



United States Department of Agriculture

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# **Food Safety and Inspection Service**

Protecting Public Health and Preventing Foodborne Illness



# Food Safety and Inspection Service:



## Undeclared Allergens in FSIS-Regulated Products: Analysis of Voluntary Product Recalls

FSIS Allergen Public Meeting  
March 16, 2017

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**Kis Robertson Hale, DVM, MPH**  
CAPT, US Public Health Service  
FSIS/Office of Public Health Science  
Deputy Director, Applied Epidemiology Staff

# Food Safety and Inspection Service: Outline

- Background on FSIS recalls
- Relevant observations
  - Recall trends since 2000
  - Allergens and other ingredients associated with recalls
  - Reported allergic reactions
  - Root causes
- Conclusions

# Food Safety and Inspection Service

## FSIS Mission and Authority

- Ensures the nation's commercial supply of meat, poultry, and processed egg products is safe, wholesome, and correctly labeled and packaged
- Regulates more than 6,000 slaughter and processing establishments nationwide
- Legal authority:
  - Federal Meat Inspection Act
  - Poultry Products Inspection Act
  - Egg Products Inspection Act



# Food Safety and Inspection Service

## Voluntary Product Recall

- Removal of product deemed unfit for consumption
- Process carried out by establishments
- Common reasons:
  - Pathogen contamination
  - Extraneous material
  - Mislabeling (e.g., undeclared allergens)
- FSIS Directive 8081.1 describes Agency procedures



