U S DURUM MILLING INC.

PRODUCT RECALL PROGRAM

1. ITALGRANI CORPORATE STRUCTURE
2. ITALGRANI ORGANIZATIONAL CHART
3. RECALL TEAM MEMBERS
    * 24-HOUR PHONE NUMBERS
    * F D A PHONE NUMBERS
    * U S D A PHONE NUMBERS
4. RECALL PROCEDURE OUTLINE
5. U S DURUM MILL PRODUCT RECALL POLICY
6. RECALL COMPLAINT FORM
7. U S DURUM CUSTOMER CONTACT PHONE NUMBERS
8. MOCK RECALL

O U T L I N E

I INTRODUCTION

II RECALL PROCEDURE

- RECALL ORGANIZATION
- PRODUCTION TRACEABILITY
- DETERMINE NEED
- CRISIS MANAGEMENT TEAM
- ACTUAL PROCEDURES
- COMMUNICATION
- PUBLIC / REGULATORY NOTIFICATION
- EFFECTIVENESS CHECKS
- PRODUCTION DISPOSITION
- TERMINATION

Common Problems Arising from Market Withdrawals and Product Recall

- **FACTS** - Collecting, organizing, evaluating, and acting on facts, including assessing their significance with respect to consumer safety and well-being
  - Developing plans and
  - Informing FDA and other agencies (where appropriate) about the facts

- **COMPANY INTERNAL ORGANIZATION** - Developing and using a recall Action Team to manage decisions and actions

- **COMMUNICATIONS** – Managing effective communications
  - within the company
  - with FDA or other agencies
  - with distributors
  - with consumers, and
  - with the media

RECALL OBJECTIVES AND RESPONSIBILITIES

Simply stated, the objectives of recall are:

1. To locate the product
2. To remove the product, and
3 To provide accurate information

Legally, responsibility involving the quality and safety of a product rests with a company's officers and employees. Setting up proper recall procedures and implementing them when necessary is also the responsibility of the company's officials.

The MANUFACTURER (Vendor) and / or SALES COMPANY including its officers and employees bears full legal responsibility for the safety, labeling and quality of its products. Product civil and criminal liabilities may be involved when illegal, unsafe or hazardous products are placed on the market.

The FOOD AND DRUG ADMINISTRATION / and U.S. DEPARTMENT OF AGRICULTURE – MEAT AND POULTRY INSPECTION SERVICE (USDA) bears the responsibility for ensuring that products that are threats or potential threats to consumer safety and well-being are removed from distribution and consumption channels as promptly and completely as the circumstances dictate.

Likewise, the FDA is responsible for determining the adequacy of procedures for and the extent of such removals, arrangements with cooperating Federal AND State regulatory agencies, the need and extent of consumer or public information and the need for additional actions under the provisions of the Federal Food, Drug, and Cosmetic Act.

FOOD AND DRUG ADMINISTRATION

DEFINITION AND CLASSIFICATION OF PRODUCT RECALLS

Neither the Food and Drug Administration (FDA) nor USDA has a direct legal authority to require a firm to recall products. These agencies may request a firm to conduct a product recall, but it has no authority to force compliance. Both may, however, seize individual products that violate the Federal Food, Drug, and Cosmetic Act. Product recalls and market withdrawals are thus voluntary actions taken, when appropriate, to prevent injury to consumers or to correct a product defect. While FDA or USDA has no direct legal authority with respect to recalls and withdrawals, it is often the first place consumers turn with complaints, and it has extensive and direct access to the media.

