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 July 6, 2012 and ending at 5:00 p.m., August 20, 2012. 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, 27533 and 46002 of the Food and Agricultural Code, and to implement, interpret or make specific sections 27510, 27510.1, 27518, 27521, 27541, 27573, 27631, 27627 and 27644, of said Code, the Department proposes to adopt section 1350 and amend section 1354 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

The Department of Food and Agriculture (Department) proposes to adopt section 1350, and amend section 1354 of Subchapter 3, Chapter 1, Division 3, of Title 3 of the California Code of Regulations. The purpose of this proposal is to ensure that eggs are produced in a uniform manner to ensure the quality and safety of shell eggs sold for human consumption by reducing the occurrence of *Salmonella enterica* serotype Enteritidis (SE) contamination of shell eggs during egg production.

This proposal would require any person registered with the Department to engage in business in California as an egg producer or egg handler, and any out-of-state egg handler or egg producer selling eggs in California to (1) implement SE reduction measures consistent with state and federal requirements; (2) comply, within a commercially reasonable time frame, with a minimum numeric enclosure requirement for egg-laying hens if the eggs produced from those hens are sold in California; and (3) comply with specified egg container label requirements to include an affirmative label statement on every package of shell eggs that are for sale in California, certifying that those eggs were sold in compliance with these standards.

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 relating to the preparation for market and marketing of shell

eggs as determined to be reasonably necessary to carry out the purposes of Chapter 1, Part 4, Division 12 of the Food and Agricultural Code.

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 27573 of the Food and Agricultural Code established an advisory committee to the Secretary of the Department on all matters pertaining to standards for shell eggs, the quality of shell eggs; recommendations concerning sampling; uniformity of inspection; adjustment of fees for proper administration and enforcement; annual budget for the administration and enforcement of the chapter and all matters pertaining to this chapter or regulations adopted pursuant thereto; and, components of the Egg Quality Assurance Plan, a voluntary food safety program, that are consistent with and promote the purposes of the chapter.

Existing law, section 27637 of the Food and Agricultural Code specifies that it is unlawful for a person to make any false, deceptive, or misleading statements concerning the quality, size, weight, condition, source, origin, or any other matter relating to eggs.

Existing law, section 27541 of the Food and Agricultural Code specifies that any person engaged in business in California as an egg producer or egg handler, or any out-of-state egg handler or egg producer selling eggs into California, shall register with the Department. 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.

In accordance with the above-noted sections of law, the Department has in place existing regulations specifying the requirements for persons marketing eggs in California under Subchapter 3, Chapter 1, Division 3, of Title 3 of the California Code of Regulations.

The Department is proposing amendments to the requirements for the marketing of eggs in California by adopting section 1350 (shell egg food safety) and amending section 1354 (marking requirements) of Subchapter 3, Chapter 1, Division 3 of Title 3 of the California Code of Regulations. The intent of this proposal is to ensure that eggs are produced in a uniform manner to ensure the quality and safety of shell eggs sold for human consumption.

Based on an initial evaluation, the Department does not believe the proposed regulations are inconsistent or incompatible with existing state or federal 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. The benefits mitigate any potential adverse economic impacts identified in this proposal. SE is among the leading bacterial causes of foodborne illness in the United States, and shell eggs are a primary source of human SE infections. California consumers and the egg industry would benefit from this proposal because 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 and clear labeling of such products.

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 of Food and Agriculture has made an initial determination that the proposed regulatory action will have significant statewide adverse economic impact directly affecting California businesses, including the ability of California businesses to compete with businesses in other states. This initial determination is based on the fact that the proposed regulation imposes mandatory egg safety requirements on California registered egg handlers and producers marketing eggs in California. Due to cost impacts, producers may choose to not market their eggs in the state.

The anticipated compliance requirements are as follows:

- ***Businesses Impacted***: Approximately 1,151 registered egg handlers consisting of 10 processing plants, 608 which are both processing plants and producers, 202 wholesalers, and 331 producers.

  This proposal requires two additional environmental tests and a SE vaccination program than what is currently required by the federal Egg Safety Rule [21 CFR Part 118]. The Department is calculating the cost of the provisions of this proposal, not the current cost for businesses to comply with existing state or federal regulations, or the cost to existing businesses that participate in the voluntary California Egg Quality Assurance Program for SE control, or the cost of the space requirements specified in Health and Safety Code sections 25990 and 25991 for egg-laying hens.

  Estimated costs to businesses to comply with the SE prevention measures by January 1, 2013:

  There are approximately 1,279 farms in California that produce eggs, of that total, the majority of the eggs are produced from 150 farms represented by 28 companies. Nationally, there are approximately 5,098 farms and a majority of those eggs produced are from 69 farms. There are approximately 20 million hens in California and 14 million out-of-state hens producing eggs for sale in California. Out-of-state facilities contribute about 40% of all eggs sold in California.

