農林水産省補助事業

米国食品安全強化法

「意図的な食品不良事故防止」規則にかかる食品防御計画雛形（冷凍チャーハン）＜英語原文＞第２版

2020 年 3 月

日本貿易振興機構（ジェトロ）

シカゴ事務所

農林水産・食品部　農林水産・食品課

本資料は、2016 年 5 月 27 日に公表された米国食品安全強化法「意図的な食品不良事故防止」規則に関して、米国の弁護士事務所 Olsson Frank Weeda Terman Mats PC(OFW)に委託して食品防御計画の雛形（冷凍チャーハン）を作成、2020 年 3 月に第 2 版として更新したものです。

お役立ち度アンケートへのご協力のお願い

ジェトロでは、米国食品安全強化法（FSMA）への対応の参考とすることを目的に本調査報告書を実施しました。ぜひお役立ち度アンケートにご協力をお願いいたします。

◆本報告書のお役立ち度　（必須）

□役に立った　□まあ役に立った　□あまり役に立たなかった　□役に立たなかった

その理由をご記入ください。

◆本報告書をご覧になり、実際にビジネスにつながった例がありましたらご記入ください。（任意）

◆今後のジェトロの調査テーマについてご希望等がございましたら、ご記入願います。（任意）

◆貴社・団体名（任意）

◆お名前（任意）

◆メールアドレス（任意）

◆企業規模　（必須）　　□大企業　　□中小企業　　□その他

FAX 送信先：03-3582-7378　ジェトロ農林水産・食品課宛

本アンケートはインターネットでもご回答頂けます

（ https://www.jetro.go.jp/form5/pub/afa/fsma_ia ）

※お客様の個人情報につきましては、ジェトロ個人情報保護方針に基づき、適正に管理運用させていただきます。また、上記のアンケートにご記載いただいた内容については、ジェトロの事業活動の評価および業務改善、事業フォローアップ、今後の調査テーマ選定等の参考のために利用いたします。

【報告書名：米国食品安全強化法「意図的な食品不良事故防止」規則にかかる食品防御計画雛形（冷凍チャーハン）
＜英語原文＞第２版】

はじめに

本調査報告書は、2016 年 5 月 26 日に公表された米国食品安全強化法「意図的な食品不良事故防止」に関して、食品防御計画の作成のための参考資料として、「冷凍チャーハン」を例に作成した雛形（第 2 版）である。

意図的な食品不良事故防止等に係る最終規則は、食品医薬品局（FDA）に施設登録が必要な米国内外の食品関連施設（食品の製造／加工、梱包、保管施設）の所有者、運営者または代理人に、食品防御計画（Food Defense Plan）の中で、広く公共の健康被害をもたらす目的で行われる異物混入等の食品不良事故が起こりそうな工程等を特定させ、事故予防・軽減のための実行可能な対策（緩和戦略）を講じさせることを狙いとしている。

これまで米国においては、意図的な汚染から食品を防御するための緩和戦略、または措置を実施するよう食品施設に義務付ける要求事項はなかったため、適用対象となる施設は、新たに対応が求められることになる。本規則の原則の適用期日は 2019 年 7 月 26 日であり、従業員 500 人未満の企業についても 2020 年 7 月 26 日、過去 3 年の年間食品売上高平均 1,000 万ドル未満の企業も 2021 年 7 月 26 日からであるため、対応を進めておくことが重要となる。

食品防御計画の様式は自由だが、本調査報告書では、FDA が公表している産業界向けガイダンス案のワークシートや、「食品防御計画作成支援ツールーFood Defense Plan Builder」をもとに作成することとした。第 4 章「脆弱性評価、実行可能な工程段階、およびリスク低減策」においては、３つの基本要素を用いた脆弱性評価の方法と、それを用いない方法の両方を紹介した。食品防御計画は、それぞれの施設によって施設のレイアウトや設備、製品、製造工程などは個々に異なるため、本報告書に記載された内容はあくまで一例である。実際の事業者の食品防御計画は、この雛形に、施設固有の管理すべき脆弱性や食品防御手順を修正・追加することによって、適切なものとなる点に留意いただきたい。

本調査報告書が、米国食品安全強化法（FSMA）への対応の参考となれば幸いである。

2020 年 3 月
日本貿易振興機構（ジェトロ）
シカゴ事務所
農林水産・食品部　農林水産・食品課

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JETRO MODEL FOOD DEFENSE AND VULNERABILITY ASSESSMENT PLAN

Rock Creek Incorporated Frozen Fried Rice Company
2345 Jasmine Road
Rapid Rock, Virginia, 45454

Ⅰ. FOOD DEFENSE PLAN MODEL

Note: Each facility is unique and should use its facility blueprint and production flowchart

1. Food Manufacturing Facility Background Information

1.1. Overhead Picture of the Facility Grounds & Building(s)

(Insert Google Earth Overhead Picture of the Manufacturing Facility and Surrounding Grounds)

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1.2. History, Background and Detailed Information of the Facility

Profile					
Manufacturing Facility Name: :					
Manufacturing Facility Address :		CITY & COUNTRY :		Postal Code :	
PRODUCT (S) MANUFACTURED AT THIS MANUFACTURING FACILITY :	Frozen fried rice prepared using steamed rice, eggs and vegetables that are cooked, mixed with seasonings and then frozen and packaged. Produce is held and shipped frozen				
Date of Food Defense Plan :		Date of Food Defense Vulnerability Assessment:		Date of Most Recent Mock Food Defense Challenge Assessment	
US FDA Food Manufacturing Facility Registration Number	[Fill in _____] *(Note: The registration must be managed by a US Agent and updated once every 2 years by the US Agent located in the US.)*				

General Information on the Facility Structure Size, Construction, and Design	
Year Built	
Year(s) for any Remodeling or New Addition(s) Projects	
Manufacturing Facility Size (ft^2 or mt^2)	
Describe Neighboring Land Use (industrial, commercial, residential, etc.)	
Utilities:	
Source of Water	
Describe & Identify All On-Site Water Storage Tanks and Reservoirs with their Location(s)	
Describe all On-Site Water Treatment Including Filtration	
Describe all On-Site Wastewater Treatment	

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Identify the Source of Electrical Power	
Identify Source(s) for Primary Heating and Generating Hot Water (boiler, etc.)	
Identify All Fuels Stored On-Site and Location of Storage Tanks and Silos (coal, natural gas, oil, etc.)	
Describe the Air Ventilation System Including the Location of All Intake Ducting	
Building Materials *(identify the type of building material(s))*:	
Exterior Walls	
Internal Walls	
Interior Floors	
Roof	
Number of Exterior Doors	
Number of Exterior Windows	

1.3. Product and Process Information

Overview of site, operation, scope of Product(s) Produced	
Provide a Short, Written Description of the Processing Product：	
Describe in Detail the Product Packaging:	
Identify the Sizes of Food Packaging:	
Days & Hours of Operation:	
Number of Processing Employees:	

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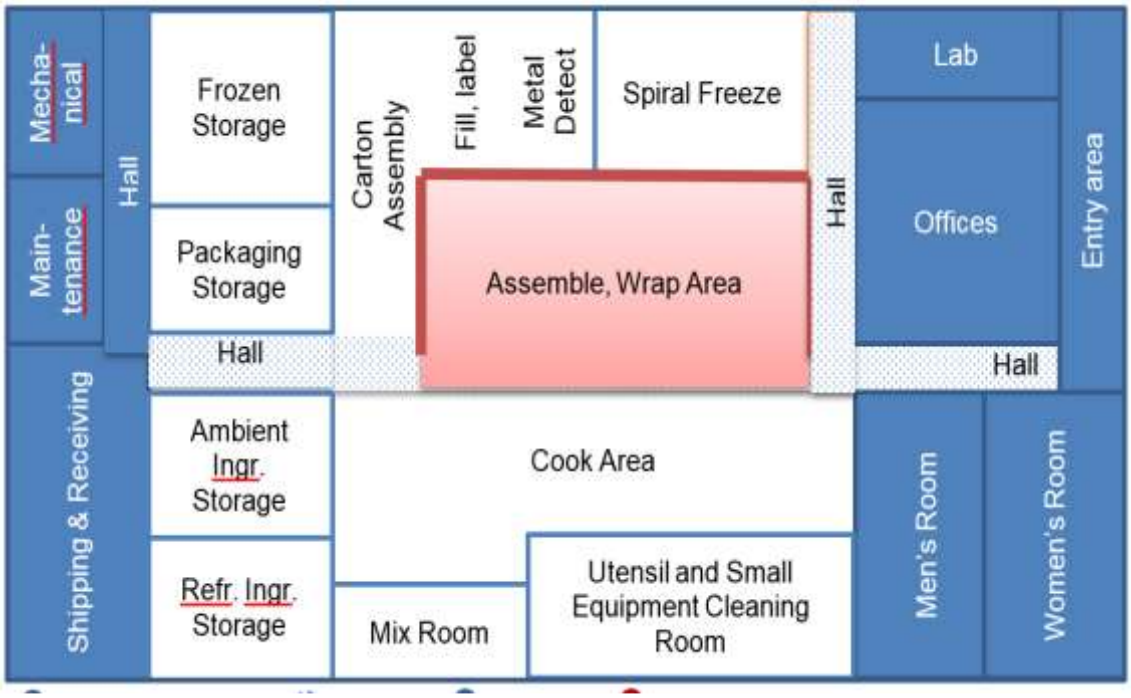
1.4. Floor Diagram(s) of all Storage and Manufacturing Facilities

(Insert Manufacturing Facility Layout Diagram with all internal and external doors, windows and roof access points identified)



1.5. Examples of Typical Frozen Fried Rice Facility With a Potential Impact on Its Food Defense Vulnerability

- The facility does not currently have an outside perimeter fence and employees and visitors park in designated parking spots around the facility. Trucks leaving and delivering supplies pull to the back of the building where the loading docks are located off the shipping and receiving area.
- Employees enter through the marked employee entrance which currently has no guard and no camera to monitor who is entering or leaving. Currently there are no employee key cards to use when accessing the facility or to access various areas in the facility.
- There are various separate storage areas that all have doors but none of them currently lock.
- Much of the production area is open and all employees must travel through the production area to access all areas of the facility.

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- The sanitation chemical storage room is under lock and key. However, a facility must determine whether there are other chemicals or ingredients that should also be maintained under lock and key
- There is a laundry room located next to the Men's Room where all frocks, maintenance clothing, gloves, etc., are laundered in the facility so nothing is removed from the facility by any of the employees.
- Based on the facility blueprint, decisions were made on what actions needed to be taken to provide better food defense. These are the actions noted in the "Action Plan" portion. Timelines that were added as well as the facility manager responsible for overseeing the implementation of the action.
- The "Accessibility" and "Vulnerability" scores were determined using the flow chart for the frozen fried rice as well as the facility blueprint. The scores are based on the FDA Food Defense Plan Builder "Accessibility and Vulnerability Assessment Wizard." This is a decision-making tool used to determine the accessibility and vulnerability for each step in a product flow chart. For each step, the score is determined based on the attached definitions used by FDA.

1.6 Emergency Contact Information

(1) Company and Emergency Contact Information

	Name	Email & Phone	Title
Manufacturing Facility Management Information:	○○ ○○	Email：XXX@xxx.xx Phone：xx-xxxx-xxxx	General/Plant Manager
	△△ △△	Email：XXX@xxx.xx Phone：xx-xxxx-xxxx	Assistant Manager
	□□ □□	Email：XXX@xxx.xx Phone：xx-xxxx-xxxx	Quality Assurance
	AA AA	Email：XXX@xxx.xx Phone：xx-xxxx-xxxx	Food Safety Manager
	BB BB	Email：XXX@xxx.xx Phone：xx-xxxx-xxxx	Facility or Maintenance Engineer
	CC CC	Email：XXX@xxx.xx Phone：xx-xxxx-xxxx	Sanitation Manager
	DD DD	Email：XXX@xxx.xx Phone：xx-xxxx-xxxx	Production Supervisor
	EE EE	Email：XXX@xxx.xx Phone：xx-xxxx-xxxx	Production Shift Supervisor #1
	FF FF	Email：XXX@xxx.xx Phone：xx-xxxx-xxxx	Production Shift Supervisor #2

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	GG　GG	Email：XXX@xxx.xx Phone：xx-xxxx-xxxx	Production Shift Supervisor #3
Food Defense Team	○○　○○	Email：XXX@xxx.xx Phone：xx-xxxx-xxxx	Team Leader
	△△　△△	Email：XXX@xxx.xx Phone：xx-xxxx-xxxx	Team Member #1
	□□　□□	Email：XXX@xxx.xx Phone：xx-xxxx-xxxx	Team Member #2
	AA　AA	Email：XXX@xxx.xx Phone：xx-xxxx-xxxx	Team Member #3
	BB　BB	Email：XXX@xxx.xx Phone：xx-xxxx-xxxx	Team Member #4
	DD　DD	Email：XXX@xxx.xx Phone：xx-xxxx-xxxx	Team Member #5

(2)　GOVERNMENT EMERGENCY CONTACTS

Contacts	Phone
Local Medical Hospital	9-1-1
City Police Department	XX-XXXX-XXXX
City Fire Department or Emergency Management Office	XX-XXXX-XXXX
Prefecture Law Enforcement Agency	XX-XXXX-XXXX
Prefecture Emergency Management Office	XX-XXXX-XXXX
Prefecture Department of Health	XX-XXXX-XXXX
National Poison Control Center	XX-XXXX-XXXX
National Police Emergency #	XX-XXXX-XXXX
National Police Non-Emergency Phone #	XX-XXXX-XXXX
US FDA 24 Hour Emergency Phone #	1-866-300-4374　or 301-796-8240
US FBI 24 Hour Emergency Phone #	(202)324-3000

(3)　PRIVATE EMERGENCY CONTACTS:

①Company Emergency Contacts

Name	Title	Phone
○○　○○	○○	XX-XXXX-XXXX

②Supplier Contacts

Company Name	Phone	Contact Persone(s)
○○○	XX-XXXX-XXXX	○○　○○

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③Customer Contacts

Company Name	Phone	Contact Persone(s)
○○○	XX-XXXX-XXXX	○○　○○

④Contractor Contacts

Company Name	Phone	Contact Persone(s)
○○○	XX-XXXX-XXXX	○○　○○

⑤Other Contacts

Company Name	Phone	Contact Persone(s)
○○○	XX-XXXX-XXXX	○○　○○

Signature： _____

Date Signed： _____

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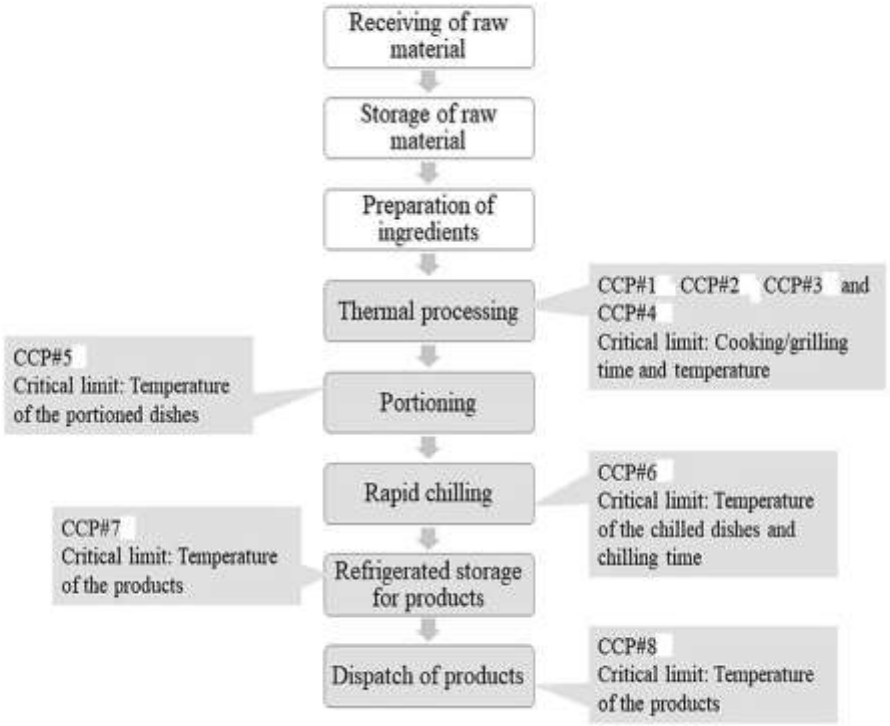
2. EXAMPLE OF FROZEN FRIED RICE PROCESS FLOW DIAGRAM & NOTES:

EXAMPLE ONLY:
HACCP PROCESS FLOW DIAGRAM FOR MIXED RICE DISH WITH COOKING AND REFRIGERATION STEPS



NOTES:

1. *"CCP" is Critical Control Point*
2. *This Process Flow Diagram is only an example and originates from the International Journal of Gastronomy and Food Science, Volume 19, April 2020, 100193, "Modernizing the Preparation of the Malaysian Mixed Rice Dish with Cook-Chill Central Kitchen and Implementation of HACCP", Authors: Noor Zafira, NoorHasnana and Sharifah Hafiza Mohd Ramlib*
3. *Develop the Process Flow Diagram specific to the Manufacturer's actual processes that include the receipt and storage of all raw materials, ingredients, packaging; blending, cooking, cooking, packaging, sealing, refrigeration or freezing, storage and distribution. Also include a narrative (see below), that clearly describes the processing for all products to be shipped to the US market.*

Signature： _____

Date Signed： _____

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3. DESCRIPTION OF FROZEN FRIED RICE PROCESS

The production method below represents the steps for preparing stir-fried cooked rice with other vegetables and ingredients including seasoning, freezing various components separately, slightly crushing them, then blending the various frozen ingredients and packaging ingredients while still frozen.

1. Receipt of raw material including:
   a. Dry materials such as rice grains, crystal sugar and seasonings
   b. Refrigerated materials such as liquid pasteurized eggs, cooking oils and fats, emulsifiers and vegetables
   c. Non-refrigerated liquids such as soy sauce and acidulants
2. Storage of raw material including:
   a. Dry materials such as rice grains and seasonings, if not used immediately upon receipt
   b. Refrigerated materials such as liquid pasteurized eggs, cooking oils and fats, emulsifiers and vegetables, if not used immediately upon receipt.
   c. Non-refrigerated liquids such as soy sauce and acidulants
3. Washing, then slicing, dicing and/or shredding of the vegetables
4. Cooking of the vegetables
5. Cooling of the cooked vegetables
6. Freezing and storage of the cooked vegetables for later use
7. Rinsing the rice grains
8. Steaming or cooking the rice grains in boiling water until soft
9. Liquid pasteurized egg and other ingredients such as salt, soy sauce, pepper, pork extract, sugars, acidulants, emulsifiers and the like added to the steamed or cooked rice grains
10. The ingredients (liquid pasteurized egg and other ingredients such as salt, soy sauce, pepper, pork extract, sugars, acidulants, emulsifiers and the like, steamed or cooked rice grains) are stir-fried.
11. The stir-fried rice is cooled and either refrigerated for later use or immediately quick-frozen.
12. The stir-fried frozen rice is ground to reduce clumping
13. The frozen vegetable pieces are ground to reduce clumping
14. The ground frozen stir-fried rice and the ground frozen vegetables are weighed to meet recipe specifications

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15. The weighed stir-fried rice and frozen vegetables are blended together
16. The stir-fried rice and frozen vegetables are packaged in a frozen state.
17. The frozen, packaged stir-fried rice with vegetables is taken immediately to a storage freezer.

The frozen, packaged stir-fried rice with vegetables is shipped to customers via refrigerated shipping containers with the capability of keeping the product frozen until arrival at the customer.

Signature： _____

Date Signed： _____

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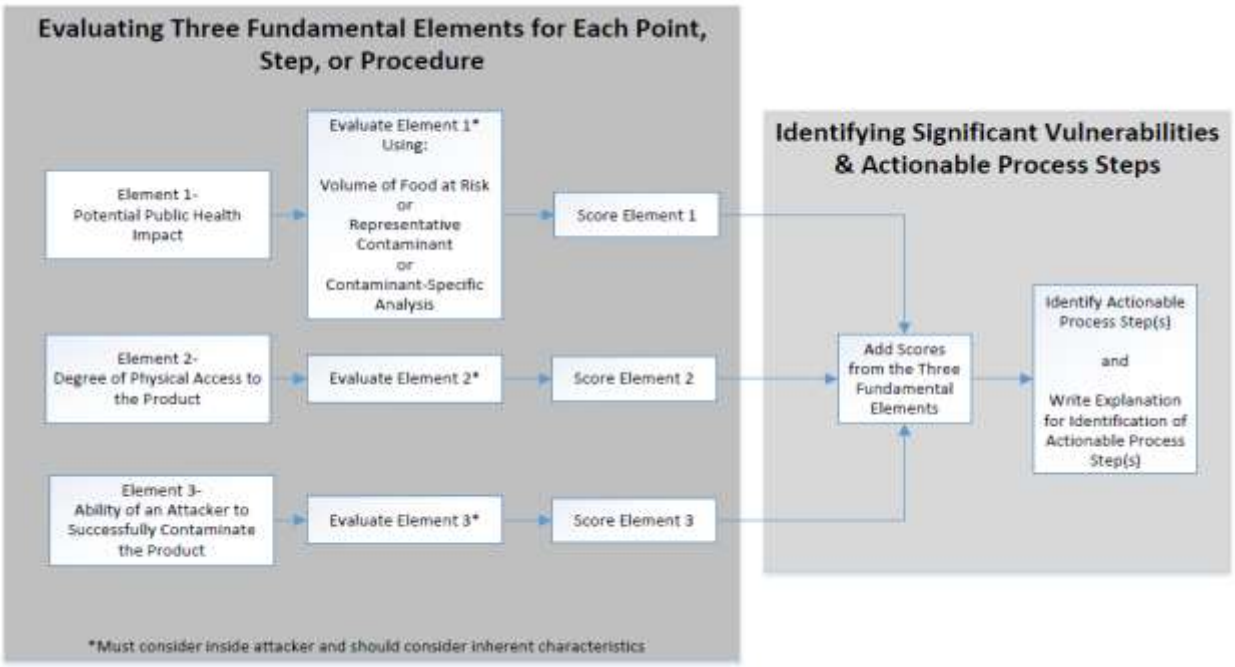
4. Vulnerability Assessment, Action Steps and Mitigation Strategy

4.1. Use & Scoring of the Three Fundamental Food Defense Elements or of Hybrid Method

4.1a. Logic Diagram for Evaluating the Three Fundamental Elements

FIgure：Logic Diagram for Evaluating the Three Fundamental Elements



**(Obtained from February 2020 Revised Mitigation Strategies to Protect Food Against Intentional Adulteration: Guidance for Industory)*

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4.1b. Hybrid Method to Identify "Action Steps" & Mitigation Strategies

Note: This is the example for the "Hybrid Method" that concentrates on primarily on processing.

Key Activity Types (KATs):

- *bulk liquid receiving and loading*
- *liquid storage and handling*
- *secondary ingredient handling*
- *mixing and similar activities*

Scoring Legend: (see Appendix for scoring references)

#1-Potential Public Health Impact – Score 1 – 10 (highest)

#2 -Degree of Physical Access to Product - Score 1 – 10 (highest)

#3-Ability by Personnel to Contaminate Product – Score 1 – 10 (highest)

#	Process Step	Score				Action Step		Justification for Element Score	Mitigation Strategy
		#1	#2	#3	Total	Yes	No		
1a	Receipt of dry materials including rice, crystal sugar and seasoning	NA	NA	NA	NA		X	Not a KAT	-
1b	Receipt of refrigerated materials such as liquid pasteurized eggs, cooking oils and fats, emulsifiers and vegetables	6	8	8	22	X		KAT - Medium potential health impact because of subsequent cooking step, higher opportunity for physical access and high ability to contaminate the finished product	Use peer monitoring (e.g., buddy system) during operations or in assigned locations; cameras and personnel identification (e.g., color coded uniforms, badges) to restrict access to location, equipment, control, and operations
1c	Receipt of non-refrigerated liquids such as soy sauce and acidulants	6	8	8	22	X		KAT - Medium potential health impact because of subsequent cooking step, higher opportunity for physical access and high ability to contaminate the finished product	Use peer monitoring (e.g., buddy system) during operations or in assigned locations, cameras and personnel identification (e.g., color coded uniforms, badges) to restrict access to location, equipment, control, and operations
2a	Storage of dry materials including rice, crystal sugar	NA	NA	NA	NA		X	Not a KAT	-

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	and seasoning								
2b	Storage of refrigerated materials such as liquid pasteurized eggs, cooking oils and fats, emulsifiers and vegetables	6	8	8	22	X		KAT - Medium potential health impact because of subsequent cooking step, higher opportunity for physical access and high ability to contaminate the finished product	Use peer monitoring (e.g., buddy system) during operations or in assigned locations, cameras and personnel identification (e.g., color coded uniforms, badges) as well as limited access door locks to restrict access to location, equipment, control, and operations
2c	Storage of non-refrigerated liquids such as soy sauce and acidulants	6	8	8	22	X		KAT - Medium potential health impact because of subsequent cooking step, higher opportunity for physical access and high ability to contaminate the finished product	Use peer monitoring (e.g., buddy system) during operations or in assigned locations, cameras and personnel identification (e.g., color coded uniforms, badges) as well as limited access door locks to restrict access to location, equipment, control, and operations
3	Washing, then slicing, dicing and/or shredding of the vegetables	6	8	8	22	X		KAT - Medium potential health impact because of the subsequent cooking step, higher opportunity for physical access and high ability to contaminate the finished product	Lower food defense risk but can use peer monitoring (e.g., buddy system) during operations or in assigned locations, cameras and personnel identification (e.g., color coded uniforms, badges) as well as limited access door locks to restrict access to location, equipment, control, and operations
4	Cooking of the vegetables	NA	NA	NA	NA		X	Not a KAT	-
5	Cooling of the cooked vegetables	NA	NA	NA	NA		X	Not a KAT	-
6	Freezing and storage of the cooked vegetables for later use	NA	NA	NA	NA		X	Not a KAT	-
7	Rinsing the rice	6	8	8	22	X		KAT - Medium	Use peer monitoring (e.g.,

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	grains							potential health impact because of subsequent cooking step, higher opportunity for physical access and higher ability to contaminate the finished product	buddy system) during operations or in assigned locations, cameras and personnel identification (e.g., color coded uniforms, badges) as well as limited access door locks to restrict access to location, equipment, control, and operations
8	Steaming or cooking the rice grains in boiling water until soft	NA	NA	NA	NA		X	Not a KAT	-
9	Liquid pasteurized egg and other ingredients such as salt, soy sauce, pepper, pork extract, sugars, acidulants, emulsifiers and the like added to the steamed or cooked rice grains	6	8	8	22	X		KAT - Medium potential health impact because of the cooking process, high opportunity for physical access and high ability to contaminate the finished product	Use peer monitoring (e.g., buddy system) during operations or in assigned locations, cameras and personnel identification (e.g., color coded uniforms, badges) as well as limited access door locks to restrict access to location, equipment, control, and operations
10	The ingredients (liquid pasteurized egg and other ingredients such as salt, soy sauce, pepper, pork extract, sugars, acidulants, emulsifiers and the like, steamed or cooked rice grains) are stir-fried.	NA	NA	NA	NA		X	Not a KAT	-
11	The stir-fried rice is cooled and either	NA	NA	NA	NA		X	Not a KAT	-

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	refrigerated for later use or immediately quick-frozen.								
12	The stir-fried frozen rice is ground to reduce clumping	8	8	8	24	X		KAT - High potential health impact, higher opportunity for physical access and high ability to contaminate the finished product	Use peer monitoring (e.g., buddy system) during operations or in assigned locations, cameras and personnel identification (e.g., color coded uniforms, badges) as well as limited access door locks to restrict access to location, equipment, control, and operations
13	The frozen vegetable pieces are ground to reduce clumping	8	8	8	24	X		KAT - High potential health impact, higher opportunity for physical access and high ability to contaminate the finished product	Use peer monitoring (e.g., buddy system) during operations or in assigned locations, cameras and personnel identification (e.g., color coded uniforms, badges) as well as limited access door locks to restrict access to location, equipment, control, and operations
14	The ground frozen stir-fried rice and the ground frozen vegetables are weighed to meet recipe specifications	8	8	8	24	X		KAT - High potential health impact, higher opportunity for physical access and high ability to contaminate the finished product	Use peer monitoring (e.g., buddy system) during operations or in assigned locations, cameras and personnel identification (e.g., color coded uniforms, badges) as well as limited access door locks to restrict access to location, equipment, control, and operations
15	The weighed stir-fried rice and frozen vegetables are blended together	8	8	8	24	X		KAT - High potential health impact, higher opportunity for physical access and high ability to contaminate the finished product	Use peer monitoring (e.g., buddy system) during operations or in assigned locations, cameras and personnel identification (e.g., color coded uniforms, badges) as well as limited access door locks to restrict access to location, equipment, control, and

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									operations
16	The stir-fried rice and frozen vegetables are packaged in a frozen state.	8	8	5	21	X		KAT - High potential health impact, higher opportunity for physical access and medium ability to contaminate the finished product	Use peer monitoring (e.g., buddy system) during operations or in assigned locations, cameras and personnel identification (e.g., color coded uniforms, badges) as well as limited access door locks to restrict access to location, equipment, control, and operations
17	The frozen, packaged stir-fried rice with vegetables is taken immediately to a storage freezer.	NA	NA	NA	NA		X	Not a KAT	-
18	The frozen, packaged stir-fried rice with vegetables is shipped to customers via refrigerated shipping containers with the capability of keeping the product frozen until arrival at the customer.	NA	NA	NA	NA		X	Not a KAT	-

Signature： _____

Date Signed： _____

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4.1c. Non-Hybrid Method to Identify "Action Steps" & Mitigation Strategies

(see Appendix for scoring references)
#1-Potential Public Health Impact – Score 1 – 10 (highest)
#2 -Degree of Physical Access to Product - Score 1 – 10 (highest)
#3-Ability by Personnel to Contaminate Product – Score 1 – 10 (highest)

Note: For the "Hybrid Method", it is acceptable to focus the Vulnerability Assessment on the detailed Processing Steps as referenced in #5 in the table below. The Processing Steps including the additional of ingredients and packaging materials must be broken out into separate and details steps and the vulnerability of each step must be assessment and scored, using the table below. This approach does not require that other parts included in the table below are included in the Vulnerability Assessment. It is our recommendation that the Hybrid Approach only be used if there are very significant controls at all points in the processing of the finished frozen fried rice products.

