SOP# 02-021.0	Standard Operating Procedure **Halal Control and Traceability Plan**	

1.0 Purpose

1.1 The purpose of this SOP is to ensure that the halal status of products is consistently maintained, effectively controlled, fully traceable, and not compromised at any stage of the production process, while also preventing cross-contamination with non-halal materials.

1.2 This procedure establishes an end-to-end traceability system covering the entire supply chain from suppliers to customers to ensure full product accountability, regulatory compliance, and preservation of halal integrity.

2.0 Scope

2.1 This plan applies to all stages of the production process, including the procurement of raw materials, receiving and storage, staging and dispensing, manufacturing and processing, equipment cleaning and sanitation, bottling and packaging, finished product goods storage and distribution at all BodyBio's facilities.

3.0 Responsibility

3.1 It is the responsibility of the Production and Facility Manager to ensure segregation of halal and non-halal materials and enforce compliance with halal requirements during all manufacturing operations to prevent cross-contamination.

3.2 It is the responsibility of the Quality Department to ensure halal compliance and traceability through record review, audit execution, and product release approval, and ensure effective implementation across all sites.

3.3 Warehouse personnel are responsible for maintaining segregation, labeling, and inventory traceability through the DataNinja software.

3.4 BodyBio Management is responsible for proper implementation, routine checks, and staff training to ensure the successful application of this procedure.

4.0 References

4.1 21 CFR 111: Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements

4.2 SOP 01-003 *Recall Strategy*

4.3 SOP 02-004 *Approved Chemicals*

4.4 SOP 02-005 *Cleaning and Sanitizing Verification Check for Water and Non-Water Based Applications*

4.5 SOP 02-008 *General Manufacturing Equipment Cleaning*

4.6 SOP 03-004 *Warehouse Management*

4.7 SOP 03-007 *BodyBio's Knife and Blade Policy*

4.8 SOP 04-005 *Procedure for Conducting Line Clearance*

4.9 SOP 04-017 *Sampling Procedure*

5.0 Definitions

5.1 Halal: Refers to products, ingredients, and processes that are permissible under Islamic law, meaning they are free from prohibited (non-halal) substances and are prepared, handled, and processed in accordance with established halal requirements to ensure purity and integrity.

5.2 DataNinja (Manufacturing Execution System (MES) software): Software platform used to manage, monitor, and document manufacturing operations in real time. It enables tracking of materials, batch records, and inventory movement to ensure traceability, compliance, and process control.

5.3 Rack: Equivalent to a rack space position in the DataNinja MES.

5.4 Floor: Equivalent to floor space position in the DataNinja MES.

5.5 Color Coded Utensils: Specific color-coded utensils and knives are used exclusively for halal and non-halal products. For example, the green scoop is reserved for non-halal products.

5.6 Halal Signage: Clear signage indicating "Halal Only" in the production area while production of halal product is ongoing.

5.7 Designated Locations: DataNinja MES software assigns designated locations, and all materials are predefined as halal or non-halal within the system. Therefore, physical segregation through separate storage locations is not required; however, system-controlled segregation shall be strictly maintained. Materials shall be received, stored, and moved within predefined quarantine and release locations in accordance with their halal status. Any locations containing non-halal materials shall be clearly identified as "Non-Halal."

6.0 Procedure

6.1 Material Receipt

6.1.1 Halal certified materials shall be received only from approved suppliers with valid halal certifications on file, as verified by the Quality Department.

6.1.2 Upon receipt, the warehouse personnel shall verify the Certificate of Analysis (COA) and the source of the materials to ensure compliance with halal requirements.

6.1.3 All delivery vehicles shall be inspected to ensure they are clean and free from contamination, including ensuring the packaging is intact and free from damage and evidence of tampering, and records of inspection shall be maintained in the DataNinja MES system.

6.1.4 The material shall then be entered into the DataNinja MES system, where a unique lot number is generated and a barcode label is created for traceability.

6.1.5 For materials verified as halal, the system-generated label shall clearly indicate "HALAL Certified," and this label shall be printed and affixed to each pallet.

6.1.6 During sampling, the sampling room shall be cleaned and verified prior to introducing any halal materials to prevent potential contamination.

6.1.7 Dedicated halal-designated knives and blades shall be used to open raw material containers and these tools shall not be used for non-halal materials.

6.1.8 This process ensures proper identification, control, and traceability of halal materials throughout the facility.

6.2 Warehouse Storage and Staging

6.2.1 All materials shall be stored and staged using the DataNinja MES system, which controls and tracks designated storage locations based on material status, including halal and non-halal classification.

6.2.2 Upon placement into storage, DataNinja shall record the exact location (rack, bin, or floor position) and maintain real-time inventory status.

6.2.3 All material movements, including transfers from quarantine to release and staging for production, shall be entered in DataNinja to ensure full traceability.

6.2.4 During storage and staging activities, appropriate handling practices shall be followed to prevent cross-contact, including avoiding spills, using clean and designated tools where applicable, and ensuring materials remain properly contained.

6.3 **Equipment Cleaning and Sanitization**

6.3.1 All production equipment and utensils shall be thoroughly cleaned prior to initiating any halal product manufacturing, in accordance with SOP 02-008 to prevent contamination from previous products.

6.3.2 Only approved cleaning agents, as defined in SOP 02-004, shall be used during the cleaning process. Following cleaning, the Quality Department shall perform ATP swab testing to verify the effectiveness of cleaning and ensure that no residual contamination or carryover from previous products is present.

6.3.3 All cleaned equipment shall be sanitized within 24 hours prior to use to maintain hygienic conditions. In cases where equipment has been exposed to non-halal products, a full cleaning process shall be performed before reuse for halal production.

