



Food Distribution 2000

*Transforming Food Distribution for the Next
Millennium*

FINAL REPORT

Commodity Holds And Recall Team

July 1999

Re-engineering the USDA Commodity Recall Process Final Report to the Senior Oversight Committee

This document presents the CHART (Commodity Holds and Recall Team) recommendations to USDA for re-engineering the process by which USDA handles commodity recalls and holds.

I. The Team

- Willie Bryant – Food and Drug Administration (FDA)
- Jeff Curry – USDA, Agricultural Marketing Service (AMS)
- Sandy Fisher – Maryland State Department of Education
- Jim Harmon – USDA, Food and Nutrition Service (FDD), Mid-Atlantic Regional Office
- Jesse Majkowski – USDA, Food Safety and Inspection Service (FSIS)
- Tim Reaman – USDA, Farm Service Agency (FSA)
- Dwight Ricker - USDA, FDD Headquarters
- Don Trumble – Washington County, Maryland Food Service Director
- Pepe Portuondo - Facilitator

The team met as a group for 3-day meetings on five different occasions:

- January 4-7, 1999
- February 1-5, 1999
- March 1-4, 1999
- April 26-29, 1999
- May 24-27, 1999

There were also numerous conference calls and individual meetings to formulate this new process.

II. Objectives

The team identified the following major concerns with the current food recall process:

- the current process is unacceptable to customers;
- limited notification procedures are currently in place;
- unsafe product remains in the distribution chain for extended periods and may be consumed;
- communication deficiencies exist between all parties involved;
- recipient agencies incur significant costs for storage and handling;
- significant delays exist in resolving all issues (e.g., product status, replacement, reimbursement, liability)

Food recalls may likely increase in the future because there is:

- more frequent and sophisticated testing;
- emerging new strains of foodborne pathogens;
- increased consumer awareness of recalls; and
- increased access to information (e.g., Internet);

In light of the above concerns, CHART identified three objectives for a redesigned process:

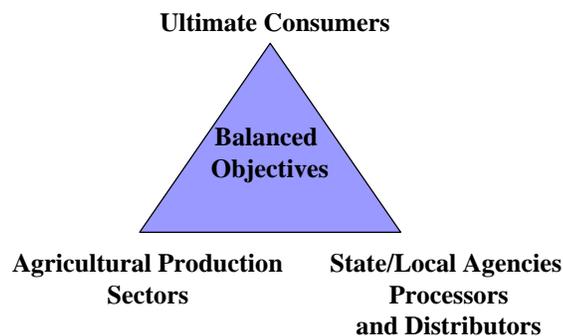
- Provide accurate and timely communication to customers;
- Ensure unsafe product is removed from the system in an effective and efficient manner; and
- Make, communicate, and complete reimbursement decision to recipient agencies in a timely and efficient manner.

These three objectives became the basis for our charter and all recommendations emanating from this report reflect one or more of these objectives.

Note - The new process described below was developed specifically to address holds and recalls for **safety** concerns. Holds and recalls for **food quality** (contract specifications) are handled on a case-by-case basis; however, much of this re-engineered food recall process will also apply.

III. Customers

Early in the process, the team identified our primary customers as the ultimate consumer (e.g. school children, needy recipients, etc.) and the agricultural production sector. However, we also decided that whatever recommendations resulted from our effort had to consider the intermediate State and local agencies, and commercial processors and distributors since they are all vital to any recall. The image below illustrates that point:



IV. Overview of New Process

For ease of discussion, we separated the recall process into three distinct parts: decisions/notification, product disposition and reimbursement. The entire process is shown in timeline form as Appendix A to this report. Please refer to Appendix B for a list of commonly used acronyms appearing in this document. The team's goals in all segments are to institutionalize the process and assign specific tasks with aggressive time frames to encourage to resolve the recall as soon as possible. **The process is designed to address most of the food safety issues that arise. Every recall is unique and deviations to this process may be necessary.**

The re-engineered process is discussed below:

Decisions/Notification

- The responsible regulatory agency (FSIS/FDA) receives a complaint from one of many sources, including a hotline, illness, lab results, vendor notification, and State and local agencies.
- OPHS **immediately** pre-alerts FDD that there is a potential recall.
 - ⇒ OPHS will act as the recall liaison between FSIS, FDA, FSA/AMS and FDD, and will be responsible for communicating all recalls to FDD.
 - ⇒ CHART members recommend that FSIS and CFSAN establish coordinator/liaison positions to handle communication/decision tasks.
- FDD **immediately** contacts the appropriate contracting agency (AMS/FSA) and starts response/resolution database.
 - ⇒ A review of the database will be conducted by management quarterly.
- FSIS/FDA begins its investigation and testing of the product and **has no longer than 10 calendar days** to make a recall decision.
 - ⇒ FSIS/FDA, in consultation with FDD' Food Distribution Division (FDD) and AMS/FSA, will be responsible for making the recommendation to put the product on hold if needed.
 - ⇒ Holds will last no longer than **10 calendar days** from notification to the States. One exception: FSIS' Office of Public Health and Safety (OPHS) has authority to extend "hold" time frames to accommodate longer waiting periods for scientific test results.
 - ⇒ Issues regarding failures to meet time frames or other concerns may be referred to FERRT or FORCG at any time.
- AMS/FSA **immediately** contacts the vendor and begins to identify what contracts and deliveries may be affected by a recall.
 - ⇒ In the past, FDD and AMS/FSA were not contacted until a recall decision was made. Because FDD and AMS/FSA will be pre-alerted to the potential for a recall, a number of days are saved in the process up-front.
- FSIS/FDA and FDD begin working on a script that will be provided to State and local agencies in the event a recall decision is made.
 - ⇒ This script will indicate why the product has been recalled and reiterate the procedures the local agencies should follow. This will allow local agency directors to adequately address inquiries from the media, parents, local government officials, etc.
- Within **10 days** of receiving the complaint, FSIS/FDA must make one of three decisions:
 - Product is safe and may be used;
 - Product is contaminated and must be recalled; or
 - Product condition is still unclear and further testing is required.
- OPHS communicates that decision immediately to FDD.
- The actions taken next depend on the decision:

1. *Product is safe and may be used*

- FDD **immediately** informs AMS/FSA of the decision and AMS/FSA **immediately** contacts the vendor to confirm.
- If product was put on hold, FDD issues a script and a notice informing all FNS Regional Offices (RO's) and affected State distributing agencies (DA's) that the product is safe.
 - ⇒ DA communicates the release notice **by the end of the next business day** to affected recipient agencies (RA's).

2. Product is contaminated and must be recalled

- FDD **immediately** issues recall notice, script and instructions to all Regional offices, affected DA's and AMS/FSA Contracting Officer.
- DA contacts the affected RA's by the **end of the next business day** and instructs them to immediately consolidate and return the product to State control.

3. Product condition is still unclear

- FDD **immediately** issues removal notice, script and instructions to all RO's, affected State distributing agencies and AMS/FSA Contracting Officer.
- DA contacts the affected RA's by the **end of the next business day** and instructs them to immediately consolidate and return the product to State control.

Major Changes in Decisions/Notification Segment

- ⇒ FSIS' OPHS will be responsible for communicating all safety decisions;
- ⇒ FSIS/FDA makes all decisions for safety holds;
- ⇒ FNS will provide prepared scripts will be provided to State and local recipient agencies to explain the action taken and assist them in handling inquiries from the media, parents, local government officials, etc.

Product Disposition

The actions taken next depend on the decisions made by FSIS/FDA (See Decisions/Notification Segment).

1. Product is safe and may be used

- If the product has already been removed to the DA, the State decides how to redistribute the product (to original RA's or to different RA's), with re-distribution costs reimbursed by USDA.
 - ⇒ If DA's have trouble re-distributing product, RO's will assist DA's to find a recipient.
 - ⇒ The product will **not** be replaced.

2. Product is contaminated and must be recalled

- All product must be consolidated within **30 calendar days** of the recall notice.
- AMS/FSA Contracting Officer issues a formal rejection notice to vendor and begins disposition discussion.
 - ⇒ On-site disposal may be an option with proper oversight, documentation and FSIS/FDA approval.
- When rejected product is fully consolidated at State level, vendor is instructed to pick up product within **30 calendar days**.

- ⇒ On-site disposal at State DA may be an option with proper oversight, documentation and FSIS/FDA approval.
- If product is not picked up by vendor within **30 calendar days**, USDA takes control of product and salvages, destroys or stores in a commercial warehouse at the vendor's expense within **15 calendar days**.

3: Product condition is still unclear

- All product should be consolidated within **30 calendar days** of the removal notice.
- Testing continues until a decision is made:
 - ⇒ **Safe:** FDD issues a re-distribution notice
 - ⇒ **Unsafe:** Recall continues
- If product condition is not resolved within **60 days** of removal notice, product is removed from State control.
- Default option is to store in a commercial warehouse until safety is determined.
 - ⇒ If the product is later determined to be safe, USDA pays for costs
 - ⇒ If the product is later determined to be unsafe, vendor pays for costs.

