

**DEPARTMENT OF FOOD AND AGRICULTURE
MEAT, POULTRY AND EGG SAFETY BRANCH
Egg Safety and Quality Management
INITIAL STATEMENT OF REASONS**

Hearing Date

No hearing is scheduled for this proposal. A public hearing will be held if any interested person, or his or her duly authorized representative, submits a written request for a public hearing to the Department of Food and Agriculture no later than 15 days prior to the close of the written comment period.

Subject Matter of Proposed Regulations

Shell Egg Food Safety: Inspection of Records, Invoices, and Premises

Sections Affected

Amend section 1358.4 of Title 3 of the California Code of Regulations

Specified Purpose of Each Adoption, Amendment, or Repeal

Existing law, section 27521 of the Food and Agricultural Code authorizes the Department of Food and Agriculture (Department) to assure that healthful and wholesome eggs of known quality are sold in this state; to facilitate the orderly marketing of shell eggs in a uniform manner; and to prevent the marketing of deceptive or mislabeled containers of eggs.

Existing law, section 27531 of the Food and Agricultural Code, authorizes the Department to adopt regulations pertaining to the preparation for market and marketing of shell eggs.

Existing law, section 27533 of the Food and Agricultural Code, specifies that regulations adopted pursuant to Chapter 1, Part 4, Division 12, relating to egg shell surveillance inspection shall be consistent with any federal standards or procedures promulgated by the United States Department of Agriculture on that subject.

Existing law, section 27541 of the Food and Agricultural Code, requires any California egg producer or egg handler, or any out-of-state egg producer or egg handler selling eggs in California, to register with the Department. An egg handler is defined in section 27510 of the Food and Agricultural Code to mean a person engaged in the business of producing, candling, grading, packing, or preparing shell eggs for market or who engages in the operation of selling or marketing eggs that he or she has produced, purchased, or acquired from a producer, or which he or she is marketing on behalf of a producer, whether as owner, agent, or employee.

Existing law, section 27571 of the Food and Agricultural Code, authorizes the establishment of an advisory committee on matters pertaining to standards for shell eggs, including egg quality and sampling, inspection, fee adjustment for administrating and enforcement purposes, budget administration, regulation adoption, and voluntary food safety programs in accordance with section 27573 of the Food and Agricultural Code.

In accordance with Food and Agricultural Code section 27680, the Department routinely performs audits and inspection of eggs and egg products whether in-state or out-of-state including the records relating to eggs of any person registered by the Department at that location as the Department considers necessary. The Department may contract with another

agency of state government or with a state department of agriculture or other similar agency where the out-of-state registrant is domiciled to conduct the inspection.

A producer is defined in section 27510.1 of the Food and Agricultural Code to mean a person engaged in the business of producing eggs from domesticated fowl for human consumption. Because an egg producer as defined, is inclusive of the activities which define an egg handler, the Department is using the term "egg registrant" throughout this proposal, as it pertains to both an egg handler and egg producer.

This proposal pertains to all egg registrants [producers and handlers] who market shell eggs and egg products in California in accordance with sections 27531 and 27541 of the Food and Agricultural Code. This proposal amends the existing record keeping requirements in section 1358.4, of Title 3 of the California Code of Regulations by expanding upon the requirements to include the inspection of not only records and invoices but all documents relating to shell egg food safety and the inspection of the premises where egg-laying hens are housed if the eggs from those hens will be shipped into or within California and sold to California consumers in compliance with existing section 1350 of Title 3 of the California Code of Regulations.

The Department has conducted a search of applicable existing statutes and regulations relating to shell egg food safety procedures. The Department does not believe the proposed regulations are inconsistent or incompatible with existing state regulations.

Problem Intended To Address

The Department needs to augment its existing records and invoices regulatory requirements to include the inspection of all records, invoices and the premises where egg laying hens are housed if the eggs are going to be marketed to California consumers. This proposal is necessary for the inspection and tracking of all shell egg shipments into or within California in accordance with sections 27521, 27531, 27541 and 27680 of the Food and Agricultural Code and section 1350 of Title 3 of the California Code of Regulations, to ensure safe and wholesome shell eggs and shell egg products are marketed in the state that are intended for human consumption.

