



Evaluation of recalls of FSIS-regulated food products: January 1994 through August 2018

Integrative Learning Experience Presentation and Defense

Submitted in partial fulfillment of requirements for the degree
Masters of Public Health

Outline

- Field experience overview
- Learning objectives
- Activities performed
- Background
- Project
- Data
- Literature review
- Conclusions
- Competencies
- References
- Questions

Field Experience

United States Department of Agriculture

Food Safety and Inspection Services

Office of Field Operations

Recall Management and Technical Analysis Division

1400 Independence Ave SW., Washington, DC

Preceptors:

William Gillingwater

Patricia Bennett

Brief Overview of USDA FSIS

- More than 100,000 USDA employees
 - Including nearly 9,600 FSIS employees
- Other regulatory and public health entities
- For the safety of our food supply
- The FSIS monitors all USDA-certified facilities
- The USDA/FSIS headquarters south building
 - Downtown Washington, DC
 - 1/2 block away from the National Mall



To Work Every Day



Department of Agriculture – South Building



My Office

Learning Objectives

- Develop an understanding of
 - FSIS as a regulatory and public health agency
 - FSIS process of recommending a food product recalls
 - Intra and inter-agency relationships that exist to ensure FSIS recalls are effective
- Create a detailed historical analysis of recalls

Activities Performed

- Attended daily and weekly meetings
- Participated in learning seminars hosted by FSIS
- Toured FSIS-regulated facilities (beef, pork, poultry & sausage)
- Networked with FSIS Recall Team
- Scanned approximately 1080 files of recall records
- Evaluated recalls that occurred between January 1994 and August 2018

Background

A food product recall:

- Voluntary action by a food producer
- Remove products from commerce
- Is initiated by the producer, manufacturer or distributor
 - Sometimes at the request of the FSIS

If a company refuses to recall:

- FSIS has legal authority to detain and seize products in commerce

Unsafe products are typically discovered one of four ways

Once notified, FSIS conducts a preliminary investigation

Background

- Preliminary investigation goals
 - Collect data
 - Consult subject matter experts
 - Define the scope
 - Create a timeline of events
 - Convene a Recall Committee meeting
- FSIS maintains a standing Recall Committee
- If sufficient evidence is presented, FSIS will request the company recall their product
- FSIS notifies the public regarding a recall through
 - Recall Press Release
 - E-mail to subscribers

Recall Committee

- May include:
 - OFO – Office of Field Operations
 - OPHS – Office of Public Health Science
 - OPACE – Office of Public Affairs and Consumer Education
 - OPPD – Office of Policy and Program Development
 - OIEA – Office of Investigation, Enforcement, and Audit
 - ODIFP – Office of Data Integration and Food Protection

Project

Project Objectives

- Created digital archive of hard-copy recall files
- Gathered information to create graphs of recall data
- Graphically depicted recalls based on various characteristics
- Further evaluated recalls contaminated with shiga toxin-producing *Escherichia coli*

Food Recall Definitions

- Recall Class
 - Class I – A reasonable probability of health problems or death
 - Class II – A remote probability of adverse health consequences
 - Class III – Should not cause adverse health
- Facility size as defined by HACCP regulations
 - Large: over 500 employees
 - Small: more than 10 employees but less than 500
 - Very Small: less than 10 employees or less than \$2.5 million annual sales
- Possible reasons for a food recall include:
 - Non-pathogen reasons:
 - Undeclared allergens, drug or chemical residue, extraneous material, misbranding, processing error etc.
 - Pathogen reasons:
 - *Listeria monocytogenes*, shiga toxin-producing *Escherichia coli*, *Salmonella*, other Pathogen

Food Recall Notification Routes

- CDC/FDA
- Compliance personnel/ investigation
- Consumer complaint
- Foreign food producer
- Health code violation
- Illness/outbreak
- In plant inspector
- Laboratories
- Plant/facility/manufacturer/distributor
- State/ local health department

Information Captured in Recall Documents

*Data collected & utilized for this project are **Bold**

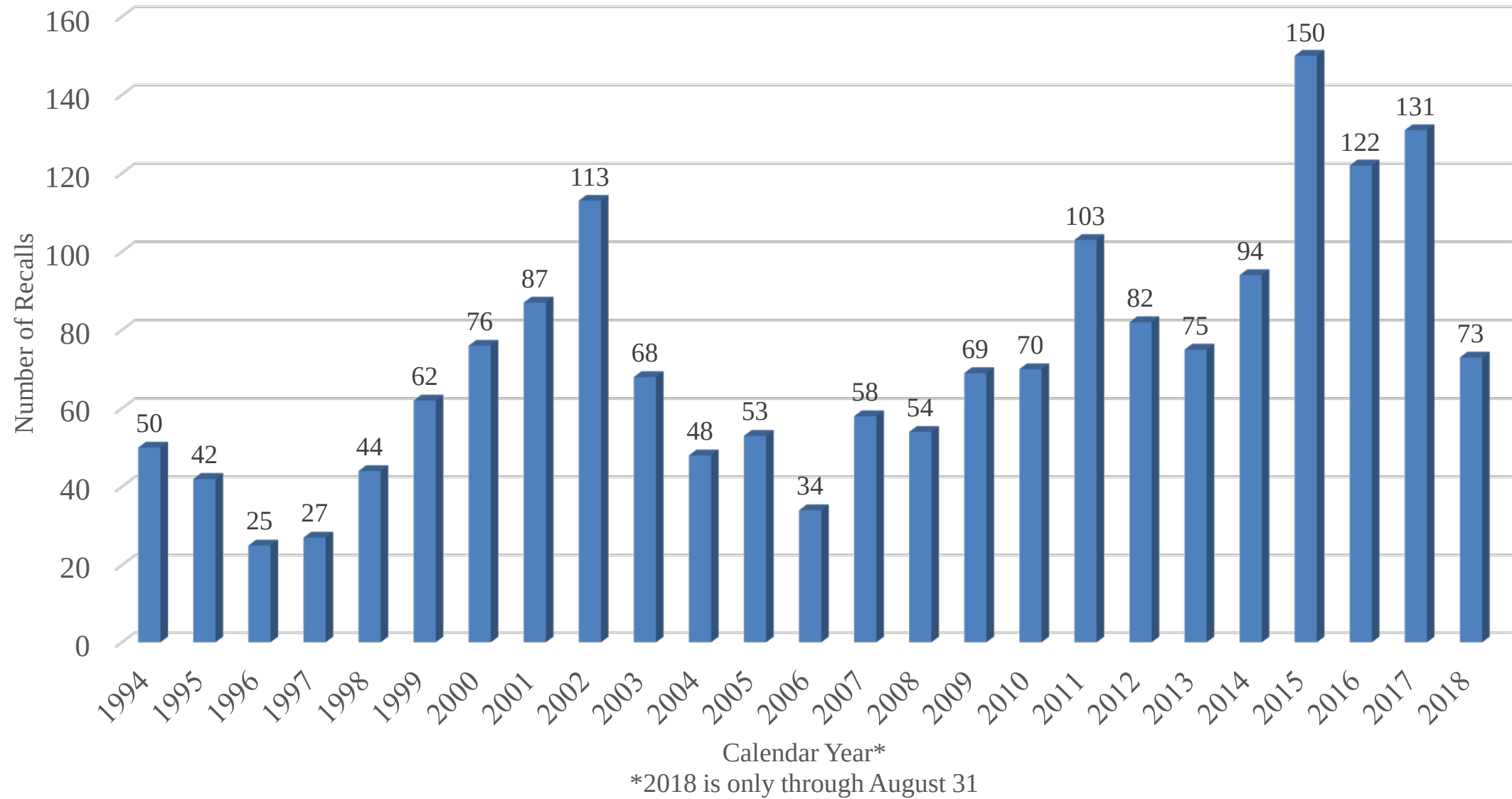
- **Recall tracking number**
- **Class**
- **HACCP-defined facility size**
- **Pounds recalled**
- **Species**
- **Reason for recall**
- **Source of initiation**
- **Year**
- **Month**
- **Specific pathogen**
- Date opened
- Date closed
- Pounds recovered
- Type/description of product
- Establishment name
- USDA establishment number
- State of origin
- District office
- Country
- Foreign establishment number
- Additional comments
- Recall effectiveness
- FDA recall & ingredient
- Specific allergen

