



U.S. Food and Drug Administration
Protecting and Promoting Public Health

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***Salmonella* Enteritidis: Outbreak, Findings, and Update**

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Office of Regulatory Affairs

FDA

AFDO Annual Meeting 2011

ORA/Office of Regional Operations



Topics

- Outbreak Information (***thank you CDC!***)
- Inspection Findings and Product Recalls
- Assessment and Update



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Outbreak Information

ORA/Office of Regional Operations



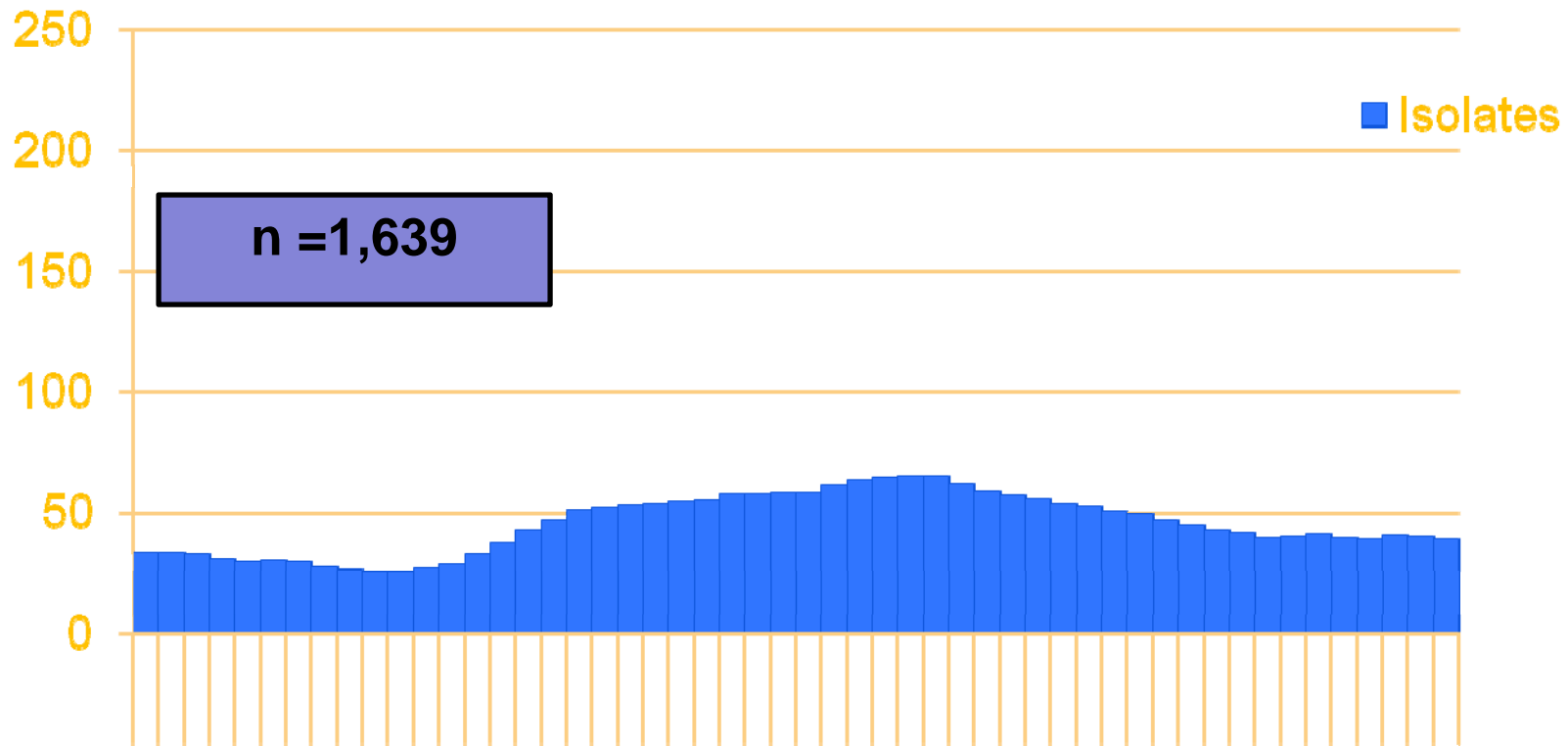
***Salmonella* Enteritidis (SE)**

- ❑ 6,000 to 7,000 laboratory confirmed infections each year
 - ~18% of all US salmonellosis

- ❑ Outbreaks often associated with chicken or eggs
 - Silent infection of ovary of hen
 - Healthy hens
 - Eggs can be internally contaminated

