Stock Feed Manufacturers' Council of Australia Inc.
ABN 84 816 063 155
PO Box 151 Curtin ACT 2605
www.sfmca.com.au

10.3.1. & 10.3.2. Recall Procedure

Standard

10.3.1 Is there a written product recall procedure which is linked to the customer complaint procedure?
See clause 10.1.

10.3.2 Does the recall system apply in other circumstances (e.g. product found to be out of specification), not just customer complaints?
A proactive system to respond to non-conforming products rather than relying on customer complaints.

Purpose

The purpose of a Recall Procedure is to capture all information required for a successful recall of product, from the market, manufacturing sites or storage facilities. Triggers for a recall needs to come from any deviation that could result in a health risk or regulatory risk.

Reason

A Product Recall is issued on identification of a problem resulting in an unsafe or ineffective product. It is imperative for an organisation to manage all product recalls accordingly and in a timely manner. Persons within the organisation should be aware of their responsibilities, in particular non-conforming products and hazardous product recalls. Persons to notify should be listed within the procedure for quick access and management of recall system. Also, recalls need to be able to be triggered from any source of deviation that could result in an unsafe product whether that is from a customer complaint or an internal source (e.g. test result or non-conformance).

What is Acceptable?

A recall procedure needs to be developed and tested at least annually to provide evidence that in the circumstance of an animal or human health risk, the identification and removal of all affected products from the market can be achieved in a short time frame. It is best practice that all products including mass balance and distribution list can be identified within 4 hours.

Recalls can be triggered from multiple sources so any procedure that could link to a recall, such as customer complaints or internal nonconformance, should specifically reference the recall procedure.

<u>Recall Procedure</u>
The Recall Procedure must contain:

1. Recall team and their responsibilities in the recall system.
    a. Ensure a recall coordinator is appointed and aware of their responsibilities (See Fact Sheet 10.3.3).
2. Emergency and out of hours contact information (See Fact Sheet 10.3.4).
3. Step by step process of obtaining information for recall purpose.
4. How to manage high-risk hazardous product removal from market (See Fact Sheet 10.3.5).
    a. Where a third-party organisation is required to remove and/or destroy hazardous products, this should be detailed in the recall procedure.
    b. Identifying high-risk hazardous products can be managed by a risk assessment and assigning a 'Recall Category'.
5. How to manage non-conforming/out of specification products.
    a. Can be managed by a risk assessment and assigning a 'Recall Category'.
6. Recall Form must be able to capture all product information that is being recalled.
    a. Ensure to include start and finish time, immediate action and investigations, batch information, total quantities, customer contact details, and persons notified.
7. Where no recalls have been carried out in the year, the procedure must contain the steps to conduct a 'Mock Recall'. A Mock Recall will determine the effectiveness of your recall procedure (See Fact Sheet 10.3.9).

<u>Example Procedure and forms can be found below.</u>

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RECALL PROCEDURE

1. PURPOSE

This procedure describes the actions to be taken in the event of a recall to prevent harm to customers and their livestock.

2. SCOPE

This procedure applies to all products.

3. TERMS & DEFINITIONS

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

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

Immediate actions: Urgent actions that are required to stop immediate issue.

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

Mock Recall: Test of the recall process annually in the absence of a real recall to ensure process will be effective in an appropriate time frame.

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

Recall: Removal of product from use, internally and externally, for reasons relating to errors in quality, feed safety, or efficacy of the product.

Recall Co-ordinator: Person nominated to manage all aspects of the recall process.

Recall Committee: Persons nominated to support the co-ordinator in executing and reviewing the recall process.

Root Cause: Analysis method used to identify the true cause(s) of an identified issue/problem that considers the actions and conditions of factors causing the issue/problem. Common method is the 5 why's.

4. PROCESS

A Product Recall will be issued on identification of a problem resulting in an unsafe or ineffective product. This could be relating to product dose, product type, label error, shipping accident or any identified cause that will impact the safety of the user, the animal, the consumer, the products registration status, or the products integrity.

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Recall Co-ordinator

The [insert position] will handle all stages of a recall.

Persons to notify when a product recall is required outside business hours are:

[Insert Name] **{Insert mobile phone number]**

Recall Site Committee

The [insert position] will assemble Recall Site Committee and ensure each person is aware of their responsibility.

[insert table of recall committee]

Stages of Recall

I. Assess information related to the recall.
II. Recall – notifications to identified customers and relevant authorities with the immediate action to be taken.
III. Follow up – any further follow up actions to be taken including corrective actions to prevent recurrence.

I. Assessing information

Details of the problems

- Name and telephone number of person reporting the problem.
- Date of report.
- Physical location of problem.
- Nature of the problem in specific detail.
- Results of tests and other investigations on suspect or other samples.
- Other relevant factors.

