



Recordkeeping:

A Public Health Vulnerability



BACKGROUND

- FSIS is the public health agency in the U.S. Department of Agriculture responsible for ensuring that the nation's commercial supply of meat, poultry, and egg products is safe, wholesome, and correctly labeled and packaged

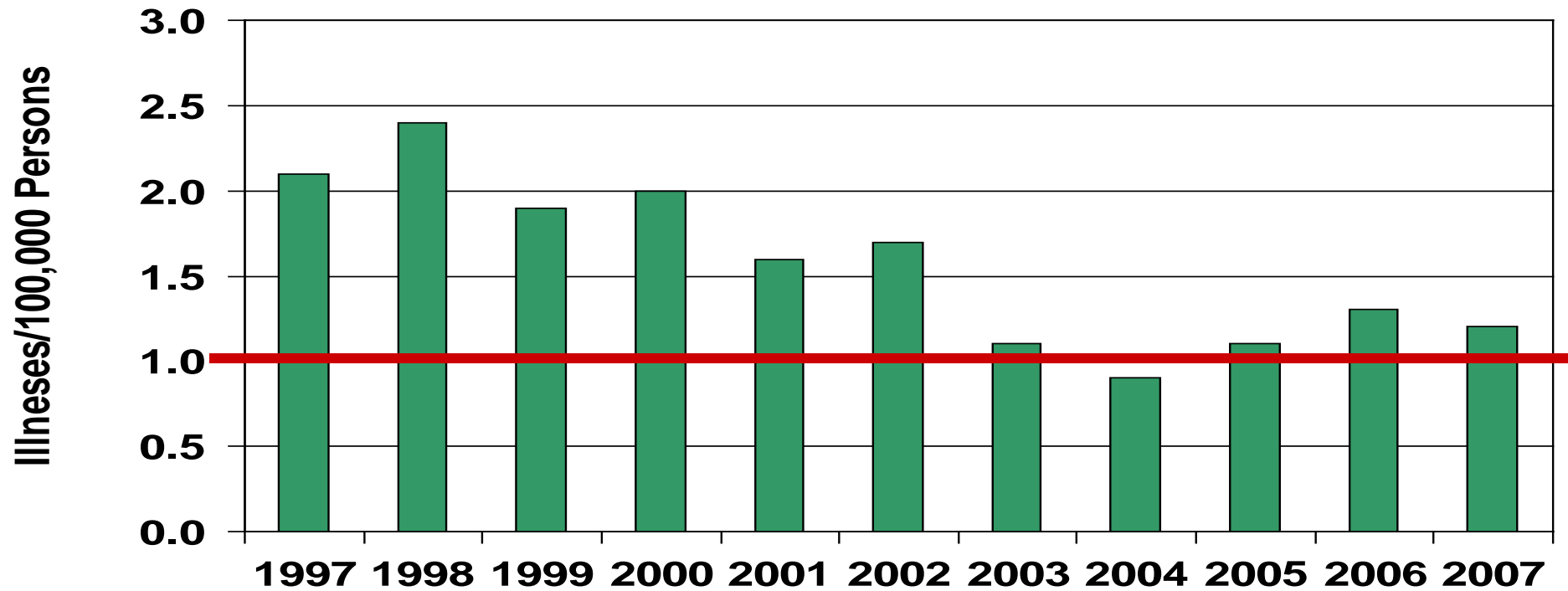
HEALTHY PEOPLE 2010

	1997	2007*	2010
<u>Cases per 100,000</u>	<u>(Baseline)</u>		<u>(Target)</u>
<i>E coli</i> O157:H7 (STEC O157)	2.1	1.2**	1.0
<i>Lm</i>	.50	0.27	0.25***
<i>Salmonella spp</i>	13.7	14.9	6.8
<i>Campylobacter</i> spp	24.6	12.8	12.3

