

How Do Holds and Recalls Work with USDA Commodities?

Brenda Halbrook, M.S., R.D.

Director, Food Safety Staff

Office of Emergency Management and Food Safety

and

Dennis Sullivan

Chief, Systems Branch

Food Distribution Division

USDA Food and Nutrition Service

ACDA 2008

Kansas City, MO

Presenters this Session:

- Bill Sessions, Associate Deputy Administrator, AMS Livestock and Seed Programs
- Peggy Cantfil, Chief, Operations Branch, FNS Food Distribution Division
- David Brothers, Operations Branch, FNS Food Distribution Division



Hallmark / Westland Beef Recall

Largest in History
143 million pounds



The Katrina of Food Safety



The Up Side

- No illnesses
- No deaths
- Much learned
- Applies to Food Defense preparedness

Hallmark/Westland Recall

- Unprecedented magnitude
- Uncharted in some areas

Hallmark/Westland Recall

- Different approaches taken (not limited to):
 - Notifications from FNS
 - Partnered with the Department of Education and other groups to reach schools
 - Replies back to FNS
 - FNS asked for SFAs by name and address
 - Accounting for further processed product
 - In some cases, required reporting outside of ECOS in some cases

Hope to Address these Areas ...

- Federal responsibilities
- State responsibilities
- Local responsibilities
- Communication and action flow
- Ideas for improvement

Federal Agencies Involved in Hold and Recall Process

- USDA AMS and FSA determine when a food product is on hold or is recalled
- AMS and FSA identify affected commodity contracts and delivery orders
- FNS communicates commodity hold or recall information to SDAs through the Rapid Alert System (RAS)

Regulatory Agencies

- Two primary regulatory agencies:
 - Food Safety and Inspection Service, USDA
 - Meat, poultry, and egg products
 - Food and Drug Administration, HHS
 - All other foods

Recall Classifications – Similar, but not Identical

Class I:

- Reasonable probability of serious, adverse health problem, or death.

Class II:

- Remote probability of adverse health problem

Class III:

- No adverse health consequences

Classes I and II are public health related

All Recalls are Voluntary

- Violations found, for example:
 - Microbiological, chemical
 - Statutory violations, mislabeling
- Regulatory agency presents data to vendor
- Vendor voluntarily complies with recall request
- Vendor conducts recall
 - Notifies consignees = distribution chain
 - Issues press release

Regulatory Agency

■ Issues Recall Release

- Lists Recall classification and why this recall happened
- Gives information to help identify product
- Explains Class I, II, and III recalls at the end

■ Provides oversight of recall

■ Conducts effectiveness checks

- Call or visit locations to verify product removal

Distribution Notification

Vendor doing recall must:

- Notify verbally and/or in writing -
All recipients of their recalled product
- Each point along the continuum must notify the next recipient down the line

State Distributing Agencies are considered part of this distribution chain

Hold

- Invoked while investigation is pending
- Initiated by AMS or FSA
- Announced by FNS
- Policy is for 10 days
 - Circumstances may require longer period
- State and local agencies must
 - Identify
 - Isolate
 - Not serve
 - Account for quantity

What you need to know about Recalls

- Similarities exist up to a point

But...

- Never identical
- Expect information to change as things develop
- Consult USDA for latest information
- SDA's are in charge

Standard Guidance

- FNS Regulations:

7CFR Part 250

Section 250.13 through 250.30 contain requirements related to food safety

- Hold and Recall Document, 2001

<http://www.fns.usda.gov/FDD/foodsafety/hold-recallpros.pdf>

State and Local Responsibilities

■ 7CFR Part 250

- Defines State Agency and/or local agency requirements
- Locals must comply with USDA and/or State direction

Warehousing, Distribution and Storage of Donated Foods

- States are required to physically separate donated commodities from other inventory
- Schools are allowed to use single inventory, if the SDA permits

Source: 7CFR 250.14

Storage Facilities

State owned, or contracted, storage facilities must:

- Clearly identify donated food
- Conduct annual reviews of facilities and document compliance
- Document to whom commodities were distributed and
- Who picked-up commodities

Source: 7CFR 250.14

Traceability is Key

Know:

- what is in inventory – easy to identify
- where it is stored
- to whom product was sent
- who picked-up product

Source: 7CFR 250.14

Records are Key

- All agencies – SDA or RA must:
 - Record what they received
- SDAs must:
 - Record what they distributed and to whom
 - Know what USDA Delivery Order went to Further Processing
 - Show receipt of reimbursement funds and
 - Disbursement of funds to SFA or Further Processor

