

8.4.1 Rework Procedure.

Standard

8.4.1. Is there a procedure for labelling, storage and handling of reworks and returns?

Purpose

The intent of this clause is to ensure the operator has a written reworks procedure describing the process for labelling, storage and handling.

Reason

A rework procedure is important to ensure the risk of inadvertent use is controlled and eliminated. A return should also be assessed prior to approving a rework to ensure the material is safe for use and can be traceable in a new manufacturing batch. Risks arise where mishandling of a return results in contamination of other feeds. Some examples to be aware of include, but not limited to:

1. Incorrect labelling and quarantine when returned to mill.
2. Return material contaminated during transport and storage (consider also biosecurity).
3. Partially opened and used return material carrying pests brought into mill.
4. Lack of identification resulting in loss of traceability during rework.
5. Poor handling of returns and reworks containing RAM or medications.

What is Acceptable?

The operator shall have a procedure capable of handling all returns. This may include reformulations or waste. The aim is to reduce all risks associated with accepting a return. For returns approved for rework and require reformulation, see Fact Sheet 4.1.6.

The operator shall be aware that returns may require an investigation or linked to a customer complaint (see fact sheet 10.1.1). Where corrective action is required (see fact sheet 10.3.1), the operator shall ensure the same Material ID is used across the process. This is to ensure the return material is traceable.

All rework or returned products shall be clearly identified and segregated from other products or materials while awaiting decision. Refer to Fact Sheet 8.4.2.

Rework Storage: Where product/material for rework through the production line is being stored in a bulka bag then this shall be clearly labelled with the batch number it is from, any warnings such as RAM or medicated ingredients, and stored in an area segregated from other materials.

Traceability: Where product or material is reworked through formulations then the batch number of the rework component shall be included to ensure full traceability through the system.

Floor Scrapings: Floor scrapings should not be reworked unless a thorough risk assessment is performed, and hygiene standards can be validated to ensure no physical or microbiological contamination from contact with the floor.

Example Rework Procedure

REWORKS PROCEDURE

1. PURPOSE

This procedure describes the actions to be taken to ensure product safety and quality in the event of rework of ingredients or products including residual, rejected, or returned product.

2. SCOPE

This procedure applies to all [insert company] products/materials.

The [insert position] is responsible for overseeing the implementation and documentation of each rework.

3. TERMS & DEFINITIONS

Complaint: An expression of dissatisfaction made either verbally or written about the quality of product, the standard of service or lack of action taken by staff, affecting an individual customer or a group of customers.

Corrective actions: Actions taken to eliminate the causes of nonconformities and prevent recurrence.

Feed Safety: Approach that feed will not cause harm to animals and/or lead to contamination. (*Codex Alimentarius modified*)

Minor: Could be a risk that product presents a hazard to animal health or human food products, or doesn't meet implied quality standard, or doesn't meet internal procedures.

Moderate: Risk that product presents a hazard to animal health or human food products or doesn't meet an agreed quality standard.

Major: Very real risk that product presents a hazard to animal health or human food products or doesn't meet a regulated quality standard.

Non-Conformance: Any non-fulfilment of required specification. Any defect, imperfection or failing against specifications, procedures and/or processes.

Quality: Degree to which a set of inherent characteristics fulfils documented and agreed requirements. (*ISO9000:2015 modified*)

Residual: A quantity remaining after production or use that is usually discarded, this can be a by-product or overage product.

Rejected: Product or material which fails to meet specification, comply with cGMP requirements, or meet any applicable regulatory requirement.

Returned: Product that has been sold and left the manufacturer but for any reason is sent back to manufacturer.

4. PROCESS

This rework procedure needs to be followed when any material or product is intended to be used after being classified as residual, rejected, or returned. The purpose of this process is to ensure that the final product meets feed safety and quality requirements and that the material or product being reworked does not create a problem that will impact the safety of the user or the animal, the products registration status, or the products integrity.

All reworked product needs to be assessed for feed safety and quality before use as well as impact on formulation. In managing and documenting product, traceability must be maintained.

Note: only like products can be reworked together.

For all returns or reworks containing RAM, additional screening and labelling shall be implemented.

There are different types of products that can be reworked:

- residual from manufacturing process,
- rejected at manufacturing facility, or
- returned from customer/warehouse.

Criteria Checklist

All reworked products must be assessed before rework. The assessment must include potential impacts on formulation, feed safety, quality, and traceability. The results of the assessment and rework decision is recorded on [insert form name].

Some examples of questions to ask during assessment could be:

- Feed Safety implications.
 - Has there been contamination during storage or transport?
 - What are the implications on the HACCP system?
 - Does any testing need to be done before use?
 - Does the product contain any RAM or medication?
- Quality implications.
 - What active materials are present?
 - Shelf-life implications?
 - Effect on specification if reworked?
 - Effect on formulations if reworked?
 - Does any testing need to be done before use?
- Traceability.
 - Is the reworked product clearly identified and traceable?
 - Can the traceability be maintained through documentation of reworked product?
- Documentation.
 - Formulations,
 - Manufacturing instructions,
 - Batch records,
 - Corrective action form (if applicable),
 - Customer complaint (if applicable).

5. DOCUMENTATION & RECORDS

The following records shall be maintained to assure this program is implemented:

- Batch records
- Corrective Action Forms
- Management Review

6. DOCUMENT HISTORY

Version	Date	Description of changes	Author
1	dd/mm/yy	Created original document.	name

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