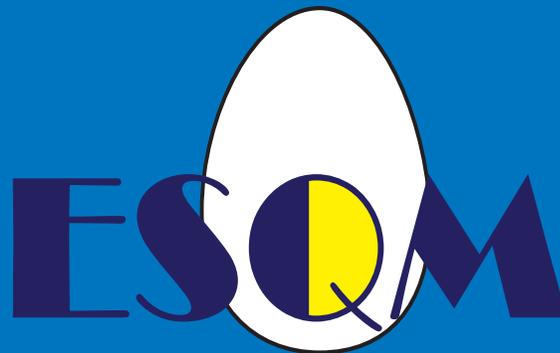




Egg Safety and Quality Management Program

Annual Report

July 1, 2018 – June 30, 2019



Egg Safety & Quality Management

“Ensuring Food Safety & Grade Standards, One Egg At A Time.”

Tony Herrera
Egg Quality Manager

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MESSAGE

from the Egg Quality Manager



The Egg Safety and Quality Management program (ESQM) entered fiscal year 2018/2019 in much the same manner as it exited fiscal year 2017/2018; providing program personnel and their expertise to the virulent Newcastle Disease (vND) incident in southern California.

Despite rotating ESQM staff to assist with the vND incident throughout the fiscal year, the program still managed to complete its mandated workload assignments for grade & quality inspections and shell egg food safety audits. The program was also able to continue its outreach and education efforts through its small flock producer workshops, contracted FDA and USDA shell egg inspections and cooperative agreement plan with FDA and Iowa Department of Agriculture.

During its winter staff meeting held in December of 2018, the ESQM program laid out an ambitious project development plan for the rest of the fiscal year and beyond.

- Enhanced Border Station Enforcement
- Enhanced Certified Farmers Market Inspection
- Other Species of Fowl/Sanitation Standards
- Consumer Video for Egg Carton Labeling Definitions

Project development for the above have been completed or are close to completion and implementation. The program also formed a Shell Egg Food Safety (SEFS) Legacy Project group. The goal is to chronicle the development of the SEFS audit program and provide recommendations for future SEFS efficiencies.

During fiscal year 2018/2019, the Egg Quality Manager fulfilled his duties as board member and assistant director of the National Egg Quality School (NEQS) and was elected President of the National Egg Regulatory Officials (NERO) organization for 2019/2020.

In closing, I'd like to offer my thanks and appreciation to the ESQM support and field staff for their continued dedication and commitment to the ESQM program. I'd also like to thank the board members, past and present, of the Shell Egg Advisory Committee (SEAC) for their support and encouragement to the ESQM program and to me personally.

As I close out my nearly 40-year career with CDFA, I realize how fortunate I've been to be associated with the finest state department of agriculture in the nation.

Best wishes to all of you,

A handwritten signature in blue ink, appearing to read 'Tony Herrera', written in a cursive style.

Tony Herrera
Egg Quality Manager
Egg Safety and Quality Management Program
Meat, Poultry, and Egg Safety Branch
Animal Health and Food Safety Services Division



ESQM Activities

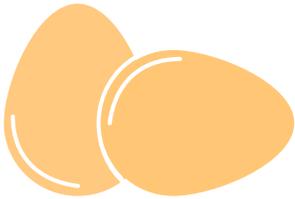
The egg safety and quality management program is responsible for the safety of shell and egg products that are procured, shipped or sold in California. The mission of ESQM is to ensure that eggs are safe, wholesome and of known quality, origin, grade and size.

Key components:

- Compliance and Risk Based Inspection (CRBI)
- FDA Contracted Egg Rule Inspection
- Federal Shell Egg Surveillance (SES)
- Retail Surveillance
- CA Shell Egg Food Safety (SEFS)

Protecting Over 39 million Californians

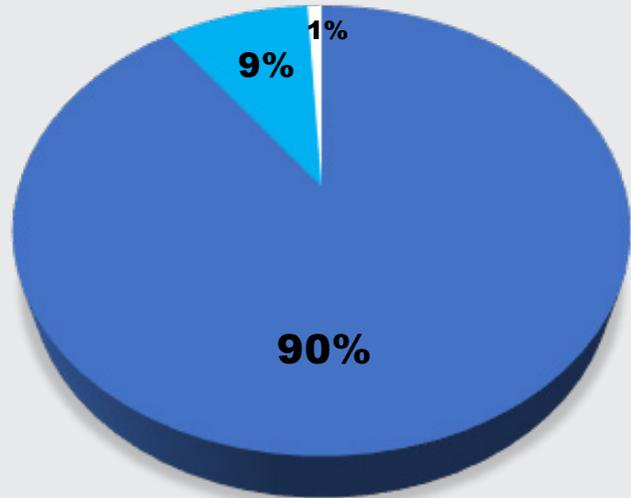




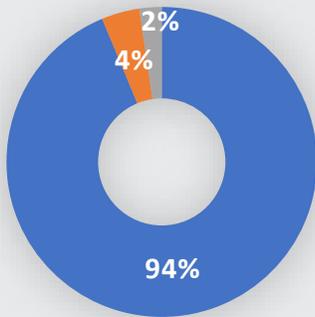
ESQM Program Components

ESQM is a state-wide regulatory program. Its funding is derived primarily from assessments and registrations fees. ESQM registers in-state and out-of-state egg producers. Retail outlets are exempt from ESQM registration.

In FY 18/19, CDFA Exterior Pest Exclusion (Border Protection Stations) reported a total of **16,230,750** shell egg cases and egg product units having entered CA.



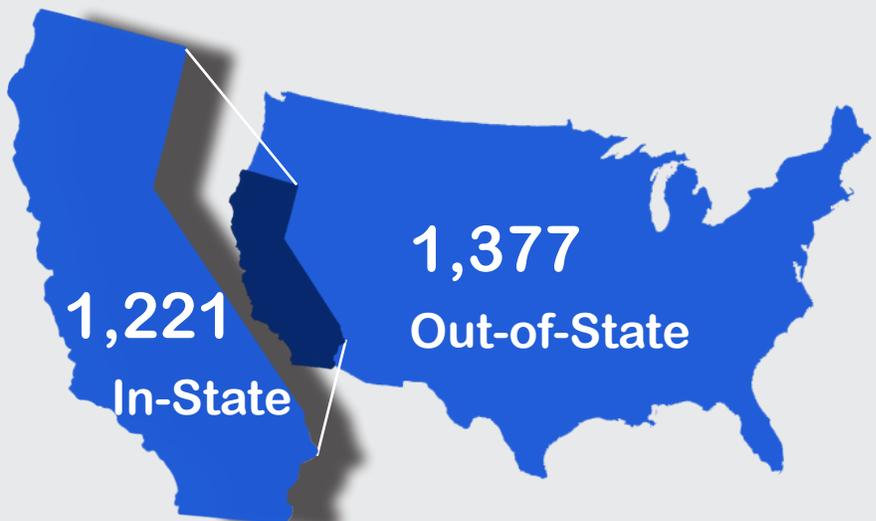
● Shell Egg Cases ● Liquid Egg Cases ○ Dry Egg Cases