6.3.4 The Production/Sanitation Department is responsible for executing cleaning and sanitization activities, while Quality is responsible for verification and release of equipment for use.

6.3.5 All cleaning and sanitization activities shall be properly documented, including details of the previous product processed, date of cleaning, personnel involved, and QA verification.

6.4 Batching / Dispensing

6.4.1 Prior to batching or dispensing activities, a line clearance shall be performed and documented to ensure that the area, equipment, and utensils are free from any residual materials, labels, or documents from non-halal activities.

6.4.2 Dedicated halal-designated knives and blades shall be used to open raw material containers and these tools shall not be used for non-halal materials.

6.4.3 Batching operations shall be conducted in a clean and controlled environment, ensuring that the room and equipment have been properly cleaned and cleared to avoid cross-contamination from previous products, especially non-halal materials.

6.4.4 During dispensing, appropriate precautions shall be followed, including the use of clean and, where applicable, dedicated utensils, proper handling to prevent spills, and maintaining material identity at all times.

6.4.5 All material usage shall be accurately recorded in the Batch Manufacturing Record (BMR), including material lot numbers and quantities used, and a unique batch number shall be assigned to ensure full traceability.

6.5 Manufacturing Process

6.5.1 All manufacturing activities shall be performed in a controlled manner to ensure compliance with halal requirements and prevention of cross-contamination. Prior to initiating any halal production, it shall be verified that no non-halal materials are present in the manufacturing area, and appropriate controls shall be implemented to prevent any mixing or contamination with non-halal substances. Only halal-compliant processing aids and materials shall be used throughout the manufacturing process.

6.5.2 A unique finished product lot number shall be assigned to each batch to ensure traceability. All packaging material lot numbers shall be accurately recorded in the BMR and all associated documentation.

6.5.3 A complete and verified cleaning of equipment and the production area is completed after every batch, ensuring removal of any residues from previous operations, especially from non-halal products.

6.5.4 Prior to the start of packaging activities, a line clearance shall be performed and documented to verify that the area, equipment, and materials are free from previous operations.

6.5.5 During packaging, strict controls shall be maintained to ensure correct labeling, including verification of product identity, halal status, and batch details.

6.5.6 Appropriate precautions shall be taken throughout the process to prevent mix-ups, including proper segregation, identification, and handling of materials.

6.5.7 All manufacturing steps shall be documented in the BMR, including line clearance, equipment identification, process parameters, and operator details to ensure full traceability and compliance.

6.6 Finished Goods Storage and Distribution

6.6.1 All finished halal products shall be stored in a controlled manner to ensure compliance with halal requiremments and prevention of cross-contamination. Segregation of halal and non-halal finished goods shall be managed primarily through the DataNinja MES system, where materials are predefined and controlled based on their halal status.

6.6.2 Each finished product shipper box containing halal finished goods shall be clearly labeled with a **"HALAL"** label to ensure external identification during handling, storage, and distribution.

6.6.3 The system tracks inventory locations. As such, physical segregation may not be required; however, clear identification and system controls shall be maintained at all times.

6.6.4 Storage conditions shall comply with product requirements, including appropriate environmental controls and general warehouse cleanliness.

6.6.5 During distribution, all transport vehicles shall be inspected to ensure they are clean and suitable for transporting halal products. Controls shall be in place to prevent mixing or cross-contact with non-halal goods during loading and transportation, supported by system-based segregation and proper handling practices.

6.6.6 Distribution records shall be maintained within DataNinja and/or supporting documentation to ensure full traceability, including customer details, product lot numbers, quantities shipped, and shipment dates. This ensures complete forward and backward traceability while maintaining halal compliance throughout the supply chain.

6.7 **Documentation:**

6.7.1 All documentation related to halal compliance and product traceability shall be maintained in a controlled and retrievable manner to ensure full accountability throughout the product lifecycle.

6.7.2 This includes supplier approval records confirming the qualification of vendors and their halal certification status, valid halal certificates for all applicable raw materials, receiving logs documenting incoming materials and their assigned lot numbers, and BMRs capturing production activities, material usage, and batch identification.

6.7.3 Cleaning and sanitization logs shall be maintained to verify equipment hygiene and prevent cross-contamination,.

6.7.4 Packaging batch records shall be maintained to ensure correct labeling and material usage, and distribution records providing full traceability of finished products to customers.

6.7.5 All records shall be reviewed, approved where applicable, and retained in accordance with BodyBio's document control procedures to ensure compliance with halal requirements and regulatory standards.

6.8 **Training**

6.8.1 All employees involved in receiving, manufacturing, quality, and distribution shall receive annual training to ensure compliance with halal requirements and good manufacturing practices.

6.8.2 Training shall include halal awareness (conducted annually), GMP principles, contamination prevention practices, and traceability procedures to ensure full understanding of material control and segregation requirements.

6.8.3 All training activities shall be maintained in accordance with BodyBio's documentation requirements.

6.9 **Internal Audit**

6.9.1 Internal audits shall be conducted at least annually to verify compliance with halal requirements, GMP standards, and established traceability procedures. These audits shall evaluate adherence to segregation controls, material handling practices, documentation accuracy, and the effectiveness of the DataNinja MES system and supporting paper-based records.

6.9.2 Any gaps or deviations identified during the audit shall be documented, investigated, and addressed through appropriate deviation and corrective and preventive actions (CAPA) using QT9 software.

6.10 **Mock Recall**

6.10.1 A mock recall shall be conducted at least annually in accordance with SOP 01-003 to evaluate the effectiveness of the traceability system.

Revision History

Revision	Comments
0	New SOP