

How to Download

The Food Defense Plan Builder v2.0 can be downloaded free of charge from FDA's website at <https://www.fda.gov/food/food-defense>



Have Questions?

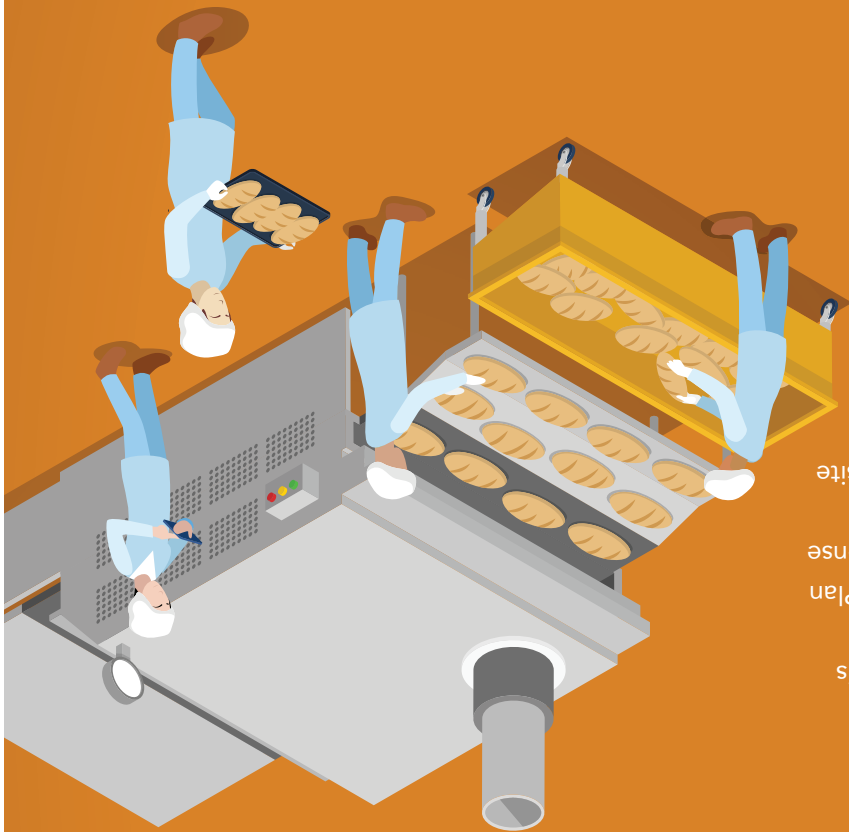
If you have additional questions or need more information, please email fooddefense@fda.hhs.gov

System Requirements

For the Food Defense Plan Builder (FDPB) v2.0 to operate correctly, your computer configuration must meet the minimum requirements outlined in the table below. FDPB v2.0 will only work on the Microsoft Windows operating system. It does not work on MAC, Chrome, or any other operating systems.

Components	Minimum	Recommended
Computer	2.80 GHz	3.0 GHz
RAM	1 GB	2 GB
Hard Disk Space	100 MB	125 MB
Operating System	Windows 7	Windows 7, 8.1 and 10
.NET	4.5	4.5 Full
Graphics Card	SXGA+	SXGA+

