



Food Defense Plan Builder 2.0 vs. a Simplified Approach

September 3, 2020



Contents Comparison

Food Defense Plan Builder 2.0	Included in Simplified Approach?
Facility Name	Yes
Parent Company Name	Usually included in facility name
Facility Address	Yes
Facility City	Yes
Facility State	Yes
Country	Included in address if not domestic
Postal Code	Yes
Phone Numbers	Emergency contact numbers included
Website	No - could be added if desired
Facility Identifier Number	No - could be added if desired
Facility Description	Yes
Employee Description	No - could be added if desired
Other Description	N/A
Food Defense Team	Yes
Food Defense Team Details	Yes

Contents Comparison (continued)

Food Defense Plan Builder 2.0	Included in Simplified Approach?
CH 3 Product/Process Description	Yes
CH 4 Vulnerability Assessment (<i>You can enter the process steps for a product/process and determine which process steps are actionable process steps using either the Key Activity Types method, 3 Elements, or a combination of the two (also known as the Hybrid Approach).</i>)	Yes
- enter the process steps. Choose the VA method.	Yes
- Select KAT or not a KAT	Yes
- - when using 3 Elements the program has calculators for determining a score	Yes - Worksheet 1-E
- - Element 1 Calculator (potential public health impact)	Yes - Worksheet 1-E
Volume of food at risk	Yes - Worksheet 1-E
Batch Size	Yes - Worksheet 1-E
amt of product in final serving	Yes - Worksheet 1-E

Contents Comparison (continued)

Food Defense Plan Builder 2.0	Included in Simplified Approach?
- Element 3 Calculator (<i>calculates the Amount of Representative Contaminant Needed per Batch. Unlike the Element 1 Calculator, the Element 3 Calculator does not automatically provide a score for Element 3. You will use Amount of Representative Contaminant Needed per Batch and the Element 3 Scoring Table to help you in the analysis and determination of the score for Element 3. </i>)	Yes - Worksheet 1-E
CH 5 Mitigation Strategies (The FDPB has the option to access and search for mitigation strategies on FDA's online Food Defense Mitigation Strategies Database (FDMSD) and allows you to incorporate content directly from the FDMSD to your food defense plan.)	Yes - if required
CH 6 Monitoring Procedures (<i>...allows you to identify and document monitoring procedures, the monitoring frequency, and the name(s) and stored location(s) of your monitoring records. </i>)	Yes - if required
CH 7 Corrective Action Procedures (<i>...allows you to identify and document corrective action procedures and the name(s) and stored location(s) of your monitoring records. </i>)	Yes - if required

Contents Comparison (continued)

Food Defense Plan Builder 2.0	Included in Simplified Approach?
CH 8 Verification Procedures (<i>... allows you to identify and document verification procedures and list the name(s) and stored location(s) of your verification records .</i>)	Yes - if required
CH 9 Supporting Documents (<i>...allows you to add supporting documents to the food defense plan.)</i>	Yes - if required
CH 10 Food Defense Plan (<i>The content entered into the FPB is automatically compiled into a food defense plan report .</i>)	Yes - VA is incorporated into FDP
Food Defense Team	Yes
Product/Process Descriptions	Yes
Vulnerability Assessments	Yes
Mitigation Strategies	If needed
Monitoring, Corrective Action, and Verification Procedures	If needed
Supporting Document List	If needed
Education, Training and/or Experience Documentation List-	Yes
Appendix (<i>calculations from the Element 1 and Element 3 calculators will appear in the appendix)</i>	Yes
CH 11 Signature	Yes

The Simplified Approach

Element 3 Hybrid-KAT Food Defense Plan

1.0 Facility Information

- 1.1 Facility Name-
- 1.2 Address-
- 1.3 Manager-
- 1.4 Food Defense Plan Author –
- 1.5 Food Defense Team Members
 - 1.5.1 Facility: (add Bios to Appendix A)
 - 1.5.1.1
 - 1.5.2 Corporate:
 - 1.5.2.1 Global Food Defense Program Manager
 - 1.5.2.2 Food Defense Specialist

2.0 Facility Description

- 2.1 Human food products manufactured –
- 2.1 Description of processes involved –

3.0 Food Defense Training

4.0 Written identification of Actionable Process Steps

5.0 Focused Mitigation Strategies for identified Actionable Process Steps, Monitoring, Corrective Actions and Verification procedures.