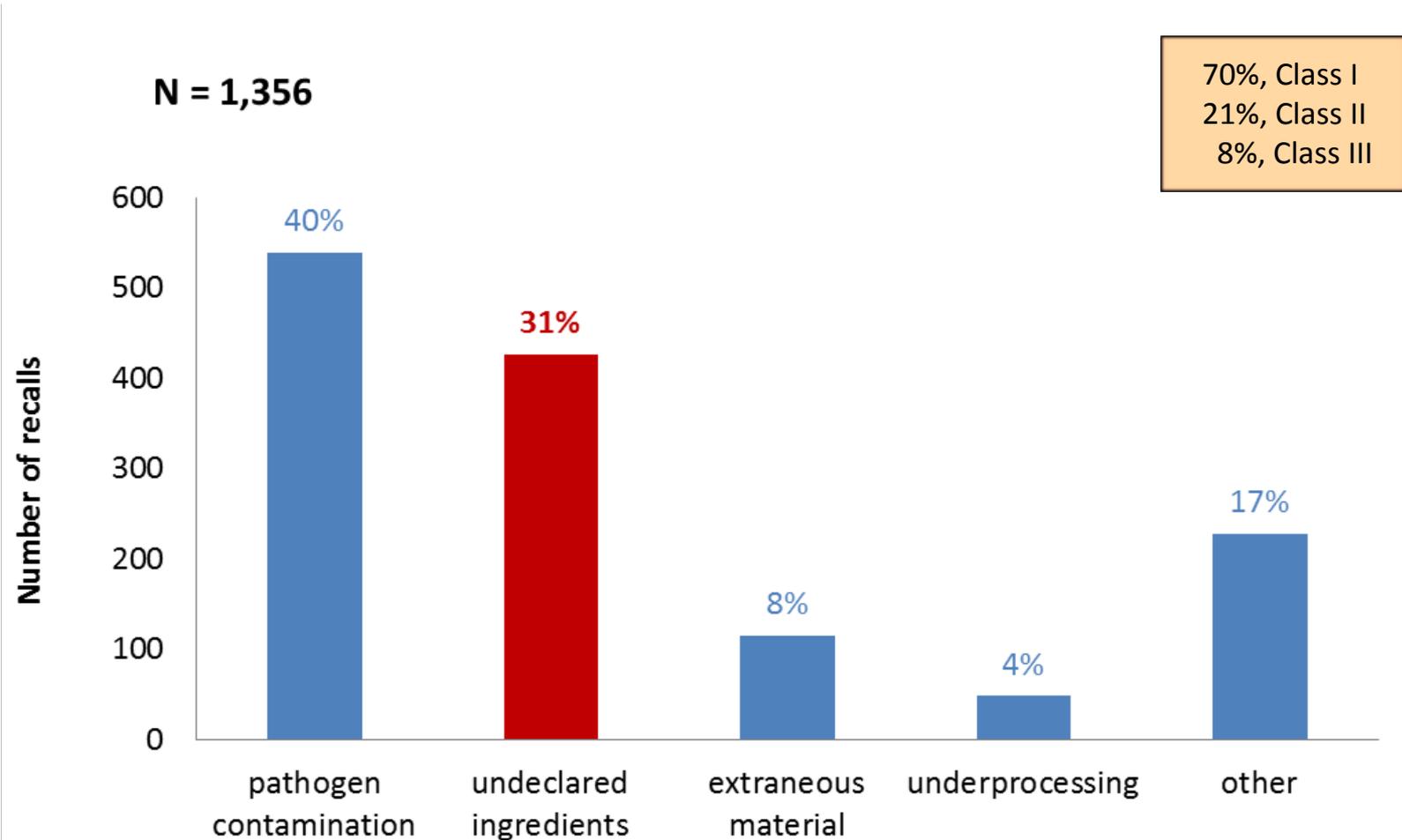
## Food Safety and Inspection Service

# Recall Classification

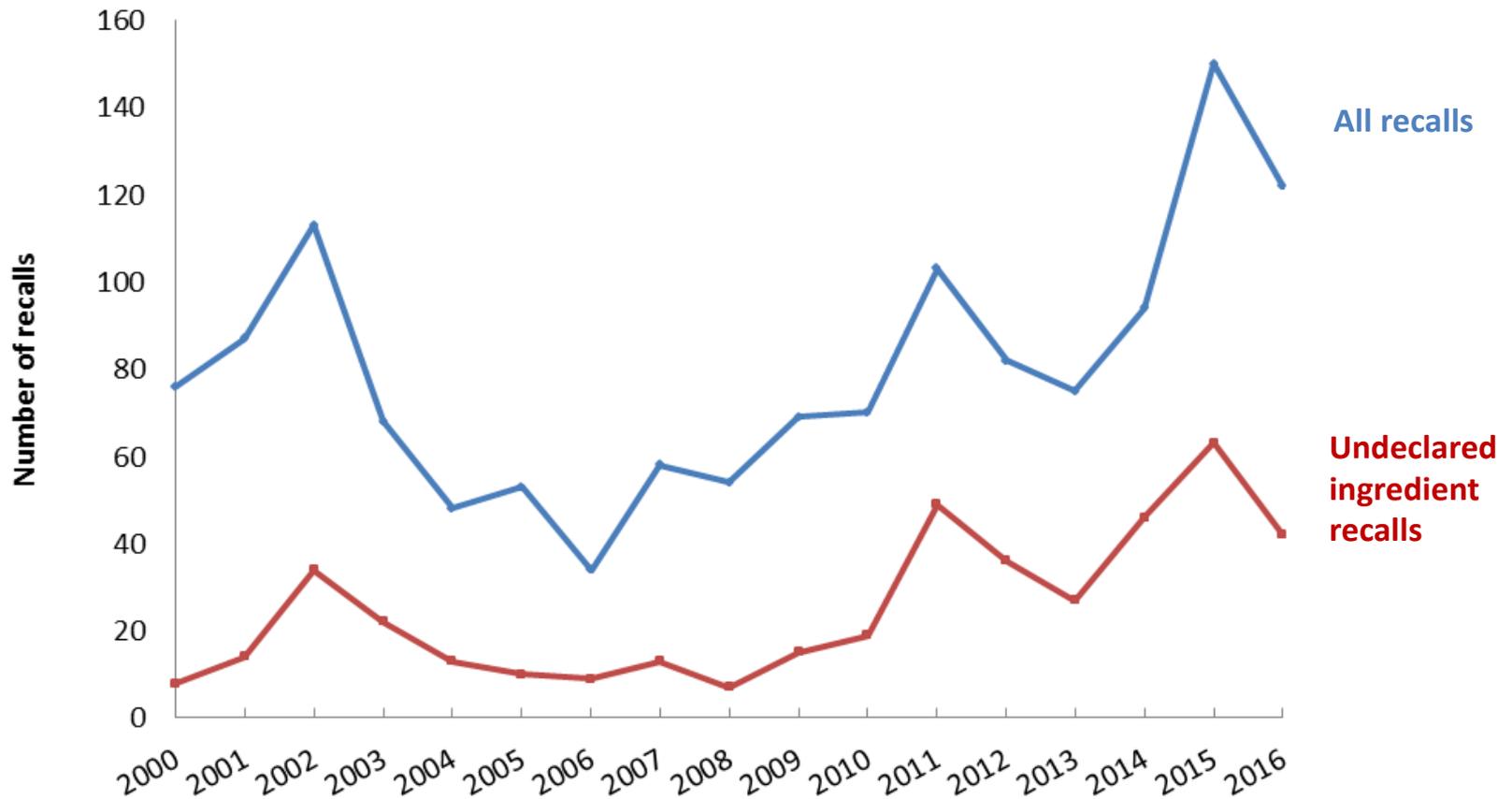
- Describes risk associated with recalled product
- Influences public notification and how FSIS verifies recall effectiveness

