May 18, 2023

Dr. Judy McMeekin
Associate Commissioner for Regulatory Affairs
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, Maryland 20993

Dear Dr. McMeekin:

Thank you for your leadership and collaborative efforts to lessen the impact of the pandemic on the regulated industry during particularly challenging times. We are specifically grateful for the manner in which the FDA's Office of Regulatory Affairs managed industry oversight during the pandemic to prevent the spread of COVID-19 by first, limiting inspections to for-cause, and later, by preannouncing routine inspections.

As you are aware, the *Food Safety Modernization Act* (FSMA) creates prevention-oriented standards through rulemaking, requiring, in part, farms and food manufacturers to identify hazards that are reasonably likely to occur and develop food safety plans that include controls for such hazards. In addition, covered entities are required to routinely perform monitoring and verification activities to assure controls are implemented appropriately and working as intended. If preventive controls are not implemented or working as intended, covered entities are required to swiftly remove contaminated product from the market, perform root cause analyses, identify contributing factors, and implement appropriate corrective actions to prevent recurrence. In addition, FSMA requires covered entities to maintain and make available to FDA officials a variety of records documenting a history of the robustness and effectiveness of the entity's food safety plan, unlike the snapshot in time that an onsite walk-through inspection provides. When conducting "full scope" preventive controls inspections, FDA consumer safety officers review these documents and records, in addition to observing grower or food manufacturing operations, and taking samples, when deemed appropriate; therefore, the need for unannounced "full scope" preventive control inspections is now significantly less important than prior to FSMA implementation.

With this in mind and as we move into a post-pandemic world, the undersigned signatories to this letter are requesting that FDA consider continuing the preannouncement of routine "full scope" preventive control inspections. We believe this would provide efficiencies that benefit both FDA and the regulated industry while assuring sufficient oversight of food safety. Companies want to make the right staff available to FDA during inspections, which cannot always be achieved when inspection teams arrive unannounced. For full scope preventive control inspections, FDA needs to review documents and records during inspections, which must be gathered and collated after the inspection team arrives when inspections are not preannounced, extending the length of the inspection by several hours or even days. It is also important to recognize that firms are inspected by State and, in some cases, other federal government agencies (e.g., USDA's food safety and inspection service and branches of the armed forces) and conduct their own internal audits and/or hire third parties to perform audits during any given year. When multiple audit/inspection teams are onsite at the same time, delays can occur as farm or facility staff juggle multiple requests for information at the same time; preannouncement of routine FDA preventive control inspections would help companies prevent

such situations and potential delays in collecting and collating documents and records for review. Additionally, continuing to preannounce such domestic food inspections would create parity with routine international food inspections, which are preannounced. In summary, for routine “full scope” preventive control inspections, we believe that FDA should continue to provide regulated entities up to five (5) working days advance notice of an inspection as the new normal post pandemic as has been done during the pandemic.

Industry welcomes and relies on FDA inspections as one of several tools to verify that food safety systems are robust and in compliance with regulatory requirements. The signatories to this letter want to emphasize that we are not asking FDA to limit the number of inspections it conducts or preannounce for-cause inspections, but instead to continue to preannounce routine, “full scope” preventive controls inspections. We appreciate your consideration of this request.

If you have any questions, please contact the co-chairs of the Food and Beverage Issue Alliance, Regulatory Affairs Working Group: Emily Moyer, emoyer@freshproduce.com and Rasma Zvaners, rzvaners@americanbakers.org.

Sincerely,

American Bakers Association

American Spice Trade Association

The Association for Dressings & Sauces

Consumer Brands Association

Institute of Shortening and Edible Oils

International Fresh Produce Association

Juice Products Association

National Association of Chemical Distributors

National Confectioners Association

National Seasoning Manufacturers Association

North American Millers' Association

Refrigerated Foods Association

Cc Dr. Steven Solomon, Director, Center for Veterinary Medicine

Michael Rogers, Assistant Commissioner, Human and Animal Food Operations