North American Millers' Association
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July 5, 2019

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Re: Docket No. FDA-2018-D-1398; *Draft Guidance for Industry: Mitigation Strategies to Protect Food Against Intentional Adulteration: Guidance to Industry* (Installment 2); (March 6, 2019)

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this opportunity to submit comments in response to the Food and Drug Administration's (FDA) second installment of the "Draft Guidance: Mitigation Strategies to Protect Food Against Intentional Adulteration" (Draft Guidance).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NAMA appreciates FDA's release of the second installment of the Draft Guidance.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. With the release of this second installment of the Draft Guidance, we want to express our appreciation for Chapters 2F, 2G, and 2H, which explain how to conduct a vulnerability assessment using the three fundamental elements in the regulation, as well as how to conduct a vulnerability assessment using the Key Activity Type (KAT) method in combination with the three fundamental elements (the hybrid approach). Because the hybrid approach allows a facility to conclude that a particular step that otherwise fits within a KAT is not an actionable process step, it can significantly reduce the burden on a facility to implement mitigation strategies and associated management components. 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 revise the Draft Guidance to help ensure the rule is implemented in the least burdensome way while protecting the public health.

While FDA has included a number of statements in the Draft Guidance noting that alternative approaches to compliance with the rule can be taken, we respectfully request additional revisions along these lines. These statements that alternative approaches are acceptable are extremely important as we move towards facility inspections for compliance with the IA rule. Many investigators and state inspectors will look to the guidance when conducting inspections and, despite its nonbinding status, will expect to see food defense plans that look like the approach outlined and the templates and examples provided. The information and examples in the Draft Guidance are helpful to industry, but we want to ensure that they do not become the only acceptable approach. As such, we respectfully request revisions to the Draft Guidance to make this point more clear, and investigator and inspector training on these points.

There are two key areas in the newly added material regarding conducting vulnerability assessments using the three fundamental elements where revisions and training are warranted: (1) the ability to use a different approach to assessing or "scoring" each of the three fundamental elements; and, (2) the inherent judgment involved in doing so. With respect to the first point, we note that there a wide range of approaches to assessing the three fundamental elements. Facilities will have templates that look different from those drafted by FDA and may use different scoring systems. The Draft Guidance should make clear that the approach to assessing the three fundamental elements contained therein is not binding on industry or a requirement, and that any approach that meets the requirements in the regulation is acceptable. With respect to the second point, assessing the degree of accessibility at an actionable process step and the ability of an attacker to successfully contaminate the product are subjective determinations that involve judgement. The Draft Guidance should be revised to explicitly make this point.

We also respectfully request FDA train investigators and state inspectors on the flexibility in the IA rule. This flexibility extends to food defense plan formatting, templates, scoring systems, vulnerability assessment methods, selection of mitigation strategies, and management components. Investigators and inspectors should also be trained to defer to the facility's judgment and decision making in creating the food defense plan (conducting the vulnerability assessment, identifying mitigation strategies, and determining management components). The facility's food defense team is in the best position to decide these key issues based on their knowledge of their products, process, and people.

Along those same lines, we also recommend that inspectors be trained to collect as few food defense plan related records as possible during inspections. Not only are we concerned about the security of those records, but also must recognize that in light of the judgments made in creating them, these records are best reviewed and understood at the facility, where questions can be asked of the food defense team.

Finally, we respectfully repeat our request for the opportunity to engage in a dialogue with the agency regarding the creation of 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,

James McCarthy
President and CEO