6.0 Food Defense Re-Analysis of Facility

7.0 Revise this written plan if a significant change is made or document the basis for the conclusion that no additional or revised focused mitigation strategies are needed.

8.0 Required Signature ([§ 121.310](#)) may be electronically signed within PolicyTech:

(owner, operator or agent in charge of facility)

(date)

The Simplified Approach

ADM Food Defense Contact Information

In the Event of an After-hours Food Defense Emergency: |

ADM Global Security Operations Center: 217-424-5205

General Food Defense Contacts

Clint Fairow
Global Food Defense Manager

Work Phone: 217-451-5023 Cell 217-419-2760
Email: clint.fairow@adm.com

Lehman Waisvisz
Food Defense Specialist

Work Phone: 217-451-3521 Cell 217-855-9808
Email: lehman.waisvisz@adm.com

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Key Activity Type Food Defense Vulnerability Assessment: Ingredients & Processing Aids

Ingredient or Process Aid	Key Activity Type?				APS? Y/N			
	Receiving	Storage	Staging	Addition	Receiving	Storage	Staging	Addition
Ingredient A	1	2	d	d	5	5	N	N
Ingredient B	1	2	d	d	5	5	N	N
Processing Aid 1	b	b	d	d	N	N	N	N
Processing Aid 2	b	b	d	d	N	N	N	N
Etc.								
Legend:								
a - received in tamper-evident sealed packaging.								
b - under pressure, inaccessible.								
c - stored in original tamper-evident sealed packaging - no partials								
d - automated system								
1 - KAT: Bulk liquid receiving and loading								
2 - KAT: Liquid storage and handling								
3 - KAT: Secondary ingredient handling								
4 - KAT: Mixing, homogenizing, grinding or coating								
5 - Element 3 calculation (Appendix B) reveals that the quantity of the FDA's Representative Contaminant required for a successful adulteration from this point in the process is excessive. Element 3 = 1.								

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Key Activity Type Food Defense Vulnerability Assessment: Process Steps

Product:

Facility Name:

Address:

Date of Assessment:

Assessment Performed by:

KEY ACTIVITY TYPE DESCRIPTIONS

1. Bulk liquid receiving and loading – Bulk liquid receiving at the facility from an inbound conveyance (the inbound movement of liquid product into a facility for its use in the food production process). This activity includes opening the inbound transport vehicle, the opening of venting hatches or other access points, attaching any pumping equipment or hoses, and unloading of the bulk liquid; Bulk liquid loading into an outbound conveyance (the outbound movement of liquid product from a facility for further processing or use). Loading includes opening the outbound transport vehicle, attaching any pumping equipment or hoses, and opening any venting hatches at the facility.

2. Liquid storage and handling – Storage or holding of liquids (bulk or non-bulk) either in storage tanks or in other tanks at the facility. This includes bulk or non-bulk liquids in storage silos. The KAT also includes the use of totes or other liquid storage containers where the tamper-evident seals are opened and the container itself is used for storage and where the container is not resealed in a tamper-evident fashion. Tanks can be used to store liquid ingredients (e.g., fats, oils, vitamin mixes, and sweeteners), hold liquid product for sample testing and other quality control activities, or to store liquid food for other processing purposes; or

- Handling, metering, surge, or other types of intermediate processing tanks used to control flow rates of liquid ingredients or product through the production system. Handling tanks also include tanks or totes where the tamper-evident seals are opened, and the container itself is used as a handling tank (e.g., when a drum is opened and a pump is attached directly onto the drum to meter an ingredient into the product line).

