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February 21, 2017

Electronic Submission

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

Re: Draft Guidance for Industry: Hazard Analysis and Risk-Based Preventive Controls for Human Food, Docket No. FDA-2016-D-2343

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North American Millers' Association (NAMA) would like to take this opportunity to submit comments in response to FDA's "Draft Guidance for Industry: Hazard Analysis and Risk-Based Preventive Controls for Human Food" published in August 2016. 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.

As the active link between the growers and bakers in the grain supply chain, NAMA members are committed to maintaining food safety in our facilities and milled products. We take our responsibility to ensure that the wholesome products produced in our mills are not compromised and understand the importance of anticipating and preventing unintentional contamination before it occurs. Described below are standards developed by the federal government, which are being implemented by NAMA members to maintain product integrity and to ensure that potential food safety problems are prevented or detected, and resolved.

U.S. Grain Standards

The United States Grain Standards Act which is administered by the USDA's Grain Inspection, Packers and Stockyards Administration (GIPSA) provides criteria for determining the kind, class, and condition of grain and oilseeds including, barley, canola, corn, flaxseed, mixed grain, oats, rye, sorghum, soybeans, sunflower seed, triticale, and wheat.¹ The standards define quality and grading factors, and set grade limits based on those factor determinations.

¹ USDA GIPSA. September 2007. Official United States Standards for Grain, Subpart A: General Provisions, 810.101. Available at: https://www.gipsa.usda.gov/fgis/standards/general_provisions.pdf Accessed 2 February 2017.

Before grain is unloaded at a milling facility, samples are taken to ensure it passes proper inspection. The raw grain is tested for a variety of grade and non-grade factors such as moisture content, test weight, defects, presence of plant diseases, and foreign material. Grain must meet the appropriate grade set by the US Grain Standards and any specific commercial specifications. Mills may use commercial specifications that are even more rigorous than the U.S. Grain Standards when testing for toxins, evidence of insect/rodent exposure, and stress cracks. For example, wheat used in milling is typically #2 grade, or higher. Sorting machines in the cleaning stage of the milling process may be used to detect any signs of insect infestation. The results from these tests then determine how the wheat will be handled and stored.

Hazard Analysis and Risk-Based Preventive Controls (HARPC) plans

Under the Food Safety Modernization Act (FSMA) Hazard Analysis and Risk-Based Preventive Controls for Human Food final rule, non-exempt food facilities subject to FDA registration are required to have a HARPC plan in place.

Using their written HARPC plan, grain millers identify potential chemical, physical, and biological food safety hazards so that key actions can be taken to reduce or eliminate the risk of those hazards. After all potential hazards are analyzed, each mill determines whether the hazard requires a preventive control, or not.

Grain milling facilities have many programs in place to significantly reduce or eliminate various hazards and risks throughout the milling process. Milling prerequisite programs include inspection and testing of raw grain as it arrives at the mill, sanitation programs, pest control programs, current Good Manufacturing Practices (GMPs), traceability and recall programs, shipping and receiving procedures that cover truck and railcar inspections and sealing, chemical control programs, allergen control programs, customer complaint responses, and lab testing procedures. These programs also cover preventative maintenance programs, machinery and equipment programs, supplier programs, as well as grounds and facilities programs.

With the above-described standards and practices in mind, below we offer comments on a few specific items included in ‘Appendix 1: Potential Hazards for Foods and Processes’ of the draft guidance that we believe to be of greatest relevance to our industry.

Biological Hazards Table 1J: Information that you should consider for potential ingredient or other food-related biological hazards for Grains, Beans and Grain Products

In the draft guidance under milled grain products #6, subcategory flour, *B. cereus*, pathogenic *E. coli*, *Salmonella ssp*, and *Listeria monocytogenes (L. monocytogenes)*, are listed as potential biological hazards for flour. It is known from previous studies that a small percentage of *Salmonella* can occur in wheat flour. In a 2006 study, the incidence rate of *Salmonella* in wheat flour was 0.14% with 6 positive samples out of 4,358 total samples collected between 2003-2005.² In the same study, the incidence rate of *Salmonella* in corn and oat milled products was 0% with 0 positive samples out of 1,772 and 714 total samples, respectively.

² Sperber WH. 2007. Role of microbiological guidelines in the production and commercial use of milled cereal grains: a practical approach for the 21st century. *Journal of Food Protection*. 70:1041–53.

Although there are very few research studies that analyze the presence of generic *E. coli* species, and *B. cereus* in wheat flour, a Galeas 2014 report³ presents data that has been collected thus far. According to this report, Berghofer, et. al found that 93% of 81 flour samples analyzed in Australia tested positive for *B. cereus*, although the most frequent count was 0.1 MPN/g.⁴ In a Turkish survey, only 6 out of 142 flour samples contained *B. cereus* at levels of more than 2.0 log CFU/g.⁵ *B. cereus* was not isolated in any of the flour samples analyzed in a 2006 Australian survey⁶ and it is not mentioned in the Sperber et. al study.

