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

RE: FDA Food Safety Modernization Act: Focus on Preventive Controls for Facilities (Docket No. FDA-2011-N-0251)

The Center for Science in the Public Interest (CSPI)\(^1\) appreciates the opportunity to comment on implementation of preventive controls under the FDA Food Safety Modernization Act (FSMA).

Preventive controls are the heart of an effective food safety system. Today, foodborne illness strikes one in six Americans, hospitalizing 130,000, and killing 3,000.\(^2\) FoodNet data since implementation of Hazard Analysis and Critical Control Points (HACCP) systems for meat, poultry, fish and juice indicates that preventive control systems are effective at reducing illnesses caused by contaminants introduced into food during its processing.\(^3\) Additionally, a number of food companies have voluntarily adopted HACCP because they understand it to be a reliable method for assuring their products are safe. FSMA mandates a system for hazard controls that contains the key principles and elements of HACCP and provides well defined roles for industry and government. Under FSMA, food facilities are responsible for identifying hazards and implementing controls that minimize or eliminate them to assure that food is not

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\(^1\) The Center for Science in the Public Interest is a nonprofit health advocacy and education organization focused on food safety, nutrition, and alcohol issues. CSPI is supported principally by the 750,000 subscribers to its Nutrition Action HealthLetter and by foundation grants. It does not accept government or industry funding.


adulterated or misbranded. The Food and Drug Administration (FDA) has responsibility for issuing regulations that ensure controls are effective and for enforcing compliance. CSPI makes the following comments for how FDA should carry out its responsibilities.

1. FDA Should Assert Its Authority to Review and Evaluate Food Safety Plans.

In order to give FDA the tools to exercise oversight that ensures food is not adulterated or misbranded, oversight of the preventive controls system must include –

- Premise and process inspections,
- Evaluation of food safety plans, and
- Sampling and analysis.

The following sections describe CSPI’s recommendations for implementing the hazard analysis and risk-based preventive controls in section 103 of FSMA.

A. Premises and Process Inspections.

Premise and process inspections should encompass a review of the documentation associated with a facility’s food safety plan. Under sections 418(g) and (h) of the Food, Drug, and Cosmetic Act as amended by FSMA, facilities are responsible for documenting instances when monitoring finds nonconformance material to food safety and results of testing or other verification steps. The facility is required to make this documentation available to inspectors during routine inspections along with the facility’s food safety plan. Access to these records gives FDA the means to review and evaluate the effectiveness of a facility’s food safety activities and should be interpreted in a way that strengthens FDA’s oversight.

The question of how the materiality of information is to be determined under subsection (g) presents one area where FDA should assert its oversight role. Materiality is a decision for the

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4 Unless otherwise indicated, all references to section numbers are references to sections of the Food, Drug, and Cosmetic Act as amended by FSMA.
regulatory agency to make and not one that can be left to a self-interested party within the facility being regulated. FDA should provide guidance on narrow and foreseeable circumstances when nonconformance is not material to food safety, but require a facility operator to consult the agency for a determination in other instances. Doing otherwise – allowing the industry to interpret materiality for itself – would provide an avenue for facilities to ignore nonconformance issues. This could deny the agency access to critical information that should have been included in the monitoring and corrective action records.

B. Evaluation of Food Safety Plans.

Review of the food safety plan should include an evaluation of its effectiveness. Under FSMA, the agency is to issue regulations that establish the standards industry must apply in developing a food safety plan. Implicit in the preventive controls section of FSMA is the authority for FDA to evaluate each facility’s plan for effectiveness. Although FSMA does not contain an express provision on evaluating a facility’s preventive controls, the agency should rely on its broad authority to protect public health in asserting this role. Such authority is inherent in FDA’s mission, being expressed in the agency’s mission statement under section 903(b)(2)(A) and in its authority under the Public Health Service Act. The Court has recognized that this is broad authority to act in the public interest, stating in United States v. Bacto-Unidisk, that “remedial legislation such as the Food, Drug, and Cosmetic Act is to be given a liberal construction consistent with the Act's overriding purpose to protect the public health”.\(^5\) FSMA also anticipates a broad exercise of authority in its structure, which includes express limits only where Congress has determined it is appropriate to restrain agency action.

Where there are limits on FDA’s regulatory power under section 418 they do not apply to its authority to establish a program for evaluating plans. Meanwhile, enforcement is based on

compliance with section 418. Compliance includes implementing preventive controls that “minimize or prevent the occurrence of such hazards and provide assurances that such food is not adulterated under section 402 or misbranded under section 403(w),”\(^6\) a task that by its nature requires a regulator’s evaluation. For this reason, FDA should include provisions for evaluating food safety plans and consider requiring facilities to submit their plans and documentation electronically for periodic review as part of the agency’s management of the preventive controls system established by FSMA.