Statement of Factual Basis and Rationale

The Department's Meat, Poultry and Egg Safety Branch (Branch) licenses and inspects the following meat, poultry and egg production establishments that are exempt from federal (USDA) inspection:

- Meat Processing Establishments that prepare meat and poultry products by curing, smoking for preservation, drying, or rendering for retail sales only, except products of fallow deer, which can be transported and sold in commerce.
- Custom Livestock Slaughterhouses that slaughter cattle, sheep, swine, goats and fallow deer raised or bought live by owners. The meat from cattle, sheep, swine and goats is used by the animal's owner, members of the owner's household, nonpaying guests and employees. It cannot be sold. Fallow deer meat can be transported and sold in commerce.
- Poultry Plants that slaughter species that don't require (non-amenable) federal inspection: rabbits; small game birds such as quail, pheasant, and partridge, or
 - Retail Poultry Plants that sell live poultry and slaughter them for customers or
 - Non-retail Poultry Plants that slaughter or process fewer than 20,000 poultry of all amenable species (chickens, ducks, geese, guineas, squab and ratites) or fewer than 5,000 turkeys a year.

- The branch also trains, licenses and evaluates Poultry Meat Inspectors (PMIs) who inspect poultry and rabbits in licensed poultry plants, Livestock Meat Inspectors (LMIs) who inspect livestock in licensed custom livestock slaughterhouses and Processing Inspectors (PIs) who inspect meat and poultry products in licensed retail meat processing establishments. PMI's, LMI's and PI's also enforce sanitation standards, pest control, humane handling and slaughter, inedible/condemned material control, marking and labeling and record-keeping requirements in licensed plants.

Additionally the branch licenses and inspects the following:

- Renderers who recycle animal carcasses, packinghouse waste and inedible kitchen grease into animal feed ingredients and inedible industrial fats, oils, and other products.
- Collection Centers used for temporary storage of animal carcasses, packinghouse waste and inedible kitchen grease before transport to a licensed rendering plant.
- Dead Animal Haulers who transport carcasses of dead livestock and horses.
- Pet Food Slaughterers who slaughter animals for use as pet food.
- Pet Food Processors who prepare fresh or frozen raw meat products for pet food.
- Pet Food Importers of fresh or frozen raw meat, meat by-products, horsemeat, poultry meat or poultry meat by-products for pet food or horsemeat for human food.
- Egg Safety and Quality Management Program inspects and regulates shell egg quality and production at the wholesale and retail levels.
- Registers transporters of inedible kitchen grease for commercial or personal use.
- Inspection of imported, slaughtered non-amenable poultry species shipped to California from other countries and reviews for approval or disapproval inspection systems of other states and foreign countries desiring to ship slaughtered non-amenable poultry species to California.
- Review sanitation and records at Federally Exempt Establishments (locker plants that cut, wrap and process meat from farm killed livestock; custom livestock slaughterhouses; poultry plants).
- Conducts Compliance Investigations into alleged violations of sections of the Food and Agricultural Code pertaining to the above activities.

This proposal pertains to the Egg Safety and Quality Management (ESQM) program within the Meat, Poultry and Egg Safety Branch. The ESQM serves to provide California consumers with eggs that are wholesome, properly labeled, refrigerated, and of established quality, while maintaining fair and equitable marketing standards in the California egg industry. The program monitors egg quality at production, wholesale, and retail levels, requires persons engaged in the business of marketing eggs in California to be registered, conducts inspections, and provides supervision and training to employees of the County Agricultural Commissioners to ensure consistency and uniform application of standards throughout California. The program also enforces and controls the movement of restricted and inedible eggs through the USDA Shell Egg Surveillance Program. The ESQM is entirely industry-funded through mill assessment and registration fees paid by the in-state and out-of-state egg producers, packers, and shippers

In accordance with Food and Agricultural Code section 27571, the Department has an established Shell Egg Advisory Committee (SEAC) to assist the Secretary in the administration of all matters pertaining to standards for shell eggs including egg quality and sampling, inspection, fee adjustments for administration and enforcement purposes, budget administration, regulation adoption, and food safety programs [Food and Agricultural Code

section 27573]. At the January 7, 2015 SEAC meeting, members discussed various issues which included the proposed amendments to the regulations relating to records, invoices, and the inspection of farms and facilities to serve to assist and ensure that producers comply with existing shell egg food safety standards if the shell eggs or shell egg food products are marketing to California consumers.

