Consumer Federation of America

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

RE: Docket No. FDA-2011-N-0920

Consumer Federation of America appreciates the opportunity to comment on the Food and Drug Administration's proposed rule on Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food [Docket No. FDA-2011-N-0920]. This rule is fundamental to prevention of human illnesses from contaminated food.

Introduction

Every year, approximately 48 million people (1 in 6 Americans) get sick, 128,000 are hospitalized, and 3,000 die from foodborne diseases, according to the Centers for Disease Control and Prevention. These illnesses and deaths are largely preventable. The Food Safety Modernization Act (FSMA), passed with bipartisan support in Congress and signed into law by President Obama in January 2011, shifts FDA's approach to food safety from reaction to prevention, with the goal of reducing foodborne illness among consumers. One of the key provisions of FSMA is the provision requiring food facilities to develop and implement preventive controls to mitigate the risk of contaminated food.

CFA generally supports FDA's proposed approach to preventive controls in the proposed rule. The following five points highlight key issues raised in CFA's comments on the proposed rule. However, CFA provides comments on numerous other areas in the proposal where changes should be made to better protect consumers.

1. FDA should take a narrow approach to the definition of "Very Small Business" and define it as one that has less than $250,000 in total annual sales adjusted for inflation.
2. FDA should require all facilities to submit their food safety plans to the agency and FDA should review a subset of plans to help determine inspection resource allocation. At a minimum, FDA should require additional information as part of a facility profile.
3. FDA should restore testing and other verification activities as part of the Preventive Controls Final Rule. FDA should require testing beyond environmental monitoring, including testing of raw materials/ingredients and finished product testing, as appropriate.
4. FDA should require manufacturers to develop, maintain and regularly update a Supplier Approval and Verification Program as part of its food safety plan.
5. CFA identifies multiple lessons from the implementation of Seafood and Meat and Poultry HACCP in our comments. FDA should revise its proposed regulations to avoid similar implementation problems.

Subpart A – General Provisions

Definitions – Very Small Business

FDA proposes several options for the definition of "Very Small Business" in its proposed regulation - either total annual sales (adjusted for inflation) of $250,000, $500,000 or $1 million. This definition is important because "Very Small Businesses" can be exempted from the requirements of the rule. Therefore the ultimate definition will have a significant impact on food safety and public health, depending on the extent and size of the exemption. FDA estimates the difference in the definitions will expose consumers to between 4,800 and 19,200 additional illnesses each year from food the rule would have regulated if there were no exemptions.[1] Consequently, CFA urges FDA to take a narrow approach to the definition of "Very Small Business" and define it as one that has less than $250,000 in total annual sales adjusted for inflation.

Further, CFA notes that Section 418(l), also known as the Tester Amendment, establishes two types of qualified facilities based on their annual sales and marketing methods that may operate under modified rules. A qualified facility may be either (1) a very small business or (2) a business with limited annual sales of less than $500,000 provided a majority of its sales are made directly to qualified end-users. Since the Tester Amendment makes clear that these are two separate categories, it stands to reason that the two categories would be defined differently and would represent different levels of annual sales. So a definition of "Very Small Business" as having annual sales less than $250,000 would be consistent with the intent of the Tester amendment and appropriate for the entirety of the rule.

Definitions – Retail Food Establishment

FDA failed to address changes to the definition of "Retail Food Establishment" that are required under section 102(c) of FSMA. These changes would require a "retail food establishment" to include roadside stands, farmers' markets, and food sold thru community supported agriculture programs (CSAs). By not making these changes in the proposed rule, FDA has fostered unnecessary opposition to the rule by small farm and sustainable agriculture interests who fear that the preventive controls rule will apply to those types of markets. FDA should revise the definition, as required by FSMA, to clarify that these activities are not covered by the preventive controls rule, as long as processing is not the primary function of the establishment's operator.

Subpart B – Current Good Manufacturing Practices

CFA supports the update to the Current Good Manufacturing Practices (CGMPs) proposed by FDA. The changes are relatively minor, but necessary ones, which streamline and simplify the existing requirements. The CGMPs are important because they set the foundational level of sanitary operations, applicable to all food establishments, even those that are exempt from the preventive control system or are only subject to modified requirements.