● Assessments
● Registrations
● Audits

\$3,910,699 collected during FY 2018/2019

CA Registered Egg Handlers





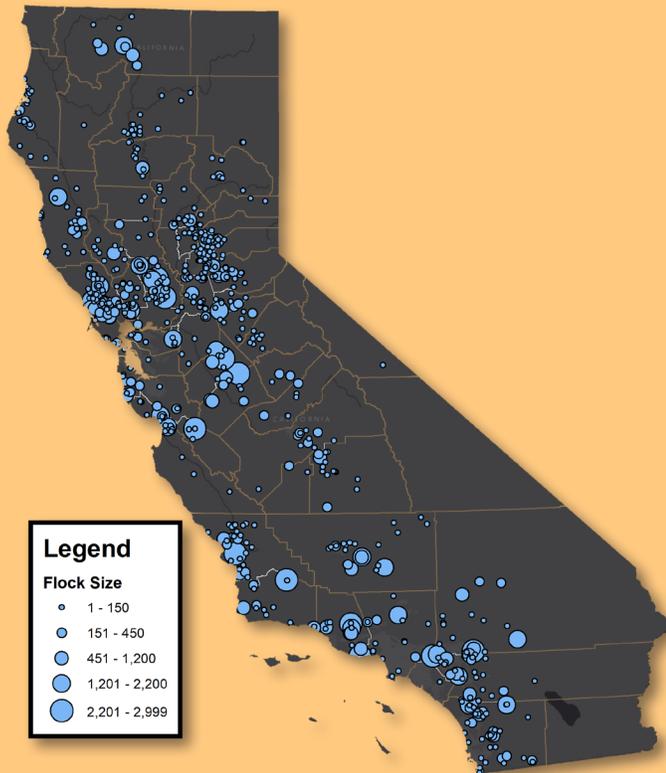
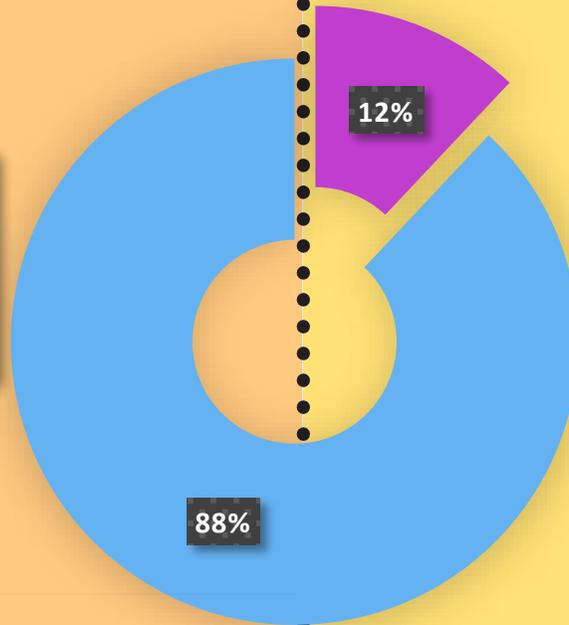
CA Egg Producers

CA Producers Under 3k Flocks

CA Producers Over 3k Flocks

728 Producers
Totaling **172,574**
birds

95 Producers
Totaling
15,352,864 birds



Looking back at FY 18/19...

Northern District

Retail Surveillance



**22,225
Dozens
Inspected**

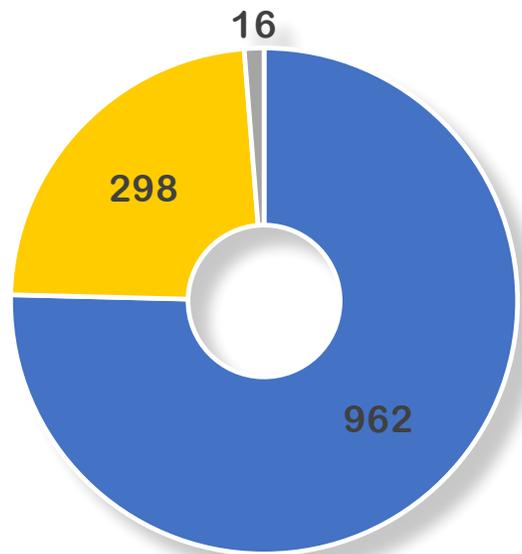


**5,260
Dozens
Rejected**



**12
Unregistered
Egg Handler**

Premises Inspected



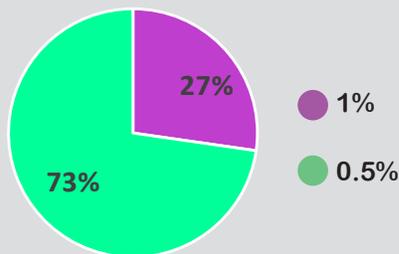
● Retail ● CRBI ● SES

Compliance and Risk Based Inspection



**1,904
100-Egg
Sampled**

Quality & Safety Compliance Rate



Federal Shell Egg Surveillance (SES)