<b>USDA Recall Classifications</b>	
<b>Class I</b>	This is a health hazard situation where there is a reasonable probability that the use of the product will cause serious, adverse health consequences or death.
<b>Class II</b>	This is a health hazard situation where there is a remote probability of adverse health consequences from the use of the product.
<b>Class III</b>	This is a situation where the use of the product will not cause adverse health consequences.

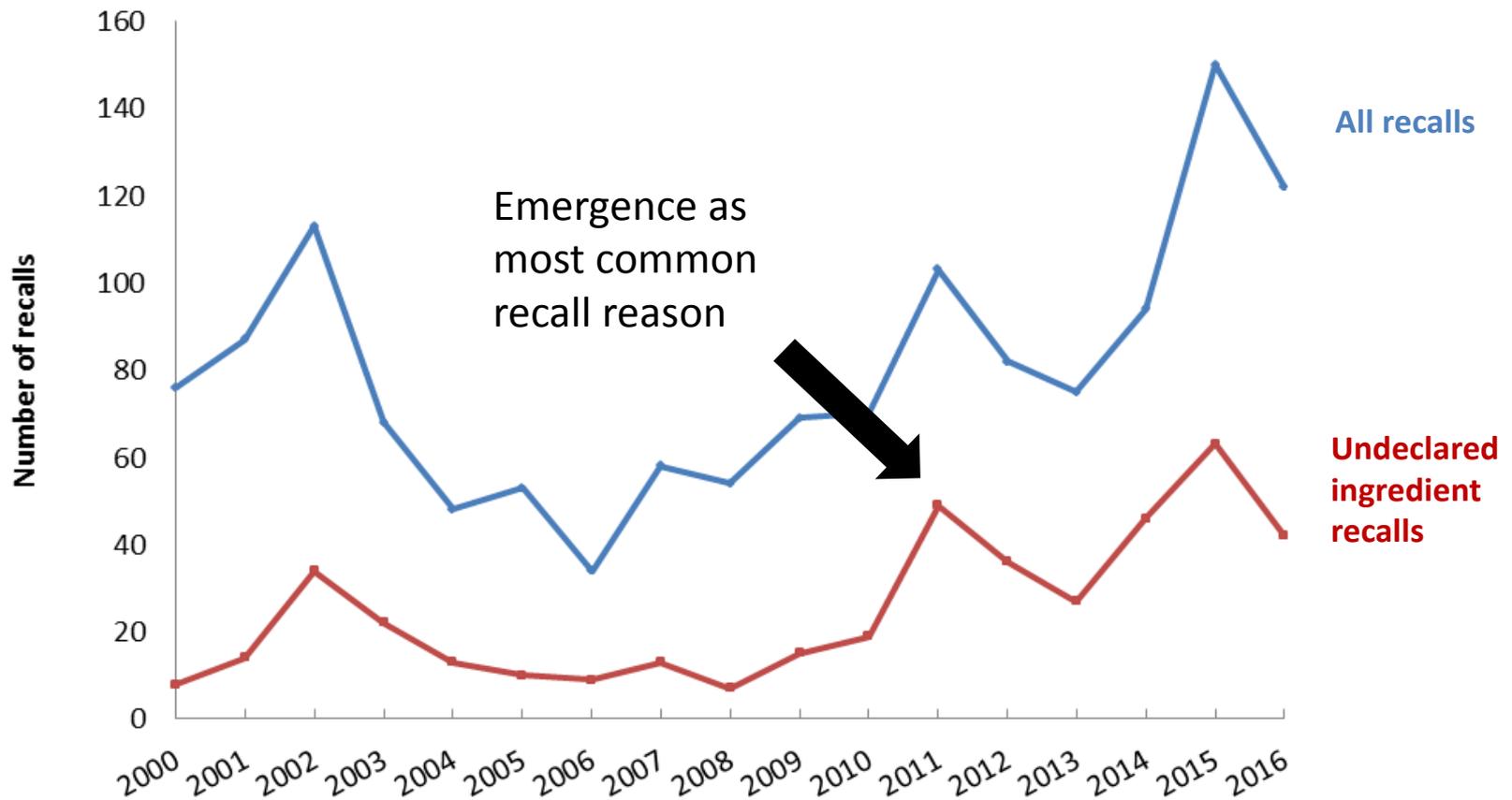
# Food Safety and Inspection Service Reasons for Recall, 2000–2016



