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February 22, 2021

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

Re: Requirements for Additional Traceability Records for Certain Foods (Sept. 23, 2020), Docket No. FDA-2014-N-0053

To Whom it May Concern:

The undersigned organizations appreciate the opportunity to provide comments on the U.S. Food and Drug Administration (FDA) proposed rule entitled "Requirements for Additional Traceability Records for Certain Foods" (hereinafter, "Proposed Rule").

Protecting consumers from potentially contaminated foods, facilitating faster recalls, and streamlining traceback investigations are priorities shared by both the food industry and the FDA. Our organizations are strong supporters of the FDA and the FDA Food Safety Modernization Act (FSMA); we support FDA fulfilling its congressional mandate under Section 204 of FSMA to develop a system within the agency for product tracing and to establish recordkeeping requirements for high-risk foods. The members of our respective trade associations have significant experience with recall and traceback investigations, as well as with recordkeeping under the Bioterrorism Act. Those experiences have shaped our perspective on the proposed rule.

We fully support the goals of the proposed rule, but are concerned that the rule is too complex, complicated, and confusing to achieve those goals. As drafted, it would be incredibly burdensome to implement by covered entities for those foods on the Food Traceability List, let alone voluntarily adopted by the entire food industry. We recommend that FDA simplify the proposed rule and focus on the key gaps in traceability today – those not addressed by the one-up, one-back recordkeeping requirements under the Bioterrorism Act. We understand that the agency would like our industry to modernize through digitization. Realizing that goal will take time and is dependent on ensuring that the requirements in this rulemaking are achievable.

Our members have spent considerable time working to understand the proposed rule and its impact on their organizations. We have held multiple meetings with our members to discuss the rule. Companies have shared information on their existing practices and considered what practices would need to change to achieve compliance. Industry-wide workshops have been held. These discussions raised a number of questions regarding the proposed rule. We appreciate the meetings we have had with FDA to date to discuss the proposal and seek clarity

on various provisions. Nonetheless, considerable confusion remains. Members continue to have questions regarding the scope of the Food Traceability List, when ingredients are covered, how certain exemptions would work, and when entities are acting as a "First Receiver," for example.

As our members have examined the proposed key data elements (KDEs) against existing traceability practices and procedures, we are concerned that the proposed rule would add a layer of detail and complexity that not only is unnecessary for tracing food, but could in fact hinder traceability. We urge FDA to focus on the KDEs that are truly necessary for traceability. An additional challenge of the proposed rule is that it would impose different recordkeeping requirements for different critical tracking events (CTEs). Due to the structure of the food supply chain and the ever changing nature of how foods move from the point of origin to the consumer, a single entity may engage in different CTEs for the same product (e.g., it could sometimes be a "receiver" and at other times be a "first receiver"). This kind of complexity makes the proposed requirements significantly burdensome. We submit that any additional recordkeeping requirements must be clear and achievable to realize their public health goal.

Not only must the requirements imposed by this rule be workable for the whole food industry, but they must also be sufficiently flexible to account for the changes to supply chains, technology, and industry that are inevitable. We encourage FDA to consider requirements that are less prescriptive and can adapt to the future, including advancements in technology. For example, there may be even better and more efficient ways to provide FDA with traceability information than via an electronic sortable spreadsheet.

We appreciate that tech-enabled traceability is a core element of FDA's Blueprint for a New Era of Smarter Food Safety. We also understand that FDA considers this rulemaking to implement Section 204 of FSMA the first step in that work. We agree, which is why it is critical that we get this rule right. Based on our members' review of this rule and existing technological capabilities, considerable work is needed before a digital end-to-end traceability system can be achieved. We urge FDA to concentrate on the foundational elements necessary to achieve its long-term goals. It is imperative that we get the basics right before we consider building on top of them.

In our view, a simple, straightforward approach that benefits public health would focus on closing the gaps presented by the existing recordkeeping framework established under the Bioterrorism Act. It is imperative that any new traceability recordkeeping requirements be workable for all entities that will be covered by the rule. We encourage FDA to consider voluntary efforts, including pilots and other initiatives, by the food industry and ensure that new requirements align with the traceability enhancements and capabilities instituted by the food industry to date.

Because FBIA is recommending fundamental revisions to this proposed rule, we respectfully request FDA issue a supplemental proposed rule as part of this rulemaking. We expect that after FDA has considered all comments, the resulting revised rule will differ substantially from the original proposed rule, necessitating a new period of notice and comment. In addition, issuing a supplemental proposed rule will allow FDA to engage further with stakeholders to understand better ways in which the proposed rule could be simplified to achieve its public health goals.

As expressed at the outset, we are committed to protecting consumers from potentially contaminated foods and facilitating faster recalls and traceback investigations. We stand ready to work with FDA to achieve these goals. We believe that we can develop better, simpler, and more nimble traceability recordkeeping requirements through further engagement with the agency. We would welcome the opportunity to provide more information on current industry practices, capabilities, and perspectives on technology, data-standardization, international implications, and more. In short, the undersigned organizations and their members would be pleased to participate in further dialogue with the agency on this rulemaking.

Thank you for your consideration of these comments. We would be pleased to address any questions you may have.

Sincerely,

1. American Bakers Association
2. American Frozen Food Institute
3. American Spice Trade Association
4. Calorie Control Council
5. Consumer Brands Association
6. Food Marketing Institute
7. Global Cold Chain Alliance
8. International Dairy Foods Association
9. International Flight Services Association
10. International Food Additives Council
11. International Foodservice Distributors Association
12. Juice Products Association
13. National Automatic Merchandising Association
14. National Association of Chemical Distributors
15. National Confectioners Association
16. National Grocers Association
17. National Fisheries Institute
18. National Pasta Association
19. National Restaurant Association
20. National Seasoning Manufacturers Association
21. North American Millers' Association
22. Peanut and Tree Nut Processors Association
23. Produce Marketing Association
24. Refrigerated Foods Association
25. The Association for Dressings & Sauces
26. The Vinegar Institute
27. United Egg Producers
28. United Fresh Produce Association
29. USApple
30. Western Growers Association