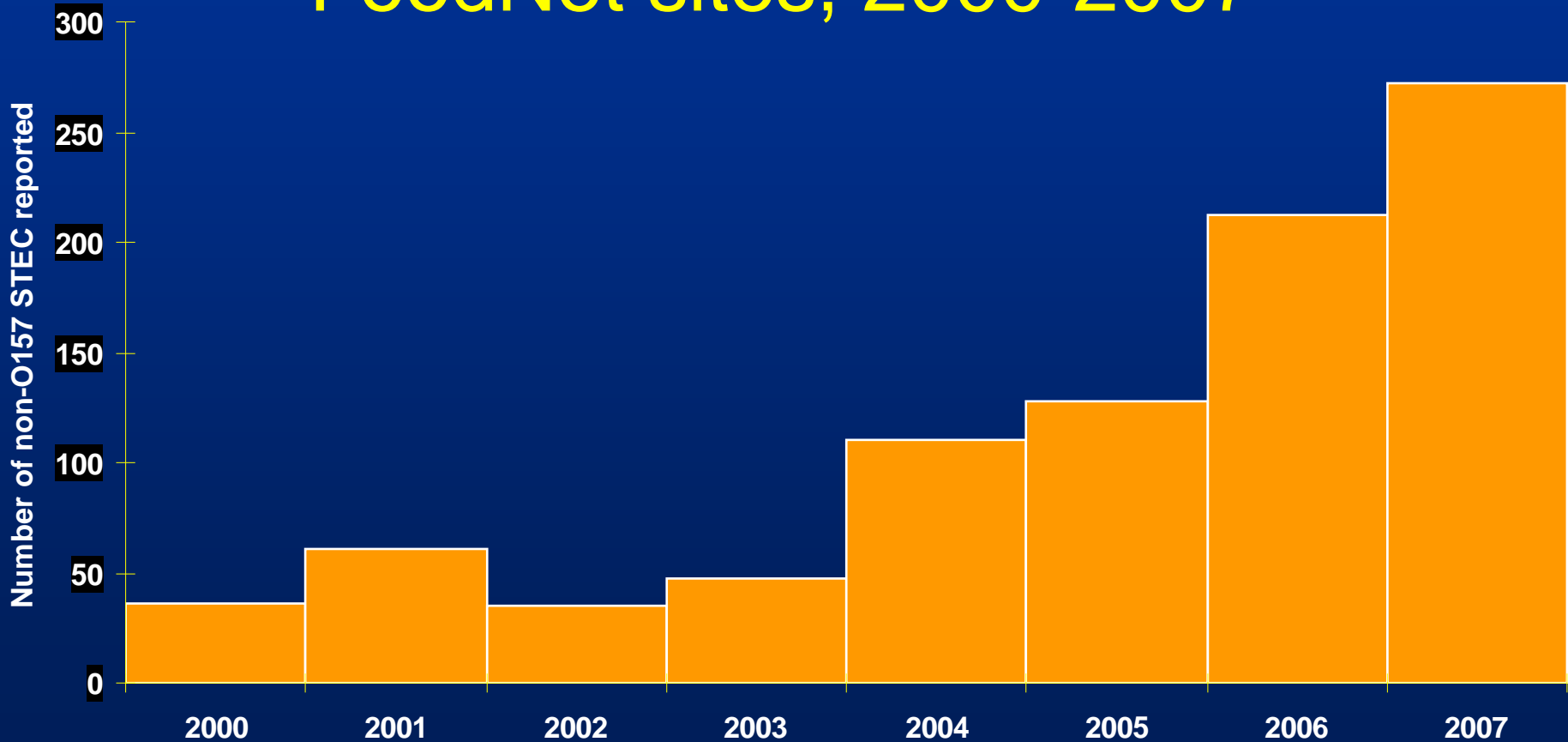
•Data sources:

- *Chapter 10 - <http://www.healthypeople.gov/document/pdf/Volume1/10Food.pdf>
- Preliminary FoodNet Data on the Incidence of Infection with Pathogens Transmitted Commonly Through Food --- 10 States, 2007 --
<http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5714a2.htm> -- goal met only in 2004
- ** FSIS estimates 0.34 cases/100,000 are from ground beef
- *** Changed to year 2005 by E.O. (President Clinton)