CATEGORY	Vulnerability Assessment Elements *(see Draft Mitigation Strategies Guidance Document for Scoring Categories)*							Identify Mitigation Strategies
	#1	#2	#3	Total Element Score	Action Step		Justification for Element Score	
					Yes	No		
1. MATERIAL HANDLING *(also identifies as "Key Activity Types – KATs")*								
a. Receiving, Storage, Handling, Bulk Liquids	3	8	8	19	X		Low potential health impact because of subsequent cooking step, higher opportunity for physical	Use peer monitoring (e.g., buddy system) during operations or in assigned locations; cameras and personnel identification (e.g., color coded uniforms, badges) to restrict access to location, equipment, control, and operations

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CATEGORY	Vulnerability Assessment Elements *(see Draft Mitigation Strategies Guidance Document for Scoring Categories)*							Identify Mitigation Strategies
	#1	#2	#3	Total Element Score	Action Step		Justification for Element Score	
					Yes	No		
							access and high ability to contaminate the finished product	
b. Storage, Holding, Handling, Metering and Surging for Liquid Ingredients	3	8	8	19	X		Low potential health impact because of subsequent cooking step, higher opportunity for physical access and high ability to contaminate the finished product	Use peer monitoring (e.g., buddy system) during operations or in assigned locations, cameras and personnel identification (e.g., color coded uniforms, badges) to restrict access to location, equipment, control, and operations
c. Handling, Staging, Preparation, Addition and Rework of Secondary Ingredient	3	8	6	17	X		Low potential health impact because of subsequent cooking step, higher opportunity for physical access and medium ability to contaminate the finished product	Use peer monitoring (e.g., buddy system) during operations or in assigned locations, cameras and personnel identification (e.g., color coded uniforms, badges) to restrict access to location, equipment, control, and operations
d. Mixing, Grind, Homogenizing, Blending, Coating & Related Activities	3	8	8	19	X		Low potential health impact because of subsequent cooking step, higher opportunity for physical access and high ability to contaminate the finished product	Use peer monitoring (e.g., buddy system) during operations or in assigned locations, cameras and personnel identification (e.g., color coded uniforms, badges) to restrict

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CATEGORY	Vulnerability Assessment Elements *(see Draft Mitigation Strategies Guidance Document for Scoring Categories)*							Identify Mitigation Strategies
	#1	#2	#3	Total Element Score	Action Step		Justification for Element Score	
					Yes	No		
								access to location, equipment, control, and operations
2. <u>FACILITY-WIDE</u>: FOOD MANUFACTURING FACILITY:								
a. Accept goods and packages that with proper documentation review, screening procedures and chain-of-custody	3	3	3	9		X	Low potential health impact because of separation between receipt area and processing area	-
b. Designate parking areas for personnel and visitors, and distinguish vehicles using parking decals or other identification	3	3	3	9		X	Low potential health impact because of separation between receipt area and processing area	-
c. Implement a policy for handling suspect persons, items and events including changes in employee health or behavior	8	8	8	24	X		High impact in all areas as personnel are the key to causing or preventing intentional contamination of ingredients, packaging or finished frozen fried rice product	Company utilizes personality screening and background checks of all potential new hires as well as requires companies providing contract workers to implement similar screening and background checks. Also, uses peer monitoring (e.g., buddy system) during operations or in assigned locations, cameras and personnel identification (e.g., color coded uniforms,

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CATEGORY	Vulnerability Assessment Elements *(see Draft Mitigation Strategies Guidance Document for Scoring Categories)*							Identify Mitigation Strategies
	#1	#2	#3	Total Element Score	Action Step		Justification for Element Score	
					Yes	No		
								badges) to restrict access to location, equipment, control, and operations with all employees trained to report unusual behaviors of fellow employees to management
d. Implement a policy for increasing security measures during elevated threat/risk levels	8	8	8	24	X		High potential health impact in all areas caused by known or expected threats	Company has a policy for additional security measures when the threat/risk level is elevated including notification of supervisor staff, additional employee monitoring and installation of more cameras in key process locations.
e. Implement a policy for protection of sensitive information (e.g., computers, food defense plans, schematics) and periodically modify instituted security measures such as passwords, keys, access cards, and codes	8	5	8	21	X		High potential health impact, medium opportunity for physical access and high ability to contaminate the finished product	Some types of processing equipment have computer-based controls or require manual input of data in order to receive computerized authorization to move to the next processing step. Company has implemented cyber-security system which is tested annually to ensure operations and operating data are not compromised.

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CATEGORY	Vulnerability Assessment Elements *(see Draft Mitigation Strategies Guidance Document for Scoring Categories)*							Identify Mitigation Strategies
	#1	#2	#3	Total Element Score	Action Step		Justification for Element Score	
					Yes	No		
f. Implement a policy for random security checks of personnel, equipment and processes	3	3	3	9		X	Low potential health impact as long as there is no elevated threat/risk level	-
g. Implement a policy for scheduling deliveries, maintenance and service	3	3	3	9		X	Low potential health impact because of separation between receipt area and processing area	-
h. Implement a policy for updating and maintaining accurate records (e.g., personnel files, training records, food defense plan documentation, emergency response contacts)	3	3	3	9		X	Low potential health impact because of separation between receipt area and processing area	*(Company Human Resource Policy covers this.)*
i. Implement a policy to prohibit employees from removing from the premises company-provided gear that could be used to gain unauthorized entry into the facility	3	3	3	9		X	Low potential health impact because the use of additional security measures including access door entry security, cameras and employee and supervisory recognition of “fake” employees	-

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CATEGORY	Vulnerability Assessment Elements *(see Draft Mitigation Strategies Guidance Document for Scoring Categories)*							Identify Mitigation Strategies
	#1	#2	#3	Total Element Score	Action Step		Justification for Element Score	
					Yes	No		
j. Implement a policy to restrict access to locations, equipment and operations and periodically modify instituted security measures such as passwords, keys, access cards, and codes	8	8	8	24	X		High potential health impact in all areas caused by known or expected threats	Company has restrict access to locations, equipment and operations and periodically modify instituted security measures such as passwords, keys, access cards, and codes
k. Implement a visitor policy which requires proper identification, escorts and adherence to rules regarding restricted access	8	8	8	24	X		High potential health impact in all areas caused by known or expected threats	Company has a Human Resources policy which covers roper identification, escorts and adherence to rules regarding restricted access for all visitors.
l. Implement an inventory management system for products, ingredients, materials, and chemicals or potential contaminants	3	3	3	9		X	Low potential health impact	Company has effective inventory management system for products, ingredients, materials, chemicals and other potential contaminants
m. Implement emergency response procedures including preventing security breaches during evacuation	8	8	8	24	X		High potential health impact in all areas caused by known or expected threats	Company has a policy for additional security measures that include emergency response procedures when security breaches are suspected, which includes notification of supervisor staff, additional

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CATEGORY	Vulnerability Assessment Elements *(see Draft Mitigation Strategies Guidance Document for Scoring Categories)*							Identify Mitigation Strategies
	#1	#2	#3	Total Element Score	Action Step		Justification for Element Score	
					Yes	No		
								employee monitoring and installation of more cameras in key process locations.
n. Keep one authorized operator with transportation vehicle at all times (e.g., use relay operators, relief driver, team driving)	3	3	3	9		X	Low potential health impact	Company has secured area where transportation vehicles are required to park
o. Maximize visibility of perimeters, entry/exit points, locations and operations (e.g., light adequately, install windows, remove visual obstructions)	3	3	3	9		X	Low potential health impact	Company has secured area where transportation vehicles are required to park in order to maximize visibility of perimeters, entry/exit points, locations and operations (e.g., light adequately, install windows, remove visual obstructions)
p. Minimize the number of access points to your facility	3	3	3	9		X	Low potential health impact	Company ha minimized the number f access points to the frozen fried rice processing areas.
q. Prohibit personal items from production, storage or other restricted areas	3	3	3	9		X	Low potential health impact	Company Human Resource Policy limits the type of personnel items allowed in the frozen fried rice processing areas and requires all personal items to be kept in the employee's assigned locker outside of any processing areas.

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	#1	#2	#3	Total Element Score	Action Step		Justification for Element Score	
					Yes	No		
r. Secure water, air and gas supplies and supply lines	8	8	8	24	X		High potential health impact to the frozen fried rice product	Company conducts periodic spot checks of water, air, gas and other lines which might impact the safety of the frozen fried rice product.
s. Use locks, fencing, gates or other physical barriers at perimeters, entry/exit points, locations and operations to restrict access	8	8	8	24	X		High potential health impact to the frozen fried rice product	Company conducts periodic spot checks locks, fencing, gates or other physical barriers at perimeters, entry/exit points, locations and operations to restrict access
t. Use personnel (e.g., guards, supervisors, trusted employees) to monitor perimeters, entry/exit points, locations and operations	3	3	3	9		X	Low potential health impact as long as there is no elevated threat/risk level	
u. Use signage at perimeters, entry/exit points, locations and operations to designate restricted areas	3	3	3	9		X	Low potential health impact as long as there is no elevated threat/risk level	
v. Use surveillance equipment (e.g., cameras) and/or alarms to monitor	8	8	8	24	X		High potential health impact to the frozen fried rice product	Company utilizes surveillance equipment (e.g., cameras) and/or alarms to monitor perimeters, entry/exit points, locations and operations

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CATEGORY	Vulnerability Assessment Elements *(see Draft Mitigation Strategies Guidance Document for Scoring Categories)*							Identify Mitigation Strategies
	#1	#2	#3	Total Element Score	Action Step		Justification for Element Score	
					Yes	No		
perimeters, entry/exit points, locations and operations								
3. FACILITY WIDE: MANAGEMENT								
a. Implement a communication policy for emergencies including internal stakeholders, the press and the public	3	3	3	9		X	Low potential health impact as long as there is no elevated threat/risk level	-
b. Implement a food defense plan and periodically reassess the plan to keep it up to date	8	8	8	24	X		High potential health impact to the frozen fried rice product	Company utilizes surveillance equipment (e.g., cameras) and/or alarms to monitor perimeters, entry/exit points, locations and operations
c. Implement a human resources policy that includes vetting candidates prior to hiring	8	9	8	25	X		High potential health impact, opportunity for physical access and ability to contaminate ingredients, raw materials, packaging, labels and the finished product by new hires that have not been properly evaluated by the human resources department	Company human resource program utilizes a verified personality assessment evaluation of all new or contract employees to identifies characteristics that may cause a new employee to take actions to contaminate the ingredients, raw materials, packaging, labels or finished products in order to minimize internal sabotage or the finished product. Also,

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CATEGORY	Vulnerability Assessment Elements *(see Draft Mitigation Strategies Guidance Document for Scoring Categories)*							Identify Mitigation Strategies
	#1	#2	#3	Total Element Score	Action Step		Justification for Element Score	
					Yes	No		
								use staff training to report suspicious personnel and behaviors; use of badges for colored identification such as hats, badges or uniforms to identify employee suspicious behaviors and strategically-placed cameras as well as locked interior door with access known only to authorized staff
d. Implement a policy for employee resignation or termination that includes the relinquishment of all items used for access to the building including badges, keys, codes, uniforms, etc.	8	9	8	25	X		High potential health impact, opportunity for physical access and ability to contaminate ingredients, raw materials, packaging, labels and the finished product by employees resigning or terminated	Company human resource program includes employee resignation or termination monitoring program that is intended to minimize that employee's access to ingredients, raw materials, packaging or finished frozen fried rice product. Also, staff training is used to monitor these individuals and to report suspicious personnel and behavior along with strategically-placed cameras.
e. Implement a policy for supplier requirements including auditing suppliers	8	8	8	24	X		High potential health impact to the frozen fried rice product	Company utilizes a supply management system that requires auditing suppliers and service contractors and maintaining

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CATEGORY	Vulnerability Assessment Elements *(see Draft Mitigation Strategies Guidance Document for Scoring Categories)*							Identify Mitigation Strategies
	#1	#2	#3	Total Element Score	Action Step		Justification for Element Score	
					Yes	No		
and service contractors and maintaining updated lists of acceptable suppliers and service contractors								updated lists of acceptable suppliers and service contractors
f. Keep current on food defense-related industry news, regulations, customer requirements	3	3	3	9		X	Low potential health impact as long as there is no elevated threat/risk level	-
g. Maintain an up-to-date list of emergency contacts for food defense events and make it available to personnel	3	3	3	9		X	Low potential health impact as long as there is no elevated threat/risk level	Company does maintain up-to-date list of emergency contacts for food defense events and make it available to personnel
h. Train appropriate personnel on proper implementation of the food defense plan, food defense awareness and to have the ability to recognize and report unusual behaviors, suspicious items and to report these to trained supervisory personnel.	8	8	8	24	X		High potential health impact to the frozen fried rice product	Company Human Resources Policy requires the training of appropriate personnel on proper implementation of the food defense plan, food defense awareness and to have the ability to recognize and report unusual behaviors, suspicious items and to report these to trained supervisory personnel.
4. FACILITY-WIDE: PERSONNEL								

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	#1	#2	#3	Total Element Score	Action Step		Justification for Element Score	
					Yes	No		
a. Implement a check in/check out procedure at security or reception areas that includes verification of proper identification, screening equipment and relinquishment of prohibited items	8	8	8	24	X		High potential health impact, opportunity for physical access and ability to contaminate ingredients, raw materials, packaging, labels and the finished product because of psychology of staff to not challenge someone allowed access to the processing facility	Company has check-in/check-out procedure that is enforced to prevent unauthorized process area access; use of staff training to report suspicious personnel and behaviors; use of badges for colored identification such as hats, badges or uniforms to identify visitors, contractors, drivers and other non-staff; strategically-placed cameras as well as locked interior door with access known only to authorized staff

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	#1	#2	#3	Total Element Score	Action Step		Justification for Element Score	
					Yes	No		
b. Implement a policy to restrict access to locations, equipment and operations and periodically modify instituted security measures such as passwords, keys, access cards, and codes	8	8	8	24	X		High potential health impact, opportunity for physical access and ability to contaminate ingredients, raw materials, packaging, labels and the finished product because of psychology of staff to not challenge someone allowed access to the processing facility	Company has policy to restrict access to locations, equipment and operations and periodically modifies instituted security measures such as passwords, keys, access cards, and codes
5. PROCESSING: CONVEYANCE & MATERIAL HANDLING OF RAW MATERIALS, INGREDIENTS AND PACKAGING								
a. Ingredient& Raw Material Receiving	3	8	8	19	X		Low potential health impact because of subsequent cooking step, higher opportunity for physical access and high ability	Use peer monitoring (e.g., buddy system) during operations or in assigned locations; cameras and personnel identification (e.g., color
b. Ingredient & Raw Material Storage								