CFA endorses FDA's proposed clarification that certain existing CGMP provisions protect not only against contamination of food, but also against cross-contact of food by allergens. CFA urges the agency to require training for employees and supervisors, including a requirement for records that document such training. As the agency notes in the preamble, ineffective employee training was the root cause of 32

[1] Food and Drug Administration, Analysis of Economic Impact, § D.1.b. (Table 4 – Estimated Dollar Burden Attributable to FDA-Regulated Food Under the Scope of This Proposed Rule-Making).

percent of CGMP-related recalls from 1999-2003. Adequate training could improve the impact of CGMPs with moderate investment by each facility.

CFA also urges FDA to require that non-food-contact surfaces of equipment be cleaned as frequently as necessary to protect against contamination of food and food-contact surfaces. Effective sanitation can have a significant impact in minimizing contamination that can lead to foodborne illnesses.

Subpart C – Hazard Analysis and Risk-Based Preventive Controls

Requirement for a Food Safety Plan

CFA supports FDA's determination that the owner, operator, or agent in charge of a facility must prepare and implement a written food safety plan. CFA also supports FDA's decision that the food safety plan should include a hazard analysis, preventive controls, procedures for monitoring the implementation of the preventive controls (including the frequency with which they are to be performed), corrective action procedures, and a recall plan, all written. This is mandated by and entirely consistent with the Food Safety Modernization Act. As proposed in the rule, the food safety plan should be prepared by (or its preparation overseen by) a qualified individual.

Submitting a Facility Profile to FDA

FDA has requested comments on whether to require facilities to submit to the agency a facility profile or a subset of information contained in a food safety plan. As previously advocated by the Safe Food Coalition and the Make Our Food Safe Coalition, CFA urges FDA to require all facilities to submit their food safety plans to the agency. Requesting that all plans be submitted, and reviewing some subset of them, would give the FDA the opportunity to verify that plans exist, both in the U.S. and in other countries. It would also be beneficial to have plans available for review prior to an inspection visit so that inspectors could use the information to help prepare for their inspection of the facility.

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 HACCP 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. The Food Safety and Inspection Service has encountered similar problems with that agency's implementation of HACCP for meat and poultry. FSIS has found that some plants did not identify *E. coli* O157:H7 as a hazard likely to occur despite producing meat products in which *E. coli* was a known hazard.

FDA could identify a statistically significant number of plans or plants that produce high risk products to review, especially to learn how preventive control plans are being implemented and whether there are systematic problems. It would help FDA to quickly determine if high-risk facilities are developing effective plans. It might also allow FDA to spot problem areas, and in some cases, help it prioritize where it should send its inspectors first. This could prove valuable, since it will be years before FDA will inspect all covered facilities and view the plans on site. Given that FDA will only initially be going out to high risk domestic facilities once every five years on average, and inspecting foreign facilities even less frequently, submission of plans could be an important aid to compliance. 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.

If FDA determines not to require facilities to submit their preventive control plans to the agency, then at a minimum, FDA should require additional information as part of a facility profile. FDA should require facilities to submit, as part of the facility profile the following information: contact information, facility type, product produced, hazards identified for each product, preventive controls for each product, facility size, and operation schedule.

This profile could be part of the facility registration system that already exists so that facilities do not have to register via two different portals. This would minimize the burden on facilities but still provide FDA with important information about the facility. The information should be submitted at the same time as facility registration and updated biennially. FDA could then use the information to prioritize inspections.

Hazard Analysis

CFA supports FDA's determination that the owner, operator, or agent in charge of a facility must identify and evaluate known or reasonably foreseeable hazards for each type of food manufactured, processed, packed, or held at the facility to determine whether there are hazards that are reasonably likely to occur. The hazard identification should consider hazards that may occur naturally or may be unintentionally introduced, including biological hazards, chemical hazards, physical hazards, and radiological hazards. The hazard analysis must be written. This is all mandated by and entirely consistent with the Food Safety Modernization Act.

FDA should require a written analysis even if the conclusion of the analysis is that no hazards exist. That way, FDA inspectors will be able to review the written analysis and determine whether the conclusions are warranted. However CFA does not believe that any establishment would be able to conclude that no hazards exist in their production process. Any such determination should be a red flag and should prompt FDA inspectors to immediately review the establishment's food safety plan and preventive controls.

