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February 22, 2021

U.S. Food and Drug Administration
Division of Dockets Management, HFA-305
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Re: Docket No. FDA-2014-N-0053, Requirements for Additional Traceability Records for Certain Foods

To Whom It May Concern:

Thank you for the opportunity to provide comments to the Requirements for Additional Traceability for Certain Foods on behalf of the Association of Food and Drug Officials or AFDO. AFDO promotes the uniform adoption and enforcement of food, drug, medical devices, cosmetics and product safety laws, rules, and regulations. Founded in 1896, AFDO is an international, non-profit professional organization consisting of state, federal and local regulatory officials as members. AFDO is a mechanism for advancing regulatory program standards that will help to advance a national integrated food safety system. The organization also provides training and continuing education as well as networking opportunities that foster understanding and collaboration among all members and an appreciation for each role in the food and medical device safety system.

AFDO supports the efforts of the Food and Drug Administration (FDA) in the proposed rule, Requirements for Additional Traceability Records for Certain Foods. This proposed rule supports the Food Safety Modernization Act (FSMA) requirement to develop a traceback and recordkeeping system for foods which require investigations as a result of outbreaks. The proposed rule is also in support of the innovative New Era of Smarter Food Safety. While in support of the proposed rule, AFDO would like to provide comments about the proposed rule.

Overall Structure and Definitions

- There are many new terms and new data elements within the proposed rule which may or may not be key in conducting traceback investigations. Determining only those new terms and data elements fundamentally necessary and not redundant in investigations would limit the changes and additions to existing industry, regulated, and regulatory database systems.

- The ability of industry and regulated partners to comply with the proposed rule will create complications with compliance due to the lack of a clear and updated definition of “farm” as it relates to the Produce Safety Rule and FSMA.
- AFDO regulatory jurisdictions support the proposed rule providing clarity to the practice of “cross-docking” as it relates to specific activities including receiving and holding or to provide clarity if “cross-docking” is considered a transportation activity.
- Using the previously defined terminology of “lot” as opposed to “traceability lot” would provide a more consistent and clear understanding by industry, regulated partners, and regulatory jurisdictions. Using the term traceability as an action to a lot would then provide a clearer understanding.

Molluscan Shellfish

The National Shellfish Sanitation Program (NSSP), with oversight by FDA through the FDA/Interstate Shellfish Sanitation Conference (ISSC) Cooperative Agreement and MOU, provides significant existing regulatory control over molluscan bivalve shellfish that includes traceability from the harvest site and through the supply chain. The requirements have been carefully and thoughtfully developed with the input from state and federal regulatory agencies, academic institutions, and the shellfish industry, many of whom are the nation’s leading experts in food safety and risk assessment as related to molluscan shellfish. We concur with the ISSC recommendation for an exemption or waiver to the traceability rule of molluscan shellfish.

Food Traceability List

- Foods listed and not listed on the Food Traceability List do not provide enough clarity and detail to determine if specific foods which may or may not be subject to the rule requirements. This will cause confusion not only with industry and regulated partners but also with those state and local jurisdictions that may have regulatory jurisdiction.
- The proposed rule should provide details and clarity of the process and timeline to which foods can be added to or removed from the Food Traceability List.
- The proposed rule does not provide clarity as to how it would address commodities on the Food Traceability List that are ingredients of food items specifically due to the ambiguity of the items on the list.

Record Keeping Requirements and Availability of Records

- The requirement of electronic records and electronic spreadsheets to be used in traceability and communication during outbreaks, while highly desirable and beneficial to regulatory jurisdictions, will provide undue financial hardship and processes to those businesses who operate in paper tracking systems.
- AFDO very much supports the requirement of all food industry and regulated partners to be required to submit customer loyalty information and/or credit card information which will support the notification of customers who have purchased products involved in outbreak investigations.
- The requirement of a location identifier as a data element may not be necessary and may be duplicative and/or similar in other information requested.

- Clarity is needed regarding the time period of 24 hours in which requested records must be made available to the regulatory jurisdiction. Is this required to be in writing, verbal, etc.

Exemptions

Generally, AFDO opposes sized-based exemptions regardless of what is used to measure. We strongly believe food-safety, including traceability, should not be based upon size, but upon science. If exemptions will be maintained, we suggest FDA consider the following revisions.

- The proposed rule requested input on the two options which were related to subpart S for small retail food establishments. AFDO offers that the exemption would be less affected by changes in business process, including automation, to have the retail exemption defined by a dollar value (annual sales) as opposed to number of employees.
- Certain exemptions, as outlined in the proposed rule, lead to confusion and inconsistency among producers, distributors, USDA (Feeding Programs), brokers, and importers. More defined and specific language for exemptions should be codified to provide clear expectations avoiding interpretations.

We believe the proposed Requirements for Additional Traceability Records for Certain Foods will assist in more rapid identification of those foods which may be implicated in a foodborne illness outbreak. Thank you for the opportunity to review and provide feedback on this proposal. As always, we are willing to continue the conversation with FDA about the proposed rule and provide further clarification as needed.

Sincerely,



Steven Mandernach
Executive Director