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TRACEABILITY SYSTEM			
SOP-03-011	Revision: 02	Effective Date: 3/19/2019	
Originated By:	Ana P Craig	Approved By:	Blake Dixon
Title:	QM	Title:	Quality Manager
Date:	08/18/2016	Date:	3/19/2019

1. Purpose
The purpose of this procedure is to describe the Applied Food Science (AFS) traceability system.

2. Scope
This SOP applied to all products received, stored, and distributed by AFS.

3. Responsibilities
   3.1. VP Operations is responsible for retaining copies of purchase orders, invoices, warehouse forms, and packing lists, and for maintaining the inventory.
   3.2. The Quality Department is responsible for testing and retaining supplier's COAs.
   3.3. The Quality Manager and the VP Scientific Affairs are responsible for generating the AFS COAs.
   3.4. The Quality Department and the VP Scientific Affairs are responsible for designating unique AFS lot numbers.
   3.5. The Quality Manager is responsible for verifying traceability exercises.
   3.6. The Quality Department and the VP Scientific Affairs are responsible for validating this program as described on section 7.

4. Definitions
   4.1. Lot: Set of units of a product, which have been produced and/or processed or packaged under similar circumstances.
   4.2. Traceability: The ability to identify uniquely, a batch of food and the raw material batches used in its production, in a way that allows tracking the physical flow of the food forward through the food chain to the immediate customer and tracking of the physical flow of raw material backwards to the immediate supplier.
   4.3. Traceability system: A series of mechanisms for traceability, by which "identification", "link", "records of information", "collection and storage of information", and "verification" are performed.
   4.4. Recall: The removal of an unsafe food from the market when it may have reached the consumer.
   4.5. Quality Department: Quality Control Technician, Quality Manager

5. Equipment and Materials – N/A

6. Procedure
   6.1. Traceability Information
      6.1.1. Tracing back

6.1.1.1. The manufacturer retains raw material traceability information, including raw material lot number, COA, date when the raw material was received and amount received.

6.1.1.2. A batch manufacturing record is generated and retained by the manufacturer for each lot allowing process traceability. The batch manufacturing record shows the date and time of each of the processing steps, the yield (before and after each processing step), and labeling and process control information.

6.1.1.3. The manufacturer tests and generates the finished product COA.

6.1.2. Internal traceability

6.1.2.1. AFS approves lots for purchase and release as per SOP-03-012 Product Release.

6.1.2.2. Lots are received and disposed as per SOP-03-001 "Receiving and disposition of Materials". The date of delivery, manufacturer name, lot number, and method of delivery are logged on the FOR-02-002 "Receiving Log".

6.1.2.3. The manufacturer COA and validation testing results are retained by the Quality Department.

6.1.2.4. Operations retain manufacturer Invoice and Packing List.

6.1.2.5. A sample of the lot is tested for identification as per SOP-04-002 "Identification by FT-NIR". The ID test provides evidence that the product is not misbranded or adulterated. QM retains record of the product spectrum data. ID results are logged on FOR-03-015 Product Release Log and FOR-02-003 Validation testing Log.

6.1.2.6. The Quality Department and the VP Scientific Affairs designate a unique AFS lot number.

6.1.2.7. The AFS COA is generated either by the Quality Manager or the VP of Scientific Affairs. If generated by the Quality Manager, the VP of Scientific Affairs must approve it before sending it to Operations.

6.1.2.8. Upon receipt of customer Purchase Order, product is packed and labeled as per SOP-02-003 Packaging & Labeling, and shipped as per SOP-02-004 Shipping. Operations retain copies of the customer Purchase Order, completed Warehouse Form (FOR-02-004), Packing List, AFS product label.

6.1.2. Tracing forward

6.1.2.1. Operations control the Inventory Log (FOR-02-003) with date product was received at AFS, manufacturer lot number, AFS lot number, the amount of product shipped to each customer, date shipped, shipping method, tracking number, and inventory left at the AFS. Warehouse also needs to be physically inspected for product before finishing FOR-03-013.

6.2. Traceability Exercise

6.1.1. Under the direction of the Quality Manager, the following traceability exercises are completed annually:

- Tracing back: each of the AFS approved suppliers will be asked to complete at least one traceability exercise per year. The lot to be traced will be chosen by the Quality Manager.
- Tracing forward: the VP of Operations will be asked to complete at least one traceability exercise per year. The lot to be traced will be chosen by the Quality Manager. Exercise must be completed within 4 hours of start time.

6.1.2. The AFS Traceability Audit Form FOR-03-013 is completed.

7. Verification and Validation Activities

7.1. The Quality Manager verifies traceability exercises listed on 6.1.1 were conducted. The verification is recorded on FOR-03-013.

7.2. Traceability exercises will be reviewed annually to assess the effectiveness of the program. The review will be documented on FOR-01-009 Pre-requisite Program Validation Form. Improvements to the program will be documented as corrective actions and implemented.

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8. References

8.1. FOR-03-013 Traceability Audit Form

8.2. FOR-01-002 QDN Form
8.3. FOR-02-002 Receiving Log
8.4. FOR-02-003 Inventory log
8.5. FOR-02-004 Warehouse Form
8.6. FOR-02-006 Product label
8.7. FOR-03-002 Validation testing plan
8.8. SOP-01-002 QDN Program
8.9. SOP-02-003 Packing & labeling operations
8.10. SOP-02-004 Shipping
8.11. SOP-03-012 Product Release
8.12. SOP-04-002 Identification by FT-NIR

9. Revision History

Date	Revised By	Rev No.	Reason for Revision
01/10/2018	Ana Craig	01	Added verification and validation activities.
03/19/2019	Blake Dixon	02	Added time frame for traceability exercise and need for physical inspection of warehouse for material at the completion of the exercise.

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