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MEMORANDUM

From: Joseph A. Levitt
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Date: September 20, 2019

Re: FSMA Implementation: FDA Launches Food Defense Plan Builder 2.0

The Food and Drug Administration (FDA) recently announced the launch of an updated version of the Food Defense Plan Builder Version 2.0 (FDPB) to help companies meet the requirements of the final rule "Mitigation Strategies to Protect Food Against Intentional Adulteration" (IA Rule) under the FDA Food Safety Modernization Act (FSMA). 1/ The FDPB is a voluntary tool intended to aid entities subject to the IA Rule in preparing customized food defense plans.

FDA is hosting a webinar to demonstrate how to download, install, implement, and use the FDPB, as well as to answer questions about how to use the system. This webinar will be held on October 10, 2019 at 1 pm ET. 2/

Background on the IA Rule and the FDPB

The IA Rule was developed to address hazards that may be intentionally introduced to foods with the intent to cause widespread harm to public health, including acts of terrorism targeting the food supply. With some exceptions, the IA Rule applies to both domestic and foreign companies that are required to register with the FDA as food facilities under the Federal Food, Drug, and Cosmetic Act. Food facilities covered by the IA Rule are required to develop and implement a food defense plan that identifies vulnerabilities and implements mitigation strategies for processes in food facilities (among other requirements).

The first compliance date for largest facilities subject to the IA Rule was July 26, 2019. Earlier this year, the FDA announced that inspections would begin in March 2020 to allow industry time to use tools such as the FDPB to develop programs and conduct training. Compliance dates for small businesses and very small businesses are July 27, 2020 and July 26, 2021, respectively. 3/

1/ Constituent Update: FDA Launches Updated Food Defense Plan Builder (Sept. 19, 2019) https://www.fda.gov/food/cfsan-constituent-updates/fda-launches-updated-food-defense-plan-builder.
2/ Registration is available at https://collaboration.fda.gov/fdpb_v2/event/registration.html.
3/ FSMA Compliance Dates, https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-compliance-dates#InternationalAdulteration

The 2013 version of the FDPB (Version 1.0) was created under a voluntary framework to assist owners and operators of food facilities with developing customized food defense plans. Importantly, it was created and published prior to the publication of the IA Rule, and thus did not address some of the IA Rule's requirements. The updated tool has been aligned with the requirements in the IA Rule so that it can be used to easily create food defense plans. 4/

FDPB Version 2.0

The updated tool harnesses existing guidance (including the templates and worksheets in the Draft Guidance) 5/ and other resources for food defense plans into one single application. Importantly, use of the tool is not required under FSMA, nor is it required to comply with the IA Rule. Rather, FDA expects this tool to supplement (and not replace) the education, training, and experience needed to understand and implement the requirements of the IA Rule. Notably, the tool does not substitute for or satisfy the training, education, and experience requirements in the rule. The person using the FDPB tool to conduct a vulnerability assessment, identify and explain mitigation strategies, prepare the food defense plan, and perform reanalysis must meet the qualification requirements in the IA Rule, even if using the FDPB to develop customized food defense plans. 6/

Entities interested in using the FDPB must first download and install the program. 7/ Once installed, the plan builder will then prompt owners and operators to enter information about their facilities into each section. Once all the sections are completed, the tool will automatically generate a food defense plan. The sections for operators to populate include:

- Facility Information
- Product/Process Descriptions
- Vulnerability Assessments
- Mitigation Strategies
- Food Defense Monitoring Procedures
- Food Defense Corrective Actions Procedures
- Food Defense Verification Procedures
- Supporting Documents
- Food Defense Plan Signatures

4/ Note, FDA specifically states that use of the tool does not guaranty the food defense plan is compliant with the applicable IA Rule requirements.

5/ FDA Revised Draft Guidance, Mitigation Strategies to Protect Food Against Intentional Adulteration: Guidance for Industry (March 2019) https://www.fda.gov/media/113684/download

6/ Individuals who prepare the food defense plan, conduct the vulnerability assessment, identify and write the written explanations for mitigation strategies, and perform reanalysis (or oversee these activities) must be qualified individuals (i.e., have the training, education, or experience necessary to perform these tasks), and have successfully completed training for the specific activity at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or be otherwise qualified through job experience to conduct the activities. Job experience may qualify an individual to perform these functions if such experience has provided an individual with knowledge at least equivalent to that provided through the standardized curriculum.

7/ Available for download at https://www.cfsanappsexternal.fda.gov/scripts/fdplanbuilder/default.cfm.

In terms of privacy and confidentiality, the FDPB exists solely as a desktop tool that resides only on the user's computer. FDA does not track or monitor its use, and does not have access to any content or documents saved using the tool. FDA also had made it clear that while the content of the tool is aligned with and tracks the requirements under the regulations, its use does not mean that a food defense plan created using the tool is approved by the FDA or compliant with the applicable IA Rule requirements.

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We will continue to monitor FDA's implementation of FSMA and the IA Rule. Please contact us if you have any questions.