This regulatory proposal is intended to ensure California egg registrants are in compliance with sections 27521, 27531 and 27541 of the Food and Agricultural Code and section 1350 of Title 3 of the California Code of Regulations. The proposal will serve to ensure that shell eggs and egg products are safe and wholesome for human consumption by implementing record keeping requirements and requiring the inspection of records, invoices, and documents relating to marketing shell eggs and egg products in California, including the inspection of the premises where egg-laying hens are housed if the eggs from those hens are marketed to California consumers to prevent or mitigate the occurrence of food borne illnesses, such as Salmonella, in shell eggs.

The proposal is outlined below.

Amend section 1358.4 of Subchapter 3, Chapter 1, Division 3, of Title 3 of the California Code of Regulations, as follows:

1) Amend the heading of section 1358.4.

The Department needs to amend the heading of this section to clearly state the purpose and contents of the section, as it relates to not only the retention of records and invoices of egg handlers and producers, but the inspection of records, invoices, documents, facilities and premises where egg-laying hens are housed if the eggs from those hens are marketed to California consumers.

2) Add subsection (a) to section 1358.4.

The Department is adding a new subsection (a) to clearly define who is affected by the records retention requirements and the inspection of the records, invoices, documents and the shell eggs and egg products, including the premises where egg laying hens are housed if the eggs from those hens are marketed to California consumers in accordance with sections 27521, 27531, 27541 and 27680 of the Food and Agricultural Code and section 1350 of Title 3 of the California Code of Regulations.

3) Re-letter former subsection (a) to read subsection (b) of section 1358.4.

The Department is making a nonsubstantive formatting change in the capitalization of the words "department" and "section" for consistency with regulations under Title 3 of the California Code of Regulations.

4) Re-letter former subsection (b)(1), (2) and (3) to read subsection (c)(1), (2) and (3) of section 1358.4.

No changes are proposed to this subsection at this time except the re-lettering for consistency purposes.

5) Re-letter former subsection (c) to read subsection (d) of section 1358.4.

No changes are proposed to this subsection at this time except the re-lettering for consistency purposes.

6) Add new subsection (e) and (e)(1) and (2) to section 1358.4.

The Department is adding new requirements for the inspection of records, invoices, documents and premises where egg-laying hens are housed if the eggs from those hens are marketed to California consumers, in compliance with existing regulation section 1350.

Section 1350 of Title 3 of the California Code of Regulations, is in place to prevent, mitigate and control the spread of Salmonella infection or salmonellosis, which is a bacterial disease of the intestinal tract in humans and animals. *Salmonella enteritidis* (SE) is the contamination of shell eggs during egg production. Salmonella is a group of bacteria that cause typhoid fever, food poisoning, gastroenteritis, enteric fever and other illnesses. People become infected mostly through contaminated water or foods, especially meat, poultry and eggs. Salmonella can be fatal to persons with weakened immune systems, or to infants and children in some case, but some severe cases can be affectively treated with antibiotics. Salmonella live in the intestines of birds, animals and humans. Most human infections are caused by eating food or drinking water that has been contaminated by feces (excrement). The most common ways of contracting Salmonella are from (1) uncooked meat and poultry; (2) uncooked eggs - Salmonella can be present in the eggs when laid if the chicken is infected, or; (3) lack of hygiene - kitchen surfaces that are not kept clean, lack of hand washing procedures during food preparation or handling raw meats or poultry. A person with contaminated hands can pass the infection on to other people by touching them, or touching surfaces which others then touch.

Therefore, in order to assist registered egg registrants with implementing SE prevention measures on farms and facilities and to serve to ensure compliance with the Department's statutes and regulations for shell egg food safety, the Department must clarify and specify the records, invoices, and all related documents that the Department or a certifying agent [e.g., United States Department of Agriculture (USDA) inspectors, contracted employees, and other authorized governmental representatives] will need to access during their audits and inspections. The Department routinely works with federal inspectors from the USDA and contracts with county inspectors and other state and federal governmental officials to perform inspections of the containers of shell eggs and egg food products that are intended for human consumption. The same inspectors would need access to not only the records, invoices and documents, but also the premises where the egg-laying hens are housed.

