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

Office of Information and Regulatory Affairs
Office of Management and Budget
Washington, DC 20503

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

To Whom it May Concern:

SNAC International is writing to comment on the Food and Drug Administration's (FDA's) proposed rule "Requirements for Additional Traceability Records for Certain Foods" under the FDA Food Safety Modernization Act (FSMA). SNAC International (formerly the Snack Food Association) is the international trade association of the snack food industry representing snack manufacturers, marketers and suppliers. Founded in 1937, SNAC International represents over 400 companies worldwide including but not limited to, manufacturers of potato chips, tortilla chips, cereal snacks, pretzels, popcorn, kettle corn, cheese snacks, snack crackers, meat snacks, pork rinds, snack nuts, party mix, corn snacks, pellet snacks, fruit snacks, snack bars, granola, snack cakes, cookies, and various other snacks.

SNAC International supports FDA fulfilling its mandate under FSMA Section 204 and establishing a recordkeeping system to facilitate the tracing of high-risk foods. We appreciate the public health and safety benefits that can be realized when FDA can perform faster tracing activities during foodborne illness outbreaks and recalls, and we are committed to working with FDA to achieve these goals.

Although we support the Proposed Rule's objectives, we are concerned the recordkeeping framework it would create is too rigid and complex for entities to be able to comply. We support creating a simpler, more flexible rule that would facilitate compliance by covered entities and increase voluntary adoption by non-covered entities.

Our comments on the Proposed Rule focus on the following key issues:

- Ensuring the scope of the Proposed Rule is appropriately focused on high-risk foods for which additional recordkeeping is needed to enhance traceability;
- Reducing the complexity of the proposed recordkeeping system by modifying the Key Data Elements (KDEs) that would be maintained at Critical Tracking Events (CTEs);
- Providing more flexibility in the proposed requirement to produce records to FDA in a sortable, electronic spreadsheet; and
- Ensuring there is enough time for entities to comply with the rule.

Our more detailed comments follow.

Scope of the Proposed Rule

We encourage FDA to ensure the scope of the Proposed Rule is focused on high-risk foods.

- Scope of the FTL: The Proposed Rule would apply to both foods on the Food Traceability List (FTL) as well as foods containing a listed food as an ingredient. However, including foods containing a listed food as an ingredient means that commodities FDA assessed and determined are not high-risk foods will fall within the scope of the Proposed Rule solely because they contain a listed food as an ingredient. For instance, FDA evaluated cookies, crackers, and granola bars, and did not identify them as high-risk, but they would be within the scope of the rule if they contain peanut butter. Including these types of processed foods also is not aligned with FDA's mandate under Section 204, which directs FDA to establish new recordkeeping requirements for foods for which additional records would provide a public health benefit. Food manufacturers already maintain records verifying suppliers and documenting the application of a kill step, as well as records regarding the immediate previous source and immediate subsequent recipient of a food. Consequently, they already maintain records needed for traceability. We therefore suggest that the Proposed Rule apply only to listed foods and that those foods listed should be the ones for which additional records are necessary because they are not addressed by other recordkeeping requirements.

- Nut Butters: We suggest FDA reconsider including nut butters on the FTL. We do not consider nut butters to be high-risk food, because the potential for nut butters to become contaminated with pathogens is a matter of the cleanliness of the production area, a potential risk that exists for virtually all foods. Moreover, since the high-profile outbreaks associated with nut butters occurred, FDA has implemented the Preventive Controls rule and industry has proactively developed its own best practices for food safety, which address the risk of contamination after the roasting of nuts. Nut butters have had a strong safety record for longer than a decade, and consumers should have confidence in their safety, especially when they are incorporated into snack foods such as cookies and crackers. If retains nut butters on the FTL, it should clarify the scope of this product category.

- Updates to the FTL: FDA should detail the procedures it will follow when it adds or removes a food from the FTL, including notice and comment rulemaking procedures and a set timeframe

for reassessment of the FTL. FDA also should create a process for stakeholders to petition the agency to add or remove a food from the FTL.

- Clarity of FTL: FDA should clarify further the foods that are included in the listed commodities. It also would be helpful for FDA to identify the foods in non-listed commodities.

- Complete Exemption for Foods Undergoing a Kill Step: FDA should provide a complete exemption for foods that undergo a kill step. The kill step will help eliminate any public health risk, and pertinent records already are maintained under the Preventive Controls rule and Subpart J.

- Foods for R&D: FDA should exempt foods for research and development (R&D), and the scope of the exemption should mirror the R&D exemption in the Foreign Supplier Verification Programs rule and under Subpart G of the Preventive Controls rule.

CTEs, KDEs, Traceability Program Records, and Record Production

We suggest the following changes to FDA's proposed recordkeeping scheme to help simplify the rule and reduce the burden on covered entities.