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	#1	#2	#3	Total Element Score	Action Step		Justification for Element Score	
					Yes	No		
c. Packaging Receiving d. Packaging Storage e. Product Label Receiving f. Product Label Storage							to contaminate the finished product	coded uniforms, badges) to restrict access to location, equipment, control, and operations
g. Ingredient Addition h. Ingredient Preparation i. Measuring j. Premixing	10	8	8	26	X		High potential health impact, high opportunity for physical access to ingredients, raw materials, packaging or finished products and high ability to misrepresent the finished product	Use peer monitoring (e.g., buddy system) during operations or in assigned locations; cameras and personnel identification (e.g., color coded uniforms, badges) to restrict access to location, equipment, control, and operations
k. Reject Materials l. Reworked Product	3	8	6	17	X		Low potential health impact because of subsequent cooking step, higher opportunity for physical access and medium ability to contaminate the finished product	Use peer monitoring (e.g., buddy system) during operations or in assigned locations, cameras and personnel identification (e.g., color coded uniforms, badges) to restrict access to location, equipment, control, and operations
m. Staging, Dry Ingredients n. Staging, Liquid Ingredients o. Weighing	10	8	8	26	X		High potential health impact, high opportunity for physical access to ingredients, raw materials,	Use peer monitoring (e.g., buddy system) during operations or in assigned locations; cameras and

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	#1	#2	#3	Total Element Score	Action Step		Justification for Element Score	
					Yes	No		
p. Tote, Conveyance q. Bin Dumping r. In-Feed Conveyor s. Conveyor Belt and/or Bucket and/or Pneumatic							packaging or finished products and high ability to misrepresent the finished product	personnel identification (e.g., color coded uniforms, badges) to restrict access to location, equipment, control, and operations
t. Forklift u. Hose	3	3	3	9		X	Low potential health impact because of limited impact on ability to contaminate ingredients, raw materials or finished fried rice products	-
v. Pump w. Valve x. Valve Matrix	3	3	3	9		X	Low potential health impact because contamination of ingredients, raw materials or finished fried rice products requires disassembly of this equipment which would be observed by other trained employees and supervisors	-
6. PACKAGING PROCESS								
a. Modified Atmospheric Packaging b. Hand/Manual Packer	10	8	8	26	X		High potential health impact, high opportunity for physical access and high ability to contaminate the finished	Use peer monitoring (e.g., buddy system) during operations or in assigned locations, cameras and personnel identification (e.g.,

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	#1	#2	#3	Total Element Score	Action Step		Justification for Element Score	
					Yes	No		
c. Packaging Process							product	color coded uniforms, badges) as well as limited access door locks to restrict access to location, equipment, control, and operations
d. Caser	3	3	3	9		X	Low potential health impact, low opportunity for physical access and low ability to contaminate the finished product because finished fried rice product in packaging so any attempt to contaminate the product will require removal of the packaging which will very likely be observed by other trained employees and supervisors	-
e. Packer								
f. Labeler								
g. Packer								
h. Palletizer								
i. Scanner								
j. Sealer								
k. Shrink Bander								
l. Shrink Wrapper								

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	#1	#2	#3	Total Element Score	Action Step		Justification for Element Score	
					Yes	No		
m. Vacuum Sealer								
7. INGREDIENT, RAW MATERIAL, REWORK AND FINISHED PRODUCT STORAGE								
a. Bin/Tub	3	8	8	19	X		Low potential health impact because of subsequent cooking step, higher opportunity for physical access and high ability to contaminate the finished product	Use peer monitoring (e.g., buddy system) during operations or in assigned locations; cameras and personnel identification (e.g., color coded uniforms, badges) to restrict access to location, equipment, control, and operations
b. Bulk Storage								
c. Chemical Storage, Dry or Wet	8	6	10	24	X		High potential health impact, medium opportunity for physical access and very high ability to contaminate the finished product	All dry and wet chemicals must be stored in a secured area with only small volumes used in an unsecured manner during specifically-designated cleaning periods of the processing day. Use staff training peer monitoring (e.g., buddy system) during operations or in assigned locations, cameras and personnel identification (e.g., color coded uniforms, badges) as well as limited access door locks to restrict access to location, equipment, control,

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	#1	#2	#3	Total Element Score	Action Step		Justification for Element Score	
					Yes	No		
								and operations
d. Dry Storage e. Dump Pit (for rice grain) f. Holding Tank g. Ingredient Storage h. Liquid Storage i. Metering Tank j. Product Storage k. Refrigerated/Frozen Storage l. Warehouse m. Warehouse, Refrigerated/Frozen n. Surge Hopper o. Surge Tank p. Thaw Room q. Storage Tank, Dry/Solid r. Storage Tank, Liquid s. Storage Tank, Refrigerated	3	8	8	19	X		Low potential health impact because of subsequent cooking step, higher opportunity for physical access and high ability to contaminate the finished product	Use peer monitoring (e.g., buddy system) during operations or in assigned locations; cameras and personnel identification (e.g., color coded uniforms, badges) to restrict access to location, equipment, control, and operations
t. Silo Storage, Liquid	3	3	3	9		X		-

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	#1	#2	#3	Total Element Score	Action Step		Justification for Element Score	
					Yes	No		
u. Silo Storage, Solid							Low potential health impact because of limited access to silo access ports and doors and unauthorized opening likely would result in product emptying out of silo	
v. Tote, Storage	3	3	3	9		X	Low potential health impact because of limited access to areas where this equipment is stored as well as all equipment is washed or rinsed prior to being used for processing purposes	-
w. Equipment Storage								
x. Drum Storage								
8. TRANSPORTATION/DISTRIBUTION								
a. Hopper Truck – Incoming	8	6	8	22	X		High potential health impact, medium opportunity for physical access and high ability to contaminate the finished product	Company require suppliers to utilize seals or locks to indicate tampering as well as receiving personnel training, peer monitoring (e.g., buddy system) during operations, cameras and personnel identification (e.g., color coded uniforms, badges) as well as limited access locked transfer hoses and silo or tank openings. Also utilizes peer monitoring (e.g., buddy
a. Tanker Truck – Incoming								
b. Refrigerated Transport – Incoming								
c. Rail Car – Incoming								
d. LTL (Less-than-Truckload) – Incoming								

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CATEGORY	Vulnerability Assessment Elements *(see Draft Mitigation Strategies Guidance Document for Scoring Categories)*							Identify Mitigation Strategies
	#1	#2	#3	Total Element Score	Action Step		Justification for Element Score	
					Yes	No		
e. Liquid Receiving - Incoming f. Receipt of Smaller Packages - Incoming								system) during operations or in assigned locations; cameras and personnel identification (e.g., color coded uniforms, badges) to restrict access to location, equipment, control, and operations
g. Tanker Ship - incoming	NA	NA	NA	NA			NA – Company does not receive direct shipments from tanker ship	
h. Refrigerated Truck – Outgoing i. Refrigerated Rail Car – Outgoing j. Refrigerated Shipping Container - Outgoing k. Refrigerated LTL (Less-than-Truckload) – Outgoing	3	3	3	9		X	Low potential health impact because of limited access to finished fried rice as it is in primary and sometimes tertiary packaging to accept to product in order to contaminate limited.	Even though the contamination risk is low, the Company utilizes shipping seals and locks to quickly identify any possible compromise of any type of shipping vehicle or container.

Signature： _____

Date Signed： _____

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4.2. Example from 2017 Food Defense Plan Builder 1.0 - *OUTDATED*

4.2a. Identifying of "Actionable Steps" Based on Definition of "High Food Defense Risk"

2017 Worksheet - *OUTDATED*

Section	Measure	Response	Plan Content	Comments	Action Steps
Outside Security					
1. Property Perimeter	1a. Is the property perimeter secured to prevent entry by unauthorized persons (e.g., by security guards, fence, wall, or other physical barriers)?	Gap		There is no fence around the facility. At present, all doors are secured. When trucks deliver, the driver must ring a door bell and a supervisor responds and checks the paperwork of the driver and provides him with the dock door that the truck should back in to. All employees enter through one door but there is no one stationed at that door to verify the identification of each employee and the door is accessible.	**Yes**
	1b. Is there adequate lighting around the property perimeter?	Currently Doing	Exterior lights are installed around the property perimeter. These lights adequately illuminate the property perimeter to deter and aid in the detection of suspicious or unusual activities.		
2. Building Perimeter	2a. Is there adequate lighting outside each building and in between buildings?	Currently Doing	Exterior lights are installed outside and in between all buildings.		

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	2b. Are primary entrances to the buildings and operating areas monitored and secured?	Gap		The employee entrance is open and not currently monitored. There is a receptionist at the main entrance that monitors visitors.	**Yes**
	2c. Are emergency exit doors self-locking from the outside, with alarms that activate when the doors are opened?	Currently Doing	Emergency exits are installed with self-locking doors and alarms that will sound when emergency exit doors are opened.		
	2d. Are operational entrances, such as the loading dock doors, secured when not in use?	Currently Doing	The loading dock is regularly monitored and doors are secured when not in use.		
	2e. Are all possible access points into the buildings covered, locked, or otherwise secured?	Gap		Doors and windows are secured unless otherwise noted.	**Yes**
	2f. Are products and ingredients that are stored outside the secured building protected by fences, tamper-evident seals, and/or locks?	N/A			
3. Vehicles	3a. Does the property have a controlled or guarded entrance for vehicles?	Gap			**Yes**
	3b. Are all vehicles entering the property identified by decals or other form of company-issued visual identification? This may include forms of permanent identification for employee vehicles, and temporary identification for vehicles belonging to visitors, contract workers, suppliers, and customers.	Gap		Employee vehicles are identified with the company name painted on doors. The Supervisor who responds to the dock doorbell must check identification of all drivers and contractors prior to entrance into the building	**Yes**
	3c. Where practical, is there some distance (i.e.,	Gap		All employees are required to	**Yes**

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	a buffer zone) between parking areas and entrances to food storage or food processing areas or utilities?			park in assigned parking spots. Visitor spots are located in front of the main entrance.	
	3d. Are vehicle seals inspected to ensure they are intact prior to be being allowed on the grounds of the food manufacturer?	Gap		Work with suppliers & customers to develop a recorded seal program. Have employees trained to check seals before loading or unloading.	**Yes**
General Inside Security					
4. Facility/Plant	4a. Is there adequate lighting throughout the facility?	Currently Doing	Lighting throughout the facility is adequate and maintained.		
	4b. Is there an emergency lighting system in the facility?	Currently Doing	Emergency lighting is installed at the facility and is tested regularly.		
	4c. Does your facility have monitored and recorded security cameras such as a closed-circuit television (CCTV) system?	Gap			**Yes**
	4d. Does your facility have established emergency procedures, including procedures for responding to an intentional contamination?	Gap	Employees are trained to notify a Supervisor of any suspicious behavior.	All employees are trained to report any suspicious behavior or personnel in unauthorized areas to their supervisor.	**Yes**
	4e. Does your facility have an emergency alert system that is tested regularly?	Gap	Employees are trained to exit the building if the fire alarms are activated and meet in the designated areas. If a tornado occurs, employees will immediately go to the assigned shelter-in-place location.		**Yes**

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	4f. Is access to production, storage and other sensitive areas restricted to a small number of employees?	Gap	All employees are trained to only enter assigned areas.	The facility requires employees to walk through areas where production may occur or product may be transferred to access their work space.	**Yes**
	4g. Is there a procedure in place for individuals who normally do not have access but have a legitimate need to gain temporary access to the restricted areas? This would include all visitors, contractors, salespeople, and employees.	Currently Doing	A policy and procedure for granting temporary access to restricted areas for visitors or employees is in place. Individuals who are not normally authorized to be in restricted areas require escort by an authorized employee at all times. Non-employees may not bring personal items into the processing areas. A log of visitors entering the facility is maintained.		
	4h. Are copies of the facility's site plan and blueprints stored in a secured location at the facility and in an offsite location?	Currently Doing	An up-to-date copy of the facility's site plan and blueprint is stored in a fire-safe locked box in the facility manager's office. In addition, a copy is located in a secure location offsite. Access to both copies is controlled.		
	4i. Are procedures in place to check maintenance closets, personal lockers, and storage areas for suspicious items or packages?	Gap	Regular inspections are conducted in all areas of the facility and documented. These are done monthly. All employees are trained to report anything suspicious and any suspicious behavior as well as employees in areas where they do not work.		**Yes**

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	4j. Do you regularly take inventory of keys to secured/sensitive areas of the facility?	Gap	Key employees are issued keys to their area. This is documented in their employee file		**Yes**
5. Utilities	5a. Are controls for the Heating, Ventilation, and Air Conditioning (HVAC) systems secured by a lock to prevent access by unauthorized persons?	Currently Doing	The control area for HVAC systems is kept locked. The main air intakes are in a fenced area.	The main air intakes are located on the roof of the facility and cannot be accessed unless through a secure area.	
	5b. Are controls for refrigeration, including the main storage areas for combustible materials like ammonia, secured by lock to prevent access by unauthorized persons?	Currently Doing	Refrigeration controls and receivers/storage vessels are in a locked and controlled area.		
	5c. Are the water systems used in the food production process, including any storage tanks or reservoirs and any water treatment components, protected from unauthorized access?	Gap	Main water valves are locked.		**Yes**
	5d. Are the controls to the electrical systems (main transformers and switchgear only) protected from unauthorized access?	Currently Doing	The main electrical supply and switchgear are controlled to allow authorized entry only.		
	5e. Are cleaning/sanitization chemical dispensing systems secured from unauthorized access?	Currently Doing	Storage areas and primary distribution systems for sanitation chemicals are kept in a locked area that is restricted to authorized individuals.	The Sanitation Manager and Sanitation Supervisor have keys to access the chemical storage area.	
6. Laboratory	6a. Is access to the laboratory facility restricted to authorized employees (e.g., by locked door, pass card, etc.)?	Gap	The laboratory is kept locked at all times and is strictly limited to authorized employees. All chemicals and reagents are kept in locked cabinets. Inventory of all		**Yes**

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			reagents is done on a weekly basis.		
	6b. Is a procedure in place to receive and securely store reagents?	Currently Doing	Reagents are received only by authorized employees. They are stored in a locked cabinet within the laboratory. If reagents need to be taken out of the laboratory, procedures are in place to track them.		
	6c. Are laboratory materials restricted to the laboratory, except as needed for sampling or other authorized activities?	Currently Doing	Laboratory materials such as chemicals and reagents are restricted to the laboratory. In instances where there is a need to have laboratory materials outside of the lab, there is a procedure in place to get pre-approval from the laboratory supervisor who then keeps a record of such instances.		
	6d. Is a procedure in place to control and dispose of reagents?	Currently Doing	Reagents are disposed of according to the facility's disposal procedures. The disposal of reagents is documented.		
7. Process Computer Systems	7a. Is access to these process control systems restricted to trusted employees?	Currently Doing	A limited number of authorized employees have the password to the system.		
	7b. Is access to process control computer systems password protected?	Gap	Passwords for the process control system must be changed on a monthly basis.		**Yes**
	7c. Are firewalls built into the computer network used for process controls?	Currently Doing	Access to process control computer systems is protected through firewalls.	Currently the process control computer is not connected to the internet or an outside system.	
	7d. Is antivirus software installed on the process controls computer system and is it frequently updated?	N/A			

