

## 10.2.1 Corrective Actions Process & Monitoring

### Standard

Is there a written process for recording and monitoring corrective actions?

*It is expected there is a process for investigating root causes of any recalls, complaints, non-conformances, internal audit findings, etc.*

### Purpose

To conduct an appropriate root cause analysis investigation for any recall, complaint, non-conforming products, internal audit findings and other deviations.

### Reason

A corrective actions procedure is an important tool designed to investigate the root cause of an issue and to prevent reoccurrence. Corrective Action plans also fall under your HACCP System, with identified control points and critical limits. However, the deviations may originate from different areas, such as human error and equipment failure. Irrespective of the nature, the process for recording and monitoring corrective actions shall be treated the same.

### What is Acceptable?

All corrective action shall be recorded and monitored in the same manner. A procedure shall be made available accompanied by a form that records the investigation, actions and verifications.

A corrective actions log shall be made available and reviewed yearly. When reviewing a log, management shall look for trends, repeat deviations, significant or adverse issues.

#### Documents

**Corrective Action Register:** This will be a log of all actions including corrective action #, date, topic, date closed. This is what can be used by management to review trends, and ensure timely actions taken.

**Corrective Action Procedure:** To outline the process to follow, training on this procedure for all personnel is recommended.

**Corrective Action Form/Records:** A form will assist in summarising the process followed, however there will likely be supporting evidence such as photos, etc which will need to be filed together.

**Corrective Action Filing:** A system of filing records and documents.

Example Procedure and form can be found below.

# CORRECTIVE ACTIONS PROCEDURE

## 1. PURPOSE

This procedure describes the actions to be taken in performing and documenting any corrective action to effectively address any complaint, deviation, out of specification or noncompliance.

## 2. SCOPE

This procedure applies to all [insert company] products and processes.

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

All personnel are responsible for initiating a corrective action as required and ensuring compliance with this procedure.

## 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*)

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

**Non-reportable:** There is no risk at all to product feed safety or quality (for example invoice incorrect) or issue was caused by customer themselves with no responsibility on [insert company] (for example customer punctured the container themselves with their forklift).

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

## 4. PROCESS

This corrective action procedure needs to be followed when any improvements or concerns are observed. These could be triggered by personnel feedback, customer complaints, system review such as internal audit or management reviews, a nonconforming process, or a test result fail.

### Describe Issue

All corrective actions will be entered into the corrective action logging system.

All corrective actions will be documented according to the corrective action form whether they are received verbally or written.

The description of the deviation to be addressed should include:

- Identifying the source of the deviation – deviations can relate to products, processes, quality systems, and feed safety systems.
- Product and batch number affected (if relevant).
- Describe the deviation and the information known at time of reporting.

The [insert position] will assign the corrective action investigation to relevant personnel who have the information necessary and are capable of investigating the deviation.

## Investigation & Actions

The assigned person or team shall investigate the cause of the deviation using appropriate sources of information such as product, process and quality records, review work operations, and any test results. This information should then be documented and used to determine the cause of the deviation. Confirmation that this is the root cause can be performed through the 5 why methodology.

Once root cause is identified then the assigned person or team are to propose corrective actions to eliminate the root cause and present these to management for review. Once approved the corrective actions are to be implemented and documentation included in corrective action form of actions taken.

## Verification

Once all corrective actions have been implemented, a review needs to be performed to verify that the corrective actions have successfully addressed the root cause thereby preventing the deviation from recurring. Any further actions that are required to satisfactorily address the underlying causes of the deviation, or further actions required to address any side effects of changes made, these are to be documented on the corrective action form.

Management reviews will include review of all corrective actions and outcomes including timely close out and any trends or repeated concerns.

A log of all corrective actions shall be maintained.

## 5. DOCUMENTATION & RECORDS

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

- Customer Complaint Records
- Corrective Action Register
- Corrective Action Forms
- Management Review

## 6. DOCUMENT HISTORY

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

# CORRECTIVE ACTIONS FORM

Corrective Action Number: \_\_\_\_\_

**Corrective Action initiated by:**

Customer     Product     Audit     Quality System     Feed Safety System     Other

**DESCRIPTION OF DEVIATION**

Date		Time	
Details of Deviation			

Product Name		Batch Number	
		Formulation	
Date of Manufacture		Date of Expiry	

Reported by	
Person assigned to investigate	

**INVESTIGATION & ACTIONS**

Immediate Actions taken	
Investigations and results	
Root Cause Analysis	
Actions taken to address root cause	

Assessed by		Date	
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### VERIFICATION

Is the following implemented and effective?

- Corrective Actions have been implemented and are being followed
- Corrective Actions have addressed the root cause
- Action taken documented
- Investigations & results attached (if appropriate)
- Registers updated
- All records filed and reported as required

Corrective Actions are verified as effective		<input type="checkbox"/> Yes, close out file	<input type="checkbox"/> No, further actions required*
Reviewed by		Date	

\*If further actions are required then return to investigations and actions step. Copy that table and verification section below.

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