ION Nutritional Labs	Standard Operating Procedure Halal Assurance System (HAS)	SOP Number QS-117	Revision 0
		Effective Date 09/01/23	Page Page 1 of 9

Written by/ Date	Reviewed by/ Date	Approved by/ Date
06/23/23	06/23/23	06-28-23
Title: Food Safety & Regulatory Supervisor	Title: Quality Assurance Director	Title: VP of Quality & Regulatory Affairs

1.0 Purpose

The procedure defines the Halal Assurance System (HAS). The Halal Assurance System complies with the specific requirements to manufacture Halal products.

2.0 Scope

This procedure applies to all selected materials, approved suppliers, purchasing, receiving, storage, processing, packaging, and shipping for all Halal products manufactured and packaged by Ion Nutritional Labs.

3.0 Responsibility

3.1 It is the responsibility of all employees to follow this procedure.

3.2 It is the responsibility of the Halal Management Team (i.e. Halal Committee) to implement, evaluate, make decisions, and continuously improve the Halal Management System.

3.3 It is the responsibility of Head of Quality to appoint and maintain an active Halal Committee.

3.4 It is the responsibility of all department Heads, Managers, and Supervisors to implement this procedure to ensure the control of storage, processing, and packaging of Halal products.

3.5 It is the responsibility of Purchasing personnel to receive proper documentation for Halal materials prior to receiving.

3.6 It is the responsibility of Warehouse personnel to ensure any Halal materials received have proper documentation, are identified, and materials are stored in a designated location.

4.0 Definitions

4.1 **IFANCA** – Islamic Food and Nutrition Council of America

4.2 **Halal** – Arabic term meaning permitted or allowed

4.3 **Mashbooh** – Arabic term meaning doubtful, suspect, or questionable

4.4 **Haram** – Arabic term meaning forbidden, not permitted, or not allowed

4.5 **Halal Assurance System** – a systematic approach to identify non-halal contamination and control measures to ensure halal and safety status of products

4.6 **QA** – Quality Assurance

5.0 References

5.1 A-108, SOP, Good Manufacturing Practices and Personal Hygiene

5.2 A-113, SOP, Training Procedure

5.3 A-118, SOP, Management Review of Quality Metrics

5.4 B-105, SOP, Preparation of Cleaning and Sanitizing Chemicals for Production and Warehouse

5.5 B-111, SOP, Cleaning of Manufacturing/Production Areas and Equipment

5.6 C-104, SOP, Master Batch Record and Issuance of Batch Production Record

5.7 C-201, SOP, Deviation and Investigation Procedure

5.8 C-502, SOP, Record Storage, Retention, and Destruction

5.9 C-707, SOP, Critical Control Point Specifications

5.10 E-101, SOP, Warehouse and Inventory Control

5.11 E-204, SOP, Receiving Process for Raw Materials and Packaging Components

5.12 E-703, SOP, Raw Material Sampling Procedure

5.13 QS-105, SOP, Food Safety Plan

5.14 QS-107, SOP, Recall Procedure

5.15 QS-108, SOP, Corrective and Preventative Action

5.16 IFANCA Porcine-Free Environment Policy, IFANCA-Ref 57

6.0 HAS Table of Contents

6.1 Section 7.0: Halal Quality Policy

6.2 Section 8.0: Halal Management Team

6.3 Section 9.0: Training and Education

6.4 Section 10.0: Halal Certified Product

6.5 Section 11.0: Raw Material

6.6 Section 12.0: Production Facilities

6.7 Section 13.0: Critical Activity Procedure

6.8 Section 14.0: Traceability & Recall/Withdrawal Plan

6.9 Section 15.0: Handling of Non-Halal and Nonconforming Materials

6.10 Section 16.0: Internal Audit

6.11 Section 17.0: Management Review

7.0 Halal Quality Policy

7.1 Ion Nutritional Labs is committed to producing Halal products in compliance with Halal Guidelines issued by the Islamic Religious authorities. Ion Nutritional Labs will ensure Halal Integrity of food processes starting from the control of raw materials to manufacturing, packaging, storing and distribution. We strive to ensure that all of our Halal products are safe for human consumption through continuous improvement.

8.0 Halal Management Team

8.1 A Halal Committee has been appointed. The Halal Committee has the ability to implement, evaluate, make decisions, and continuously improve the Halal Management System. A Halal Committee shall have a lead member to assign responsibilities when conducting activities.

8.2 Each member of the Halal Committee shall have proper knowledge/training of Halal Requirements.

8.3 The Halal Committee will meet once per year or if there is a change to operational procedures that may affect halal products.

9.0 Training and Education

9.1 QA/Training Department shall provide all employees Halal Awareness Training during the Annual GMP Training. Training materials are evaluated to ensure employees are trained to any updated Halal Requirements.

