**Comments of**
**The Make Our Food Safe Coalition and Safe Food Coalition**
**To**
**US Food and Drug Administration**
**FDA Food Safety Modernization Act: Preventive Controls for Facilities**
**May 20, 2011**

The FDA Food Safety Modernization Act (FSMA) was designed to take a preventive approach to food safety—to put programs in place that would prevent foodborne disease outbreaks before they happen. Inspired by the outbreaks like the one at Peanut Corporation of American (PCA) that caused nine deaths, preventive controls for facilities are at the heart of this legislation. It therefore is critical that the Food and Drug Administration (FDA) take steps to ensure the effective implementation of Section 103 of FSMA (Docket No. FDA-2011-N-0251).

The legislation instructs companies, both domestic and foreign, that process food for the US market to analyze known or reasonably foreseeable hazards, create food safety plans, and establish preventive controls. This must include monitoring and verification that the plan works to eliminate or minimize potential hazards. It instructs FDA to issue regulations on what should be in the plans, and to issue guidance to companies on how to prepare them.

The following comments on implementation of the FSMA are submitted by the following members of the Make Our Food Safe Coalition and the Safe Food Coalition: Center for Foodborne Illness and Prevention; Canter for Science in the Public Interest, Consumer Federation of America, Consumers Union, The Pew Charitable Trusts, and STOP Foodborne Illness (formerly S.T.O.P.--Safe Tables Our Priority).

## FDA Should Request All Initial Food Safety Plans

The law states that plans should be made available to the FDA "upon oral or written request." We urge FDA to request initial plans from all facilities known to be covered by the requirement, starting when companies are required to have prepared such plans, and review at least some of them.

The agency could facilitate submission of preventive control plans by making this part of the registration process. Adding a feature to the Food Facilities Registration Module that provides a mechanism for filers to attach electronic copies of their plans would make them readily available to FDA.

The law does not require FDA to approve the food safety plans, and we know that it would be near impossible to review expeditiously all of the several hundred thousand

plans that must be prepared. However, requesting that all plans be submitted, and reviewing some subset of them, would give the FDA the opportunity to at least determine that plans exist, both in the US and in other countries. This could prove valuable, since it will be years before FDA will inspect all covered facilities and view the plans on site. Further, since FDA intends to rely on state governments and foreign governments in many cases to conduct inspections, FDA itself may actually never see certain facility plans or have the opportunity to verify that plans exist unless such plans are forwarded to the agency.

Lessons from FDA's experience in implementing the Seafood HACCP Rule should inform the agency's approach to assuring that industry properly implements the requirement to have food safety plans. Ten years after requiring plans for seafood processors, FDA continued to find a significant level of non-compliance and/or delay in full compliance. FDA conducted a review of HACCP implementation in 2005 and found that almost 15 percent of the firms required to have food safety plans lacked them and 33 percent of firms where histamines were a risk did not adequately monitor for this hazard. Missing or inadequate Seafood HACCP plans continue to account for almost half of the warning letters issued by FDA in recent years, indicating that full compliance may still be an issue.

Requesting all the plans and initially reviewing some subset of them would give the FDA the opportunity to see if at least a subset of them is adequate. FDA might also be able to see if there are any systemic problems that companies are having in understanding the preventive control requirements. It could also help FDA quickly determine if high-risk facilities are developing effective plans. It might allow FDA to spot problem areas, and in some cases help it prioritize where it should send its inspectors first. Given that FDA will only initially be going out to high risk domestic facilities once every five years on average, and getting to foreign facilities even less often, submission of plans could be an important aid to compliance and advance the basic goal to prevent foodborne illness.

It would also be beneficial to have plans available for review prior to an inspection visit so that inspectors could use a plan to help prepare for their review of the facility, or respond in the event that a facility is linked to an outbreak.

**Regulations and Guidance Should Be Specific and Require Pathogen Testing**

With regard to the FDA regulations and guidance, FDA should state clearly and explicitly what elements a food safety plan should include. To provide effective guidance, FDA should also include examples of plans (both good ones and ones that are unacceptable), demonstrating a plan's goals and objectives, as well as the interventions that will be used to mitigate the hazard(s). FDA should require proof of validation for intervention techniques and technologies that are used in a company's food safety plan.

We are particularly concerned that it be made clear to companies that the effectiveness of their plan should be verified through actual testing for pathogens, and that the testing protocol should be truly effective and available to FDA during inspections.

High risk plants should be required to do microbial sampling to a standard and frequency set by FDA. FDA should require plants to conduct both environmental sampling and testing of finished product to provide assurances that product coming off the end of the line has been produced in accordance with the plant's preventive control plan. Finished product testing is particularly important for bagged fresh produce that is to be consumed raw. In addition, we saw in the case of Peanut Corporation of America how the company ignored positive test results for pathogens. Any positive result should be a trigger for analysis of the source of contamination and taking of corrective action.

**Exempt Facilities**

Several types of facilities are exempt from the requirement to develop a food safety plan. These include very small on-farm facilities engaged in what FDA determines to be "low risk activities involving low risk foods," "very small businesses" and businesses that gross under $500,000 a year and sell directly to consumers, restaurants or retail food establishments within their state or within 275 miles of the production facility. FDA should carefully and specifically identify what it considers to be "low risk activities involving low risk foods." It should also move quickly to define a very small business, and we strongly urge the agency to follow the intent of the law, which is that these businesses are significantly smaller than those that gross $500,000 a year.

Facilities that qualify for the "under $500,000" exemption have the option of submitting a streamlined food safety plan, or of demonstrating that they comply with state and local food safety laws. We urge FDA to do more than accept minimal documentary compliance. We urge FDA to seek out and create incentives, through devices such as a model plan or other assistance, that will encourage firms eligible for qualified facility status to fully comply with provisions in FSMA that are most protective of public health.

**Conclusion**

In sum, preventive controls are an absolutely essential, central part of the FSMA. If companies comply intelligently and conscientiously, both they and the public will benefit because problems will be stopped before they can affect anyone. We urge FDA to be as prescriptive and specific as possible, in its regulations and guidance, though virtually every plan will have to be different. We think it would be particularly useful, however, if FDA requests that all plans be sent to it at an early date, so that it can get a handle on how implementation of this critical part of the law is proceeding.