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The U.S. Food and Drug Administration (FDA) has released the third and final installment of its Draft Guidance to support compliance with the Mitigation Strategies to Protect Food Against Intentional Adulteration (IA rule). 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 (or FDP) 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FDA released the first four chapters of the Draft Guidance in June 2018.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. The second installment of the Draft Guidance provided new content addressing an alternative vulnerability assessment approach, which could be more tailored to a facility by using the three factors in the regulation. The installment also provided guidance on training requirements for individuals performing various tasks under the rule.

This last installment of the IA rule Draft Guidance adds to the previous chapters, covering topics focused on food defense corrective actions, food defense verification, reanalysis, and recordkeeping. 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 final installment in its entirety.

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