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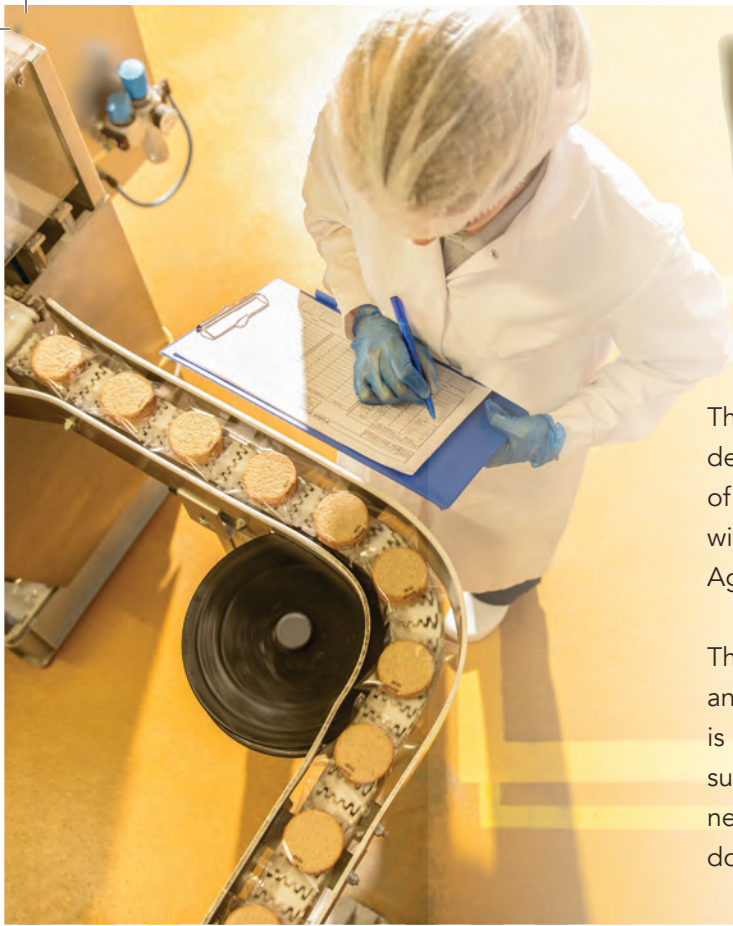


Although the content of the Food Defense Plan Builder v2.0 is consistent with the Food and Drug Administration's (FDA) existing regulations and guidance, use of the Food Defense Plan Builder v2.0 does not constitute FDA approval of a food defense plan or guarantee compliance with FDA's requirements. Please see the full FDPB v2.0 Legal Disclaimer on FDA's website at <https://www.fda.gov/food/food-defense>.

Disclaimer



FDA's FREE software tool to help you develop a food defense plan.



A food defense plan is a set of written documents that is based upon food defense principles and incorporates a vulnerability assessment, includes mitigation strategies, and delineates food defense monitoring, corrective action, and verification procedures to be followed.



The Food Defense Plan Builder (FDPB) version 2.0 is a user-friendly tool designed to help owners and operators of a food facility in the development of a food defense plan that is specific to their facility and may assist them with meeting the requirements of the Mitigation Strategies to Prevent Food Against Intentional Adulteration regulation (21 CFR Part 121) (IA rule).

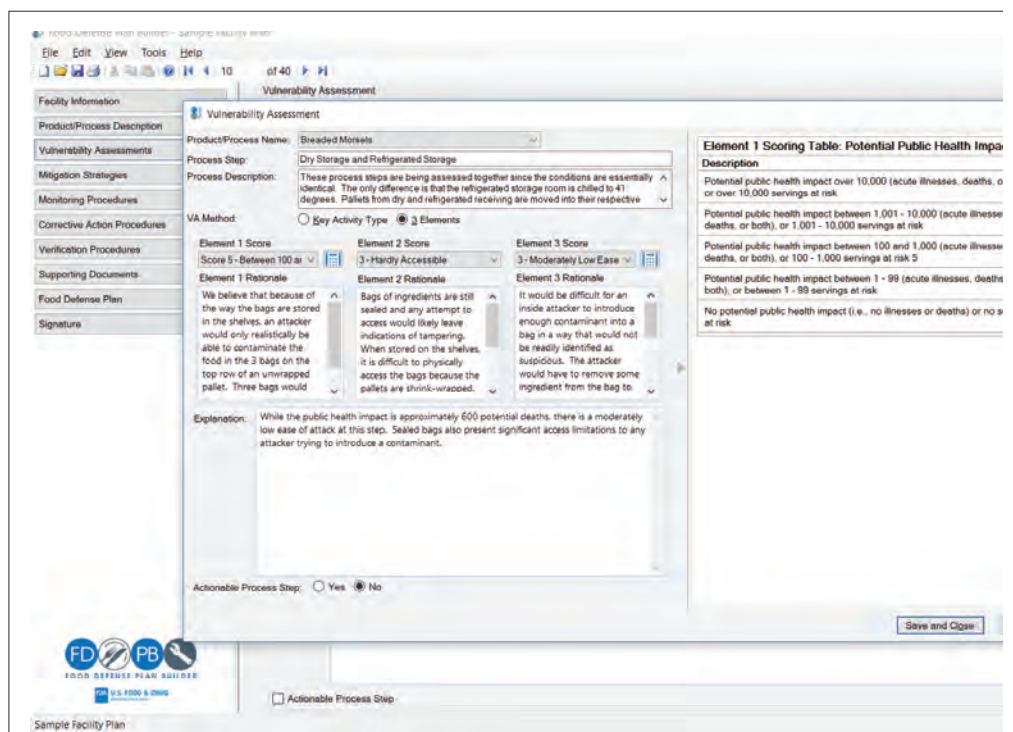
This desktop software program harnesses existing FDA tools, guidance, and resources for food defense into one single application. Use of this tool is not required to comply with the IA rule. FDA expects the FDPB to supplement and not replace other education, training, and experience needed to understand and implement the requirements of the IA rule. FDA does not have access to the information that users input or store in the tool.

