

	Standard Operating Procedure	SOP Number QS-106	Revision 5
	Allergen Control	Effective Date 01/24/23	Page 1 of 7
Written by/ Date <i>CS</i> 12/21/22	Reviewed by/ Date <i>Mat R</i> 12/22/22	Approved by/ Date <i>K. Bunn</i> 12/22/22	
Title: Food Safety & Regulatory Supervisor	Title: Senior VP of Operations	Title: Quality Assurance Director	

## 1.0 Purpose

The purpose of this procedure is to address the prevention of cross-contamination with major food allergens. It is intended to ensure compliance to 21 CFR 111, 117, requirements of Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA), and Food Allergy Safety, Treatment, Education, and Research Act of 2021 (FASTER).

## 2.0 Scope

This procedure is applicable to all processes at Ion Labs, Inc.

## 3.0 Responsibility

- 3.1 It is the responsibility of the Head of Quality or designee to implement and maintain this procedure.
- 3.2 Management is responsible for ensuring procedures are implemented for controlling the storage and movement of allergenic materials through the plant.

## 4.0 Definitions

4.1 **Major Food Allergen** – Under FALCPA & FASTER, an ingredient that is one of the following foods or is an ingredient that contains protein derived from one of the following:

- 4.1.1 Milk
- 4.1.2 Egg
- 4.1.3 Fish

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4.1.4 Crustacean Shellfish

4.1.5 Tree Nuts

4.1.6 Wheat

4.1.7 Peanuts

4.1.8 Soybeans

4.1.9 Sesame

## **5.0 References**

- 5.1 A-108, SOP, Good Manufacturing Practices and Personal Hygiene
- 5.2 A-113, SOP, Training Procedure
- 5.3 B-103, SOP, Small Parts Cleaning and General Sanitation
- 5.4 B-111, SOP, Cleaning of Manufacturing/Production Areas and Equipment
- 5.5 B-901, SOP, Blending Procedure - Powders
- 5.6 B-908, SOP, Blending Procedure - Liquids
- 5.7 B-910, SOP, Weighing and Dispensing Procedure
- 5.8 C-104, SOP, Master Batch Record and Issuance of Batch Production Record
- 5.9 C-201, SOP, Deviation and Investigation Procedure
- 5.10 C-403, SOP, Change Control Procedure
- 5.11 C-501, SOP, Document Control Procedure
- 5.12 C-502, SOP, Record Storage, Retention, and Destruction
- 5.13 C-708, SOP, Printed Packaging Compliance Procedure

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- 5.14 D-111, SOP, Allergen Testing for Production Equipment
- 5.15 E-101, SOP, Warehouse and Inventory Control
- 5.16 E-204, SOP, Receiving Process for Raw Materials and Packaging Components
- 5.17 E-703, SOP, Raw Material Sampling Procedure
- 5.18 QS-105, SOP, Food Safety Plan
- 5.19 QS-108, SOP, Corrective and Preventive Action
- 5.20 Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA),  
<http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Allergens/ucm059116.htm>
- 5.21 Food Allergy Safety, Treatment, Education, and Research (FASTER) Act 2021  
<https://www.fda.gov/food/food-labeling-nutrition/food-allergies#:~:text=Under%20the%20FASTER%20Act%20of,recognized%20by%20the%20United%20States.>

## **6.0 General Requirements**

- 6.1 Food allergies cause immune system responses that range from discomfort to life threatening reactions. Allergen cross contamination in a food product is a serious food safety hazard and could cause injury or death to the customer. The following requirements are intended to protect Ion Labs' customers by preventing allergenic cross-contamination and inadequate labelling.
- 6.2 Ingredients that contain allergens are listed in the raw material database.
- 6.3 Changes to products and processes that involve allergenic materials are assessed for impact via the change control system per C-403 Change Control Procedure.
- 6.4 Receiving and Storage

6.4.1 Ingredients that contain allergens are identified and labeled with specific allergen identification upon receipt and before being placed into the designated storage area per E-204 Receiving Process for Raw Materials and Packaging Components.

6.4.2 Allergens will be stored with like allergens.

6.4.3 Ingredients that contain allergens are stored in a separate area from non-allergens in the warehouse and raw ingredient cooler per SOP E-101 Warehouse and Inventory Control.

- Allergenic ingredients are physically separated by racks, plastic or a cardboard separator and labeled with the ingredient name and allergen type.
- An allergenic ingredient cannot be stored over a non-allergenic ingredient. Additionally, only like-allergens can be stored above the same type of allergen.

6.4.4 Each allergenic ingredient has its own designated utensil for dispensing and sampling that is not used for other products per SOP B-910 Weighing and Dispensing Procedure and SOP E-703 Raw Material Sampling Procedure.

