Impact of Exemptions and Verification Provisions on Consumer Health and Safety

FDA Food Safety Modernization Act: Supplemental Notices of Proposed Rulemaking Public Meeting

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My comment provides consumer perspectives on revisions to the proposed rule on preventive controls for human food. I am David Plunkett, senior staff attorney for the Food Safety Program at the Center for Science in the Public Interest. With only three minutes to speak, my remarks today are of necessity brief. CSPI will file more extensive written comments.

Opposition to Exemption and Reinstatement under the Qualified Facilities Program.

Let me begin by registering our opposition to the changes affecting qualified facilities. Adopting a $1 million threshold for very small businesses conflicts with the statutory structure laid out in the Food Safety Modernization Act. As a result, half of the qualified facility program is nullified by administrative fiat—expanding food safety exemptions beyond what Congress intended. Meanwhile, providing for reinstatement after a qualified facility has lost its status removes Congress’ careful design for accountability in the program. CSPI filed extensive comments on these two points in the first round of rulemaking that we will refile and amplify in our written comments.

Support for Product Testing and Supplier Verification.

We support the product testing and supplier verification provisions, which had been omitted in the earlier proposed rule. Product testing plays in important role in protecting
consumer health by verifying that process controls are effective. Supplier verification is a widely adopted procedure within the food industry and a common component of science-based prevention programs. We encourage the agency to retain these requirements in the final rule with improvements that will be covered in our written comments.

Need for Including Consumer Complaints as a Verification Procedure.

We are disappointed that FDA saw fit to delete a requirement for facilities to review consumer complaints as part of the verification process. This is required under FDA’s Seafood and Juice HACCP rules. It is a way of identifying failures in a facility’s food safety plan and/or its implementation. It should be required for the rest of the food industry.

Environmental Testing Should Cover Non-RTE Foods Where Risk is Present.

Environmental testing should not be limited to just ready-to-eat products. As we discussed in earlier comments, environmental testing should be required generally as a means of identifying problems with a facility’s sanitation measures. It should also be required to identify unexpected risks, regardless of whether or not the food is a ready-to-eat item, if there is a reasonably foreseeable hazard such as the likelihood that people will eat raw cookie dough.

Thank you.