Overview of General Recall Data

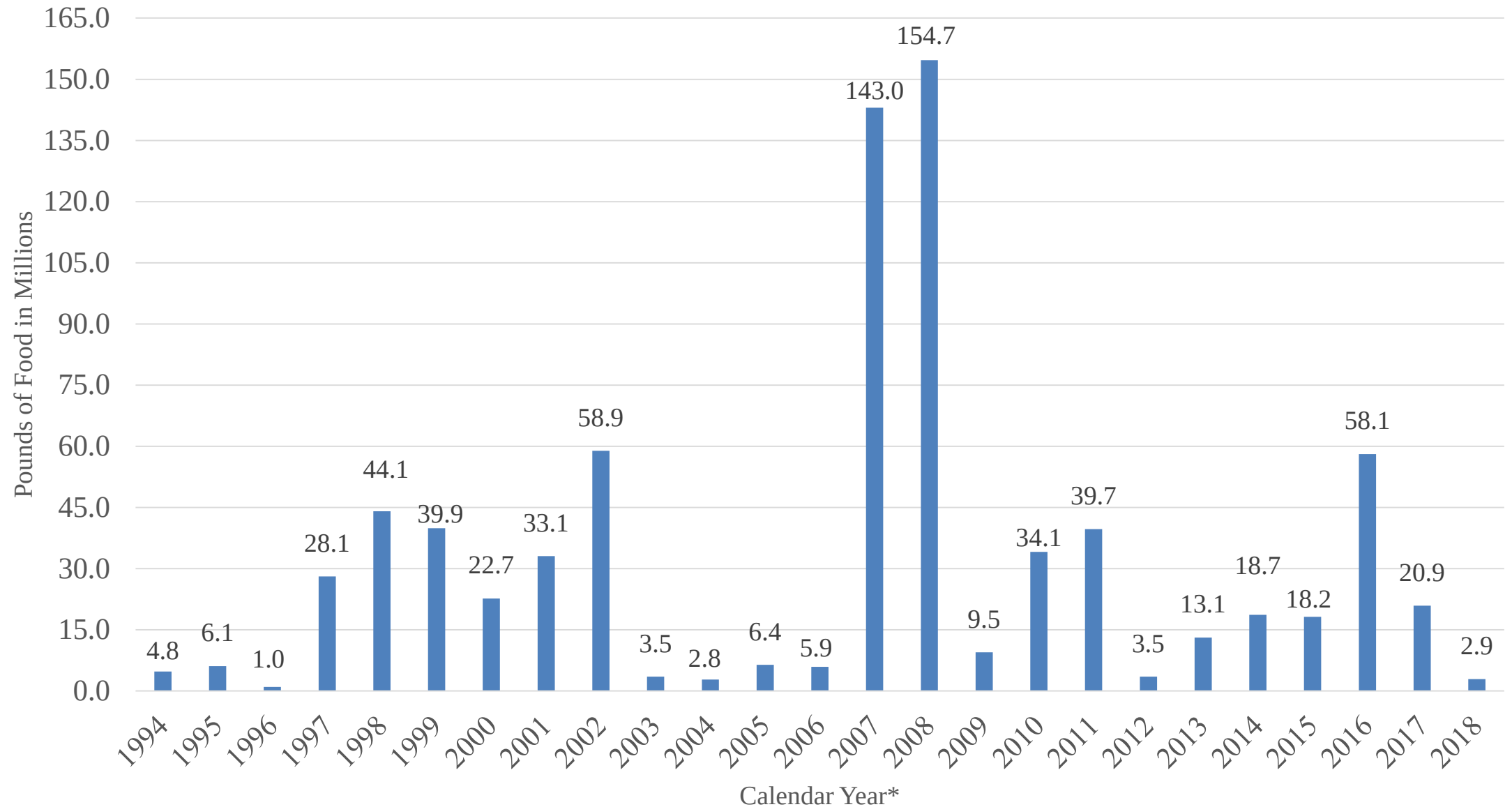
Evaluation of data by Calendar Year:

- Total number of recalls
- Total pounds recalled
- Proportion of each specified pathogen
- Total number by
 - Recall class
 - HACCP-defined facility size
 - Type of meat involved (Species)
 - Source or route of initiation
 - Reason recall was initiated
 - Pathogens vs. non-pathogens

Total number of recalls of FSIS-regulated food products by calendar year from January 1994 through August 2018

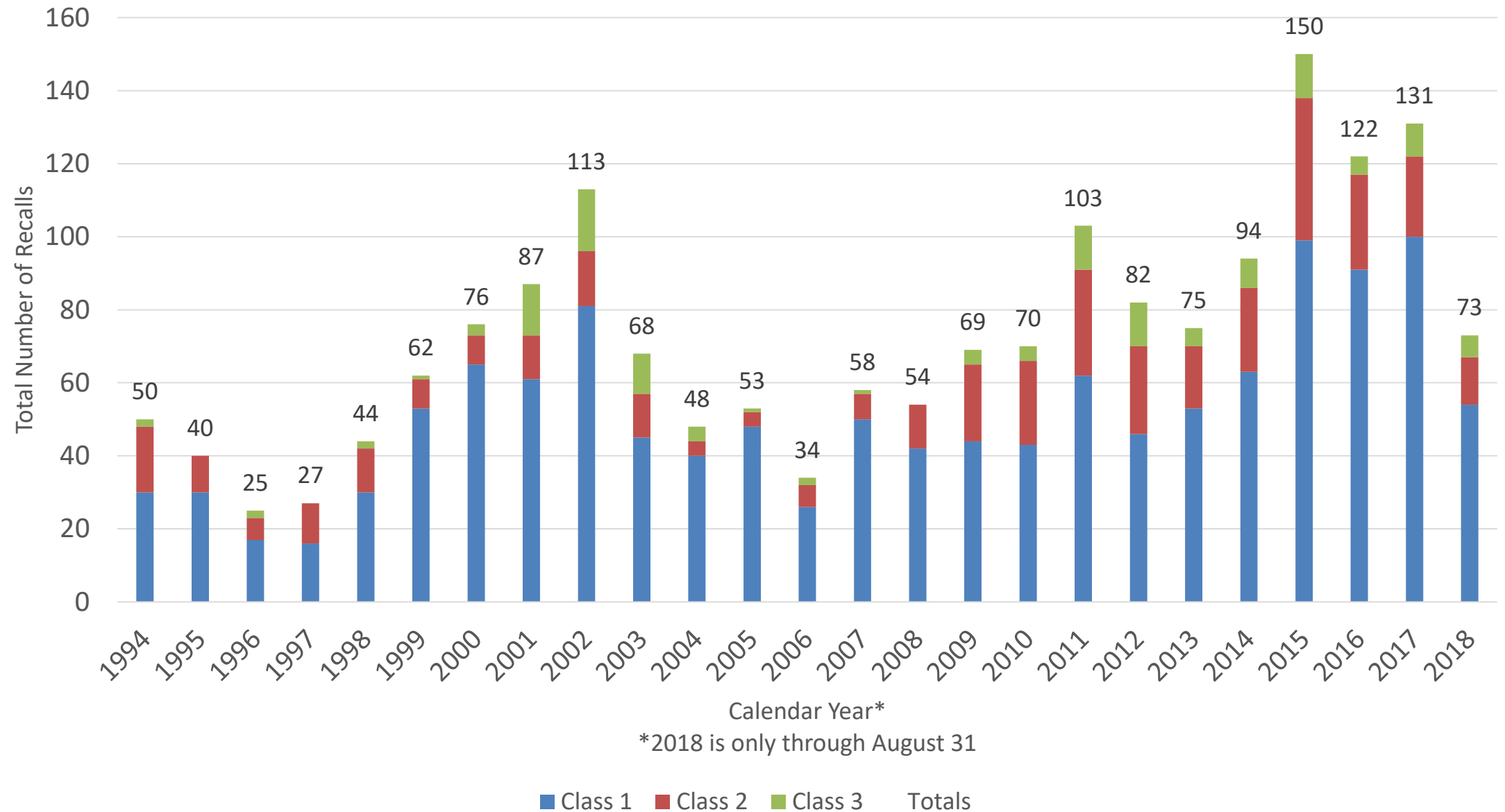


Total pounds (in millions) of recalls of FSIS-regulated food products by calendar year from January 1994 through August 2018