Major Changes to Product Disposition Segment

- ⇒ Product is immediately withdrawn from RA once it is found to be unsafe;
- ⇒ If status of product is still uncertain after 10 days, product will be removed to State control;
- ⇒ There will be limited holds in recipient agencies (no more than 10 days);
- ⇒ Location and count information will be available faster;
- ⇒ On-site disposal may be an option with proper oversight, documentation and FSIS/FDA approval;
- ⇒ Product is removed by vendor **within 30 calendar days** of consolidation notification, or else it is removed from DA and transferred to USDA control;
- ⇒ Vendors will not be awarded new contracts unless they comply with these provisions (contract language revision);
- ⇒ Product disposed of under one of four options:
 - returned to vendor
 - salvaged
 - destroyed
 - removed from DA to commercial warehouse
- ⇒ Default option is to remove to commercial storage;
- ⇒ Product disposition process de-coupled from establishment of liability;
- ⇒ Process made part of contract language;

Reimbursement Segment

- Upon receiving the recall notice, the DA instructs the affected RA's to begin documenting allowable costs*.
 - ⇒ In order to receive reimbursement within 30 days, RA's must submit case counts and total allowable expenses to DA's within **7 calendar days**. RA's missing the initial cutoff date will be paid at closeout.

⇒ Reimbursement for product recall and removal are treated the same.

- DA consolidates this information for all RA's and submits it to RO within **3 more business days**.
 - ⇒ Prompt receipt of this information will assist FDD in making its reimbursement request to AMS and assist the Contracting Officer in discussions with the vendor.
- RO communicates the total request from all States to FDD, FDD consolidates the reimbursement requests nationally, and sends a pre-approved letter to AMS requesting Section 32 funds.
- After obtaining the Secretary's signature, AMS transfers requested funds to FNS.
- RA's are reimbursed within **30 calendar days** of recall decision.
 - ⇒ FDD is examining a number of options to expedite payment to RA's, with a goal to reimburse RA's that meet the reporting deadlines within 30 calendar days of recall decision.
 - ⇒ RA's that do not meet the reporting deadline will be reimbursed within 90 calendar days of recall decision.
- FDD and AMS/FSA make decision regarding replacement of product or entitlement credit within **60 days** of recall decision.
 - ⇒ The preferred method is replacement of product. If the vendor agrees to replace the product, it will not be delivered to the DA between April 1 and August 1.
- AMS/FSA continues determination of liability with vendor.
 - ⇒ Any funds returned to USDA as a result of a determination of liability will be returned to AMS' Section 32 account.
- FDD makes final disbursements to RA's within **90 calendar days** of the recall decision.

* See Appendix C for a discussion of reimbursement policy.

Major Changes to Reimbursement Segment

- ⇒ AMS and FDD streamline the reimbursement process by eliminating interagency funds transfer;
- ⇒ Reimbursable costs and time frames are defined up front;
- ⇒ Reimbursement is based on standardized costs rather than actual costs;
- ⇒ Cut-off dates are established for RA's to submit costs and get reimbursed;

Post-Incident Review

- FDD, FSIS/FDA and AMS/FSA conduct an analysis of each recall to determine any areas of the process that did not work properly and recommend appropriate changes to the process.

V. Presentations to Interested Parties

We have made presentations to a number of groups that are directly affected by this new recall policy. The CHART members have also discussed the proposals with Agency staff who will be directly involved in the operation of the new process.

<u>Group</u>	<u>Event</u>	<u>Location</u>
Industry	BPR Meeting	Washington, DC
State Distributing Agencies	ACDA Conference	Costa Mesa, CA
Food Service Directors	ACDA Conference	Costa Mesa, CA
FERRT	Special Meeting	Washington, DC
Regional Program Directors	Meeting	Alexandria, VA

The reaction from all groups has been quite favorable and there is overwhelming support for this new recall process.

