



April 17, 2019

Betsy Booren, Ph.D.
Senior Vice President, Science
and Technology
Grocery Manufacturers Association
1001 19th Street North, 7th Floor
Arlington, Virginia 22209

Dear Dr. Booren:

Thank you for your correspondence of March 12, 2019. In your letter, you and your co-signers urge the Food and Drug Administration (FDA) to extend for one year the compliance deadline for the Mitigation Strategies to Protect Food Against Intentional Adulteration final rule (IA rule). Your letter states that industry does not have all the guidance and other supporting materials from FDA industry feels it needs to comply by the deadline.

The IA rule helps prevent acts intended to cause wide-scale harm, including acts of terrorism targeting the food supply. While such acts are unlikely to occur, the rule advances protection of the food supply. Owing to the importance of the public health protections embodied in the IA rule, the availability of draft guidance and training courses on the IA rule, and due in part to the prolonged time period between publication of the final rule and the initial compliance date (3 years), we deny your request to extend the compliance deadline.

Since the final rule published in May 2016, we have been impressed with the level of engagement from many industry members. Some stakeholders sought a better understanding of the rule and our expectations around its implementation, while others asked specific questions as they finalized their food defense plans. The IA rule is the first of its kind, and because it is new regulatory territory for both FDA and industry, we have particularly appreciated collaborating with industry. We believe both industry and FDA have benefitted from our many technical discussions, site visits, and implementation dialogues. Industry's questions about and feedback on the final rule helped shape the content of the draft guidance documents we have issued, and the other supporting materials we are developing. We prioritized the topics about which industry was most concerned, and incorporated those topics into the first two installments of the guidance

and many of the Food Safety Preventive Controls Alliance (FSPCA) training courses that are currently available. We look forward to continued collaboration and dialogue, including at the April 17 public meeting, and via stakeholder enrollment in the recently publicized schedule for the FSPCA Vulnerability Assessment course.

As with other FSMA rules, our modus operandi as we commence IA rule inspections will be to “educate while we regulate.” In the context of the IA rule, that means that our initial routine inspection activity for IA rule compliance will consist of straightforward “quick checks” conducted during routine food safety surveillance inspections. Via the quick checks we will verify that the facility has satisfied the basic requirements of the rule (e.g., “do you have a food defense plan?”). This approach is intended to serve both industry and the FDA in identifying those areas of the IA rule that are most in need of additional educational emphasis.

Also by way of education, we recognize the importance to industry of having access to the training modules and other technical assistance materials mentioned in your letter. We are working hard to provide these resources, including the final portion of the draft guidance which we expect to release later this year. Upon careful consideration, we have determined not to change the rule’s compliance date. However, to allow industry sufficient time to benefit from the forthcoming materials, tools, and trainings, and because the IA rule represents new regulatory territory for all of us, we will not start routine IA rule inspections until March 2020. We trust the forthcoming resources and opportunities will assist your member companies in preparing for the start of quick check inspections at that time.

Thank you again for your letter. I look forward to working with you and other stakeholders in pursuing our common mission of implementing the food defense protections afforded by the IA rule.

Sincerely,

A handwritten signature in blue ink, appearing to read 'FY', with a long horizontal flourish extending to the right.

Frank Yiannas
Deputy Commissioner
Food Policy and Response