# Food Safety and Inspection Service Recalls By Year

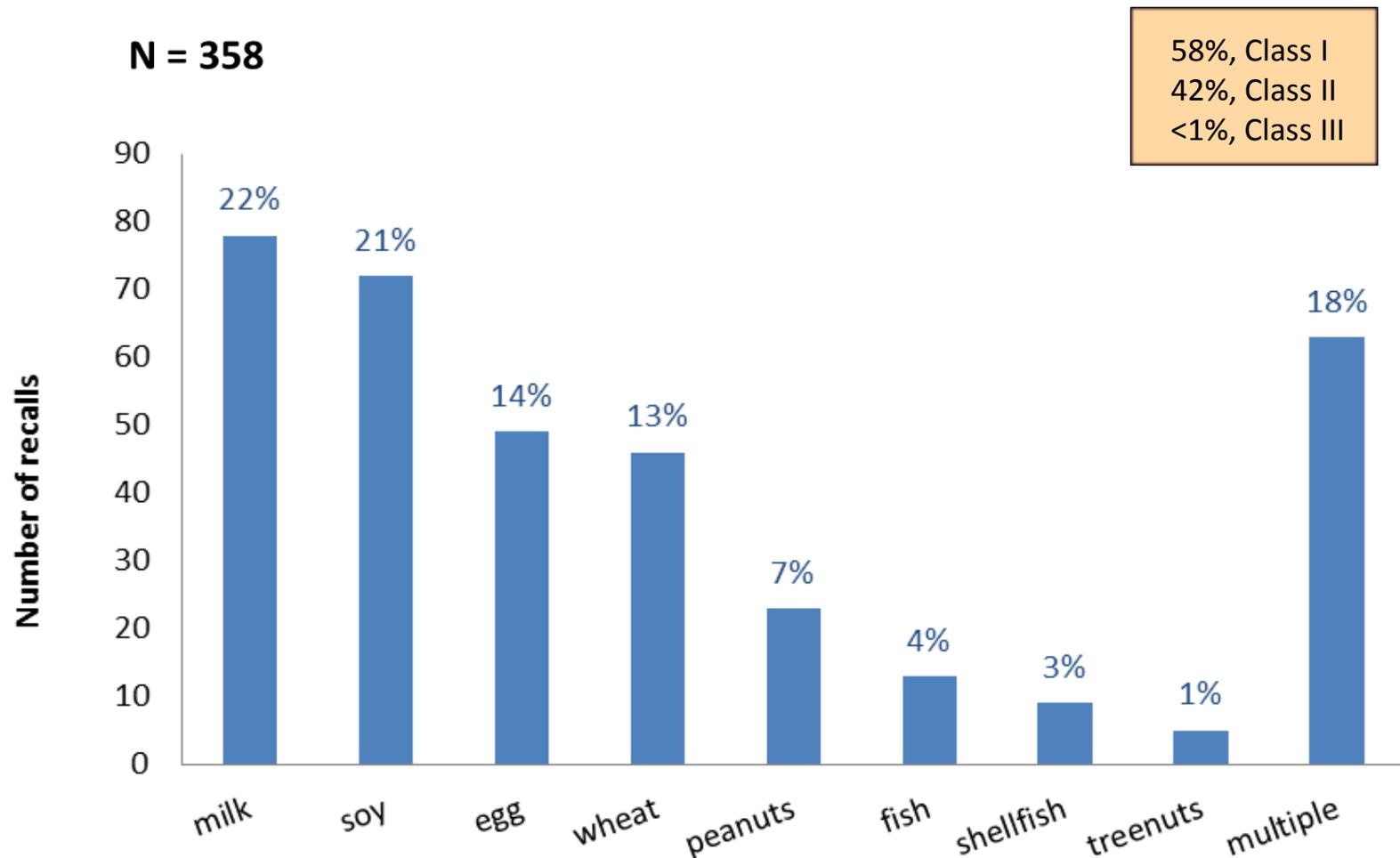


# Food Safety and Inspection Service Recalls By