

Example Procedure

PRODUCT RECALL

1. PURPOSE

This Procedure describes how [COMPANY NAME] shall identify and manage a product recall to prevent harm to its customers and their livestock.

[COMPANY NAME] shall be proactive and prompt in a product recall crisis situation.

Recall action may include alerting end users of products, ceasing supply of product or retrieval of product from the market place.

2. SCOPE

This procedure applies to all [COMPANY NAME] products where testing and identification has ascertained that serious harm will potentially occur to customers and/or the animals consuming the feed.

3. TERMS & DEFINITIONS

Harm: Serious illnesses to customers and/or their livestock from the product due to a physical, chemical or biological contamination.

Quality: Degree to which a set of inherent characteristics fulfils documented and agreed requirements.

Root Cause: Analysis method used to identify the true cause(s) of an identified issue/problem that takes into account the actions and conditions of factors causing the issue/problem.

Urgent actions: Urgent actions are preventive actions to eliminate the causes of nonconformities.

4. PROCESS

The key actions to be taken by [COMPANY NAME] in conducting a successful product recall are:

- Obtain and consolidate all necessary information about the product involved:
 - Nature of the problem (including testing results)
 - Product description (including name and batch identification)
 - Quantity involved
 - Location of the product
- Determine the level of recall required:
 - Depending on the extent of distribution

RECALL SITUATIONS

Category A (Risk – High: Severity – High)

Relates to high potential impact on livestock health, performance, product quality, welfare and or human health. Potential serious impact on company performance nationally.

Category B (Risk – High: Severity – Low)

Relates to high potential impact on livestock health, performance, product quality, welfare and or human health. Potential serious impact on company performance regionally.

Category C (Risk – Low: Severity – High)

Relates to low potential impact on livestock health, performance, product quality, welfare and or human health. Potential serious impact on company performance nationally.

Category D (Risk – Low: Severity – Low)

Relates to low potential impact on livestock health, performance, product quality, welfare and or human health. Potential serious impact on company performance regionally.

If the Product Recall Committee enacts a recall, its directions shall take precedence over all other Company activities, accept where human safety would be compromised. The General Manager and the recall committee shall have priority for staff and material resources necessary to give effect to the recall with expediency.

- Notification to all relevant parties;
 - APVMA (if product is registered)
 - Third-party warehouse suppliers
 - Distributors
 - Customers

The Managing Director is the only person authorised to issue press statements. Such statements shall be arranged in conjunction with the [COMPANY NAME] Management Team and Customer Relation Consultants.

The communication shall release substantiated facts; a frank and open approach shall be maintained to ensure the publication of the truth.

External communications and public policy decisions shall not compromise the implementation of the Product Recall Procedures as deemed necessary.

The General Manager, only, shall be responsible for contacting medical, health and technical authorities, industry associations, etc, as applicable:

- Notification information shall include:
 - Name and batch code of product covered by the recall
 - Why the product is being recalled
 - Where and how to return the product
 - Contact at [COMPANY NAME] for further information
- To concisely identify all product affected both internally and despatched to customers;
 - Internal stock control
 - Customer despatch records
- To ensure total removal of product from the market place;
 - Recall distribution register
- To isolate all product involved;
 - Product to be clearly identified as “DO NOT USE”

- Product to be isolated from all other products in store
- To determine the appropriate corrective action with the affected product
- To determine appropriate disposal of the affected product (if required);
- To implement appropriate preventative action to avoid a recurrence
- To report on the product recall;
 - Circumstances leading to the recall
 - Copies of communication to distributors and customers
 - Details of all actions taken
 - Extent of distribution
 - Result of the recall (quantity of stock recovered)
 - Corrective actions
 - Disposal methods
 - Preventative actions
 - Difficulties experienced and suggestions for improvement.

MOCK/TEST RECALLS

[COMPANY NAME] will conduct annual mock recalls to ensure all systems in place are working correctly and determine what if any changes are required for the procedure to function smoothly.

We will conduct a minimum of one of each for, direct on Farm and to resellers. Additional mock recalls will be conducted following any changes to the procedure or failures in applying the procedure.

OUTCOME

All product recalls shall be handled in a polite and professional manner with the goal of mutual resolution and satisfaction.

INCIDENT IDENTIFIED – RECALL REQUIRED

Step		Recall A or B	Recall C or D
1.	Non Conformance Investigation	Recall Investigation Checklist is to be used to determine extent of issue.	Recall investigation Checklist is to be used to determine extent of issue.
		All incident information must be logged in the NC database	All incident information must be logged in NC database
2.	Determine the Recall Class	If classed A or B (Potentially Hazardous)	If classed C or D
2i		Refer issue to the General Manager to further classify.	Determine if product should be retrieved or concession offered.
2ii		Go to step 4	Go to step 3
3.	Determine if product should be retrieved or concession offered		The Retrieved Factors to include: <ul style="list-style-type: none"> • Cross contamination • Costs of Return • Can it be reworked • The Disposal Factors to consider are. • Segregation • Verification of Disposal • EPA regulations • Costs
3i			The Concession Factors to consider are:

			<ul style="list-style-type: none"> • Issue a Credit Note • Issue a Discount
3ii			<p>Steps to Follow with a Recall</p> <ul style="list-style-type: none"> • Identify suspect batch in question • Isolate Product • Gather details of Customers involved and quantities of product • Cease distribution of the suspect product • Contact customers to cease usage
3iii			Go to step 7
4.	If issue is classed as an A or B (Potentially Hazardous) further categorise recall status.	A decision will be made via the Managing Director & Recall Committee within a reasonable timeframe if the issue is a: Category A (Mandatory Recall) or Category B (Non Mandatory)	
5.	Recall Category Selected	The committee will look at the following aspects when assessing the recall category: <ul style="list-style-type: none"> • Hazard to Health • Whether a Recall is required • Plant Closure • Liaise with Regulatory Bodies 	
5i		<p>Steps to Follow with a Recall</p> <ul style="list-style-type: none"> • Identify suspect batch in question • Isolate Product • Gather details of Customers involved and quantities of product • Cease distribution of the suspect product • Contact customers to cease usage 	
6.	Public needs to be notified. NO - Go to Step 7.	The [COMPANY NAME] Recall committee shall advise the Managing Director so that the Management Team and Public authorities can prepare a Press release.	
7.	Termination of the Recall	<p>The Recall Committee will consider:</p> <ul style="list-style-type: none"> • If all product has been located and isolated • Liaison with customers confirms that recall was successful <p>The final report is to be submitted to the Managing Director and all Recall committee members for Category A recalls only.</p> <p>All recommendations for preventing reoccurrence and what improvements to consider will be included with in this report</p>	



5. DOCUMENTATION & RECORDS

The following records shall be maintained to assure this program was conducted according to the Quality Policy.

- Non-Conformance Reports
- Customer Complaints
- Corrective Actions
- Corrective Actions Register
- Recall Checklist

6. DOCUMENT HISTORY

Version No.:			
Last saved by:		Date:	
Original Author:		Date:	
Approved by:		Date:	

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