The Food Defense Plan Builder guides the user through the following sections:

- 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
- Signature

Features:

- Built-in vulnerability assessment calculators
- Integration with FDA's online Mitigation Strategies Database (when connected to the Internet)
- Food Defense Plan format aligns with FDA's guidance
- Spell Check



Screenshot of Vulnerability Assessment section.

Product/Process Name	Mitigation Strategy	Monitoring Procedures and Frequency	Corrective Action Procedures	Verification Procedures	Records
1a) Liquid ingredient storage tank	Use a lock to secure access hatch on ingredient storage tank. Keys to the lock are held in the security office and can only be retrieved with good reason and approval from the facility security manager or food defense coordinator.	Employee assigned to ingredient storage observes whether the lock is in place and locked at the beginning and end of the tank's 48-hour cleaning cycle. Frequency: At the end of 48-hour cleaning cycle.	If lock is not locked, properly engage lock, and restrain employee on proper lock use. If lock is broken, replace lock.	QA technician reviews tank observation records to verify monitoring (weekly), and reviews correction action log (weekly). Review records to verify reanalysis every 3 years and when required by 21 CFR 121.157(b).	Liquid storage tank observations record Corrective actions log Food defense verification log
2a) Bulk liquid receiving	Use tamper-evident seals on inbound shipping conveyances. Match the numbers on the seals with the numbers provided on the shipping documentation from the supplier. If the seals do not match, the load will be rejected to prevent potentially adulterated ingredient from entering the facility.	Technician assesses whether the seal is intact and matches seal on documentation numbers upon arrival of the load, before hooking up the hose for each delivery. Frequency: Upon arrival of load and before hooking up the hose for each delivery.	If seals do not match, are broken, or are missing, the load will be rejected.	Supervisor reviews receiving/delivery paperwork, and reviews corrective actions log (monthly). Review records to verify reanalysis every 3 years and when required by 21 CFR 121.157(b).	Food defense corrective actions log
2b) Bulk liquid receiving	Use tamper-evident tape on hose ends after capping.	After daily operations, supply chain supervisor confirms that the hose caps are on and taped. Frequency: After daily operations.	If caps are broken, replace caps. Clean and flush hose. If tape is ripped, reapply tape. Clean and flush hose. Retrain employee on capping and tape use.	Supervisor reviews monitoring and corrective action logs (weekly). Review records to verify reanalysis every 3 years and when required by 21 CFR 121.157(b).	Food defense monitoring log Food defense corrective actions log

Screenshot of sample Mitigation Strategies Management Components section of the Food Defense Plan.

Element 1 Calculator

Product/Process Name: Breaded Morsels

Process Step: Bulk Liquid Storage

Volume of Food at Risk Representative Contaminant Approach

Batch Size	Qty: 50000	Unit: gallons
Amount of Product (Ingredient) in Final Serving	Qty: 1	Unit: cups
Servings per Batch	Qty: 800,000	
Mortality Rate	Qty: 50	%
Number of Deaths	Qty: 400,000	
Public Health Impact Score	Qty: 10	

Update Score Clear Data Close

Screenshot of Vulnerability Assessment Element 1 Calculator.