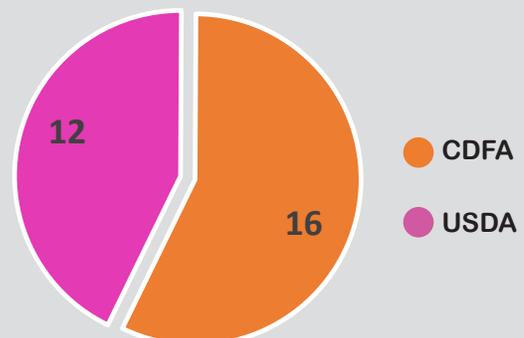
**248.75 Total
Travel Hours**

2.3% Increase in total travel costs
from FY 17/18



**\$29,787.05
Total Costs**

Quarterly Surveillance for Federal Fiscal Year 18/19



Anticipate licensing 4 more inspectors
for the coming Federal FY

Southern District

Retail Surveillance



**80,373
Dozens
Inspected**

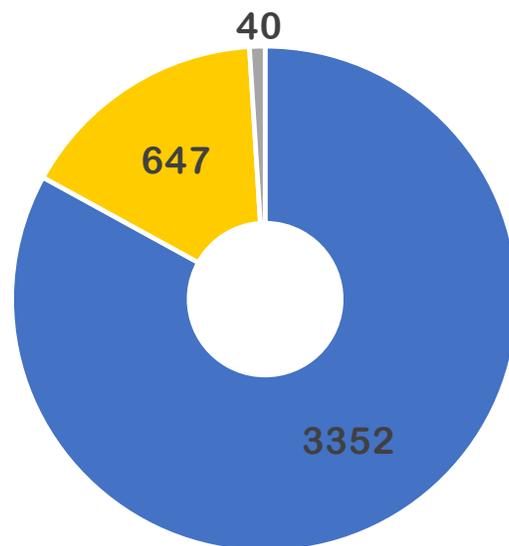


**11,604
Dozens
Rejected**



**21
Unregistered
Egg Handler**

Premises Inspected



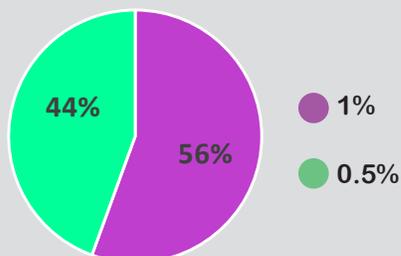
● Retail ● CRBI ● SES

Compliance and Risk Based Inspection



**3,221
100-Egg
Sampled**

Quality & Safety Compliance Rate



Federal Shell Egg Surveillance (SES)



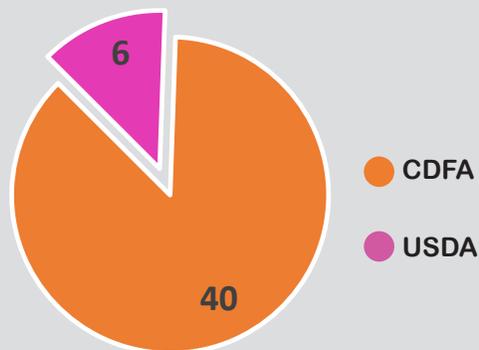
**117.75 Total
Travel Hours**



**\$17,087.24
Total Costs**

50.6% Decrease in total travel costs from FY 17/18 due to Virulent New Castle Disease. Phone call inspections were done for areas in vND quarantine zones.

Quarterly Surveillance for Federal Fiscal Year 18/19



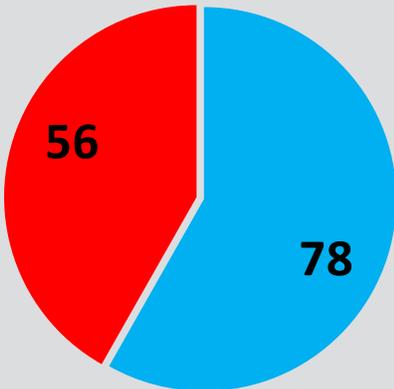
Anticipate licensing 2 more inspectors for the coming Federal FY



Shell Egg Food Safety

To support the consumption of high quality, safe eggs, the Egg Safety and Quality Management Program (ESQM) regulates Section 1350 (Shell Egg Food Safety) and amended 1354 (Product Labeling) of Title 3 of the California Code of Regulations. These regulations require any in-state or out-of-state egg producer or egg handler selling chicken eggs in California to implement Salmonella enterica serotype Enteritidis reduction measures and label products accordingly. These requirements were implemented in phases beginning on July 1, 2013 and January 1, 2015

Total SEFS Audits in CA



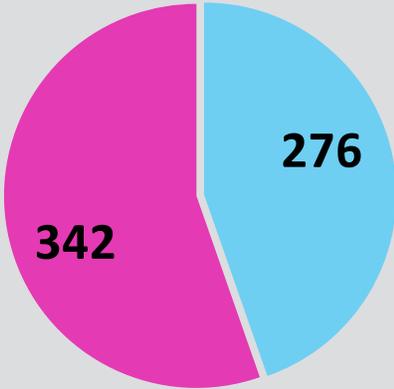
FY 17/18 FY 18/19

**28%
Reduction**

Due to Virulent Newcastle Disease (vND) outbreak, the number of California SEFS Audits completed were significantly lower in Fiscal Year 2018-2019 than in 2017-2018.

11 In Person Audits

Total Out-of-State SEFS Audits



FY 17/18 FY 18/19

**24%
Increase**

Out-of-state SEFS Audits were also affected by the vND outbreak. The numbers went up substantially from Fiscal Year 2017-2018 to 2018-2019, since efforts could be focused on the out-of-state facilities.

23 In Person Audits

ESQM develop a Risk Based Point System for Shell Egg Food Safety inspection. We have developed a Shell Egg Food Safety Risk-Based Point System, which created a new inspection protocol which recognizes and quantifies the contribution of various risk factors to Salmonella Enteritidis (SE) contamination in shell eggs. This point system can help minimize the subjectivity of risk assessment and standardize the inspection process.

Shell Egg Food Safety Enforcement



A total of **78** Notice of Violations issued. 25 in-state and 53 out-of-state



2 Notice of Proposed Actions were issued in-state

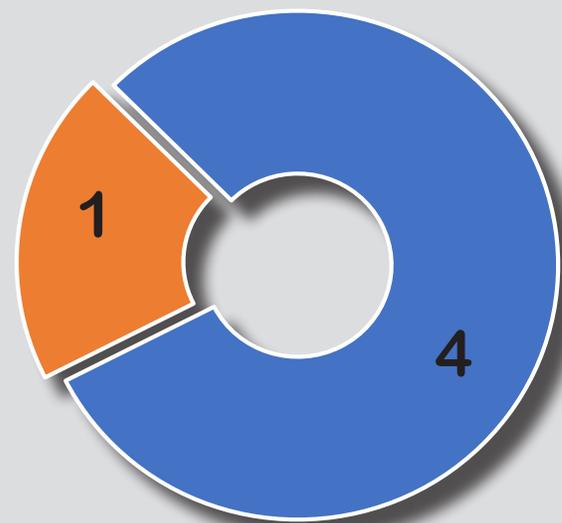
FDA Contract

ESQM is in the middle of a 5 year contract with the FDA to complete egg inspections according to the FDA Egg Rule, Code of Federal Regulations, 21 CFR 118.

Due to VND, the number of contract egg inspections completed were significantly impacted.

