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|  | Standard Operating Procedure | | SOP Number QS-109 | Revision 2 |
| | Food Defense Plan | | Effective Date 03/06/24 | Page Page 1 of 7 |
| Written by/ Date K. Summers 01/02/24 | | Reviewed by/ Date [Signature] 01/02/24 | | Approved by/ Date [Signature] 01-03-24 |
| Title: Quality Assurance Director | | Title: Quality Control Director | | Title: VP of Quality & Regulatory Affairs |

1.0 Purpose

The purpose of the Food Defense plan is to describe how Ion Nutritional Labs will protect the food supply/product against intentional contamination due to sabotage, terrorism, counterfeiting, or other illegal, intentionally harmful means.

2.0 Scope

This procedure is applicable to all food processes at Ion Nutritional Labs.

3.0 Responsibility

- 3.1 A multi-disciplinary Management Team (Operations, Quality, and Facilities) is responsible for ensuring that the organization is prepared to respond to emergency situations and for preparing a Food Defense Plan.
- 3.2 It is the responsibility of all employees to follow the Food Defense Plan and act as the first line of defense in guarding against any intentional contamination.
- 3.3 It is the responsibility of Quality to organize a challenge of the Food Defense Plan annually.

4.0 Definitions

- 4.1 **Emergency Situation** – an event that can have a negative impact on food safety, that is not controlled by the daily controls of the Food Safety Management System
- 4.2 **Food Defense Plan** – the practices implemented to control/minimize the risk of an intentional contamination incident, which can reduce the overall vulnerability of the

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facility's food operation from intentional contamination

- 4.3 **Intentional Contamination** – a deliberate action to introduce something into a product, often with intention to do harm to the customer, company, or both
- 4.4 **Insider Attacks/Threats** – acts of sabotage or adulteration committed by disgruntled employees, consumers, or competitors (Acts of Terrorism)
- 4.5 **Broad Mitigation Strategies** – steps taken to defend the facility against intentional contamination, in which identified deficiencies can then be assessed and action plans can be developed to improve security measures as needed (must be included in the Food Defense Plan)

5.0 References

- 5.1 Training Presentation: cGMP, HACCP/HARPC, Food Safety and Defense, Allergen Awareness, Internal Audits, Control of Glass, Brittle Plastic, Ceramics, and Wood, Dietary Supplement, and Pet Supplement Overview
- 5.2 FDA Food Safety Modernization Act (IA Rule)
- 5.3 QS-108, SOP, Corrective and Preventive Actions
- 5.4 E-601, SOP, Vendor Qualification
- 5.5 Disaster Recovery and Business Continuity Plan
- 5.6 QS-105, SOP, Food Safety Plan
- 5.7 A-108, SOP, Good Manufacturing Practices and Personal Hygiene
- 5.8 A-117, SOP, Personnel Qualifications
- 5.9 A-113, SOP, Training Procedure

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- 5.10 QS-107, SOP, Recall Procedure
- 5.11 A-118, SOP, Management Review of Quality Metrics
- 5.12 C-502, SOP, Document Storage, Retention, and Destruction
- 5.13 H-101, SOP, Internal Audits
- 5.14 QS-112, SOP, Core Quality Systems and Quality Events
- 5.15 21 CFR part 121 Mitigation Strategies to Protect Food Against Intentional Adulteration

6.0 Food Defense Plan

- 6.1 Senior Management will prepare a Food Defense Plan that includes the following:
 - 6.1.1 The names of the management team members who are responsible for food defense.
 - 6.1.2 Methods to ensure only authorized personnel have access to manufacturing storage areas.
 - 6.1.3 Measures to ensure the secure the storage of raw materials, packaging, equipment, and hazardous chemicals.
 - 6.1.4 Measures to ensure that finished product is held under secure storage and transportation conditions.
 - 6.1.5 Methods implemented to record and control access to the premises by employees, contractors, and visitors.
 - 6.1.6 Requirements of employees to be trained on food defense practices (New Hire and Annual cGMP Training).
- 6.2 Employee training resources are available through the FDA website.

