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I. OBJECTIVE

Elaborate a food defense vulnerability analysis to establish control measures to reduce the probability of intentional contamination in any of the products manufactured at Empacadora del Golfo de México S.A. de C.V.


II. SCOPE

Applies to the internal and external areas of Empacadora del Golfo de México S.A. de C.V.

III. RESPONSIBLE

#	Name	Position	Responsibilities
1	Mónica Fabiola Núñez Rechy	Food Safety Head Food defense team coordinator	1. Manage the food defense program 2. Ensure team training 3. Verify that the responsibilities of the defense team are being carried out. 4. Coordination of the food defense team 5. Management of internal audits 6. Regulatory compliance management
2	Domingo de las Rivas	Commercial Director	1. Provide tools and resources to support the defense plan 2. Spokesperson during incidents 3. Approve / authorize document change control
3	Aida Vargas	Human Resources Manager	1. Coordinate and manage the training of employees and equipment 2. Ensure that job profiles are met 3. Conduct induction for new personnel 4. Manage legal compliance (Secretary of Labor)
4	Javier Pérez	Production Director	1. Ensuring production continuity 2. Management of resources to cover incidents 3. Ensuring compliance with the On-Site Defense Plan 4. Follow up on corrective actions according to the Plan
5	Esther Huerta	Quality Head	1. Manage vulnerability assessment according to procedure 2. Maintenance and control of the plan 3. Complaint management and supplier follow-up
6	Rodrigo Sainz Trápaga Fernández	Purchase Manager	1. Plant-supplier communication channel 2. Ensuring timely distribution of inputs and outputs 3. Monitor supplier compliance (guidelines and policies)

Prepared by:	Review by:	Approved by:
Food Safety Head	Food defense team	Food defense team

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#	Name	Position	Responsabilities
7	Griselda Pérez Palomeque	Administration Manager	1. Ensure compliance with internal policies related to access security, security systems (closed circuit cameras and key control), and security management 2. Management of internal plant access security and control of incoming and outgoing raw material, ingredient and finished product transports 3. Transport inspection management 4. Evaluate the economic impact of an incident
8	José Antonio Saíñz Trápaga	Projects Manager	1. Ensuring and controlling the external security of the plant and perimeter areas, including the water well 2. Development of changes and improvements to the facilities 3. Ensuring the custody of external personnel
9	Ramón Sánchez Rocha	Warehouse Manager	1. Ensure the loading and unloading of inputs and finished product 2. Internal inspection of transportation 3. Providing information on status and routing of products 4. Reception and control of hazardous chemicals
10	Enrique Rivera	Maintenance Manager	1. Execution of plant equipment maintenance improvements derived from the defense plan 2. Ensuring the necessary maintenance controls, handling and storage of equipment, spare parts and instruments 3. Ensuring the custody of external personnel 4. Ensure water storage safety controls
11	Rodrigo Saíñz Trápaga	CEO	Ensure food defense culture and provide resources to the system.

IV. CONDITIONS / REGULATIONS

BRCGS Food Safety Standard Requirement 4.2 Establishment protection and sanitary defense
 21 CFR Part 121 Mitigation strategies to protect product from intentional adulteration.

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V. DESCRIPTIONS

The company shall have a food defense team that will be responsible for conducting the vulnerability analysis and implementing the resulting mitigation strategies.

The members and responsibilities of the defense team shall be described in the Food Defense Plan.

The defense team shall conduct a food defense vulnerability analysis based on the requirements of 21 CFR 121 and the defined key activity types (KATs).

The 4 key activity types defined by the FDA are:

1. Receiving and loading of bulk liquids
2. Storage and handling of liquids
3. Handling of secondary ingredients
4. Mixing and similar activities

Once the key activities in our process have been identified, we proceed to perform the evaluation to identify the actionable process steps, based on the 3 elements, in order to identify the Actionable Process Steps (APS) and establish the mitigation strategies as appropriate.

For a process step to become a PPA, it must have a value equal to or greater than 26 in the sum of the evaluation.

Based on the results of the vulnerability assessment, for those stages that result, according to their weighting, in a PPA, mitigation strategies should be established in order to reduce the risk.

Strategies should be verified to corroborate that they remain in place and are being effective at least once a year and evidence of this verification should be left.

- An additional verification should be conducted once a year through a Food Defense Challenge, which should test control measures to reduce the likelihood of intentional contamination of products.
- If during the verification of the strategies or in the food defense challenge, a non-effective result is obtained, corrective and preventive measures must be taken to avoid recurrence.

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Training will be conducted at 2 levels:

1. Training to managers, supervisors.
 - a. The managers will be made aware of the mitigation strategies and their participation in these strategies.
2. Training at the operational level
 - a. It will be given on the floor, with lectures.

For facility protection purposes, the vulnerability analysis and food defense plan should not be copied or shared by any means. For on-site audit purposes only, how it was developed and implemented can be explained.

VI. GLOSSARY:

- Food Defense: initiative to protect the product from acts of intentional contamination.
- KAT (Key activity type): A key activity type is one that falls into the category of activities defined by the FDA as those where an act of intentional adulteration may be committed because of the type of process.
- PPA (Actionable Process Step): Point, step or procedure in a process where a significant vulnerability exists and where mitigation strategies can be applied.
- Mitigation strategy: Reasonably appropriate risk-based measures to significantly reduce the likelihood of intentional adulteration in HAPs.


VII. ANNEXES

ANNEX 1. Critical Zone Entry and Exit Log ACDF/02

ANNEX 2. Register for the use of keys (Sensitive Areas) ACFD/04

ANNEX 3. Authorization Record ACFD/06

ANNEX 4. Closed padlock for well and buffer tank PREL 64-1

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VII. CHANGES CONTROL

Section	Description	Date	Made by
N/A	Revision	20/07/2018	Laura Hernandez
N/A	Update	03/02/2020	Esther Huerta
N/A	The document has been revised and modified almost in its entirety, for which reason it is recommended that it be read in its entirety.	Ene-2022	Mónica Núñez

VIII. DISTRIBUTION LIST

# Copy	Printed or electronic	Area	Receives
N/A	E	Production	Production Head
N/A	E	Production	Production Director
N/A	E	Maintenance	Maintenance Manager
N/A	E	Projects	Projects Manager
N/A	E	Purchases	Purchases Manager
N/A	E	Warehouse	Warehouse Manager
N/A	E	Quality	Quality Head
N/A	E	Food safety	Food Safety Coordinator
N/A	E	Administration	Administration Manager
N/A	E	Sales	Commercial Director
N/A	E	-	CEO