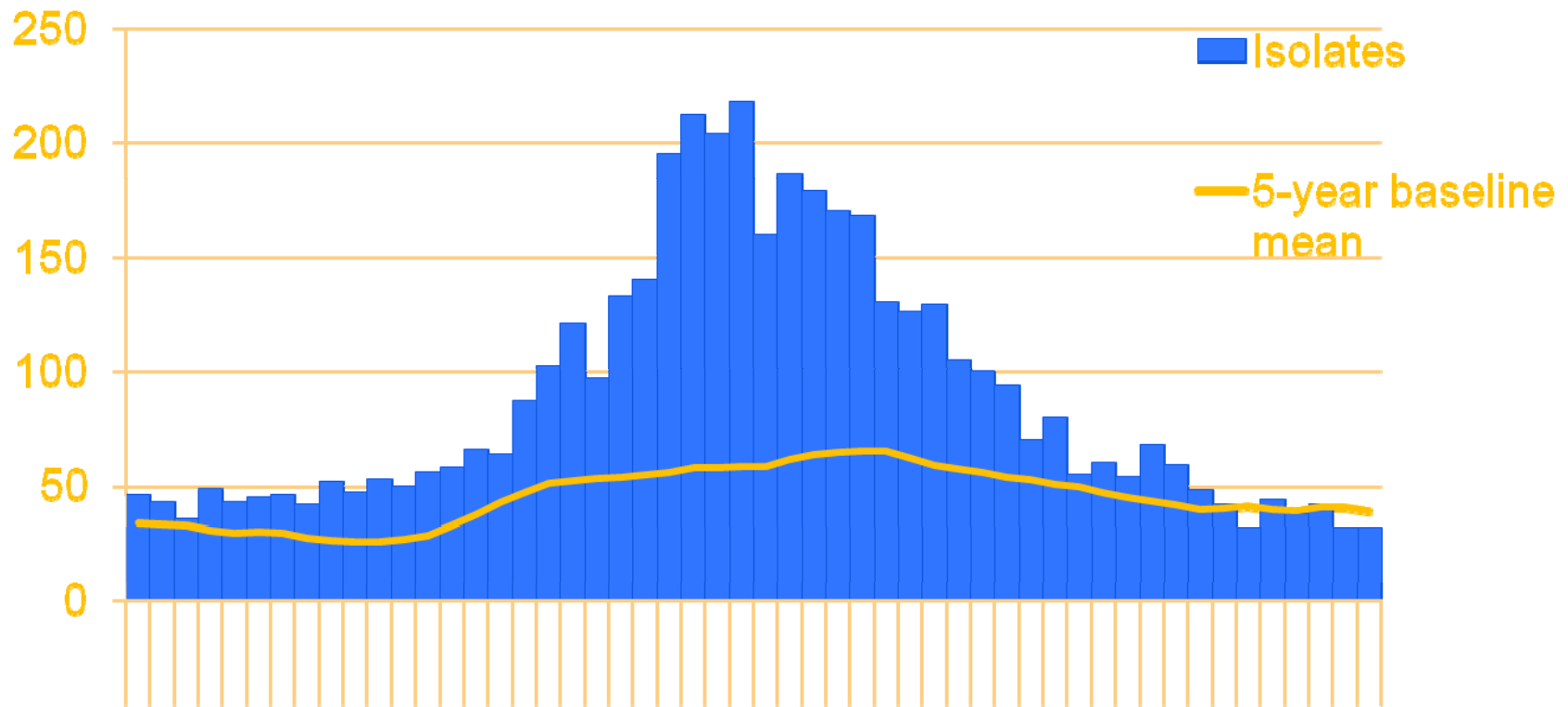


Mean Number of SE Pattern 4 Isolates Reported to PulseNet Annually, US, 2004- 2009