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- 6.3 The Food Defense Plan is reviewed annually, at a minimum, to determine the effectiveness of the procedure, methods, and practices, or when changes occur that could impact the Food Defense Program.
- 6.4 Food Defense Audits (Broad Mitigation Strategy Checklist) are performed annually, at a minimum, to provide assurance to our customers, to assess or improve the level of food defense safety, and to demonstrate compliance to food safety regulations.

7.0 Forms and Records

- 7.1 The Food Defense Plan will be maintained by Quality, to include all related documentation.
- 7.2 Any activity found to directly affect the security of the facility will be reported during Management Review.
- 7.3 The Food Defense Plan and all related documentation will be maintained as per SOP C-502 Document Storage, Retention, and Destruction.
- 7.4 The Food Defense Plan will be issued a report number as outlined in SOP QS-112 Core Quality Systems and Quality Events, to ensure proper traceability.

8.0 Broad Mitigation Strategies

- 8.1 Broad mitigation strategies include security and screening procedures for the facility, materials, and people. Understanding and evaluating broad mitigation strategies will be used to document current monitoring/verification practices and determine any gaps or deficiencies. Broad Mitigation Strategies for food defense are similar to the Current Good Manufacturing Practices (GMPs) or prerequisite programs for food safety.
- 8.2 Broad Mitigation Strategy Responses:
- 8.2.1 **Not Applicable** – the measure (question) is not applicable or not appropriate for the facility/company

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8.2.2 **Currently Doing** – the measure (question) is already being addressed sufficiently by the facility/company

8.2.3 **Gap** – the measure (question) is currently not being addressed or not fully being addressed by the facility/company. If a gap is detected, it will be documented in the comments/action steps of the Broad Mitigation Strategies. Corrective Action will be taken to ensure the gap is addressed and resolved. This action will be verified.

9.0 Vulnerability/Mitigation Strategies

9.1 Vulnerability/Mitigation strategies assessment is intended to assist in identifying, quantifying, and prioritizing facility weaknesses regarding food safety and defense, offering mitigation strategies/suggestions for situations with a potential risk for intentional contamination.

9.2 Corrective/Preventative Actions will be assigned by Quality to the respective department. Quality will document all corrective actions. Follow-up to corrective actions will be performed, along with verification to ensure effectiveness.

10.0 Intentional Contamination

10.1 The possibility of intentional contamination is a part of safety considerations and measures to prevent sabotage.

10.2 In the event of a suspected incident involving intentional contamination of food, Ion Nutritional Labs has implemented procedures and plans to assist and minimize the adverse consequences of the incident.

11.0 Inside Attack or Threat

11.1 Ion Nutritional Labs has developed First Response steps in the event of an inside attack or threat. Refer to the Disaster Recovery/Business Continuity Plan (Act of Terrorism).

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11.2 Employees are trained to recognize and report any unusual or suspicious activity.

12.0 Challenging the Food Defense Plan

12.1 Annually, the Food Defense Plan will be challenged to validate whether procedures are effective when implemented as expected, as well as highlighting any failures in implementation. The challenge will be performed as outlined in the following steps.

12.1.1 Decide on a challenge action. For example, a common food defense challenge test is a penetration test, in which an unauthorized person attempts to gain access to a sensitive area.

12.1.2 Create a food defense challenge report. In the report, document exactly what steps are planned in the challenge test. Include what, when, how, who, and next steps.

12.1.3 Include written contingency plans in case of escalation, for example, what will be done if police are called.

12.1.4 Get approval for the plan from Senior Management.

12.1.5 In the report, record the following:

12.1.5.1 Name of Senior Manager who has signed off on the plan.

12.1.5.2 Names of employees who have been informed of the challenge test.

12.1.5.3 Names of people who will be working in the affected areas at the time of the challenge, ensuring that all have been trained in Food Defense.