Experience from FSIS' implementation of HACCP showed that many plants did not identify a hazard in their HACCP plans despite FSIS' consideration that all products under its jurisdiction would carry some type of microbiological hazard. This occurred in the early days of HACCP all the way through to more recent years. Several OIG reports[23] [45] identified this as a key failure of FSIS' implementation program and recommended that FSIS approve an establishment's HACCP plans to assure that the agency was conducting adequate oversight. Similarly, FDA's evaluation of HACCP implementation for seafood found that a substantial number of seafood processors (11% of domestic and 33% of foreign) did not

[2] USDA Office of Inspector General, Implementation of the Hazard Analysis and Critical Control Point System." Report No. 24001-3-At, June 2000.
[3] USDA Office of Inspector General, "FSIS Oversight of Production Processes and Recall at ConAgra Plant (Establishment 969)." Report No. 24601-2-Kc, September 2003.
[4] USDA Office of Inspector General, "FSIS Oversight of the Listeria Outbreak in the Northeastern United States." Report No. 24601-2-Hy, June 2004.
[5] USDA Office of Inspector General, "HACCP Implementation at Very Small Plants." Report No. 24601-5-At, June 2005.

adequately identify hazards in their HACCP plans eight years after seafood HACCP was required.[6] Considering this, FDA should consider ways in which the agency might avoid this problem by conducting reviews of establishments' preventive controls plans, or issuing guidance that would advise the industry on hazards likely to occur in particular types of products.

CFA supports FDA's determination that the hazard analysis must include an evaluation to determine whether the hazards are reasonably likely to occur. This should include an evaluation of whether environmental pathogens are reasonably likely to occur whenever a ready-to-eat food is exposed to the environment prior to packaging.

CFA supports FDA's determination that facilities must consider the effect of the following on the safety of the finished food for the intended consumer: the formulation of the food; the condition, function, and design of the facility and equipment; raw materials and ingredients; transportation practices; manufacturing/processing procedures; packaging activities and labeling activities; storage, and distribution; intended or reasonably foreseeable use; sanitation, including employee hygiene; and any other relevant factors. CFA suggests that FDA develop hazard analysis guidance that would include recommendations relating to these factors.

Finally, FDA should require that facilities include any supporting documentation in the hazard analysis. This is required by FSIS under their meat and poultry regulations.[7] Supporting documentation would be useful for FDA inspectors to better understand the scientific rationale behind the facility's hazard analysis.

Preventive Controls

CFA supports FDA's determination that the owner, operator, or agent in charge of a facility must identify and implement preventive controls, including at critical control points, to provide assurances that hazards identified in the hazard analysis will be significantly minimized or prevented and the food manufactured, processed, packed, or held by such facility will not be adulterated or misbranded. The preventive controls should be written and should include process controls, food allergen controls, sanitation controls, a recall plan, and other controls as appropriate and necessary. This is mandated by and entirely consistent with the Food Safety Modernization Act.

CFA supports FDA's determination that the preventive controls required under this section should be subject to monitoring, corrective actions, and verification, as required by FSMA. Monitoring and verification are essential to demonstrate that the plan is effectively eliminating or minimizing potential hazards. Corrective actions are necessary to address any problems identified with the preventive controls through the monitoring and verification process.

- **Critical Control Points**

In the proposed rule, FDA maintains that, under FSMA "preventive controls may be required at points other than at critical control points and critical limits would not be required for all preventive controls." Therefore FDA takes a slightly broader approach to its preventive controls requirements than the typical HACCP approach which emphasizes identification of critical control points. Requiring preventive controls at other points in the food production facility is appropriate. However, it should be noted that

[6] Government Accountability Office, "FDA Can Better Oversee Food Imports By Assessing and Leveraging Other Countries' Resources." GAO-12-933, September 2012.
[7] 9 CFR 417.5(a)(1)

Congress clearly intended critical control points to be identified as a component of preventive controls as well. Section 418(c) of FSMA states that "The owner, operator, or agent in charge of a facility shall identify and implement preventive controls, *including at critical control points, if any*, to provide assurances that" hazards are identified and "significantly minimized or prevented" (emphasis added). Further, the NACMCP HACCP guidelines, the Codex HACCP Annex, seafood HACCP, juice HACCP, and meat and poultry HACCP all recommend that written preventive controls include identified critical control points.

Considering Congressional intent, as well as the importance critical control points play in preventive control plans, FDA should require facilities to identify critical control points, if any, and include them in their written preventive control plan. If critical limits, or parameters, exist for the control point (such as parameters associated with heat processing, acidifying, irradiating, and refrigerating foods), those should be identified as well. FDA should provide guidance to the industry on how to define critical control points.

Requiring facilities to identify any critical control points and parameters in their preventive control plans will provide greater assurances that facilities are recognizing the points in their systems where they should be focusing to prevent or mitigate hazards. FDA would also be able to review the identified CCPs to assess whether hazards were being properly controlled at key points in production.