It's anticipated that FDA will resume joint inspection reviews in 2020

FDA Contract Inspections in FY 18/19

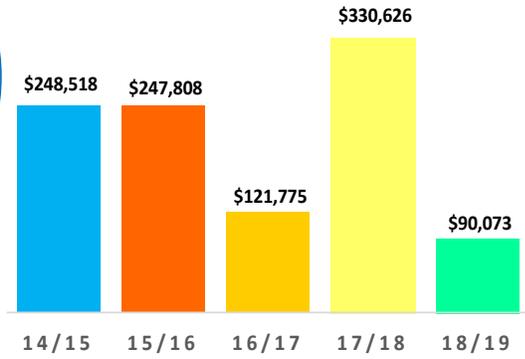


● Northern CA ● Southern CA

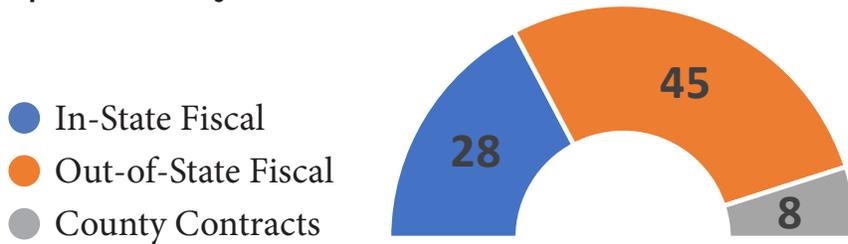
Financial Audit Function

“Through the work performed by the Audit Office, ESQM has collected over **one million** in **assessments** and **penalties** over a five year fiscal period”

Egg Program Financial Audit Collections
FYs 14/15 to 18/19



Completed Audits During FYs 14/15 to 18/19

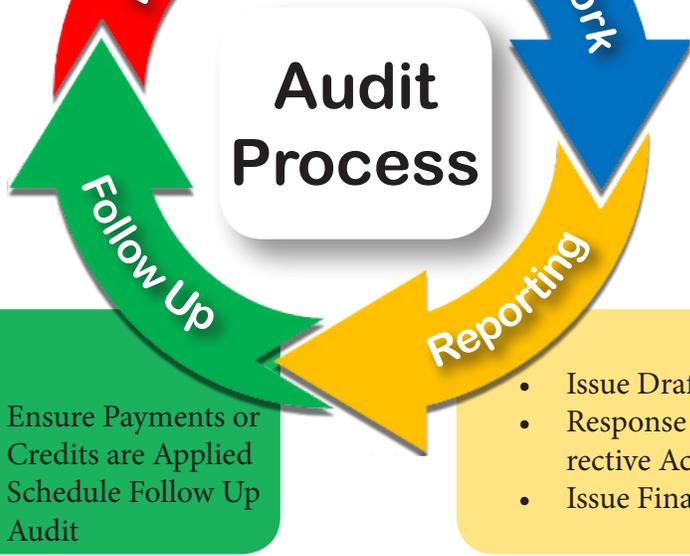


Duties and Facts

- Conducts Egg Mill Fee Audits
- Conducts Audits of the County Inspection Contracts
- Issues Demand Notices
- Processes Refund Requests
- Issues Notice of Violations and Notice of Proposed Actions for Audits
- Obtains Registrations
- Processes Registration Revocations

- Assess Payment and Non-Compliance Risks
- Contact Egg Handler to Schedule Audit
- Gather Information

- Conduct Interviews
- Gather Data
- Analyze Data and Documents
- Provide Preliminary Results



- Ensure Payments or Credits are Applied
- Schedule Follow Up Audit

- Issue Draft Report
- Response to Corrective Action
- Issue Final Report

“During FY 14/15 to 17/18, staff consisted of one audit supervisor and one staff auditor; now currently stands at one audit supervisor”
-Juan G.

FDA Egg Cooperative Agreement Program

& Egg Safety Regulatory Program Standards Work-group

U.S. Food and Drug Administration (FDA), California Department of Food and Agriculture/Egg Safety and Quality Management (CDEA/ESQM), and Iowa Department of Agriculture and Land Stewardship (IDAL) were in a Cooperative Agreement Program (CAP) effective from September 1, 2016 to August 31, 2019.

The purpose of this CAP is to advance efforts to improve the national egg safety programs through conducting an egg regulatory program self-assessment including a review of State egg laws and regulations in comparison to the current Federal egg safety laws and regulations; developing and implementing an agreement and protocol for sharing egg regulatory inspections and information between States and the FDA; and identifying gaps and areas of improvement between Federal and State egg programs; and providing recommendations for national Egg Safety Regulatory Program Standards (ESRPS) for States. CDEA/ESQM will continue to be represented as a lead in a voluntary work-group consisting of States, FDA, & advisors to develop and finalize national ESRPS.



FoodSHIELD

Database platform that was agreed on to share information between the States and FDA.

Egg Safety Regulatory Program Standards

Standard 1 - Regulatory Foundation

Standard 2 - Training

Standard 3 - Inspection

Standard 4 - Inspection Audit Program

Standard 5 - Egg-related Illness, Outbreak & Emergency Response

Standard 6 - Compliance & Enforcement

Standard 7 - Outreach Activities

Standard 8 - Program Resources

Standard 9 - Program Assessment

Standard 10 - Comprehensive Sampling & Laboratory Program (OPTIONAL)

Figure 1 - Proposed ESRPS Recommendations

Egg Safety Program Standards Work-group

Make recommendations for elements of a national egg regulatory program standard for State egg regulatory programs, including identification of elements of the MFRPS and AFRPS that are not applicable to egg regulatory programs, elements that are appropriate, and additional elements that shall be included. California has been working with Iowa on making recommendations for elements of a national egg regulatory program standard. *Figure 1* shows the ESRPS recommendations that have been completed to date.

Conduct a baseline program self-assessment and develop an improvement plan using the MFRPS Standard 9 as the foundation. The program self-assessment requires the completion of the appendices and worksheets found in Standards 1- 8 and 10, or equivalent forms. We completed baseline self-assessments and a revised assessment report based on the suggestions and guidance from FDA was submitted to FDA in 2017. We developed an improvement plan based on the self-assessments to further enhance the efficiency of existing State egg inspection program.

Completed the task of identifying gaps and areas of improvements between Federal and State egg programs. The comparison between FDA and California State egg programs was summarized in four areas: regulatory authorities, compliance actions, inspection requirements, and review of inspection procedures.

Iowa (Michelle Boyd) and California (Emma Middlemiss) have worked closely with the FDA and have completed the recommendations for draft national ESRPS. The 10 ESRPS recommendations have been completed to date.

A voluntary work-group has been put together to develop finalized national egg standards. Currently, the work-group consists of State, FDA, and advisor representatives who will move forward with the next phase in the final development of egg standards. Refer to *Figure 2* for the breakdown of the entities that make up the National Egg Standards voluntary work-group. The work-group will dissect each recommendation

(Add, change, or remove) and finalize the standards to be rolled out nationally. The work-group will be creating a framework for national egg standards.