RECALL DEFINITION:

A **Product Recall** is a firm's removal or correction of a marketed product. It may be firm-initiated or FDA / USDA requested and occurs where either:

- considers the product to be in violation of the laws it administers
- would take legal action against the product

A **Product Withdrawal** is a firm's removal or correction of a distributed product where:

- there is no violation of the law
- there is only a minor violation, which would not be subject to FDA legal action

RECALL CLASSIFICATIONS:

CLASS I RECALL

This is an emergency situation in which there is a reasonable probability that the uses of, or exposure to, a violative product will cause serious adverse health consequences or death

Examples :

1. C. botulinum toxin in foods
2. Label mix-up of a potent drug
3. Excessive exposure to radiation

CLASS II RECALL

This is a priority situation in which use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote

Examples :

1. Pathogenic micro-organisms in food, exclusive of C. botulinum
2. Sub or super-potent drug, not life threatening
3. Egregious labeling violations, e.g. failure to label sulfating agents

CLASS III RECALL

This is a situation in which use of, or exposure to, a violative product is not likely to cause adverse health consequences

Examples :

1. Filth in food relating to aesthetic qualities
2. Labeling violations

STEPS TAKEN AS A PART OF RECALL ACTION PLAN

1. Obtain and organize known information on the extent and nature of the problem, place the product on an internal "hold", and evaluate the level of hazard or risk

2. Analyze the problem

3. Institute a log of events and actions

4. Make a company decision to recall immediately or to investigate further

5. Notify company officials, and make a decision when to inform FDA / USDA. The FDA / USDA must be notified of any product recall, but not for market withdrawals

6. Develop and begin to implement a recall strategy

7. Contact Franchise Owners and Company Center Management to inform them of the recall

8. Contact clients who may have purchased the affected product and retrieve suspect product

9. Determine the number and location of consignees to contact and the quantities and lots of product to retrieve

10. Notify FDA / USDA about the hazard, the company evaluation of risk, and the proposed recall strategy. FDA / USDA will give the problem a "recall classification" and will assess the recall strategy. A company should not wait for either the classification or the assessment before commencing recall, as valuable time could be lost

11. Prepare and issue (with Agency concurrence, where applicable) recall requests (letters, telegrams, public statement, etc.) to known prime distribution, including necessary recall instruction to sub-distribution, etc. Extent of communications will vary depending upon recall classification and may be fewer in the event of market withdrawal

12. Initiate retrieval of all suspect product

13. Prepare and issue, subject to Agency review and comment where appropriate, public warning if necessary and appropriate for given recall classification

14. Prepare statements to release to Home Office Personnel, centers, clients and / or the media

15. Direct distribution centers to retrieve product, place it on hold and ship it back to vendors

16. Assure that all affected product lots are recovered and accounted for

17. Determine disposition of the affected product

18. Prepare, and submit to FDA / USDA, status reports as appropriate for level or recall

19. Conduct recall effectiveness checks, reporting their results to company officials and the FDS / USDA District Office

20. Establish criteria for termination of recall

21. Develop a health hazard evaluation

22. Complete preventive and corrective measures to avoid a recurrence

A SUCCESSFUL RECALL DEPENDS ON
ADVANCE PLANNING
AND
SPEED, ACCURACY AND SIMULTANEOUS ACTIONS
DURING EXECUTION

PRODUCT RECALL AND WITHDRAWAL ACTIVITIES FLOW CHART

PRODUCT COMPLAINT RECEIVED

Preliminary Investigation

Notification of Recall Action Team

Identification of Problem

Recommendation for Recall or Withdrawal

Decision

PRODUCT RECALL	PRODUCT WITHDRAWAL
Notify appropriate internal functions	Notify appropriate internal functions
Inform field representatives	Inform field representatives
Notify FDA / USDA/AIB Within three days for each agency. at GFSI@aibinternational.org	Notify the distribution centers to discontinue shipment of suspect product
Issue public warning if necessary	Hold all suspect product at Weight Loss Centers
Immediately pick up suspect product	Return product to single location
Return product to single location	Control and account for withdrawal of product
Control and account for recall of product	Dispose off product (rework, relable, destroy etc.)
Dispose off product	
Terminate recall	

PRODUCT COMPLAINT RECEIVED

The **Franchise or Corporate Operations Department** is generally the initial Corporate contact with any dissatisfied consumer. In a product recall situation, they will provide liaison between the consumer and centers

