



NATIONAL PECAN
COMPANY

825 West Main Steet Fabens Texas 79838

COR.QA.N3.014

Recall Procedure

1.0 PURPOSE

To define terms, and assign roles and responsibilities when a food safety/ quality issue arises with any of our products.

2.0 RESPONSIBILITIES

Recall Coordinator (QA Manager) should:

- Keep upper management informed for decisions making.
- Coordinate information between upper management and operational personnel.
- Maintenance an activities log.
- Facilities recall meeting.
- Participate in all discussion with regulatory agencies.
- Prepare ongoing process reports of recall activities.
- Coordinate individuals' reports for all team members.
- Write final report for recall closure.
- To notify the certification body and the SQFI in writing at foodsafetycrisis@sqfi.com within twenty-four (24) hours of the event.
- To coordinate the mock recall at least every year.

VP of Operations Should:

- Provide records of suspect product.
- Provide product identification of suspect product.
- Reconcile ingredients usage with receiving and warehousing records.
- Schedule replacement production.
- Provide names of suppliers.
- Provide emergency contact numbers of suppliers.
- Coordinate communication with supplier.

Inventory and Logistic Manager should:

- Provide receiving paperwork for all ingredients used in suspect product.
- Provide inventory records.
- Provide quantities of remaining ingredients used in suspect product in warehouse.
- Place all suspect ingredients on hold pending final recall outcome.
- Stop loading and dispatching truck containing suspect product.
- Provide records of suspect product received in finish product warehouse.
- Provide first shipping locations of suspect product shipped.
- Provide quantities shipped to each location.
- Provide dates of all shipments.

Prepared by:	QA Manager	Reviewed by:	Plant Manager			
Authorized by:	Plant Manager	Effective Date:	06-05-2023	Version	E	Page 1 of 5



Recall Procedure

- Provide inventory of suspect product remaining in the warehouse.
- Reconcile production quantities against received quantities.
- Prepared necessary instructions for all suspect products.
- Get replacement product to appropriate customer.

Sales should:

- Provide name of customers
- Provide emergency contact number of customer.
- Notify customer of issue.
- Visit outside distribution companies and customers.

Legal advisor:

- Provide legal guidance and advice. Ensure adequate preparation of pertinent documents.

CEO should:

- Be the initial spokesperson by communicating with media and regulatory agencies and customers.

3.0 APLICABLE DOCUMENTS

- **COR.QA.N4.052** Emergency Contact List
- **COR.QA.N5.050** Mock Recall Form
- **COR.QA.N5.051** Recall Notification to Certificate Body and SQFI
- Regulatory Procedures Manual Chapter 7 – Recall Procedures August 2018.

4.0 PROCEDURE:

4.1 Definitions

- **Product Recall** – A product recall is a voluntary action by the firm that marketed the product or an action requested by a regulatory agency. An actual product recall is removing from marketing and distribution channels those products that are adulterated or mis-branded to the extent such products are subject to seizure under current policy and guidelines of The United States Department of Agriculture (USDA) or the federal Food and Drug Administration (FDA). Product recall is an efficient and effective means of removing sizable quantities of products from the marketplace. The alternative to product recall is seizure or other legal action by regulatory agencies.
- **Market Withdrawal** – This is a situation where no violation is minor and product is not subject under current FDA or USDA policy and guidelines.
- **Stock Recovery** – This is a situation where none of the product has left the direct control of the manufacturer or primary distributor. This type of action would be a product recall or market withdrawal if the product were in distribution channels.
- **Effectiveness Checks** – Contact verifications made based on regulatory agency direction to assure that the recall has been effectuated. An alphabetic letter represents the extent to which these verifications are made.

Prepared by:	QA Manager	Reviewed by:	Plant Manager		
Authorized by:	Plant Manager	Effective Date:	06-05-2023	Version	E
					Page 2 of 5



Recall Procedure

- There are three major product recall classifications:
 - **Class I** – A reasonable probability of serious adverse health consequences or death. Product must be removed from all market channels
 - **Class II** – A potential for remote and/or temporary adverse health consequences, which are reversible by medical attention. Products must be removed from distribution channels and the retail market
 - **Withdrawal** – Product is under the control of customers or consumers. No health hazard exists but a major quality defect exists