In order to finalize the ESRPS, a series of work-group webinars are taking place and a face-to-face work-group meeting is scheduled for early 2020. While this is a primarily a voluntary effort, funding is currently being ascertained to fund any travel funds for the face-to-face meeting. The work-group is currently in the process of applying and securing these funds through the FDA for the Scientific Conference Grant program.

In February 2019, National Egg Regulatory Officials (NERO) voted to continue to provide support for the development of National ESRPS. NERO will continue to help promote State efforts in finalizing the Standards. The goals of the work-group are to finalize egg standards with continued NERO support & stewardship. A summary of work-group efforts to date will be presented at the next NERO meeting at San Diego in March 2020.

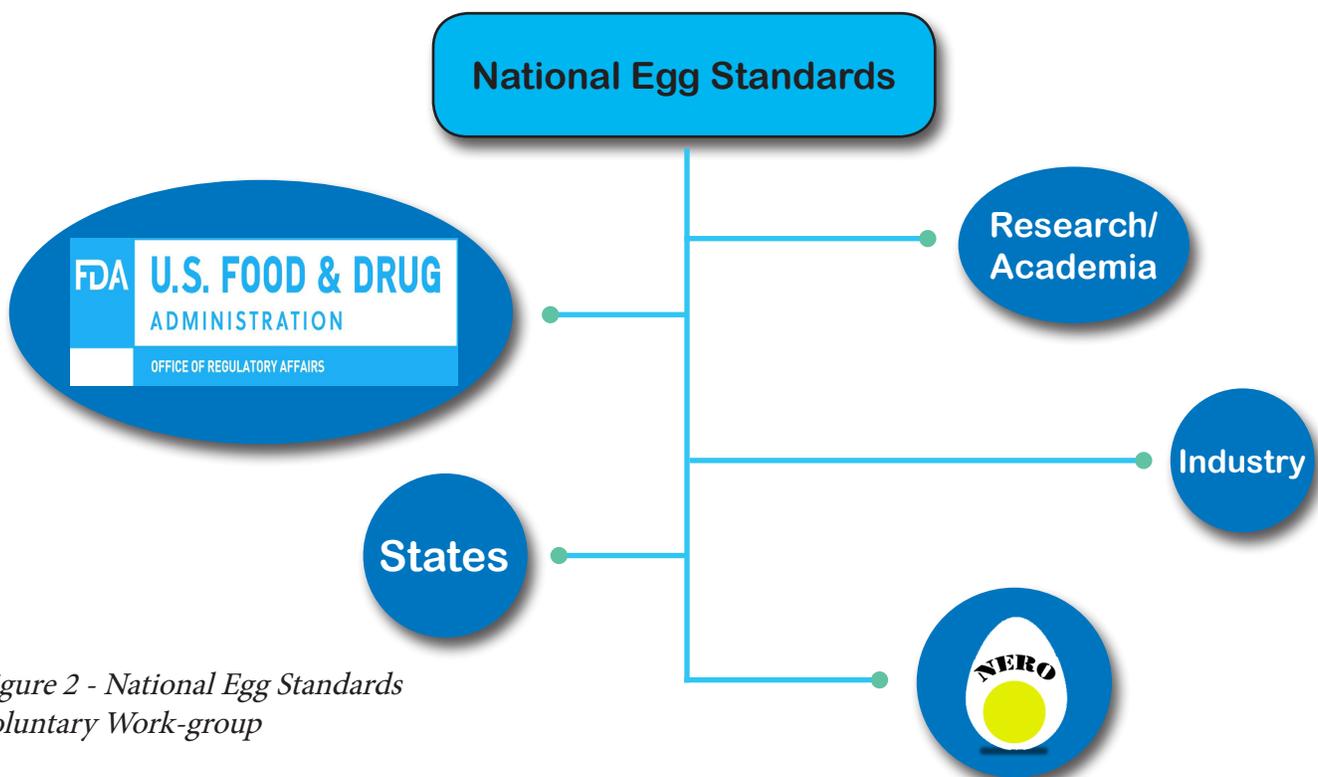


Figure 2 - National Egg Standards voluntary Work-group

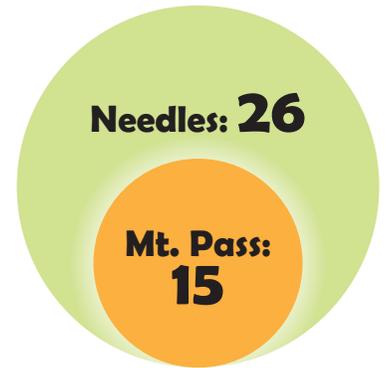
Enhanced Border Station Enforcement



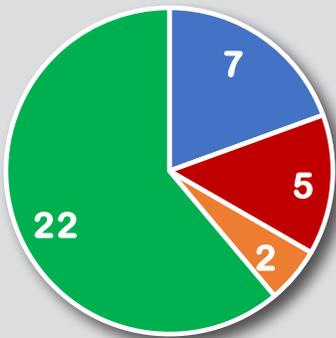
Beginning March 4, 2019 through June 30, 2019, ESQM partnered with Border Protection Station (BPS) to initiate the Enhanced Border Station Enforcement Pilot Program.

During this period, Enhanced Border Enforcement only operated at Needles and

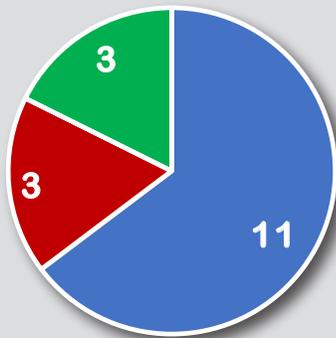
Mountain Pass. **41** hold notices were placed on egg loads entering California.