The Department is requiring the retention of all records, invoices and documents to be kept by egg registrants for a minimum of three years from the date the shell eggs and shell egg products are packaged for transport within or into California. This is needed in the event a food borne illness outbreak occurs, investigators at the local, state, and/or federal level will return to the egg handler as identified by the processing plant number to review the (business) records to further identify where the eggs were first processed. The Department believes that the three-year retention of records is reasonable as any necessary investigation into a food borne illness outbreak would may require inquiry into records up to, but no longer than, the period of three years. The maintenance of records is a critical piece to solving and ceasing the spread of food borne illnesses.

Additionally, it is necessary for the Department or a certifying agent to have access to the premises of the farm and facility where the eggs are produced and processed for transport within or into California for marketing to California consumers to ensure they are implementing SE prevention and surveillance measures. The inspections of the premises and environment will serve to ensure the health of the egg laying hen and the wholesomeness of

the shell eggs and shell egg products in accordance with sections 27521, 27531 and 27541 of the Food and Agricultural Code.

7) Add new subsection (f) to section 1358.4.

The Department is specifying the types of documents and the premises of a farm or facility that would require inspection by the Department or certifying agent to ensure the tracking of all shipments of shell eggs within or into California, as well as assuring the premises are in compliance with the Departments statutes and regulations relating to shell egg food safety. The inspection of records will ensure proper assessments are made on the shell eggs and egg products that are intended for sale in California, and that the number or quantity shipped to California matches the number that was tracked from the farm or facility. It will also provide the necessary trace-back to the farm or facility should a disease outbreak occur, such as, Salmonella. The inspection of the premises where shell eggs are produced, processed and packages will serve to ensure the eggs are healthful and wholesome and that the environment where the egg-laying hens are housed will serve to reduce the likelihood of Salmonella in shell eggs that are destined for the marketplace for human consumption.

8) Add new subsection (f)(1) to section 1358.4.

The Department is requiring the inspection of pre-harvest and post-harvest SE testing and grade out reports of shell eggs and egg products sold, labeled, or represented as California Shell Egg Food Safety Compliant, and sampling for analysis, including the inspection and audit of any related areas, records and egg containers.

The two most common ways SE can be transmitted to eggs, vertical transfer and horizontal transfer. Vertical transfer means laying hens and pullets ingested SE (most likely from contaminated feed) which translocated from the gastrointestinal tract of affected birds to their reproductive tracts, hence to their developing eggs. Some freshly produced eggs can be contaminated before the shell forms around their contents. An infected hen can lay many eggs without SE and only occasionally lay an egg contaminated with the *Salmonella* bacterium before returning to lay normal, uninfected eggs. Horizontal transfer means SE in the environment (i.e., manure) was exposed and subsequently penetrated the shells of freshly laid eggs. Other factors that may influence horizontal transfer include the sanitation of cages and grounds, heavy rodent populations, and the age of the flock (older flocks are more likely to have SE than younger flocks). Most types of *Salmonella* live in the intestinal tracts of animals and birds and are transmitted to humans by contaminated foods of animal origin.

To verify the egg registrant has complied with the testing requirement for pullets and egg laying hens and the environment where eggs are produced, and to track the number of shell eggs packaged for retail [or for processing into other egg food products], there is a need to access the producer's records, documents, egg containers, and take samples for analysis of the environment where the egg laying hens are housed. The inspection requirements will serve to prevent, mitigate and maintain a tracking system of any potential outbreaks of food borne illnesses, such as Salmonella, in shell eggs and shell egg food products and in accordance with sections 27521, 27531, 27541 and 27680 of the Food and Agricultural Code and regulation 1350 of Title 3 of the California Code of Regulations.

Additionally, the Department conducts routine inspections of "grade out" reports, which show the amount of eggs collected from a laying house, how many of those eggs were sized and graded and how many were not graded, due to defects. This serves to track the eggs that will ultimately be packaged for sale or for further processing into egg food products that may be sold to California consumers.

9) Add new subsection (f)(2) to section 1358.4.

The Department is requiring the inspection of pastures, fields, equipment, and structures where shell eggs or egg products may be produced, processed, handled, stored or transported, including the inspection of the enclosure area for egg laying hens.