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	7e. When an employee's employment ends, is their access to process control computer systems disabled?	Currently Doing	Disabling an employee's access to computer systems is part of the close out and sign off process for all personnel when their employment ends.		
Logistics and Storage Security					
8. Suppliers and Vendors	8a. When choosing suppliers for your packaging materials, labels, ingredients, and raw materials, do you check if they have developed a Food Defense Plan?	Currently Doing	Company policy requires all suppliers to have a Food Defense Plan and to implement food defense measures at their facilities.		
	8b. Do you have a supplier approval certification system in place to ensure that you purchase supplies only from known, reputable sources?	Currently Doing	All suppliers must be approved within our supplier certification program. The contractual agreements require the supplier to have adequate food defense measures.	All suppliers must be approved prior to receipt of any supplies.	
	8c. Do you audit or inspect supplier food defense programs or require that they have third party audits or inspections?	Currently Doing	Audits of our suppliers include an assessment of their food defense measures.		
9. Incoming Shipments	9a. Are trailers and trucks on the premises maintained under lock and/or tamper-evident seal when not being loaded or unloaded?	Gap	Prior to loading or unloading a trailer, the doors shall be opened and the trailer inspected for evidence of damage and cleanliness.		**Yes**
	9b. Is there close supervision of the unloading of vehicles transporting raw materials, finished products, ingredients or other materials used in food processing?	Currently Doing	Unloading of vehicles transporting raw materials, finished products, ingredients or other materials used in food processing is conducted with close supervision. All supervisors are trained in food defense procedures related to shipping and receiving.		
	9c. Are there procedures that require the	Currently Doing	Loading and unloading activities		

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	acceptance of authorized, expected shipments only?		are scheduled and/or monitored. Only scheduled shipments are received. Unscheduled or unauthorized shipments are held until authorization is obtained.		
	9d. Is access to loading docks controlled to avoid unverified or unauthorized deliveries?	Currently Doing	Loading dock access is controlled by a lock and is monitored regularly. Only authorized personnel have the key to the lock.		
	9e. Are incoming shipments of raw materials, ingredients, and packaging materials required to be sealed with tamper-evident or numbered seals (and documented in the shipping documents)?	Gap	Record the seal number on receiving paperwork for any supplies or ingredients that arrive with a seal.		**Yes**
	9f. Are tamper-evident seals verified prior to acceptance?	Gap	Seal numbers must be verified with incoming paperwork when present.		**Yes**
	9g. Are less-than-truckload (LTL) or partial load shipments vehicles checked?	Gap	All less than full load shipments must be inspected prior to unloading.		**Yes**
10. Outgoing Shipments	10a. Are shipping vehicles (trucks, tankers, rail cars) inspected prior to loading to detect the presence of any foreign/hazardous materials?	Currently Doing	Outgoing vehicles are examined for suspicious activity, evaluated for previous use or presence of potentially hazardous materials. Inspections of outgoing shipments are documented.		
	10b. Are outgoing shipments enclosed and sealed with tamper-evident seals (or locks)? Are the seal numbers on outgoing shipments documented on the shipping documents?	Currently Doing	Outgoing shipments are sealed with tamper-evident seals. Documentation of outgoing shipments is required. Multiple transports seals are documented and justified.		
	10c. Are chain-of-custody (possession) records	Currently Doing	Shipping documents are required for each		

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	maintained for all shipments of finished goods?		load indicating the proper inventory, date and time, and the number of the tamper-evident seal that was applied to the load.		
	10d. Are effective product recall procedures in place?	Currently Doing	A documented product recall plan is in place. It must be reviewed annually. Trace-back and trace-forward records are maintained and tested regularly through mock-recall events. The recall plan ensures segregation and proper disposition of recalled product and documentation of disposition.		
11. Returned Products/Goods	11a. Are all returned products/goods examined at a separate designated location in the facility for evidence of possible tampering before salvage or use in rework/reconditioning?	Gap		Currently no returned product is accepted into the facility but this is not addressed in the Preventive Controls plan.	**Yes**
	11b. Are records maintained of returned products/goods used in rework?	N/A			
12. Ice/Water/Processing Aids	12a. Is access to the piping systems used to transfer potable water, oil, or other ingredients limited?	Currently Doing	Access to lines that transfer water or ingredients are restricted.		
	12b. Are the piping systems used to transfer potable water, oil, or other ingredients inspected periodically?	Currently Doing	Water lines are regularly inspected for integrity.		
	12c. Is access to water wells restricted (e.g., by locked door/gate or limiting access to designated employees)?	N/A			
	12d. Are there water storage tanks, reservoirs, or water treatment	N/A			

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	systems? Is access to them restricted?				
	12e. Is access to ice-making equipment and ice storage areas restricted?	N/A			
	12f. If a public water supply is used, have arrangements been made with local health officials to ensure they immediately notify the plant if the safety of the public water supply is compromised?	Currently Doing	An agreement has been established with our water supplier to notify us directly if the water becomes unfit for use. We are required to review this agreement once each year. Ensure that secondary water supply contracts and agreements are in place.	The public water system notifies us if there are any issues and also provides a chemical and microbiological analysis on a yearly basis.	
13. Storage/Warehouse	13a. Is access to raw material and ingredient storage areas restricted to designated employees (e.g., by locked door or gate)?	Gap	Employees are only permitted in their authorized work areas.		**Yes**
	13b. Is an access record maintained to indicate who has entered raw material or ingredient storage areas?	Gap			**Yes**
	13c. Is access to finished product storage areas restricted to designated employees?	Currently Doing	Access to finished goods storage areas is restricted to authorized personnel.		
	13d. Is access to any additional or temporary storage facilities, such as leased warehousing, shipping containers, storage sheds, or vehicles/trailers, restricted?	Currently Doing	Leased warehouses are required to have access controls similar to our facility controls. Any temporary storage on our facility must be locked and accessible only by authorized personnel.		
	13e. Do you conduct random security inspections of all storage facilities (including temporary storage facilities)?	Gap	All storage areas will be audited on a random basis monthly.		**Yes**
	13f. Are product labels and packaging held in a controlled manner to	Gap	All packaging and labels are to be stored in a sanitary manner		**Yes**

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	prevent theft and misuse (e.g., counterfeiting)?		in the packaging storage area.		
	13g. Is finished product inventory regularly checked for accuracy?	Currently Doing	Periodic inventory and examinations for tampering of materials in storage are performed. Previously unattended materials are checked before use. Unexpected changes in inventory (product or equipment) are reported to appropriate personnel.		
14. Hazardous materials/chemicals	14a. Are storage areas that contain hazardous materials/chemicals—such as pesticides, industrial chemicals, cleaning materials, sanitizers, and disinfectants—restricted to allow access by authorized personnel only?	Currently Doing	Hazardous materials and chemicals, including pesticides, cleaning chemicals, and sanitizers, are in a restricted area and secured by a lock. Only authorized personnel have access to the restricted area.		
	14b. Is a regular inventory of hazardous materials/chemicals maintained?	Gap	Sanitation chemicals are inventoried on a weekly basis. Daily usage is recorded by the Sanitation Supervisor or authorized designee.		**Yes**
Management					
15. Personnel Security	15a. Are basic background checks and/or reference checks with previous employers conducted for all new employees?	Gap	Background or reference checks are conducted for all new hires.		**Yes**
	15b. Are more comprehensive background checks conducted on employees who will be working in sensitive operations?	Gap			**Yes**
	15c. Are background checks and/or reference checks conducted on all contractors (both permanent and seasonal) who will be working in sensitive operations?	Gap	All temporary and seasonal employees have background checks done prior to working in the facility.		**Yes**

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	15d. Do all employees receive training on security procedures and food defense awareness as part of their orientation training?	Gap	All employees are trained on food defense and security of the facility. Refresher training is done on an annual basis. Employees are to report any unauthorized personnel or suspicious behavior to their supervisor.		**Yes**
	15e. Are employees, visitors, and contractors (including construction workers, cleaning crews, and truck drivers) identified in some manner at all times while on the premises?	Currently Doing	A procedure to recognize or identify employees in the facility is in place. It consists of color-coded smocks and badges for visitors, contractors, cleaning crews and others.		
	15f. Do you control employee and contractor access into the facility during working hours (e.g., coded doors, receptionist on duty, swipe card, etc.)?	Gap	All employees are to enter the facility through the employee entrance.		**Yes**
	15g. Does your facility c5ntrol the entry of employees and contractors into the facility during non-working hours?	Gap	All employees or contractors working during non-working hours will ring the bell at the loading docks and a supervisor will check their identification prior to entrance into the facility.		**Yes**
	15h. Does your facility have a way to limit temporary employees and contractors (including construction workers, cleaning crews, and truck drivers) to areas of the facility relevant to their work?	Currently Doing	Contractors, temporary employees, and non-facility personnel are restricted only to the specific area they have been authorized. They must display temporary badges that list where they are authorized to be within our facility.		
	15i. Is there a way to identify employees that correlates with their specific functions/assignments/ departments (e.g.,	Currently Doing	Color-coded smocks are used to identify different functions. Visitors and contractors that require an escort are		

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	corresponding colored uniforms)?		required to use a specific colored smock.		
	15j. Does management maintain an updated shift roster (i.e., who is absent, who the replacements are, and when new employees are being integrated into the workforce) for each shift?	Currently Doing	Each supervisor is responsible for maintaining and reporting the employee roster for each shift. The roster must identify regular, seasonal, and temporary employees.		
	15k. Does your facility restrict personal items and food within production areas?	Currently Doing	Employees and visitors are restricted as to what they can bring in or take from the facility, including personal items, food, and cameras. Employee lockers are inspected periodically and at random.		
	15l. Is there a policy in place that prohibits employees from removing company-provided clothing and protective gear from the premises?	Currently Doing	Locker rooms and laundry services are available on the facility. Employee uniforms and protective gear may not be taken out of the facility.		
16. Food Defense Plan	16a. Is there a designated person or team to implement, manage, and update the Food Defense Plan?	Currently Doing	Leadership of the food defense team is delegated to the Quality Manager. A cross-functional team has been formed to support food defense. The list of members of the food defense team is updated at least once a year and when major changes are made to the team.		
	16b. Have supervisors, management, and key personnel received additional food defense training geared towards management?	Gap	All key management personnel are trained on what is in the food defense plan.		**Yes**
	16c. Do you conduct regular food defense exercises to test the effectiveness of your Food Defense Plan?	Gap			**Yes**

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	16d. Is the Food Defense Plan reviewed (and revised if necessary) periodically?	Currently Doing	The food defense team is required to review and update the Food Defense Plan at least annually. Self-assessments are conducted annually by the team and every two years by the other company personnel.		
	16e. Are the details of food defense procedures within the Food Defense Plan kept secure or confidential?	Currently Doing	The Food Defense Plan is a confidential document. A summary of the plan and a summary of results of audits may be shared. Detailed elements and vulnerabilities will not be shared.		
	16f. Is the emergency contact information for local, state, and federal government regulatory authorities and public health officials included in the Food Defense Plan?	Currently Doing	Facility personnel contact information is kept up to date and reviewed/updated annually. Emergency contact lists are kept up to date and are located in conspicuous areas––near phones, break rooms, locker areas, etc.		
	16g. Are procedures for responding to threats and actual incidents of product contamination detailed in the Food Defense Plan?	Gap	Personnel are to notify their supervisor of any suspicious behavior or activity. If product is found to be contaminated, employees are to stop production and notify their supervisor.		**Yes**
	16h. Does the Food Defense Plan have procedures to ensure that contaminated or potentially harmful products are held at the facility?	Currently Doing	Established quality "HOLD" procedures will be used to mark and segregate products where an intentional contamination is known or suspected. In addition, the products will be physically isolated, locked where possible, to support		

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			potential criminal investigations.		
	16i. Does the Food Defense Plan have procedures for safe handling and disposal of contaminated products and decontamination of the facility in accordance with local environmental guidelines and regulations?	Currently Doing	Potentially hazardous waste (biological or chemical) is controlled and disposed of properly. Disposal and decontamination procedures are included as part of the food safety plan and are attached as a supporting document to this Food Defense Plan. Contact information for the local environmental agency is in the emergency contact section of the Food Defense Plan.		
	16j. Are employees encouraged to report signs of possible product contamination, unknown or suspicious persons in the facility, or breaks in the food defense system?	Gap	Employees are to notify their supervisor if they observe any unauthorized personnel or possible product contamination.		**Yes**
	16k. Does your facility have evacuation procedures in case of an emergency that include controlling access to the facility during evacuation?	Currently Doing	Established facility evacuation procedures are required to address the physical security of the facility and entrances during an evacuation. Only properly identified emergency responders will be allowed access to the facility during an evacuation.		

Signature： _____

Date Signed： _____

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4.2b Example Of Food Defense Action Plan For Fried Rice (Outdated)

**[These yellow colored columns must be filled in based on each facility and who it determines should be responsible to oversee the action step, and when it believes the action step should be completed by.]*

（ジェトロ注）以下は、これから輸出を開始する会社を想定したものです。日付欄には、実際の日付を記入していきます。

Measure # or Process Step	Action Step	Status	Responsibility	Priority	Dates
1a. Is the property perimeter secured to prevent entry by unauthorized persons (e.g., by security guards, fence, wall, or other physical barriers)?	**Add a security guard or at minimum a camera that is monitoring the door that is constantly being reviewed when personnel enter or exit. Provide key cards to employees to scan at entrance and at exit to the building.**	New	Plant Manager	High	Trgt Cmplt:9/30/2020 Pln Strt:8/21/2020 Act Strt:8/21/2020 Act Cmplt:9/21/2020
2b. Are primary entrances to the buildings and operating areas monitored and secured?	**Provide a security guard or add a camera that can be constantly monitored when personnel enter and exit. Provide keycards to all employees that must be swiped when entering or exiting the building.**	New	Plant Manager	High	Trgt Cmplt:9/30/2020 Pln Strt:8/21/2020 Act Strt:8/31/2020 Act Cmplt:9/20/2020
2e. Are all possible access points into the buildings covered, locked, or otherwise secured?	**The employee entrance must be monitored. In addition, all doors must be monitored to ensure the self-locking functions are working properly and that the doors are not being propped open. The ladder that provides access to the roof must be secured to prevent unauthorized access.**	New	Plant Manager	High	Trgt Cmplt:9/30/2020 Pln Strt:8/21/2020 Act Strt:8/31/2020 Act Cmplt:9/20/2020
3a. Does the property have a controlled or guarded entrance for vehicles?	**A fence must be added to enclose the property and facility. There is plans to add an employee parking lot outside the fenced area and have a guard posted at all times that will check employee**	New	Plant Manager	Medium	Trgt Cmplt:11/30/2020 Pln Strt:8/21/2020 Act Strt:8/31/2020 Act Cmplt:11/21/2020