Violations Issued



Needles



Mountain Pass

- CA SEFS/Not for CA Consumption
- Labels Didn't Match Bill of Lading
- Registrations
- False/Misleading Statements

Hold notices may have more than one violation

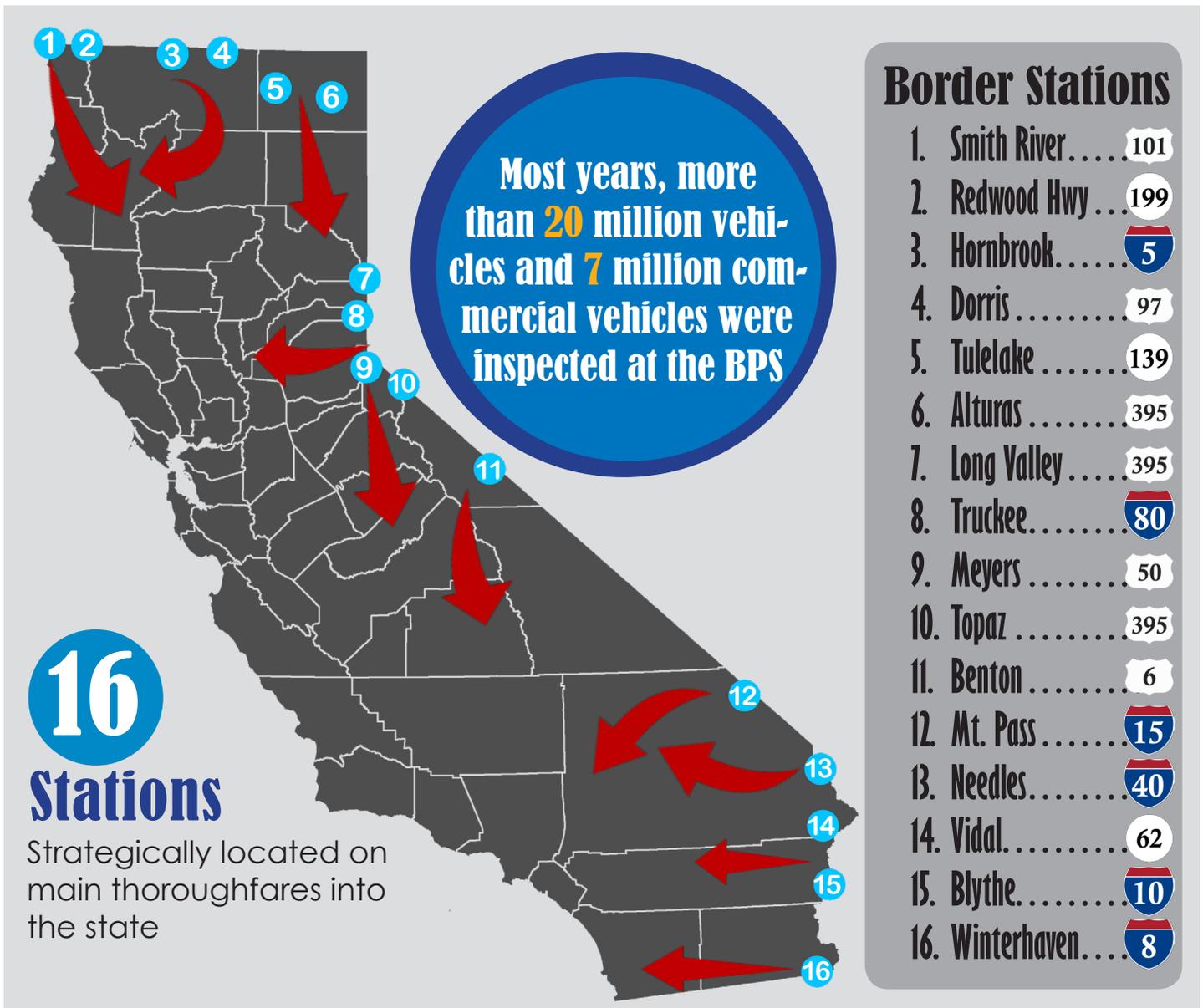
Border Protection Station

California's Border Protection Stations are the first line of defense in our pest exclusion efforts. At these stations, vehicles are inspected for commodities infested with invasive species. California established its first agricultural inspection stations in the early 1020s. At these stations, vehicles and commodities are checked to ensure they are pest free and meet all state regulatory requirements.



Border Protection Station Duties with ESQM

- ✔ Inspect Egg Shipments for proper compliance with SEFS regulations
- ✔ Complete egg compliance and Hold/Disposal Notice for shipments that do not meet SEFS regulations
- ✔ Collect data on egg shipments entering California
- ✔ Input data into Egg Passing Report Database

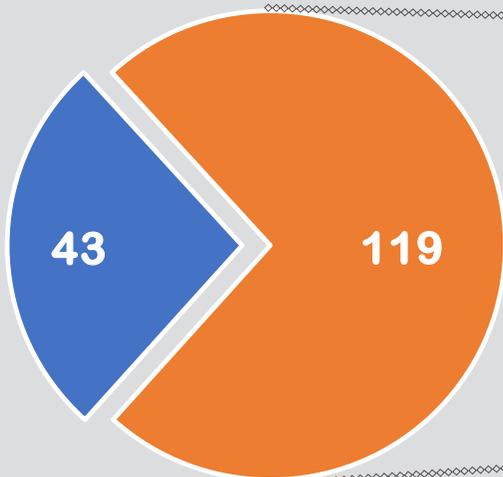




Egg Investigations

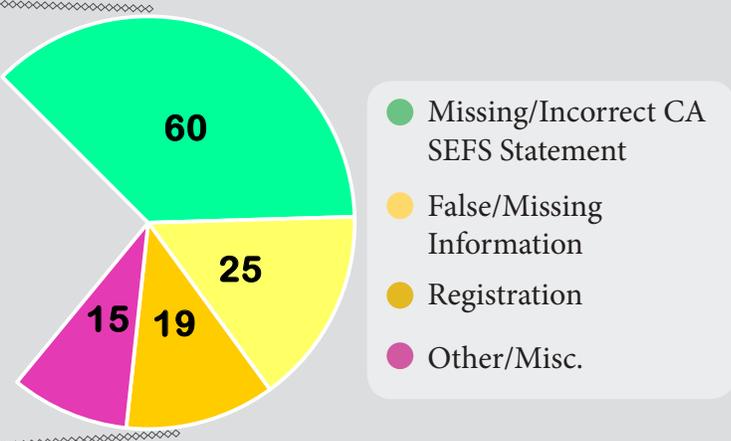
The Enhanced Border Enforcement initiated the opening of 65 investigations that resulted in 35 Notice of Violations (NOV) for violations of various sections of the Food and Agricultural Code and Title 3 California Code of Regulations. Inspection of one of the loads placed under Hold Order uncovered a fraudulent labeling operation. After consultation with CDFA legal office, the ESQM Program began the process of utilizing its enforcement authority to issue Administrative Penalties and issue the Notice of Proposed Action (NOPA).

Total Investigations

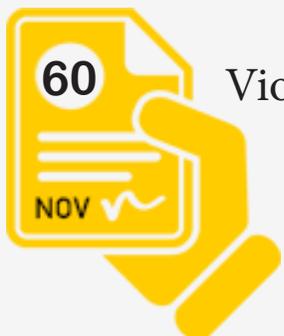


● FY 17/18 ● FY 18/19

Investigations in FY 18/19



- Missing/Incorrect CA SEFS Statement
- False/Missing Information
- Registration
- Other/Misc.