## 6.5 Production

6.5.1 Allergenic ingredients required for a specific formulation are identified on the Master Batch Record per SOP C-104 Master Batch Record and Issuance of Batch Production Record.

6.5.2 Allergenic ingredients are labeled with proper identification and traceability.

6.5.3 Equipment is dedicated to one product when possible.

6.5.4 Equipment is thoroughly cleaned and sanitized after every product formulation change.

6.5.5 Cleaning is verified through analytical methods after an allergenic product has

been run unless the cleaning process has been validated.

- 6.5.6 Production rooms are identified with an allergen tag when allergenic products are being processed.
- 6.5.7 If employees are assigned to a production room where allergen product is running, they must remain there if possible. If an employee is assigned to another production where there is a non-allergen product running or a different type of allergen product running, the employee must fully re-gown (change all PPE) and conduct proper hygienic practices, such as washing hands.
- 6.5.8 If an employee moves room to room to conduct a task/activity, the employee must conduct proper hygienic activities as to prevent cross contamination. Proper hygienic activities may include sanitizing or discard/replace gloves, sanitize production frock or change to a clean frock, change shoe covers, sanitized designated shoes (ensure shoes are dried after sanitizing- safety purposes), etc. If an employee's PPE/designated shoes has excessive dust from an allergen, the employee must fully re-gown (change all PPE), wash hands, and wear shoe covers- no exceptions.
- 6.5.9 During facility tours, avoid going from an allergen production room to a production room where there is a non-allergen product running or a different type of allergen product running, when possible. IF this is unavoidable all personnel would have to conduct proper hygienic practices to prevent cross contamination.

## 6.6 Cleaning

- 6.6.1 Equipment which has come into contact with an allergenic ingredient is washed and sanitized prior to changing over to another product. Refer to SOP B-103 Small Parts Cleaning and General Sanitation and SOP B-111 Cleaning of Manufacturing/Production Areas and Equipment.
- 6.6.2 Allergen-containing containers are rinsed and cleaned last. Cleaning equipment and sinks are thoroughly cleaned to ensure allergen removal.

6.6.3 Allergenic ingredient raw material containers are not reused even after cleaning.

6.7 Analytical Testing for Cleaning of Production Equipment

6.7.1 Cleaning of production equipment is verified and tested per SOP D-111 Allergen Testing for Production Equipment.

6.8 Employee Hygiene (reference SOP A-108 Good Manufacturing Practices and Personal Hygiene)

6.8.1 Hands must be washed and sanitized after coming in contact with an allergenic product and prior to handling another product not containing the specific allergen.

6.8.2 Garments must be changed prior to entering another production area in which non-allergenic ingredients are processed, or a different allergenic ingredient is present.

6.9 Labeling

6.9.1 All allergen(s) in a finished product are declared on the product label per SOP C-708 Printed Packaging Compliance Procedure

- FALCPA requires that in the case of tree nuts, the specific type of nut must be declared (e.g., almonds, pecans, or walnuts).
- The species must be declared for fish (e.g., bass, flounder, or cod) and Crustacean shellfish (crab, lobster, or shrimp).

6.9.2 Label reconciliation is performed to account for all labels issued for production use per SOP C-104 Master Batch Record and Issuance of Batch Production Record.

6.9.3 In the event of allergen cross-contamination or mislabeling of finished products, an investigation and corrective action are required per SOP C-201 Deviation and Investigation Procedure.

6.10 Training (reference SOP A-113 Training Procedure)

6.10.1 Annual training is conducted for all employees on the Allergen Control Program.

6.10.2 Training on related department-specific procedures is conducted by the respective department management for preventing cross-contamination of products by an allergen.

**7.0 Records**

7.1 Records are maintained as outlined in SOP C-502 Record Storage, Retention, and Destruction.

**8.0 Revision History**

Revision	Date	Description of Changes	CCN	By
0	03/05/14	New	14-0201	V. Ilcheva
1	09/02/16	Biennial review: added reference to SQF Code	16-0785	E. Hasanbasic
2	06/08/17	Added statement that allergen materials will be stored in a designated quarantine area with all like allergen materials until released by quality.	17-0667	S. Millar
3	10/18/17	Added note for gluten testing in section 4.0.	17-1066	S. Millar
4	12/23/19	Added additional information in section 6.4.3.	19-0966	J. Murphy
5	12/06/22	Added the requirements of Food Allergy Safety, Treatment, Education, and Research Act of 2021 (FASTER). Added Sesame as a Major Allergen. Added SOP, A-113, B-908, and B-910. Removed section 6.5.3. Revised section 6.5.5. to current practices. Updated SOP titles.	CC-22-0461	C. Horelle