3. Secondary ingredient handling – Staging of secondary ingredients, i.e., the process of opening the tamper-evident packaging of a secondary ingredient and moving the ingredient to the production area in advance of being added into the primary product stream;

- Preparation of secondary ingredients, i.e., the process of measuring, weighing, premixing, or otherwise manipulating the ingredient prior to addition to the product stream;
- Addition of secondary ingredients, i.e., the process of physically adding ingredient directly into the product stream or into surge or meter hoppers to deliver the ingredient into the product stream; or
- Rework product, i.e., removing clean, unadulterated food from processing for reasons other than insanitary conditions or that has been successfully reconditioned by reprocessing and that is suitable for use as food. This KAT also includes the storage of partially used, open containers of secondary ingredients where the tamper-evident packaging has been breached.

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4. Mixing and similar activities – Mixing (i.e., to blend a powder, dough, or liquid ingredient together);

- Homogenizing (i.e., to reduce the particle size of an ingredient and disperse it throughout a liquid);
- Grinding (i.e., to reduce the particle size of a solid ingredient or mass to a smaller granularity); or
- Coating (i.e., to layer a powder or liquid onto the surface of a product, such as a batter, breading, glazing, or flavoring).

Equipment associated with these activities include: mixers, blenders, homogenizers, cascade-style breaders, mills, grinders, and other similar equipment.

Instructions: Add Process Step Name. Provide a brief description of the process step being sure to indicate if the equipment design makes it impossible for a contaminant to be added at this process step (e.g., sealed unit, welded/bolted closed or operating under pressure or vacuum). Removable access control measures like hasp/padlock combinations do not make a process step inaccessible for the purpose of this assessment. Compare the process step description to the Key Activity Types above and enter the appropriate number(s). Enter the response that accurately depicts whether or not the process step is an actionable process step.

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The KAT Process Step involves actions which can be described as:

- 1) Bulk liquid receiving and loading
- 2) Liquid storage and handling
- 3) Secondary ingredient handling
- 4) Mixing, homogenizing, grinding or coating
- 5) None of the above

Yes) This process step is an Actionable Process Step because it does fit within one or more of the Key Activity Type descriptions above.

No) This process steps fits within one of the Key Activity Type descriptions above but is not an Actionable Process Step due to exceptions in Description section.

Process Step	Description	KAT?	APS ?
Process Step 1	Not a Key Activity Type	5	
Process Step 2	Dust removal via aspiration. Not a Key Activity Type	5	
Secondary Mixer	Mixes ingredient; mixer is enclosed with no access points. Inaccessible.	4	No
Liquid Storage	Liquid Storage Tank Element 3 calculation (Appendix B) reveals that the quantity of the FDA's Representative Contaminant required for a successful adulteration from this point in the process is excessive. Element 3 = 1	2	No
Truck Loadout	Liquid Loadout of product xxxxxxxxxxxx Element 3 calculation (Appendix B) reveals that the quantity of the FDA's Representative Contaminant required for a successful adulteration from this point in the process is excessive. Element 3 = 1	1	No

The Simplified Approach

Appendix A: Qualifications of Persons Performing or Overseeing the Vulnerability Assessment, Preparing the Food Defense Plan and Identifying and Explaining Mitigation Strategies.

Corporate Food Defense Team Members:

Clint Fairow earned a B.S. in Zoology with a Chemistry Minor and an M.S. in Environmental Biology from Eastern Illinois University Charleston IL. He pursued post-graduate studies in Toxicology at the University of Illinois, Urbana and recently earned a Master's in Public Health from the University of Illinois-Springfield. Clint is currently the Food Defense Manager at Archer Daniels Midland Company. His work since late 2010 has focused on assessing the risk of intentional contamination of the foods produced using a probabilistic risk assessment model. The modeling incorporates information on physical and chemical limitations of potential contaminants and the processing parameters to which they would be subjected.

Lehman Waisvisz earned a B.A in Biological Sciences at Southern Illinois University, Carbondale IL; a B.S. in Food Industry at the University of Illinois in Urbana-Champaign and a Graduate Certificate in Agricultural Biosecurity and Food Defense from Pennsylvania State University. He works with Clint Fairow assessing the vulnerabilities within food manufacturing processes.

Facility Food Defense Team Members:

	Plant Manager
	Quality/Food Safety Manager
	Etc.

The Simplified Approach

Appendix B: Worksheet 1-E. Element 3: Calculating Potential Public Health Impact using a Representative Contaminant.