FDA should be aware that plants may limit the number of critical control points or other points in their preventive controls as a way to limit FDA oversight of their food safety plans. In meat and poultry HACCP, establishments limited the number of CCPs they identified as a way to reduce the points at which FSIS inspectors would conduct checks, a failing identified by the OIG in its 2000 report on HACCP implementation.[8] FDA would be wise to anticipate this possibility and amend its proposal accordingly.

- **Sanitation Controls**

CFA supports FDA's determination that facilities should include sanitation controls in their preventive controls plans. Assuring adequate sanitation is a fundamental element of the safe production of food. By including sanitation controls in a facility's preventive controls plan, FDA can better verify that facilities are maintaining adequate sanitation. This was made clear in an OIG report[9] on FSIS' implementation of HACCP that found that many plants' sanitation plans were inadequate and needed to be regularly reviewed.

Sanitation controls are particularly important for reducing the risk that an environmental pathogen could contaminate a ready-to-eat food that is exposed to the environment prior to packaging. In order to emphasize the importance of this, FDA should explicitly include *Salmonella spp.* and *Listeria monocytogenes* as examples of environmental pathogens that should be addressed via sanitation control because of their likelihood to occur in a ready-to-eat food. This will highlight the relevant pathogens that facilities should be addressing.

Recall Plans

CFA supports FDA's determination that the owner, operator, or agent in charge of a facility must establish a written recall plan as part of the facility's preventive controls. In defining "preventive

[8] USDA Office of Inspector General, Implementation of the Hazard Analysis and Critical Control Point System." Report No. 24001-3-At, June 2000.
[9] *Ibid.*

controls" under Section 103 (o)(3), FSMA says that preventive controls may include "a recall plan," clearly anticipating that recall plans would be part of a food safety plan.

In addition to notifying direct consignees and the public that a food is being recalled, companies should also be required to notify FDA of the recall. While this typically happens, this will further assure that FDA is aware of the recall and can facilitate communications to suppliers, retailers and consumers. Verification of all preventive controls, including recall plans, is important to provide assurances that the controls are effective.

As a means to verify that a facility's recall plan is effective, FDA should require each facility to conduct a mock recall at least annually. Food recalls are typically complex and managed during crisis. The GAO found that only 36 percent of recalled food is recovered in any one FDA recall event.[10] Preparation is essential to preventing or reducing serious health consequences for consumers when companies are in the middle of a recall situation. A report submitted to FDA by the Institute of Food Technologists noted that many of the food facilities participating in a pilot program on traceability were surprised by the product tracing process and "had never considered how their records would need to be pieced together with those of their supply chain partners to facilitate an effective traceback."[11] The pilot process allowed these facilities to better understand how a product trace might work and provided them the opportunity to improve their internal processes.

Similar to a mock traceback exercise, CFA believes that all firms would benefit from thinking through the record-keeping and organizational needs that can be derived from a mock recall exercise. Including mock recalls in the facility's verification program improve the facility's capacity to conduct effective and efficient recalls in the event of a contamination event. Mock recalls would also provide FDA with data on the effectiveness of the facility's plan and support development of guidance on best practices.

FDA should learn from the lessons of the Food Safety and Inspection Service and require that recall plans be part of a facility's written food safety plan. A 2003 OIG report[12] on FSIS' handling of a massive recall of 18 million pounds of ground beef by the ConAgra Beef Company emphasized the importance of a functional and tested recall plan. The OIG noted that two of the plants involved in the recall had no recall plans. As a result recall procedures where much slower and less effective than they should have been, unnecessarily exposing consumers to contaminated beef.

The OIG noted that FSIS policy recommended but did not require that establishments have a recall plan and that recall plans were not considered part of an establishment's HACCP plan. This is clearly a failing of the FSIS system, as the OIG indicates that "The absence of recall plans can impact the timely and efficient identification and recovery of potentially contaminated product." The OIG further stated: "Based on the inefficiencies experienced during this current recall, we concluded that recall operations can be improved if a recall plan is required as part of each plant's HACCP plan." FDA should heed this recommendation and require written and tested recall plans as part of a facility's preventive controls.

[10] Government Accountability Office, "USDA and FDA Need to Better Ensure Prompt and Complete Recalls of Potentially Unsafe Food." October 2004.
[11] Institute of Food Technologists, "Pilot Projects for Improving Product Tracing along the Food Supply Chain – Final Report." August 2012.
[12] USDA Office of Inspector General, "FSIS Oversight of Production Processes and Recall at ConAgra Plant (Establishment 969)." Report No. 24601-2-Kc, September 2003.