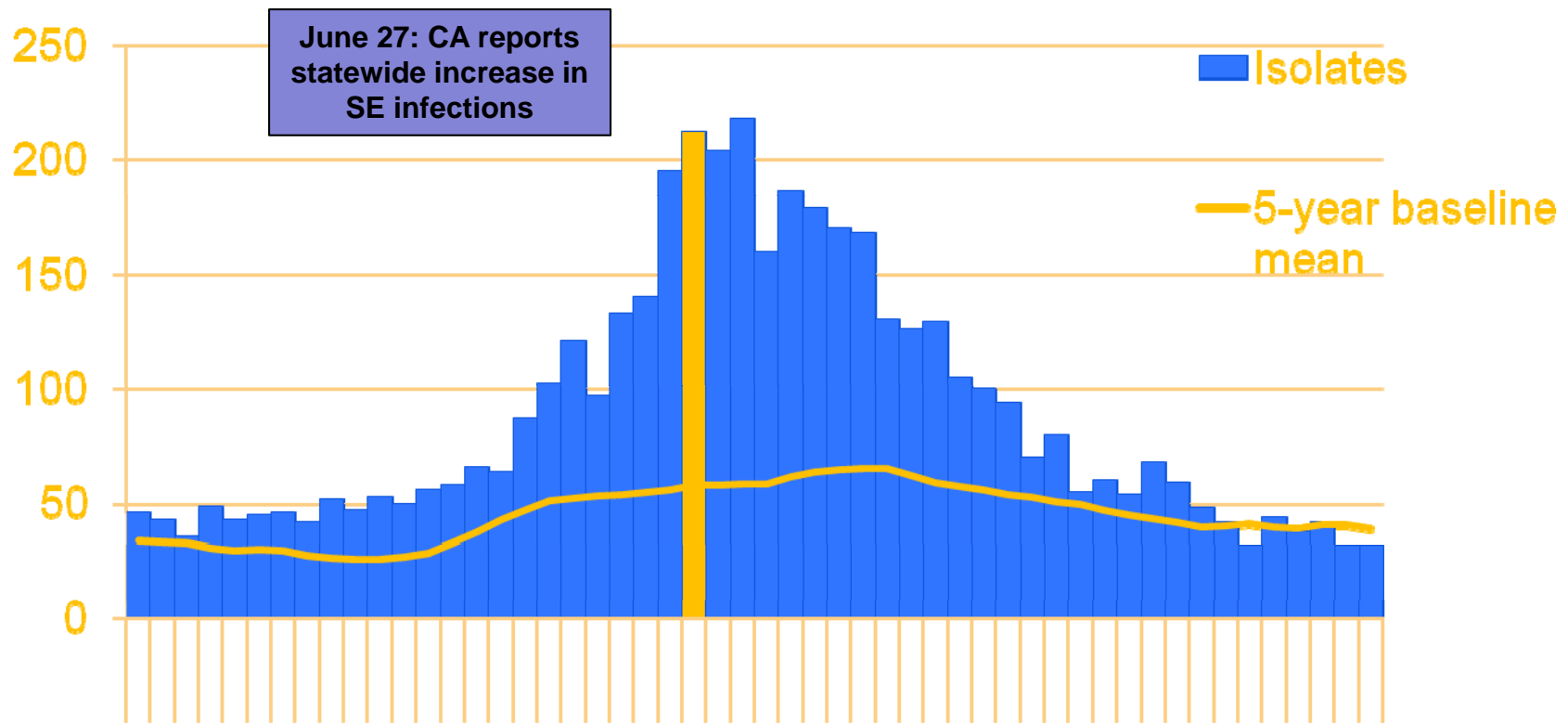


Number of SE Pattern 4 Isolates Reported to PulseNet, US, 2010



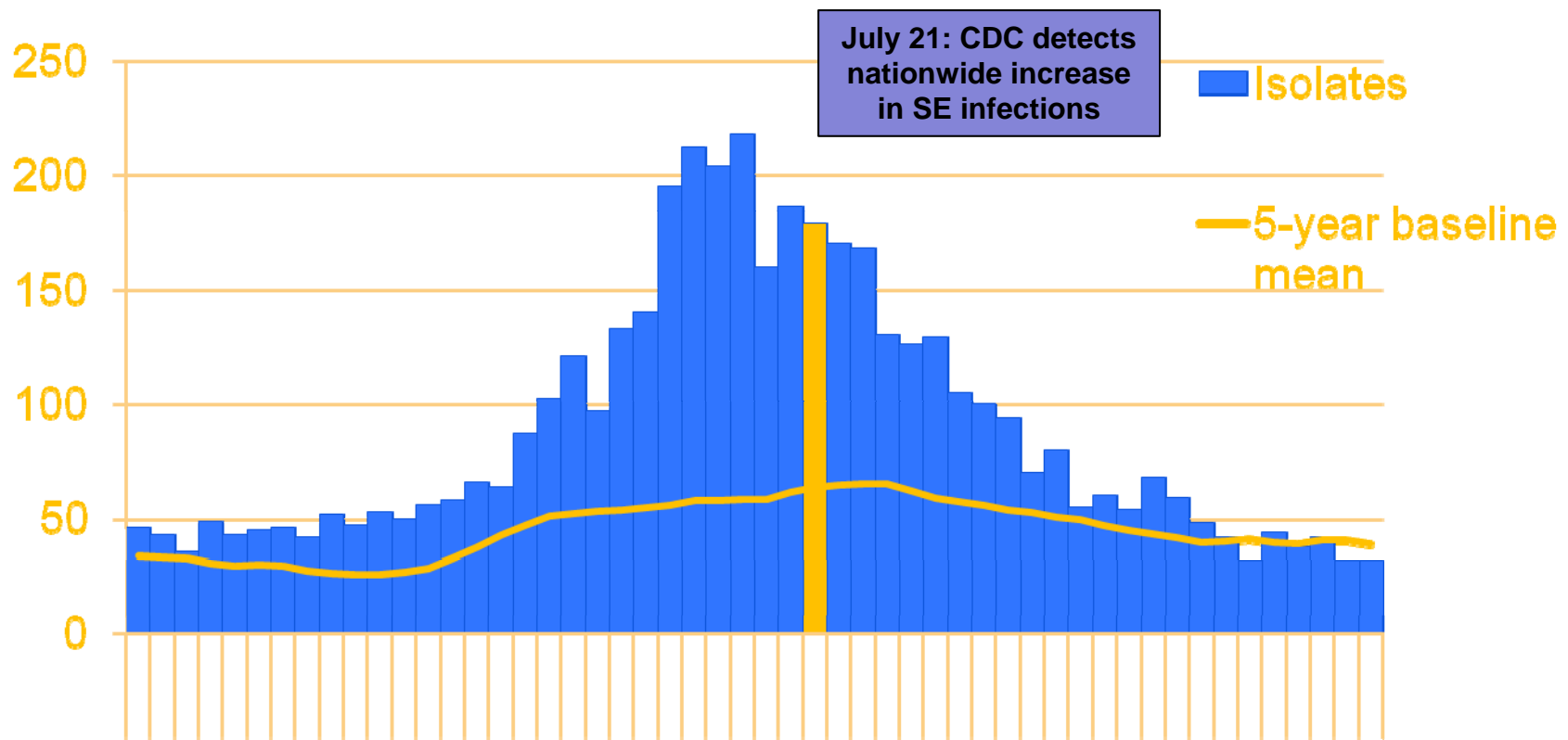


Number of SE Pattern 4 Isolates Reported to PulseNet, US, 2010



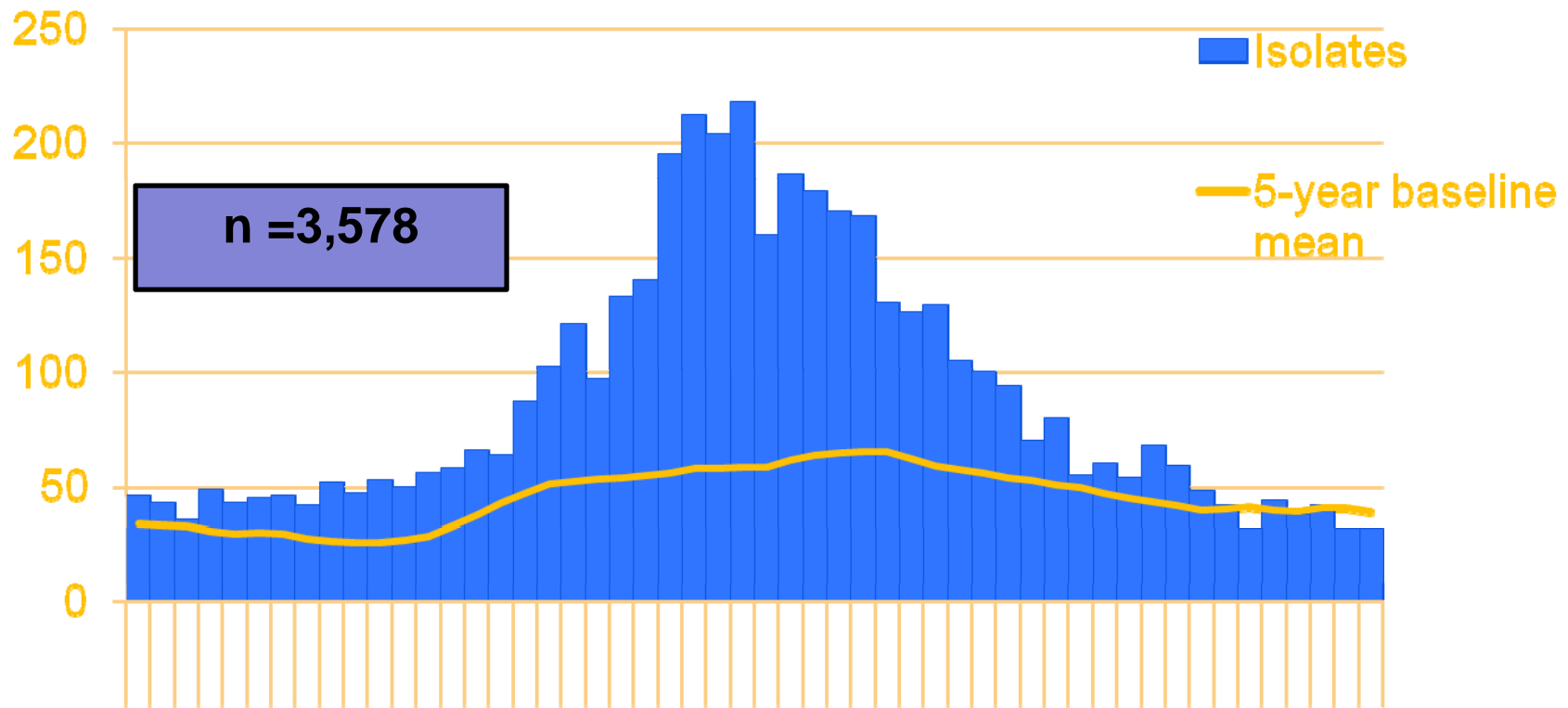


Number of SE Pattern 4 Isolates Reported to PulseNet, US, 2010



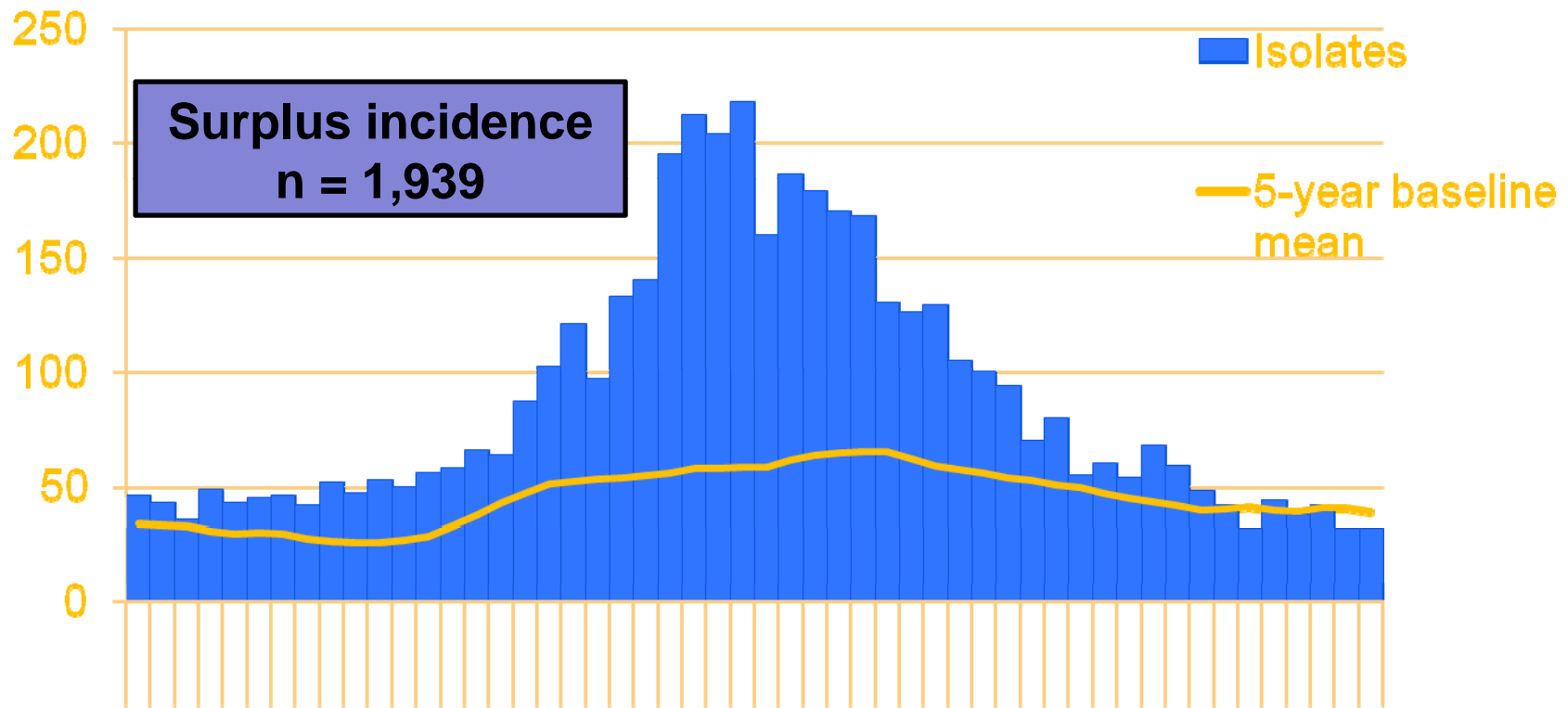


Number of SE Pattern 4 Isolates Reported to PulseNet, US, 2010





Number of SE Pattern 4 Isolates Reported to PulseNet, US, 2010





Challenges

- ❑ **SE pattern 4 most common PFGE pattern**
 - 40-50 cases reported weekly to CDC
 - Case definition based on PFGE subtype has high probability of including non-outbreak cases

- ❑ **SE often associated with chicken or eggs**
 - Both commonly consumed
 - Eggs 'stealth' ingredient in many prepared dishes
 - Case-control unlikely to be successful

