Traceability Procedure

Purpose

The purpose of this procedure is to define how traceability is established, maintained, and verified within the Food Safety & Quality Management System (FSQMS) at **[COMPANY NAME]**.

This procedure ensures that the site's traceability system enables the accurate and timely identification of the origin, processing history, and distribution of raw materials, intermediate products, and finished products, supporting effective control of food safety, legality, and quality and enabling prompt and reliable response where traceability information is required.

Scope

This procedure applies to the establishment, operation, and verification of the internal traceability system at **[COMPANY NAME]**.

This procedure applies to traceability activities covering:

- Raw materials, including primary and secondary packaging
- Intermediate and work-in-progress materials
- Finished products
- The linkage between receipt, processing or batching, and dispatch
- The maintenance of traceability records necessary to demonstrate product history
- The planning, execution, and evaluation of traceability tests, including mass balance where required

This procedure does not define incident management, product withdrawal, or recall execution activities, which are defined in:

- PRO-3.11 Incident Management, Product Withdrawal & Recall Procedure

This procedure does not define record completion, control, or retention requirements, which are defined in:

- PRO-3.3 Record Completion & Maintenance Procedure

This procedure does not define supplier approval, supplier performance monitoring, or verification of suppliers' own traceability systems, which are defined in:

- PRO-3.5 Supplier & Raw Material Approval and Performance Monitoring Procedure

All traceability activities governed by this procedure shall be consistent with the intent of:

- POL-3 Food Safety & Quality Management System Policy
- POL-3A Documented Information & Records Management Policy

- POL-3C Traceability, Withdrawal & Recall Policy

Responsibilities

Senior Management

Senior management are responsible for:

- Ensuring that adequate resources are available to establish, implement, and maintain an effective traceability system.
- Supporting the implementation of traceability arrangements that meet regulatory, customer, and certification requirements.
- Reviewing the effectiveness of the traceability system as part of broader Food Safety & Quality Management System oversight.

Technical / Quality Management

Technical / quality management are responsible for:

- Establishing and maintaining the site's internal traceability system in accordance with this procedure.
- Defining traceability requirements, including traceability points, record linkages, and data integrity controls.
- Ensuring traceability records are complete, accurate, and available to demonstrate product history.
- Planning, conducting, and evaluating traceability tests, including mass balance where required.
- Reviewing traceability test outcomes and initiating appropriate follow-up where deficiencies are identified.
- Ensuring that traceability arrangements remain effective following changes to processes, products, or systems.

Production / Operations Management

Production and operations management are responsible for:

- Implementing traceability requirements within operational processes.
- Ensuring that traceability information is accurately recorded at defined points of receipt, processing, and dispatch.
- Supporting traceability testing activities and providing access to relevant records and systems.

All Employees

All employees are responsible for:

- Following traceability requirements applicable to their roles.
- Accurately completing traceability records where required.
- Reporting issues that may compromise the integrity or effectiveness of the traceability system.

Procedure Requirements

How the Traceability System Works

[COMPANY NAME]'s traceability system operates by maintaining a documented linkage between:

- Incoming raw material and primary packaging identification codes (supplier lot/batch or other unique identifiers)
- Internal batch, mix, or process identifiers used during manufacture
- Finished product batch/lot and date coding applied at packing
- Dispatch documentation identifying which finished product batches/lots were supplied to each customer

Traceability is achieved by capturing and linking identification information at defined traceability points, including, as applicable:

- Goods receipt, where supplier identity, delivery details, and raw material or packaging lot/batch identification are recorded at intake
- Storage and issue to production, where materials issued to a specific batch, mix, or production run are recorded
- Batching, mixing, and processing, where input material identifiers and processing batch identifiers are linked to intermediate, work-in-progress, and finished product identifiers
- Packing and labelling, where finished product identifiers are applied and linked to the production batch and the materials and packaging used
- Dispatch, where finished product batch or lot identifiers are linked to customer deliveries to enable one-step-forward traceability

Where systems are computerised, the above linkages may be created and maintained through controlled inventory, production, and dispatch transactions. Where paper-based systems are used, the linkages shall be created and maintained through controlled batch records, production sheets, packing records, and dispatch documentation.

