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Dockets Management Staff (HFA-305)
U.S. Food and Drug Administration (FDA)
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

**Re: Proposed Rule; Requirements for Additional Traceability Records for Certain Foods
[Docket No. FDA–2014–N–0053-0056]**

The Pew Charitable Trusts (Pew) welcomes the opportunity to comment on the proposed traceability regulations. Pew is an independent non-partisan research organization, which applies a rigorous, analytical approach to improve public policy, inform the public, and invigorate civic life. Our work on food safety began with the successful campaign to enact the FDA Food Safety Modernization Act (FSMA), and we continue to focus on ensuring that FSMA is faithfully implemented through effective regulations that are aimed at preventing food contamination and the human illness it causes.

Pew strongly supports FDA’s proposed traceability rule. End-to-end traceability throughout the entire food supply is key to improved public health, which is the promise of FSMA. It will enable quicker resolution of foodborne illness outbreaks; too many times in recent years outbreak investigators have been unable to identify food vehicles causing illnesses because of inconsistent recordkeeping and incomplete paper records. A system that can traceback and trace forward to identify specific food products will significantly reduce the number of unsolved outbreaks and illnesses. It will also enable FDA to quickly warn consumers not to consume potentially contaminated food items and to implement targeted recalls.

Moreover, a comprehensive traceback system that identifies the food source responsible for an outbreak will facilitate root cause analyses, which enable investigators to focus on how and why the contamination happened. The findings of these analyses can prevent similar problems from recurring.

The core elements of the rule will facilitate traceability throughout much of the supply chain by ensuring that key data is preserved as product moves between parties. The language of Section 204 of FSMA, which establishes the traceability requirements, constrains FDA in a number of ways, in particular, by limiting the requirements to “high risk foods.” We believe that the agency could have relied on other provisions of the Federal Food Drug and Cosmetic Act to more broadly apply its traceability requirements.¹ Nevertheless, we encourage all food producers and processors to

¹ See, e.g. Section 701(21 U.S.C. 371(a))(FDA has the “authority to promulgate regulations for the efficient enforcement of this Act.”)

voluntarily follow the provisions of the traceability rule. It is clearly in their business interests to do so: recent experience with expansive recalls have hurt companies' bottom lines and undercut consumer confidence not only in the safety of particular products but also in the overall food supply.

The remainder of our comments will focus on three specific aspects of the proposed rule.

Updating the Food Traceability List

The proposed rule sets forth a process for FDA to update the "Food Traceability List" (FTL). Since this list defines which food items require full traceability, it is imperative that it be updated regularly and frequently. FDA has indicated that it has not yet set a schedule for considering updates to the FTL, beyond a "periodic review" of the relevant data. We recommend that this review occur at least on a quarterly basis, thereby ensuring that the FTL reflects the most up-to-date science as well as knowledge obtained from recent foodborne illness outbreak investigations.

Encouraging Use of Electronic Records

Pew supports the requirement that entities subject to this rule must provide, in the form of an electronic sortable spreadsheet, the relevant traceability information to FDA within 24 hours of a request from the agency, when it is necessary to assist FDA in responding to an outbreak or public health threat.

As noted above, not all FDA-regulated food operations are subject to the additional recordkeeping requirements. For that reason, the agency indicates in the proposal that it "strongly encourage[s]" all entities in the food industry to maintain fully electronic data systems. We are concerned that members of the food industry might delay adopting electronic recordkeeping if not required to do so. Therefore, beyond "strong encouragement," FDA should develop policies that will incentivize and assist all food processors in electronic data migration and tracking. For example, FDA could consider a food processor's data management practices in the agency's risk-based prioritization of inspections and import screenings.

Exempting Entities, in particular Small Retail Food Establishments

Pew requests that FDA reconsider all of the proposed full and partial exemptions not expressly required by Section 204 to ensure that they strike the right balance between protecting public health and reducing the burden on small businesses. We also recommend that in lieu of providing exemptions, the agency should consider providing technical assistance to help smaller operations develop scale-appropriate traceability systems. FDA should also reach out to the various companies that provide traceability platforms and work with them to develop basic, affordable traceability programs.

In terms of the two specific options proposed by FDA for small retail food establishments, we support "Option 2," which is a partial – instead of a complete – exemption for these entities. Option 2 would require small retailers to comply with the core recordkeeping provisions of the rule.

At the same time, we request that FDA consider narrowing the parameters regarding which entities qualify as a small retail food establishment under this partial exemption. The agency is proposing that this partial exemption cover retailers with 10 or fewer full-time equivalent employees. With increased use of online grocery platforms, thanks in large part to the pandemic, the number of employees needed to run a retail establishment is likely to continue to decrease in the coming years. To address this reality and keep the exemption appropriately narrow, we recommend that the agency revise the current requirement by adding to it an inflation-adjusted gross annual income ceiling for qualifying small retail establishments.

Conclusion

We commend FDA for finally issuing a proposed rule on traceability, one of the major loose ends of FSMA implementation. We hope that our comments and those of the other stakeholders result in traceability requirements that can lead to meaningful public health improvements.

Sincerely

A handwritten signature in blue ink that reads "Sandra B. Eskin". The signature is fluid and cursive, with a long horizontal flourish at the end.

Sandra B. Eskin
Project Director, Safe Food
The Pew Charitable Trusts