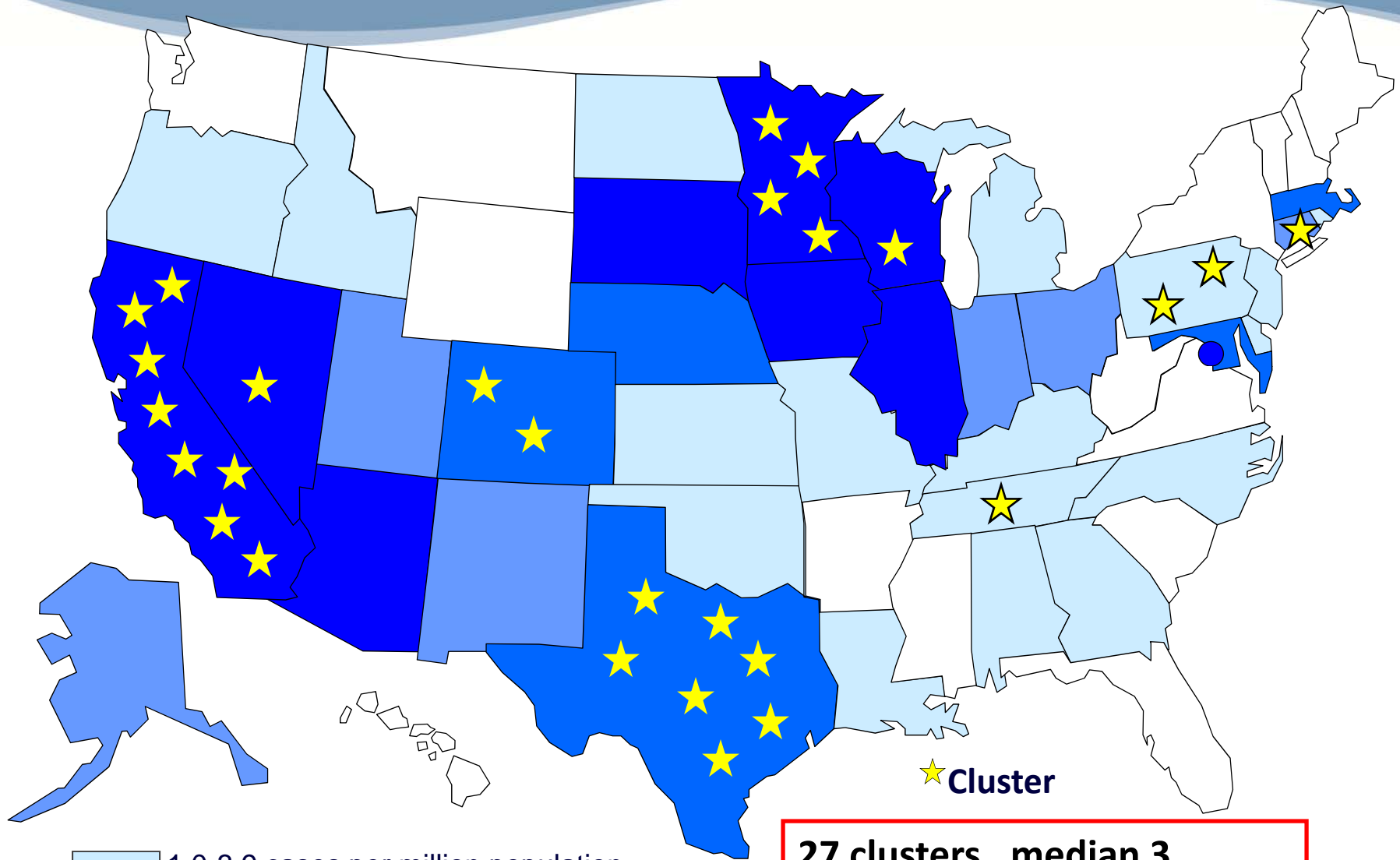


Investigation Strategy

- ❑ **Focus on restaurant or event clusters**
 - **Narrows focus to specific set of exposures**
 - **Menu items, food preparation practices**
 - **Facilitates traceback to common source**



Surplus incidence of SE per million population, May 1 - November 30, 2010



- 1.0-3.9 cases per million population
- 4.0-6.9 cases per million population
- 7.0-9.9 cases per million population
- 10.0 or more cases per million population

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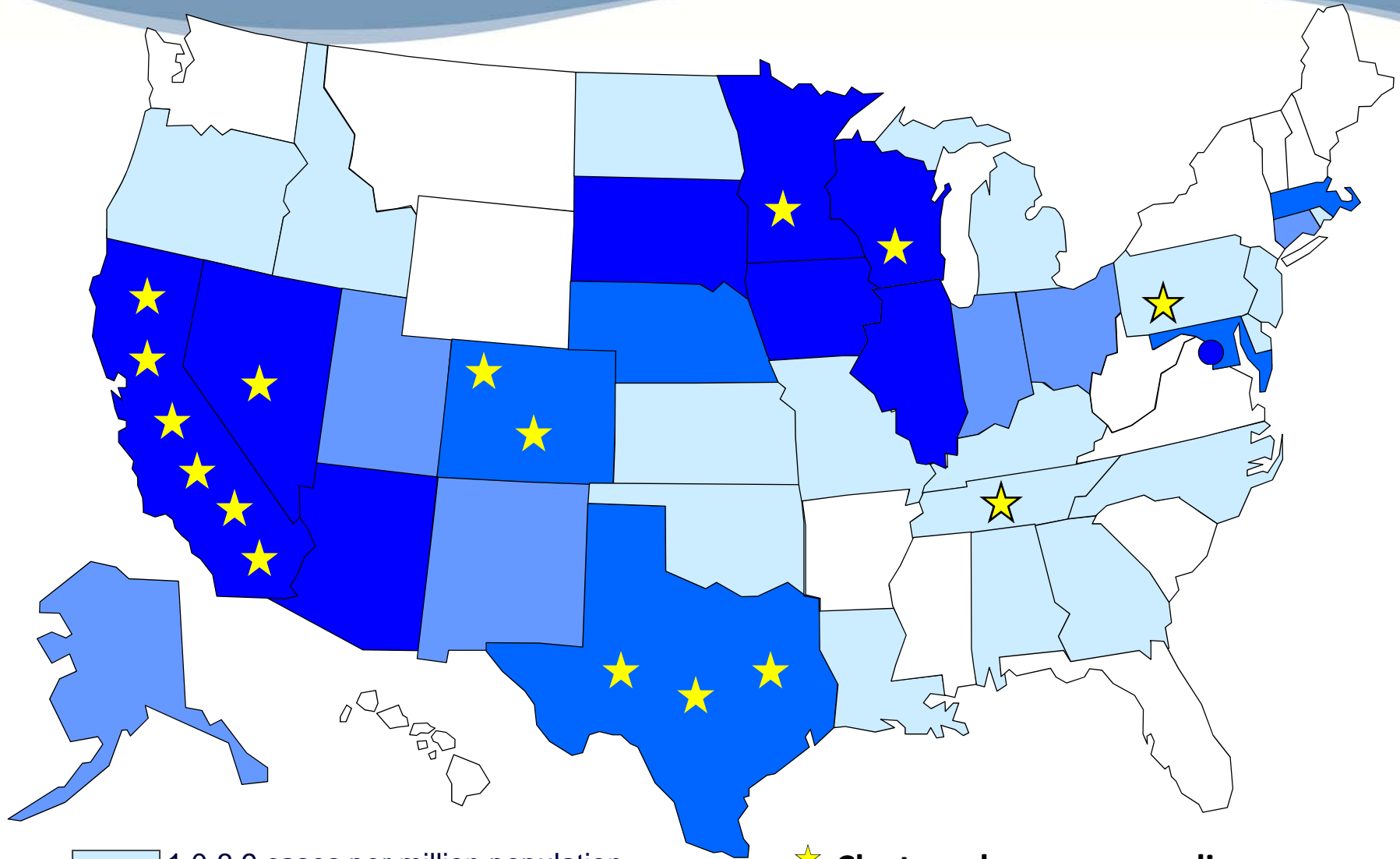


Suspect Food Items in Clusters

- ❑ **6 case-control studies**
 - 5 implicated eggs
 - 1 undetermined
- ❑ **2 cohort studies**
 - 2 implicated eggs
- ❑ **19 food histories**
 - 7 identified exposure to eggs
 - 1 identified exposure to chicken dishes
 - 1 identified exposure to ill food handlers
 - 10 undetermined
- ❑ **Source of eggs determined for 16 clusters**
 - Difficulties identifying suppliers



Surplus incidence of SE per million population, May 1 - November 30, 2010



- 1.0-3.9 cases per million population
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★ Cluster where egg supplier determined (n=16)