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	identification and trucks entering and leaving the premises				
3b. Are all vehicles entering the property identified by decals or other form of company-issued visual identification? This may include forms of permanent identification for employee vehicles, and temporary identification for vehicles belonging to visitors, contract workers, suppliers, and customers.	**A fence must be added to enclose the property and facility. There are plans to add an employee parking lot outside the fenced area and have a guard posted at all times that will check employee identification, all contractors, and all trucks entering and leaving the premises.**	New	Plant Manager	Medium	Trgt Cmplt:11/30/2020 Pln Strt:8/21/2020 Act Strt:8/31/2020 Act Cmplt:11/21/2020
3c. Where practical, is there some distance (i.e., a buffer zone) between parking areas and entrances to food storage or food processing areas or utilities?	**A fence must be added to enclose the property and facility. There are plans to add an employee parking lot outside the fenced area and have a guard posted at all times that will check employee identification and trucks entering and leaving the premises. Visitor identification will be checked and they will be permitted to park in front of the main entrance in the marked visitor's spots.**	New	Plant Manager	Medium	Trgt Cmplt:9/30/2020 Pln Strt:8/21/2020 Act Strt:8/31/2020 Act Cmplt:9/20/2020
4c. Does your facility have monitored and recorded security cameras such as a closed circuit television (CCTV) system?	**There are no security cameras in the facility at present. A camera may only be added at the employee entrance for monitoring employees.**	New	Plant Manager	High	Trgt Cmplt:9/30/2020 Pln Strt:8/21/2020 Act Strt:8/31/2020 Act Cmplt:9/20/2020
4d. Does your facility have established emergency procedures, including procedures for responding to an intentional contamination?	**While employees are trained to report anything suspicious; the procedure must be expanded to address procedures on what supervisors should do if something is reported.**	New	Operations Manager	Medium	Trgt Cmplt:11/30/2020 Pln Strt:8/21/2020 Act Strt:8/31/2020 Act Cmplt:11/21/2020
4e. Does your facility have an emergency alert	**While natural disasters and fire is addressed; currently the plan does**	New	Human Resources Manager	Medium	Trgt Cmplt:11/30/2020 Pln Strt:8/21/2020

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system that is tested regularly?	**not address an attack inside the building.**				Act Strt:8/31/2020 Act Cmplt:11/21/2020
4f. Is access to production, storage and other sensitive areas restricted to a small number of employees?	**Determine whether or not employees can be routed directly to work areas without passing through other work areas.**	New	Maintenance Manager	High	Trgt Cmplt:9/30/2020 Pln Strt:8/21/2020 Act Strt:8/31/2020 Act Cmplt:9/20/2020
4i. Are procedures in place to check maintenance closets, personal lockers, and storage areas for suspicious items or packages?	**Employees are trained but not using the FDA FIRST food defense materials. These need to be added to the training materials.**	New	Human Resource Manager	Medium	Trgt Cmplt:11/30/2020 Pln Strt:8/21/2020 Act Strt:8/31/2020 Act Cmplt:11/21/2020
4j. Do you regularly take inventory of keys to secured/sensitive areas of the facility?	**A procedure needs to be implemented to verify employees still have the keys they were issued. Once complete, all areas should be re-keyed. Unique keys should be issued to each employee that state they cannot be copied. Research should be done to install a system using electronic swipe keys so documentation exists of who accessed each area.**	New	Maintenance Manager	High	Trgt Cmplt:9/30/2020 Pln Strt:8/21/2020 Act Strt:8/31/2020 Act Cmplt:9/20/2020
5c. Are the water systems used in the food production process, including any storage tanks or reservoirs and any water treatment components, protected from unauthorized access?	**The treatment area for incoming water is open to employees at present. The area must be walled off and must be secured to permit access by authorized personnel only.**	New	Maintenance Manager	High	Trgt Cmplt:12/30/2020 Pln Strt:8/21/2020 Act Strt:8/31/2020 Act Cmplt:12/20/2020
6a. Is access to the laboratory facility restricted to authorized employees (e.g., by locked door, pass card, etc.)?	**The laboratory is attached to the production facility. Plans are to build a separate building so that there is no opportunity that microbial contaminants could be introduced into the production facility. Until that happens, testing for pathogens or indictor organisms are**	New	QA Manager	High	Trgt Cmplt:10/30/2020 Pln Strt:8/21/2020 Act Strt:8/31/2020 Act Cmplt:10/21/2020

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	being sent to an off-site commercial laboratory for analysis.				
7b. Is access to process control computer systems password protected?	**There must be a better plan put into effect to clearly track who has been provided access to the process control computer system.**	New	IT Manager	High	Trgt Cmplt:9/30/2020 Pln Strt:8/21/2020 Act Strt:8/31/2020 Act Cmplt:9/21/2020
9a. Are trailers and trucks on the premises maintained under lock and/or tamper-evident seal when not being loaded or unloaded?	**All incoming supplies must be received with a seal from the supplier of that product. All outbound trailers must be sealed and the seal recorded on the paperwork to provide evidence of security for customers.**	New	Warehouse Manager	High	Trgt Cmplt:9/30/2020 Pln Strt:8/21/2020 Act Strt:8/31/2020 Act Cmplt:9/21/2020
9e. Are incoming shipments of raw materials, ingredients, and packaging materials required to be sealed with tamper-evident or numbered seals (and documented in the shipping documents)?	**Notify all suppliers that seals will be required on all shipments with the seal number recorded on shipment paperwork. If the seal is broken, the shipment will be rejected. If a less-than-full shipment is done - the trailer must be locked in between drops.**	New	Purchasing Manager	High	Trgt Cmplt:9/30/2020 Pln Strt:8/21/2020 Act Strt:8/31/2020 Act Cmplt:9/21/2020
9f. Are tamper-evident seals verified prior to acceptance?	**Require seals on all incoming shipments.**	New	Purchasing Manager	High	Trgt Cmplt:9/30/2020 Pln Strt:8/21/2020 Act Strt:8/31/2020 Act Cmplt:9/21/2020
9g. Are less-than-truckload (LTL) or partial load shipments vehicles checked?	**Provide notice to all less than full load suppliers that trailers must be locked between drop-offs or a seal must be applied. If a seal is used, each number must be recorded as it is applied and when it is removed.**	New	Purchasing Manager	High	Trgt Cmplt:9/30/2020 Pln Strt:8/21/2020 Act Strt:8/31/2020 Act Cmplt:9/21/2020
12a. Are all returned products/goods examined at a separate designated location in the facility for evidence of possible tampering before salvage	**Re=analyze hazard analysis to include a step that no returned products are accepted into the facility.**	New	QA Manager	High	Trgt Cmplt:9/15/2020 Pln Strt:8/21/2020 Act Strt:8/31/2020 Act Cmplt:9/10/2020

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or use in rework/reconditioning?					
14a. Is access to raw material and ingredient storage areas restricted to designated employees (e.g., by locked door or gate)?	**All storage areas need to be reviewed to determine whether doors can be added with key card entries to only permit access by authorized personnel. If certain areas preclude the addition of locked doors; determine the viability of cameras that monitor entrances and exits as well as the storage area for unauthorized personnel or activities.**	New	Plant Manager	High	Trgt Cmplt:10/30/2020 Pln Strt:8/21/2020 Act Strt:8/31/2020 Act Cmplt:10/21/2020
14b. Is an access record maintained to indicate who has entered raw material or ingredient storage areas?	**While entry into various storage areas is by authorized personnel only; there is currently no records. All storages areas are being reviewed to determine whether doors with key card access can be added. If this cannot be done - the use of cameras that will be monitored will be used.**	New	Plant Manager	High	Trgt Cmplt:10/30/2020 Pln Strt:8/21/2020 Act Strt:8/31/2020 Act Cmplt:10/21/2020
14e. Do you conduct random security inspections of all storage facilities (including temporary storage facilities)?	**Ensure that all audits are random and unannounced.**	New	QA Manager	Medium	Trgt Cmplt:9/30/2020 Pln Strt:8/21/2020 Act Strt:8/31/2020 Act Cmplt:9/21/2020
14f. Are product labels and packaging held in a controlled manner to prevent theft and misuse (e.g., counterfeiting)?	**Need to add a process to sign in and out packaging and labeling. Also, all packaging and labeling should be inventoried on a monthly basis. All obsolete labeling and packaging must be properly destroyed with documentation of destruction.**	New	Purchasing Manager	Medium	Trgt Cmplt:11/30/2020 Pln Strt:8/21/2020 Act Strt:8/31/2020 Act Cmplt:11/21/2020
15b. Is a regular inventory of hazardous materials/chemicals maintained?	**Review current records and determine if more frequent inventory of sanitation chemicals is needed.**	New	Sanitation Manager	High	Trgt Cmplt:9/30/2020 Pln Strt:8/21/2020 Act Strt:8/31/2020 Act Cmplt:9/21/2020

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16a. Are basic background checks and/or reference checks with previous employers conducted for all new employees?	**Review the hiring process and determine whether or not more comprehensive checks are needed for key facility positions.**	New	Human Resource Manager	Medium	Trgt Cmplt:12/30/2020 Pln Strt:8/21/2020 Act Strt:8/31/2020 Act Cmplt:12/21/2020
16b. Are more comprehensive background checks conducted on employees who will be working in sensitive operations?	**Review the current hiring process and determine whether or not a more comprehensive background check is needed for personnel in key positions.**	New	Human Resource Manager and QA Manager	Medium	Trgt Cmplt:11/30/2020 Pln Strt:8/21/2020 Act Strt:8/31/2020 Act Cmplt:11/21/2020
16c. Are background checks and/or reference checks conducted on all contractors (both permanent and seasonal) who will be working in sensitive operations?	**Currently contractors working in the facility must only show their employee identifications to enter the facility. A review of whether all companies doing work in the facility run background checks on their respective employees must be conducted.**	New	Human Resources Manager and Maintenance Manager	High	Trgt Cmplt:10/30/2020 Pln Strt:8/21/2020 Act Strt:8/31/2020 Act Cmplt:10/21/2020
16d. Do all employees receive training on security procedures and food defense awareness as part of their orientation training?	**Employees must be trained using the FDA FIRST food defense materials.**	New	Human Resources Manager	Medium	Trgt Cmplt:11/30/2020 Pln Strt:8/21/2020 Act Strt:8/31/2020 Act Cmplt:11/21/2020
16f. Do you control employee and contractor access into the facility during working hours (e.g., coded doors, receptionist on duty, swipe card, etc.)?	**The employee entrance must be monitored by a guard at all times or cameras must be installed that are monitored at all times as well as a key card system installed.**	New	Plant Manger	High	Trgt Cmplt:9/30/2020 Pln Strt:8/21/2020 Act Strt:8/31/2020 Act Cmplt:9/21/2020
16g. Does your facility control the entry of employees and contractors into the facility during non-working hours?	**Review the ability to install key card readers at all entrances into the facility as well as the installation of cameras that will be monitored.**	New	Plant Manager	High	Trgt Cmplt:9/30/2020 Pln Strt:8/21/2020 Act Strt:8/31/2020 Act Cmplt:9/21/2020
17b. Have supervisors, management, and key personnel received additional food defense	**All management and key employees must be trained using the FDA FIRST awareness training**	New	Human Resources Manager	Medium	Trgt Cmplt:11/30/2020 Pln Strt:8/21/2020 Act Strt:8/31/2020 Act Cmplt:11/21/2020

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training geared towards management?	**as well as the FDA ALERT training.**				
17c. Do you conduct regular food defense exercises to test the effectiveness of your Food Defense Plan?	**Develop a procedure to test the actual food defense plan and determine whether unauthorized personnel can access restricted areas of the facility.**	New	Human Resources Manager	Medium	Trgt Cmplt:11/30/2020 Pln Strt:8/21/2020 Act Strt:8/31/2020 Act Cmplt:11/21/2020
17g. Are procedures for responding to threats and actual incidents of product contamination detailed in the Food Defense Plan?	**The food defense plan must be updated to appropriate notification when needed and to also address response to various threats.**	New	QA Manager	Medium	Trgt Cmplt:11/30/2020 Pln Strt:8/21/2020 Act Strt:8/31/2020 Act Cmplt:11/21/2020
17j. Are employees encouraged to report signs of possible product contamination, unknown or suspicious persons in the facility, or breaks in the food defense system?	**All employees need to receive FDA FIRST training.**	New	Human Resources Manager	Medium	Trgt Cmplt:11/30/2020 Pln Strt:8/21/2020 Act Strt:8/31/2020 Act Cmplt:11/21/2020
Frozen Fried Rice - dry good storage	**Use peer monitoring (e.g., buddy system) during operations or in assigned locations** **Use personnel identification (e.g., color coded uniforms, badges) to restrict access to location, equipment, control, and operations**	New	Plant Manager	Medium	Trgt Cmplt:11/27/2020 Pln Strt:9/11/2020 Act Strt:9/25/2020 Act Cmplt:11/11/2020

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Date Signed： _____

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5. Food Defense Monitoring, Verification and Records Example Table

(1) #	(2) Actionable Process Step	(3) Mitigation Strategy	(4) Monitoring Procedure & Frequency	(5) Verification Procedures	(6) Corrective Action Procedures	(7) Recourds
1	Receipt and Storage of non-refrigerated liquids such as soy sauce and acidulants	Use peer monitoring (e.g., buddy system) during operations or in assigned locations, cameras and personnel identification (e.g., color coded uniforms, badges) as well as limited access door locks to restrict access to location, equipment, control, and operations	Employees assigned to the receipt and storage of non-refrigerated liquids monitor the area and ensure that the mitigation strategy(#3) works well, and report any unusual activities or behaviors of fellow workers to supervisors or management and record these unusual activities or behaviors in a log book at the end of every day.	Supervisors compare the receiving and storage logs against inventory tracking system and reconcile any discrepancies once per month	Discrepancies identified during verification (#5) are identify and either resolved or the Company's corrective action plan is activated with a root cause analysis determined.	• Receiving and storage logs • Bar code scans • Inventory tracking spreadsheets • Camera video tapes
2	Rinsing the rice grains	Use peer monitoring (e.g., buddy system) during operations or in assigned locations, cameras and personnel identification (e.g., color coded uniforms, badges) as well as limited access door locks to restrict access to location, equipment, control, and	Employees assigned to the rinsing the rice grains report any unusual activities or behaviors of fellow workers to supervisors or management and record these unusual activities or behaviors in a log book at the end of	Supervisors review daily manufacturing records once per week to confirm proper rinsing of the rice grains	Discrepancies identified during verification (#5) are identify and either resolved or the supervisor investigate by talking with and coaching responsible employees.	• manufacturing processing records

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(1) #	(2) Actionable Process Step	(3) Mitigation Strategy	(4) Monitoring Procedure & Frequency	(5) Verification Procedures	(6) Corrective Action Procedures	(7) Recourds
		operations	every day.			
3	The stir-fried rice and frozen vegetables are packaged in a frozen state.	Use peer monitoring (e.g., buddy system) during operations or in assigned locations, cameras and personnel identification (e.g., color coded uniforms, badges) as well as limited access door locks to restrict access to location, equipment, control, and operations	Employees assigned to the packaging of the stir-fried rice and frozen vegetables report any unusual activities or behaviors of fellow workers to supervisors or management and record these unusual activities or behaviors in a log book at the end of every day.	Supervisors review daily manufacturing records at the end of each processing day to confirm proper packaging of the frozen fried rice	Discrepancies identified during verification (#5) are identify and either resolved or the Company's corrective action plan is activated with a root cause analysis determined.	• manufacturing processing records
4	Implement a human resources policy that includes vetting candidates prior to hiring	Company human resource program utilizes a verified personality assessment evaluation of all new or contract employees to identifies characteristics that may cause a new employee to take actions to contaminate the ingredients, raw materials, packaging, labels or	Twice per year internal Human Resources review of employ dismissals, personnel actions and employee complaints to monitor effectiveness of current policy	Annual review of the Human Resources reports from the twice per year evaluations (see #4) and direct changes if problems are identified	Discrepancies identified during verification (#5) are identify and either resolved or the Company's corrective action plan is activated with a root cause analysis determined.	Compiled Human Resources Reports on: • employ dismissals • personnel actions • employee complaints