Source: 7CFR 250.16

Other Records

- Food Service Management Companies
- Warehouses
- Others with contracts

Must keep records on:

- Distribution
- Disposal
- Storage
- Inventory

Source: 7 CFR 250.16

Other Records -- continued

■ Further Processors

Must keep records on:

- Distribution
- Disposal
- Storage
- Inventory
- Commingling

SFA Requirements

- SFA or its commercial storage facility must comply with
 - State or local laws and regulations on safety
 - Applicable Federal, State, or local laws or regulations regarding destruction
 - State and local health authorities provide disposal instructions, which can vary

SDAs and Others....

- Are, in fact Food Distributors
- So are State Contracted Warehouses and Distributors
- All are subject to FSIS Recall Requirements
 - Locations of product and quantities
 - Documented removal/destruction
 - Effectiveness checks

FSIS Recall

FSIS and Manufacturer

FSIS and vendor
discuss voluntary
recall

Manufacturer Begins recall



Consignees

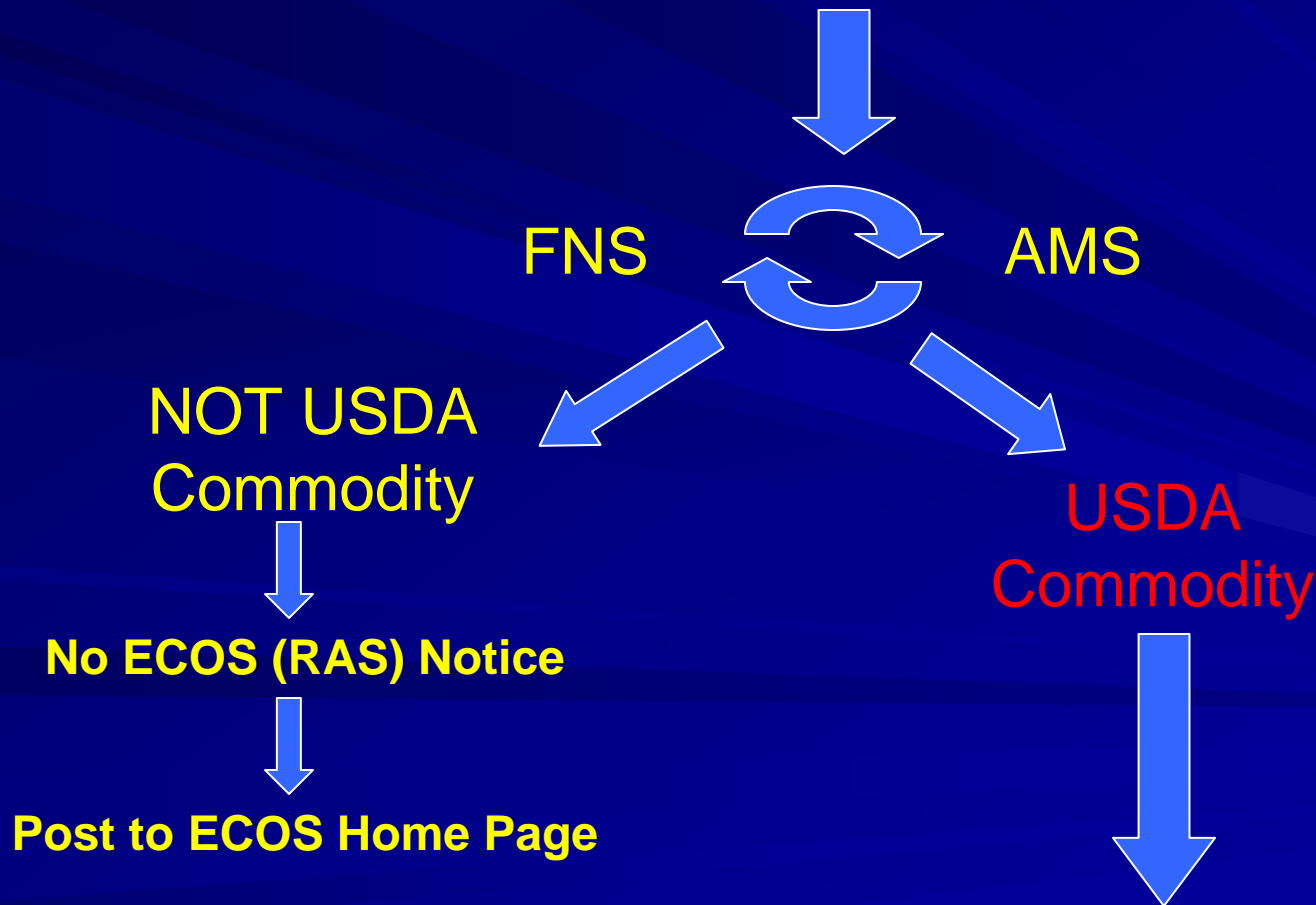
Vendor begins to
notify further
processors and
other customers



