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	Food Defense Plan and Food Fraud Plan	

1.0 Purpose

- 1.1 To provide measures to protect food and food production processes from intentional harm.
- 1.2 The purpose of the Food Defense Plan is to protect food from intentional contamination, adulteration, tampering or sabotage by malicious actors. The primary goal is to prevent harm, protect public health, and ensure the integrity of the food system.
- 1.3 The purpose of a Food Fraud mitigation plan is to prevent economically motivated adulteration (EMA) of food products. Food fraud typically involves the deliberate substitution, dilution, misrepresentation, or mislabeling of food products for economic gain, without any intent to harm consumers directly.

2.0 Scope

- 2.1 This procedure applies to all BodyBio personnel, contractors, suppliers and visitors in the production, storage, distribution, and sale of nutraceutical products.
- 2.2 The scope of the Food Defense Plan includes all BodyBio facilities whose processes are involved in the production, storage, distribution, and transportation.
- 2.3 The scope of the Food Fraud Plan addresses all activities related to the procurement, processing, storage and distribution of raw materials and finished products.

3.0 Responsibility and Frequency

- 3.1 Compliance with this procedure is the responsibility of all BodyBio employees. All employees are required to report any signs of tampering or suspicious activity.
- 3.2 It is the Quality Department's responsibility to ensure that all personnel are properly trained on and follow this procedure.
- 3.3 It is the responsibility of the Quality Department to ensure that an annual vulnerability assessment is conducted and any necessary corrective actions are enacted and enforced.
 - 3.3.1 The vulnerability assessment will identify key areas where a food defense risk exists and the potential threats to those areas.

4.0 References

- 4.1 21 CFR Part 121 Mitigation Strategies to Protect Food Against Intentional Adulteration
- 4.2 21 CFR Part 1 General Enforcement Regulations



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5.0 Food Defense Preventative Measures

5.1 Pre-employment Screening

- 5.1.1 All potential employees will undergo a background check, and will not officially be hired/cleared to start working at BodyBio until the background check has been completed.
- 5.1.2 Previous employment references will be contacted.

5.2 Onboarding Process

- 5.2.1 During the onboarding process, every employee will be issued a Key FOB. This FOB grants the employee access to the building through the secured entrances of the building.
- 5.2.2 New employees who work onsite at BodyBio's facilities will be trained to recognize suspicious behavior, signs of tampering and how to report concerns.
- 5.2.3 New employees who work onsite at BodyBio's facilities will be trained on the following general company procedures that directly relate to security of the facility and products:
 - 5.2.3.1 SOP 01-001 *Employee Training*
 - 5.2.3.2 SOP 01-005 *Receiving Government Agency Inspectors*
 - 5.2.3.3 SOP 01-008 *BodyBio's Visitor Policy*
 - 5.2.3.4 SOP 04-021 *Personnel Hygiene*
 - 5.2.3.5 SOP 04-045 *Hand washing and Sanitizing*

5.3 Preventative Measures to manage potential security risks to product:

- 5.3.1 Security cameras installed outside of all facilities with random inspections to ensure there is no unauthorized entry or suspicious activity outside the facilities.
- 5.3.2 Outside lighting is present on the exterior of all facilities.
- 5.3.3 Windows can only be opened from the inside of the buildings.
- 5.3.4 Incoming shipments and the vehicles they are delivered in are inspected (SOP 03-002 *Receipt of Inventory Materials*)
- 5.3.5 Loading dock doors are locked when not in use.



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5.3.6 Access Controls are in place which require a key FOB for entry into each building.

5.3.7 Metal detection on production line.

5.3.8 Tamper evident seals are required for all products, either under cap or over cap.

5.3.9 BodyBio monitors the environment in production facilities pursuant to SOP 04-027 *Environmental Monitoring*

5.3.10 BodyBio conducts regular water testing of the USP purified water system pursuant to SOP 04-014 *Sampling and Testing of USP Purified Water*.

5.3.11 BodyBio trains all employees on disaster management pursuant to SOP 01-009 *Disaster Recovery Plan*

5.4 Supplier Requirements

5.4.1 BodyBio will qualify its suppliers and contract manufacturing partners to ensure they follow secure and reputable practices.

5.4.2 BodyBio will require suppliers to provide documentation demonstrating the integrity of their products and adherence to food defense protocols.

5.5 BodyBio will control documentation by keeping the following Approved Documents in locked cages, locked offices, or QT9 QMS which are only accessible by in which only specific employees have keys and access:

5.5.1 SOPs

5.5.2 Specification Sheets

5.5.3 Master Manufacturing Records

5.5.4 Packaging Process sheets

5.5.5 Deviation Records

5.5.6 Complaint Records

5.5.7 Investigation Records

5.5.8 Completed Batch Folders

5.5.9 Completed Specification Sheets



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5.6 This plan will be challenged annually. Refer to **Figure 1** for template.

6.0 Incident Response and Recovery

6.1 BodyBio will establish a protocol for identifying incidents such as contamination or suspicious activity and an alert system for immediate reporting to the Quality Department.

6.2 BodyBio will identify key personnel who will respond to an incident including representatives from the Quality Department and Operations.

6.2.1 BodyBio will establish procedures to contain and address the threat, including product recalls if necessary.

6.3 BodyBio's Quality Department will conduct a root cause analysis after an incident to identify weaknesses in the plan, implement corrective actions and reassess vulnerabilities to prevent recurrence.