Role

- Gather all pertinent information from each consumer and post on the Client Product Complaint Form
- Inform the appropriate Corporate function of **facts** relevant to consumer dissatisfaction
- Instruct the Centers on what to tell the client after discussions with Quality Assurance if appropriate. Ensure this feed back is completed in a timely manner (same day as complaint)
- Have the client or center forward and potentially hazardous product to Quality Assurance for analysis
- Furnish the Recall Coordinators with an information update on a timely basis
- Monitor the telephone to provide clients or centers with appropriate information if a phone number is provided in a recall news release

PRELIMINARY INVESTIGATION

The **Quality Assurance Department** will be contacted immediately by Operations when a complaint, involving a potential health hazard, is received. From time to time, Quality Assurance will be contacted directly from field personnel or from regulatory agencies.

Role

- Initiate follow up action to determine the magnitude of the problem
- Secure suspect raw material and finished goods samples
- Perform analysis on raw materials and finished products
- Determine appropriate response to regulatory inquiry
- Contact the appropriate Vendor to determine magnitude of potential problem

NOTIFICATION OF CRISIS MANAGEMENT TEAM

The **Recall Coordinators** will be notified if, after preliminary investigation the potential exists for product recall.

Role

- Meet with key members of the Crisis Management Team (Legal, Public Affairs, Quality Assurance, Research & Development).
- Review all facts pertaining to the problem
- Determine if a meeting of the full Recall Action Team is required

IDENTIFICATION OF PROBLEM

The full **Crisis Management Team** will be called together if, after preliminary review of the facts, there is a high probability of recall action.

Role

- Review existing facts and gather additional information if necessary
- Develop a strategy for a recall action
- Inform all pertinent Corporation personnel of a potential recall

RECOMMENDATION FOR RECALL OR WITHDRAWAL

Once all available information is reviewed and a consensus is obtained, the **Crisis Management Team**, through the Recall Coordinators, will advise the Chairman and CEO of their recommendation.

Role

- Consolidate and summarize all facts
- Finalize the recall strategy
- Present final recommendations to the Chairman and CEO

NOTIFY APPROPRIATE INTERNAL AND EXTERNAL FUNCTIONS

Once a decision is reached to recall product, communication and timing is of utmost importance. Several members of the **Crisis Management Team** will be involved.

Role - Product Recall

- **Recall Coordinators** will notify Senior Management that a recall action is taking place
- **Operations** will inform field personnel of product recall action
- **Public Affairs** will prepare an official Company statement which addresses media inquiries and consumer concerns
- **Center Managers** will immediately remove all suspect product from the shelves and determine clients who potentially purchased suspect product
- **Distribution** will hold all suspect product remaining in the Distribution Centers and arrange for product return to a single location
- **Finance Administration** will ensure that all recalled product is accounted for and that all customers receive proper accounting treatment
- **Quality Assurance** will contact the Vendor and ensure proper disposal of returned product and will interface with FDA / USDA to assure appropriate recall termination