Notice of Violations Issued
(58% are Enhanced Border Enforcement related)



Penalties will be assessed based on the schedule and corresponding penalty range of “serious”, “moderate”, and “minor”



Notice of Proposed Action Submitted



\$9,100 collected in penalties for various violations for FY 18/19





Special Projects

The ESQM program is always looking to stay abreast of current and future industry trends.

We strive to offer innovative leadership in developing and supporting resources, materials and sound policies in support of the Egg industry, with food safety and consumer satisfaction as our guiding principles.

This year, we have identified and pursued the following five “Special Projects” with those principles in mind.

1) Small Producer Workshop

1

Rebecca McCallister
Kathryn Tockey
Ginny Carlson

2) Certified Farmer’s Market Enhancement Project

2

Jenna Celigija

3) Shell Egg Safety & Plant Sanitation Guidelines

3

Melissa Vasquez
Alan Pham

4) Shell Egg Food Safety Legacy Project

4

Kim Ellis
Kathryn Tockey
Emma Middlemiss

5) Public Education Outreach Video

5

Ginny Carlson
Joanne Ortiz
Beverly Littlejohn

Small Flock Producers Workshop

This project seeks to educate Small Producers (less than 3,000 birds) in all aspects of egg production, including; chicken husbandry, bio-security, good processing sanitation practices, egg grade and quality factors, labeling and other regulatory requirements by holding free workshops throughout California. Producers leave the class with a certificate of participation, educational materials and resources, and a greater understanding of the importance of food safety and bio-security.



A total of 17 workshops scheduled, 7 completed so far

3 SPW's and 1 school left to go. 6 canceled due to vND and low RSVP

- ✓ Awareness about bio-security, laws and regulations
- ✓ Promote safe egg handling
- ✓ Connect directly with regulated industry and public

<https://www.cdffa.ca.gov/ahfss/mpes/spop.html>



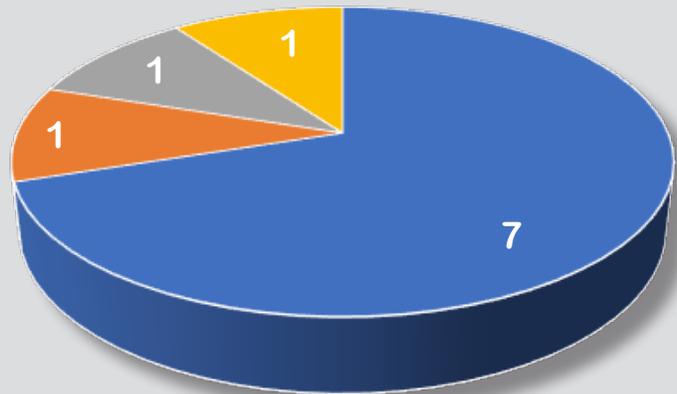


Certified Farmer's Market Enhancement Project

This project establishes a cooperative relationship between the ESQM and Direct Marketing Program to gain greater oversight and monitoring of eggs sold at Certified Farmer's Markets, including labeling requirements, special quality enhancement claims, and that eggs are of the seller's own production. Information collected from inspections will be verified for accuracy and truthfulness to ensure a level playing field for all producers, and provide assurance to consumers that their eggs were produced the manner stated on the carton or advertising placard.

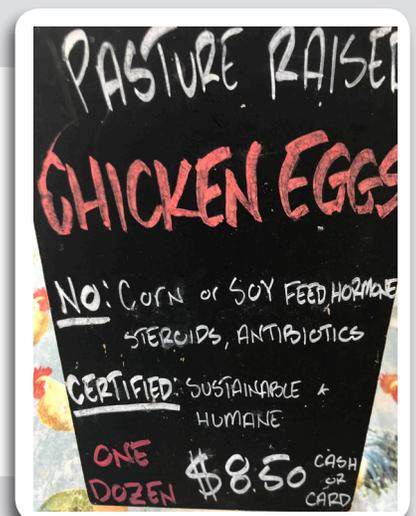
Notices of Noncompliance Violations (Some vendors had more than 1 violation)

- **3** Direct Marketing Program Supervisors Trained
- **4** Markets Visited During Training
- **12** Stalls Inspected
- **10** Total Violations Found
- **8** Notices of Noncompliance



- Carton Labeling Violation
- Sign/Placard Marking Violation
- Lack of Registration
- Valid Registration, License not Present

In an effort to ensure that California consumers can have confidence in the truthfulness of labeling claims for specialty type eggs, and to promote the fair and orderly marketing of eggs throughout the egg industry, ESQM entered into an agreement with the Direct Marketing Program in the Division of Inspection Services in April 2019. This agreement seeks to cooperatively inspect egg vendors for labeling compliance, and truth in advertising verification as it pertains to feed types, methods of production and/or special claims as to the nutritional content of their eggs.





Shell Egg Safety & Plant Sanitation Guidelines

ESQM has noted a consumer-driven trend towards eggs from turkey, duck, geese, guinea and quail. This research-based project seeks to establish guidelines for the safe and wholesome production of eggs from non-chicken species of fowl, which currently do not fall under state or federal regulations. The ESQM Program is seeking to establish a sanitation certification program to provide producers of non-chicken eggs verifying their good sanitation practices to ensure that consumers of all types of eggs have access to wholesome and safe eggs.



“Eggs sold in California are of known quality, origin, grade, and size, have been properly handled, labeled, and transported refrigerated and are wholesome and safe to eat”

Food safety is important at every level: beginning at the farm, to processing, storage, and *finally* to the consumer. That is why ESQM takes a proactive role in identifying areas of improvement to address potential food safety and sanitation concerns to ensure the production of safe food and minimize contamination during processing and eliminate food borne illness outbreaks.



ESQM has launched a pilot program for Shell Egg Safety & Plant Sanitation Guidelines (SESPS) to meet and exceed egg safety controls and plant sanitation practices at processing, packing, and warehousing facilities.

Only 3% of registered egg handlers volunteer with USDA’s Agricultural Marketing Service in which processing plants undergo rigorous food safety and sanitation inspections.



Registered egg handlers include producers, processors, packers, or warehouses that hold chicken eggs as well as “other fowl” eggs.



Shell Egg Food Safety Legacy Project

This project was initiated with the goal of chronicling the development of the SEFS audit program to provide recommendations for future SEFS efficiencies. The SEFS Legacy Project's purpose is to document the history of SEFS so we can look back on where we started and see how far the program has come since then.