The reason for the inspection of the grounds, including equipment and structures, is that SE contamination can exist in the environment (i.e., manure) and subsequently penetrate the shells of freshly laid eggs. However, as stated, other factors that may influence horizontal transfer of SE such as the sanitation of cages and grounds, heavy rodent populations, and the age of the flock (older flocks are more likely to have SE than younger flocks). Additionally, regulation section 1350 requires egg-laying hens be housed in minimum enclosures to serve to ensure the health of the flock. The Department needs to gain access to all areas of the pastures, fields, equipment and structures to ensure the egg registrants are in compliance with SE prevention measures and the minimum enclosure requirements to promote shell egg food safety. The inspections by the Department [or certifying agent] will serve to ensure the shell eggs transported within or into California meet the requirements of the Department's existing statutes and regulations relating to shell egg food safety. The inspections of the facilities, pastures, and enclosures will serve to prevent and mitigate any potential outbreaks of food borne illnesses, such as Salmonella, in shell eggs and shell egg food products in accordance with sections 27521, 27531, 27541 and 27680 of the Food and Agricultural Code and section 1350 of Title 3 of the California Code of Regulations.

10) Add new subsection (f)(3) to section 1358.4.

The Department [or certifying agent] needs to inspect all documents and records pertaining to the production, processing, storage, transportation, or handling of shell eggs or shell egg products identified as California Shell Egg Food Safety Compliant.

The Department needs to inspect and track all shell eggs and shell egg products that are destined for the California marketplace, whether the eggs were produced in-state or out-of-state, to ensure all statutes and regulations are met. The ESQM enforces and controls the movement of restricted and inedible eggs through the USDA Shell Egg Surveillance Program. The ESQM is entirely industry-funded through mill assessment and registration fees paid by the in-state and out-of-state egg producers, packers, and shippers. The inspection of these records as specified, will enable the Department to verify egg registrants are in compliance with all applicable statutes and regulations for the ESQM program. Additionally, it will identify the eggs that are marketed in the state, as not all producers are processing shell eggs for in-state use, but may be transported out of state. If the shell eggs and shell egg products are marketed to California consumers, the label on all containers must be verified that they include a statement that they are California shell egg food safety complaint in accordance with section 1354 of Title 3 of the California Code of Regulations.

11) Add new subsection (e)(4), (5) and (6) to section 1358.4.

During the Department's audit and inspections, they will need to verify that the egg producer and handler is registered with the Department to market shell eggs and shell egg food products in California in accordance with Food and Agricultural Code section 27541. The Department is also requiring to inspect the shell egg and egg product sales records to verify that the number or quantity that was shipped into [or within] California to a distribution and retail location, matches the number reported to the Department [registration fees are not based on the amount of egg production, unlike collected assessment fees, which are based on the volume of eggs marketed within California]. This will not only ensure the assessments

are properly tracked and charged to each producer but will ensure the egg shipments can be traced to their source in the event of a food borne illness outbreak.

Additionally, the Department needs to verify the quantity processed from each layer facility or farm unit, the size of the layer facility unit, the number of layers, and the date of harvest and production, to ensure the egg registrant is in compliance with regulation section 1350. That section requires that registered egg producers or handlers with 3,000 or more laying hens whose shell eggs are not processed with a treatment such as pasteurization to ensure safety, shall incorporate SE prevention measures on their farms and in their facility operations. This requirement will serve to ensure the premises where egg-laying hens are housed are free from bacteria that could cause food borne illnesses for consistency compliance with regulation section 1350, and provide a means to conduct a trace-back to a specific farm or facility, and to the flock that could be the source of any food borne illness outbreak.

12) Add new subsection (e)(7) to section 1358.4.

The Department is requiring information on the name and address of all suppliers of shell eggs and egg food products and the date of transaction, unless the layers were hatched and raised by the egg registrant for each shipment of eggs destined for the California marketplace. This will ensure the Department can track the assessments charged to registrants and provide further means to conduct a trace-back to a specific supplier and the date of the transaction of the shell eggs and egg food products in instances of any food borne illness outbreak, such as Salmonella.

13) Add new subsection (e)(8) to section 1358.4.

The Department is requiring the inspection of the documentation of a treatment for shell eggs to achieve at least a 5-log destruction of SE as defined in 21 CFR section 118.3 for shell eggs marketed as pasteurized or an equivalent process. This requirement is needed to ensure egg registrants are in compliance with regulation section 1350, and they would be exempt from SE prevention measures if they use a treatment such as pasteurization for their shell eggs that are intended for human consumption, and are marketed to California consumers. The reason for this is because treatments such as pasteurization use a heat process to destroy bacteria, including Salmonella. Pasteurized eggs are currently sold to consumers in the marketplace and are also exempt from the federal Egg Safety Rule [21 CFR Part 118]. The eggs are stamped with the USDA certification, which is a red "P" on each egg in a carton or container of eggs.