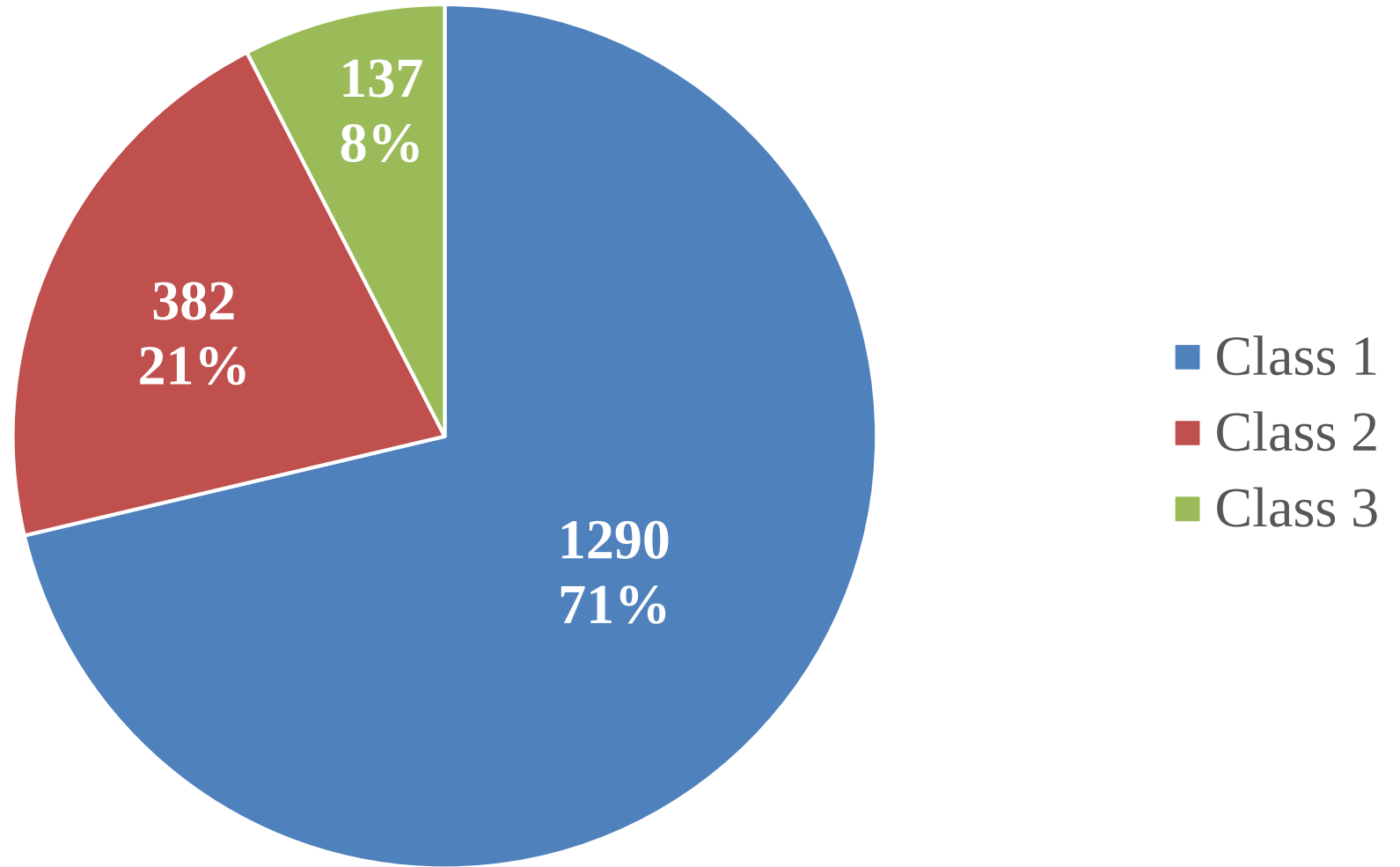


*2018 is only through August 31

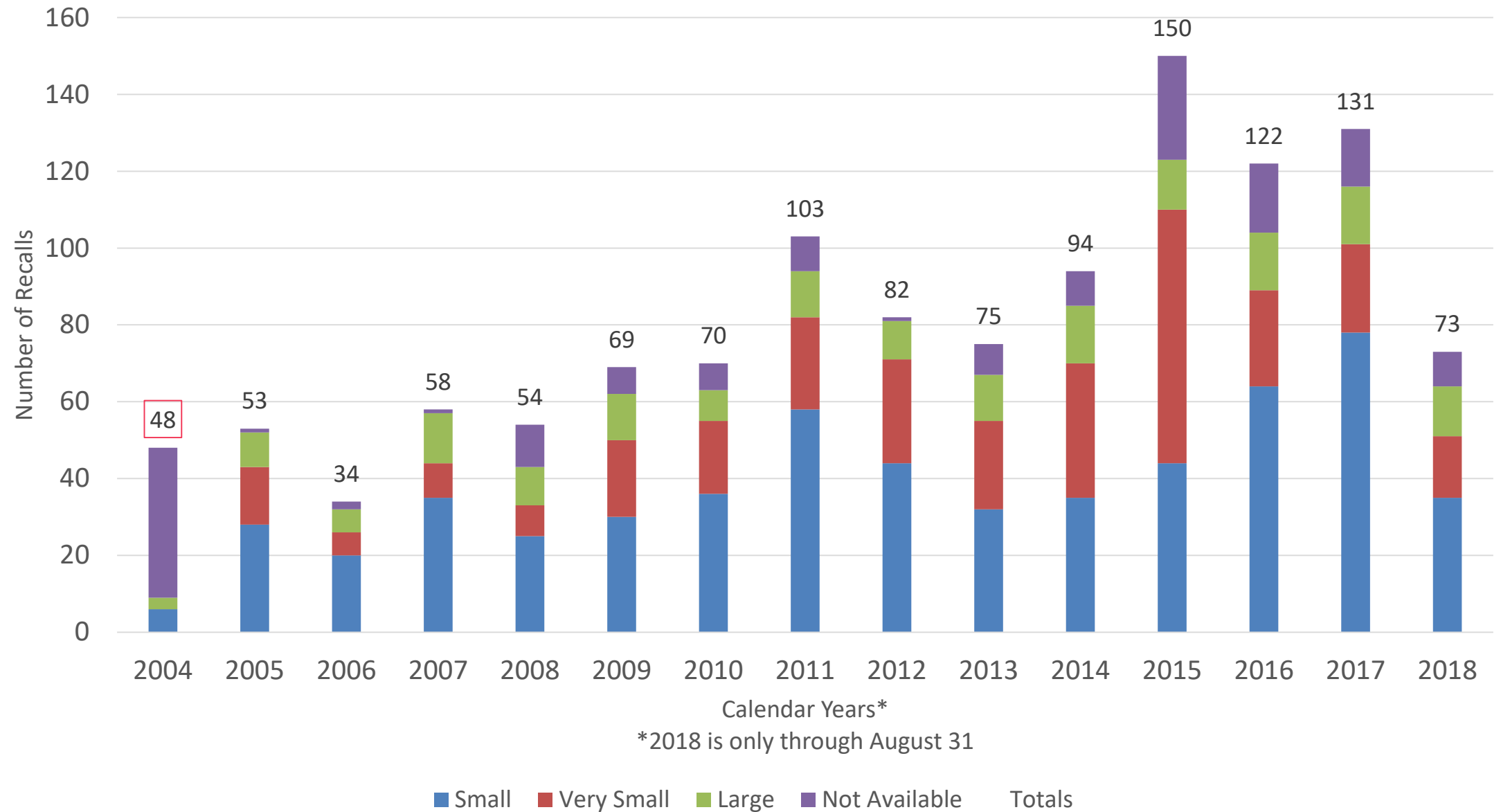
Total number of recalls of FSIS-regulated food products by recall class per calendar year from January 1994 through August 2018



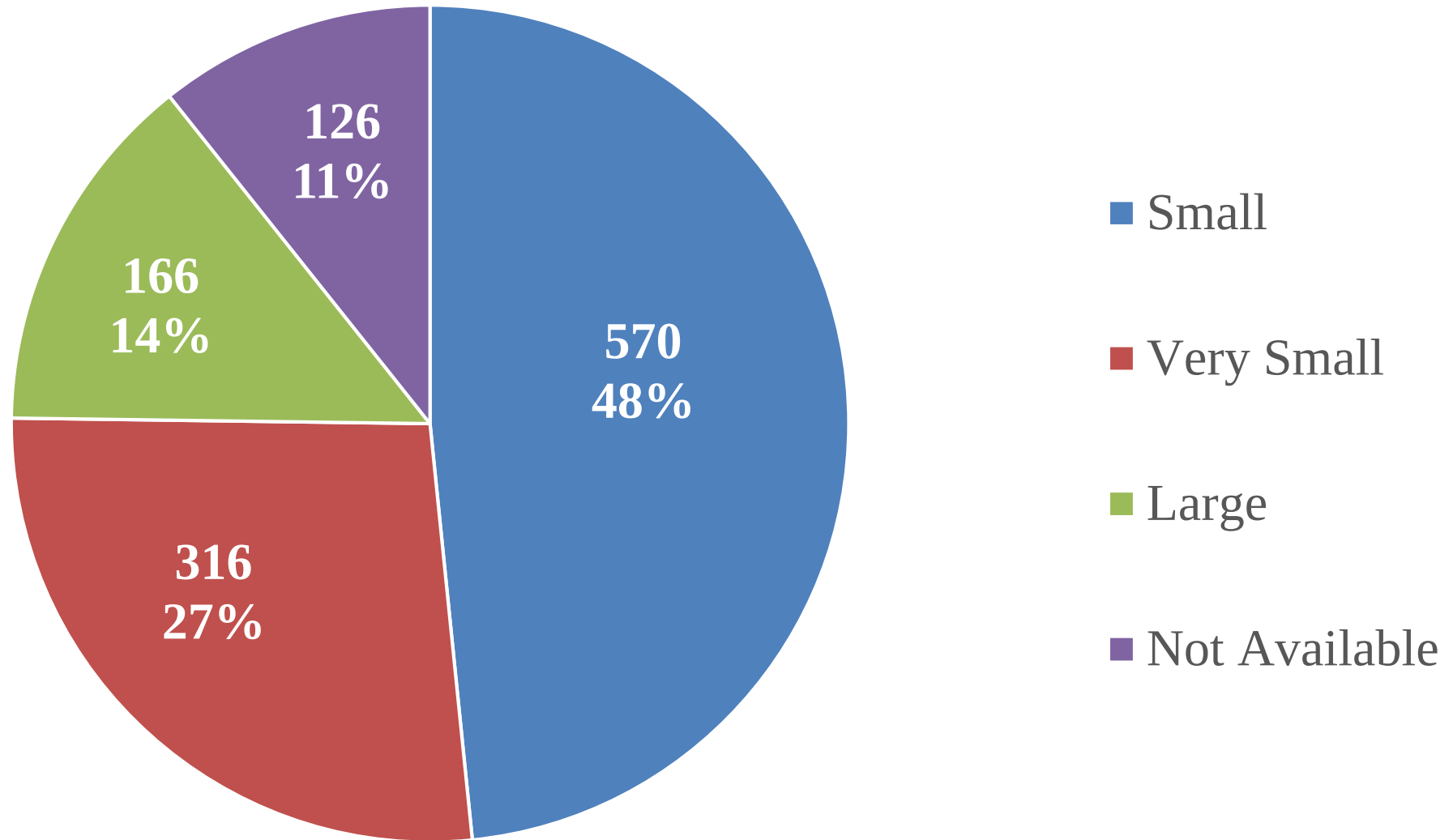
Proportion of all recalls of FSIS-regulated food products sorted by USDA **recall class** combining all data from January 1994 through August 2018



