

November 15, 2013

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

Re: Docket No. FDA-2011-N-0920

Dear Sir/Madam:

The North American Millers' Association (NAMA) hereby submits comments on the U.S. Food and Drug Administration's (FDA's) proposed rule *Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food* (78 Fed. Reg. 3646, January 16, 2013). NAMA is the trade association representing the wheat, corn, oat and rye milling industry. NAMA's 45 member companies operate 170 mills in 38 states and Canada. Their aggregate production of more than 160 million pounds per day is approximately 95 percent of the total industry capacity.

We previously submitted comments in response to FDA's request for information about preventive controls and other practices used by facilities to identify and address hazards associated with specific types of food and specific processes (76 Fed. Reg. 29767, May 23, 2011, *Docket No. FDA- FDA-2011-N-0238*). In those comments, we described our members' adoption of HACCP, the applicability of U.S. Grain Standards, practices and equipment intended to ensure product integrity, and our concerns about potential impacts on small business. Those comments are attached for your reference. Below we offer specific comments on various aspects of FDA's proposed rule.

Definition of "Ready-to-Eat"

In proposed § 117.3, FDA defines ready-to-eat (RTE) as follows:

Ready-to-eat food (RTE food) means any food that is normally eaten in its raw state or any other food, including processed food, for which it is reasonably foreseeable that the food would be eaten without further processing that will significantly minimize biological hazards.

Flour does not fall within the scope of the proposed definition of "RTE food" because flour is not normally eaten in its raw state, nor is it reasonably foreseeable that flour would be eaten without further processing that would significantly minimize any biological hazards potentially associated with flour. Flour is a minimally processed agricultural ingredient that is not intended to be eaten raw. The heat processes of baking, frying, boiling and cooking that are normally applied by consumers are generally regarded as minimizing any potential risk of food borne illness associated with raw flour.

Furthermore, for sensitive products, any risk can be eliminated through the use of a commercial heat treatment system.

Environmental Monitoring and Finished Product Testing

The proposed rule does not include provisions for environmental monitoring and finished product testing. However, FDA requested comment on when and how these types of testing are an appropriate means of implementing the directives in § 418 of the Federal Food, Drug, and Cosmetic Act.

Environmental monitoring and finished product testing impose significant burdens and yield little benefit in the context of activity/food combinations that are low-risk. For purposes of this comment, we define “low-risk activity” as FDA did in its *Qualitative Risk Assessment Risk of Activity/Food Combinations for Activities (Outside the Farm Definition) Conducted in a Facility Co-Located on a Farm* (Draft RA).¹ In the context of low-risk activity food combinations, it is not practicable to develop and implement a scientifically valid approach to sampling and testing because of the very low incidence of microbiological and other hazards. Similarly, it is not practicable to develop and implement a scientifically valid approach to environmental monitoring (particularly Zone 1 monitoring). The low incidence of such hazards comes as no surprise given that flour milling is conducted in a dry, enclosed system which has minimum contact with human operators or the environment, thereby minimizing the risk of contamination.

Proposed § 117.5 recognizes that the following are low-risk activities when performed on grains and grain products: packing or re-packing; sorting, culling, or grading; storing; drying/dehydrating; grinding/milling/cracking/crushing; sifting; treating; labeling; and packaging. Although we understand that the scope of the draft RA is limited to on-farm activities, the tentative conclusions of the draft RA are consistent with our understanding of the low level of risk posed by such activities as carried out by milling facilities. That low level of risk was confirmed by a survey conducted by Sperber et al., which documented “an extremely low incidence of salmonellae and excellent microbiological profiles” in the products surveyed (namely wheat, corn, oats, whole wheat, and durum). Sperber, W.H. and the North American Millers’ Association Microbiology Working Group, *Journal of Food Protection*, Vol. 70, No. 4, 2007, Pages 1041–1053.

¹ A “low-risk activity” is one that: (1) Is performed on, or during production of, a food that has inherent controls for foodborne pathogens, provided that the food does not require preventive controls to significantly minimize or prevent other types of hazards (e.g., a chemical hazard such as mycotoxins); or (2) Satisfies both of the following criteria (a) Is not reasonably likely to introduce (or increase the potential for) a hazard for which there is a reasonable probability that use of, or exposure to, the food will cause serious adverse health consequences or death to humans (a SAHCOD hazard); and (b) Does not significantly minimize or prevent a SAHCOD hazard.

Allergen Control

Proposed § 117.135(d)(2) requires food allergen controls as part of preventive controls, as appropriate. Food allergen controls include procedures, practices, and processes employed for (1) ensuring protection of food from cross-contact, and (2) labeling the finished food.

Implementation of food allergen controls poses particular challenges in the context of milling operations. As an example, most milling operations do not handle soy. However, cross-contact between grains and soy can occur at various points in the chain of production and transport, such that grains arriving at a milling facility might already contain low levels of soy. The presence in a desired grain of low levels of soy or of other grains is consistent with U.S. Grain Standards. For example, the Grain Inspection, Packers and Stockyards Administration (GIPSA) definition of corn allows for the presence of between 2% and 7% foreign material, depending on the grade of corn, and the presence of up to 10% of other grains for which standards have been set. Although millers use equipment that helps to separate the desired grain from soy or other grains, complete elimination of soy and other grains is not practicable even under current good manufacturing practice (CGMP).

In light of the challenges described above, we urge FDA to acknowledge in the final rule that complete elimination of cross-contact is not feasible in certain operations even under CGMP. Further, the final rule should acknowledge that the intermittent presence of undeclared allergens is possible in certain foods, notwithstanding the observance of CGMP. We note that FDA has already acknowledged the potential for cross-contact as the result of “customary methods of growing and harvesting crops, as well as from the use of shared storage, transportation, or production equipment” (see Question 18 of *Guidance for Industry: Questions and Answers Regarding Food Allergens, including the Food Allergen Labeling and Consumer Protection Act of 2004 (Edition 4); Final Guidance*, available at <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Allergens/ucm059116.htm>).

Scope of the Exemption in Proposed § 117.5(j)

Proposed § 117.5(j) would exempt from the requirements of Subpart C those “facilities that are solely engaged in the storage of raw agricultural commodities (other than fruits and vegetables) intended for further distribution or processing.” It is clear that this exemption would apply to grain elevators and warehouses that are solely engaged in the types of storage described. We note that, in some instances, grain elevators are associated with a processing facility. Such elevators should nonetheless qualify for the exemption in proposed § 117.5(j), provided that they are solely engaged in the types of storage described in that section.

Definition of Very Small Business

Under the proposed rule, a “very small business” is subject to the modified requirements in § 117.201. The proposed rule provided three options for the definition of “very small business,” depending on the total annual sales of the business (\$250,000, \$500,000, or \$1,000,000, adjusted for inflation). We believe that the term “very small business” should be defined by reference to the number of employees, and not total annual sales. Defining the term by reference to the number of employees would be consistent with the approach taken by the Small Business Administration in its size standards for the flour milling industry.

Sincerely,

Sherri Lehman

Director of Government Relations