9.2 Halal training will be included with New Hire Training.

9.3 All training is documented and maintained by the QA/Training Department per SOP A-113 Training Procedure.

10.0 Halal Certified Product

10.1 Ion Labs will maintain a list of all products under Halal Certifications, including:

10.1.1 A list of products using the same equipment as those under halal certification.

10.1.2 A list of products repacked, relabeled, and/or stored in the same facility.

10.2 Potential Halal certified product labels shall be sent to IFANCA for review prior to production.

10.3 QA will maintain Halal Certificate or Statement for registered Halal products.

10.4 Production Batch Records will identify Halal products.

11.0 Raw Material

11.1 Materials used for Halal products must not be derived from or contain any Haram (forbidden):

11.1.1 Pork and/or any of its derivatives

11.1.2 Alcoholic beverages

11.1.3 Blood and its products

11.1.4 Carrion or products from Carrion

11.1.5 Carnivorous Animals

11.1.6 Any/all parts of human body

11.2 Ion Labs utilizes an electronic system for inventory status of all raw materials and packaging components. A list of products may be available upon request. Refer to SOP E-101 Warehouse and Inventory Control.

12.0 Production Facilities

12.1 Ion Nutritional Labs will maintain a list of all production lines within the facility that are used for Halal products. Production lines will be segregated to prevent cross contamination of porcine materials.

12.2 Ion Nutritional Labs has two locations in Florida; 8031 114th Ave. Largo, FL 33773 (manufacturing and shipping) and 19050 Belcher Rd. S Seminole, FL 33777 (warehouse, receiving, storage, weighing/dispensing and shipping).

13.0 Critical Activity Procedure

13.1 Material Purchasing

13.1.1 Financial records supporting the purchase and procurement of raw materials and packaging items used in the production should be retained for 6 years per SOP C-502 Record Storage, Retention and Destruction.

13.2 Incoming Material Checking

13.2.1 Incoming materials shall be compared to the packing list and Batchmaster item description. Warehouse associate will verify the material. Checklist includes:

13.2.1.1 Material Name

13.2.1.2 Manufacturer name and address

13.2.1.3 Country of Origin

13.2.1.4 Halal Logo (if applicable)

13.2.1.5 Halal Certificate (if applicable)

13.2.2 Ingredients that are intended for use in the manufacturing and packaging of Halal products must be identified as Halal and placed into the designated storage area as to prevent them from being mixed or contaminated with haram materials (materials that are not Halal e.g. porcine). Refer to SOP E-204 Receiving Process for Raw Materials and SOP E-101 Warehouse and Inventory Control.

13.3 Production

13.3.1 Standard operating procedures are written for production operations. Refer to Standard Operation Procedures Section B - Manufacturing.

13.3.2 Process Flow Diagrams are maintained by QA and have documented CCPs.

13.4 Production Facility Cleaning

13.4.1 Cleaning procedures are written and available for review by all employees. Refer to SOP B-111 Cleaning of Manufacturing/Production Areas and Equipment. All detergents, sanitizers, and cleaning chemicals that are potentially used for food contact surfaces are kept on file.

13.4.2 Halal and non-Halal items (e.g. bovine) are manufactured at Ion Nutritional Labs. Major cleaning will be conducted between Halal and non-Halal items per SOP B-111 Cleaning of Manufacturing/Production Areas and Equipment, with no exceptions. Equipment used to manufacture and package Halal products shall not be shared with porcine materials.

13.4.3 An Approved Chemical and Lube list is maintained by the Sanitation Department. Refer to SOP B-105 Preparation of Cleaning and Sanitizing Chemicals for Production and Warehouse.

14.0 Traceability & Recall/Withdrawal Plan

14.1 Procedures are in place to ensure product traceability, one-step forward and one-step backward.

14.2 Ion Nutritional Labs has established a Recall Procedure to perform a recall to remove or correct consumer products that are in violation of Islamic laws or laws administered by the Food and Drug Administration in compliance with FDA 21 CFR part 7. Two mock recalls are performed annually as a traceability exercise. Reference SOP QS-107 Recall Procedure.

14.3 A traceability exercise (trace forward and backward) will be conducted annually on a Halal finished product.

14.4 Ion Labs will notify IFANCA within 24 hours of learning of either a planned or in-progress recall/withdrawal of IFANCA certified products. IFANCA will be provided with a list of product(s) involved, with a detailed identification of nonconformity.

14.5 A post recall will be provided to IFANCA as soon as possible. Information shall include:

14.5.1 List of products involved

14.5.2 Identification of nonconformity

14.5.3 Cause of nonconformity

14.5.4 Evaluation of the need for action to ensure recurrence of nonconformity does not occur

14.5.5 Determination and implementation of needed actions

14.5.6 Recording and reviewing of the results for the actions taken

15.0 Handling of Non-Halal and Nonconforming Materials

15.1 Ion Nutritional labs has established written procedures to control nonconforming products. Refer to SOP C-201 Deviation and Investigation Procedure.

15.2 If the nonconformance is related to the Halal status of the product, Ion Nutritional Labs shall not label/market the product as Halal or rework the product into another batch of product to be labeled/market as Halal.

16.0 Internal Audit

16.1 A Halal internal audit will be conducted and documented, at a minimum, once per year, to verify Ion Nutritional Labs fulfills the requirements of IFANCA Halal certification and that the HAS is effectively implemented and maintained. Audit reports shall be made available for IFANCA upon request.

17.0 Management Review

17.1 Management Review activities will be conducted, at a minimum, once per year, to ensure the suitability and effectiveness of the HAS. Reviews shall include:

17.1.1 Follow up action from previous management reviews

17.1.2 Changing circumstances which may affect halal production

17.1.3 Review of customer complaint data

17.1.4 External audit results

18.0 Revision History

Revision	Date	Description of Changes	CCR	By
0	06/23/23	New procedure.	N/A	C. Horelle