Monitoring
FSMA clearly requires establishments to monitor the effectiveness of preventive controls and we support FDA's determination that the owner, operator, or agent in charge of a facility must establish and implement written procedures, including the frequency with which they are to be performed, for monitoring the facility's preventive controls. This should include monitoring records for critical control points, if any, and parameters, including actual times, temperatures or other quantifiable values, as determined in the preventive control plan. Monitoring should be documented and subject to FDA review.

Corrective Actions
CFA supports FDA's decision to require the owner, operator, or agent in charge of a facility to establish and implement written corrective action procedures that must be taken if preventive controls are not properly implemented, as required under FSMA. Corrective action procedures should include steps taken to identify and correct a problem, assure that food is evaluated for safety and all affected food is prevented from entering into commerce if the owner cannot ensure that the food is not adulterated or misbranded. Procedures should also be developed to ensure corrective actions are taken in the event of an unanticipated problem. If an unanticipated problem occurs and corrective actions are implemented, the facility should reanalyze the food safety plan to determine if it should be modified. All corrective actions should be documented and subject to FDA review.

Verification
CFA supports FDA's determination that the owner, operator, or agent in charge of a facility must validate that the preventive controls identified and implemented to control the hazards identified in the hazard analysis are adequate to do so. As noted above, verification should be conducted for recall plans in the form of mock recalls.

The owner of a facility must verify that monitoring is being conducted and that appropriate decisions about corrective actions are being made, as required by FSMA. The owner must verify that the preventive controls are consistently implemented and are effectively and significantly minimizing or preventing the hazards that are reasonably likely to occur through calibration of process monitoring instruments and verification instruments; and through review of monitoring and corrective action records within a week after the records are made and calibration records within a reasonable time after the records are made, by a qualified individual.

The timeliness of the record review is important. This will ensure that the records are complete, the activities reflected in the records occurred in accordance with the food safety plan, the preventive controls are effective, and appropriate decisions were made about corrective actions. CFA supports FDA's proposal that review of monitoring and corrective action records should be conducted a week after the records are made. This is consistent with FDA's seafood and juice HACCP regulations. CFA supports FDA's requirement that the owner of a facility must establish and implement written procedures for the frequency of calibrating process monitoring instruments and verification instruments.

FSMA requires that the owner of a facility conduct a reanalysis of the facility's food safety plan at least once every three years. We would note that other HACCP regulations, such as meat and poultry HACCP and seafood and juice HACCP, require annual reanalysis of HACCP plans which is a more appropriate frequency. Facilities should not be allowed to review plans at a frequency longer than every three years. CFA anticipates that facilities will reanalyze their food safety plans whenever a significant change is

made that could create or increase a hazard, a new hazard is identified, or whenever a preventive control is not properly implemented or is found to be ineffective.

Consumer Complaints

CFA recommends that a review of consumer and costumer complaints be required as part of a company's verification activities. A review of consumer or customer complaints can confirm whether a facility's preventive controls are effectively minimizing the occurrence of hazards. Seafood and juice HACCP require that verification activities include a review of consumer complaints to determine whether they relate to the performance of the HACCP plan or reveal the existence of unidentified CCPs. As the agency notes in the Preamble, complaints can uncover problems with identified critical control points and can identify critical control points that have been overlooked.

Consumer complaints can also identify problems that may get past an establishment's preventive controls system. In 2012 a consumer complaint to the Reportable Food Registry identified an undeclared milk protein that caused a severe allergic reaction in a consumer[13]. Another example occurred in 2012 when a review of consumer complaints by FDA helped to identify brands of dry pet food produced by a single manufacturing facility in South Carolina that were linked to 53 human Salmonella illnesses. Seventeen different major brand names were recalled and 13 subsequent reports were received by the agency.[14] Though this was a reactionary measure, it demonstrates the importance of evaluating every source of data that might indicate a failure in the preventive control measures.

Even if FSMA does not specifically mention consumer complaints, it is clearly within the agency's authority to establish this requirement. FDA should require consumer complaints to be reviewed as they are received to ensure that any serious problems are investigated immediately.

Requirements Applicable to a Qualified Individual

CFA supports FDA's determination that the preparation, validation, records review, and reanalysis of the food safety plan must be conducted by a qualified individual(s). It is reasonable that the qualified individual must have completed training in development of preventive controls or be otherwise qualified through job experience. Training should be documented in records including the date of training, type of training and person(s) trained.

