Hogan Lovells US LLP
Columbia Square
555 Thirteenth Street, NW
Washington, DC 20004
T +1 202 637 5600
F +1 202 637 5910
www.hoganlovells.com

MEMORANDUM

From: Joseph A. Levitt
Maile Gradison Hermida
Elizabeth Barr Fawell
Leigh G. Barcham

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Re: FDA Releases Draft Guidance for FSMA Intentional Adulteration Rule

The U.S. Food and Drug Administration (FDA) has released the first of three installments of its long awaited Draft Guidance to support compliance with the Mitigation Strategies to Protect Food Against Intentional Adulteration (IA) rule. 1/ Under the IA rule, the last of the major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. This first installment includes the first four chapters of the Draft Guidance, which provide FDA's recommendations on how to develop a food defense plan, including one particular method for conducting a vulnerability assessment to identify significant vulnerabilities and actionable process steps, developing mitigation strategies for actionable process steps, and monitoring mitigation strategies. It also contains templates for various components of a food defense plan.

On March 28, FDA Commissioner Scott Gottlieb published a blog post, in which he explained the agency's intent to implement the IA rule as practically and flexibly as possible for the food industry, while still maintaining an adequate level of public health protection. The Draft Guidance builds on Commissioner Gottlieb's post by identifying many areas where FDA has provided facilities with flexibility in their implementation of food defense plans. 2/ This memorandum includes the highlights we identified from our initial review of the guidance, but is by no means a comprehensive summary. We encourage food facilities covered by the IA rule to read the Draft Guidance in its entirety, as well as Commissioner Gottlieb's March 28 blog post.

Comments on the Draft Guidance are due December 17, 2018, and must be submitted to Docket No. FDA-2018-D-1398.

1/ "Mitigation Strategies to Protect Food Against Intentional Adulteration," (June 2018), available at https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM611043.pdf.

2/ "We're Committed to Guarding Against the Intentional Adulteration of Food and Implementing the New Rule Efficiently," FDA Voice (Mar. 28, 2018), available at https://blogs.fda.gov/fdavoice/index.php/2018/03/were-committed-to-guarding-against-the-intentional-adulteration-of-food-and-implementing-the-new-rule-efficiently/.

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.

As indicated above, FDA is releasing chapters of the Draft Guidance in three installments:

- This first installment, including the introduction and chapters 1 through 4, focuses 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. 4/
- The second installment, which will be released later this year, will focus on a vulnerability assessment approach that can be more tailored to a facility by using the three factors in the regulation and will provide guidance on training requirements for a food facility's employees.
- The third 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.

FDA intends to continue to engage stakeholders as it develops the additional installments and works to finalize the guidance, including holding a public meeting on the Draft Guidance later this year after it releases the second installation. In addition, FDA is working to develop additional training opportunities in collaboration with the Food Safety Preventive Controls Alliance (FSPCA) and plans to release those trainings as soon as it can.

Highlights of Draft Guidance

Prior to releasing the Draft Guidance, FDA engaged with stakeholders to learn more about their perspectives and concerns about complying with the rule. Much of the feedback FDA received was incorporated into the Draft Guidance or will be incorporated in the forthcoming installments. Importantly, as with all FDA Draft Guidance documents, the Draft Guidance states at the outset that it is not binding on facilities, which "can use an alternative approach if it satisfies the requirements of

3/ 81 Fed. Reg. 34,116.

4/ Part F of Chapter 2, how to do a vulnerability assessment using the three factors to identify significant vulnerabilities and actionable process steps, is not included in the first installment, but will be included in the second installment later this year.

the applicable statutes and regulations." In addition, where the Draft Guidance provides sample templates for components of a food defense plan, FDA notes that the templates are just one possibility, and that food facilities may format their food defense plans differently.

Vulnerability Assessments

Chapter 2 in the Draft Guidance is devoted to assisting facilities in conducting a vulnerability assessment to identify significant vulnerabilities and actionable process steps. FDA explains that the vulnerability assessment requirement is flexible and allows each facility to choose the method that is most appropriate for it, provided the method considers the following elements:

1. The potential public health impact (severity and scale) if a contaminant were added;
2. The degree of physical access to the product; and
3. The ability of an attacker to successfully contaminate the product.

This first installment of the Draft Guidance only outlines the option to conduct a vulnerability assessment using the KAT method (the four KATs are: (1) bulk liquid receiving and loading, (2) liquid storage and handling, (3) secondary ingredient handling, and (4) mixing and similar activities). FDA has stated previously that facilities that are able to perform a more complex vulnerability assessment using the KAT method plus the three additional factors may determine that a KAT is not an actionable process step. FDA does not address this method in this installment of the Draft Guidance, however, and will address it in forthcoming guidance.

Facilities should pay close attention to FDA's recommendations for preparing vulnerability assessments and the model templates. For example, FDA encourages facilities to develop a list or draw a process flow diagram of each point, step, or procedure in the process under evaluation, and then describe each process step in detail. Facilities also should keep in mind that under the regulations, written explanations as to why each point, step, or procedure is or is not an actionable process step are required. FDA also recommends facilities record the type of vulnerability assessment used for each process step in the food defense plan.

The chapter also includes a lengthy description of various activities that FDA does and does not consider to be KATs. For example, FDA considers the following actions to fall within the KAT of secondary ingredient handling:

- the staging of secondary ingredients (i.e., opening the tamper-evident packaging and moving the secondary ingredient to the production area);
- the storage of partially used, open containers of secondary ingredients where the tamper-evident packaging has been breached;
- the preparation of secondary ingredients;
- the addition of secondary ingredients; and,
- rework product (i.e., removing clean, unadulterated food from processing for reasons other than insanitary conditions or that has been successfully reconditioned by reprocessing that is suitable for use as food).