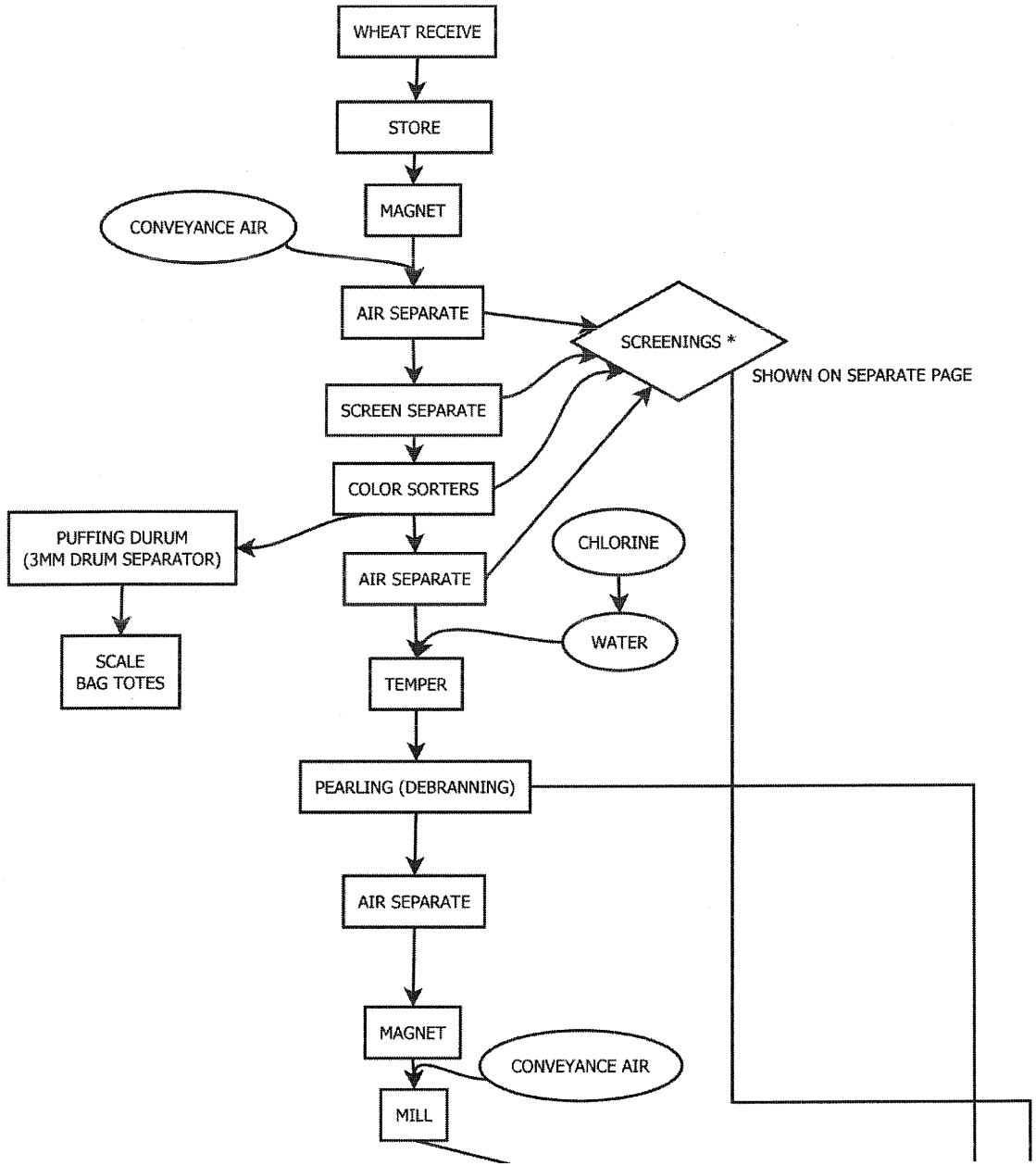
Role - Product Withdrawal

- **Recall Coordinators** will notify Franchise and Corporate Operations
- **Operations** will inform field personnel of product withdrawal actions
- **Center Managers** will remove all suspect product from the shelves
- **Distribution** will hold all suspect product remaining in the Distribution centers
- **Quality Assurance** will contact the vendor and ensure proper disposal of returned product