The Sperber et. al study also reported mean counts of 0.7 log CFU/g for *E. coli* (petrifilm) in 2,921 samples analyzed, up to a maximum of 3.0 log CFU/g. Berghofer et al. detected *E. coli* in 1 out of 72 flour samples analyzed at the level of 9 MPN/g, while in another Australian survey 2 out of 300 flour samples were positive for *E. coli*.⁷

L. monocytogenes is not referenced in the Galeas report, and there are very few, if any, research studies that examine the presence of *L. monocytogenes* in raw grain and milled grain products. Therefore, it is requested that additional review of both *B. cereus* and *L. monocytogenes* be conducted in consultation with industry, government, and academia prior to these biological pathogens being added to a final guidance document for raw grains, or milled flour products.

Process Hazards Table 3J: Information that you should consider for potential process-related biological, chemical, and physical hazards for Grains, Beans and Grain Products

Under both grains #1, subcategory raw grains, and milled grain products #6, subcategory flour, were identified with risk of being “re-contaminated with environmental pathogens.” According to the Federal Food Drug and Cosmetic Act,⁸ a processed food is defined as “any food other than a raw agricultural commodity that has been subject to processing, such as canning, cooking, freezing, dehydration, or milling.” Although this definition interprets milled grain products to be processed foods, milled grain products are only a step removed from being a raw agricultural commodity. Raw grains are received at the milling facility and then go through the milling process to produce flour, which involves a series of steps including separating, tempering, grinding, and sifting.

In the definitions Established in 21 CFR 117.3, pg 5, a Ready-to-eat (RTE) food is stated to be “any food that is normally eaten in its raw state or any other food, including a processed food,

³ 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.

⁴ Berghofer, L.K., Hocking, A.D., Miskelly, D., and Jansson, E. 2003. Microbiology of wheat and flour milling in Australia. International Journal of Food Microbiology. 85:137-149.

⁵ Aydin, A., Pulsen, P., and Smulders, J.M. 2009. (a) The physico-chemical and microbiological properties of wheat flour in Thrace. Turkish journal of agriculture and forestry. 33: 445-454.

⁶ JC Augustin et al. 2006. Lessons From the Organization of a Proficiency Testing Program in Food Microbiology by Interlaboratory Comparison: Analytical Methods in Use, Impact of Methods on Bacterial Counts and Measurement Uncertainty of Bacterial Counts. Food Microbiology 23 (1), 1-38.

⁷ Eglezos, S. 2010. Microbiological Quality of Wheat Grain and Flour from Two Mills in Queensland, Australia. Journal of Food Protection. 73:1533-1536.

⁸ U.S. Food and Drug Administration. 2004. Federal food, drug, and cosmetic act. Chap. II- definitions.

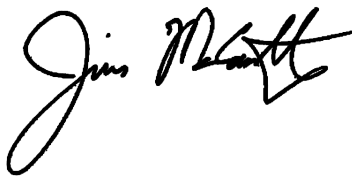
for which it is reasonably foreseeable that the food will be eaten without further processing that would significantly minimize biological hazards.”⁹ It is understood that further processing of milled grain products to reduce or eliminate microbial pathogens, such as cooking or baking, is needed before consumption. Due to this, milled flour would not fall under the RTE food definition. Additionally, the use of the term “re-contaminated” would imply the milling of the raw grain is an ultimate control step for the elimination of microbiological pathogens. We feel it is impossible for milled flour to be re-contaminated with environmental pathogens when it is fundamentally in a raw, or near-raw form, and has not undergone any lethality or kill step for microbial pathogens. However, 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 prevent harborage sites that could lead to environmental contamination of our products.

Conclusion

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 request that the changes mentioned above be strongly considered by FDA before a final guidance document is released. We believe that additional review and dialogue about the potential risks associated with raw grain and milled grain products, in particular both *B. cereus* and *L. monocytogenes*, should be conducted by FDA in consultation with the industry, federal agencies, and academia before these pathogenic microorganisms are added to a final list in Appendix 1, Table 1J, of potential biological hazards associated with flour. Lastly, due to both raw grain and flour not going through any lethality or kill step for microbial pathogens, we believe it is not possible to “re-contaminate” these products with environmental pathogens. As such, we feel that this should not be listed as a potential process-related biological hazard for #1 and #6 in Table 3J.

NAMA appreciates the opportunity to submit these comments. If we can provide any additional material that would clarify our comments, please allow us the opportunity to do so. Should the agency have any further questions regarding our comments, feel free to contact us at 202-484-2200 or jmccarthy@namamillers.org. We encourage the agency to reach out to us to further discuss our comments.

Sincerely,

A handwritten signature in black ink, appearing to read "Jim McCarthy". The signature is fluid and cursive, with a large initial "J" and a stylized "M".

Jim McCarthy
President and CEO

⁹ U.S. Food and Drug Administration. 21 CFR 117.3. “Ready-to-eat (RTE) food.” pg 5.