The traceability system shall be operated such that traceability information can be retrieved accurately and in a timely manner when required, including during traceability tests and incident response.

Establishment of the Traceability System

The site shall establish and maintain an internal traceability system that enables the identification and linkage of raw materials, intermediate materials, and finished products throughout all relevant stages of receipt, processing, and dispatch.

The traceability system shall ensure that product history can be determined accurately and within four hours of initiation, using traceability records generated during normal operations.

The traceability system shall meet legal traceability requirements in the country of sale or intended use.

Operation of the Traceability System

The site traceability system operates through the creation and maintenance of linked records at defined control points throughout receipt, processing, storage, and dispatch. Traceability is achieved by ensuring that each stage of material handling and production records the unique identification of inputs and outputs in a manner that maintains a continuous and verifiable link between suppliers, raw materials, internal processes, products, and customers.

Traceability records are structured to enable:

- backward traceability from finished product to all constituent raw materials and packaging, and
- forward traceability from raw materials and packaging to finished products and customer dispatch.

Unique identifiers, such as batch, lot, or production codes, are assigned, recorded, and transferred between stages so that material identity is preserved or appropriately linked where materials are split, combined, reworked, or further processed. The integrity of these linkages is maintained through controlled record completion at each stage of the process.

Traceability of Raw Materials and Packaging

Raw materials, including primary and secondary packaging, shall be traceable from receipt through to their use in intermediate and finished products.

Traceability records shall enable the identification of:

- The supplier and delivery details of materials received including quantity
- Batch, lot, or other unique identification codes
- The point at which materials are introduced into the production process

These records establish the initial traceability link between supplier deliveries and internal material identification used throughout subsequent processing stages.

Traceability of Intermediate and Work-in-Progress Materials

Intermediate and work-in-progress materials shall be traceable through all relevant processing or handling stages.

During processing, traceability records shall maintain the relationship between input material identifiers and the identifiers assigned to intermediate or semi-processed products, ensuring continuity of traceability across processing stages.

Traceability records shall enable linkage between:

- Input materials, including quantities

- Processing or batching activities
- Output materials generated at each stage, including quantities

Where raw materials, work-in-progress, or finished product are decanted, split, part-used, re-packed, or otherwise removed from their original packaging, the resulting container or unit shall be identified in a manner that preserves the original lot or batch linkage and associated status. This may include retention of original label information, controlled re-labelling, or system-based identification, to ensure continuity of traceability and prevent loss of lot or batch identity.

Traceability identification and records shall be sufficient to maintain traceability for part-used materials, work-in-progress, and any materials or product pending investigation, such that their status and linkage to relevant batches and processing stages remain clear and retrievable.

Traceability of Rework
Where rework or any reworking operation is performed, traceability shall be maintained such that reworked material can be linked to the source batch(es), the point of rework generation, and the finished product batch(es) into which it is incorporated.

Traceability of Finished Products
Finished products shall be traceable from production through to dispatch.

Traceability records shall enable the identification of:
- Finished product batch or lot identification, including quantities
- Production dates and associated processing information

Finished product identification shall be recorded in a manner that enables the finished product batch or lot to be traced back through all relevant processing stages to the originating raw materials and packaging.

Traceability at Dispatch
Dispatch records shall ensure that finished product identifiers are linked to customer deliveries in a manner that enables full forward traceability from finished product through to point of dispatch.

Dispatch traceability records shall, as applicable, include:
- Finished product identification (e.g. batch, lot, or date code)
- Quantity dispatched
- Customer identification
- Dispatch date
- Delivery reference or transport documentation reference

These records shall complete the traceability chain by enabling the identification of:

- which finished product batches were dispatched, and
- to which customers those batches were supplied.

