Division of Dockets Management (HFA- 305)  
Food and Drug Administration  
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The Center for Science in the Public Interest (“CSPI”) appreciates the opportunity to comment on the proposal to collect profile information on food facilities [Docket No. FDA-2012-N-0430]. CSPI is a non-profit consumer advocacy and education organization that focuses largely on food safety and nutrition issues. We are supported principally by the 850,000 subscribers to *Nutrition Action Healthletter* and by foundation grants.

CSPI supports efforts by the Food and Drug Administration (“FDA”) to gather information that will improve its oversight of the preventive food safety system established by the FDA Food Safety Modernization Act. Food facilities, when they register, are required to provide their name and address and all trade names under which they conduct business, the e-mail address for a contact person, and the general food category of any food manufactured, processed, packed, or held at the facility.\(^1\) FDA wants to augment this mandatory information with voluntarily submitted profile information. The agency anticipates requesting information on the type and size of the facility; products, hazards and control measures; and food safety training, operational schedule and number of employees.\(^2\)

We agree that additional profile information could assist the agency in allocating its resources. However, a voluntary system for submitting profile information does not have sufficient reliability to permit FDA to determine if a facility is high-risk or non-high risk. We believe, instead, that FDA should consider a mandatory profile program.

A voluntary program is unlikely to result in the benefits that FDA projects of better-informed investigators and shorter inspection times. Any voluntary reporting system suffers from selection bias. This may mean the profiles will not reflect safety risks across the industry, nor even within an industry category. An equal, but opposite, possibility exists that some facilities may misrepresent safety and facility information in order to appear less risky and avoid frequent inspection. In either case generalizations about safety risks at profiled or similar facilities could lead to unprepared investigators and incomplete inspections.

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\(^1\) 21 U.S.C. § 350d(b) (2010)  
To solve for these deficiencies, we encourage FDA to require mandatory reporting of profile information as part of the biennial registration process. This action would enable the agency to manage limited inspection resources with confidence. It would ensure the agency has accurate information on a facility’s type, size and operating schedule before investigators enter. Prior to and during inspections investigators could use information on a facility’s hazard analysis, preventive controls and employee training regimen to appropriately target an inspection’s focus. The information would also provide the agency with more reliable data on industry practices and standards which would help define where there are industry-wide gaps or deficiencies, in order to better identify the areas where oversight and guidance would improve safety.

If FDA intends to use the profiles to allocate inspections of specific facilities, then it must control for potential selection bias or misrepresentation that would corrupt the profiles. The best method to avoid problems with the information collection is to mandate participation.

Respectfully submitted,

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