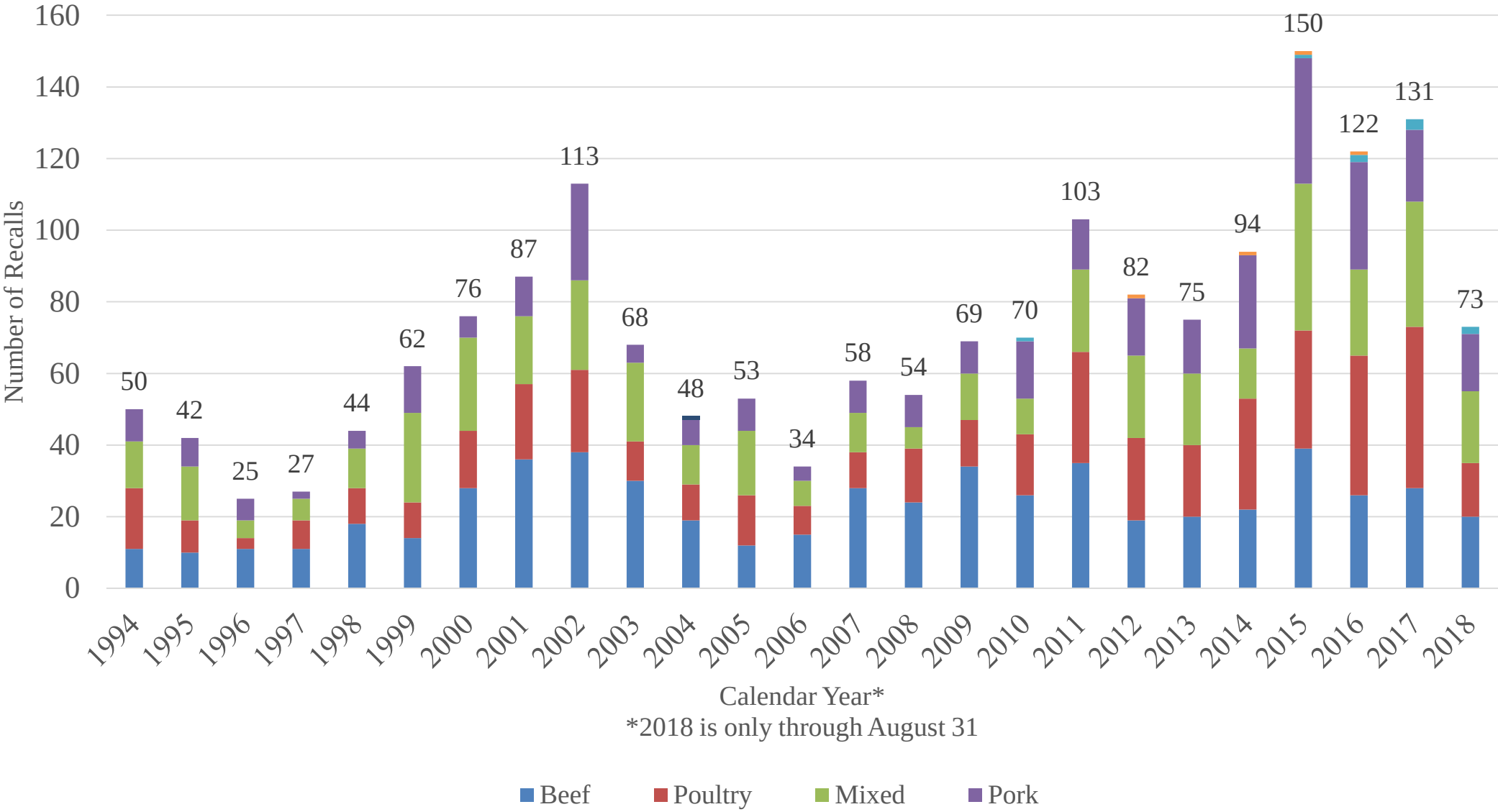
Total number of recalls of FSIS-regulated food products by HACCP-defined facility size by calendar year from January 2004 through August 2018



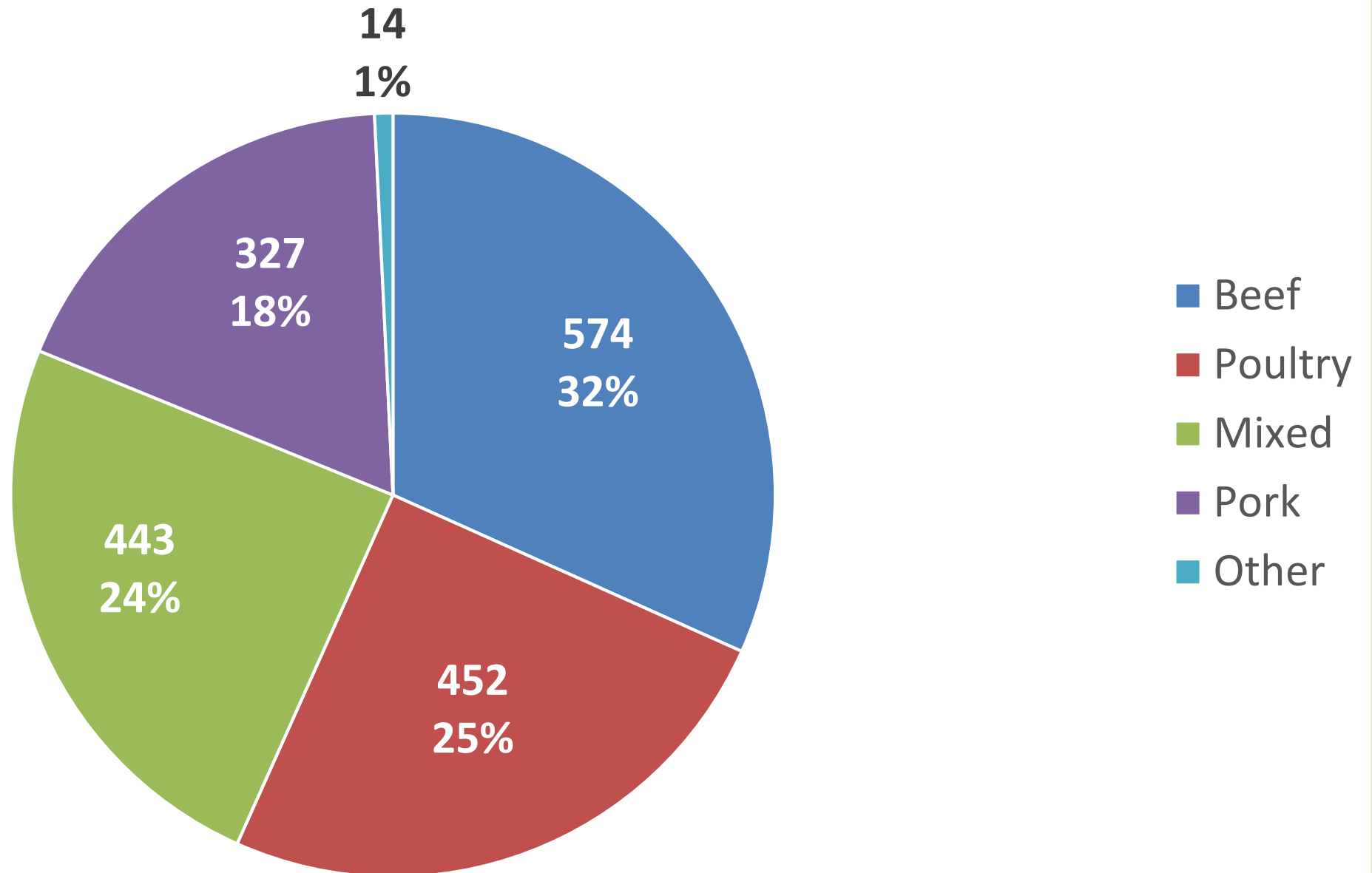
Proportion of total number of recalls of FSIS-regulated food products by HACCP-defined **facility size** from January 2004 – August 2018



Total number of recalls of FSIS-regulated food products by species of meat product involved by calendar year from January 1994 through August 2018



Proportion of the total number of recalls of FSIS-regulated food products by type of meat (species) product involved from January 1994 - August 2018



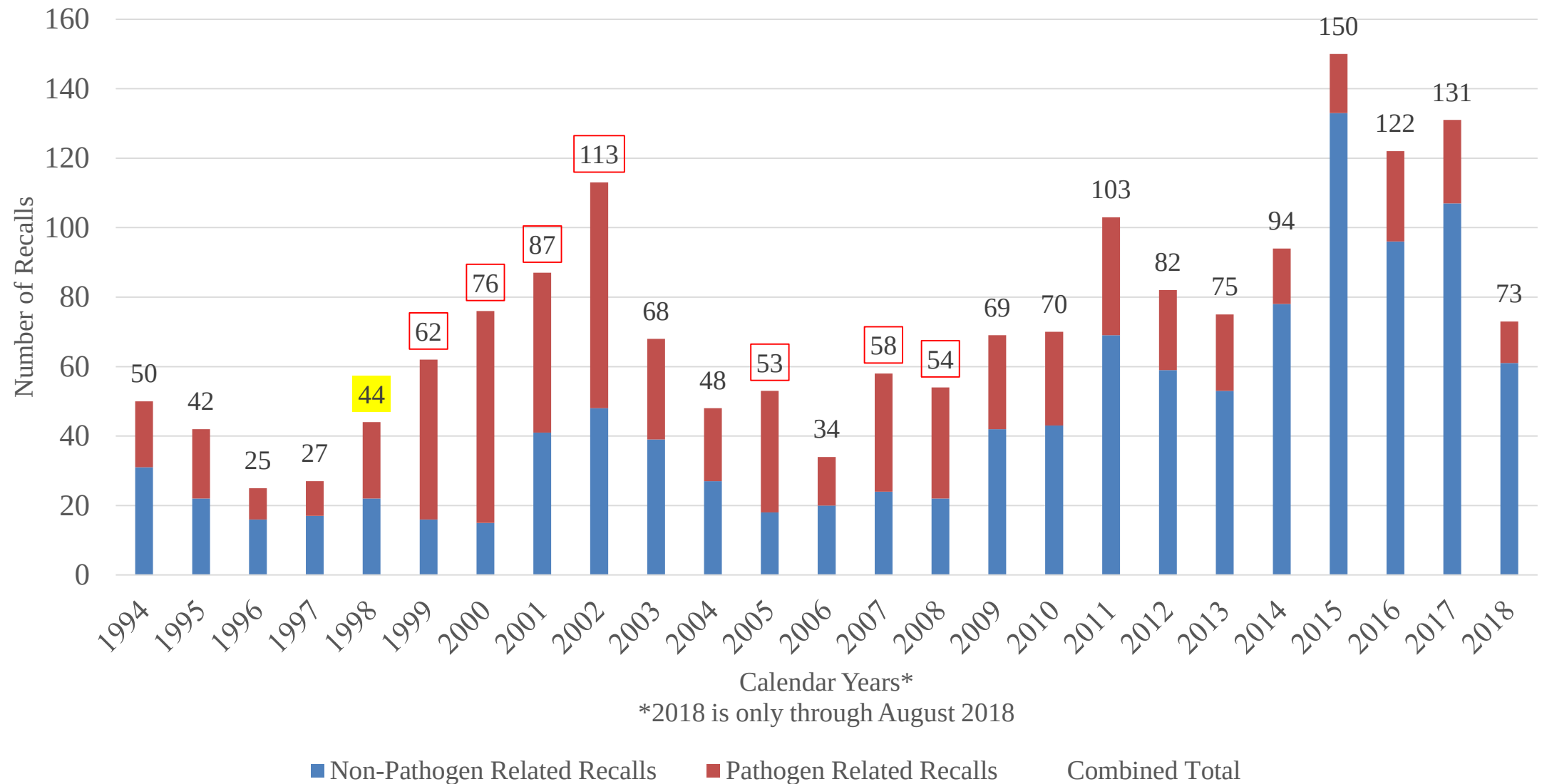
Proportions of the total number of recalls of FSIS-regulated food products by source or **route of initiation** from January 1994 through August 2018