14) Add new subsection (e)(9) and (10) to section 1358.4.

The Department is requiring the inspection of documentation to show the egg registrants are implementing SE prevention measures in accordance with the Food and Drug Administration, Department of Health and Human Services' requirements for the production, storage, and transportation of shell eggs as specified in 21 CFR Part 118. The Department is requiring the inspection of all documentation to show the egg registrants are in implementing an SE environmental monitoring program.

This requirement is needed for the Department to verify egg registrants are in compliance with regulation section 1350. That section references 21 CFR Part 118 in accordance with Food and Agricultural Code section 27533. As eggs move from the farm to the table, state governments share egg safety responsibilities with the federal government. USDA assumes responsibility for enforcing refrigeration requirements for shell eggs during storage and transportation and the FDA retains overall responsibility for shell egg safety as well as for

egg products after they leave the processing plant. The FDA has sole federal authority for regulating food safety on egg farms. They conduct on-farm investigations when an outbreak of food borne illness has been identified. Once the source of an outbreak is determined, FDA requires that eggs from SE-positive flocks be diverted from sale to the public and destroyed or sent to egg breaking plants for pasteurization.

The FDA Egg Safety Rule [21 CFR Part 118] requires many but not all of the prevention activities that were previously adopted through state voluntary quality assurance programs. It requires that pullets must be raised under SE-monitored conditions to reduce the occurrence of SE; producers must implement biosecurity measures for farms and poultry houses; control rodents, flies, and other pests that may spread disease; implement environmental sampling and testing to monitor flock health; clean and disinfect facilities and grounds; refrigerate eggs during transport; sample and test eggs at regular intervals, and maintain current and accurate records of operations. State Egg Quality Assurance Programs (EQAPs) are voluntary programs based on Hazard Analysis Critical Control Point (HACCP) system principles and designed around production, management, and monitoring practices implemented to decrease the risk of SE illness. EQAP's have been found to play a major role in the reduction of Salmonella illness in the United States.

The Department must verify all egg registrants are in compliance with the federal Egg Safety Rule, and the components from California's shell egg food safety regulations [section 1350] which no longer requires a voluntary egg quality assurance program, but is now mandated under California regulations. The inspection of the records and documents will serve to ensure the shell eggs and egg food products are uniformly marketed to California consumers for consistency and compliance with both state and federal requirements.

15) Add new subsection (e)(11) to section 1358.4.

The Department is requiring the inspection of documentation to show the egg registrants are implementing and maintaining a vaccination program or documentation of a demonstrated equivalent SE vaccination program approved by the Department. Most standard vaccination programs as implemented by a state licensed or accredited veterinarian include, at a minimum, two attenuated live vaccinations and one killed or inactivated vaccination. Inactivated vaccines use killed organisms to stimulate the immune system to protect against subsequent infection with live organisms that cause disease. Inactivated vaccines stimulate the development of antibodies, which provide protection to the pullet/hen and reduce the likelihood of systemic infections that can spread SE to the eggs destined for human consumption. Attenuated live vaccines are made from pathogens that are still viable but do not cause disease so they more closely resemble a natural infection and therefore stimulate a more lasting immunity. All vaccines are approved for use by specific routes and doses, and the instructions are detailed on the product data sheet.

A vaccination program is another proactive way to help protect a flock against infections by helping to reduce infections in individual chickens, helps to reduce the number of infected flocks and helps minimize the amount of Salmonella shed into the environment. Vaccinating poultry flocks for Salmonella will help reduce the potential risk of human SE outbreaks. The Department needs to ensure egg registrants are in compliance with SE vaccination requirements for consistency and compliance with regulation section 1350 to further serve to ensure shell egg food safety for shell eggs and shell egg food products marketed to California consumers.

16) Add new subsection (e)(12) to section 1358.4.

The Department is requiring the inspection of all company shipping invoices, bills of lading, and/or shipping manifests shall contain a statement of whether the shipment is California Shell Egg Food Safety compliant. The statements [or abbreviation, as specified] shall be clearly legible handwriting or a stamp may be used. The requirements are needed for consistency and compliance with both regulation sections 1350 and 1354.