Dispatch traceability information shall be maintained in a format that allows timely retrieval to support traceability verification, product withdrawal, or recall activities where required.

Traceability Record Integrity

Traceability records shall be completed, controlled, and maintained in accordance with the Record Completion & Maintenance Procedure to ensure the integrity, reliability, and availability of traceability information.

Records generated through the operation of the traceability system shall be completed accurately at the point of activity and maintained in a manner that supports effective traceability verification, investigation, and response activities.

Traceability records shall be managed so that they remain suitable for timely retrieval when required, including during traceability testing, incident response, product withdrawal, or recall activities.

Traceability Testing

The effectiveness of the traceability system shall be verified through planned traceability tests conducted at a predetermined frequency, at a minimum annually.

Traceability tests shall:

- Cover the range of product groups manufactured at the site, ensuring that traceability can be determined from the supplier of raw material (including primary packaging) to the finished product and vice versa.
- Be completed in both directions, demonstrating backward traceability from finished product to raw materials (including primary packaging) and forward traceability from raw materials to finished products and dispatch.
- Include a quantity check / mass balance for food raw materials and finished products, including printed packaging and labels with food safety and legal information.
- Be completed within 4 hours.

Each traceability test shall include a documented summary of the records and documents referenced during the test and shall clearly show the links between them, sufficient to demonstrate how traceability was established through receipt, processing, and dispatch.

Evaluation of Traceability Tests

Traceability test outcomes shall be evaluated by technical / quality management to confirm whether traceability objectives have been met.

Where traceability tests identify deficiencies or failures, these shall be recorded and addressed to restore the effectiveness of the traceability system.

Maintenance of the Traceability System

The traceability system shall be reviewed and maintained to ensure continued effectiveness following changes to products, processes, materials, or systems that may impact traceability. Changes affecting traceability shall be implemented in a controlled manner to ensure continuity of product history and data integrity.

Training Requirements

Personnel with responsibilities for establishing, operating, maintaining, or verifying traceability shall be suitably trained and competent to perform their assigned roles.

Training requirements shall include, as applicable:

- Understanding of traceability principles and objectives within the food safety and quality management system
- Site-specific traceability arrangements, including identification, recording, and linkage of raw materials, work in progress, and finished products
- Accurate completion, maintenance, and retrieval of traceability records relevant to the individual's activities
- Execution of traceability exercises and timely provision of traceability information when required

Training shall be provided:

- On appointment to a role with responsibilities under this procedure
- When significant changes are made to traceability systems, processes, products, or record formats
- Where deficiencies or improvement needs are identified through traceability testing, audits, incidents, or performance review

Training, competence assessment, and associated records shall be managed and maintained in accordance with PRO-7.1 Training & Competence Procedure.

Records and References

Records

Records generated through the implementation of this procedure may include:

- Traceability records linking raw materials, intermediate products, and finished products
- Batch, lot, or date-code identification records
- Production, packing, and dispatch records used to demonstrate one-step-back and one-step-forward traceability

- Traceability test records, including the documented summary of records/documents referenced and the linkage map demonstrating how traceability was established, and mass-balance calculations and reconciliation outcomes
- Records of traceability verification or validation activities conducted under this procedure

References

- POL-3 Food Safety & Quality Management System Policy
- POL-3A Documented Information & Records Management Policy
- POL-3C Traceability, Withdrawal & Recall Policy
- PRO-3.3 Record Completion & Maintenance Procedure
- PRO-3.11 Incident Management, Product Withdrawal & Recall Procedure

Review and Approval

This procedure shall be reviewed at least every five years, or sooner where there are significant changes to products, processes, systems, organisational structure, customer requirements, or regulatory requirements that may affect traceability arrangements.

Approval, version control, and controlled distribution of this procedure shall be managed in accordance with PRO-3.2 Document Control Procedure.