Category	Percentage of Total
Compliance Personnel/Investigation	26.6%
Plant/Facility/Manufacturer/Distributor	24.5%
In Plant Inspector	21.1%
Consumer Complaint	9.1%
Laboratories	8.7%
Illness/Outbreak	5.3%
Foreign Food Producer	2.0%
CDC/FDA	1.6%
State & Local Health Departments	1.1%

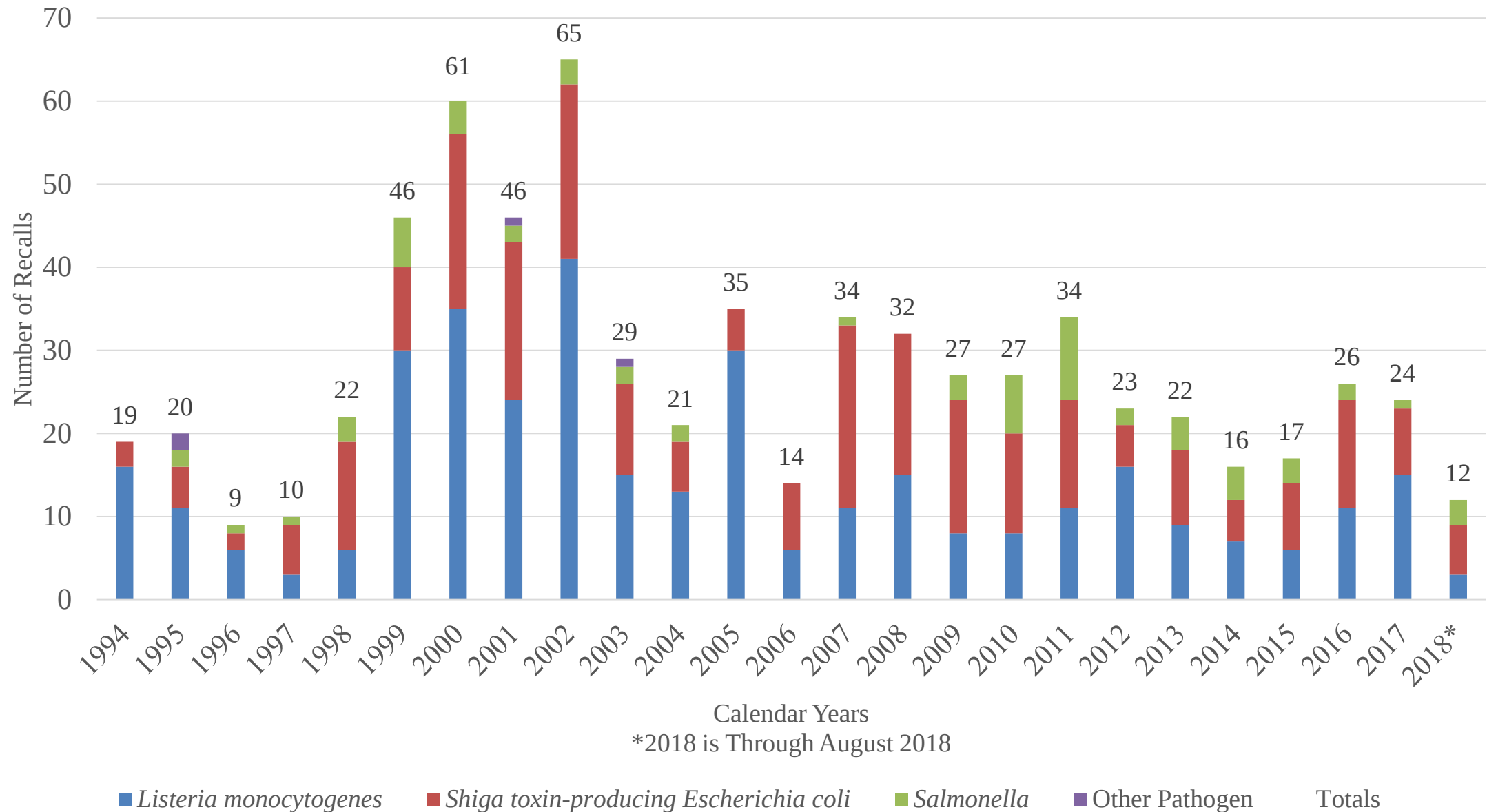
Proportion of recalls of FSIS-regulated food products by the **reason the recall was initiated** from January 1994 through August 2018

Initiation Reason	Proportion
Undeclared Allergen	21.5%
<i>Listeria monocytogenes</i>	19.7%
Shiga toxin-producing <i>Escherichia coli</i>	14.6%
Miscellaneous	13.4%
Extraneous Material	10.8%
Misbranded	8.6%
Processing Error	5.4%
<i>Salmonella</i>	3.6%
Chemical Residue	1.1%
Drug Residue	0.7%
Spoilage Bacteria	0.3%
Other Pathogens	0.2%

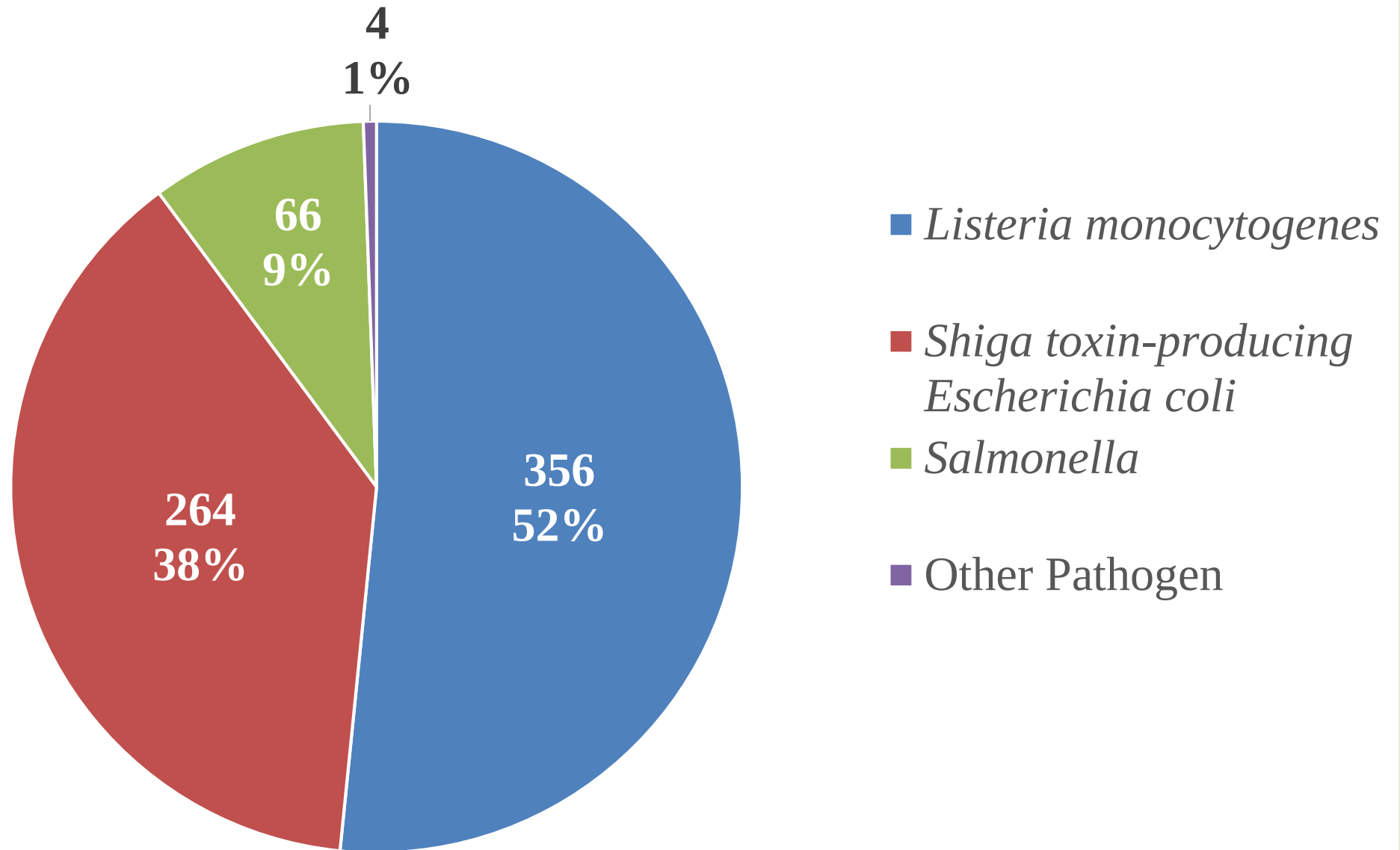
Total number of recalls of FSIS-regulated food products showing the portions of the total number of recalls for each calendar year categorized as **pathogen related or **non-pathogen** related from January 1994 through August 2018**



