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

July 26, 2017

Electronic Submission

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

Re: Docket No. FDA-2008-D-0096; *Draft Guidance for Industry: Control of* Listeria monocytogenes *in Ready-To-Eat Foods*; 82 Fed. Reg. 4803 (Jan. 17, 2017)

Dear Sir or Madam:

The North American Millers' Association (NAMA) would like to take this opportunity to submit comments in response to FDA's "*Draft Guidance for Industry: Control of* Listeria monocytogenes *in Ready-To-Eat Foods*," published in January 2017. 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.

Our comments emphasize the following points regarding the Draft Guidance:

1. The Guidance would benefit from additional language to reinforce its scope and intended audience: (1) that it applies only to read-to-eat (RTE) foods and is not pertinent to not ready-to-eat (NTRE) foods; and (2) that its focus is those RTE foods where *Listeria monocytogenes* is a hazard requiring control measures to prevent the food from becoming adulterated.
2. FDA should more clearly explain when it considers a food to be RTE and NRTE.
3. Milled grain products should be classified as NRTE.
4. The scientific evidence does not support identifying *L. monocytogenes* as a "hazard requiring a preventive control" in milled grain products.

5. Supplier control and verification of supplier control are only appropriate when *Listeria monocytogenes* is a hazard in the raw material or ingredient requiring control and the supplier can and is controlling for *L. monocytogenes*.

First, we support focusing the scope of the Guidance on controlling *Listeria* in RTE foods where *Listeria monocytogenes* is a hazard requiring control, as opposed to all foods, including NRTE foods. When good manufacturing practices (GMPs) are in place, there is no benefit from focusing on *Listeria* control in NRTE operations, such as milling flour. There is inherently no kill step in an NRTE operation, so it does not make sense to control or test for pathogens in the environment. Likewise, recipients of these ingredients should not be testing the product for pathogens such as *L. monocytogenes*.

We believe that the Guidance would benefit from revisions to more clearly explain that the Guidance is not intended for NRTE foods. This will help ensure that companies focus their resources on *Listeria* control only when doing so is appropriate for their product, process, facility, and intended use. We recognize that the title of the Draft Guidance specifies that it is for RTE foods, but a short introductory section explaining this point also would be helpful.

Relatedly, although *Listeria* control is appropriate for many RTE foods that are exposed to the environment prior to packaging and will not receive a treatment or otherwise include a control measure to significantly minimize *L. monocytogenes*, there are many RTE foods, for which *Listeria monocytogenes* is not a hazard requiring control (e.g., nuts, dried fruits, crackers, cereals, and cookies) to prevent the product from becoming adulterated. FDA should revise the Guidance to clarify that is targeted to facilities producing RTE foods where, based on scientific evidence, *L. monocytogenes* is a hazard requiring control to prevent product from becoming adulterated. Both industry and FDA resources should be focused on controlling *Listeria monocytogenes* in foods where the scientific evidence shows there has been a history of outbreaks or incidences of listeriosis and thus *Listeria monocytogenes* is a hazard requiring control.

We are concerned that some companies may misinterpret the Guidance as applying to their operations, even when *Listeria* is a not a significant risk. This could misdirect attention away from hazards that are a greater risk in their facility. In addition, as many of the agency's recommendations in the Guidance are relevant to wet processing or cleaning activities, FDA should explicitly state in the Guidance that it is targeted to wet operations and that it does not recommend facilities with dry processing environments undertake wet cleaning procedures.

Second, industry would benefit from additional insight on the agency's thinking regarding the delineation between RTE and NRTE foods. We understand that FDA has plans to issue a companion guidance document on this issue and encourage the agency to expedite issuance of that document. This additional guidance regarding how to determine which foods are RTE will help ensure that the agency's *Listeria* control recommendations are not misapplied to NRTE foods.