  - Testing of chick papers at delivery for about 8,000-30,000 chicks total about $35 per truck (a farm can receive about 100,000 chicks per delivery)

- The cost for SE control and surveillance is about $0.12 cents per hen (11 cents for vaccination and one cent for environmental testing)
- Annual costs of SE environmental testing and vaccination are approximately $1,413,320 for producers

Costs to businesses to implement the minimum enclosure size requirements for egg-laying hens by January 1, 2015:

The implementation date of January 1, 2015 was set to avoid conflict with Health and Safety Code section 25996. The space requirements specified in this proposal were set to be consistent with the European Union (EU) standard, but do not conflict with Health and Safety Code sections 25990 and 25991. Therefore, the enclosure requirements of this proposal impose minimal to non-existent additional costs to businesses, and are not included in the cost impacts to businesses. It is not the intent of the Department to capture costs already imposed by other state or federal laws or regulations.

The businesses impacted by the enclosure requirements are approximately 1,279 egg producing farms in California that total the majority of the eggs that are produced from 150 farms represented by 28 companies. Nationally, there are approximately 5,098 farms and a majority of those eggs produced are from 69 farms. There are approximately 20 million hens in California and 14 million out-of-state hens producing eggs for sale in California. Out-of-state facilities contribute about 40% of all eggs sold in California.

- The Department has made an initial determination that there are no adverse economic impacts to businesses to comply with the labeling requirements under section 1354 as amended by this proposal, in regards to adding specified wording or statements to existing labels on all containers of eggs sold in California. The extended implementation date of January 1, 2015 allows for stockpiled materials to be exhausted and new packaging to be obtained.

- *Registration costs:* There are existing application and registration fees in statutes or regulations; however, no new registration fees are imposed by this proposal.

- *Paperwork/Reporting:* There are no new reporting requirements under this proposal. The Department is proposing an expanded labeling statement on containers of all eggs sold in California. It is anticipated any costs associated with the labeling requirements would be negligible, as producers are already complying with specified labeling requirements pursuant to existing regulation section 1354, and the implementation date of January 1, 2015 allows for the depletion of current packaging inventories.

- *Record-keeping:* This proposal may incur additional record-keeping requirements due to the expanded labeling requirement on all containers of eggs to ensure compliance with this proposal, as well as records of environmental testing and vaccinations. However, the records are not required to be sent to the Department. The Department would conduct audits and inspections of facilities to ensure compliance with the requirements as specified in this proposal. Any additional record-keeping costs are anticipated to be negligible since record-keeping is a standard business practice for persons marketing eggs in California.

Impact on Jobs/New Businesses: The Department has determined that this regulatory proposal will impact on the creation of jobs or businesses or the elimination of jobs or existing businesses or the expansion of businesses in California.

Cost Impacts on Representative Private Persons or Businesses: The Department of Food and Agriculture is aware of the cost impacts that a representative private person or businesses would necessarily incur in reasonable compliance with the proposed action. The anticipated compliance requirements are as follows:

- ***Businesses Impacted***: Approximately 1,151 registered egg handlers consisting of 10 processing plants, 608 which are both processing plants and producers, 202 wholesalers, and 331 producers.

  This proposal requires two additional environmental tests and a SE vaccination program than what is currently required by the federal Egg Safety Rule [21 CFR Part 118]. The Department is calculating the cost of the provisions of this proposal, not the current cost for businesses to comply with existing state or federal regulations, or the cost to existing businesses that participate in the voluntary California Egg Quality Assurance Program for SE control, or the cost of the space requirements specified in Health and Safety Code sections 25990 and 25991 for egg-laying hens.

  Estimated costs to businesses to comply with the SE prevention measures by January 1, 2013:

  There are approximately 1,279 farms in California that produce eggs, of that total, the majority of the eggs are produced from 150 farms represented by 28 companies. Nationally, there are approximately 5,098 farms and a majority of those eggs produced are from 69 farms. There are approximately 20 million hens in California and 14 million out-of-state hens producing eggs for sale in California. Out-of-state facilities contribute about 40% of all eggs sold in California.

