North American Millers' Association
1400 Crystal Drive • Suite 650 • Arlington, VA 22202
202-484-2200 • Fax 202-488-7416

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Submitted electronically via regulations.gov

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

Re: Proposed Rule: Laboratory Accreditation for Analyses of Foods; Docket No. FDA-2019-N-3325 (November 4, 2019)

Dear Sir or Madam:

The North American Millers' Association (NAMA) appreciates the opportunity to submit comments in response to the Food and Drug Administration's (FDA) Proposed Rule titled *Laboratory Accreditation for Analyses of Foods*. NAMA is the trade association representing the wheat, corn, oat, and rye milling industry. NAMA's member companies operate over 160 mills in 38 states, as well as Canada and Puerto Rico. NAMA members take raw grain and, through grinding and crushing, create flour and other products that are used to make such favorite foods as bread, pasta, cookies, cakes, and snack foods. NAMA member companies represent more than 90 percent of total industry production capacity.

NAMA appreciates FDA's efforts to implement Section 202 of the FDA Food Safety Modernization Act (FSMA) and establish a program for the testing of food by accredited laboratories. We echo the comments being submitted by other food industry trade associations, including the Food and Beverage Issues Alliance. We write separately to reinforce our concerns with the Food Testing Order (FTO) provisions of the proposed rule. In particular, our comments discuss the importance of placing more limitations on the definition of "identified or suspected food safety problem related to an article of food" and explain why pathogens in a raw agricultural commodity, like flour, should not be considered an "identified or suspected food safety problem" under this rule.

1. Food Testing Orders Should Not Be Included in the Final Rule

NAMA is concerned that FTOs would be a significant new investigative and enforcement tool, but that FDA has neither provided an adequate justification for their need nor sufficient guardrails for

their use. The preamble to the proposed rule does not explain a problem with the current reliability of laboratory test results that would justify the need for this new tool; nor does it explain why this tool is needed when FDA already has the authority to engage in sampling and testing at FDA labs. Likewise, FDA fails to address numerous significant issues such as who can issue FTOs, what situations would trigger their issuance, how long they could be in place, and how they can be lifted. Most importantly, neither FSMA nor the Federal Food, Drug, and Cosmetic Act (FFDCA) explicitly address the concept of FTOs, and neither law provides FDA with implied authority to establish FTOs. Therefore, FDA lacks the statutory authority to adopt this tool.

Accordingly, NAMA urges FDA to omit FTOs from the final rule. The agency can still fulfill its rulemaking mandate under FSMA Section 202 without adoption of FTOs, since this concept is not included in the law. Omitting FTOs from the final rule will also help the agency meet the February 2022 deadline for the final rule that it agreed to under a Consent Decree. However, to the extent that FDA elects to move forward with FTOs and believes it has the legal and policy support necessary for their establishment, the agency should issue a supplemental proposed rule to provide industry with the opportunity to comment on the many significant issues that were not addressed in this proposal.

2. Pathogens in an NRTE Food Should Not Be Considered an Identified or Suspected Food Safety Problem

The codified language of the proposed rule places few guardrails on when an FTO could be issued. It states in proposed § 1.1108(a): "FDA may require the owner or consignee of an article of food to conduct food testing, or to have food testing conducted on their behalf, under this subpart to address an identified or suspected food safety problem related to the article of food." The phrase "identified or suspected food safety problem related to the article of food" is not defined in the proposed rule.

In the preamble, FDA offers limited examples of what would constitute an identified or suspected food safety problem that could trigger issuance of an FTO. FDA tentatively concludes that such circumstances could include "the presence of *Listeria monocytogenes* on a food-contact surface; the presence of multiple positives for *Listeria* spp. on a food-contact surface; and potential contamination events."[1] The agency does not explain what it means by "potential contamination events."

If FDA moves forward with establishing FTOs, the agency will need to define these significant phrases to provide further clarity and guardrails on when FTOs can be issued. In doing so, FDA should expressly recognize that pathogens in a not-ready-to-eat (NRTE) food are not an "identified or suspected food safety problem." In particular, milled grains are a raw agricultural commodity and are not subject to a kill step during the milling process. The kill step for milled grains occur when milled grains are used as an ingredient, either commercially or by consumers. It would not be appropriate for FDA to consider pathogens in raw milled grains to be an "identified or suspected

[1] 84 Fed. Reg. 59452, 59462 (Nov. 4., 2019).

food safety problem" because the food is not intended to be consumed raw. Quite simply, pathogens in raw milled grains are not a "food safety problem."

We are concerned that FTOs could be used as a basis to require the milling industry to sample food manufacturing environments[2] or products through use of accredited laboratories. This would not be warranted because milled grains are a NRTE food. We also submit that such testing also is not appropriate or necessary in any circumstances, regardless of whether use of an accredited laboratory is required.

NAMA has been working closely with FDA to address food safety considerations unique to flour and we look forward to the opportunity to continue to do so. Including flour within the scope of foods with an "identified or suspected food safety problem" that need testing to be conducted by accredited laboratories, however, would not be a helpful path forward because there is no benefit to come from such testing given the lack of mitigation steps to address any positives. To the extent that FDA feels a need to collect more data regarding the presence of pathogens in flour, we would welcome the opportunity to work with the agency to develop an appropriate sampling plan that would have minimal disruptions for manufacturing and food in commerce.

* * *

NAMA strongly believes in the importance of producing safe, milled grain products that can be used by our customers to make a variety of wholesome foods that consumers know and love. We appreciate the opportunity to submit these comments. Should the agency have any further questions regarding our comments or if any additional information may be helpful, feel free to contact Dale Nellor, NAMA's Vice President of Government and Technical Affairs at 202-484-2185 or dnellor@namamillers.org.

Sincerely,

James McCarthy
President and CEO

[2] Relatedly, as discussed in more detail in other industry trade association comments, NAMA believes that the term "food" in FSMA Section 202 should be limited to food product samples and should not include environmental samples from a food manufacturing facility.