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(1) #	(2) Actionable Process Step	(3) Mitigation Strategy	(4) Monitoring Procedure & Frequency	(5) Verification Procedures	(6) Corrective Action Procedures	(7) Recourds
		finished products in order to minimize internal sabotage or the finished product. Also, use staff training to report suspicious personnel and behaviors; use of badges for colored identification such as hats, badges or uniforms to identify employee suspicious behaviors and strategically-placed cameras as well as locked interior door with access known only to authorized staff				
5	Use surveillance equipment (e.g., cameras) and/or alarms to monitor perimeters, entry/exit points, locations and operations	Company utilizes surveillance equipment (e.g., cameras) and/or alarms to monitor perimeters, entry/exit points, locations and operations	Employees assigned to the surveillance equipment monitor daily log of unusual occurrences including surveillance and unauthorized access and door alarms at the end of everyday .	Trained supervisor reviews daily logs once per week and conducts investigation into any unexplained or unresolved security breaches	Unexplained or unresolved security breaches during verification (#5) trigger the Company's corrective action plan with a root cause analysis determined.	Logs of: • unusual occurrences • camera surveillance tapes • unauthorized access and door alarms notices

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(1) #	(2) Actionable Process Step	(3) Mitigation Strategy	(4) Monitoring Procedure & Frequency	(5) Verification Procedures	(6) Corrective Action Procedures	(7) Recourds
6	Packaging Frozen Fried Rice	Use peer monitoring (e.g., buddy system) during operations or in assigned locations, cameras and personnel identification (e.g., color coded uniforms, badges) as well as limited access door locks to restrict access to location, equipment, control, and operations	Employees assigned to the packaging frozen fried rice monitor the area and daily packaging processing records and ensure that the mitigation strategy(#3) works well and report any unusual activities or behaviors of fellow workers to supervisors or management and record these unusual activities or behaviors in a log book at the end of every day.	Supervisors review daily packaging records at the end of each processing day to confirm proper packaging of the frozen fried rice	Discrepancies identified during verification (#5) are identify and either resolved or the Company's corrective action plan is activated with a root cause analysis determined.	• Packaging records

Signature： _____

Date Signed： _____

6. PERIODIC RE-ANALYSIS OF THE FOOD DEFENSE PLAN

General Re-Analysis Tasks	Description of Specific Validation Activity	Mitigation Strategy	Completion Date	Outcome and Actionable Items
1. Review of Plant History since _____	No raw material, ingredient or packaging changes since the last re-analysis. No identify new food defense risks identified since the last re-analysis			
2. Review of Consumer Complaint Files since _____	All consumer complaints for the last 12 months addressed without the need to modify the HACCP program other than one incident. See #1.			
3. Identifying emerging food defense challenges specific to products produced by the food manufacture				
a. Experts contacted regarding emerging new food defense challenges:	i.e. contacted, Attorny, Food defense experts, Japanese government, etc.			
b. Scientific Literature Internet Search Using Google Scholar on new food defense challenges	Completed an internet search on key words, xx, xxx, xxxx and xxxxx			
c. On-line Search of food processing trade publications	Also did a library search of the following scientific journals and trade industry publications. • Food Safety • Food Processing • Packaging • Plant Services • Food Engineering • Automation World • Industrial Networking • Food Protection Trends • Dairy Foods • International Dairy Magazine • PFQ • Food Quality • Prepared Foods • Control • Food Product			
d. Contact Educational Institutions Specializing in Food Defense to Identify Any Emerging or New Food Defense Challenges	Institute of Food Safety and Defense, 327 N Tower Ave, Centralia, Washington, USA 98531 or the Food Protection and Defense Institute University of Minnesota, R285 LES Building 1954 Buford Ave., St. Paul, MN 55108			

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General Re-Analysis Tasks	Description of Specific Validation Activity	Mitigation Strategy	Completion Date	Outcome and Actionable Items
4. In-depth review of the most recent written food defense plan.	Did a step-by-step review of all parts of the plan and found no gaps			
5. In-depth review of the most recent Vulnerability Assessment.	Did a step-by-step review of all parts of the Vulnerability Assessment and identified employee food defense training as out of date			
6. Based on outcome of #4 & $5, update the written food defense plan, sign and date the updated version.	Food Defense Plan updated, signed and dated by the most senior manager at the manufacturing facility			
7. Scheduled food defense update training for all manufacturing facility managers, supervisors and processing staff.	Conduct periodic food defense mock challenges to determine the effectiveness of the training.			

Signature： _____

Date Signed： _____

Ⅱ. Appendix

1. Scoring of Vulnerability Assessment Recommendations

(Information obtained from revised March 2019 Mitigation Strategies draft guidance URL: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-mitigation-strategies-protect-food-against-intentional-adulteration)

Table 1. Potential Public Health Impact [1]

Description	Score
Potential public health impact over 10,000 (acute illnesses, deaths, or both), or over 10,000 servings at risk	10
Potential public health impact between 1,001 – 10,000 (acute illnesses, deaths, or both), or 1,001 – 10,000 servings at risk	8
Potential public health impact between 100 and 1,000 (acute illnesses, deaths, or both), or 100 – 1,000 servings at risk	5
Potential public health impact between 1 - 99 (acute illnesses, deaths, or both), or between 1 – 99 servings at risk	3
No potential public health impact (i.e., no illnesses or deaths) or no servings at risk	1

[1]The range between scores of 5 and 8 is larger than the ranges between other scores to facilitate the separation between points, steps, or procedures that are significantly vulnerable compared to those that are not.

Worksheet 1-E: Calculating Potential Public Health Impact using a Representative Contaminant Element 1 Calculations using Representative Contaminant					**Element 3 Calculations**				
A	**B**	**C**	**D**	**E**	**F**	**G**	**H**	**I**	**J**
Process Step	Batch Size	Amount of Product (Ingredient) in Final Serving	Servings per Batch **B ÷ C**	Mortality Rate of Contaminant *(FDA provided value = 50%)*	Number of Potential Deaths **D x E**	Score from Table 1 Above	Notes	Representative Contaminant Dose Needed per Serving *(FDA provided value = 40 milligrams)*	Amount of Representative Contaminant Needed per Batch **D x I**

How to Fill in Worksheet 1-E: Calculating Potential Public Health Impact using a Contaminant-Specific Analysis

Calculating potential public health impact using specific contaminants is essentially the same as using the representative contaminant approach already discussed. The calculation should be repeated for each contaminant considered. The contaminant with the largest estimated public health impact should be used to identify the appropriate score from Table 1, as this is the estimate that adequately captures the full extent of the potential public health impact.

A. Process Step: Provide the name of each of the process steps from the process flow diagram or other source.

B. Batch Size: Provide an estimate of the amount of product held or processed at the process step. The batch size is usually the volume of the process step's operation (e.g., the volume of food in a mixer or tank, or the amount of product in a constant flow process). For constant flow process steps, batch size is the amount of product you determine an attacker could contaminate, given the time the attacker would have to add a contaminant to a constant flow process and the flow rates of product at that step.

C. Amount of Product (Ingredient) in Final Serving: Provide the amount of the product being processed at the step under evaluation in the final consumable serving. For process steps that involve single ingredient products or that occur after all ingredients are added to the product line, this is likely the same as the serving size. For process steps that involve an ingredient, the amount of the ingredient in the final serving would not be the same as the serving itself. For example, the amount of concentrated fruit juice in a final serving of 8 ounces of fruit juice might be 0.8 ounces.
The column is used to calculate the number of finished servings an ingredient may affect if that ingredient were intentionally adulterated. You should consult your finished product formulations to determine the amount of product (ingredient) in final servings.

D. Servings per Batch: Divide the value in Column B by the value in Column C. This number is the estimate of the volume of food at risk.

E. Mortality Rate of Contaminant: Provide the mortality rate for the specific contaminant. If an LD50 value is used to calculate the dose per serving, 50% should be placed in this Mortality Rate column. The mortality rate should be from the same source (e.g., scientific literature) used for the contaminant dose needed per serving calculation.

F. Number of Potential Deaths: Multiply the value of Column D by the value of Column E (D x E).

G. Score from Table 1: Provide the number from the "Score" column in Table 1. Determine into which "Description" from Table 1 the number of potential deaths from Column F in this worksheet fits and then find the corresponding "Score" in Table 1. For example, if Column F in this worksheet shows 3,000 potential deaths, then you would determine it fits into the Table 1 "Description" of "Potential public health impact between 1,001 – 10,000 (acute illness or deaths), or 1,001 – 10,000 servings at risk" which corresponds to a score of 8. The score from column G of this worksheet goes into Column 4 (Element 1) in Worksheet 1-F.

H. Notes: Provide any information that would assist during review of this VA.

I. Representative Contaminant Dose Needed per Serving: Provide an estimated contaminant dose per serving derived from oral toxic dose information found in scientific literature. The value is typically reported as the dosage per kilogram of bodyweight, which is then converted to a dose per serving. For example, if a substance has a reported LD50 of 1 mg/kg and you assume a typical adult male weighs 85 kg, then the LD dose is 85 kg * 1 mg/kg = 85 mg/serving. Only oral routes of exposure should be considered.

J. Amount of Representative Contaminant Needed per Batch: Multiply the value in Column D by the value in Column I (D x I). This will provide the total amount of contaminant the attacker needs to intentionally adulterate the food at this process step to achieve wide scale public health harm. This estimate informs the amount of the contaminant the attacker needs to carry out the attack, which is a component of Element 3.

Table 2. Degree of Physical Access to the Product

Description[1]	Score
Easily Accessible. • Inside attacker has access to the product (e.g., attacker can physically touch the product). • There are no inherent characteristics that would make access to the product difficult (e.g., enclosed systems, pressurized equipment, railings, equipment safety features, or shields). • Product is open and unsecured by packaging, equipment, or other physical access barriers. • Product is handled, staged, or moved in an easily accessible manner.	10
Accessible. • There are limited inherent characteristics that would make access to the product difficult (e.g., enclosed systems, pressurized equipment, railings, equipment safety features, or shields). • Product is in equipment that can be accessed without tools or specialized supplies. • Access to the food is not difficult (e.g., there are minimal physical space constraints that limit access to food) but may require opening equipment, access points, or non-tamper-evident packaging.	8
Partially Accessible. • Inside attacker has partial access to the product. • There are some inherent characteristics that would make access to the product somewhat difficult (e.g., enclosed systems, pressurized equipment, railings, equipment safety features, or shields).	5
Hardly Accessible. • There are significant inherent characteristics that would make access to the product very difficult (e.g., enclosed systems, pressurized equipment, railings, equipment safety features, or shields). • Product is in equipment that make access difficult without tools or specialized supplies. • Physical space constraints limit access to food being processed or stored.	3

Not Accessible. • Inside attacker has no access to the product (e.g., attacker cannot physically touch the product). • There are significant inherent characteristics that would make access to the product impossible (e.g., enclosed systems, pressurized equipment, railings, equipment safety features, or shields). • Product is enclosed and secured by packaging, equipment, or other physical access barriers. • Product is handled, staged, or moved in an inaccessible manner (e.g., bucket conveyors being moved via elevated track, an elevated ingredient surge tank with no means of access).	1

[1] Descriptions are meant to be illustrative of the conditions that may be present at a process step that can indicate the nature of the vulnerability. Every condition need not be present to warrant the corresponding score.

Table 3. The Ability of an Attacker to Successfully Contaminate the Product

Description[1]	Score
Highest Ease of Successful Contamination. • The process step is in an isolated area, or obscured from view, enabling an inside attacker to work unobserved with little or no time limitations. • It is easy to successfully add sufficient volume of contaminant to the food. • Inherent characteristics of the point, step, or procedure (e.g., uniform mixing) would evenly distribute the contaminant into the food. • It is highly unlikely the inside attacker would be detected adding a contaminant to the food; an attacker would need to act with little to no stealth to introduce the contaminant. • There are no, or few, workers in the area, and it is highly unlikely that they would notice a contamination attempt by an inside attacker. • There is a low likelihood of the contaminant being removed (e.g., by washing, screening, vibration), diluted, or neutralized at this or later points, steps, or procedures in the process.	10
Moderately High Ease of Successful Contamination. • The process step is seldom observed, enabling an inside attacker to work unobserved with minor time limitations. • It would be relatively easy for an inside attacker to successfully add a contaminant in sufficient volume. • It is unlikely the inside attacker would be detected adding a contaminant to the food; an inside attacker would need to act with minimal stealth to introduce the contaminant. • There are few workers in the area, and it is unlikely that they would notice a contamination attempt by an inside attacker. • Mixing, or agitation, is present but the contaminant may not be evenly distributed throughout the food because of inherent characteristics of the point, step, or procedure. • There is a moderately low likelihood of the contaminant being removed (e.g., by washing, screening, vibration), diluted, or neutralized at this or later points, steps, or procedures in the process.	8

Description[1]	Score
Moderate Ease of Successful Contamination. • The process step is observed about half of the time, or semi-obscured from view; an inside attacker would be under time limitations. • It would be somewhat difficult for an inside attacker to successfully add a contaminant in sufficient volume without being detected. • An inside attacker only would be able to add a reasonably small volume of contaminant (e.g., what can be carried in a pocket) without being detected. • It is moderately likely the inside attacker would be detected adding a contaminant to the food; an inside attacker would need to act with some degree of stealth, irregular, or suspicious activity to introduce the contaminant. • There is no intended mixing or agitation of the product, but processing conditions may distribute the contaminant into the surrounding food because of inherent characteristics of the point, step, or procedure. • There is a moderate likelihood of the contaminant being removed (e.g., by washing, screening, vibration), diluted, or neutralized at this or later points in the process.	5
Moderately Low Ease of Successful Contamination. • The process step is observed more than half of the time; an inside attacker would be under relatively strict time limitations. • It would be difficult for an inside attacker to successfully add a contaminant in sufficient volume without being detected. • It is highly likely the inside attacker would be detected adding a contaminant to the food; an inside attacker would have to conduct suspicious or irregular activities to contaminate the product. • There are some, or many, workers in the area, and it is highly likely that they would notice a contamination attempt by an inside attacker. • Mixing or agitation is not present, and the contaminant would not be effectively distributed into surrounding food because of inherent characteristics of the point, step, or procedure. • There is a high chance that the contaminant would be removed (e.g., by washing, screening, vibration), diluted, or neutralized at this or later points in the process.	3
Lowest Ease of Successful Contamination. • The process step is under constant observation, or the view of the step is unobscured, preventing an inside attacker from adding a contaminant without being detected. • It is extremely likely the inside attacker would be detected adding a contaminant to the food due to the need to conduct highly irregular or suspicious activities to contaminate the food; successful introduction of a contaminant at the point, step, or procedure is extremely difficult or impossible. • There are numerous workers in the immediate area that would notice a contamination attempt by an inside attacker. • An inside attacker would need to add a large volume of contaminant without being detected. • The contaminant likely would be removed (e.g., by washing, screening, vibration), diluted, or neutralized at this or later points in the process. • Other inherent characteristics of the point, step, or procedure (e.g., multiple workers are required to be present for the step to function; positive airflow would prevent introduction of a contaminant; product is moving at a high rate of speed; introduction of a contaminant would result in human injury such as burns, cuts, or lacerations) significantly reduce the ability of an inside attacker to contaminate the product.	1

[1] Descriptions are meant to be illustrative of the conditions that may be present at a process step that can indicate the nature of the vulnerability. Every condition need not be present to warrant the corresponding score.