  - Testing of chick papers at delivery for about 8,000-30,000 chicks total about $35 per truck (a farm can receive about 100,000 chicks per delivery)
  - The cost for SE control and surveillance is about $0.12 cents per hen (11 cents for vaccination and one cent for environmental testing)
  - Annual costs of SE environmental testing and vaccination are approximately $1,413,320 for producers

  Costs to businesses to implement the minimum enclosure size requirements for egg-laying hens by January 1, 2015:

  The implementation date of January 1, 2015 was set to avoid conflict with Health and Safety Code section 25996. The space requirements specified in this proposal were set to be consistent with the EU standard, but do not conflict with Health and Safety Code sections 25990 and 25991. Therefore, the enclosure requirements of this proposal impose minimal to non-existent additional costs to businesses and are not included in the cost impacts to businesses. It is not the intent of the Department to capture costs already imposed by other state or federal laws or regulations. The businesses impacted by the enclosure requirements are: Approximately 1,279 farms in California produce eggs, of that total, the majority of the eggs are produced from 150 farms represented by 28 companies. Nationally, there are approximately 5,098 farms and a majority of those eggs produced are from 69 farms. There are approximately 20 million hens in California and 14 million out-of-state hens producing eggs for sale in California. Out-of-state facilities contribute about 40% of all eggs sold in California.

- The Department has made an initial determination that there are no adverse economic impacts to businesses to comply with the labeling requirements under section 1354 as amended by this proposal, in regards to adding specified wording or statements to existing labels on all containers of eggs sold in California. The extended implementation date of January 1, 2015 allows for stockpiled materials to be exhausted and new packaging to be obtained.

- *Registration costs:* There are existing application and registration fees in statutes or regulations; however, no new registration fees are imposed by this proposal.

- *Paperwork/Reporting:* There are no new reporting requirements under this proposal. The Department is proposing an expanded labeling statement on containers of all eggs sold in California. It is anticipated any costs associated with the labeling requirements would be negligible, as producers are already complying with specified labeling requirements pursuant to existing regulation section 1354, and the implementation date of January 1, 2015 allows for the depletion of current packaging inventories.

- *Record-keeping:* This proposal may incur additional record-keeping requirements due to the expanded labeling requirement on all containers of eggs to ensure compliance with this proposal, as well as records of environmental testing and vaccinations. However, the records are not required to be sent to the Department. The Department would conduct audits and inspections of facilities to ensure compliance with the requirements as specified in this proposal. Any additional record-keeping costs are anticipated to be negligible since record-keeping is a standard business practice for persons marketing eggs in California.

In making these determinations, the Department has considered alternatives that would lessen any adverse economic impact on businesses. No adverse impacts to small businesses are anticipated for the labeling requirements under regulation section 1354, as amended by this proposal. There is an exemption for small businesses from the federal egg safety rule and additional environmental testing and vaccination as required by this proposal for facilities housing less than 3,000 hens, as specified. There is no exemption from the enclosure requirements for producers marketing eggs in California, regardless of flock size, but the Department anticipates that most flocks with less than 3,000 hens will not need to make enclosure modifications to meet the proposed enclosure standards.

The Department has not considered other alternatives than the proposed regulation and invites the public to submit such proposals during the written comment period. Submissions may include the following considerations:

- The establishments of differing compliance or reporting requirements or timetables that take into account the resources available to businesses.
- The consolidation or simplification of compliance and reporting requirements for businesses.
- The use of performance standards rather than prescriptive standards.
- Exemption or partial exemption from the regulatory requirements for businesses.

<u>Effect on Housing Costs:</u> None

RESULTS OF ECONOMIC IMPACT ASSESSMENT

The Department of Food and Agriculture (Department) has prepared an economic impact assessment that is included in this filing. The total estimated dollar cost of new provisions required by the Department as a result of this proposal is estimated at $1,413,320 annually. The Department has made an initial determination that the proposed regulatory action would have significant statewide adverse economic impact directly affecting businesses, including the ability of California businesses to compete with businesses in other states. This initial determination is based on the fact that the proposed regulation imposes new requirements on egg producers and handlers marketing eggs in California. As part of an economic impact assessment, the Department has determined that the proposal will affect the ability of California businesses to compete with other states by making it more costly to produce goods or services, and that it will create or eliminate jobs or occupations. The Department's proposal does not impact multiple industries. 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.

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

Impact on Jobs/New Businesses: The Department has determined that this regulatory proposal will have significant impact on the creation of new or elimination of existing jobs, businesses or the expansion of businesses in the State.

Occupations/Businesses Impacted: The Department has made an initial determination that this regulatory proposal will impact egg producers or handlers marketing eggs in California as follows: approximately 1,151 registered egg handlers consisting of 10 processing plants, 608 which are both processing plants and producers, 202 wholesalers, and 331 producers.

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. There are related federal regulations concerning disease control and flock management for 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.

Documents Incorporated by Reference: None.