H A C C P PROGRAM

PROCESS FLOW SHEET FOR DURUM WHEAT, SEMOLINA, FLOUR & BY-PRODUCTS

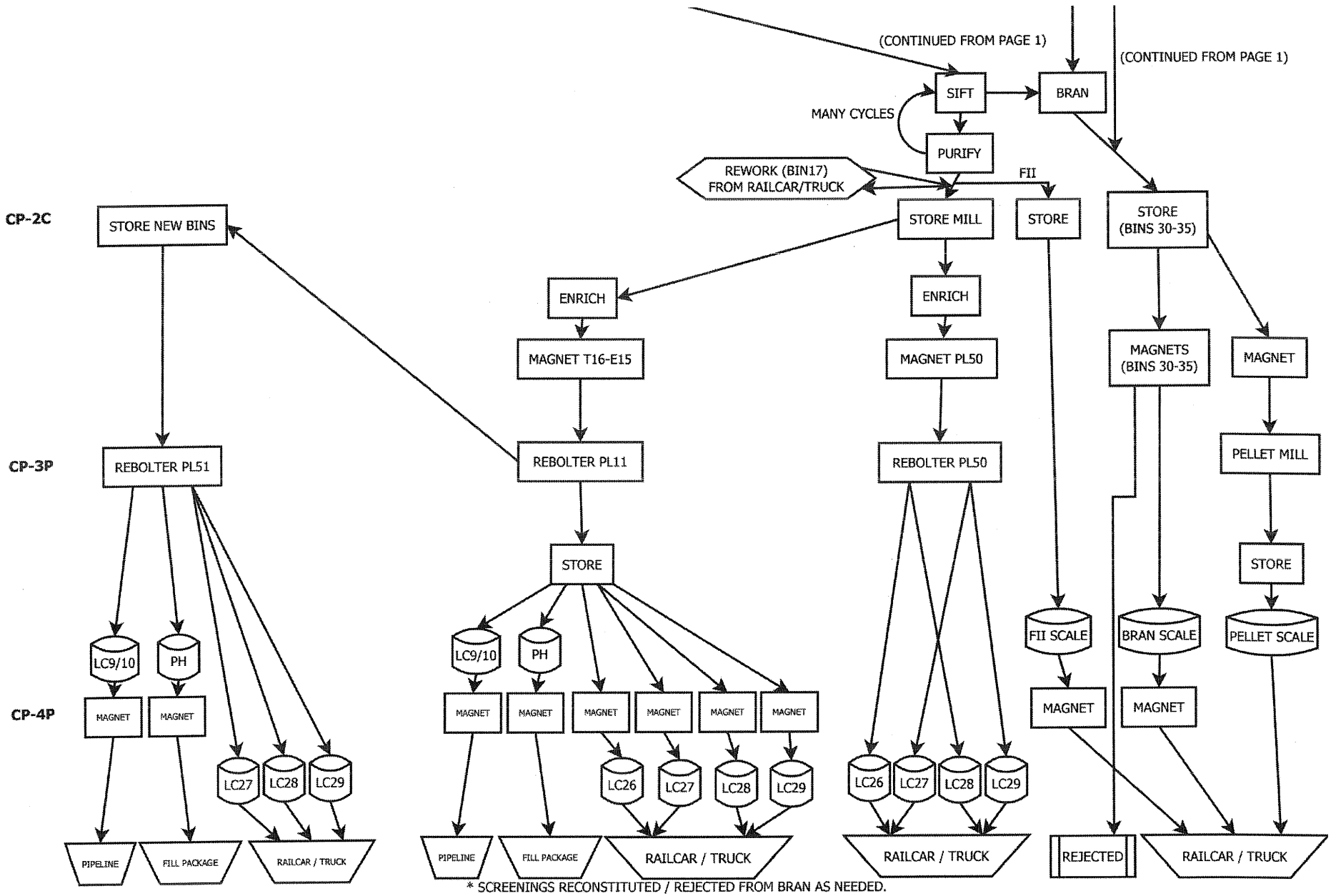
CP-1C



U.S. Durum Milling

H A C C P PROGRAM

PROCESS FLOW SHEET FOR DURUM WHEAT, SEMOLINA, FLOUR & BY-PRODUCTS



* SCREENINGS RECONSTITUTED / REJECTED FROM BRAN AS NEEDED.

RECALL EXECUTION GUIDELINES

The purpose of this action is to identify specific issues and executing steps for each function represented on the Crisis Management Team. If a recall action is required, departments throughout the organization should refer to pertinent sections to ensure that all appropriate steps are completed.