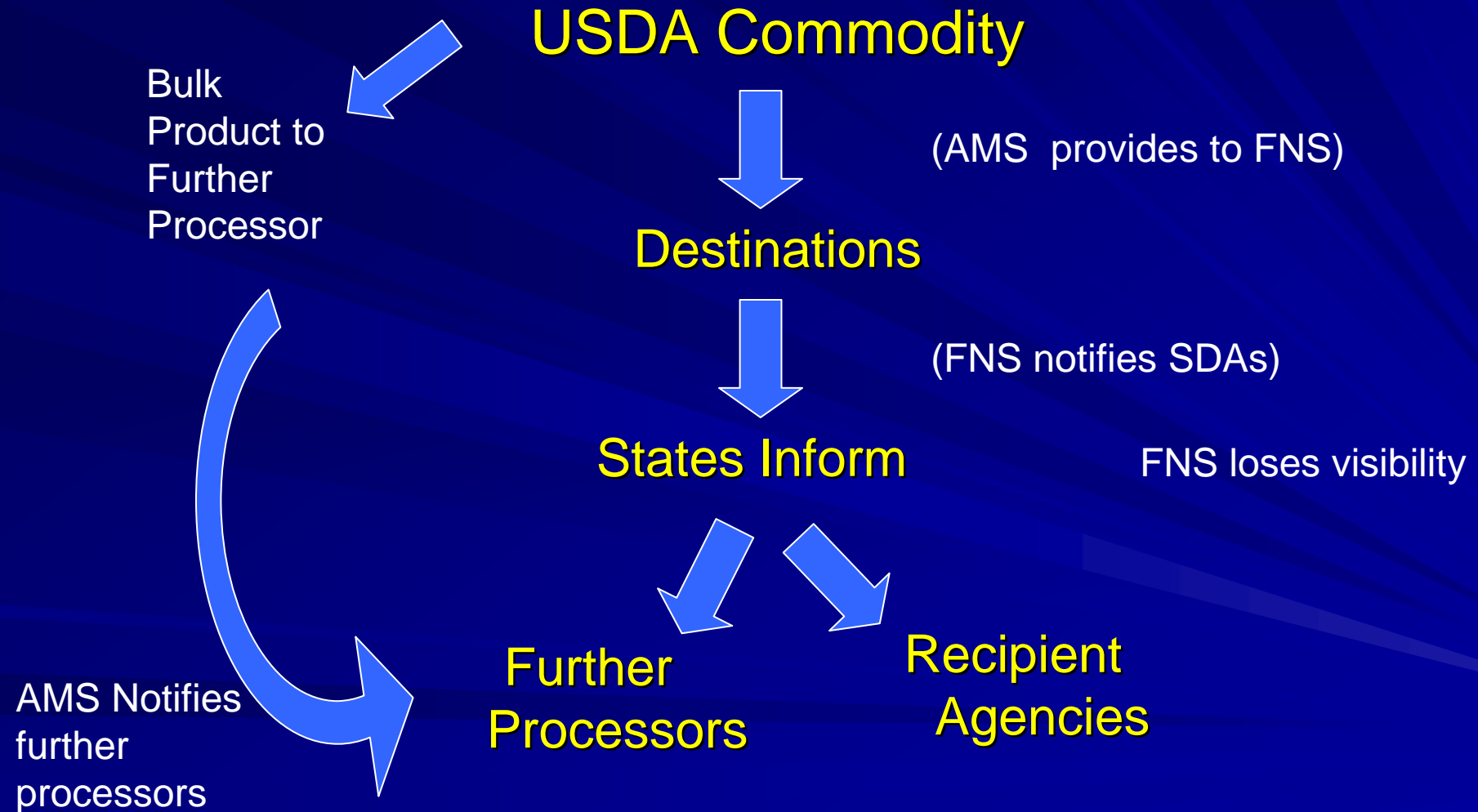
**FSIS Press
Release**

FNS Recall Events

FSIS
Public Notice



FNS Recall Events



Information AMS Receives When a Product is Recalled:

- Production date(s) or timeframe for recall?
- Product(s) involved?
- Are USDA commodities included?