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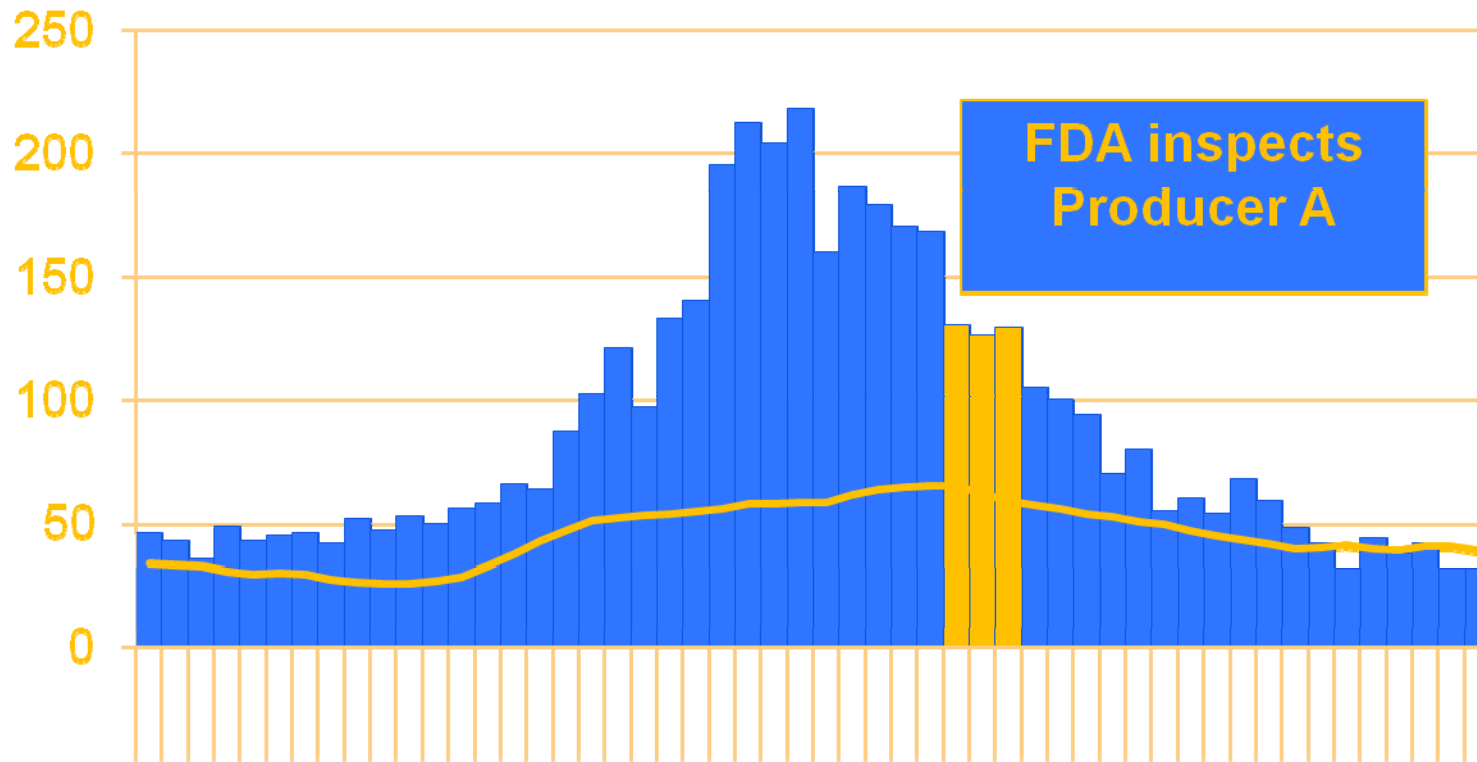
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Inspection Findings and Product Recalls

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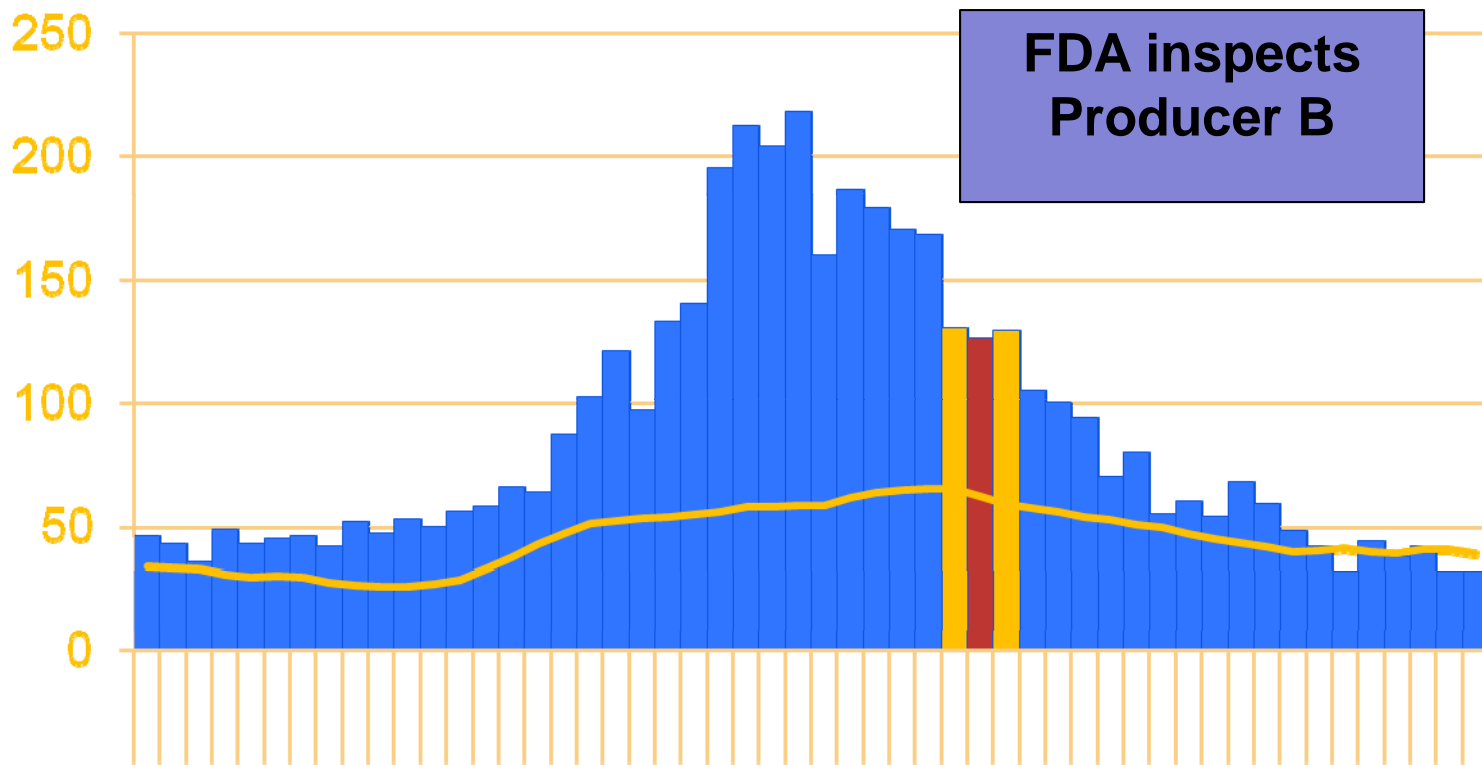