Facility: xxxxxxxxxxxx

Product: xxxxxxxx

Serving Size (kg): 0.03 30 grams

Finished Storage qty (Kg): 45500 100310 lbs.

Truck L/O qty (kg): 15876 35000 lbs.

Rail Carl L/O qty (kg): N/A #VALUE!

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Element 1 Calculations Using Representative Contaminant									Element 3 Calculations	
A		B	C	D	E	F	G	H	I	J
Process Step	Concentration in finished product (ppm)	Batch Size (or finished storage qty.) in Kg	Amount of Product (ingredient) in Final Serving. (Concentration in finished product x Serv Size) Kg	Product Servings per batch (B/\$F\$5)	Mortality Rate of Contaminant (FDA provided value = 50%)	Number of Potential Deaths (D x E)	Score from Table 1	Notes	Representative Contaminant Dose Needed per Serving (FDA provided value = 40 mg or 0.00004 kg)	Amount of Representative Contaminant Needed per Batch (D x I). kg
Ingredient A	150000	45500	0.0045	1516666	0.5	7.58E+05	10		0.00004	60.67
Ingredient B	1000000	45500	0.03	1516666	0.5	7.58E+05	10		0.00004	60.67
Processing Aid 1	1000	45500	0.00003	1516666	0.5	7.58E+05	10		0.00004	60.67
Processing Aid 2	500	45500	0.000015	1516666	0.5	7.58E+05	10		0.00004	60.67
Process Step 1	1000000	45500	0.03	1516666	0.5	7.58E+05	10		0.00004	60.67
Process Step 2	1000000	45500	0.03	1516666	0.5	7.58E+05	10		0.00004	60.67
Liquid Storage	1000000	45500	0.03	1516666	0.5	7.58E+05	10		0.00004	60.67
Truck Loading	1000000	15876	0.03	529200	0.5	2.65E+05	10		0.00004	21.17
Note: 1000000 indicates evaluation as if this constitutes 100% of the finished product; most severe outcome.										

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Appendix B: Worksheet 1-E. Element 3: Calculating Potential Public Health Impact using a Representative Contaminant.

Facility: xxxxxxxxxxxx

Product: xxxxxxxx

Serving Size (kg): 0.3402 340 grams

Finished Storage qty (Kg): 45000 99207 lbs.

Truck L/O qty (kg): 28000 61729 lbs.

Rail Carl L/O qty (kg): N/A #VALUE!

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Element 1 Calculations Using Representative Contaminant									Element 3 Calculations	
A		B	C	D	E	F	G	H	I	J
Process Step	Concentration in finished product (ppm)	Batch Size (or finished storage qty.) in Kg	Amount of Product (ingredient) in Final Serving. (Concentration in finished product x Serv Size) Kg	Product Servings per batch (B/\$F\$5)	Mortality Rate of Contaminant (FDA provided value = 50%)	Number of Potential Deaths (D x E)	Score from Table 1	Notes	Representative Contaminant Dose Needed per Serving (FDA provided value = 40 mg or 0.00004 kg)	Amount of Representative Contaminant Needed per Batch (D x I). kg
Ingredient A	282142	45000	0.095984708	132275	0.5	6.61E+04	10		0.00004	5.29
Ingredient B	1000000	45000	0.3402	132275	0.5	6.61E+04	10		0.00004	5.29
Processing Aid 1	1000	45000	0.0003402	132275	0.5	6.61E+04	10		0.00004	5.29
Processing Aid 2	500	45000	0.0001701	132275	0.5	6.61E+04	10		0.00004	5.29
Process Step 1	1000000	45000	0.3402	132275	0.5	6.61E+04	10		0.00004	5.29
Process Step 2	1000000	45000	0.3402	132275	0.5	6.61E+04	10		0.00004	5.29
Liquid Storage	1000000	45000	0.3402	132275	0.5	6.61E+04	10		0.00004	5.29
Truck Loading	1000000	28000	0.3402	82304	0.5	4.12E+04	10		0.00004	3.29
Note: 1000000 indicates evaluation as if this constitutes 100% of the finished product; most severe outcome.										

Thank You

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