Recordkeeping

Accurate and adequate recordkeeping is critical so that FDA can verify that companies are maintaining, verifying and following their food safety plans. CFA supports FDA's determination that the owner, operator, or agent in charge of a facility must establish and maintain records including the written food safety plan, the written hazard analysis, preventive controls, monitoring procedures, corrective action procedures, verification procedures, and recall plan. Records that document the monitoring of preventive controls, corrective actions, verification, validation, reanalysis, and applicable training for the qualified individual should be maintained.

[13]Food and Drug Administration, "The Reportable Food Registry: Targeting Inspection Resources and Identifying Patterns of Adulteration. Third Annual Report: September 8, 2011 – September 7, 2012." May 1, 2013. Available at: http://www.fda.gov/downloads/Food/ComplianceEnforcement/RFR/UCM349856.pdf.

[14] *Ibid.*

Subpart D – Modified Requirements

Under the Tester amendment, qualified facilities may adopt modified food safety requirements rather than meeting the preventive controls requirements in the rule or demonstrate that they are in compliance with State, local, county or other non-Federal food safety law. In implementing the Tester amendment, FDA should maintain and exercise its oversight authority, particularly for foods that are shipped in interstate commerce. Only federal authorities can adequately oversee food shipped across state lines. States cannot enforce laws designed to protect citizens in another State. Likewise, States cannot require recalls from companies in another State.

FDA should amend the language under § 117.201(a)(2)(ii) to clarify that a qualified facility must comply with all applicable State, local, country or non-Federal food safety laws. The purpose of the provision clearly intends such compliance, but is poorly worded. FDA should clarify the wording to limit any confusion and avoid circumstances where a qualified facility believes it can comply with only one of the many non-Federal food safety laws, local ordinances, or regulations that may be applicable to its operation.

FDA requests comment on its proposal to use electronic self-certification at the time a qualified facility registers. Self-certification will deprive the agency of important information about compliance practices in qualified facilities. The Tester Amendment exempts a large number of facilities from having effective preventive controls. The potential exposure of the public to food safety risks justifies requirements for qualified facilities to document their safety. This documenting process provides the only assurance the public will have that every food processor, regardless of size, understands and is acting on its food safety responsibilities. For that reason, FDA needs to ensure that documentation is complete, accurate, reliable, and available for inspection. Submitting copies of the actual documentation would allow FDA to review food safety plans or inspection reports. These documents would allow FDA to target its efforts to qualified facilities that pose a greater risk because of inadequate prevention measures or deficient inspections.

FDA has also requested comment on its proposal to replace the term “place of business” with a requirement for the complete business address of a qualified facility. We agree with FDA’s interpretation and that a complete business address should include the street address or P.O. Box, city, state and zip code. We also agree that this information should appear prominently and conspicuously on the label of the food, or if food labeling is not required, notification at the point of purchase.

Subpart E – Withdrawal of an Exemption Applicable to a Qualified Facility

Under the Tester amendment, qualified facilities may adopt modified food safety requirements rather than meeting the preventive controls requirements in the rule or demonstrate that they are in compliance with State, local, county or other non-Federal food safety law. In order to protect the public health, FDA was provided the authority to withdraw the exception for these facilities if they are directly linked to an active investigation of a foodborne illness outbreak or “if the Secretary determines it is necessary to protect the public health and prevent or mitigate a foodborne illness outbreak based on conduct or conditions associated with a qualified facility that are material to the safety of the food manufactured, processed, packed or held at such facility.”

FDA's proposed rule correctly interprets the exemption in FSMA and the process for withdrawing the exemption. CFA supports the provision which offers an appropriate level of due process and correctly interprets FSMA to provide no means for restoring a qualified facility's exempt status after its withdrawal. No exempted facility, once linked to an outbreak of foodborne illness, should be allowed to continue to operate under an exemption. FDA should use this authority early and preemptively to protect public health. The provision provides for adequate due process, but once a qualified facility loses its exemption, its exempt status cannot be restored. This is appropriate and consistent with FSMA.

New Section – Testing Requirements

FDA Should Require Testing as Part of the Preventive Controls Regulation

Sampling and testing plays an essential role in verifying that an establishment's food safety program is working. Congress clearly anticipated that sampling and testing would be a part of a facility's preventive control plan. As defined under Section 418 of FSMA, facility operators are required to verify that their preventive controls "are effectively and significantly minimizing or preventing the occurrence of identified hazards, *including through the use of environmental and product testing programs* and other appropriate means" (emphasis added). Yet FDA did not require testing in its proposed rule, in clear violation of the both the mandate and intent of Congress.