The specific issues that must be dealt with include:

1. Identification of the real or potential problem
2. Assessment of the problem
3. Recommendation for action
4. Decision based on recommendation
5. Legal and financial implications of decision
6. Operational actions to discontinue, locate and remove stocks, and dispose off recalled product
7. Communications within Company, with customers, with FDA / USDA and other regulatory agencies, with the news media and with the consumer

and 8. Follow-up regulatory actions by FDA / USDA

The executional steps must include :

RECALL COORDINATORS	- Keep top decision making officers informed - Keep all organizational components informed - Participate in all discussions with FDA / USDA - Coordinate recall activities
OPERATIONS	- Provide liaison between the Company and the consumer - Provide manning of REACT Action Line to handle calls from consumers - Ensure that customer concerns and relationships are handled in an appropriate manner - Ensure that replenishment product is provided at the earliest possible time
LEGAL	- Provide legal guidance and advice - Ensure adequate preparation of pertinent documents
PUBLIC AFFAIRS	- Handle all press releases - all media - Provide manning for the Recall Action Line to handle media calls
QUALITY ASSURANCE	- Obtain lot identification and samples - Provide technical information and analytical support - Handle all regulatory inquiries - Coordinate recall activities through the recall coordinator - Account for and control all returned product - Assure destruction or clearance of product
RESEARCH & DEVELOPMENT	- Provide scientific, technical and regulatory assistance in reviewing the nature and extent of health concerns - Provide adjunct analytical support - Investigate for cause of problem
DISTRIBUTION	- Stop all loading and dispatching of trucks containing suspect product - Prepare inventory and distribution status of suspect - Product showing where, when and to whom the product was shipped - Prepare recovery instructions for all affected merchandise
FOOD MANAGEMENT	- Assist in supplier identification - Coordinate communication with supplier - Identify raw material lot number, amount produced and - shipping destination

After withdrawal of product is complete, all involved persons should complete a written report to their superior and forward a copy to the Recall Coordinator. A final report will be 8ilmade available to the appropriate managers once all reports have been submitted.

I. WHEATS

Inbound wheats are inspected, information documented and wheats assigned to predetermined bins at the elevator. Daily activity sheet is filled out for each bin movement. Samples are submitted to the lab for necessary evaluations. Lab will report back the results to the elevator. Elevator department will maintain results on elevator bin board for reference. Lab will collaborate with the grain department and will determine the wheat blend and percentages of the wheats for the mill mix bins. Elevator then transfers the mill mix blends to the identified mill bins. All transfers will be recorded on to the daily activity sheet of the elevator, including the bins utilized in the transfer. On every transfer of wheats from elevator bins to the mill mix bins, samples are submitted to the lab for monitoring the wheat quality traits. Lab will keep track of all the wheat movement information from the elevator to the mill mix wheat bins.

II. MILLING

Mill Manager / Lab Manager will designate the mill mix wheat blends and percentages to be pulled from the mill wheat bins. Samples of dirty wheat pulled at regular intervals and submitted to milling crew for the evaluation of physical quality characteristics. Mill maintains the milled product information in which bin(s) the finished product is being put into. This daily production report is being retained in the files for product tracking purposes. Samples of the milled product are pulled at regular intervals and submitted to lab for product analysis.

III. BULK LOADING

Lab maintains a "Finished Product Manual", in which the customer information, product being shipped, specifications etc. are documented. Bulk Loader refers to the product stored information and pull the semolina / flour etc. with the required enrichment at specified addition rate to the product and load onto the truck, or the rail cars. Bulk Loader maintains the information like date, loading time, bins from which the product is being pulled etc.

A representative sample from each product shipped along with the customer and product information, registration number, invoice number and truck number is being submitted to the lab for necessary evaluations on the product. Lab, after checking the submitted sample will maintain this information on "customer Analysis Record" and the same is faxed to the customer also. Further the sample is being retained on the shelf for 30-days from the date of shipping for future reference.

Mill Supervisor will record the disappearance of the product from the bins once every day at 7 a.m. This information is filed for future reference. Bulk Loader collects the overs from the sifter into a "tailings" bag representing each shipment loaded with

information like date, Customer, Bin #, load cell #, rebolt sifter # and the tailings bag is submitted to the Lab. Lab will check these bags and all findings are recorded on "Tailings Report" sheet and any unusual findings are immediately brought to the notice of Lab Manager and Production Manager. Tailings information is documented and maintained for future use.

