Consumer Federation of America

December 15, 2014

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 supplementary notice of proposed rulemaking 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.

CFA appreciates the efforts FDA has made to draft this rule, seek stakeholder input through public meetings and the public comment process, and remain open to ideas and suggestions to improve the rule. CFA's comments on the supplemental proposal follow.

Definition of a Very Small Business

FDA proposes to revise its definition of very small business to a business with total annual food sales of less than $1 million. CFA does not support this revision; CFA had previously urged 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. Establishment of a $1 million threshold is contrary to Congressional intent and conflicts with other statutory provisions in the law, specifically Section 418(l), also known as the Tester Amendment. Under this provision, qualified facilities are 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. Adopting a $1 million threshold effectively nullifies this provision because the annual sales for a very small business would be larger than the second definition for a qualified facility. CFA reiterates our position that the definition of very small business should be limited to a business that has less than $250,000 in total annual sales adjusted for inflation.

Product Testing and Environmental Monitoring

Sampling and testing plays an essential role in verifying that an establishment's food safety program is working. CFA is pleased to see that FDA has incorporated product testing into the preventive controls proposed rule and urges the agency to include this provision in the final rule. Under the supplemental proposal, FDA requires facilities to conduct product testing for pathogens or indicator organisms, as appropriate, to verify the effectiveness of the preventive controls. CFA supports this requirement and urges FDA to provide guidance to industry on appropriate testing protocols and parameters.

Under the proposal, FDA requires environmental monitoring for the appropriate pathogen or indicator organism only in the specific circumstance where ready-to-eat food is exposed to the environment prior

to packaging and the packaged food does not receive a treatment that would significantly minimize the pathogen. CFA agrees that environmental monitoring should be conducted in this particular case, but FDA should not limit its requirement for environmental monitoring just for ready-to-eat foods. FDA should expand its proposal to require any facility in which there is a risk of contamination by an environmental pathogen to conduct environmental testing.

CFA further reiterates its recommendation that FDA consider mandating finished product testing for food products designated as high-risk. 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 its shelf life.

Supplier Approval and Verification Program

CFA is pleased to see that FDA has incorporated a supplier verification program into the preventive controls proposed rule and urges the agency to include this provision in the final rule. Supplier approval and verification programs are widely accepted in the food industry. 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.

FDA proposes that facilities could select one or more verification activities including an onsite audit, sampling and testing of the raw material/ingredient, review of the supplier's relevant food safety records, and other appropriate verification activities based on the risk associated with the ingredient and the supplier. Facilities must base their verification activity on a consideration of the hazard and risk of the supplier. FDA proposes that a facility could substitute a government inspection for an audit. FDA should clarify in the final rule that the inspection must have been conducted within the past 12 months so that the timeframe of the inspection report is consistent with the timeframe for an annual audit.

For hazards for which there is a reasonable probability of serious adverse health consequence or death to humans or animals (SAHCODHA), FDA proposes to require facilities to have documentation of an onsite audit of the supplier before using the raw material and at least annually thereafter. FDA proposes to allow the facility to select less frequent onsite auditing or other verification activities provided adequate assurance is made that the hazards are controlled.

CFA reiterates our support for annual onsite audits of suppliers, particularly for SAHCODHA hazards. Onsite inspection of suppliers provides the greatest assurance that the supplier is adequately addressing food safety hazards. As we know from inspection results, onsite verification can identify potential problems in ways that paperwork reviews cannot. Seeing how a supplier is conducting their business onsite is critical.

FDA's allowance of alternative activities assumes that the facility will always choose the best verification option to assure the food is safe rather than a lower level of verification that might cost less. Considering the financial pressures facing food companies, it is easy to envision multiple scenarios when a lower level of verification would be chosen that saves the facility money but is inappropriate for a SAHCODHA hazard.

If FDA does move forward with this proposal, we urge the agency to consider annual onsite audits for SAHCODHA hazards the default action and require facilities to affirmatively inform FDA if they are opting to perform any type of variation (another activity or a different activity frequency) from an annual onsite

audit. Facilities must be able to justify and document how a chosen variation provides the same level of assurance as an annual onsite audit. If FDA permits facilities to conduct other types of verification activities or conduct activities at frequencies other than annually, FDA should specify the type of documentation required in order for the agency to determine whether those activities are in compliance with the law and are sufficient to protect the public health.

Consumer Complaints

FDA has chosen not to require facilities to review customer complaints as part of its verification program. 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. 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. For these reasons, FDA should reinstate a requirement that a facility should review customer complaints as part of its verification program.

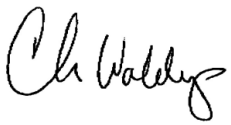
Withdrawal of an Exemption Applicable to a Qualified Facility

In the supplemental proposal, FDA modified its proposed provisions on withdrawal of exemptions for qualified facilities to include a series of steps that provide qualified facilities with due process before withdrawal. These steps are reasonable and will provide qualified facilities greater clarity on the withdrawal process. Though CFA notes that it may not be necessary to enshrine those steps in regulation; guidance could serve the same purpose while not locking FDA into those steps if the agency needs to act more quickly to protect the public health.

CFA opposes FDA's decision to provide for reinstatement of an exemption that is withdrawn. Reinstatement was not provided for under FSMA, reflecting Congress' determination that the exemption was a privilege, not a right, and that if a qualified facility was linked to a foodborne illness outbreak that sickened consumers, that qualified facility should no longer be permitted to be exempt from federal food safety regulations. This was a "one strike, you're out" approach that was carefully negotiated by stakeholders during the debate on FSMA in Congress. There should be 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. CFA opposes the inclusion of a reinstatement provision and urges FDA to remove it from the final rule.

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

Sincerely,



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