONCLUSION

Because FDA has chosen to have universally applicable rules, it is not surprising that some of those rules may have disproportionately negative effects on small operations and relatively new kinds of operations such as food hubs. While we support the principle of one set of clear rules, we are concerned that some of these rules may inhibit the development of new businesses and new ways of doing business. We ask that FDA consider these comments in finalizing these rules. Thank you for the opportunity to comment.

Respectfully Submitted,

Kathleen A. Masters