



The Link Between Grain and Goodness

*Submitted electronically via regulations.gov*

November 20, 2021

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

**Re: Docket No. FDA-2021-N-0929 for "FDA New Era of Smarter Food Safety Summit on E-Commerce" (September 7, 2021)**

Dear Sir or Madam:

On behalf of our nation's grain millers, the North American Millers' Association (NAMA) appreciates the opportunity to provide comments on Docket No. FDA-2021-N-0929 for the "FDA New Era of Smarter Food Safety Summit on E-Commerce."

NAMA represents millers of wheat, corn, oats, and rye across the continental United States, Puerto Rico, and Canada. Our members take raw grain and, through grinding and crushing, create flour and other products that are used to make favorite foods, such as bread, cereals, tortillas, pasta, cookies, cakes, and snack foods. As the link between grain and goodness, 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.

NAMA appreciates FDA's desire to improve its understanding of how human foods are sold through Business to Consumer (B2C) e-commerce models and to identify areas that may need additional improvements. Milled grain products have traditionally reached consumers in two forms: direct as a raw ingredient (such as retail flour / meal) or as an ingredient in a baked food product (such as bread). As consumer demands evolve and new business models emerge to meet those demands, it will be critical for food safety regulations and guidance to be relevant to the times.

As FDA reviews various food safety issues associated with B2C e-commerce models, NAMA encourages FDA to consider three key issues that are of particular importance for the milled grain industry: (1) product integrity, (2) education, and (3) guidance for new business models coming into the B2C e-commerce space.

First, there are several aspects that impact product integrity. It starts with Good Manufacturing Practices (GMPs) to ensure that B2C e-commerce models are prepared to address issues related to intentional and unintentional adulteration and cross-contamination. Programs need to be in place throughout the supply chain to ensure that the end products reaching consumers are safe and traceable. Where facilities are preparing

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foods or repackaging ingredients, it is critical that GMPs are in place to ensure proper sanitation and handling of ingredients and food. Additionally, it is important to maintain traceability of repackaged products. In many cases, we have found that repackaged ingredients do not carry forward traceback identifiers that allow for the proper traceability during a food safety event.

Examples of this include a meal-kit containing flour that was repackaged to be used as an ingredient, or a B2C entity that breaks down a commercial size bag of flour into smaller individual packages for resale with limited to no labeling. In both scenarios, additional visibility is needed to ensure overall product integrity as well as the traceability of the product. Relatedly, the use of tamper-evident packaging may be warranted when the product will be out of the direct control of the shipper for extended periods of time (either on primary packaging, secondary packaging, or both). Finally, product safety during transportation is also important. Although our products are shelf-stable and do not require temperature control, proper consideration should be given to issues like how packages may interact in the shipping box. For example, raw ground beef needs to be packaged to ensure it does not leak or affect a ready-to-eat ingredient.

Second, education efforts should be made to focus on proper handling of food and food ingredients from the production facility to the consumer. As mentioned earlier, repackaged ingredients and food products often lose the label information provided by the original manufacturer. For example, retail flour packaging includes language alerting consumers that flour is a raw ingredient and should be properly cooked before consuming. Passing forward this label information to the consumer is important for reducing food safety risks. In the case of meal-kits, incorporating proper handling information into the recipe would be one way to provide proper handling information to the consumer. FDA should not mandate a one-size-fits-all approach, but rather should ensure education efforts include repackaging operations so that they understand the importance of passing along food safety label information to consumers. Relatedly, consumer education may be needed on matters like product acceptance, so that consumers understand that they should read such use directions, check products on-hand if they become aware of a recall, and not use or accept products that may have been affected through tampering (e.g., if tamper-evident packaging is not intact).

Third, as new business models form to meet consumer demand, it will be important for FDA to develop and provide them with easy-to-understand guidance and other resources that explain their food safety responsibilities. The legal framework in this area can be complicated and many new entrants to this space are not familiar with issues like the Food Code, FDA facility registration, cGMPs, and FSMA. Businesses that are new to the food industry through non-traditional channels may not always have awareness of federal and state regulations, let alone the food safety risks associated with food preparation and repackaging. It is essential that FDA develop a thoughtful approach that ensures food safety, product integrity, and consumer confidence, while also encouraging business growth and new innovative ways to serve the consumer. Practical approachable guidance developed specifically for the B2C audience could go a long way toward achieving these goals.

In conclusion, we appreciate the opportunity to provide comments to the FDA docket connected with the “FDA New Era of Smarter Food Safety Summit on E-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 welcome the opportunity to further discuss the issues raised in our comments.

Sincerely,

A handwritten signature in black ink that reads "Dale J. Nellor". The signature is written in a cursive, flowing style.

Dale Nellor  
Vice President, Government & Technical Affairs  
North American Millers' Association