- Intracompany Shipments: FDA should clarify that intracompany shipments do not constitute "shipping" or "receiving" activities that trigger recordkeeping requirements. Records are not needed for intracompany shipments because relevant information already is retained under the Preventive Controls rule and Subpart J, and this clarification will substantially reduce entities' recordkeeping burden under the rule.

- Continual Processing: FDA should clarify that foods that undergo continual processing to make a new commodity do not require creation or transformation records at each step in the process. For instance, a company that produces its own peanut butter for inclusion in various snack products should not be required to produce records for the creation of the peanut butter because separate records will exist for the resulting snack products.

- Volume of KDEs: FDA should reduce the KDEs required at each CTE by focusing only on those KDEs that are necessary to for traceability. We suggest that the following KDEs could be eliminated: the entry number for imported products; the category code/term, category description, and brand name within product description; the physical location name within the location description; location identifiers; the point of contact for lot code generators; date and time for a CTE; location information for where the CTE occurred; and the name of the transporter. Eliminating this duplicative or unnecessary information will reduce the burden of the rule's recordkeeping requirements, particularly the requirement to produce this information to FDA in an electronic, sortable spreadsheet within 24 hours. SNAC International maintains that the traceability lot code and product description are the key pieces of information needed for traceability.

- Traceability Program Records: FDA should eliminate the requirement that entities maintain a list of foods on the FTL that they ship. Creating and updating this list would be a time-intensive

process that would not assist in a traceback investigation. We also request that FDA clarify that the requirement for reference records to be linked to certain tracing events does not mean that records must be digitally or electronically linked; it will be sufficient for an entity to use information in one record to identify additional relevant records.

- Electronic, Sortable Spreadsheet: In all but very limited circumstances when the request is limited to only a few lot codes, entities will not be able to produce an electronic, sortable spreadsheet to FDA in 24 hours. We encourage FDA to revise this requirement to provide more flexibility and extend the deadline depending on factors such as the number of lot codes and days of production involved, the extent to which the product has been distributed, the nature of the issue necessitating the request, and the entity's recordkeeping systems.

  We also recommend that the circumstances when FDA may request an electronic, sortable spreadsheet be limited as follows: only for foodborne illness outbreaks or to address credible threats of serious adverse health consequences or death (other than allergen issues) and only when requested by the CFSAN Director in conjunction with the Director of the Coordinated Outbreak Response and Evaluation Network (CORE).

Compliance, Enforcement, and Cost to Industry

Implementing the Proposed Rule will be incredibly challenging to industry, requiring substantial time and resources. We suggest FDA consider the following factors when developing its approach to compliance and enforcement.

- Compliance Date: We strongly urge FDA to provide more than the proposed 2 years to comply with the rule. We think 4 years would be a more appropriate compliance period, given the time needed to understand the final rule, establish a new recordkeeping system, deploy new technologies, and train employees.

- Compliance Based on Suppliers: Entities' ability to comply with the rule will be contingent upon their receiving required information from their suppliers. We urge FDA to clarify that entities that do not receive the required information from their suppliers may continue to use the food without being in violation of the regulations based solely on the supplier's failure to provide requested information.

- International Community: It will be imperative that our international suppliers understand and come into compliance with the rule. We request that FDA explain its plan for producing guidance and training materials in multiple languages and providing education to foreign suppliers.

- FDA's Estimated Costs: FDA's time and cost estimates in the Paperwork Reduction Act (PRA) and Preliminary Regulatory Impact Analysis (PRIA) are far too conservative. First, FDA should take into account that the rule will impose costs on essentially all of industry, and not just entities that manufacture, process, pack, or hold a listed food or food containing a listed food as an ingredient. We anticipate entities will not bifurcate their recordkeeping systems for listed and non-listed foods, and instead will require the same information for all foods they handle.

Accordingly, the rule will have secondary effects throughout industry that must be considered. Second, FDA's estimates for discrete tasks are far too low. A primary example is FDA's estimate that entities other than distribution centers and warehouses will need to maintain records for only 1,000 FTL lots, when the number of lots per entity will be far, far higher. FDA's estimates for the time and cost to read and understand the rule, purchase and deploy capital investments, establish recordkeeping systems, maintain records, train employees, and respond to an update to the FTL are also too low.

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We support the creation of a more robust recordkeeping system to enhance traceability, but the Proposed Rule needs to be simplified significantly and provide greater flexibility to account for industry practices. We expect that FDA will need to make substantial revisions to its proposals in response to industry comments, and that the revised regulation will differ substantially from the Proposed Rule. Accordingly, we request that FDA issue the revised regulation as a supplemental proposed rule, to allow stakeholders an opportunity to provide comment on the revised regulation. This process also will allow FDA greater time to engage with stakeholders and better understand how the recordkeeping system can fit within existing industry practices. We would welcome the opportunity to collaborate further with FDA on this process.

SNAC International appreciates the opportunity to provide comments to FDA on the Proposed Rule. We would be pleased to answer any questions FDA has regarding these comments.

Sincerely,

Elizabeth Avery
President and CEO
SNAC International