Third, milled grain products should be classified as NRTE (and therefore outside of the scope of this Guidance). In the definitions established in 21 CFR § 117.3 (and incorporated into the *Listeria* Guidance), a RTE food is defined as "any food that is normally eaten in its raw state or any other food, including a processed food, for which it is reasonably foreseeable that the food will be eaten without further processing that would significantly minimize biological hazards." There is no definition established for NRTE, but presumably NRTE foods are those that do not meet the RTE definition.

It is well established that milled grain products cannot be considered RTE in the absence of further processing to reduce or eliminate microbial pathogens and that further processing, such as cooking or baking, is needed before consumption. When these products leave the mill, they have not undergone any lethality treatment or kill-step for microbial pathogens. Therefore, there is no concern about these products being subject to re-contamination from environmental pathogens within the milling operation. Milled products are fundamentally in their raw or near-raw form, and therefore should be treated the same way as raw agricultural commodities. That said, the industry still believes in the importance of following proper GMPs, as well as maintaining proper dry sanitation programs and other food safety practices within our milling facilities to ensure products are processed under sanitary conditions.

Fourth, we want to highlight that the scientific evidence does not support identifying *L. monocytogenes* as a "hazard requiring a preventive control" in milled grain products. As we discussed in our comments regarding FDA's *Draft Guidance for Industry: Hazard Analysis and Risk-Based Preventive Controls for Human Food*,[1] Appendix 1 to the *Hazard Analysis* draft guidance identifies *L. monocytogenes* as a potential hazard for milled grain products such as flour, but the agency has not provided any citations supporting this conclusion. Our earlier comments explained that a Galeas 2014 report[2] presenting data regarding the microbiology of wheat milled products does not reference *L. monocytogenes* and there are very few, if any, research studies that examine the presence of *L. monocytogenes* in raw grain and milled grain products. We believe this is because *L. monocytogenes* is not a hazard requiring control in milled grain products and we request FDA provide the basis for listing L. *monocytogenes* as a potential hazard in milled grains. Additionally, we reiterate our earlier request for FDA, in consultation with industry, government, and academia, to conduct an additional review regarding whether there is adequate scientific support to identify *L. monocytogenes* as a biological hazard for milled flour products.

Finally, in keeping with the general scope of the Guidance, FDA should revise Section VIII regarding controls on raw material and other ingredients to emphasize that (1) an assessment of whether a raw material has the potential to be contaminated with *L. monocytogenes* should be based on science; (2) even if an ingredient has the potential to be contaminated with *L. monocytogenes*, based on a risk assessment, *L. monocytogenes* may not be a hazard requiring control; and (3) supplier control and verification of supplier control are only appropriate when

[1] Docket No. FDA-2016-D-2343-0017 (February 21, 2017)

[2] Galeas, Luis E. Sabillon. 2014. Understanding the factors affecting microbiology of wheat milled products from wheat fields to milling operation. Dissertations & Theses in Food Science and Technology. Paper 49.

the supplier can and is controlling for *L. monocytogenes*. For example, because there is no practical kill step in the milling process, inbound pathogen testing does not ensure the safety of raw materials that have not been subjected to a microbiological kill step. Testing inbound raw cereal grain products at a RTE facility are unnecessary and will only lead to undue burden on the industry. We agree that manufacturers of RTE foods where *L. monocytogenes* is a hazard requiring control should consider the risk posed by the ingredients used in their food, but that assessment should be based on science and any controls should be appropriately tailored to the nature of the raw material or ingredient.

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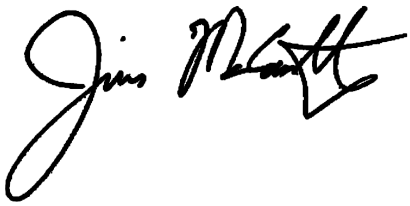
NAMA strongly believes in the importance of producing safe, milled grain products that can be used by our customers to make a variety of wholesome foods that consumers know, and love. We appreciate the opportunity to submit these comments. Should the agency have any further questions regarding our comments or if any additional information may be helpful, feel free to contact us at 202-484-2200 or jmccarthy@namamillers.org.

Sincerely,



Jim McCarthy
President and CEO