Food & Beverage ISSUE ALLIANCE

Submitted electronically via regulations.gov

July 02, 2020

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

Re: Lab Accreditation for Analyses of Foods; Proposed Rule; Docket No. FDA-2019-N-3325; 84 Fed. Reg. 59452 (Nov. 4, 2019)

Dear Sir or Madam:

The undersigned organizations are members of the Food and Beverage Issue Alliance (FBIA), a coalition of food and beverage trade associations. We appreciate the opportunity to provide comments on the U.S. Food and Drug Administration (FDA) proposed rule entitled *Laboratory Accreditation for Analyses of Foods*, 84 Fed. Reg. 59452 (November 4, 2019).

The safety of consumers is a priority shared by both the food industry and the FDA. Our organizations are strong supporters of the FDA and the FDA Food Safety Modernization Act (FSMA) and appreciate the intent of the proposed rule to ensure reliable and accurate lab testing results. Although there are several aspects of the proposed rule we support, we do not support the provision regarding food testing orders (FTOs). As such, we recommend that FDA remove this provision from the final rule. If not, then due to the number of legal issues and open questions concerning FTOs, we believe FDA should issue a supplemental proposed rule to provide a meaningful opportunity for public comment on this significant new regulatory tool.

Industry Supports the Following Aspects of FDA's Proposed Rule

The industry appreciates FDA's inclusion of and supports maintaining the following aspects of the proposed rule in the final rule:

- Excluding routine testing, i.e., verification testing conducted under a Food Safety Plan, or associated with Foreign Supplier Verification Programs (FSVP), from the scope of the rule;

- Phasing in the effective dates to account for the time needed for accreditation body recognition, laboratory accreditation and the establishment of adequate laboratory capacity;
- Accrediting laboratories on a method-by-method basis;
- Permitting the accreditation of in-house laboratories;
- Excluding the accreditation of samplers;
- Permitting sampling and testing to be conducted prior to entry of imported food, under certain circumstances; and
- Including the conditions established as to when imported foods would need to be tested.

Food Testing Orders (FTOs)

As noted above, one aspect of the proposed rule that the undersigned associations do not support is the establishment of FTOs. FDA's proposed rule establishes what equates to a new investigatory and enforcement tool, FTOs. The concept of FTOs is not mandated or mentioned anywhere in FSMA, and would require that certain food testing be performed by laboratories accredited by an FDA-recognized accreditation body and the results of the testing performed sent directly to FDA.

Lack of Statutory Authority to Develop FTOs

Section 202 of FSMA requires FDA to establish a program for the testing of food by accredited laboratories, whereby FDA-recognized accreditation bodies would accredit laboratories that must be used to perform certain food testing. These laboratories must provide testing results directly to FDA. FSMA does not, however, include or mention the concept of FTOs; there is no legal requirement under FSMA to develop FTOs under Section 202 or elsewhere. Congress did not provide FDA with the authority to create what could be construed as either a new enforcement tool or investigative tool. Therefore, FDA's inclusion of FTOs is beyond the scope of the statutory mandate in FSMA. Because of this and other legal weaknesses with FDA's proposal with respect to FTOs, we recommend that FDA remove this provision from the final rule.

If FDA determines it has the authority to issue FTOs through FSMA Section 202, we urge FDA to deploy this tool judiciously and to establish specific guardrails for use. This is critical as a legal matter, as not to undermine the robust environmental monitoring and product testing programs that industry has implemented under FSMA, and the resulting public health benefits of such programs. In particular, we are concerned that because a FTO could be issued based on a company's own testing results, FTOs as proposed, could discourage robust routine testing programs.

Clarifications Needed Regarding FTOs

As proposed by FDA, the scope of FTOs is very broad and there is limited discussion in the preamble about why they are needed and how they relate to the purpose of

ensuring reliable and accurate test results. There also are a number of procedural and practical considerations regarding FTOs that lack clarity and that are not sufficiently addressed in the proposed rule. This includes such things as: who within FDA would issue these orders, under what circumstances, based on what facts and conditions, and when and how would FTOs be lifted. It is also unclear as to who would receive a FTO, how a FTO would be delivered, whether the owner or consignee can simultaneously receive the test results that are provided by the laboratory performing the testing under the order to FDA, and whether FTOs will be made public. For example:

- The proposed rule simply states that FDA would issue a FTO. The final rule needs to clearly state who in the FDA has the authority to issue a FTO. We do not believe this authority should be delegated beyond the FDA Commissioner. This is consistent with mandatory recall and suspension of facility registration orders, both of which must be issued by the Commissioner.
- The proposed rule is also considerably vague regarding the circumstances that could lead to the issuance of a FTO. FTOs should be limited to circumstances where there is an established, identified, or suspected food safety problem that presents a reasonable probability of serious adverse health consequences or death to humans or animals (SAHCODHA) and a substantiated concern that the laboratory being used by the owner or consignee is inadequate, such that the testing needed "to address" the problem and determine whether it has been resolved needs to be performed by an accredited lab with the results sent directly to FDA. We do not believe that the results of a facility's routine testing programs, if reacted to appropriately, should trigger a FTO.
- The opportunity for a hearing on a FTO should be guaranteed, and the window for making a hearing request should be 10 business days.
- FTOs should be terminated as soon as the identified food safety problem is resolved, and that there should be clear, specific procedures for terminating a FTO.
- A FTO should be limited to product testing only and should not include environmental testing.

FDA Should Explicitly State that Routine Testing Results Would Typically Not Trigger a FTO or Testing Under FDA's Program Established under FSMA 202

The undersigned organizations believe that FDA should repeat its statements in the final rule that routine product and environmental test results obtained by facilities as part of their food safety programs to verify the effectiveness of controls are not required to be conducted at laboratories accredited under FDA's laboratory accreditation program. Further, the final rule should clarify that follow-up sampling and testing conducted in response to pathogen/indicator organism positives found during routine environmental monitoring should also be excluded from coverage under this rule.

Conclusion

In conclusion, we appreciate the opportunity to provide comments to the FDA on its proposed Laboratory Accreditation for Food Analyses proposed rule. We understand the intent and importance of this specific rulemaking and support the FDA's effort to move forward with finalizing this rule. With that said, we have raised significant concerns with the proposal with regards to FTOs that should be addressed before moving forward with a final rule. We are concerned that industry was not engaged in a conversation regarding FTOs prior to the introduction of this new regulatory tool in an FDA proposed rule and that FDA introduced FTOs without a specific Congressional or administrative mandate to do so. We stand ready to discuss the issues raised through our comments further with the agency to arrive at a solution that works for everyone. We are hopeful that the final rule will address our collective concerns.

Sincerely,

American Bakers Association

American Frozen Food Institute

American Spice Trade Association

Consumer Brands Association

Independent Bakers Association

Institute of Shortening and Edible Oils

International Food Additives Council

National Confectioners Association

North America Millers' Association

United Fresh Produce Association