

# FMI Webinar

**Illness Outbreak Investigations  
and  
Membership/Shopper Card Initiative  
Presented by USDA FSIS  
May 28, 2015**

# WELCOME!

## FMI ANTITRUST STATEMENT

FMI believes strongly in competition. Our antitrust laws are the rules under which our competitive system operates. It is FMI's policy to comply in all respects with the antitrust laws.

Association meetings or workshops by their very nature bring competitors together. It is expected that all member representatives involved in FMI activities, as well as FMI consultants and other participants, will be sensitive to the legal issues and act in compliance with applicable antitrust and competition laws both at FMI meetings and FMI-sponsored events.

Accordingly, it is necessary to avoid discussions of sensitive topics that can create antitrust concerns. Agreements to fix prices, allocate markets, engage in product boycotts and to refuse to deal with third parties are illegal under the antitrust laws. At any association meeting discussions of prices (including elements of prices such as allowances and credit terms), quality ratings of suppliers, and discussions that may cause a competitor to cease purchasing from a particular supplier, or selling to a particular customer, should be avoided. Also, there should be no discussion that might be interpreted as a dividing up of territories.

An antitrust violation does not require proof of a formal agreement. A discussion of a sensitive topic, such as price, followed by action by those involved or present at the discussion is enough to show a price fixing conspiracy. As a result, those attending an association-sponsored meeting should remember the importance of avoiding not only unlawful activities, but even the appearance of unlawful activity.

As a practical matter violations of these rules can have serious consequences for a company and its employees. Antitrust investigations and litigation are lengthy, complex and disruptive. The Sherman Act is a criminal statute, and may even result in penalties punishable by steep fines and imprisonment. The Justice Department, state attorneys general and any person or company injured by a violation of the antitrust laws may bring an action for three times the amount of the damages, plus attorney's fees.

If you have any questions or concerns at this meeting, please bring them to the attention of FMI staff.

# Presenters

- **Sara M. Baucher**
  - Deputy Director – Compliance and Investigations Division (CID), Office of Investigation, Enforcement and Audit (OIEA), FSIS, USDA
- **Karen Becker**
  - Director of the Applied Epidemiology Staff within FSIS's office of Public Health Science
- **Daniel Engeljohn**
  - Assistant Administrator, Office of Policy and Program Development



United States Department of Agriculture

## One Team, One Purpose



# Food Safety and Inspection Service

Protecting Public Health and Preventing Foodborne Illness



# Food Safety and Inspection Service



## Illness Outbreak Investigations and Membership/Shopper Card Initiative



# Food Safety and Inspection Service



The public health agency in the USDA responsible for ensuring that meat, poultry, and processed egg products are safe, wholesome, and accurately labeled.

## Our Authority

Through a series of Acts, Congress empowers FSIS to inspect all meat, poultry, and processed egg products in interstate commerce.

- Federal Meat Inspection Act (FMIA)
- Agricultural Marketing Act (AMA)
- Poultry Products Inspection Act (PPIA)
- Humane Methods of Slaughter Act (HMSA)
- Egg Products Inspection Act (EPIA)

# Objectives of an FSIS Foodborne Illness Investigation

- Determine whether FSIS-regulated products are the source of reported human foodborne illnesses
- Identify the source of production, as well as the distribution, of the suspect meat, poultry, or processed egg product
- Gather information that FSIS can use to guide its response to prevent further illnesses associated with implicated product
- Develop information to guide efforts to prevent further consumer exposure to the contaminated product

# Illness Outbreak Investigations

- A foodborne illness investigation is a multi-faceted, multidisciplinary undertaking that involves collecting and analyzing data from epidemiologic, laboratory, and environmental assessments
- Foodborne illness investigations are a priority because they involve the health and well-being of consumers
- Timely assistance with foodborne illness response and traceback can improve consumer trust in the food supply chain

# Issue

- In as timely a way as possible, FSIS needs to identify the source of production, as well as the distribution, of the FSIS-regulated meat, poultry, or processed egg product possibly linked to illness
- FSIS Compliance Investigators require detailed purchase information to support traceback during foodborne illness outbreak investigations
- Businesses requiring notarized or signed statements from case-patients before sharing a case-patient's shopper card purchase history information leads to delays or lack of information

# Outbreak Investigations are Time-Sensitive

Speed and accuracy are essential in illness outbreak investigations because they:

- Identify the suspect product more quickly, which:
  - May prevent additional illnesses
  - May prevent future outbreaks
  - Keeps the American public confident in the food supply and public health system
  - Minimize economic and public health costs

# Primary Team Members of an Illness Investigation

- FSIS
  - Office of Public Health Science (OPHS)
  - Office of Investigation, Enforcement and Audit (OIEA)  
Compliance Investigators
  - Office of Field Operations (OFO)
- State and local health and agriculture departments
- Centers for Disease Control and Prevention (CDC)
  - Multistate investigation or at the request of state

# FSIS Compliance Investigators



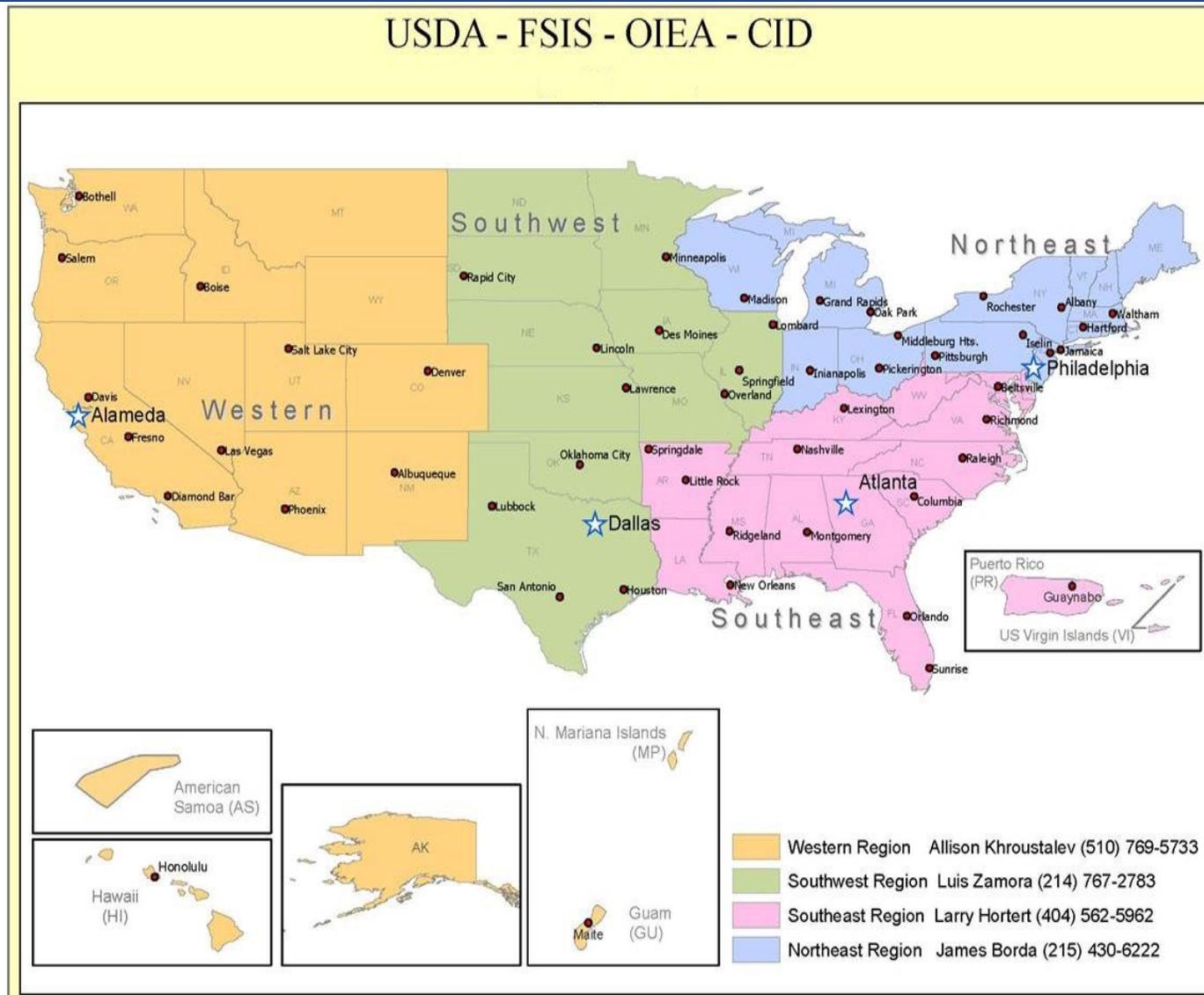
- Conduct foodborne illness investigations
  - Traceback/Traceforward activities
- Collect case-patient purchase history
- Initiate product control actions (e.g., detentions and seizures)
- Collect samples of meat, poultry, and egg products in commerce for testing as needed

