

### **TITLE 3. FOOD AND AGRICULTURE**

**NOTICE IS HEREBY GIVEN** that the Department of Food and Agriculture (Department) is proposing to take the action described in the Informative Digest. A public hearing is not 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 no later than 15 days prior to the close of the written comment period. Any person interested may present statements or arguments in writing relevant to the action proposed to the person designated in this Notice as the contact person beginning May 1, 2015 and ending at 5:00 p.m., June 15, 2015. Following the public hearing, if one is requested, or following the written comment period if no public hearing is requested, the Department, upon its own motion or at the instance of any interested party, may thereafter adopt the proposals substantially as described below or may modify such proposals if such modifications are sufficiently related to the original text. With the exception of technical or grammatical changes, the full text of any modified proposal will be available for 15 days prior to its adoption from the person designated in this Notice as contact person and will be mailed to those persons who submit written or oral testimony related to this proposal or who have requested notification of any changes to the proposal.

Authority and Reference: Pursuant to the authority vested by sections 407, 27531, and 27533, Food and Agricultural Code, and to implement, interpret or make specific sections 27510, 27510.1, 27518, 27521, 27541, 27573, 27631, 27637, and 27680 of said Code, the Department is proposing to amend section 1358.4 of Subchapter 3, Chapter 1, Division 3, of Title 3 of the California Code of Regulations, to read as follows:

#### **INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW/BENEFITS**

Existing law, section 27521 of the Food and Agricultural Code authorizes the 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.

Anticipated Benefits of the Proposal: 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.

Consistency and Compatibility with Existing State Regulations: The Department has evaluated this proposal and it is not inconsistent or incompatible with existing state regulations.

Documents Incorporated by Reference: None.

Documents Relied Upon in Preparing Regulations:

- Economic Impact Assessment
- Shell Egg Advisory Committee meeting minutes, January 7, 2015
- Excerpt of *General U.S. Statistics, Egg Industry Fact Sheet, Revised February 2015*, showing national egg production numbers and California's national ranking.
- 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].

## **FISCAL IMPACT ESTIMATES**

Fiscal Impact on Public Agencies Including Costs or Savings to State Agencies or Costs/Savings in Federal Funding to the State: None

Nondiscretionary Costs/Savings to Local Agencies: None

Local Mandate: None

Cost to Any Local Agency or School District for Which Government Code Sections 17500 et seq. Require Reimbursement: None

Business Impact: The Department has made an initial determination that the proposed regulatory action will have no significant statewide adverse economic impact directly affecting California businesses, including the ability of California businesses to compete with businesses in other states. This determination is based on the fact that the 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.

Cost Impacts on Representative Private Persons or Businesses: The Department is not aware of any cost impacts that a representative private person or businesses would necessarily incur in reasonable compliance with the proposed action. 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.

Persons/Businesses affected by the proposal:

- There are approximately 2,130 egg registrants. Of that number 1,854 are in-state and 276 are out-of-state. 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.

Effect on Housing Costs: None

Effect on Small Businesses: The Department's proposal may affect small businesses.

## **RESULTS OF ECONOMIC IMPACT ASSESSMENT**

Impact on Jobs/New Businesses: The Department has determined that this regulatory proposal will not have any impact on the creation of jobs or businesses or the elimination of jobs or existing businesses or the expansion of businesses in California.

The Department has made a determination that this regulatory proposal:

- Will have no 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.
- Will 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.

- Does not impact multiple industries.
- Benefits the shell egg and shell egg food industry by implementing inspection requirements by the Department on egg registrants marketing shell eggs and shell egg food products in California to prevent or mitigate food borne outbreaks, such as, Salmonella in shell eggs 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 regulation to the health and welfare of California residents, worker safety, and the State's environment: The proposed regulation benefits human health and welfare, worker safety, and the environment by serving to verify egg registrants' compliance with pathogen reduction measures that are intended to ensure that shell eggs and shell egg food products are safe and wholesome for human consumption. This proposal benefits the shell egg and shell egg food products industry by implementing inspection and audit criteria for shell eggs and shell egg food products to ensure safe and wholesome shell eggs and shell egg products are marketed in the state.

This proposal will promote safe handling of shell eggs and shell egg food products by the industry workers as the Department will conduct an inspection of the premises where egg laying hens are housed and where shell eggs are produced and processed in accordance with section 1350 of Title 3 of the California Code of Regulations. This proposal will serve to ensure farms and facilities have mechanisms 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 above determinations are based on the fact this regulatory 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.

Occupations/Businesses Impacted: The Department has made an initial determination that this regulatory proposal will impact all persons required to be registered with the Department as an egg producer or egg handler, or any out-of-state egg producer or egg handler selling eggs in California pursuant to section 27541 of the Food and Agricultural Code.

Business Reporting Requirement: The regulation does not require a report, which shall apply to businesses.

Comparable 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.

## **CONSIDERATION OF ALTERNATIVES**

The Department must determine that no reasonable alternative considered or that has otherwise been identified and brought the attention of the Department would be more effective in carrying out the purpose for which the action is proposed or would be as effective 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 regulatory 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.

Any interested person may present statements or arguments orally or in writing relevant to the above determinations at the hearing (if a hearing is requested) or during the written public comment period.

## **INITIAL STATEMENT OF REASONS AND INFORMATION**

The Department has prepared an initial statement of reasons for the proposed action and has available all the information upon which the proposal is based.

## **TEXT OF PROPOSAL**

Copies of the exact language of the proposed regulations and of the initial statement of reasons, and all the information upon which the proposal is based, may be obtained by contacting the persons named below or by accessing the Department of Food and Agriculture's website as indicated below in this Notice.

## **AVAILABILITY AND LOCATION OF THE FINAL STATEMENT OF REASONS AND RULEMAKING FILE**

All the information upon which the proposed regulations are based is contained in the rulemaking file, which is available for public inspection by contacting the persons named below.

Any person may obtain a copy of the final statement of reasons once it has been prepared, by making a written request to the contact persons named below or by accessing the website listed below.

### **CONTACT PERSONS**

Inquiries concerning the substance of the proposed regulations, or any written comments concerning this proposal are to be addressed to the following:

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The backup contact person is:

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Website Access: Materials regarding this proposal can be found by accessing the following Internet address: <http://www.cdfa.ca.gov/ahfss/regulations.html>