

Standard Operating Procedure Control of Non-conforming Product

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PURPOSE or POLICY

- To ensure that non-conforming materials are placed on hold, segregated and controlled against inadvertent shipment.

RESPONSIBILITY

- Quality Assurance, Warehouse, Operations, Account Management (Customer Service)

FREQUENCY

- Per hold occurrence

PROCEDURE

Definition

- Non-conforming product** could be any material, such as an ingredient, finished product, or packaging that **does not meet** product specifications, customer specifications, other quality, food safety standards, or regulatory requirements (e.g. out-of-spec micros, metal, glass, hard plastic inclusion, or thermal processing violation). Non-conforming product is typically found because of testing, inspection, verification, routine observations, or customer complaints.

Procedures for managing non-conforming products (BRC 3.8.1)

- Vita-Pakt procedures for managing non-conforming products include:
 - Employees** identifying and reporting product that is potentially non-conforming
 - QA** electronically coding the non-conforming product in the system for clear identification and **Warehouse & QA** placing physical hold tag labels on the product
 - QA** electronically isolating product holds to prevent accidental release.
 - Account Management (Customer Service)** contacting the brand owner, as applicable
 - Employee and management responsibilities**, including personnel authorized and responsible for decisions related to non-conforming products.
 - QA** maintaining records of all products placed on hold (e.g. Material Disposition Report, reconciliation of hold tags).
 - QA & Warehouse** monitoring product hold inventory.
 - QA** maintaining records of destruction, as applicable, where a product is destroyed for food safety reasons

Process Roles & Responsibilities:

- All employees** are responsible for identifying non-conforming product and reporting it to their immediate supervisor.
- Production Supervisor** reports the information regarding the occurrence to the **QA Supervisor** or **designate**.
- QA Supervisor** or **designate** will:
 - place the potentially affected product/lot on electronic hold using applicable hold code
 - record the hold product/lot information on the Material Disposition Report
 - issue hold tags, as applicable.
- Warehouse & QA Supervisor** or **designates** will:
 - place **HOLD** tags on respective product.
- QA management & other departments (as applicable)** will evaluate product for disposition.

- evaluation may include comprehensive review that consists, but is not limited to, finding(s) if any from the Foreign Material Report for this lot, a review of similar past incidents and customer complaints.
- disposition may include release to normal stock inventory, rework or destroying product.
- **QA, Technical, and Operations management** will meet at a minimum of monthly (as part of management review) to review the summary of products held, actions taken and to decide on product disposition.
- **QA Supervisor or designate** will:
 - receive the disposition from management and will assign a reason code in the system to either release the product to normal inventory, rework, or destroy.
 - update the Material Disposition Report.
- **Warehouse & QA Supervisor or designates** will **remove the hold tags** from the product.
- **QA Supervisor or designate** will take the hold tags and verify them with to the Material Disposition Report for reconciliation and recordkeeping.
- **Warehouse personnel** will then be able to scan and relocate the product physically and within the ERP system.
- If product disposition is to **REWORK**, then:
 - **Production Supervisor or designate** will determine the product formulation, not to exceed 10% rework material.
 - **Operations** will contact **Warehouse** for # of drums/pails/totes needed for blending.
 - **Warehouse** will contact **QA** to remove hold tags and product off of hold in NAV
 - **Warehouse** will move product to batching area for use.
- If final disposition is to **DESTROY** the product, then:
 - **QA Supervisor or designate** will notify **Warehouse**.
 - **Warehouse** will move the product out of freezer/storage area, collect hold tags for QA recordkeeping, and place a discard sign on the product.
 - **Production** will handle the disposal of the product.
 - All packaging labeling must be removed.
 - Solid food material can be sent to product waste bins.
 - Liquid waste e.g. juice concentrate can be disposed into the dedicated industrial waste water line.
 - **Warehouse** will handle the disposal of packaging material.
 - Packaging can be sent to recycling or municipal waste.

Monitoring of holds

- **QA & Warehouse** will work together to monitor any on site HOLD inventory on a monthly basis.
 - **QA Supervisor** or designate will generate a monthly VP Product Hold Report.
 - **Warehouse Supervisor** or designate will generate a Warehouse Hold Inventory Report.
 - **QA & Warehouse** together will verify the actual pallets, quantity, & physical location of products that are on hold.

Preventive Action

- **QA** will initiate a root cause analysis, particularly when a recurring issue has been identified. (Refer to SOP 3.7.1 Corrective and Preventive Action Program)

Brand-owned products

- **Account Management (Customer Service)** will contact, as applicable, any brand owners to notify them of non-conforming issues affecting food safety.

VERIFICATION

- Ongoing verification that the requirements of the SOP are met is achieved through monitoring inventory, reconciliation of hold tags, and internal auditing.

DEVIATION

- All deviations are recorded on respective forms. Corrective actions are implemented when standards are not met.

RECORDS

- FRM-QAS-4.4.1-1 Material Disposition Report
- FRM-QAS-4.4.1-2 Hold Tags
- VP Product Hold Report
- Warehouse Hold Inventory Report
- SOP 3.7.1 Corrective and Preventive Action