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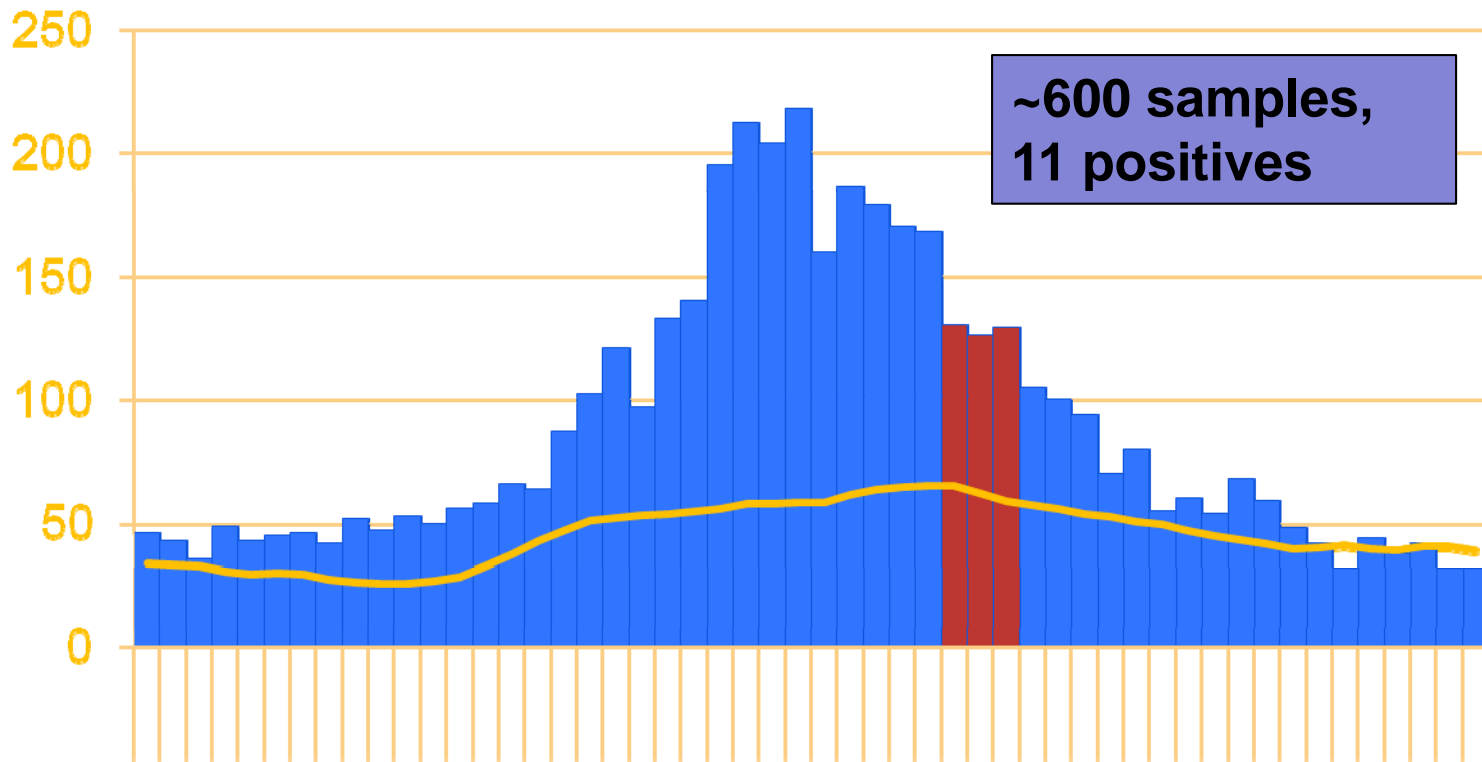


Number of SE Pattern 4 Isolates Reported to PulseNet, US, 2010





Number of SE Pattern 4 Isolates Reported to PulseNet, US, 2010





FDA Inspectional Observations

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION	
DISTRICT OFFICE ADDRESS AND PHONE NUMBER FDA Kansas City District Office 11630 W 80 th St Lenexa, KS 66214-3340 (913) 752 2100	DATE(S) OF INSPECTION 8/12/10-8/30/10 FEI NUMBER 3006481643, 3004793793, 3005280357
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED TO: [REDACTED] FEI: 3004797952, 3006481709, 3003073159	
FIRM NAME [REDACTED]	STREET ADDRESS 2674 Highway 69
CITY, STATE AND ZIP CODE [REDACTED]	TYPE OF ESTABLISHMENT INSPECTED Shell Egg Manufacturer
DURING AN INSPECTION OF YOUR FIRM WE OBSERVED: <p>THIS DOCUMENT LISTS OBSERVATIONS MADE BY THE FDA REPRESENTATIVES (S) DURING THE INSPECTION OF YOUR FACILITY. THEY ARE INSPECTIONAL OBSERVATIONS, AND DO NOT REPRESENT A FINAL AGENCY DETERMINATION REGARDING YOUR COMPLIANCE. IF YOU HAVE AN OBJECTION REGARDING AN OBSERVATION OR HAVE IMPLEMENTED, OR PLAN TO IMPLEMENT CORRECTIVE ACTION IN REPOSE TO AN OBSERVATION, YOU MAY DISCUSS THE OBJECTION OR ACTION WITH THE FDA REPRESENTATIVE (S) DURING THE INSPECTION OR SUBMIT THIS INFORMATION TO FDA AT THE ADDRESS ABOVE. IF YOU HAVE ANY QUESTIONS, PLEASE CONTACT FDA AT THE PHONE NUMBER AND ADDRESS ABOVE.</p> <p>Observations listed below cover inspections of your egg laying farms/plants inspected from 08/12/2010 through 08/30/2010. Inspections of Layers 1, 3 and 6 included record review and environmental assessments of all houses. Inspections of Layers 2 and 4 included record review of all houses and environmental assessments for Layer 2 – Houses 7 and 11 and Layer 4 – House</p>	



FDA Inspectional Observations

Manure... approximately
4 feet high to 8 feet high...