12.1.5.4 A description of what staff are supposed to do in the chosen scenario and what procedures are to be followed.

12.1.6 Define and document the criteria for failure and success:

- 12.1.6.1 What will happen if the food defense procedures are working 100% correctly?
- 12.1.6.2 What will happen if the food defense procedures are working only partially?
- 12.1.6.3 How might the scenario progress if there is a complete failure of procedures and systems?

12.1.7 Run the challenge. Have a staff member observe from a discreet distance.

12.1.8 Describe in the report what happened.

12.1.9 Convene a meeting of the food defense team and analyze the results of the challenge.

12.1.10 Perform root cause analysis and raise corrective actions for any failures in the system.

12.1.11 Take action to prevent a scenario like this from reoccurring, based on the root cause analysis performed.

13.0 Revision History

| Revision | Date | Description of Changes | CCR # | By |
|----------|----------|---|------------|-------------|
| 0 | 04/04/17 | New | 17-0329 | S. Millar |
| 1 | 10/07/20 | Added definitions of Intentional Contamination and Insider Threat/Attack. Added reference to Training Presentation: to include HARPC, Internal Audits, Control of Glass, Brittle Plastic and Ceramics, and Pet Supplements, Added SOP H-101 Internal Audits. Added reference 21 CFR part 121 Mitigation Strategies to Protect Food Against Intentional Adulteration, Added reference New Hire and Annual cGMP Training. Added reference to Intentional Contamination. Added Inside Attack or Threat with reference to Disaster Recovery/Business Continuity Plan. Defined audit frequency | CC-20-0712 | C. Martinez |
| 2 | 12/27/23 | Schedule review: updated format and logo. Clarified steps throughout procedure. Added requirements for food defense plan challenge. | CC-23-0616 | K. Burris |



FOOD DEFENSE PLAN

ION NUTRITIONAL LABS

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Seminole, Florida 33777

Phone: 727-527-1072 Fax: 727-527-6758

Facility Identification

Largo Facility FDA Registration Number: 13199019672

Seminole Facility Registration Number: 11799726996



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Facility Description

Ion Nutritional Labs is a contract manufacturer that has been providing new and existing clients with the highest quality products in nutrition and health supplement manufacturing since 1983. From product development to contract manufacturing and packaging, adherence to GMP compliance in an FDA registered facility has been our formula for integrity and product fulfillment for over thirty years.

Employee Type Description

Ion Nutritional Labs currently employs over 260 associates dedicated to providing only the safest, highest quality products to our customers. This is achieved through GMP compliance, strong attention to detail, and adherence to all relevant regulatory requirements. Our mission is to achieve total customer satisfaction.

Product and Processes

Ion Nutritional Labs specializes in the manufacture of dietary supplements, pet products, and food products in the United States of America. The core of our operation is a custom-built factory, outfitted with over twenty-five individual rooms, designed to support precision and high volume. Ion Nutritional Labs offers international shipping and proof of all necessary permits, credentials, and certifications for all contract manufacturing requirements.



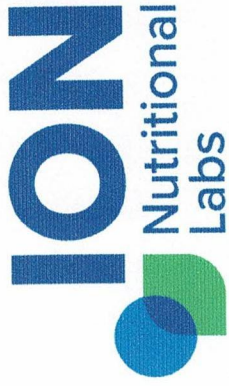
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FOOD DEFENSE TEAM

| Name | Title | Phone |
|------------------|--|--------------|
| Dennis Herd | VP of Quality & Regulatory Affairs | 727-220-1281 |
| Kimberlee Burris | Director of Quality Assurance | 727-220-1332 |
| Jennifer Sassman | Director of Quality Control | 727-220-8046 |
| Robert White | Maintenance & Facility Senior Manager | 727-220-1342 |
| Rebecca Gordon | Director of Human Resources | 727-220-1334 |
| Matthew Keib | Chief Operating Officer | 727-220-1323 |
| Millie Zhou | Director of Supply Chain | 727-220-1365 |
| David Wagner | VP of Information Technology | 727-220-1291 |
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BROAD MITIGATION STRATEGIES

