Food Defense Plan Builder 2.0 vs. a Simplified Approach

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Contents Comparison

- The Simplified Approach shares many of the attributes of the Food Defense Plan Builder 2.0
  - Basic elements that are included:
    - Facility Name
    - Address Name/Parent Company Name
    - Facility Address (City/State/Country/Postal Code)
    - Phone Numbers
    - Facility Description
    - Food Defense Teams listed
      - Corporate level
      - Facility Level
    - Product and Process Description
    - Vulnerability Assessment
    - Education, Training and/or Experience Documentation List
    - Signature

Contents Contrast – Simplified Approach additions

- A section where Food Defense Training Information is to be added
- A section that lists the requirements for Re-analysis
- A section that reminds the facility operator to connotate if a revision is necessary

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- A table that condenses processing aids and ingredient listings with a legend
- The listing of the KATS out of the March 2019 Revised Guidance
- A slightly modified version of Worksheet 1-E : Use of the Hybrid approach
- Using all the options available for analysis
    - KAT approach
    - 3 Elements approach
    - Representative Contaminate approach
    - Revised Guidance on page 57
- If all else fails; need Mitigation Strategies

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

	Key Activity Type?				APS? Y/N			
Ingredient or Process Aid	**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.

The listing of the KATS out of the March 2019 Revised Guidance

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.
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 for filling out Process Steps

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.

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 xxxxxxxxxxx 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

A modified version of Worksheet 1-E

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

Facility: **xxxxxxxxxxx**
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/F5)	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.									

Using of all the Hybrid approach elements

1. Determine if the processing aid/ingredient is a Key Activity Type
    1. If not a KAT; explanation is “Not a Key Activity Type”

2. Determine if the identified Key Activity Type scores a “1” on the 3 Element test
    1. If any element scores a “1”; not a significant vulnerability; not an APS

3. Use the modified worksheet 1-E to calculate value of the Representative contaminant
    1. If the value exceeds “8 Kg”; not an APS; Element 3 scores a “1”.

4. Refer to page 57, Chapter 2, Subsection F of the March 2019 Revised Guidance document
    1. If the value is below “8 Kg”; justify reasoning why its not an APS

5. Create Mitigation Strategies, with corresponding monitoring, corrective actions, and verifications

Thank You

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