

May 24, 2018

Jenny Scott
Center for Food Safety and Applied Nutrition (HFS-300)
Food and Drug Administration
5001 Campus Drive
College Park, MD 20740

Via Electronic Filing at <http://www.regulations.gov>

RE: Hazard Analysis and Risk-Based Preventive Controls for Human Food; Draft Guidance for Industry; Availability, Docket No. FDA-2016-D-2343

Dear Ms. Scott:

The National Association of Chemical Distributors (NACD) submits the following comments in response to the Food and Drug Administration (FDA) request for public comment regarding Docket No. FDA-2016-D-2343, Hazard Analysis and Risk-Based Preventive Controls for Human Food; Draft Guidance for Industry; Availability (guidance).

About NACD

NACD is an international association of nearly 440 chemical distributors and their supply-chain partners. NACD members represent more than 85 percent of the chemical distribution capacity in the nation and generate 93 percent of the industry's gross revenue. NACD members, operating in all 50 states through more than 2,800 facilities, are responsible for nearly 130,000 direct and indirect jobs in the United States. NACD members are predominantly small regional businesses, many of which are multi-generational and family owned.

NACD members meet the highest standards in safety and performance through mandatory participation in NACD Responsible Distribution®, the association's third-party-verified environmental, health, safety, and security program. Through Responsible Distribution, NACD members demonstrate their commitment to continuous performance improvement in every phase of chemical storage, handling, transportation, and disposal operations.

Approximately 63 percent of NACD distributor member companies distribute or process chemicals that will ultimately become ingredients in food; the food market is a substantial and growing part of NACD members' business. Keeping the U.S. food supply safe through Responsible Distribution and compliance with FDA food safety regulations is of utmost importance to NACD members.

FDA Should Modify the Requirements for Verification and Approval of a Supplier's Supplier

FDA should modify the guidance to allow more flexibility in satisfying the requirement for approval and verification of a supplier's supplier. The guidance as currently written requires practices that are resource intensive and may not be feasible due to non-disclosure

agreements or because of limitations such as a lack of a contractual relationship between the importer or receiving facility and their supplier's supplier. Further, it would be prohibitively difficult to check on each individual company that supplies ingredients to a direct supplier. The FDA should modify the guidance to allow firms to meet these requirements by confirming that their direct suppliers have good supplier approval and verification programs in place.

FDA Should Create A Process for Transparency Around DUNS Numbers

Under current practice, any company's Dun & Bradstreet's Data Universal Numbering System number (DUNS number) can be declared when a Foreign Supplier Verification Program (FSVP) entry is filed in the Customs and Border Protection's Automated Commercial Environment. This means that any company can use another's DUNS number for FSVP without their knowledge or consent, making them responsible as the FSVP importer and therefore for all FSVP compliance related to that import. FDA should implement a process to create more transparency around the use of DUNS numbers when declared at entry. Companies should have the ability to check and verify when their DUNS numbers are being used to ensure they are able to perform FSVP compliance when it is their shipment and to provide a correction when it is not.

FDA Should Revise Its Ingredient Testing Recommendations

The guidance includes a recommendation on when it may be appropriate for firms to conduct testing on food or raw materials obtained from suppliers. FDA should revise these recommendations to be consistent with the industry practice of "test and hold" to avoid recall situations. Typically, if an importer tests a product, they will hold the rest of the lot in that batch in case a positive result is received. FDA should revise the guidance, specifically the questions related to ingredient testing, to reflect this standard industry practice.

Conclusion

NACD appreciates FDA's efforts to provide guidance for complying with the Preventive Controls for Human food rule. We believe the recommendations outlined above would significantly improve industry compliance.

Thank you for the opportunity to comment on the guidance. If you have questions or need additional information, please do not hesitate to contact me.

Sincerely,



Jennifer C. Gibson
Vice President, Regulatory Affairs