4.2 General Procedures

- Receive complaint or other alert of defective product. (Determine reason for recall).
- Assemble recall team (listed on this procedure)
- Assess potential classification (FDA makes final classification)
- Determine date of manufacture
- Determine lot number
- Determine quantity shipped
- Determine distribution (dates and customers) i. Shipping documents for each shipment are to include the following information:
 - Lot Number
 - PO#
 - Case/pallet count
 - Destination
 - Shipping condition (room temperature, frozen, refrigerated).
 - Product Temperature
 - Code date, if different from lot number
 - Product type
- *Absence of above information delays recall.
- Prepare press announcement (if necessary ie. Class I recall)
- Determine requested disposition of recalled lot in hands of customers
- Get copy of invoice from office (file it with recall information)
- Get copy of Bill of Lading from office (file it with recall information)
- Contact customers to determine amount of product received
- Request holding/return of lot based on I above
- Review batch record to determine lot of seasonings, nuts and oil used in “recalled lot”
- Place copies of invoices for raw materials in recall folder
- Depending on reason for recall (if it is due to a raw material) determine if any other product lots may/or should be involved in the recall)
- If other lots involved, get shipment information and identify customers
- Timely notification of arrival to Quality Services, Production, and Sales is essential to customer service and corrective action, (i.e. mold and micro complaints, replacement/substation orders).

Prepared by:	QA Manager	Reviewed by:	Plant Manager		
Authorized by:	Plant Manager	Effective Date:	06-05-2023	Version	E
					Page 3 of 5



Recall Procedure

4.3 Recall Initiation Procedures

- Notification of Regulatory Agencies and Third Party Agencies
- Upon a recall for a Food Safety related reason, National Pecan Shelling Operations LLC should notify the appropriate regulatory agency (Food Safety Manager, QA Manager of the location) having jurisdiction with information including:
 - Reason for Recall: Foreign Material, food borne illness, contamination, etc.
 - Recalled product information, including name, code marks or lot numbers, plant number/name, date of production, etc.
 - The amount of product involved, broken down as follows:
 - Total quantity of recalled product originally in company’s possession
 - Total quantity distributed at the time of recall
 - Total quantity remaining in the company’s possession
 - Area of distribution of he recalled product: by area, cities, states, country if exported, along with retailers’ and wholesalers’ names and addresses.
 - Information on any other product, which could be affected by the same hazard.
- The Food Safety Manager or the QA Manager should communicate to the certification body and the SQFI in writing at foodsafetycrisis@sqfi.com within twenty-four (24) hours of the event. See **COR.QA.N4.052** Emergency Contact List.

4.4 Internal Notification and Instructions:

- Upon the possibility that a product recall may be initiated, CEO will notify National Pecan Shelling Operations Recall Committee.
- Once the Team has formalized the need for a product recall, an internal notification will be written to all plant personnel outlining the details of the recall.
- The notification will include instructions about the return of goods from the recall including exact step-by-step details on how to receive the product, what status the product is to be categorized as upon the return, the quarantine station where all returned product will be stored, testing and ultimate disposition of product.
- A listing of the recall committee will be included in the letter for any questions an employee may have.
- This notice will be distributed to all personnel as well as posted on plant bulletin board.
- In addition, the recall action team will initiate their responsibilities in accordance with the written procedure.

4.5 Product Recovery and Disposition

- Transportation of suspect product to National Pecan Shelling Operations LLC designated location must be handled in an expedient manner.
- An accurate inventory of returned goods must be kept.
- Records of product picked up from customers must be accurate.

Prepared by:	QA Manager	Reviewed by:	Plant Manager		
Authorized by:	Plant Manager	Effective Date:	06-05-2023	Version	E
			Page 4 of 5		



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COR.QA.N3.014

Recall Procedure

- Upon receipt product should be segregated and tested if appropriate. Product must be held until final disposition is reached.

4.6 Termination of Recall

- The point at which satisfactory disposition of the recalled product has been made and the information required for the summary of the recall is complete.
- The summary of the recall would include confirmation of the corrective measures taken by National Pecan Shelling Operations LLC to eliminate from its manufacturing and distribution processes those conditions or practices which created the recall.
- The internal team should prepare an action plan to avoid any recurrence of the incident, apply the corrective and preventive procedure for each location.

4.7 Mock Recall

- The quality assurance manager must organize a mock recall it can be ingredients, raw material, packaging material and finished product, at least every year (or according to customer requirements) to ensure that the system for achieving the above requirements is functioning correctly in a 2 hours period. For some customer the test should be conducted minimum 2 hours, outside of normal business hours. The report must specify the following Mock Recall Form **COR.QA.N5.050** and include the form of recall notification to certificate body and SQFI **COR.QA.N5.051**:
 - Date
 - Product (Raw material, finish product, packaging material).
 - Lots (internal lots or supplier lots).
 - Lots quantity.
 - Total quantity accounted for
 - TOTAL QUANTITY ACCOUNTED FOR / QUANTITY OF LOT QUANTITY = % RECOVERED (100%).
 - Time started and time finished (time taken 2 hours).
 - Personnel Involved mock recall.

Prepared by:	QA Manager	Reviewed by:	Plant Manager			
Authorized by:	Plant Manager	Effective Date:	06-05-2023	Version	E	Page 5 of 5