FDA also notes that process steps that are not specifically designed to evenly mix product may still be included in the KAT of mixing and similar activities because mixing is a result of the process conducted. As an example, FDA explains that a roaster with the primary purpose of evenly roasting beans or nuts that uses paddles or other agitation mechanisms could effectively mix a contaminant into the food during the roasting process.

Mitigation Strategies

FDA begins its chapter on mitigation strategies by explaining that facilities have flexibility to identify and implement mitigation strategies from among all procedures, practices, and processes available to them that would provide assurances that they are significantly minimizing or preventing identified significant vulnerabilities.

Additional noteworthy statements from FDA include the following.

- Mitigation strategies that increase food safety risks or negatively impact worker safety should not be implemented.
- FDA does not expect facilities will reengineer processing lines or undertake other major structural changes to facilitate clear lines of sight or eliminate visual obstructions.
- FDA expects facilities will implement the most cost-effective mitigation strategy that addresses their significant vulnerabilities, and not implement strategies that would be prohibitively expensive when other, less costly strategies would suffice.
- Facilities may use a single mitigation strategy to significantly reduce vulnerabilities. In addition, in some cases, layering two or more relatively inexpensive mitigation strategies may be as effective as a more expensive single mitigation strategy.
- Some mitigation strategies may leverage a facility-wide security measure as part of their implementation.
- Existing practices such as prohibiting personal items from food production areas or buddy systems for worker safety may serve as mitigation strategies.
- Mitigation strategies could include low-cost personnel programs, such as authorizing only senior or long-term employees, or those who otherwise have established elevated trust by management, to work at a particular actionable process step. Another mitigation strategy could be identifying employees with access to an area with particular clothing (e.g., red caps and instructing employees to escort non-authorized personnel out of the area).

FDA notes that when workers are relied on to implement a mitigation strategy that restricts access to only employees authorized to be in an area, proper training of employees is critical.

The Draft Guidance also explains that mitigation strategies are practices or conditions that are not inherent to the operation of a process step. This means that if the process step could still function if a measure were not applied, it is a mitigation strategy. In contrast, inherent characteristics of a process step are not mitigation strategies and should be evaluated during a vulnerability assessment. Inherent characteristics are conditions, activities, practices, or characteristics that are integral to the operation of a process point, step, or procedure (e.g., integrated safety features that stop operation of a processing line, inward opening hatches that cannot be opened when food is inside the tank). FDA will publish additional guidance on consideration of inherent characteristics of process steps when conducting a vulnerability assessment.

Accordingly, the Draft Guidance explains that vulnerability assessments should not consider existing measures that are not inherent characteristics of the process step's operation (what some companies refer to as "foundational programs") when identifying whether a process step is an actionable process step. Rather, facilities should consider conditions in the absence of controls when assessing a particular process step. FDA provides as an example the placement of a senior employee who has undergone additional vetting at a particular process step. This could be because the step is sensitive due to ingredient cost or perhaps because it is a preferred position for senior employees due to working conditions. Under such circumstances, FDA explains that the placement of the senior employee at the process step would not be considered inherent, and therefor would not be considered as part of a vulnerability assessment, because the process step would be able to operate without a more trusted employee working there. Instead, the facility would need to assess

the process step absent the placement of a senior employee when determining whether the process step is an actionable process.

In addition, FDA generally expects that mitigation strategies will target only the latter two factors of the three factors identified above. In other words, FDA expects mitigation strategies to limit the degree of physical access to a process step or the likelihood of a successful attack, but not the public health impact, because, as FDA notes, steps to limit the public health impact typically would reduce the volume of food being processed. The mitigation strategies listed in FDA's Food Defense Mitigation Strategies Database are generally designed to address one or both of these elements.

Finally, under the final rule, food defense plans must include written explanations of how a mitigation strategy is effective, and this requirement is further explained in the Draft Guidance. We encourage companies to closely review FDA's expectations for explaining how each mitigation strategy will protect the respective actionable process step.

Food Defense Monitoring

The Draft Guidance also focuses on food defense monitoring, a required management component for mitigation strategies. The Draft Guidance explains that facilities have the flexibility to determine what to monitor, how often the monitoring will occur, and who will monitor the mitigation strategy. FDA notes that because food defense monitoring is conducted to ensure the mitigation strategy is operating as intended, it occurs less frequently and therefore is less resource intensive than monitoring in a food safety context. Further, existing quality and food safety activities may function as food defense monitoring procedures.

Additional statements of note include the following:

- Facilities have the flexibility to consider how monitoring a mitigation strategy could be incorporated into normal operations or job duties.
- In some cases, monitoring can occur concurrently with the implementation of the mitigation strategy. For example, when restricting access to an area to only certain individuals who are denoted by their attire or identification badges is used as a mitigation strategy, its implementation can be monitored by the authorized employees who are constantly observing whether there are unauthorized individuals in the area.
- Monitoring procedures occurring on a periodic basis but at irregular intervals can be beneficial.
- Exception records may be appropriate methods of documenting monitoring (e.g., whenever a secure gate alarms, or whenever an authorized person enters an area). Situations where mitigation strategies are implemented to maintain a static situation that is not under constant monitoring do not lend themselves to a monitoring procedure that uses an exception record approach (e.g., the presence of a lock on a tank).

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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.