Year



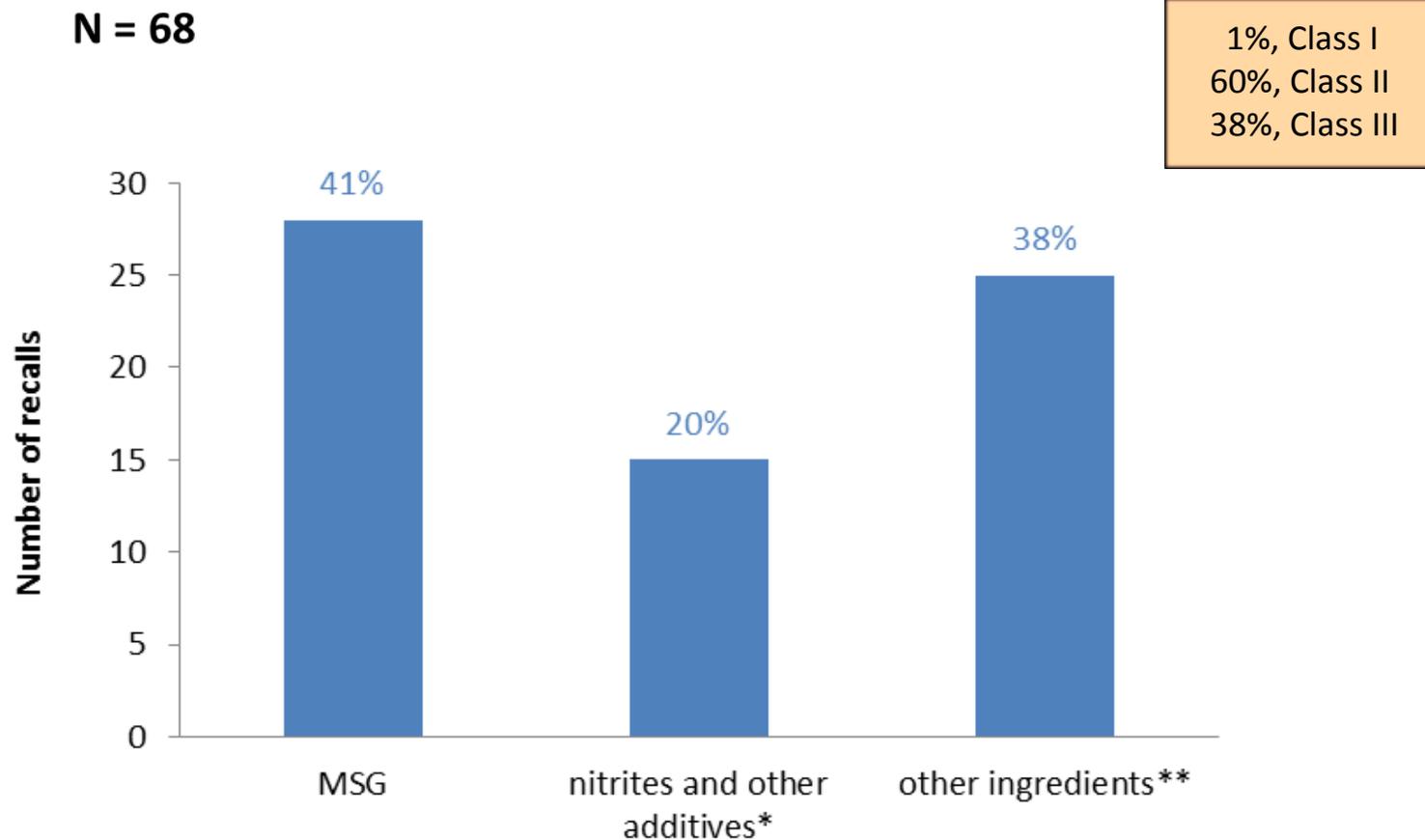
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## Big 8 Allergens in Recalls, 2000–2016