Total number of recalls of FSIS-regulated food products due to and by **pathogen type** from January 1994 through August 2018



Proportion of the total number of recalls of FSIS-regulated food products due to and separated by pathogen from January 1994 through August 2018



Milestones – Shiga toxin-producing *Escherichia coli*

- 1993 – Major Outbreak of *E. coli* O157:H7
- 1994 – FSIS mandated *E. coli* O157:H7 an adulterant
- 1996 – FSIS mandated Sanitization SOP, microbial testing, 5-log pathogen reduction and HACCP plans
- 1997 – Baseline incidence of STEC O157:H7 illness established for Healthy People 2010
 - 2.1 per 100,000
- 1997 – FSIS changed laboratory methods to increase detection
- 1998 – HACCP mandatory: large facilities
- 1999 – HACCP mandatory: small facilities
- 1999 – FSIS changes approach to increased test sensitivity
- 2000 – HACCP mandatory: very small facilities
- 2002 - FSIS released guidance to combat *E. coli* O157:H7

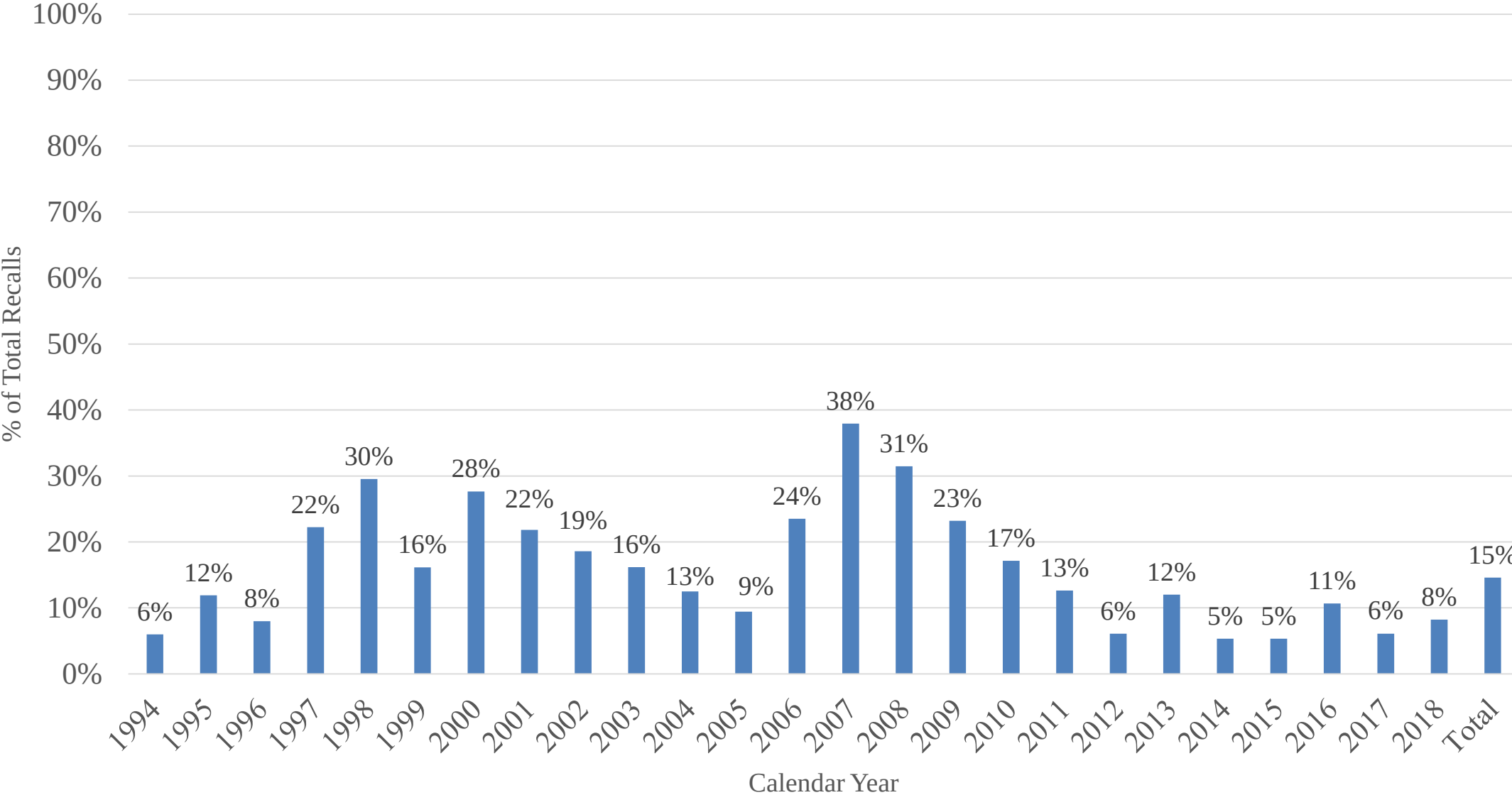
Milestones – Shiga toxin-producing *Escherichia coli*

- 2002 – FSIS introduced mitigation strategies to reduce STEC
 - Stopped carry over practice
 - Tested hides and carcasses of cattle
 - Targeted R&D for interventions
 - Implemented microbial testing plans
- 2004 – FSIS revised FSIS Directive 10,010.1
- 2005 – FoodNet indicates incidence of STEC O157:H7 is 0.9/100,000 people
- 2005 – New screening implemented to decrease false positives
- 2008 – FSIS explores food irradiation for microbial control
- 2011 – Meetings held for microbial education in STEC
- 2012 – FSIS mandated additional serotypes for adulterant list: O26, O45, O103, O111, O121, O145

Historical STEC Illness and Outbreak Recalls

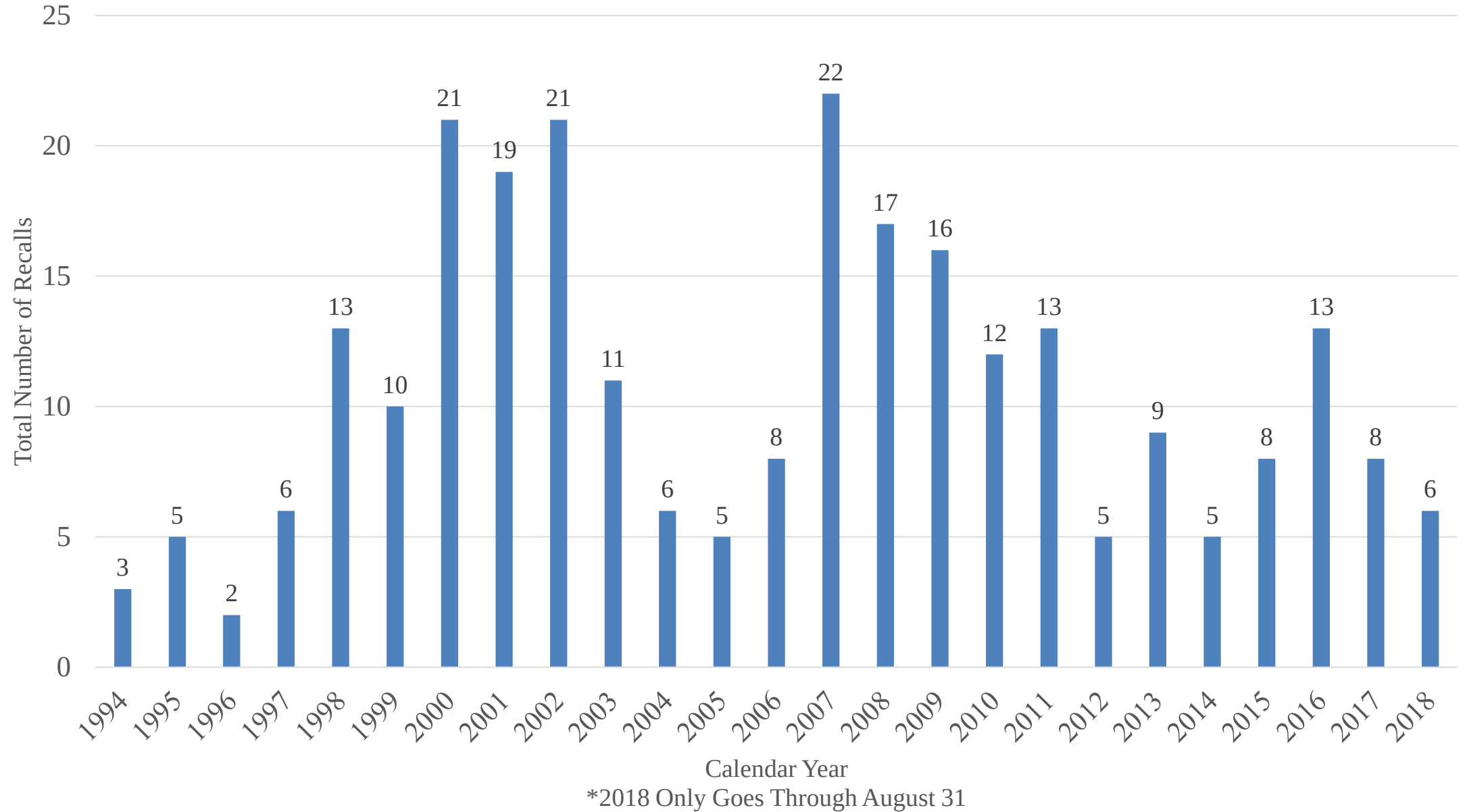
- Historical Outbreaks of *E. coli* O157:H7
- 1993 outbreak due to under cooked ground beef
 - Over 700 illnesses, 171 hospitalizations, 4 deaths
- Since STEC O157:H7 became an adulterant:
 - 28 Recalls due to outbreaks of STEC O157:H7
 - More than 46 million pounds
 - 29 Recalls due to illness of STEC O157:H7
 - More than 30 million pounds
 - 4 Recalls due to outbreak of STEC non-O157
 - More than 10.5 million pounds

