



Food & Beverage

ISSUE ALLIANCE

November 2, 2020

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**

Dear Sir or Madam,

We are writing to request that the U.S. Food and Drug Administration (“FDA”) extend the deadline for comments on the Proposed Rule on Requirements for Additional Traceability Records for Certain Foods (hereinafter, “Proposed Rule”), including the deadline for comments on the collection of information under the Paperwork Reduction Act of 1995 (“PWA”), until March 24, 2021. Under different circumstances, the 120-day comment window FDA proposed would likely provide sufficient time for affected parties to digest the rule, assess its impact on their operations, and provide thoughtful feedback. However, the complexity of the rule, the numerous holidays between now and the comment deadline, and the continued stress of both the holidays and the COVID pandemic on production and distribution, make the current deadline difficult for our respective trade associations to coordinate with our members in time to provide meaningful feedback.

Digesting the Proposed Rule is more challenging than for some other proposals because of the rule’s complexity. It includes numerous different complete and partial exemptions, introduces significant new terminology, and would substantially affect the information sharing among different entities within the food supply chain. Our members are finding that even for a single food they manufacture/produce/receive, the analysis of whether and how the rule would apply requires consideration of numerous different factors, such as whether the originator for the food is exempt from the rule; if produce is involved, whether it will receive commercial processing and whether a disclosure is provided under the Produce Safety Rule; whether a particular production process constitutes transformation; and whether a kill step is applied, among numerous other considerations. The rule’s scope alone necessitates a long comment period to thoroughly digest its many components and develop thoughtful comments.

In addition, the numerous public holidays between now and the comment deadline will slow down the comment development process. Presently, the deadline for comments on the Proposed Rule, other than collection of information under the PWA, is January 21, 2021. Between now and January 21, many businesses will be closed, or employees will be on leave for the days surrounding election day, Thanksgiving, Christmas, New Year's Day, Martin Luther King Jr. Day, and inauguration day.

To complicate the scheduling logistics further, FDA's public meetings on the proposed rule will not begin until November 6 or conclude until December 2. FDA's public meetings are an important forum for affected parties to better understand proposed rules and the agency's interpretation of them, and it will be important for our members to take these public meetings into account when considering their feedback on the Proposed Rule. The timing of the public meetings consequently further compresses the already challenging comment deadline.

We also note that the fourth quarter of the year is a challenging time of year for the food industry as our members are focused on meeting the increased production, distribution, and sale demands of the holidays. This year, we also are navigating the challenges of the COVID-19 pandemic, which necessitates increased attention to worker safety, supply chain logistics, and more.

As such, we ask that FDA extend the deadline for comments on the proposed rule by sixty (60) days. We also urge FDA to align the comment deadline for information collection under the PWA with the comment deadline for the remainder of the rule. Presently, FDA would require affected parties to submit comments on the information collection under the rule by November 23, 2020, approximately two months before they submit comments on the remainder of the rule and before the agency's public meetings on the proposal have concluded. Firms cannot provide meaningful feedback on the information collection burden of the rule without first having given the entire proposal thorough consideration. For this reason, the deadline for these two components should be the same.

In sum, to allow affected parties sufficient time to understand the Proposed Rule, assess how it would work in practice for their operations, and provide feedback to the agency, we respectfully request that the agency extend the comment deadline for the Proposed Rule until March 24, 2021.

We would be pleased to address any questions you may have.

Sincerely,
American Bakers Association
American Frozen Foods Institute
American Herbal Products Association
American Spice Trade Association
Consumer Brands Association
FMI – The Food Industry Association
Global Cold Chain Alliance
Independent Bakers Association
International Dairy Foods Association
International Food Service Distributors Association
Juice Products Association

National Confectioners Association
National Fisheries Institute
National Grocers Association
Peanut and Tree Nut Processors Association
Refrigerated Foods Association
SNAC International
The Association for Dressings and Sauces
The Vinegar Institute
United Egg Producers