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## Non-Big 8 Ingredients in Recalls, 2000–2016



\* Includes Yellow # 5 and sulfites

\*\* Includes undeclared meat and poultry, as well as non-Big 8 allergens (e.g., sesame seeds)

## Food Safety and Inspection Service Reported Allergic Reactions

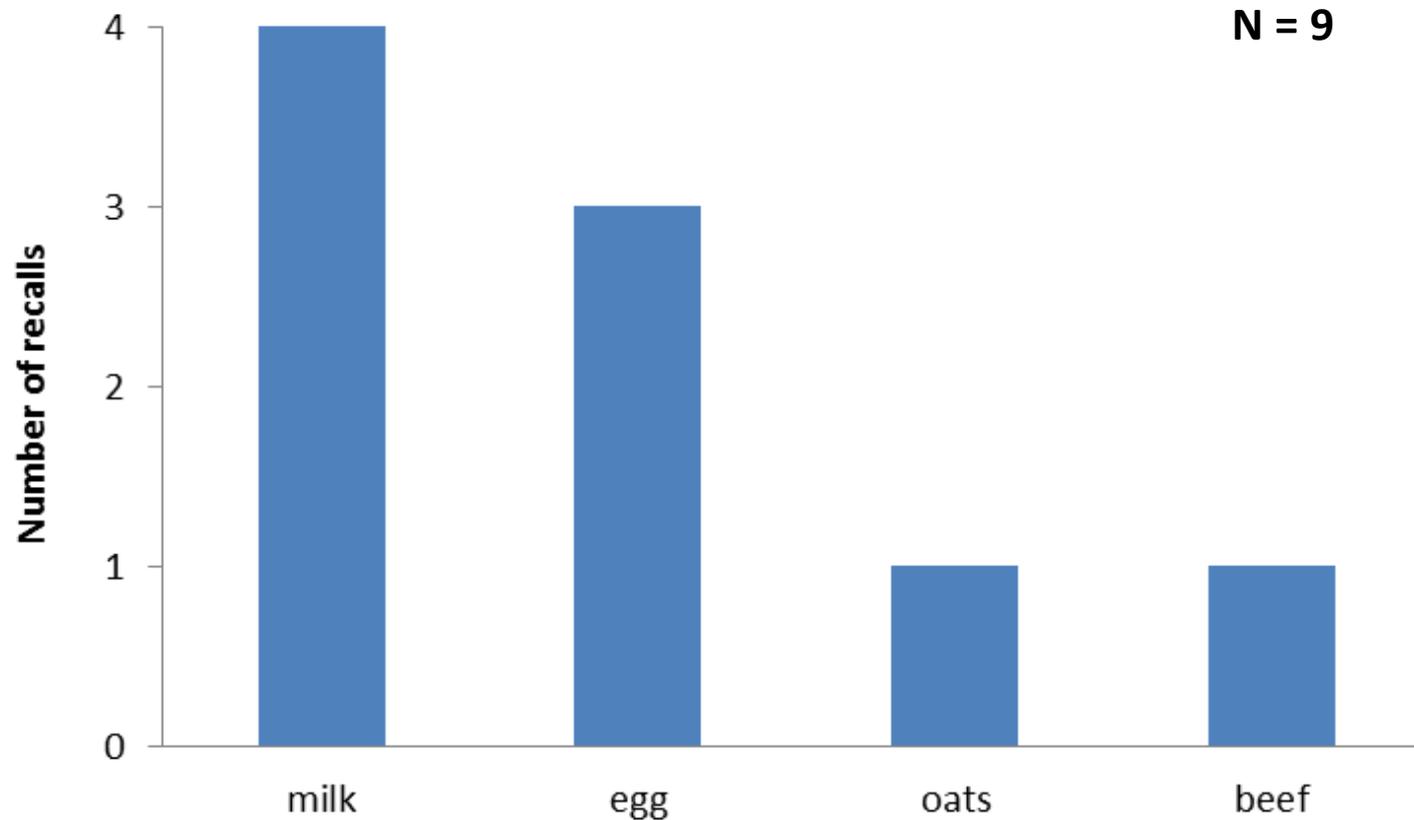
- Of 249 undeclared ingredient recalls during 2000–2012:
  - 39 (16%) prompted by a consumer complaint investigation
  - 9 (4%) precipitated by one or more reports of allergic reaction
- Of the 9\* recalls associated with reported allergic reactions:
  - 8 (89%) triggered by complaints reported to establishments
  - 2 (22%) triggered by complaints reported to FSIS

