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MEMORANDUM

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Re: FDA Releases Second Installment of Draft Guidance for FSMA Intentional Adulteration Rule

The U.S. Food and Drug Administration (FDA) has released the second of three installments of its Draft Guidance to support compliance with the Mitigation Strategies to Protect Food Against Intentional Adulteration (IA) rule. 1/ Under the IA rule, the last of the major FDA Food Safety Modernization Act (FSMA) rules to be released, food facilities must develop and implement a food defense plan that identifies their significant vulnerabilities and mitigation strategies to address those vulnerabilities, and they must take steps to ensure those mitigation strategies are working.

FDA released the first four chapters of the Draft Guidance in June 2018. Those chapters (1) provided templates for various components of a food defense plan, (2) addressed how to develop a food defense plan, including one particular method for conducting a vulnerability assessment to identify significant vulnerabilities and actionable process steps (the Key Activity Type (KAT) method), and (3) included information regarding mitigation strategies for actionable process steps and monitoring. 2/

The second installment of the Draft Guidance adds to and incorporates the previous chapters, also providing new content addressing a vulnerability assessment approach. This approach can be more tailored to a facility by using the three factors in the regulation and provides guidance on training requirements for individuals performing various tasks under the rule. This memorandum provides an overview of the new material, and is by no means a comprehensive summary. We encourage food facilities covered by the IA rule to read the second installment in its entirety.

Comments on content in both the first and second installments will be accepted until July 5, 2019, and should be submitted to Docket Number FDA-2018-D-1398.

1/ "Mitigation Strategies to Protect Food Against Intentional Adulteration," (Mar. 2019), available at https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM611043.pdf.

2/ *See* HL Memo - FDA Releases Draft Guidance for FSMA Intentional Adulteration Rule (June 25, 2018).

Background

FDA issued the IA rule on May 27, 2016. 3/ The compliance date for large facilities is July 26, 2019. Facilities that qualify as small businesses (i.e., businesses that employ fewer than 500 full-time equivalent employees) must comply with the rule by July 27, 2020. Very small businesses (defined for this purpose as those averaging less than $10 million in sales per year during the 3-year period preceding the applicable calendar year) are exempt from the rule, except that upon request they must provide documentation sufficient to show that the facility meets the exemption. The compliance date for these facilities to maintain such documentation is July 26, 2021.

FDA's Draft Guidance is intended to facilitate compliance for those facilities covered by the IA rule. When it is completed, the Draft Guidance will consist of the following chapters:

(1) The Food Defense Plan;
(2) Vulnerability Assessment to Identify Significant Vulnerabilities and Actionable Process Steps;
(3) Mitigation Strategies for Actionable Process Steps;
(4) Mitigation Strategies Management Components: Food Defense Monitoring;
(5) Mitigation Strategies Management Components: Food Defense Corrective Actions;
(6) Mitigation Strategies Management Components: Food Defense Verification;
(7) Reanalysis;
(8) Education, Training, or Experience; and
(9) Records.

FDA is releasing chapters of the Draft Guidance in three installments:

- The first installment, including the introduction and chapters 1 through 4, focused on the components of the food defense plan, how to conduct vulnerability assessments using the key activity type (KAT) method, how to identify and implement mitigation strategies, and food defense monitoring requirements.
- The newly released second installment explains a vulnerability assessment approach that can be more tailored to a facility by using the three fundamental elements in the regulation and includes chapter 8 on education and training.
- The third, forthcoming installment will provide greater detail on how to take corrective actions, how to verify that a facility's system is working, food defense plan reanalysis requirements, and recordkeeping requirements.

A public hearing on the first two installments currently is being planned by FDA.

Vulnerability Assessments

The second installment supplements chapter 2 by providing information on how to evaluate the three fundamental elements in the regulations (potential public health impact, degree of physical access to the product, and ability of an attacker to successfully contaminate the product) when conducting a vulnerability assessment. It also includes a subchapter on identifying significant vulnerabilities and actionable process steps using the three fundamental elements, as well as information on identifying actionable process steps using a hybrid approach that combines the KATs and the three fundamental elements.

In these subchapters, FDA provides information regarding:

- Consideration of the inside attacker and inherent characteristics when evaluating processing steps;

3/ 81 Fed. Reg. 34,116.

- Ways to evaluate Element 1 – potential health impact – by using the "volume of food at risk approach," the "representative contaminant approach," or the "contaminant specific approach";
- Additional factors facilities may choose to include when assessing Element 3 – ability of an attacker to successfully contaminate the product – when using either of the contaminant-based approaches;
- How to score all three fundamental elements;
- How to sum individual element scores, rank the summed scores, and identify based on the ranking which steps are actionable process steps; and
- Written explanations for why each step is or not an actionable process step.

With respect to the hybrid approach, the Draft Guidance explains:

> The hybrid approach allows you to use the strengths of both the KAT and three elements methods. In the hybrid approach, a facility first assesses each point, step, or procedure to identify steps that fit within any of the four key activity types. Then, rather than concluding the VA with those steps identified as the actionable process steps, the facility uses the three elements to conduct a more in-depth evaluation of some of the steps. A facility may choose to conduct a more in-depth evaluation of those process steps that, while fitting within the KATs, may have factors present at the step (e.g., inherent characteristics) that would further inform the analysis as to whether a significant vulnerability exists. The hybrid approach combines the speed of KATs with the in-depth analysis of the three fundamental elements. Using the hybrid approach, a facility can conduct its vulnerability assessment faster than if evaluating the three fundamental elements at all of its steps and may possibly identify fewer actionable process steps than if using the KAT method alone.

Along with the subchapters identified above, FDA also has provided vulnerability assessment examples in Appendix 4 demonstrating how to perform a vulnerability assessment using the three fundamental elements (using breaded morsels as an example) and the hybrid approach (using a cold pressed energy bar as an example).

In addition, FDA has provided additional templates/worksheets for performing a vulnerability assessment, including:

- Worksheet 1-C: Vulnerability Assessment Analysis Summary;
- Worksheet 1-D: Calculating Volume of Food at Risk;
- Worksheet 1-E: Calculating Potential Public Health Impact Using a Representative Contaminant; and
- Worksheet 1-F: Identifying Significant Vulnerabilities and Actionable Process Steps using the Three Fundamental Elements.

Education and Training

The second installment also includes a new chapter 8 focused on employee education and training. This chapter addresses the education and training required for:

- Individuals who perform activities required by Subpart C (e.g., food defense monitoring);
- Individuals assigned to an actionable process step;
- Individuals who perform or oversee the preparation of the food defense plan, the vulnerability assessment, identification and explanation of the mitigation strategies, or reanalysis of the food defense plan; and
- Supervisors.

The chapter also discusses the frequency of training and associated documentation. FDA provides information regarding how job experience can qualify an individual to perform certain activities.

The Draft Guidance also explains that FDA is not establishing minimum standards for competency and does not intend to routinely directly assess the qualifications of food defense qualified individuals. Instead, FDA will focus on the adequacy of the food defense plan.

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We will continue to monitor developments related to implementation of the IA rule. Please contact us if you have any questions or would like to discuss strategies your business can take to comply with the rule.