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**The outside access doors...had
been pushed out by the weight
of the manure...**



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**The outside access doors...had
been pushed out by the weight
of the manure...**

**Live and dead flies too
numerous to count...**



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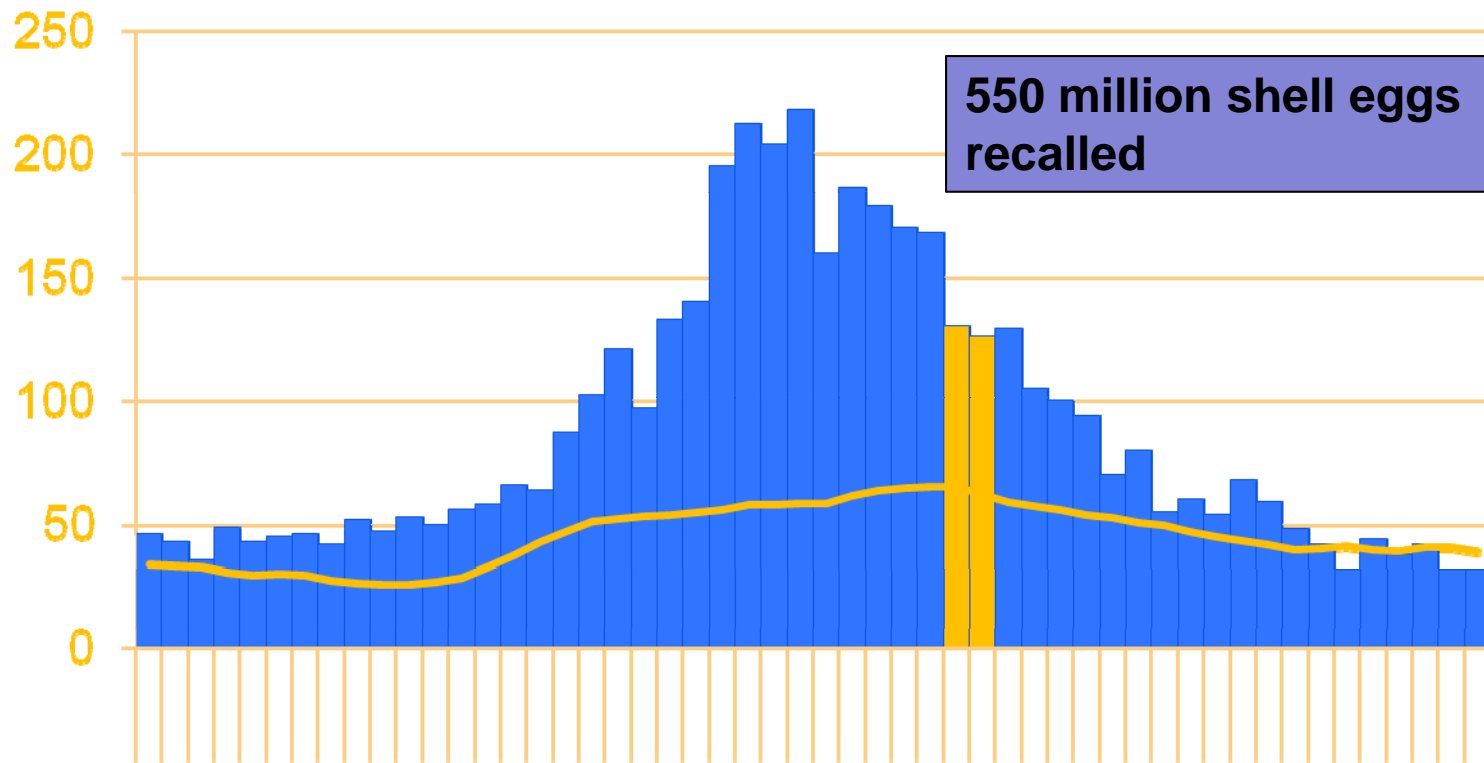
Two live rodents were observed...

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Liquid manure was observed streaming out...



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550 million shell eggs recalled



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Assessment and Update

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Assessment of Public Health Impact

- **Estimated 56,000 people sickened**
 - 1 laboratory-confirmed case: 29 unreported cases
- **Called public attention to food safety**
 - 10's of thousands of visits to CDC Features article and to FDA's website
 - Congressional hearing on September 22, 2010
 - Historical new food safety legislation signed by President Obama on 1/4/11
- **Resulted in intensified and accelerated FDA assessment of industry's implementation of the new egg rule.**



As a reminder...

21 CFR 118

- SE-monitored chicks and pullets
- Rodent/pest control, biosecurity, and cleaning and disinfection
- Refrigeration
- Environmental testing, egg testing if environment is SE+, and diversion of SE+ eggs
- Recordkeeping, registration, and training



Proactively Looking Forward

- The egg rule is becoming more fully implemented and compliance assessed by FDA
 - Because eggs become contaminated through transmission from laying hens, requires on-farm controls, SE prevention plans, testing, and recordkeeping; egg rule landed in about the right place.
 - Will reduce annual egg-related SE illnesses by nearly 60% (~ 79,000 illnesses averted)



Current Field Operations

- FDA invested significant resources into assessing corrective actions and ongoing compliance before supporting firms from resuming operations.
- On-going inspection assignment. Committed to 600 inspections by end of 2011
 - first targeted about 30 highest risk facilities with a comprehensive inspection approach
 - followed by targeting about 570 firms with a targeted inspection approach (which can turn comprehensive as conditions warrant).
 - Pursuing partnering with our state regulatory counterparts to cover some portion of the 570.



Lessons Learned-General

- Comprehensive inspections are time intensive and critically important to perform right, including in this area careful attention to our own commitment to Biosecurity.
- Analytical support is needed and time intensive – SE requires plating.
- State participation is critical – pursuing contracts with states but otherwise working and communicating closely.
- Training is critical. FDA courses have been revamped and going well with up to 50% state participation
- The need for sufficient scientific/operational expertise to apply to review of plans, assessment of conditions, targeting of inspections, initiation of enforcement, approach toward recovery, is critical and is developing.
- The egg rule seems to have hit at about the right place.



Lessons Learned – Continue What's Working

- Rapid focus on restaurant and event clusters critical to outbreak response
- External Communication
 - Establishing an email mailbox for the recall eggs@fda.hhs.gov was very helpful. PIO personnel assisted in responding to the emails
 - Public awareness – study showed 80% aware
 - FDA performed outreach to industry, and obviously the media and congress, but it is all critical.
- Internal Communication
 - Incident Management Group formed
 - Use of a group email list kept all informed



Lessons Learned – Improvement Opportunities

- Regional and District Offices should have sufficient cell phones, air cards, etc. to ensure response teams can communicate at all times within/without the Agency.
- Difficult working through recovery efforts outside of the controls and mechanisms of an injunction.
- Training in, and effective use of, the Incident Command System (ICS)
- Need for a Logistics Officer in the field
- Strategies, and templates to deliver strategies, should be developed beforehand.
- Single POCs and more predictable communication times (that consider field team available) from HQ to field and vice versa
- Benefits of an effective JIC
- “Tell the story” earlier in the event as appropriate (i.e. this is what happened, this is what we’re doing, this is what you should do, this is when we’ll provide more info)
- Better use new communication mechanisms (e.g. social media)



Acknowledgements

- CDC
- Several States
- Several Components of FDA



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The End

Thanks
Questions?

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