IV. PACKAGING

Packing House Supervisor, based on product shipping particulars, refers to the product stored information and pull the type of product from the appropriate bins. He will keep track of the disappearance of the product from the bins from time to time. He will also submit to the Lab a representative sample from each product shipped along with the sample particulars like date, bin # from which the product is being pulled, quantity, etc.

Lab, after checking the submitted sample will maintain this information on "customer Analysis Record" and the same is faxed to the customer also. Further the sample is being retained on the shelf for 30-days from the date of shipping for future reference. Packing Supervisor will record the disappearance of the product from the bin as and when required. Packing crew will collect the overs from the sifter into a "tailings" bag representing each shipment loaded with information like date, Customer, Bin #, rebolt sifter # and the tailings bag is submitted to the Lab. Lab will check these bags and all findings are recorded on "Tailings Report" sheet and any unusual findings are immediately brought to the notice of Lab Manager and Production Manager. Tailings information is documented and maintained for future use.

For identification purpose, each lot is stamped individually on each bag with month, date, and year. Eg: 03-25-2000

V INGREDIENTS

The following ingredients are presently being used at U.S. Durum Mill in St. Louis, MO plant:

Type M4 Enrichment (premix concentrate)

Each lot of the above ingredient upon arrival at the premises is inspected, information like Lot #, Code date, quantity received is recorded and assigned to the predetermined storage area. On every occasion, Bulk Loader or the Packing House crew, whenever he takes this ingredient bag and before feeding them into the feeder hopper will log the lot #, code date, # of bags fed into the feeder onto the respective "Ingredient Feeder Log". These sheets are filed with Lab from time to time.

VI REJECTED FINISHED PRODUCT BUT WITHIN USABLE LIMITS

In-house rejected finished product due to minor quality errors and within the usable limits is being used for regrind / and Lab cautiously monitors the movement of this flour on to the customers to whom this flour is blended-with making sure that the shipped product is still within the customer specifications. Special instructions are passed on to the Bulk Loaders / Packing House crew so that the feed-in information is recorded for any future tracking purposes.

Similarly, whenever any finished product shipments are rejected by the customer, Lab Manager will obtain the necessary information from the rejected source. Upon receiving back the rejected product, the container is physically checked for any sanitation evidence, and after making sure that the rejected product is still within the workable limits, any required appropriate corrective actions are applied within the permissible limits. Then the product is fed into an empty bin and all its movements are tracked down in a similar manner as explained above.

VII CONTAMINATED WHEAT

Upon arrival of the contaminated (presumed) wheat, a thorough inspection along with necessary physical tests are being conducted including the insect fragment count and information is well documented. If arrived wheat is within the usable limits and after making sure that all corrective measures are taken, the wheat is assigned to predetermined empty bin (s) for later use. From then on, all the movements of this wheat is kept a close watch and all its movements are recorded in a similar fashion as that of regular inbound wheats.

VIII FUMIGATION

Plant, rail and box cars are fumigated on scheduled times or as and when situation demands it. All related information is documented including the fumigants and extent of its usage.

IX SUGGESTIONS

1) On each occasion, Bulk Loader / Packing House crew, whenever takes ingredient bag from the warehouse and before feeding them into the feeder hopper will need to log the lot #, code date, # of bags fed into the feeder onto the respective "Ingredient Feeder Log." These sheets need to be filed with Lab from time to time.

CONSUMER RECALL COMPLAINT FORM

DATE_____ **TIME** _____ **RECEIVED BY** _____

COMPLAINT DESCRIPTION

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

FACILITY _____

LOCATION _____

CONTACT _____ PHONE # (WORK) _____
(HOME) _____

QUALITY / PRODUCTION SUPERVISOR CONTACT _____ PHONE # _____

NOTE : ALL COMPLAINTS MUST BE IMMEDIATELY BROUGHT TO THE ATTENTION OF ALL RECALL TEAM MEMBERS

JIM MEYER
GIOVANNI ZAGO
SUBRAHMANYAM NUKALA
PATRICK BEEM
~~PAT JACOBY~~
MaH-T

LISA RUCKER