Prop 2 Passes 2008

- ◇ Chickens must be able to stand up and extend their wings. Thus begins the development of SEFS. CDFA works with UC Davis to come up with exact space requirements

FDA Egg Rule 2010-2012

- ◇ Title 21 CFR 118
- ◇ At first only required for those with 50,000+ layers, then later goes into effect for everyone with 3,000+ layers
- ◇ FAC section 27551 amended assessment which allowed ESQM to hire more staff to complete inspections

Phase 1 SEFS 2013

- ◇ CCR 1350 adopted and CCR 1354 amended
- ◇ SEFS Phase 1 goes into effect for all layers hatched 7/1/13 and thereafter
- ◇ Corrective Action Matrix development begins and Projection tool developed

1st SEFS Audit 2014

- ◇ First SEFS Audit completed
- ◇ Missouri and several other states file suit against CA

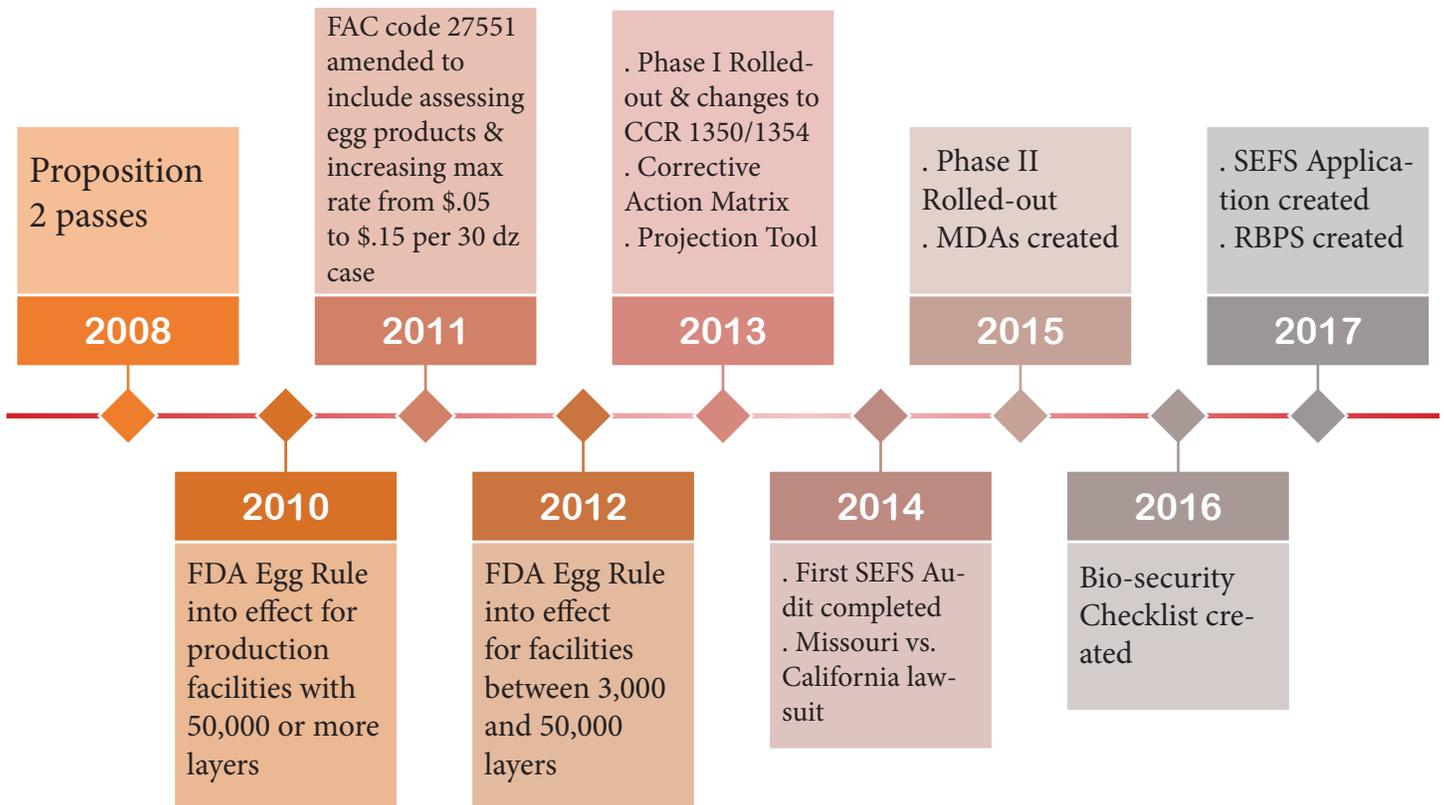
Phase 2 SEFS 2015

- ◇ SEFS Phase 2 goes into effect 01/01/2015. Layers are required to be given a specific amount of space per bird. SEFS statement must be on all labels

SEFS Tools 2016-2017

- ◇ Tools to assist with SEFS inspections developed
- ◇ Bio-security checklist to determine adequacy of bio-security/SE plans
- ◇ SEFS application developed to create digital inspection forms and upload to Emerging Threats database
- ◇ Risked Based Points System to determine a farm's risk and help determine frequency of inspection

SEFS Timeline



SEFS Moving forward

The SEFS Review Team identified the following improvement areas for maximizing SEFS efficiency:

- Missing and outdated Standard Operating Procedures
- Defining/quantifying, “Critical Food Safety Issues”
- Underutilization of Administrative Penalties for compliance issues
- Time management concerns for document submission by industry
- Modified Desk Audit (MDA) enhancement to cover periods of outbreak and quarantine
- Elements missing in regulations

The following actions have been implemented in response to identified improvement areas:

NOV to NOPA protocols for SEFS Enforcement

Internal audit of the inspection process to measure performance of the SEFS program so as to make recommendations for program improvements

Public Education Outreach Video

This project seeks to educate consumers on the frequently asked questions about eggs and egg products, to educate them on egg safety, carton labeling and the ESQM Program functions that support a safe and wholesome supply of eggs to all California consumers.

Progress:

- Script development
- Narrator Character
- Interview with Access Sacramento

Goals & Ideas:

- Budget for video development
- White Board Animation

Script material covers:



- ✓ Markings
- ✓ Codes
- ✓ CA SEFS Compliant Statement
- ✓ Responsibility
- ✓ Refrigeration
- ✓ Different Egg Types



New egg safety and quality management guides have arrived. On September 11, Tony Herrera and Beverly Littlejohn met with LiveWire to discuss the program's "farm to fork" food safety inspection services for table eggs.

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Title

Branch Chief

Egg Quality Manager

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Fruit & Vegetable Quality Control Inspector
Agriculture Program Supervisor II
Office Technician
Staff Services Analyst
Staff Management Auditor
Office Technician
Environmental Scientist
Environmental Scientist
Environmental Scientist
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Agricultural Technician II
Fruit & Vegetable Quality Control Inspector
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Environmental Scientist
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