| 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)? | | | | |
| | 1b. Is there adequate lighting around the property perimeter? | | | | |
| | 2a. Is there adequate lighting outside each building and in between buildings? | | | | |
| 2. Building Perimeter | 2b. Are primary entrances to the buildings and operating areas monitored and secured? | | | | |
| | 2c. Are emergency exit doors self-locking from the outside, with alarms that activate when the doors are opened? | | | | |
| | 2d. Are operational entrances, such as the loading dock doors, secured when not in use? | | | | |
| | 2e. Are all possible access points into the buildings covered, locked, or otherwise secured? | | | | |
| 3. Vehicles | 3a. Does the property have a controlled entrance for vehicles? | | | | |
| | 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. | | | | |
| | 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? | | | | |



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| Section | Measure | Response | Plan Content | Comments | Action Steps |
|--------------------------------|--|----------|--------------|----------|--------------|
| General Inside Security | | | | | |
| 4. Facility/Plant | 4a. Is there adequate lighting throughout the facility? | | | | |
| | 4b. Is there an emergency lighting system in the facility? | | | | |
| | 4c. Does your facility have established emergency procedures, including procedures for responding to an intentional contamination? | | | | |
| | 4d. Does your facility have an emergency alert system that is tested regularly? | | | | |
| | 4e. Is access to production, storage and other sensitive areas restricted to a small number of employees? | | | | |
| | 4f. 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. | | | | |
| | 4g. Are copies of the facility's site plan and blueprints stored in a secured location at the facility and in an offsite location? | | | | |
| | 4h. Are procedures in place to check maintenance closets, personal lockers, for suspicious items or packages? | | | | |
| | 4i. Is there an Environmental Monitoring Program in place ensuring temperature and humidity meets the required guidelines? Are they monitored and recorded? | | | | |
| | 4j. Are there any potential threats from neighboring facilities or environmental conditions? If so, are there physical measures in place to manage exterior environmental risks. | | | | |



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| 5. Utilities | 5a. Are controls for the Heating, Ventilation, and Air Conditioning (HVAC) systems secured to prevent access by unauthorized persons? | | | | |
| | 5b. 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? | | | | |
| | 5c. Are cleaning/sanitization chemical dispensing systems secured from unauthorized access? | | | | |
| | 6a. Is access to the laboratory facility restricted to authorized employees (e.g., by locked door, pass card, etc.)? | | | | |
| 6. Laboratory | 6b. Is a procedure in place to receive and securely store reagents? | | | | |
| | 6c. Are laboratory materials restricted to the laboratory, except as needed for sampling or other authorized activities? | | | | |
| | 6d. Is a procedure in place to control and dispose of reagents? | | | | |
| | 7a. Is access to these process control systems restricted to trusted employees? | | | | |
| 7. Process Computer Systems | 7b. Is access to process control computer systems password protected? | | | | |
| | 7c. Are firewalls built into the computer network used for process controls? | | | | |
| | 7d. Is antivirus software installed on the process controls computer system and is it frequently updated? | | | | |
| | 7e. When an employee's employment ends, is their access to process control computer systems disabled? | | | | |
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| Section | Measure | Response | Plan Content | Comments | Action Steps | |
|---|---|--|--------------|----------|--------------|--|
| Logistics and Storage Security | | | | | | |
| 8. Suppliers and Vendors | 8a. When choosing suppliers for your packaging materials, labels, ingredients, and raw materials, do you consider whether they have developed a Food Defense Plan? | | | | | |
| | 8b. Do you have a supplier approval certification system in place to ensure that you purchase supplies only from known, reputable sources? Are suppliers qualified and re-qualified? | | | | | |
| | 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? | | | | |
| | | 9b. Is there close supervision of the unloading of vehicles transporting raw materials, finished products, ingredients or other materials used in food processing? | | | | |
| | 9c. Is access to loading docks controlled to avoid unverified or unauthorized deliveries? | | | | | |
| | 9d. 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)? | | | | | |
| 9e. Are seals verified prior to acceptance? | | | | | | |
| 9f. Is there an Allergen Control Program in place to address the prevention of cross-contamination with major food allergens? | | | | | | |



