



North American Millers' Association
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December 17, 2018

Electronic Submission

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

Re: Docket No. FDA-2018-D-1398; *Draft Guidance for Industry: Mitigation Strategies to Protect Food Against Intentional Adulteration: Guidance to Industry (Installment 1); (June 20, 2018)*

Dear Sir or Madam:

The North American Millers' Association (NAMA) would like to take this opportunity to submit comments in response to the Food and Drug Administration's (FDA) "Draft Guidance: Mitigation Strategies to Protect Food Against Intentional Adulteration" (Draft Guidance). 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NAMA appreciates FDA's release of this Draft Guidance. Because the "Mitigation Strategies to Protect Food Against Intentional Adulteration" (IA) rule imposes new regulatory requirements on food companies to develop and implement written food defense plans, guidance for industry regarding compliance with the rule is extremely important. Many of the recommendations, examples, explanations, and clarifications in the Draft Guidance will be helpful to our members, resulting in higher rates of compliance and enhanced food protection. We understand that FDA is committed to implementing the rule in a way that is efficient, practical, and that achieves its public health goal, without creating unnecessary burdens or costs on industry. As such, we write to respectfully suggest additional ways that FDA can provide further education and guidance to the food industry, to help ensure the rule is implemented in the least burdensome way while protecting the public health.

In the milling industry, there is substantial similarity between processing operations. As such, for our industry it would be inefficient for each operation to independently conduct a vulnerability assessment. It would be far more efficient for NAMA, working with FDA, to create a template vulnerability assessment that our members can customize to their operations. Similarly, we would like to create a specified list of example mitigation strategies for actionable process steps that are likely to be present in milling facilities. This would help illustrate to our members the options available, while providing them flexibility to choose the mitigation strategy that is most appropriate in their particular circumstances. We believe that model templates like this will help reduce the burden on the milling industry and achieve higher rates of compliance with the rule, enhancing protection of the food supply.

We recognize that food defense plans are sensitive documents and that facilities should take steps to protect food defense plans and associated information and records. The grain milling industry has a long history of working in conjunction and alongside federal agencies to collaborate, develop, and educate on regulations and standards that impact our industry. Accordingly, NAMA would like to work with FDA to ensure that any templates are appropriate and that we take suitable measures to protect the information contained within them, such as only making them available at workshops or through a password protected website. We respectfully request the opportunity to engage in a dialogue with the agency regarding model food defense plans and additional educational materials and guidance we can provide to our members in a safe and secure way.

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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 Dale Nellor, NAMA's Vice President of Government and Technical Affairs at 202-484-2185 or dnellor@namamillers.org.

Sincerely,



Jim McCarthy
President and CEO