# FSIS Compliance Investigators



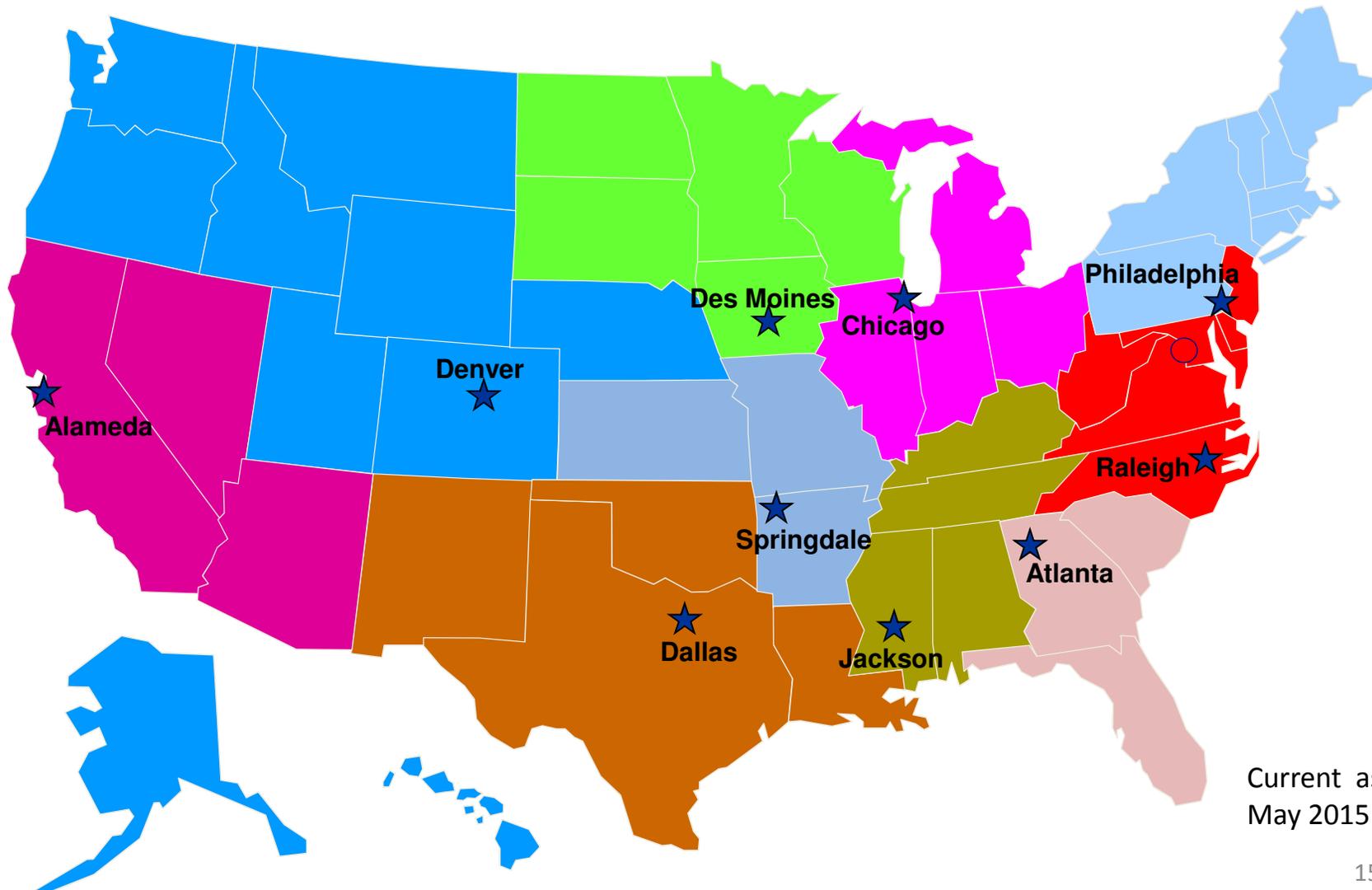
- Build liaisons and relationships
  - State and local health and agriculture departments
  - Industry contacts
    - Retail corporate offices
    - Chain retailer
    - Privately owned retailer
  - Distributors
  - USDA establishments