The Department monitors compliance with official United States standards, grades, weight classes, so forth, by egg packers who do not use the United States Department of Agriculture, Agricultural Marketing Service (USDA/AMS) shell egg grading services pursuant to Food and Agricultural Code section 27532. Egg cartons from these plants will bear a grade mark however without the USDA shield.

Regulation section 1354 requires a labeling statement on egg containers for persons marketing eggs in California. The USDA is only involved in grading eggs, not enforcing label requirements for eggs sold in California. Therefore, the labeling statement on each carton or container of eggs is to indicate how the eggs were produced. The label statement applies to the carton of eggs stating that it meets egg food safety standards as established by regulation section 1350.

Any packed shell eggs that fail to have the required markings will be put off-sale, and regulation section 1354 cited on the non-compliance tag that is used by program inspectors. Food and Agricultural Code section 27641 states, in part, that "...it is unlawful for any person to prepare, pack, place, deliver for sale, load, ship, transport, or sell eggs in the shell unless the eggs and their containers conform to all of the requirements of the chapter or any regulation adopted pursuant to this chapter". Therefore, the eggs and their containers would be put off-sale if the producer or producer/packer failed to comply with the required labeling standards as specified in this proposal.

17) Amend the "note" portion of section 1358.4.

The Department is also amending the authority and reference citations for the section pursuant to Government Code section 11349.1 and section 14 of Title 1 of the California Code of Regulations.

Technical, Theoretical, and Empirical Study, Report, or Similar Document

1. Economic Impact Assessment
2. Shell Egg Advisory Committee meeting minutes, January 7, 2015
3. Excerpt of *General U.S. Statistics, Egg Industry Fact Sheet, Revised February 2015*, showing national egg production numbers and California's national ranking.
4. Sample *Bill of Lading* to show how shell eggs containers are labeled and packaged for shipment to distribution centers for sale in California [or transported through California to another state].

Statement of Justification for Prescriptive Standards

This regulation does not mandate the use of specific technologies or equipment or prescriptive standards.

Consideration of Reasonable Alternatives

No reasonable alternative considered or that has otherwise been identified and brought to the attention of the Department would either be more effective in carrying out the purpose for which the action is proposed or would be as effective as and less burdensome to affected private

persons than the proposed action, or would be more cost effective to affected private persons and equally effective in implementing the statutory policy or other provision of law. This proposal is necessary for the prevention and mitigation of any potential outbreaks of food borne illnesses, such as Salmonella, in shell eggs and shell egg food products in accordance with sections 27521, 27531 and 27541 of the Food and Agricultural Code and section 1350 of Title 3 of the California Code of Regulations.

Reasonable alternatives the Department has identified that would lessen any adverse impact on small business

No alternatives were identified by the Department and no adverse impact to small businesses is anticipated. This proposal is necessary for the prevention and mitigation of any potential outbreaks of food borne illnesses, such as Salmonella, in shell eggs and shell egg food products in accordance with sections 27521, 27531, and 27541 of the Food and Agricultural Code and section 1350 of Title 3 of the California Code of Regulations.

Benefits of the Proposed Regulations

This proposal benefits the health and welfare of the citizens of California by serving to ensure only healthful and wholesome eggs are marketed to consumers in accordance with Food and Agricultural Code section 27521. This proposal provides an additional mechanism for disease traceability that are critical to solving and ceasing food borne illness events, such as Salmonella in shell eggs, which will protect the health and welfare of the public.

The specific strain of Salmonella, as stated in this proposal, *Salmonella enteritidis* (SE) is the contamination of shell eggs during egg production. SE is among the leading bacterial causes of food borne illness in the United States and shell eggs are the primary source of human SE infections. The purpose of this proposal is to ensure egg registrants are in compliance with existing recording keeping requirements, which will include the Department's inspection of all records and invoices and the premises where egg laying hens are housed if the eggs from those hens are marketed to California consumers to prevent or mitigate any potential outbreaks of food borne illness. Shell eggs from hens housed on a farm or facility that implements SE prevention measures in compliance with existing section 1350 of Title 3 of the California Code of Regulations, will serve to reduce or eliminate pathogenic bacteria in shell eggs and in the environment where the egg laying hens are housed.

