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FDA Releases the First of Three Draft Guidances on FSMA's Food Defense Requirements

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Food, Beverage, and Dietary Supplements

Today (June 20, 2018), FDA published in the Federal Register the availability of the first four chapters of a nine-chapter draft guidance ("IA draft guidance") intended to address the requirements in its final rule, Mitigation Strategies to Protect Food Against Intentional Adulteration ("IA rule").[1]

In its press release announcing the IA draft guidance, FDA explained that these first four chapters focus on the components of the food defense plan, including how to conduct vulnerability assessments using the key activity type method and how to identify and implement mitigation strategies and food defense monitoring requirements.

FDA intends to release the remaining chapters of the IA draft guidance in two other installments "later this year." The second set of chapters will focus on a vulnerability assessment approach that can be more tailored to a facility. FDA will also provide guidance on training requirements for a food facility's employees. The third set of chapters will provide greater detail on how to take corrective action, how to verify that a facility's system is working, food defense plan reanalysis requirements, and record-keeping requirements.

The Food Defense Plan (FDP)

The IA rule generally requires covered facilities to: (1) conduct an assessment of vulnerable processes in their operations susceptible to acts that could cause large-scale public harm; (2) prepare and implement a written food defense plan (FDP); (3) conduct personnel training; and (4) prepare and keep written records. The IA draft guidance is intended specifically to help industry develop and implement an FDP in accordance with the IA rule's requirements.

Under the IA rule, an FDP must include the following elements:

- Vulnerability assessment (VA) to identify significant vulnerabilities and actionable process steps;

[1] The IA rule is one of the seven foundational food safety rules that FDA issued over the past few years under the Food Safety Modernization Act (FSMA). Our client alert on the Intentional Adulteration final rule is available here.

- Mitigation strategies for each actionable process step;
- Food defense monitoring procedures for the mitigation strategies;
- Food defense corrective action procedures that must be taken if mitigation strategies are not properly implemented; and
- Food defense verification procedures.

In the IA draft guidance, FDA explains that "[t]here is no standardized or required format for an FDP," and that facilities have the flexibility to use whatever format works best for their operations. The agency notes that it intends to update its Food Defense Plan Builder to align with the IA rule, and also includes, as an appendix to the IA draft guidance, sample FDP worksheets for the particular elements of an FDP addressed in the draft guidance.

The IA draft guidance provides very detailed recommendations for implementing three of the required FDP elements: vulnerability assessment, mitigation strategies, and food defense monitoring procedures. We summarize below key points from the IA draft guidance for each of these elements. FDA indicated that it intends to expand this draft guidance to include sections on food defense corrective action procedures, food defense verification procedures, and a number of other related issues, including records and education requirements, as those sections are completed.

Vulnerability Assessments

A facility's FDP must include a VA for each type of food manufactured, processed, packed, or held at the facility, in order to identify significant vulnerabilities and actionable process steps at each point, step, or procedure in the food operation. A significant vulnerability means a vulnerability that, if exploited, could reasonably be expected to cause wide scale public health harm. The IA rule requires a VA to include the following elements: (1) potential public health impact if a contaminant were added; (2) degree of physical access to a product; and (3) ability of an attacker to successfully contaminate the product.

In the IA draft guidance, FDA recommends that facilities use the Key Activity Types (KAT) method to conduct its VAs; the agency developed the KAT method by analyzing multiple VAs for a range of food types and manufacturing settings. The KAT method addresses four KATs: bulk liquid receiving and loading; liquid storage and handling; secondary ingredient handling; and mixing and similar activities. For those points, steps, or procedures that fall within one or more of the KATs, a facility would further evaluate whether it is an "actionable process step." If a point, step, or procedure does not fall within one or more of the KATs, it is not an "actionable process step" and does not require mitigation strategies.

The IA draft guidance includes detailed recommendations for using the KAT method and examples of VAs conducted using this method. The IA draft guidance does *not* include recommendations for performing a VA by evaluating the three fundamental elements in the IA rule through a method other than the KAT method, but FDA indicates that such recommendations will be coming soon. In the IA draft guidance, FDA also provides clarification on a number of concepts in the VA requirements, including the scope of "point, steps, and procedures" a facility must evaluate and how a facility can group similar food products in conducting VAs.

Mitigation Strategies

For each actionable process step that a facility identifies through its VAs, the facility must identify and implement mitigation strategies. The FDP must include written explanations that describe how the mitigation strategies the facility has selected sufficiently minimize or prevent each significant vulnerability.

In support of a key concern regarding "rogue employees," FDA explains in the IA draft guidance that it would expect facilities to generally design mitigation strategies that either minimize the accessibility of the food to an inside attacker (e.g., physical protections), or reduce the opportunity for an inside attacker to contaminate the food (e.g., enhanced oversight).

The IA draft guidance also includes a range of examples of mitigation strategies that would minimize product accessibility or would reduce the ability of an attacker to contaminate food, sample worksheets for identifying mitigation strategies within a FDP, and sample explanations describing why a mitigation strategy is appropriate. In addition, the agency recommends that facilities consult its Food Defense Mitigation Strategies Database to identify mitigation strategies that may be appropriate for a given actionable process step.

Food Defense Monitoring

A facility's FDP must include written procedures for monitoring each mitigation strategy, as appropriate to the nature of the strategy and its role in the facility's food defense system. The IA rule requires monitoring procedures to be appropriate for assessing whether a mitigation strategy is operating as intended. The IA draft guidance explains that a facility's food defense monitoring procedures should address four questions -- (1) What will be monitored; (2) How monitoring will be done; (3) How often monitoring will be done; and (4) Who will do the monitoring -- and includes detailed recommendations for how to address each of these issues. The draft guidance also includes a table with multiple examples of food defense monitoring procedures that correlate to the mitigation strategy examples in the IA draft guidance.

Compliance Dates

For most businesses, the compliance date for the IA rule is July 26, 2019; for small businesses (fewer than 500 full time equivalent employees), the compliance date is July 27, 2020, and for very small businesses (those averaging less than $10 million in sales of human food over the prior three years), the compliance date is July 26, 2021.

Considerations Regarding FDA's Perspective on the IA Draft Guidance

In announcing the IA draft guidance, FDA explained that the IA draft guidance should reflect much of the feedback it received from stakeholders, including concerns that the IA rule was overly burdensome and would require tremendous use of resources and time for what might be low risk settings. FDA intends the IA draft guidance to be practical and to provide facilities needed flexibility when conducting vulnerability assessments. In addition, FDA believes the IA draft guidance provides greater clarity and predictability for manufacturers, and that the requirements are cost-effective and not overly burdensome, while still protective of the food system.

In a previous blogpost released prior to issuing the IA draft guidance, the agency, responding to stakeholder concerns, stated that in the IA draft guidance, facilities would have flexibility to choose from range of options and tailor FDPs as needed, there would be no requirement to

drastically modify existing facilities (build structures, advanced software, reengineer processing lines), and there would be no expectation to hire additional employees for monitoring & verification of mitigation strategies.

Stakeholders who review the IA draft guidance may want to ensure it sufficiently addresses these and any other concerns, provides facilities sufficient flexibility, and raises no new concerns. FDA is accepting comments until December 17, 2018 and intends to hold a public meeting later this year after it publishes the second guidance.

Covington is experienced in advising clients on legal matters related to FSMA implementation and is available to provide individualized compliance counseling concerning these issues. If you have any questions concerning FDA's IA draft guidance or any food, beverage, and dietary supplement legal or regulatory questions, please contact any of the following members of our Food & Beverage practice group:

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