# FSIS CID Regions with Contacts



Current as of  
May 2015

# FSIS OFO District Offices



# Actions During an FSIS Foodborne Illness Investigation

- Obtain product distribution information via store invoices, customer sales receipts and/or shopper cards
- Conduct traceback/traceforward movement of product in commerce
- Facilitate removal of product in commerce
- Collect and document investigative findings that can lead or be used to support an enforcement action
- Share information with partners involved (e.g., federal, state, local)

# Investigation Authority

- The FMIA, PPIA, and EPIA provide FSIS personnel authority to examine facilities, inventory, and records at federal establishments and at warehouses, distribution centers, and other in-commerce facilities subject to the statutes (21 U.S.C. 460, 642, 1034, and 1040)
- These statutory provisions also provide FSIS personnel authority to copy certain business records. Investigators and other authorized program employees use photography, under these authorities, as a technique to examine facilities, inventory, and records, and to copy business records

# Records Authority

Section 202 of the FMIA (21 U.S.C. 642) states, in part, that a firm that engages, for commerce, in the business of preparing, packaging, or labeling any cattle carcasses, or parts or products of carcasses for use as human food shall keep such records as will fully and correctly disclose all transactions involved in their business. Regulations issued by this Department (9 C.F.R. § 320.1) describe the records required to be kept. These provisions apply to all transactions in or for interstate commerce or such products held for sale after such transportation.<sup>1</sup>

*1. Similar language in Section 11 (21 U.S.C. 460 of the PPIA and Section 11 (21 U.S.C. 1040 of the EPIA)*

# Title 9 C.F.R. § 320.1 and § 381.175

- The language in § 320.1 and § 381.175 are nearly identical in describing business types and “required records” ...
- Applies to any person that engages in the business of buying or selling (as a meat broker, wholesaler, or otherwise), or transporting in commerce, or storing in or for commerce, or importing, any carcasses, or parts or products of carcasses, of any such animals<sup>1</sup>
- Describes records as those that “will fully and correctly disclose all transactions involved in ... its (the firm’s) business....”
- Examples of required records are bills of sale, invoices, bills of lading, and receiving and shipping records

*1. Title 9 C.F.R. § 320.1(a)(2)*

# Examples of Records Needed for Traceback/Traceforward

- Transportation records
  - Identify the transporter
  - Product origin
  - Product destination
- Grinding logs
- Sanitation logs
- Consumer complaint logs
- In-house sampling logs