Documents Relied Upon in Preparing Regulations:

- Salmonella Enteritidis Outbreak in Shell Eggs, U.S. Food & Drug Administration, November 30, 2010; summary Egg Safety Final Rule, July 7, 2009
- FDA Nationwide Recall
- FDA Press Release, July 9, 2010, New Final Rule to Ensure Egg Safety, Reduce Salmonella Illnesses Goes Into Effect
- Federal Register/Vol. 74, No. 134/Thursday, July 9, 2009/Rules and Regulations
- Department of Food and Agriculture meeting agendas, April 1 and 4, 2011
- Shell Egg Advisory Committee meeting, February 17, 2010
- CEQAP brochure
- CEQAP Inspection Sheet
- Pullets

- California Egg Sales Exploding, August 2010
- Schwarzenegger: Eat Local, California Eggs are Safe, September 7, 2010
- Food and Agricultural Code sections 27510 and 27510.1
- The Egg Safety Rule at a Glance
- Food and Agricultural Code section 27541
- Health and Safety Code sections 25990, 25991, and 25996
- Farm Welfare Statutes, excerpts
- Shini, 2003: Physiological Responses of Laying Hens to Alternative Housing Systems, International Journal of Poultry Science, 357-360
- *Hen Welfare in Different Housing Systems*, © 2011, Poultry Science Association Inc.
- The Hy-Line W-36 white egg strain is the most common type used for egg production. There are also the Hy-Line brown egg strain and the Hy-Line W-98, which is selected for optimal egg mass.
- *The effect of feeder space allocation on productivity and physiology of Hy-Line W-36 hens housed in conventional cages,* 2009, Poultry Science Association Inc.
- Final Report – CDFA Agreement 09-0854, "*Determination of Space Use by Laying Hens*" by Joy Mench, Department of Animal Science, University of California, Davis, CA 95616
- European Union (EU) Council Directive 1999/74/EC
- 21 CFR section 101.5
- Sample of egg container label
- HR 3798
- Economic Impact Assessment

CONSIDERATION OF ALTERNATIVES

The Department of Food and Agriculture (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.

Alternatives considered at this time that were rejected are as follows:

1) Do nothing and rely on the FDA Egg Safety Rule and potential national enclosure legislation to protect California consumers from food borne illness.

The Department rejected this option because the higher food safety standards currently adopted by California egg farmers on a voluntary basis [the California Egg Quality Assurance Program] include critical additional testing for SE and vaccination for salmonella, adding greater food safety assurance for the California consumer.

With regard to enclosures, Congress introduced House of Representatives (HR) 3798 January 23, 2012, to provide for a uniform national standard for the housing and treatment of egg-laying hens, under the "Egg Products Inspections Act Amendments of 2012". Waiting until the enactment of HR 3798 delays the adoption of clear standards potentially for several years and because this legislation has only recently been introduced, the outcome is uncertain. Currently, as of this writing, HR 3798 would ultimately propose 124 square inches of floor space per white bird when fully implemented as opposed to the use of 116 square inches per white bird as currently utilized by the European Union (EU). At this point there has been very little scientific research and practical experience with a 124 square inch minimum standard; consequently, the Department supports the 116 square inch requirement for egg-laying hens. The Department

believes all three major components (SE surveillance; enclosure requirements; labeling) of this proposal are important to ensure the safety of shell eggs marketed to consumers, and believes a proactive approach is reasonable and necessary to ensure the quality and safety of eggs marketed to California consumers.

2) Enact SE testing and vaccination as proposed and more prescriptive enclosure provisions like those found in the European Union (EU) Council Directive 1999/74/EC, July 19, 1999. The directive, passed in 1999, banned conventional cages in the European Union commencing January 1, 2012 after a 13-year phase-out, and included other various requirements, as specified.

The Department's minimum cage size requirements are consistent with the EU standard, which requires 116 square inches per white hen. However, the Department is not specifying the type of birds housed, only the minimum cage requirements. Since white egg-laying hens account for about ninety percent of the table eggs in the United States, and a significantly larger percent of birds housed in conventional cages, for simplicity purposes the Department is not specifying the type of hen. The Department also rejected the alternative of providing many detailed mandates, such as, floors, lighting, construction, design of feeding systems, and requirements for cage-free facilities as provided by the EU Directive. The Department believes that building structure design, plans for construction, and various related issues may be considered in future regulatory actions, however, at this time, the Department believes that providing minimum standards for a complete SE surveillance program will form a solid basis for any future regulatory actions based on evolving science and standards of the poultry industry.

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 of Food and Agriculture 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:

Tony Herrera, Program Supervisor
Egg Safety and Quality Management
Department of Food and Agriculture
Meat, Poultry, and Egg Safety Branch
Mailing: 1220 N Street
Sacramento, CA 95814
(916) 900-5060
E-mail: Herrera,Tony@CDFA

The backup contact person is:

Nancy Grillo, Associate Analyst
Department of Food and Agriculture
Animal Health and Food Safety Services
Mailing: 1220 N Street
Sacramento, CA 95814
(916) 900-5033
E-mail: Grillo,Nancy@CDFA

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