AMS determines which DOs are involved

Recall Scenario #1: Product was Shipped Directly to States

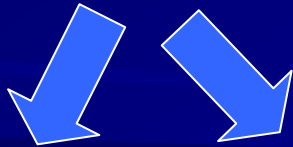
USDA Commodity



SDA Destinations



States Deliver Further



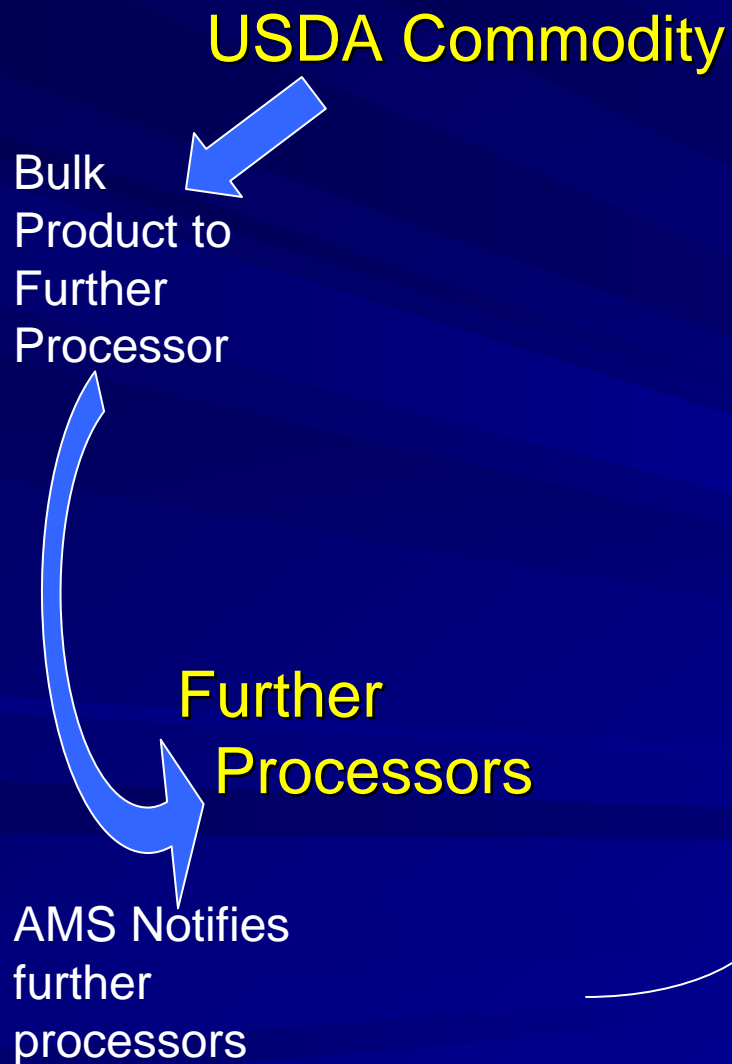
Further Processors

Recipient Agencies

- AMS Role: work with FNS to get product inventoried and located (how much, and where is it?)

- AMS works with contractor to get product recalled and replaced

Recall Scenario #2: Product was Shipped to Further Processors



- AMS notifies processor & provides information about what's involved
- Processor determines disposition of the product(s)
- AMS works with further processor to get product recalled
- Processor is responsible for contacting States and recalling product

ECOS RAS Hold/Recall Process

- Case created in ECOS when hold / recall is declared
 - Documents current information
 - Creates a RAS alert notification message
 - Transmits RAS notice to Recall Contacts identified in ECOS
 - Updates can occur for new information on:
 - Additional Affected Agencies
 - Increased scope (i.e., products, delivery periods, etc.)
 - Any new information that is critical

ECOS RAS Hold/Recall Process

- Recall contacts acknowledge receipt of notification and check ECOS for details
- FNS monitors ECOS to ensure all Agencies are aware of hold / recall

ECOS Hold / Recall Case

■ ECOS Recall Case Limitations

- Supply Chain visibility ends at delivery point
 - Rely on SDA, distributors & processors to track further
 - Substitution & redirection of orders unknown to ECOS
- Delivery Order product quantity and type is identified
 - Processed product calculations required to determine donated food quantities
 - Co-mingling of raw product further complicates donated food accounting
- ECOS design allows only SDA Recall Contact to provide product quantity and disposition information