Details of the product

- Product name and description including strength, pack size or type.
- Batch number.
- Expiry date.
- Quantity of the batch, date and amount released.
- Distribution.

Other relevant information

- Availability for investigation of suspect sample or other samples.
- Type of hazard and assessment of risk (eg. will another batch be affected?).

Determine the level of recall required

Using the below risk matrix:

- Risk = potential impact on livestock health, performance, product quality, welfare, and/or human health.
- Severity = potential serious impact on company performance.

Risk ⇨ Severity ⇩	High	Low ⇩
High	Cat A*	Cat B
Low	Cat C	Cat D

*Immediate retrieval from marketplace and notification to relevant authorities

II. Recall

Commence recall

- Complete all information as per Recall Form.
- Follow recall process flow diagram (Appendix One).
- Ensure all products are identified and isolated, and any returned product is identified and isolated.

Notifications

The following notifications need to be considered:

- APVMA (if product is registered).
- SFMCA.
- Emergency Animal Disease.
- Third-party warehouses.
- Distributors.
- Customers.
- Public.

APVMA
Recalls Coordinator
T: 026210 4793/4800
F: 02 6210 4813
E: recalls@apvma.gov.au

SFMCA
Executive Officer
Duncan Rowland
T: 0419 891 494
E: contact@sfmca.com.au

Public notifications can only be authorised by [insert position]. External communications and public policy decisions shall not compromise the implementation of the product recall procedures as deemed necessary.

Where public or external communication is required, (including medical, health, technical authorities, industry associations, etc, 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 details for further information.

III. Follow Up

The recall committee should ensure all documents and records are kept of recall process and well as supporting evidence and actions taken. This could include:

- Concise identification all product affected both internally and despatched to customers.
    - Internal stock control.
    - Customer despatch records.
    - Mass balance report.
- Ensure total removal of product from the marketplace.
    - Recall distribution register.
    - Customer disposal notifications.
- Ensure isolation all product involved.
    - Product to be clearly identified as "DO NOT USE".
    - Product to be isolated from all other products in store.
    - Mass balance report.
- Ensure the appropriate immediate actions were completed with the affected products.
- Assess if any further actions / corrective actions are required to prevent recurrence of issue.
- Final report on 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).
- Disposal methods.
- Further corrective actions taken.
- Difficulties experienced and suggestions for improvement of recall process.

Mock Recall

Where there have not been any actual recalls in the last 12 months, then a mock recall is required to be performed to ensure the above procedure is effective in a timely manner. The goal for product identification and mass balance is **less than 4 hours,** reporting and notifications are outside this time goal.

5. DOCUMENTATION & RECORDS

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

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

6. DOCUMENT HISTORY

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

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RECALL FORM

DESCRIPTION OF PROBLEM

Customer complaint?	☐ Yes ☐ No Complaint Number: _____
Corrective Action?	☐ Yes ☐ No Corrective Action Number: _____

Product Name		Batch Number Formulation	
Date of Manufacture		Date of Expiry	
Details of Issue			
Other details			

ASSESSMENT OF RECALL CATEGORY

Immediate Actions taken				
Investigations and results				
Risk assessment^	Risk Score	☐ High ☐ Low	Severity Score	☐ High ☐ Low
Classification*	☐ Cat A	☐ Cat B	☐ Cat C	☐ Cat D

^Risk Assessment matrix as per Recall Procedure
*Classification as per Recall Procedure.

Recall commenced?	☐ Yes ☐ No	Time Commenced:	

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MASS BALANCE FOR RECALL

Raw Material / Final product batch of concern:	Batch #	Quantity:

Used in Production		In Storage	
Batches	Quantity used	Pallet/Silo	Quantity stored
Total used:		Total in storage:	

RM / Product Received (kg):		RM/Product Identified (kg):	
Time Completed:			

RECALL

Batch #	Customer Name	Contact Details	Product Volume sent	Volume identified
		Total		

NOTIFICATIONS

Who to contact	Contact Details	Person responsible	Date Notified	Copy attached
				☐ Yes ☐ No
				☐ Yes ☐ No
				☐ Yes ☐ No
				☐ Yes ☐ No
				☐ Yes ☐ No

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CHECKLIST REVIEW

Has the following been completed and attached:

□ Copy of notification to customer

□ Copy of notification to others (SFMCA, media, regulators)

□ Action taken documented

□ Investigations & results attached (if appropriate)

□ Mass balance of all product identified and quantity of stock recovered

□ All product disposed or quarantined (disposal methods identified)

□ All records filed and reported as required

Recall committee feedback on recall process:

Reviewed by		Date	