Two examples highlight the importance of including testing in the final preventive controls rule. In 2000, USDA's Office of Inspector General reviewed the initial implementation of FSIS' HACCP program.[15] One of the key findings of that report was that FSIS needed to place greater emphasis on pathogen testing and that expanded pathogen testing would increase food safety. The report noted that at the time, FSIS did not require plants' HACCP plans to include pathogen testing of the plant environment, product contact surfaces or ready-to-eat products. OIG found this to be a key failing of the implementation of FSIS' HACCP program.

FDA's adoption of HACCP for seafood raises similar problems. In finalizing the seafood HACCP rule, FDA failed to mandate testing as part of the verification procedure for seafood safety plans. As a result, initial implementation was unsuccessful and it took years for the seafood industry to adopt effective preventive controls.

It is critical that FDA act to restore testing and other verification activities as part of the Hazard Analysis and Risk-Based Preventive Controls Rules. These provisions are mandated by FSMA and their absence could threaten the successful implementation of the law. Further, FDA should require testing beyond environmental monitoring, including testing of raw materials/ingredients and finished product testing, as appropriate. In particular, FDA should consider mandating finished product testing for food products designated as high-risk. Testing programs should be a part of, not outside of, a facility's preventive control plan. FDA should address testing in an Interim Final Rule rather than issue a supplemental rulemaking proposal. This approach would provide opportunity for stakeholders to comment, but not delay implementation of the rest of the regulation.

[15] USDA Office of Inspector General, Implementation of the Hazard Analysis and Critical Control Point System." Report No. 24001-3-At, June 2000.

Testing Requirements
In order to make clear the agency's expectations for testing, FDA should establish the parameters under which testing would be required in different types of establishments and the necessary components of a testing program. The testing program should clearly and directly address the hazards identified in the hazard analysis. Testing should be conducted for pathogens rather than indicator organisms whenever possible. The testing plan should describe the target organisms, test methods and frequency, points of sampling (environmental, ingredients, finished product), and corrective actions when positives are found. FDA should specify testing that is to be required by facilities and testing that will be conducted by the agency.

Companies should use the results of testing programs to conduct trend analysis to identify patterns and, with this information, refine food safety processes and controls and testing programs. A written trend analysis plan that includes corrective actions corresponding to positive results is essential for continuous improvement. In addition, test and hold should be strongly encouraged as a best practice.

Environmental Testing
FDA should establish the circumstances under which environmental sampling would be required. Such conditions should include, but not be limited, to:

- Handling or processing products with a history of contamination;
- Handling or processing steps that could introduce contamination;
- Producing Ready to Eat (RTE) products; and
- Whether there is potential for colonizing and/or promoting growth of a pathogen once it enters the facility, or in the product.

FDA should specify that environmental testing should, when possible, target specific pathogens over indicator microbes. Indicator organisms can serve an important function, but should only be used if specific surrogates have been identified and substantiated for specific pathogens. Generally, indicator organisms identify conditions that can lead to the potential presence of pathogens more than the confirmed presence of a specific pathogen.

Other circumstances that FDA should consider in requiring environmental testing are: If a plant is "wet" and produces ready-to-eat products that can permit or facilitate *Listeria monocytogenes* growth, then the plant should test for *Listeria monocytogenes*. If the plant produces ready-to-eat products in a "dry" environment, then it should, at a minimum, test for *Salmonella* spp.

Environmental testing should be used as a signal; that is, a positive test result should trigger additional action and provide incentive for improvement. For example, a positive sample from a drain would trigger additional testing of product contact surfaces; a positive on product contact surfaces would trigger product testing; and a history of negative results could signal it is appropriate to back off intensified testing. Dividing processing into distinct zones should be used, with increased testing within zones in response to positives. CFA notes that FDA proposes mandating the use of zones and we support this approach. This type of approach has been used successfully to manage *Listeria* in a number of food processing settings. Finally, FDA should provide via guidance a decision tree for facilities to determine if and when environmental monitoring is needed.

Raw Materials Testing
A supplier approval and verification program can help ensure that raw materials and ingredients are sourced from those suppliers that meet company specifications and have appropriate programs in place

to address the safety of raw ingredients. Unfortunately, the proposed rule does not contain a supplier verification program, which greatly increases the need for raw material and ingredient testing programs to ensure the public health.