Hold & Recall Coordination

■ State Agencies

- Monitor ECOS for DO information
- Monitor ECOS for instructions
- Coordinate RA and Industry partner efforts
- Collect and compile case information to enter into ECOS case file
 - Product quantities
 - Illness or injury
- Manage financial aspects of hold / recall

Hold & Recall Coordination

■ Processors & Distributors:

- Locate and sequester product in possession
- Provide information to State
 - Identify Recipient Agencies who received product
 - Quantities of product sequestered, delivered or unaccounted for
- Dispose of product as directed

RAS ECOS User Functions

- Two RAS user functions in ECOS
 - Recall Contact
 - Recall Role
- Establish User functions in ECOS Administration User Profile
 - User may have either or both functions assigned
- Recommend at least 2 persons per organization for each function

RAS ECOS User Functions

■ Recall Contact

- User who will receive alerts
- User specifies up to 3 devices (i.e., email, fax, phone, text messaging)
- Specify device order for notification
 - If no contact made on first device then contact on next specified device is attempted
- Contact prompted to acknowledge message
- Must have at least one Recall Contact identified in an organization

RAS ECOS User Functions

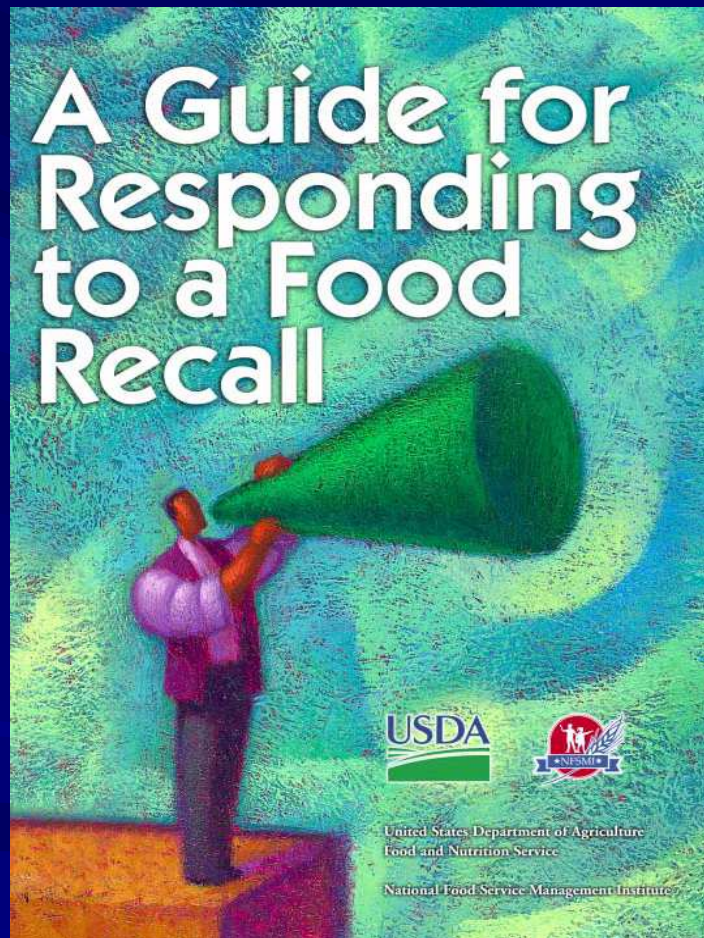
■ Recall Role

- User who responds to information requests
- Access to Recall Case response form
 - Provides information on commodity quantities isolated, destroyed or distributed
- ECOS Delivery Order or Receipt Acknowledgement provides initial quantities
- Must have at least one Recall Role defined in an organization

Ideas for Improvement

- Hold a “lessons learned” meeting and act upon those lessons
- Revise and update the 2001 “Hold and Recall Procedures”
- Train on hold and recall procedures
- Train on inventory management
- Resolve issues with further processed products
- Formalize communication strategies with other organizations – information multipliers

Responding to a Food Recall Under Revision!!



- **Resource for foodservice directors and managers.**
- **Contains a checklist with procedures for responding to a food recall.**

From NFSMI

<http://www.nfsmi.org/Information/recallmanual.pdf>

Resources

- **National Food Service Management Institute**
www.nfsmi.org
 - free training – just ask!
- **Training Available from the FNS Food Safety Staff : Inquire through the Food Safety Staff Mailbox**
FoodSafety@fns.usda.gov
- **FNS Food Safety web page:**
http://www.fns.usda.gov/fns/food_safety.htm