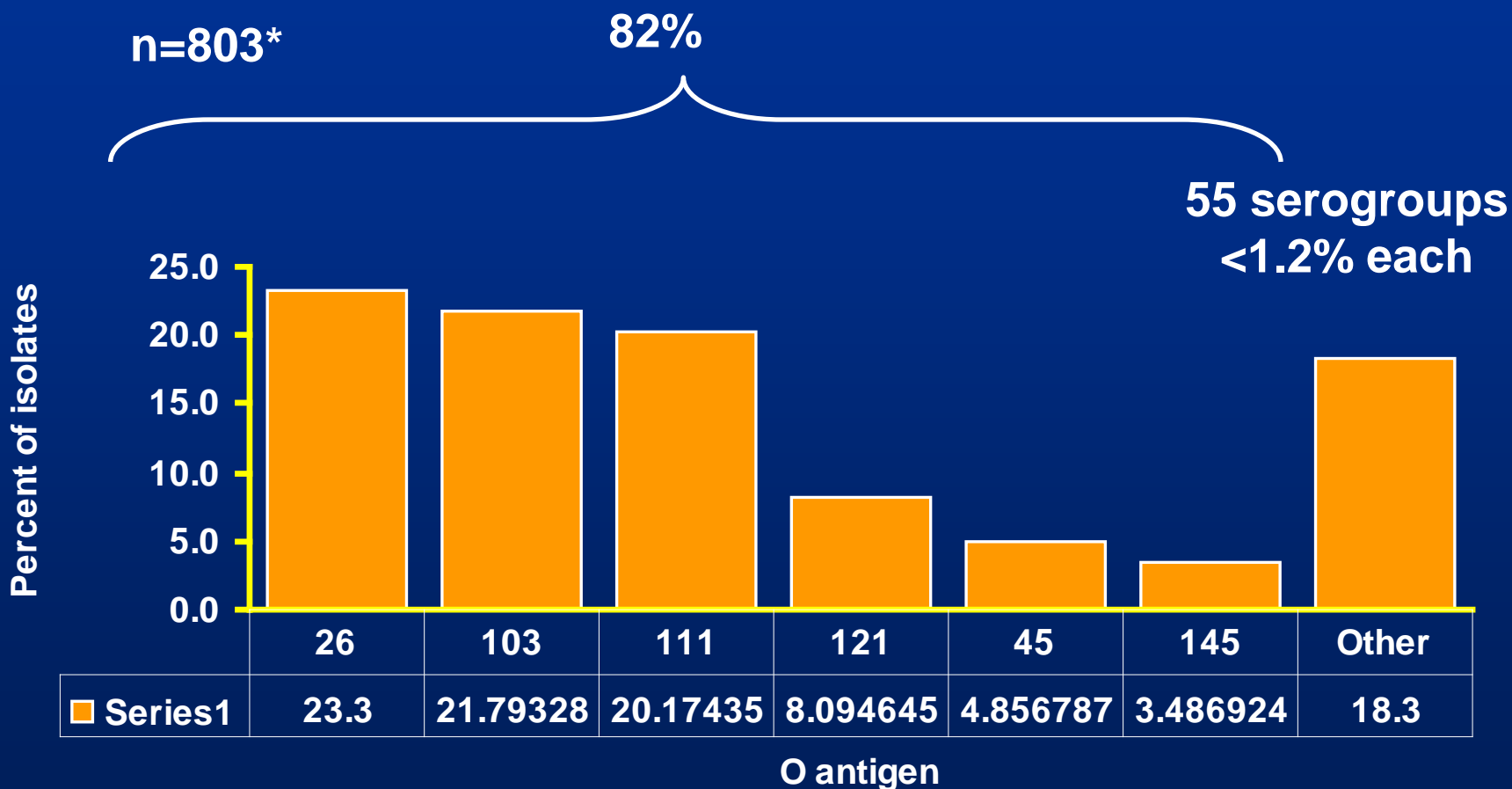
Healthy People 2010 - *E. coli* O157:H7



Number of non-O157 STEC reported in FoodNet sites, 2000-2007



Human isolates of non-O157 STEC by O serogroup, FoodNet sites, 2000-2007



*An additional 86 isolates had missing O group information

2007(2008) Recall-Related Actions

- 57(46) recall actions; 4(5) public health alerts
 - 9(7) – Allergen
 - 1 – Botulinum
 - 1 – Improper cooling
 - 3 - Improper documentation/insanitation
 - 22(17) – *Escherichia coli* O157:H7
 - 11(11) – *Listeria monocytogenes*
 - 2(5) – Metal/other
 - 3(2) – *Salmonella* (frozen NRTE)
 - 1 – *Staphylococcus aureus*
 - 3 – Under-processing
 - 5(5) – Undeclared ingredient/adulteration
 - (4) - SRM



ISSUE

- FSIS relies heavily on records maintained by industry to identify trace back and trace forward on FSIS-regulated products associated with foodborne illness and other food safety incidents
- Retail records are a critical component in trace back and trace forward activities
- Essential to quickly and effectively determine source product and ensure controls are enhanced by affected product manufacturers (e.g., official establishment, retail, foodservice)

Statutes & Regulations

- 21 U.S.C. 621 authorizes Secretary to make rules and regulations necessary for the efficient execution of the statutes
- 21 U.S.C. 642 requires firms to keep and make available full and correct business records of transactions in food
- 9 CFR 320.1 specifies businesses and types of records required, such as bills of sale, bills of lading, receiving and shipping papers
- Similar authorities for poultry