VI. Pending Actions/Unresolved Issues

CHART members have identified the following actions to be addressed by team members once the process receives endorsement from the SOC and CIC:

- ◆ Develop a memorandum of understanding between FSIS, FNS, AMS, and FSA
- ◆ Develop an agreement between FSIS and FDA/CFSAN
- ◆ Develop a procedure to expedite Section 32 authorization and payments to affected RA's.
- ◆ Establish coordinator/liaison positions within FSIS and CFSAN
- ◆ Develop options for reimbursements for "processed" commodities
- ◆ Develop a memo on reimbursement procedures
- ◆ Develop policy, thresholds and documentation requirements for on-site destruction of product
- ◆ Document procedures for regionalizing costs and processing state claims
- ◆ Develop prototype scripts
- ◆ Develop an education component on food recalls in cooperation with NFSMI
- ◆ Develop a recall tracking form to assist RA's to identify and count affected product
- ◆ Develop a memo to state and local agencies announcing and describing the new recall process
- ◆ Develop a memo requiring states to notify recipient agencies within 24 hours
- ◆ Develop the database to support recall tracking/monitoring
- ◆ Ensure that the new process works for the household programs (e.g. TEFAP, FDPIR)
- ◆ Identify changes needed as a result of CORE process

The Commodity Hold and Recall Team truly appreciates the support of the Senior Oversight Committee and Commodity Improvement Council in this endeavor. We believe this new process will positively impact our customers in the following ways:

- much faster/better communication to recipient agencies;
- contaminated product will be removed from local agencies within 30 days and State agencies within 60;
- storage and handling costs will be contained;
- the entire process is significantly streamlined;
- reimbursement for local level costs will be made timely; and
- customer satisfaction and confidence in the food distribution programs will be enhanced.

The CHART members respectfully request your endorsement of this proposal in its entirety.

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James Harmon, Co-Chair

Willie Bryant

Jeff Curry

Jesse Majkowski

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Appendix B

Commonly Used Acronyms

ACDA	American Commodity Distribution Association
AMS	Agricultural Marketing Service (USDA)
ASAP	As soon as possible
ASFSA	American School Food Service Association
CHART	Commodity Hold and Recall Team
CFSAN	Center for Food Safety & Applied Nutrition (FDA)
DA	State distributing agency
FDA	Food and Drug Administration (US Dept of Health and Human Resources)
FERRT	Food Emergency Rapid Response Team (multi-agency)
FDD	Food Distribution Division (FNS)
FDPIR	Food Distribution Programs on Indian Reservations
FNS	Food and Nutrition Service (USDA)
FORCG	Foodborne Outbreak Response and Coordination Group (multi-agency)
FSA	Farm Service Agency (USDA)
FSIS	Food Safety and Inspection Service (USDA)
NFSMI	National Food Service Management Institute
OPHS	Office of Public Health and Science (FSIS)
RA	Recipient agency (e.g. school district)
RO	FNS Regional Office
Section 32	Funding source used to purchase commodities under surplus removal mandates
TEFAP	The Emergency Food Assistance Program
USDA	U.S. Department of Agriculture

Appendix C

Documentation and Reimbursement of Allowable Costs

There was much discussion among the CHART members about the method for reimbursing local agencies for the costs associated with the storage, distribution, handling and destruction of recalled product. The existing system is cumbersome and untimely, in part because total costs can not be established until the entire product is removed from the RA. Also, because each RA's costs are unique, each RA's report has to be scrutinized to ensure that only allowable costs are included. As a result, it was several months before the local agencies recouped their costs.

CHART advocates using standard costs (not actual costs) to reimburse RA's. These standard costs may be State-wide or regionalized within the State to more accurately reflect each RA's situation. The DA will be responsible for determining the standardized costs; however, we recommend regionalized costs. For instance, if a given RA is served by a commercial distributor, that RA would use the distributor's contracted storage and handling charge and transportation costs.

Using this method, the RA will be reimbursed for two trips (from and to the distributor) and one month's storage costs (since the product will be out of the RA within 30 days of the notice) for the recalled product. As soon as the RA determines its case count of recalled product, it will be able to calculate its reimbursable costs and report those costs to the DA within 7 days. Any residual costs, such as destruction costs or additional storage, will be reimbursed at close-out. Using these standard costs will reduce monitoring and errors in cost calculations, and avoid delays.

The American Commodity Distribution Association food safety committee conducted a survey of State distributing agencies to determine their opinion. Each agency was asked to prioritize three reimbursement options: 1) a national standardized cost; 2) State by State standardized costs; and 3) actual costs. 29 distributing agencies responded to the survey and the results are below (1 being most desirable and 3 being least):

	<u>Preferred</u>	<u>Next Preference</u>	<u>Last Preference</u>
National Standardized Costs:	2	4	21
State by State Costs:	12	16	1
Actual Costs:	14	7	7

The actual costs vs. State costs was quite close (12 to 14 in favor of actual costs). Combining the first and second choices, the State by state standardized costs are more desirable (28 to 21 votes). We believe this survey helps to support the team's recommendations to use State standardized costs. We also support standardizing costs down to the closest common point at which standardized costs can be calculated. For instance, all school food authorities served by one commercial or state-run warehouse could use the same standardized costs.