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\* One recall was triggered by a complaint reported to both FSIS and an establishment

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# Recalls with Reported Allergic Reactions by Allergen, 2000–2012



# Food Safety and Inspection Service

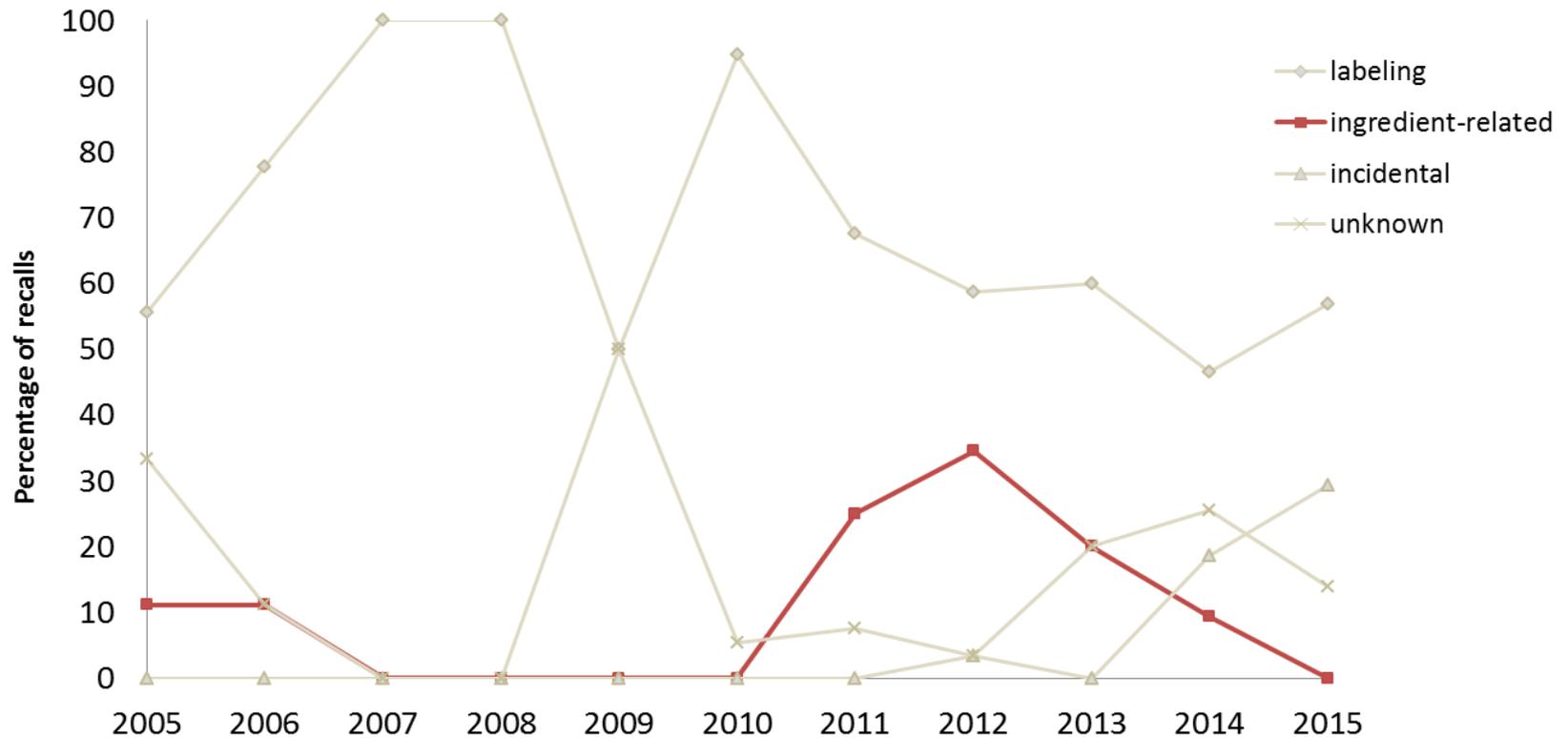
## Root Causes

For undeclared Big 8 allergen recalls during 2005–2015 (n = 263), press releases were reviewed to identify root causes

Category	Description	No. (%)
Labeling errors	Incorrect label, package, or ingredient statement, ingredient statement was missing, or statement omitted allergens known to be present by establishment	<b>167 (63%)</b>
Ingredient-related errors	An ingredient had a formulation change, an externally supplied ingredient contained an undisclosed allergen, or an allergen-containing ingredient was used where not intended	<b>31 (12%)</b>
Incidental contact	Allergen introduced into product via releasing agents or contaminated food contact surfaces	<b>26 (10%)</b>
Unknown	Cause not documented in press release	<b>39 (15%)</b>

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## Ingredient-Related Errors in Time



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## Conclusions

- Undeclared allergens are a major cause of recalls; notable increase since 2011
- Reported allergic reactions underscore public health concern, and are not limited to Big 8
- Root causes suggest most recalls are not for trace amounts of allergens
- Identifying risk factors requires additional study



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## Acknowledgements

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  - Monique Wiggins



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**FSIS Analysis of Verification Activities**

**Scott Seys, PhD, MPH**

Office of Data Integration and Food Protection  
Food Safety and Inspection Service  
U.S. Department of Agriculture

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## Addressing Trends

- Sustained increase in the number of recalls of FSIS-regulated products that contain undeclared allergens
  - Prompted data and policy analyses, policy clarification, FSIS verification activities, reiteration of establishment responsibilities

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2011-2013: FSIS Notices 35-11, 54-11, 29-13

- Inspection personnel were to discuss with establishments the rising concerns with undeclared allergen recalls
- Verification that ingredients used in product formulations are appropriately declared
- Verification of control procedures
- Verification that establishment has addressed chemical food safety hazard



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## FSIS Notice 29-13 Data Analyses

- 36% of establishments reported no allergens
- Soy, wheat, milk most common allergens
- 56% incorporate multi-ingredient component
- 68% of establishments had an allergen control plan/program (typically prerequisite program)
- Noncompliance: 64% labeling, 43% hazard analysis, 7% sanitation

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## 2015 Ongoing, Monthly Formulation Verification Task

Verify that all ingredients

- being used in the production of the product are present on the product formulation record

Verify that all ingredients

- from the product formulation are declared in the ingredients statement on the product label by common and usual name

Verify the label approval is on file

- and the applied labels are consistent with the establishment's label approval on file

# Food Safety and Inspection Service

## 2015 Ongoing, Monthly Formulation Verification Task

- Soy, wheat, milk most common allergens
  - Fish, tree nuts, shellfish, peanuts uncommon
- Increasing number of establishments incorporate multi-ingredient component
- Increasing number of establishments had an allergen control plan/program

# Food Safety and Inspection Service

## 2015 Compliance Guidelines



- Allergens and Ingredients of Public Health Concern: Identification, Prevention and Control, and Declaration through Labeling
- Final and Federal Register Notice published fall 2015
- Focus on meat and poultry establishments
- Scenarios, diagrams, checklists

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## Establishment Responsibilities

**Identify:** Inspection of Incoming Ingredients, Cross-referencing Components, Separation

**Prevent and Control:** Equipment, Sanitation, and Processing

**Declare:** Packaging, Labeling, Storage

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## Acknowledgments

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- Kis Robertson Hale



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