Agency Responsibilities

- OPHS epi-officers lead agency illness outbreak investigations
- OPEER investigators conduct trace back and trace forward investigations for outbreak investigations & other public health activities
- OPEER investigators conduct periodic surveillance in-commerce, including at retail, and collect ground beef samples to enhance public health protection and decision making

Retail Record Vulnerability

- Recent outbreak investigations were impeded by poor retail records
 - OPHS investigated 16 cases of foodborne illness implicating raw ground beef products manufactured at retail in 2007-2008
 - Of the 16, only 9 retail operations kept production logs (e.g., grinding logs) sufficient for trace back and trace forward activities
 - Of the 9, 5 resulted in a recall

Review of the 9 Retail Operations

- 7 recorded establishment producing source beef
- 6 recorded descriptions of the source beef
- 6 recorded grinding date/time
- 5 recorded descriptions of products ground
- 2 recorded sanitizing/cleaning between grinds
- 1 ground bench trim without sanitizing/cleaning, and then ground other product to replenish stock

Ground Beef Sample Collection

- Conditions when OPEER investigators are to collect a sample for *E. coli* O157:H7 (Directive 8010.1, Appendix 1)
 - Grinding primals, subprimals, or boxed beef
 - Grinding store generated bench trim derived from own operations
 - Grinding beef labeled “natural” or “all-natural” (with exceptions)
 - Not cleaning and sanitizing grinder between use of different source materials
 - Grinding purchased trim not accompanied by records of negative test results for *E. coli* O157:H7
 - Using meat cuts (steaks or roasts) with expired sell-by dates
 - Mixing irradiated and non-irradiated beef
 - Grinding beef to sell as raw ground beef and failing to keep records that identify Federal or state establishment numbers of suppliers (source materials used in grinding)



FSIS INTENTIONS

- Pursue rulemaking to enhance and modernize FSIS recordkeeping requirements
- Regulations expected to explicitly define required recordkeeping for ground beef manufacturing at retail
- Develop compliance guidelines retailers can use to meet FSIS' trace back and trace forward activities

FSIS INTENTIONS

- Develop additional guidance for investigators focused on activities at retail level
- Continued retail surveillance, including food safety, food defense, records, and sampling
- Look at corporate practices, where applicable
- Investigate, document, and act on violations
- Use findings for decisions, such as for enforcement, product control, recalls, and other public health activities

Production Records

- Producing retail operation's name and address (city, state, zip code)
- Product information
 - Date and time product was ground
 - Exact name and type of store ground product
 - Quantity of product ground
 - Production code of each lot of store ground product
 - Sell-by or use-by dates
 - Other info used to identify the store ground product
- Source (supplier) information
 - Establishment # for each source material used
- Cleaning/sanitizing information (e.g., date/time, especially significant between varied source materials)

Other Information

- Telephone numbers of retail store
- Store contact person and phone #
- Number of outside/shipping containers of each source product
- Club Card information (if applicable)
- Retail store's pull-date policy
- Retail store's rework policy
- Retail store's cleaning and sanitizing policy



Grind Log Example

Date of Grind	Time of Grind	Name of Source Product	Name of Supplier	Sell by Date	Est. #	Pack Date	Approximate Quantity Ground	Initials of Store Employee
6-4	9:15	Sirloin 10#	USA Beef	6-8	12345	5-22		J. Doe
6-4	9:20	Cleaned	And Sanitized	---	---	---	x	J. Doe
6-4	9:25	Angus Round 10#	Mighty Fine Beef	6-7	06789	5-20		J. Doe
6-4	9:35	Cleaned	And Sanitized	---	---	---	x	J. Doe
6-4	9:40	Chuck 40#	USA Beef	6-15	12345	5-29		J. Doe
6-4	10:00	Chuck 80#	USA Beef	6-17		5-31		J. Doe
6-4	10:10	Cleaned	And Sanitized	---	---	---	X	J. Doe
6-4	11:30	Sirloin 20#	USA Beef	6-9	12345	5-23	Patties 20#	J. Doe
6-4	11:45	Round 20#	USA Beef	6-16	12345	5-30	Patties 20#	J. Doe
6-4	12:00	Chuck 20#	USA Beef	6-17	1245	5-31	Patties 20#	J. Doe
6-4	12:30	Angus Round 10#	Mighty Fine Beef	6-7	06789	5-20	Patties 10#	J. Doe
6-4	12:45	Angus Chuck 20#	Mighty Fine Beef	6-14	06789	5-27	Patties 20#	J. Doe