Proportion of total number of all recalls of FSIS-regulated food products initiated due to STEC by calendar year from January 1994 through August 2018

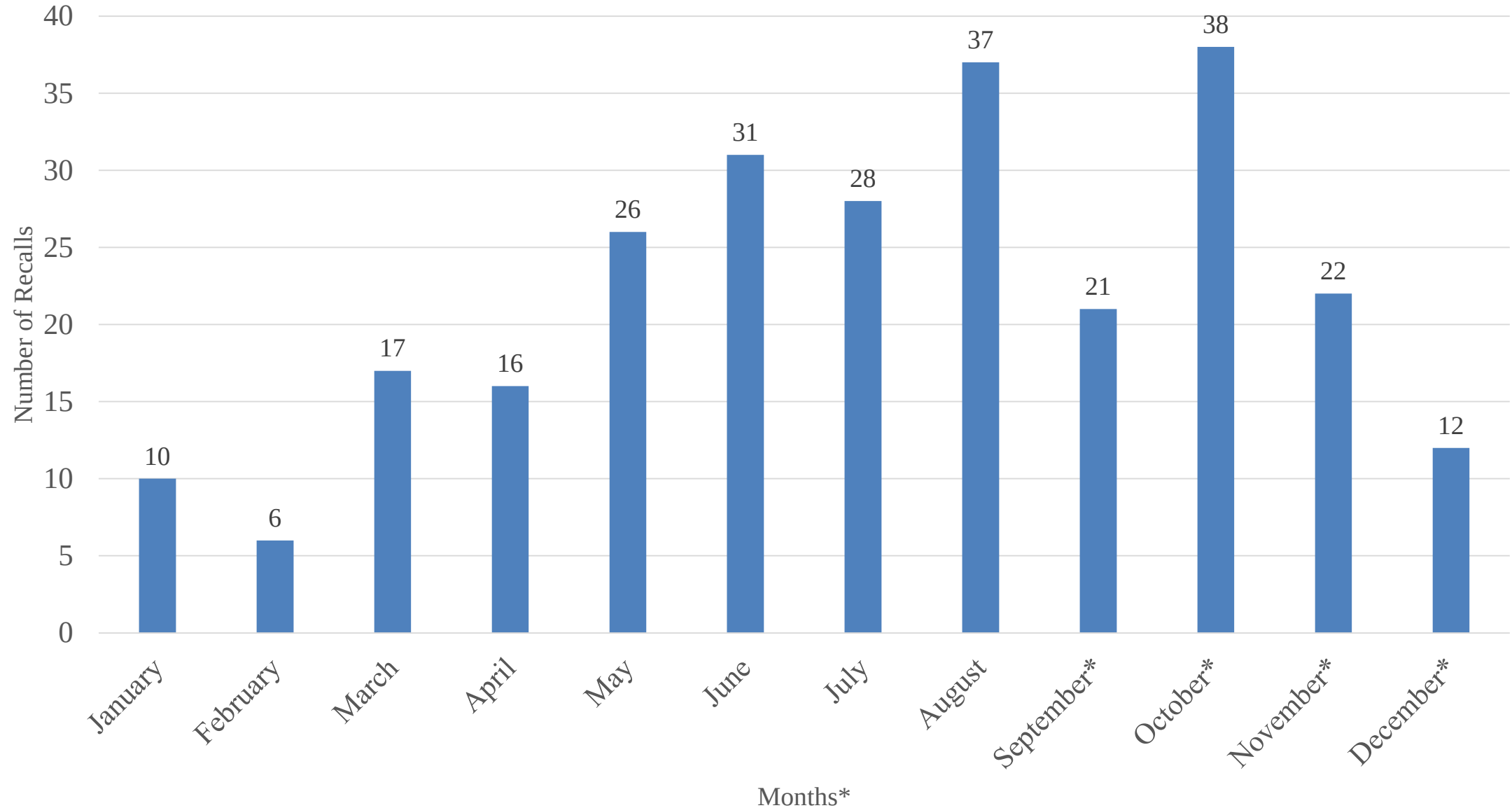


*2018 Only Goes Through August 31

Total number of recalls of FSIS-regulated food products due to STEC by calendar year January 1994 through August 2018

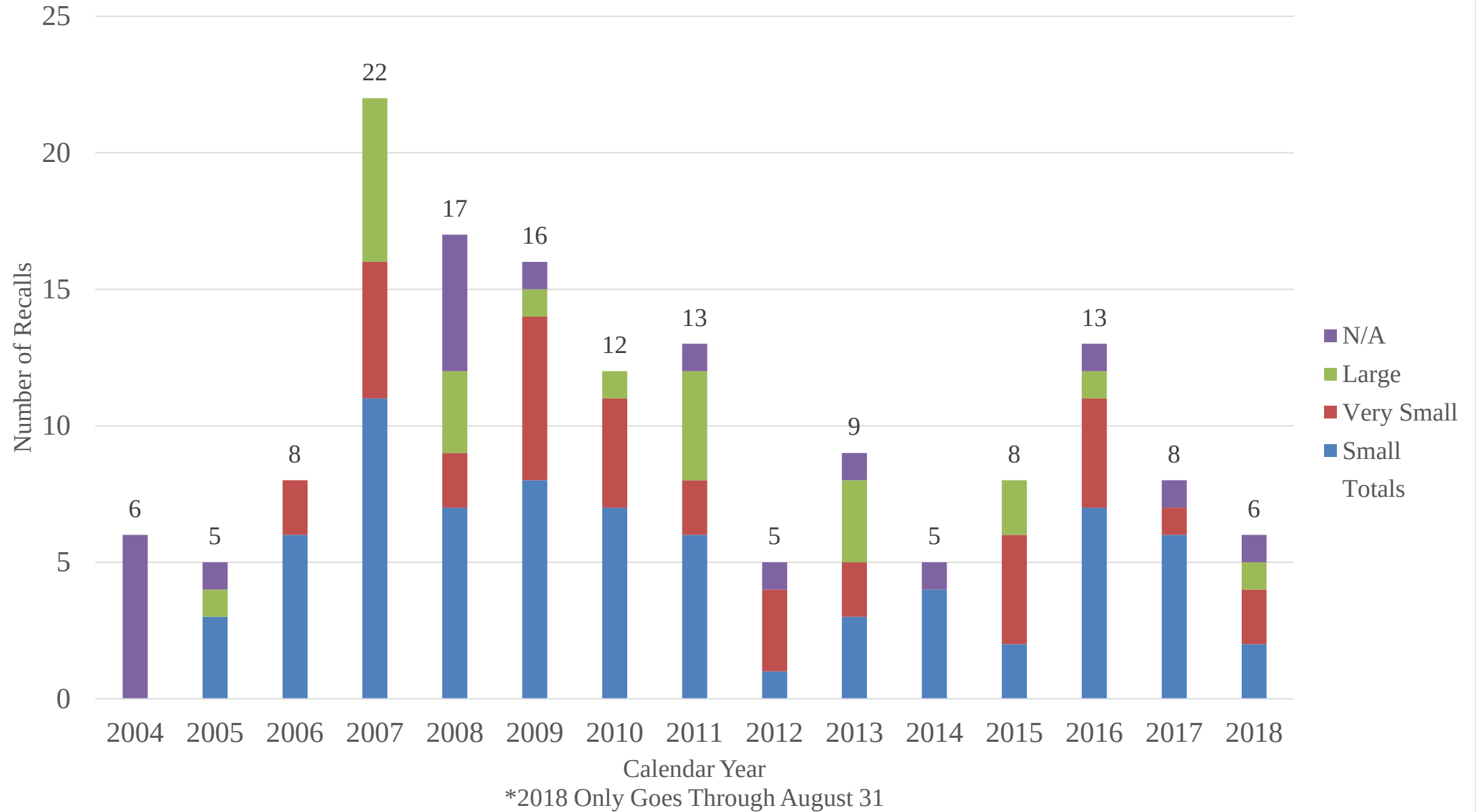


Total number of recalls of FSIS-regulated food products due to **STEC** by month from January 1994 to August 2018