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| 10. Outgoing Shipments | 10a. Are shipping vehicles (trucks, tankers, rail cars) inspected prior to loading to detect the presence of any foreign/hazardous materials? | | | | |
| | 10b. Are outgoing shipments enclosed and sealed with tamper-evident seals (or locks)? | | | | |
| | 10c. Are chain-of-custody (possession) records maintained for all shipments of finished goods? | | | | |
| | 10d. Are effective product recall procedures in place? | | | | |
| 11. Returned Product | 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? | | | | |
| | 11b. Are records maintained of returned products/goods used in rework? | | | | |
| | 11c. Are procedures in place for the approval and monitoring of reprocessing/rework? | | | | |
| 12. Water / Processing Aids | 12a. Is access to the piping systems used to transfer potable water, oil, or other ingredients limited? | | | | |
| | 12b. Are the piping systems used to transfer potable water, oil, or other ingredients inspected periodically? | | | | |
| | 12c. Are there water storage tanks, reservoirs, or water treatment systems? Is access to them restricted? | | | | |



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| 13. Storage / Warehouse | 13a. Is access to raw material and ingredient storage areas restricted to designated employees (e.g., by locked door or gate)? | | | | |
| | 13b. Is an access record maintained to indicate who has entered raw material or ingredient storage areas? | | | | |
| | 13c. Is access to finished product storage areas restricted to designated employees? | | | | |
| | 13d. Do you conduct random security inspections of all storage facilities? | | | | |
| | 13e. Are product labels and packaging held in a controlled manner to prevent theft and misuse (e.g., counterfeiting)? Label accuracy/allergen review is performed. | | | | |
| | 13f. Is finished product inventory regularly checked for accuracy? | | | | |
| 14. Hazardous Materials / Chemicals | 13g. Is the warehouse environmentally controlled to ensure preservation of product/material? Controls are with limited access? | | | | |
| | 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? | | | | |
| | 14b. Is a regular inventory of hazardous materials/chemicals maintained? | | | | |



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| Management | | | | | |
| 15. Personnel Security | 15a. Are basic background checks and/or reference checks with previous employers conducted for all new employees? | | | | |
| | 15b. Do all employees receive training on security procedures and food defense awareness as part of their orientation training? | | | | |
| | 15c. Are employees, visitors, and contractors (including construction workers, cleaning crews, and truck drivers) identified in some manner at all times while on the premises? | | | | |
| | 15d. Do you control employee and contractor access into the facility during working hours (e.g., coded doors, receptionist on duty, swipe card, etc.)? | | | | |
| | 15e. Does your facility control the entry of employees and contractors into the facility during non-working hours? | | | | |
| | 15f. 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? | | | | |
| | 15g. Does management maintains 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? | | | | |
| | 15h. Does your facility restrict personal items and food within production areas? | | | | |
| | 15i. Is there a policy in place that prohibits employees from removing company-provided clothing and protective gear from the premises? | | | | |



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| 16. Food Defense Plan | 16a. Is there a designated person or team to implement, manage, and update the Food Defense Plan? | | | | |
| | 16b. Have supervisors, management, and key personnel received additional food defense training? | | | | |
| | 16c. Do you conduct regular food defense exercises to test the effectiveness of your Food Defense Plan? | | | | |
| | 16d. Is the Food Defense Plan reviewed (and revised if necessary) periodically? | | | | |
| | 16e. Are the details of food defense procedures within the Food Defense Plan kept secure or confidential? | | | | |
| | 16f. Is the emergency contact information for local, state, and federal government regulatory authorities and public health officials included in the Food Defense Plan? | | | | |
| | 16g. Does the Food Defense Plan have procedures to ensure that contaminated or potentially harmful products are held at the facility? | | | | |
| | 16h. 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? | | | | |
| | 16i. Are employees encouraged to report signs of possible product contamination, unknown or suspicious persons in the facility, or breaks in the food defense system? | | | | |
| | 16j. Does your facility have evacuation procedures in case of an emergency that include controlling access to the facility during evacuation? | | | | |



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