Grinder Log Example

Date of Grind	Time of Grind	Name of Source Product	Name of Supplier	Sell by Date	Est. #	Pack Date
June 1	Startup	Sirloin	USA BEEF	6-14	12345	5-28
	7:00	Round	USA BEEF	6-14	12345	5-28
		Angus Rd	MIGHTY FINE BEEF	6-8	06789	5-21
		Angus Chuck	MIGHTY FINE BEEF	6-8	06789	5-26
		Chuck	USA BEEF	6-14	12345	5-28
		Clean	and sanitized			
	1:00	PS Round	MIGHTY FINE BEEF	6-8	06789	5-21
		PS Chuck	MIGHTY FINE BEEF	6-8	06789	5-21
		Chuck 90#	USA BEEF	6-14	12345	5-28
	1:20	Grinder	cleaned and	Sanitized		
		Trim into	Hamburger	30#		
	1:30	Grinder	cleaned and	sanitized		

- Note using same source material after cleaning and sanitizing in between
- Note made bench trim into hamburger but didn't identify source products or source information

United States Department of Agriculture Food Safety and Inspection Service



Supermarkets, Inc Retail Ground Beef Production Records

Store Name Store #1

Today's Date 4-13-07

Time

95% Natural Ground Beef	# of Pkgs	Counter Pulls	95% trim packs will consist of round eyes, tops, or knuckles. Box code #34567	<Dist A> Order # 123-4567	No Trim in 95%
1.5 lb Pkgs	12	9	Packer	Est A	
1 lb Pkgs	30	11	Plant #	Est 987	
.50 lb Pkg			Pack Date	4-3-07	
			Distributor	Dist. A	

Plate size—9/64 for Grinder and Mixer

90% Natural Lean Ground Beef	# of Pkgs	Counter Pulls	90% trim packs will consist of chuck rolls, clods, or outside rounds. Box code #34560	<Dist A> Order # 123-4568	Lbs. Natural Trim?
1.5 lb Pkgs	40	14	Packer	Est A	
1 lb Pkgs	70	19	Plant #	Est 9873	
.50 lb Pkg			Pack Date	3-27-07	
			Distributor	Dist. A	

Plate size—9/64 for Grinder and Mixer

85% Natural Lean Ground Beef	# of Pkgs	Counter Pulls	85% trim packs will consist of chuck meat. Box code #34565	<Dist A> Order # 123-4569	Lbs. Natural Trim?
1.5 lb Pkgs	10	10	Packer	Est A	
1 lb Pkgs	20	11	Plant #	Est 987	
.50 lb Pkg			Pack Date	4-3-07	
			Distributor	S.V.	

Plate size—9/64 for Grinder and Mixer

80% Natural Lean Ground Beef	# of Pkgs	Counter Pulls	All trim for family packs will come from commodity trim, DAC trim, or natural trim		Lbs. Trim?
4 lb Pkgs		6	Packer		AA
			Plant #		
			Pack Date		
			Distributor		

Plate size—9/64 for Grinder and Mixer

Grinding Order	
First	Natural Beef
Second	Commodity Beef
Third	Veal
Fourth	Lamb
Last	Pork

Cleaning and Sanitizing during grinding process

When grinding, all equipment which includes augers, plates, knives, and grinder-mixer must be washed and sanitized between each species.

Grinder Signature <Name> Sanitizer Signature <Name>

- Not recorded:
 - Lot number of source material
 - Time of production
 - Identity of trim for 80% GB
 - Equipment not cleaned and sanitized between each lot
 - Use of counter pulls i.e. reworked product

Recorded: Store, date of production, product description*, identity* and pack date of source product, and signatures
* Note novel use of product code and distributor order numbers to describe source product



“Gold Standard” Log example

Time of Grind	Lot/ Batch Number (lot = same source material)	Exact Name/ Type of Product Produced	Package Size of Product Produced	Amount (in pounds) of Product Produced	Production Code of Product Produced	Manufacturer Name of Source Material Used for Product Produced	Product Code and/or Pack Date of Source Material Used	Establishment Number of Source Product Used	Comments	Initials
0700-0830 AM	Lot 001	91/9 Gold Standard Ground Chuck	Catch-weight retail trays	1,250 lbs total of 91/9 Ground Chuck	033109-01 GSGC; Sell-by 04/02/09	Boneless Chuck, twenty-one 60 lb boxes from USA Beef Company	BC031509US A Packed on 03/15/09; BC031709US A Packed on 03/17/09	Est. 00321 M	Cleaned and sanitized grinder after Lot 001; excess source material (approx. 10 lbs) made into RTE chili; switched source materials	John Doe ID # 222