FDA’s review should cover all aspects of the plan to ensure that –

- The facility’s operators have considered all reasonably likely hazards, evaluated them, understand the conditions giving rise to those hazards, and have identified appropriate controls;
- Preventive controls are applied at the points where hazards are likely to arise and are appropriate for eliminating or significantly minimizing the hazard;
- Critical limits have been set and monitoring programs designed around them will accurately inform the processor of any variance from those limits;
- Monitoring procedures are structured to assess whether the program is under control and critical limits are being maintained, while deviations are immediately identified so that corrective actions can be taken;
- Corrective actions will be effective in isolating and controlling product affected by the deviation, and the corrective action procedures include investigation of the cause of the deviation, effective measures to prevent a recurrence, and verification of the effectiveness of the corrective action;

\(^6\) § 418(a).
Methods, procedures, tests and other evaluations are applied (including sampling and testing) with an appropriate frequency to verify that the food safety plan is working correctly; and

Each of the steps above are documented and records generated under the food safety plan are complete, accurate and up-to-date.

C. Sampling and Analysis.

Without the oversight provided by sampling programs, a food safety system will default to little more than an industry honor system. Laboratory testing of product samples is essential to assuring that food safety plans are effective. FDA should avoid repeating its flawed decision under the Seafood HACCP rule to make verification testing optional. Because FDA did not require testing, the agency had few ways to measure if controls a seafood processor implemented were effective at reducing hazards. FSMA requires environmental and product testing as a verification step under section 418(f)(4) and provides FDA with access to testing records under section 418(g). Furthermore, testing that is performed in response to a specific testing requirement under FSMA must be conducted by an accredited laboratory and the results reported to FDA under section 422(b). FDA should use its authority to require verification testing when any food has an identified hazard for which a facility has implemented a preventive control.

2. FDA Should Apply Lessons Learned from Implementation of Seafood HACCP.

FDA has extensive experience with HACCP systems, having implemented and administered the Seafood HACCP and Juice HACCP rules. Lessons from this experience should

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8 Food Safety Modernization Act: Focus on Preventive Controls: Public Meeting before the Food and Drug Administration, Office of Foods, Transcript at 50, April 20, 2011 (statement of David Plunkett, Senior Staff Attorney, Center for Science in the Public Interest).
inform the agency’s approach to assuring industry meets the deadlines in FSMA for conducting a hazard analysis and implementing preventive controls. A key lesson from the Seafood HACCP rule experience is that forbearance on enforcing compliance results in a significant level of non-compliance and/or delay in full compliance. The Seafood HACCP rule provided a 2 year implementation period, but full implementation actually took longer.\(^9\) Even now full compliance is questionable with missing or inadequate Seafood HACCP plans accounting for half of the warning letters issued by FDA for adulterated foods in the last 10 years.\(^10\) While FDA recognized the need for stepped up regulatory action after compliance levels stalled in 2001,\(^11\) it apparently did not pursue aggressive action as indicated by the decline in “official action indicated” rates after 2002 without significant changes in non-compliance rates.\(^12\) FDA should not repeat this error and instead establish an aggressive compliance inspection program to ensure facilities are implementing appropriate preventive control systems.

3. **Food From A Non-Compliant Facility Is Adulterated Under Section 402(a)(4).**

To ensure facilities meet the compliance deadlines under FSMA, FDA should, in addition to prosecution for committing a prohibited act under section 301(uu), base enforcement actions on the insanitary conditions provision under section 402(a)(4). FDA has already interpreted section 402(a)(4) to apply to non-compliance with seafood HACCP requirements.\(^13\) Applying the same interpretation to preventive controls under FSMA would allow the agency to act more quickly under its new administrative powers to bring a facility into compliance. For example,

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\(^9\) FDA's Evaluation of the Seafood HACCP Program for Fiscal Years 2004/2005, July 10, 2008 (reporting nearly 15 percent non-compliance among inspected firms that were required to have HACCP plans).

\(^10\) CSPI reviewed 2,010 warning letters issued by FDA from 2000-2010.

\(^11\) FDA's Evaluation of the Seafood HACCP Program for Fiscal Years 2000/2001, Sept. 30, 2002 (noting, “processors that are most willing and able to achieve compliance have done so, thus accounting for an apparent slowing in the rate of progress from year to year. The previously described increase in the OAI rate seems to confirm that regulatory action may be necessary to correct much of the remaining noncompliance)."

\(^12\) See, FDA's Evaluation of the Seafood HACCP Program for Fiscal Years 2004/2005, supra, note 10.

\(^13\) Hazard Analysis and Hazard Analysis Critical Control Point (HACCP) Plan, 21 CFR 123.6(g) (2010).
any non-compliance would create a reasonable belief that food is adulterated or misbranded allowing an inspector to detain the product until it can be tested under section 304(h)(1)(A). In a more serious case where the potential hazard has a reasonable probability of causing serious adverse health consequences or death, FDA could close the facility by suspending its registration under section 415(b). This ability of FDA to act under its own authority properly shifts the burden to a non-compliant facility for proving it is producing safe food in spite of its failure to comply with basic food safety standards required by law. As such it is critical to obtaining full compliance and responding to potential threats to public health before they cause illnesses.

3. Conclusion.

In implementing section 103 of FSMA, FDA should make a broad exercise of its authority to protect public health. This will ensure that preventive controls are effective at minimizing or eliminating potential hazards in processed food. While FSMA places responsibility for producing safe food on industry, FDA’s role in setting standards and enforcing compliance is critical to the success of the preventive programs established under FSMA. CSPI believes the recommendations above would provide the best balance of industry and government responsibilities, and result in a system that is the most protective of public health.

Sincerely,

David W. Plunkett
Senior Staff Attorney,
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