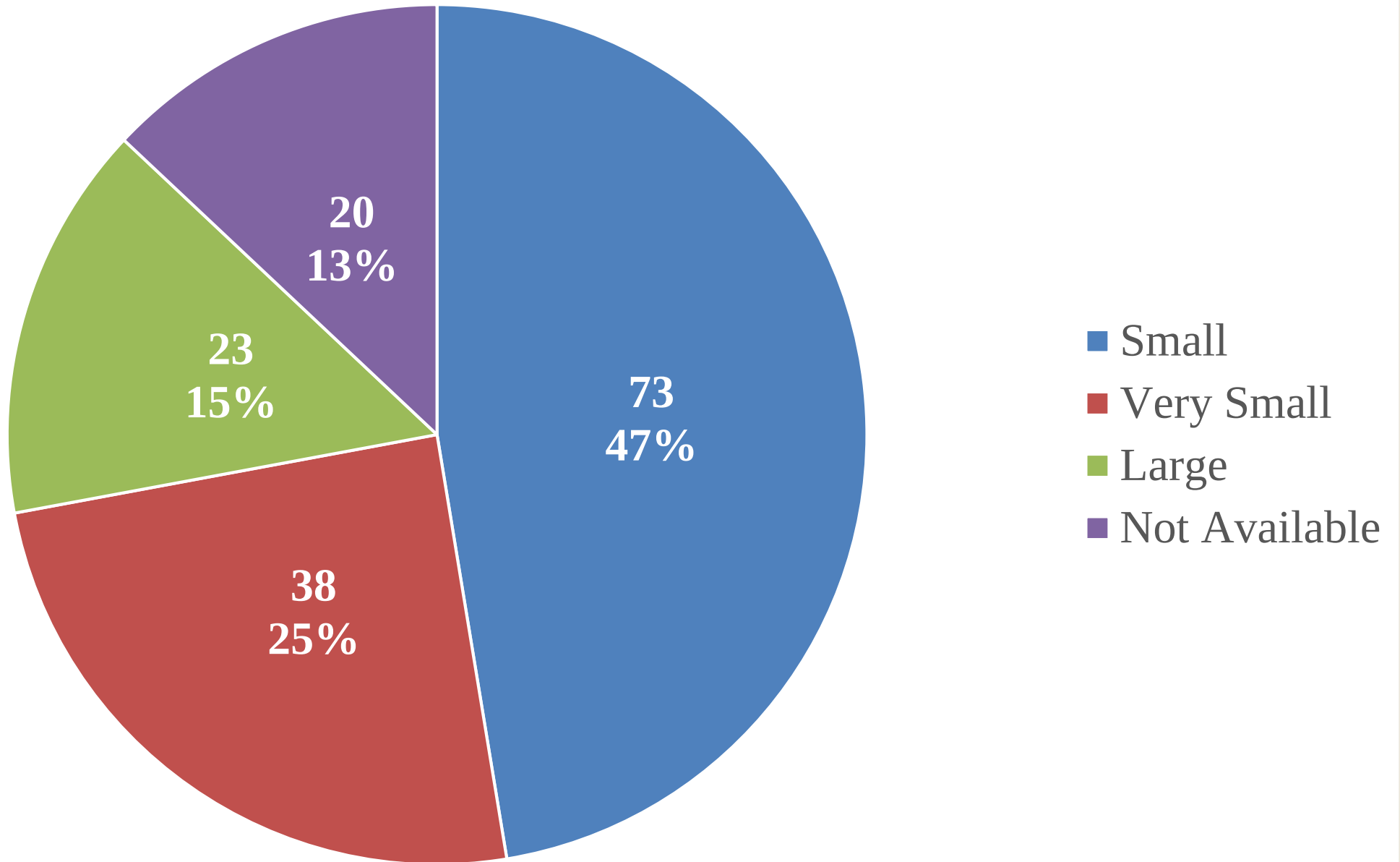


*September, October, November, December only through 2017

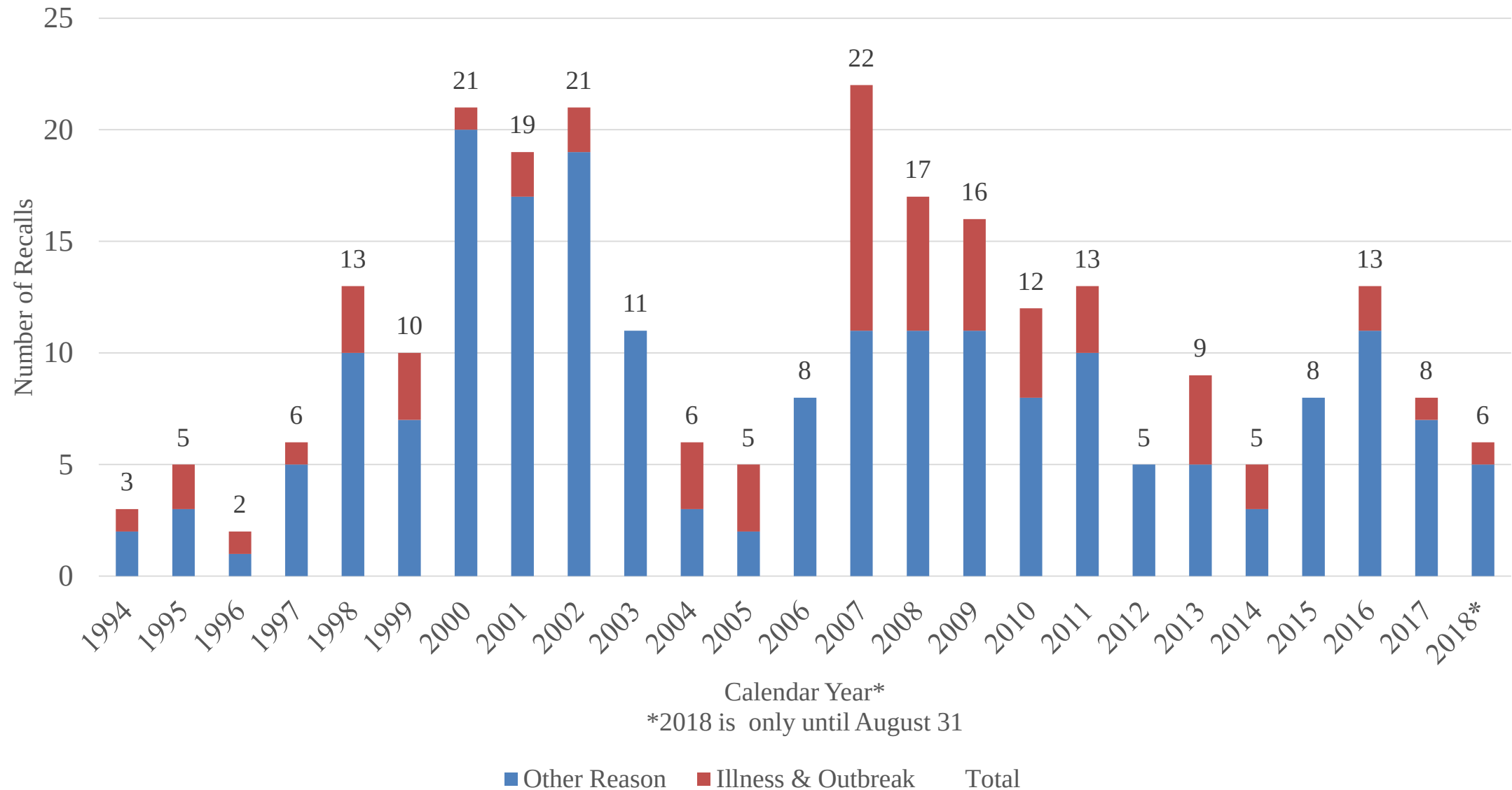
Total number of recalls of FSIS-regulated food products due to **STEC** by HACCP-defined **facility size** by calendar year from January 2005-August 2018



Proportion of the total number of recalls of FSIS-regulated food products due to STEC by HACCP-defined **facility size** from January 2005 through August 2018



Total Number of recalls of FSIS-regulated food products due to **STEC** recalled because of **illness & outbreak** or by **other reason** by calendar year from January 1994 through August 2018



Literature Comparison

- | | | |
|------------------------------|-------------------------------|--|
| • Gorton & Stasiewicz (2017) | • Raharjo, S. (2000) | • Green, et al. (2014) |
| • 1994-2015 | • 1995-1999 | • 2006-2010 |
| • 1515 recalls | • 179 recalls | • Illness/outbreak investigation |
| • Average 69 recalls/year | • Average 36 recalls/year | • 88 cases of STEC related to FSIS-regulated food products |
| • 690 million pounds total | • 74.4 million pounds total | • 29 cases led to recalls |
| • 6,800 pounds/recall | • 2 million pounds per recall | |
| • Class I = 71% | • Class I = 85% | |

Conclusion/Take Away Points

- Over 1810 recalls of FSIS-regulated food products
 - 73 in 2018
- Overall top 3 reasons recalled:
 - Undeclared allergens
 - *Listeria monocytogenes*
 - Shiga toxin-producing *Escherichia coli*
- 2018 top 3 reasons (January-August)
 - Other
 - Undeclared allergens
 - Extraneous materials
- Despite changes in policy, STEC still prevalent
- STEC 2nd major cause of recall due to illness in the last 5 years
 - Salmonella (10)
 - STEC (9)

Competencies

Number and Competency	
1	Applied epidemiologic methods to the breadth of settings and situations in public health practice
4	Interpreted results of data analysis for public health research, policy or practice
9	Designed a population-based policy, program, project or intervention.
17	Applied negotiation and mediation skills to address organizational or community challenges
19	Communicated audience-appropriate public health content, both in writing and through oral presentation.
21	Performed effectively on interprofessional teams.
22	Applied systems thinking tools to a public health issue

References

- Gorton, A., & Stasiewicz, M. J. (2017). Twenty-two years of US meat and poultry product recalls: Implications for food safety and food waste. *Journal of Food Protection*, 80(4), 674-684. doi:10.4315/0362-028X.JFP-16-388
- Green, Seys, Douris, Levine, & Robertson. (2014). Factors associated with regulatory action involving investigation of illness associated with shiga toxin-producing *Escherichia coli* in products regulated by the Food Safety and Inspection Services. *Foodborne Pathogens and Disease*, 11(7), 568-573. Doi:10.1089/fpd.2013.1720
- Raharjo, S. (2000). Food recall protects consumers from consuming hazardous meat and poultry products: a review on 1995 -1999 recall cases from FSIS-USDA. *Indonesian Food and Nutrition Progress*, 7(2), 52-55. Retrieved from: <https://journal.ugm.ac.id/agritech/article/view/13578/9742>



Thank You

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Questions