

# Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

## DEPARTMENT OF AGRICULTURE

### Agricultural Marketing Service

#### 7 CFR Part 981

[Docket No. FV06-981-1 PR]

#### Almonds Grown in California; Outgoing Quality Control Requirements and Request for Approval of New Information Collection

**AGENCY:** Agricultural Marketing Service, USDA.

**ACTION:** Proposed rule.

**SUMMARY:** This proposed rule invites comments on adding outgoing quality control requirements under the administrative rules and regulations of the California almond marketing order (order). The order regulates the handling of almonds grown in California and is administered locally by the Almond Board of California (Board). This proposed rule provides for a mandatory program under the order to reduce the potential for *Salmonella* bacteria in almonds. This action would help ensure that quality almonds are available for human consumption. This proposal also announces the Agricultural Marketing Service's (AMS) intention to request approval of a new information collection issued under the order.

**DATES:** Comments must be received by January 22, 2007. Pursuant to the Paperwork Reduction Act, comments on information collection burden that would result from this proposal must be received by February 5, 2007.

**ADDRESSES:** Interested persons are invited to submit written comments concerning this rule. Comments must be sent to the Docket Clerk, Marketing Order Administration Branch, Fruit and Vegetable Programs, AMS, USDA, 1400 Independence Avenue, SW., STOP 0237, Washington, DC 20250-0237; Fax: (202) 720-8938, E-mail: [moab.docketclerk@usda.gov](mailto:moab.docketclerk@usda.gov), or Internet: <http://www.regulations.gov>. All comments should reference the docket

number and the date and page number of this issue of the **Federal Register** and will be available for public inspection in the Office of the Docket Clerk during regular business hours, or can be viewed at: <http://www.ams.usda.gov/fv/moab.html>.

**FOR FURTHER INFORMATION CONTACT:**

Maureen T. Pello, Assistant Regional Manager, or Kurt J. Kimmel, Regional Manager, California Marketing Field Office, Marketing Order Administration Branch, Fruit and Vegetable Programs, AMS, USDA, Telephone: (559) 487-5901, Fax: (559) 487-5906, or E-mail: [Maureen.Pello@usda.gov](mailto:Maureen.Pello@usda.gov), or [Kurt.Kimmel@usda.gov](mailto:Kurt.Kimmel@usda.gov).

Small businesses may request information on complying with this regulation by contacting Jay Guerber, Marketing Order Administration Branch, Fruit and Vegetable Programs, AMS, USDA, 1400 Independence Avenue, SW., STOP 0237, Washington, DC 20250-0237; Telephone: (202) 720-2491, Fax: (202) 720-8938, or E-mail: [Jay.Guerber@usda.gov](mailto:Jay.Guerber@usda.gov).

**SUPPLEMENTARY INFORMATION:** This proposed rule is issued under Marketing Order No. 981, as amended (7 CFR part 981), regulating the handling of almonds grown in California, hereinafter referred to as the "order." The order is effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601-674), hereinafter referred to as the "Act."

The Department of Agriculture (USDA) is issuing this rule in conformance with Executive Order 12866.

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule is not intended to have retroactive effect. This rule will not preempt any State or local laws, regulations, or policies, unless they present an irreconcilable conflict with this rule.

The Act provides that administrative proceedings must be exhausted before parties may file suit in court. Under section 608c(15) (A) of the Act, any handler subject to an order may file with USDA a petition stating that the order, any provision of the order, or any obligation imposed in connection with the order is not in accordance with law and request a modification of the order or to be exempted therefrom. Such handler is afforded the opportunity for a hearing on the petition. After the

hearing USDA would rule on the petition. The Act provides that the district court of the United States in any district in which the handler is an inhabitant, or has his or her principal place of business, has jurisdiction to review USDA's ruling on the petition, provided an action is filed not later than 20 days after the date of the entry of the ruling.

This proposed rule invites comments on adding outgoing quality control requirements under the administrative rules and regulations of the order. This rule provides for a mandatory program to reduce the potential for *Salmonella* bacteria in almonds. This action would help ensure that quality almonds are available for human consumption. This action was unanimously recommended by the Board at a meeting on August 22, 2006. This proposal also announces AMS's intention to request approval of a new information collection issued under the order.

Section 981.42(b) of the order provides authority for the Board to establish, with approval of the Secretary, such minimum quality and inspection requirements applicable to almonds to be handled or to be processed into manufactured product, as will contribute to orderly marketing or be in the public interest. In such crop year, no handler shall handle or process almonds into manufactured items or products unless they meet the applicable requirements as evidenced by certification acceptable to the Board. The Board, with approval of the Secretary, may establish rules and regulations necessary and incidental to the administration of this provision.

#### Salmonella Outbreaks Linked to Almonds

In 2001, a *Salmonella* outbreak was identified in Canada, which was linked to a specific retailer, traced back to raw almonds sold in bulk bins, and ultimately traced back to the handler and the grower. The *Salmonella* strain was extremely unusual and had not previously been associated with contamination in a non-animal product. Three orchards where the almonds were produced were identified, and samples gathered from the orchards contained *Salmonella*. With oversight by the California Department of Health Services (CDHS), procedures were implemented by the grower, huller/

sheller, and handler to specify how the almonds from those orchards were to be processed using a treatment to reduce the potential for *Salmonella* before the almonds were moved into commercial channels. The Board initiated an extensive research program to help understand the occurrence of *Salmonella* in almond orchards.