California consumers and the egg industry would benefit from this proposal as the Department is charged with the mission of assuring that healthful and wholesome eggs of known quality are sold in this state and to facilitate the orderly marketing of shell eggs in a uniform manner in accordance with Food and Agricultural Code section 27521. Monetary benefits would be the potential reduction of the occurrence of SE in shell eggs which could cost the industry millions in recalling contaminated eggs from the marketplace and could lead to illnesses to the public. Nonmonetary benefits would be consumer confidence that comes from knowing that eggs sold in California meet the nation's highest food safety standards and market stability derived from strong food borne illness prevention measures applied equally to all suppliers into California markets.

Facts, evidence, documents, testimony, or other evidence of no significant adverse impact on business

No facts, evidence, documents, testimony, or other evidence of no significant adverse economic impact on business have been identified.

Persons/Businesses affected by this proposal:

- There are approximately 2,130 egg registrants. Of that number 1,854 are in-state and 276 are out-of-state.
- Geographically, commercial egg production in the western United States is concentrated in California, and in the eastern United States is centered in Ohio, Indiana, Iowa, and Pennsylvania. Other States in which major producers are located include Texas, Minnesota, and Georgia. Over 4,000 farm sites have approximately 3,000 or more egg-laying hens, representing 99 percent of all domestic egg-laying hens and accounting for 99 percent of total egg production. There are an additional approximate 65,000 farms with fewer than 3,000 egg-laying hens, accounting for the balance of eggs produced. The Department's inspectors, or a certifying agent, conduct random audits, both in-state and out-of-state, of egg registrants' compliance with specified standards in accordance with Food and Agricultural Code section 27680 and Title 3, California Code of Regulations section 1358.4.

Anticipated compliance requirements as a result of this proposal:

- *Record keeping requirement:*

Egg registrants are required to keep certain records or invoices as specified in existing regulation section 1358.4. This proposal expands upon that requirement by adding that egg registrants shall keep and maintain records, invoices and documents relating to farm and facility operations for at least three years from the date the shell eggs and egg food products are shipped to, or within, California, that are intended for human consumption to California consumers. The Department believes this proposal does not adversely affect businesses or small businesses engaged in marketing eggs in California. The Department believes the three-year requirement is necessary and is reasonable as any needed investigation into a food borne illness outbreak would require inquiry into records up to, but no longer than, the period of three years. This requirement is not anticipated to incur increased costs to businesses as record keeping is an existing standard business practice for persons marketing eggs in California. The Department's inspectors [or certifying agents] conduct random audits, both in-state and out-of-state, of egg registrants' compliance with specified standards in accordance with Food and Agricultural Code section 27680 and Title 3, California Code of Regulations section 1358.4. The maintenance and inspections of all records, invoices, and related documents provides an additional mechanism for disease traceability that are critical to solving and ceasing food borne illness events, such as Salmonella in shell eggs, which will protect the health and welfare of the public.

Results of Economic Impact Assessment

The Department has made an initial determination that the proposed regulatory action will not have any significant, statewide adverse economic impact directly affecting businesses, including the ability of California businesses to compete with businesses in other states by making it more costly to produce goods or services, and that it will not create or eliminate jobs or occupations. The proposal does not affect the creation of new businesses or the elimination of existing businesses within the State of California, and does not affect the expansion of businesses currently doing business within the State of California. The proposed regulation benefits human health, worker safety, and the environment by serving to verify egg registrants' compliance with pathogen reduction intervention measures that are intended to ensure that shell eggs and egg products are safe and wholesome for human consumption. This proposal is necessary for the prevention and mitigation of any potential outbreaks of food borne illnesses, such as Salmonella, in shell eggs and shell egg food products in accordance with sections 27521,

27531, and 27541 of the Food and Agricultural Code and section 1350 of Title 3 of the California Code of Regulations.

Duplication or Conflicts with Federal Regulations

This proposal does not duplicate or conflict with federal regulations. The Department believes this proposal is consistent with federal standards and necessary to reduce the occurrence of SE in shell eggs that are marketed to California consumers. There are related federal regulations concerning disease control and flock management in poultry under 7 CFR sections 56.76 and 56.77, 9 CFR Parts 56, 145, 146 and 147 and 21 CFR Parts 16 and 118.