7.0 Record Keeping

7.1 BodyBio will keep detailed records of all food defense activities including training, risk assessments and incident responses and maintain logs for access control, security measures and audits.

8.0 Food Fraud

8.1 All raw materials, packaging components, and in-process materials that are purchased from vendors will be qualified and approved via the following SOPs:

8.1.1 SOP 04-002 *Vendor Qualifications*

8.1.2 SOP 04-004 *Contract Manufacturing and Packaging Audit*

8.1.3 SOP 04-036 *Vendor Qualification, Requalification, and Disqualification Criteria*

8.2 The Vendor Qualification Form lists the risk factor for that vendor, and all items purchased from the vendor.

8.3 All materials received are tested against the current specification sheet for that item.

8.4 The vendor audits will be reviewed no less than every two years.



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8.5 BodyBio will conduct a risk assessment for Food Fraud annually which reviews fraudulent risks including: substitution of a high-value ingredient with a lower-cost one; adulteration through adding an unauthorized substance to a product; and/or mislabeled products. Refer to Figure 2.

8.5.1 The risk assessment process will include conducting a fraud risk assessment across the supply chain, including raw materials, suppliers and/or distribution channels; identifying high-risk ingredients or products that are more likely to be subject to fraud and ranking fraud risks based on their likelihood and impact.

8.6 BodyBio will take preventative measures including using reputable suppliers who are regularly audited; verify materials using analytical testing and certificates of authenticity to verify the quality and origin of key ingredients; perform quality control checks including testing raw materials and finished products; and ensuring labeling and packaging is compliant with all regulatory requirements.

8.7 Incident Detection and Response

8.7.1 BodyBio will regularly conduct internal audits and/or third party reviews to identify discrepancies or signs of fraud. It will also implement a reporting process for employees to report suspected fraud.

8.7.2 In case fraud is detected, BodyBio will isolate the affected products, assess the scale of the issue, investigate the source of the fraud and enact the appropriate corrective actions.

8.8 BodyBio will train all employees on recognizing signs of fraud such as unusual ingredient substitutions or mislabeled products and will encourage a culture of integrity and ethical behavior in the workplace.

8.9 BodyBio will maintain records of all fraud prevention activities including risk assessments, audits, supplier certifications and test results and will document any incidents of food fraud and actions taken to resolve them.

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Food Defense Annual Challenge

Objective: The purpose of this test is to evaluate the effectiveness of the food defense plan, identify any vulnerabilities, and ensure compliance with regulations. This test will assess how well the plan addresses potential food defense hazards, how prepared personnel are for a food defense incident, and how quickly the facility can respond to a real or simulated threat to food safety.

Scope: This test will evaluate the preparedness of employees, response actions, and the effectiveness of food defense practices across the entire facility.

Test Scenario: (select scenario – see examples below)

- Scenario 1: Unauthorized Access to Facility: A team member posing as an unauthorized individual attempts to gain access to restricted areas using various methods (e.g., tailgating, using a fake ID).
- Scenario 2: Suspicious Package or Contamination Threat: A package or item is placed in a storage area or loading dock with instructions for employees to identify, report, and isolate it.
- Scenario 3: Sabotage or Tampering with Product: Introduce a mock sabotage incident (e.g., minor tampering with a batch of products, marking a product with a harmful substance) and measure employee response.
- Scenario 4: Cybersecurity Attack on Food Safety Systems: Simulate a cyber-attack or breach (such as a fake email from "IT support" asking for access to records or attempts to manipulate food safety data).

Expected Outcome: (describe expected outcomes)

Actual Outcome: (describe actual outcomes)

Prepared By/Date: _____

Reviewed By/Date: _____

Approved By/Date: _____



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Figure 2



Food Fraud Vulnerability Challenge

Category	Description	Supplier	Manufacturer	Supplier Approved?	Material History				Risk	Mitigation
					Substitution	Dilution	Mislabeled	Counterfeit		
Raw Materials	Flaxseed Oil	Barleans	Barleans	Yes	No history	No history	No history	No history	Low	Add part number to raw material order and during release, ensure correct material was ordered
Raw Materials	Calcium Hydroxide	Univar	Mississippi Lime	Yes	No history	No history	No history	No history	Low	Add part number to raw material order and during release, ensure correct material was ordered
Raw Materials	Butyric Acid	Chempoint	Eastman	Yes	No history	No history	No history	No history	Low	Add part number to raw material order and during release, ensure correct material was ordered
Raw Materials	Potassium Phosphate	Jost	Jost	Yes	No history	No history	No history	No history	Low	Add part number to raw material order and during release, ensure correct material was ordered
Raw Materials	Potassium Chloride	AIC	Aurorium	Yes	No history	No history	No history	No history	Low	Add part number to raw material order and during release, ensure correct material was ordered

Prepared By/Date: _____

Reviewed By/Date: _____

Approved By/Date: _____



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Revision History

Revision	Comments
0	New
1	• Overhauled entire SOP • Updated responsibility section to include an annual test • Specified onsite employees with be trained on specific SOPs • Added SOP titles throughout document • Added verbiage that the Food Fraud Vulnerability Plan will be tested annually • Added Figure 1 and 2 templates for the Food Defense Challenge and Food Fraud Vulnerability test