# Examples of Records Needed for Traceback/Traceforward

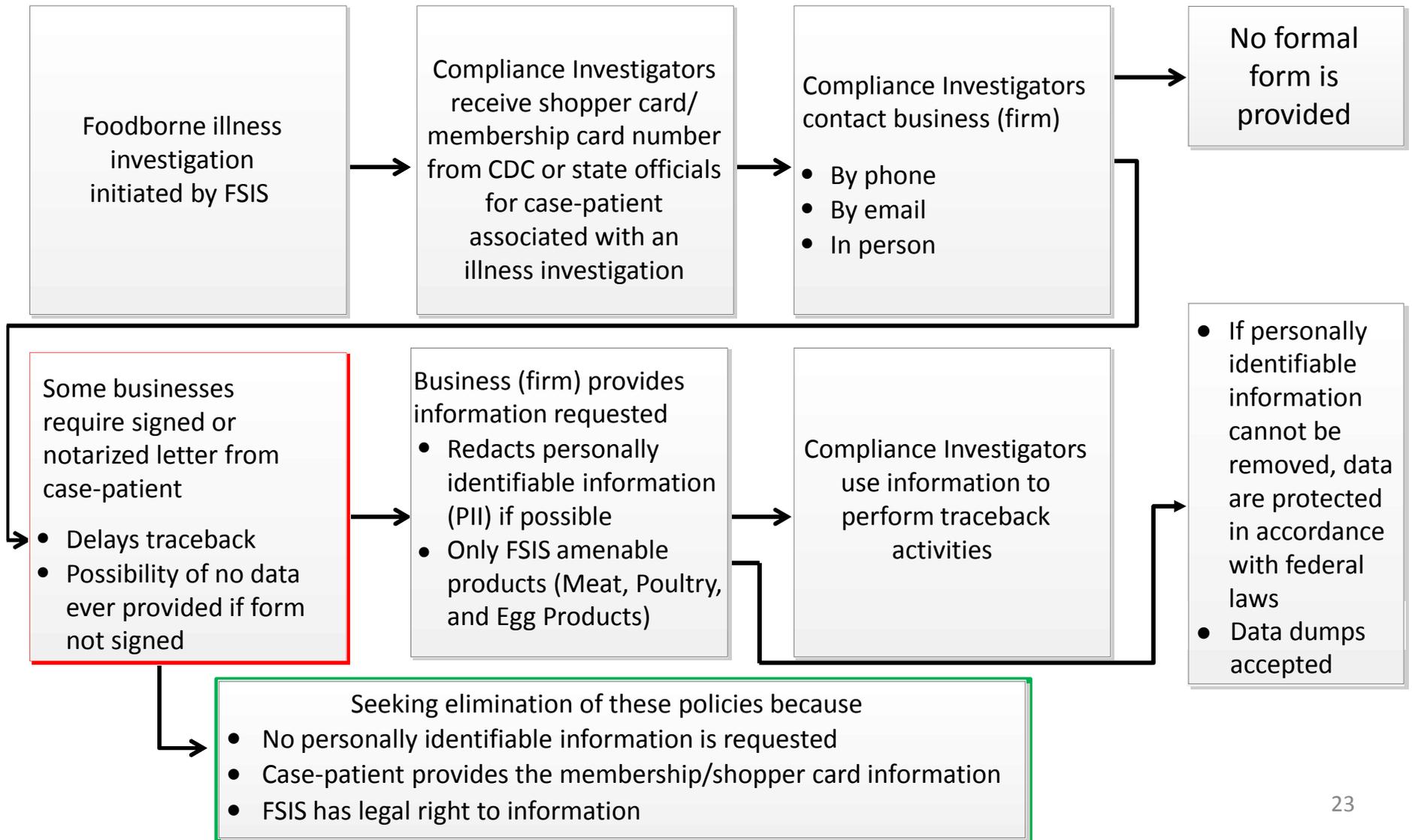
- Producing store name
- Address (city/state/zip)
- Date and amount of each lot of product produced
- Exact name/type of product produced
- Net weight of packaged product
- Full name(s) and product code(s) of source product(s)
- Federal or state establishment numbers
- Bills of sale (e.g. sales receipt)
- Invoices(s) and bill(s) of lading for source product(s)

**Recommended format for results – Excel spreadsheet**

# Personally Identifiable Information (PII)

- Information that can be used on its own or with other information to identify, contact, or locate a single person, or to identify an individual in context
- Examples of personally identifiable information are: A person's date and place of birth, social security number, age, marital status, salary, personal medical, financial information
- FSIS does **not** request personally identifiable information

# FSIS CID Membership/Shopper Card Inquiry Process



# Request for Assistance

- Firms keep records that fully disclose all transactions
- Elimination of any requirements that would slow down getting needed information to conduct traceback/traceforward
  - Eliminate notary requirement
  - Eliminate requirement of case-patient signatures
- Remove all personally identifiable information (if possible)
- Update membership/shopper card policies (where necessary) to make consumers aware how information will be used to protect public health
- Requested records be turned over as soon as possible

# Benefits of Cooperating

- Traceback investigations occur more efficiently and faster
- Recall initiated earlier
  - Product(s) removed from commerce faster
  - Possible illnesses prevented from purchased products
- Assist with identifying actual source of contamination
- Contribute to prevention of foodborne illnesses
- Press releases more favorable
- The scope of recalls are more targeted, thus enhancing efficiencies
- Beneficial for both public health and industry

# Examples from Outbreak Investigations

- 2010 *Salmonella* Montevideo
  - Public health officials were not able to determine the source of the outbreak until retailer chain A provided shopper card purchase records
  - Washington State Department of Health identified a common brand of product among 5 case-patients, which led to the recall of salami products
- 2010 *E. coli* O26
  - As soon as FSIS received the shopper card number, the agency was able to conduct traceback that same day
  - Shopper card purchase records collected from 2/3 (67%) case-patients who purchased ground beef from retailer chain B led to recall of ground beef products from one (1) production date
- 2014 *Salmonella* Typhimurium
  - Ohio Department of Health notified CDC and FSIS that they were unable to collect shopper card purchase records from retailer C without written consent/notarized form from case-patient
  - Time from FSIS notification of the issue to collection of purchase records for traceback: 11 days
  - One (1) of the factors which led to an unresolved outbreak

# Questions?