FDA should require facilities to test incoming raw materials as part of their supplier verification programs, particularly under the following conditions:

- The ingredient will be included in a RTE product, especially when no pathogen inactivation treatment is applied to the product after the ingredient is added.
- The ingredient has a history of pathogen contamination or re-contamination.
- The ingredient is high risk, i.e., it is likely to contain a contaminant that can make people very ill if consumed or used in foods for high-risk populations such as infants or the elderly.
- There is no validated "kill" step as part of the processing/production of the ingredient.
- Supplier verification information is inadequate or there is not validated CCP at the supplier level.

The frequency of raw material testing should be based on inherent product risk, how the product or ingredient will be used, an assessment of supplier performance, and the ability of the facility to control risk. Food facilities should beware of exempting ingredients or raw materials if the product could be diverted for other uses; for example, an ingredient subject to contamination going into product that is not fully processed.

Finished Product Testing

Finished product testing is a useful way to know whether the product, at the end of the production line which is destined to go to consumers, has been safely produced. It is especially important when the product supports pathogen growth over the shelf life of the product. Generally, there should be a direct relationship between the risk associated with a product and the frequency of finished product testing. A finished product's risk depends on the following:

- The overall robustness of environmental and ingredient testing programs and controls, as described in the above sections.
- The risk of pathogen growth over the product's shelf life. For example, if the product, post packaging, has a likelihood of bacterial growth under temperature abuse conditions.
- The history of the product as being associated with numerous foodborne illness outbreaks.
- The results of trend analysis within a facility of presence of microbial pathogens or other hazards.
- The results of statistical process control or lot sample, e.g., evidence of an ingredient "hot spot" or process failure.

Elements that point to the need for finished product testing include the absence of CCPs; products or ingredients with higher contamination rates; trend analysis; product risk (RTE vs. ready to cook); and results of statistical process control or lot sampling, including evidence of an ingredient "hot spot" or processing failure.

For regulatory purposes, FDA should define the frequency for finished product testing requirements. A standardized definition for target organisms across different commodities will be useful so that the same hazards are defined in facilities that process the same food or ingredients. In addition, FDA should also see comparable sampling protocols, testing plans and results across similar types of facilities.

One objective of government prescribed testing is to allow for inter- and intra-company comparisons. This can only be done if the target organism, test methods and frequency are comparable for facility

testing or if the tests are conducted by the government according to the same protocols across the industry.

New Section – Supplier Approval and Verification Program

FDA Should Require a Supplier Approval and Verification Program as Part of the Preventive Controls Regulation

FDA makes a strong case in the appendix to the proposed rule regarding the importance of a robust supplier verification program. The agency points to food safety events and recalls in which a lack of supplier controls had a direct impact on the food safety problem identified. In addition, Congress clearly anticipated that supplier verification activities would be a part of a facility's preventive control plan, as defined under Section 103 (o)(3)G) of FSMA.

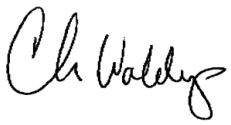
Supplier approval and verification programs are widely accepted in the food industry and recommended by industry associations. If manufacturers are to produce safe food, they need assurances that the ingredients they are purchasing are produced safely as well. An adequate supplier verification program can help manufacturers take the necessary steps to address potential problems and prevent food safety hazards from occurring. Maintaining a safe and secure supply chain is a best practice in the food industry and should be incorporated into the final rule on preventive controls.

FDA should require manufacturers to develop, maintain and regularly update a Supplier Approval and Verification Program as part of its food safety plan. The Program should be adequate to assure that the manufacturer's suppliers are producing food in compliance with the law. Manufacturers should review the compliance status of their suppliers, conduct hazard analyses for hazards reasonably likely to occur with the food, review the supplier's own hazard analysis, review consumer complaints, obtain all relevant documentation, conduct verification activities on a regular basis, carry out corrective actions, and maintain adequate recordkeeping.

Manufacturers should also conduct periodic sampling and testing of the food and periodic review of the supplier's food safety records. FDA should require manufacturers to conduct onsite audits of their suppliers at least annually. Onsite inspection of suppliers is essential to provide assurance that the supplier is adequately addressing food safety hazards. Manufacturers should be required to conduct a reassessment of their Supplier Approval and Verification Program at the same time it reassesses its food safety plan and whenever circumstances would warrant a reassessment, such as a change in supplier, a change in the activities of the supplier, a new hazard is identified or a supplier's preventive controls are found to be ineffective.

CFA appreciates the opportunity to provide comments on this important proposed rule. We urge FDA to finalize the rule as soon as possible.

Sincerely,



Chris Waldrop
Director, Food Policy Institute
Consumer Federation of America