Description: Characteristics of the relevant point, step, or procedure that can assist you in differentiating the level of ability of an attacker to contaminate the product at each point, step, or procedure under evaluation. Some characteristics (e.g., amount of contaminant needed, concentration, dilution, removal) are only applicable if you are using a contaminant-based approach to estimate potential public health impact for Element 1.

Score: The score associated with the ability of an attacker to contaminate the product at each point, step, or procedure under evaluation. After determining the most appropriate description of the degree of difficulty for an attacker to contaminate the product at each point, step, or procedure, as provided in the "Description" column, assign the appropriate score and record that score in Section #5, "Example of Blank Itemized Generic Vulnerability Assessment"

Considerations when Determining the Score from Table 3 Above:

1. *Amount of Contaminant Needed:* If you have determined the amount of contaminant needed as part of a contaminant-based approach to evaluating Element 1 (Column J in Worksheet 1-E), you can use this information as part of your consideration of the difficulty of an attacker introducing that volume of the contaminant to the point, step, or procedure under evaluation. For example, a few ounces of contaminant, which could easily fit in a pocket, would be less difficult to introduce than 5 gallons of contaminant, which would be difficult to conceal. There are no definitive criteria regarding the volume of contaminant that would be considered large enough to impact the ability of an attacker to successfully contaminate the product. Each food processing facility is unique but knowing your facility's practices should help you determine whether the amount of contaminant could realistically be concealed, moved, and introduced into the product without being detected.

   Even if an attacker could bring enough contaminant into the area without detection, some process steps may make it very difficult to introduce sufficient volume of the contaminant to cause wide scale public health harm. For example, a narrow aperture sample port on an otherwise enclosed tank might make it difficult to introduce a large amount of contaminant into the tank in the time available for an attacker. Similarly, a rapidly moving conveyor where an attacker would need to stand at the point of introduction for an extended period while constantly adding the contaminant over food as it passes might make it difficult to contaminate many servings.

2. *Concentration or Dilution of a Contaminant:* The volume of a contaminant that needs to be added at the current step under evaluation to cause wide scale public health harm may be affected by processing activities that concentrate or dilute the contaminant at downstream points, steps, or procedures. For example, food paste at a holding step may be followed by a process step where the volume of liquid is reduced. The subsequent process step that removes liquid may increase the concentration of a contaminant and thereby decrease the amount of contaminant needed to cause wide scale public health harm. By decreasing the amount of contaminant needed, the downstream process step may increase the score you assign to Element 3 at earlier steps. Conversely, a downstream process step that increases the amount of contaminant needed (e.g., adds a significant amount of liquid), may decrease the score you assign to Element 3 at earlier steps.

3. *Removal of a Contaminant:* Steps that are intended to remove contaminants, such as screening or washing processes, may reduce the ability of an attacker to successfully contaminate a product. Washing, screening, distillation, and other methods intended to remove natural contaminants may also remove intentionally introduced contaminants. Further, if a contaminant added to the product would be discarded as waste (e.g., a contaminant applied to the exterior of a product that will be peeled), this would significantly reduce the ability of an attacker to successfully contaminate the product and lead to a lower score for Element 3. The evaluation as to whether a process step would remove a contaminant should consider the removal of all contaminants. Processes that are designed only to remove common food safety hazards or detritus may not remove the types of contaminants that an attacker may select.

4. *Neutralization of Contaminant:* Although facilities could exclude some specific contaminants from consideration for specific process steps based on neutralization, in almost every instance other contaminants will not be neutralized during those processing steps. For example, there are many chemical contaminants that would not be neutralized by a thermal processing step designed to kill spore forming bacteria. Furthermore, even if a particular contaminant can be neutralized at one process step, an attacker could potentially contaminate the food after the neutralization step. Therefore, you should evaluate subsequent process steps to determine the ability of an attacker to successfully introduce a contaminant at those points. We expect the consideration of contaminant neutralization to be uncommon, given the numerous contaminants that could potentially be used and the level of

knowledge needed to determine whether each contaminant can be neutralized for each of a facility's process steps.

2. Current US FD Food Defense Self-Assessment Checklist – Completed, Signed & Dated

**Important: Use checklist before creating the facility wide vulnerability assessment*

Contains Nonbinding Recommendations
U.S. Food and Drug Administration
Food Defense Self Assessment Tool for
Food Producers, Processors, and Transporters

Food Establishment Operations:

*Mark each item either Y (Yes), N (No), N/A (Not Applicable) or DNK (Do Not Know).

Management

Y	N	N/A	DNK	
○	○	○	○	Prepare for the possibility of tampering or other malicious, criminal, or terrorist actions
○	○	○	○	Assign responsibility for security to knowledgeable individual(s)
○	○	○	○	Conduct an initial assessment of food security procedures and operations
○	○	○	○	Have a security management strategy to prepare for and respond to tampering and other malicious, criminal, or terrorist actions, both threats and actual events, including identifying, segregating and securing affected product
○	○	○	○	Plan for emergency evacuation, including preventing security breaches during evacuation
○	○	○	○	Maintain any floor or flow plan in a secure, off-site location
○	○	○	○	Become familiar with the emergency response system in the community
○	○	○	○	Make management aware of 24-hour contact information for local, state, and federal police/fire/rescue/health/homeland security agencies
○	○	○	○	Make staff aware of who in management they should alert about potential security problems (24-hour contacts)
○	○	○	○	Promote food security awareness to encourage all staff to be alert to any signs of tampering or other malicious, criminal, or terrorist actions or areas that may be vulnerable to such actions, and reporting any findings to identified management
○	○	○	○	Have an internal communication system to inform and update staff about relevant security issues
○	○	○	○	Have a strategy for communicating with the public

Supervision

○	○	○	○	Provide an appropriate level of supervision to all staff, including cleaning and maintenance staff, contract workers, data entry and computer support staff, and especially new staff.
○	○	○	○	Conduct routine security checks of the premises, including automated manufacturing lines, utilities and critical computer data systems (at a frequency appropriate to the operation) for signs of tampering or malicious, criminal, or terrorist actions or areas the may be vulnerable to such actions.

Recall strategy

○	○	○	○	Identify the person responsible, and a backup person
○	○	○	○	Provide for proper handling & disposition of product
○	○	○	○	Identify customer contacts, addresses and phone numbers

Investigation of suspicious activity

Y	N	N/A	DNK	
○	○	○	○	Investigate threats or information about signs of tampering or other malicious, criminal, or terrorist actions
○	○	○	○	Alert appropriate law enforcement and public health authorities about any threats of or suspected tampering or other malicious, criminal, or terrorist actions

Evaluation program

○	○	○	○	Evaluate the lessons learned from past tampering or other malicious, criminal, or terrorist actions and threats
○	○	○	○	Review and verify, at least annually, the effectiveness of the security management program, revise the program accordingly
○	○	○	○	Perform random food security inspections of all appropriate areas of the facility (including receiving and warehousing, where applicable) using knowledgeable in-house or third party staff
○	○	○	○	Verify that security contractors are doing an appropriate job, when applicable

Human element – staff

Screening (pre-hiring, at hiring, post hiring)

○	○	○	○	Examine the background of all staff as appropriate to their position, considering candidates' access to sensitive areas of the facility and the degree to which they will be supervised.

Daily work assignments

○	○	○	○	Know who is and who should be on premises, and where they should be located, for each shift
○	○	○	○	Keep information updated

Identification

○	○	○	○	Establish a system of positive identification and recognition that is appropriate to the nature of the workforce, when appropriate
○	○	○	○	Collect the uniforms, name tag, or identification badge when a staff member is no longer associated with the establishment

Restricted access

○	○	○	○	Identify staff that require unlimited access to all areas of the facility
○	○	○	○	Reassess levels of access for all staff periodically
○	○	○	○	Limit access so staff enter only those areas necessary for their job functions and only during appropriate work hours
○	○	○	○	Change combinations, rekey locks and/or collect the retired key card when a staff member who is in possession of these is no longer associated with the establishment, and additionally as needed to maintain security

Personal items

Y N N/A DNK

- Restrict the type of personal items allowed in establishment
- Allow in the establishment only those personal use medicines that are necessary for the health of staff and ensure that these personal use medicines are properly labeled and stored away from food handling or storage areas
- Prevent staff from bringing personal items into food handling or storage areas
- Provide for regular inspection of contents of staff lockers, bags, packages, and vehicles when on company property

Training in food security procedures

- Incorporate food security awareness, including information on how to prevent, detect, and respond to tampering or other malicious, criminal, or terrorist actions or threats, into training programs for staff, including seasonal, temporary, contract, and volunteer staff
- Provide periodic reminders of the importance of security procedures
- Encourage staff participation in security procedures

Unusual behavior

- Watch for unusual or suspicious behavior by staff

Staff health

- Be alert for atypical staff health conditions that staff may voluntarily report and absences that could be an early indicator of tampering or other malicious, criminal, or terrorist actions, and reporting such conditions to local health authorities

Human element -- public

Visitors (Non-Employees)

- Inspect incoming and outgoing vehicles, packages and briefcases for suspicious, inappropriate or unusual items or activity, to the extent practical
- Restrict entry to the establishment
- Ensure that there is a valid reason for the visit before providing access to the facility - beware of unsolicited visitors
- Verify the identity of unknown visitors
- Restrict access to food handling and storage areas
- Restrict access to locker room

Facility

Physical security

Y N N/A DNK

- Protect perimeter access with fencing or other deterrent, when appropriate
- Secure all doors, windows, roof openings/hatches, vent openings, ventilation systems, utility rooms, ice manufacturing and storage rooms, loft areas, trailer bodies, tanker trucks, railcars, and bulk storage tanks for liquids, solids, and compressed gases, to the extent
- Use metal or metal-clad exterior doors to the extent possible when the facility is not in operation, except where visibility from public thoroughfares is an intended deterrent
- Minimize the number of entrances to restricted areas
- Secure bulk unloading equipment when not in use and inspect the equipment before use
- Account for all keys to establishment
  Monitor the security of the premises using appropriate methods
- Minimize, to the extent practical, places that can be used to temporarily hide intentional contaminants
- Provide adequate interior and exterior lighting, include emergency lighting, where appropriate, to facilitate detection of suspicious or unusual activities
- Implement a system of control vehicles authorized to park on the premises
- Keep parking areas separated from entrances to food storage and process areas and utilities, where practical

Storage and use of poisonous and toxic chemicals
(for example, cleaning and sanitizing agents, pesticides)

- Limit poisonous and toxic chemicals in the establishment to those that are required for the operation and maintenance of the facility and those that are being held for sale
- Store poisonous and toxic chemicals as far away from food handling and storage areas as practical
- Limit access to and secure storage areas for poisonous and toxic chemicals that are not being held for sale
- Ensure that poisonous and toxic chemicals are properly labeled
- Use pesticides in accordance with the Federal Insecticide, Fungicide, and Rodenticide Act
- Know what poisonous and toxic chemicals should be on the premises and keeping track of them
- Investigate missing stock or other irregularities outside a normal range of variation and alert appropriate law enforcement and public health authorities about unresolved problems, when appropriate

Operations

Incoming materials and contract operations:

- Use only known, appropriately licensed or permitted (where applicable) contract manufacturing and packaging operators and sources for all incoming materials, including ingredients, compressed gas, packaging, labels, and materials for research and development

Y	N	N/A	DNK	
○	○	○	○	Take reasonable steps to ensure that suppliers, contract operators and transporters practice appropriate food security measures
○	○	○	○	Authenticate labeling and packaging configuration and product coding/expiration dating systems (where applicable) for incoming materials in advance of receipt of shipment, especially for new products
○	○	○	○	Request locked and/or sealed vehicles/containers/railcars, and, if sealed, obtain the seal number from the supplier and verify upon receipt, making arrangements to maintain the chain of custody when a seal is broken for inspection by a governmental agency or as a result of multiple deliveries
○	○	○	○	Request that the transporter have the capability to verify the location of the load at any time, when practical
○	○	○	○	Establish delivery schedules, not accepting unexplained, unscheduled deliveries or drivers, and investigate delayed or missed shipments
○	○	○	○	Supervise off-loading of incoming materials, including off hour deliveries
○	○	○	○	Reconcile the product and amount received with the product and amount ordered and the product and amount listed on the invoice and shipping documents, taking into account any sampling performed prior to receipt
○	○	○	○	Investigate shipping documents with suspicious alterations
○	○	○	○	Inspect incoming materials, including ingredients, compressed gas, packaging, labels, product returns, and materials for research and development, for signs of tampering, contamination or damage or "counterfeiting", when appropriate
○	○	○	○	Evaluate the utility of testing incoming ingredients, compressed gas, packaging, labels, product returns, and materials for research and development for detecting tampering or other malicious, criminal, or terrorist action
○	○	○	○	Reject suspect food
○	○	○	○	Alert appropriate law enforcement and public health authorities about evidence of tampering, "counterfeiting" or other malicious, criminal, or terrorist action

Storage

○	○	○	○	Have a system for receiving, storing, and handling distressed, damaged, returned, and rework products that minimizes their potential for being compromised or to compromise the security of other products
○	○	○	○	Keep track of incoming materials and materials in use, including ingredients, compressed gas, packaging, labels, salvage products, rework products, and product returns
○	○	○	○	Investigate missing or extra stock or other irregularities outside a normal range of variability and report unresolved problems to appropriate law enforcement and public health authorities, when appropriate
○	○	○	○	Store product labels in a secure location and destroy outdated or discarded product labels
○	○	○	○	Minimize reuse of containers, shipping packages, cartons, etc., where practical

Finished products

○	○	○	○	Ensure that public storage warehouse and shipping operations (vehicles and vessels) practice appropriate security measures
○	○	○	○	Perform random inspection of storage facilities, vehicles, and vessels
○	○	○	○	Evaluate the utility of finished product testing for detecting tampering or other malicious, criminal, or terrorist actions
○	○	○	○	Request locked and/or sealed vehicles/containers/railcars and provide the seal number to the consignee
○	○	○	○	Request that the transporter have the capability to verify the location of the load at any time
○	○	○	○	Establish scheduled pickups, and not accepting unexplained, unscheduled pickups
○	○	○	○	Keep track of finished products
○	○	○	○	Investigate missing or extra stock or other irregularities outside a normal range of variation and alerting appropriate law enforcement and public health authorities about unresolved problems, when appropriate
○	○	○	○	Advise sales staff to be on the lookout for counterfeit products and to alert management if any problems are detected

Access to computer systems

○	○	○	○	Restrict access to computer process control systems and critical data systems to those with appropriate clearance
○	○	○	○	Eliminate computer access when a staff member is no longer associated with the establishment
○	○	○	○	Establish a system of traceability of computer transactions
○	○	○	○	Review the adequacy of virus protection systems and procedures for backing up critical computer based data systems
○	○	○	○	Validate the computer security system

If a food import establishment operator suspects that any of his/her products that are regulated by the FDA have been subject to tampering, "counterfeiting", or other malicious, criminal, or terrorist action, FDA recommends that he/she notify the FDA 24-hour emergency number at 301-443-1240 or call their local FDA District Office. FDA District Office telephone numbers are listed at: http://www.fda.gov/ora/inspect_ref/iom/iomoradir.html. FDA recommends that the operator also notify local law enforcement and public health agencies.

Signature: _____

Date Signed: _____

米国食品安全強化法「意図的な食品不良事故防止」規則にかかる食品防御計画雛形
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