The Board also initiated an education program for the industry regarding Good Agricultural Practices (GAP's), Good Manufacturing Practices (GMP's), and Sanitation Standard Operating Procedures (SSOP's). GAP's provide guidelines to growers on how to minimize potential biological hazards during the production and harvesting of almonds. GMP's define procedures to be used by handlers to allow almonds to be processed, packed, and sold under sanitary conditions. SSOP's help to ensure a clean and sanitary environment in the packing facility. Together, these practices and procedures provide a framework for a Hazard Analysis Critical Control Point (HACCP) program for the industry to proactively eliminate or minimize potential sources of *Salmonella* contamination.

In the spring of 2004, a second *Salmonella* outbreak occurred in Oregon that was linked to raw almonds purchased at a particular retailer. The *Salmonella* strain was very similar to that identified in 2001. One handler had been the supplier to the retailer, and the handler initiated a voluntary recall of 5 million pounds of almonds sold in the U.S. The Food and Drug Administration (FDA) subsequently announced that the almonds had been exported to eight countries. The handler then initiated a full recall of the 6 suspect almonds produced, packed, and shipped, increasing the recall to approximately 15 million pounds.

In the summer of 2004, the Board unanimously approved a voluntary action plan that called for treating all almonds to reduce the potential for *Salmonella*. Handlers were encouraged to treat the almonds prior to shipment, or ship the almonds to a manufacturer who agreed to treat the almonds. The Board continued to fund research on various technologies that could be used to help reduce the potential for *Salmonella* in almonds.

#### **Board Recommendation for a Mandatory Treatment Program**

To further its efforts in providing a high quality product to consumers, in August 2006, the Board recommended that a mandatory treatment program be implemented under the order, pursuant to authority provided in § 981.42(b). Specifically, handlers would have to

subject their almonds to a process that achieves a minimum 4-log reduction in *Salmonella* bacteria prior to shipment. The program would provide for an exemption for handlers who ship untreated almonds under a direct verifiable (DV) program to manufacturers within the U.S., Canada, or Mexico who agree to treat the almonds accordingly. The program would also provide for an exemption for handlers who ship untreated almonds to locations outside of the U.S., Canada, or Mexico. All containers of untreated almonds shipped under the two exemptions would have to be prominently identified with the term "unpasteurized." The program would become effective for the 2007–08 crop year which begins on August 1, 2007.

#### **Specific Parameters of Proposed Mandatory Program**

Under the Board's proposal, handlers would have to subject their almonds to a treatment process or processes that achieve in total a minimum 4-log reduction of *Salmonella* bacteria, or ship their almonds under one of the two exemptions cited above. The proposal would only affect those who meet the definition of "handler" in § 981.13 of the order (thus exempting growers selling through roadside stands). Log reduction describes how much bacterial contamination is reduced by a treatment process. A 4-log reduction decreases bacteria by a factor of 10,000 (4 zeros). One treatment process that independently achieved a minimum 4-log reduction could be used, or a combination of different treatments could be used that collectively achieve a minimum 4-log reduction ("hurdle" technologies).

The Board initially supported a 5-log reduction, which is FDA's performance standard. However, the Board subsequently funded research with the University of California, Davis, in conjunction with Rutgers University, whereby a risk assessment model was developed using data from the two *Salmonella* outbreaks, as well as data from an industry pathogen survey.<sup>1</sup> The risk assessment model demonstrated that a minimum 4-log reduction could provide an appropriate level of consumer protection. Thus, the Board concluded that a 4-log reduction was an appropriate standard for almonds.

#### *Treatment Processes*

Acceptable treatment processes for handlers would have to utilize technologies that have been determined

to achieve a minimum 4-log reduction of *Salmonella* bacteria in almonds, pursuant to a letter of determination issued by the FDA, or acceptance by a scientific review panel as identified by the Board (known as the Technical Expert Review Panel, or TERP).

The FDA reviews studies utilizing specific protocols and treatment parameters, and issues a letter of determination when it determines that a process has sufficiently demonstrated its effectiveness to achieve a 5-log reduction of *Salmonella* in almonds. To date, FDA has issued letters of determination for propylene oxide (PPO), oil roasting, blanching, and for a moist heat process.

The TERP would evaluate various treatment technologies against specific criteria, based on recommendations provided by the National Advisory Committee on Microbiological Criteria in Food (NACMCF). The NACMCF was formed in 1988 under Departmental Regulation 1043–28, and provides impartial, scientific advice to Federal food safety agencies for use in the development of an integrated national food safety systems approach from farm to final consumption to assure the safety of domestic, imported, and exported foods. It is co-sponsored by USDA's Food Safety and Inspection Service, the FDA, the Center for Disease Control and Prevention, the National Marine Fisheries Service, and the Department of Defense Veterinary Service Activity.

While the TERP would not "recommend" or "approve" technologies, its review would ensure that technologies utilized by the industry have been evaluated against specific science-based criteria demonstrating the technology's ability to deliver a lethal treatment for *Salmonella* in almonds. Documentation and data would be provided to the TERP (by a company pursuing TERP acceptance for its technology) for review to ensure that the proposed technologies are consistently achieving the minimum 4-log reduction.

The TERP, initially formed by the Board in the fall of 2004 to review treatment technologies, consists of four scientists, with a representative from the FDA serving as an ex-officio member. The TERP has been evaluating various technologies and treatments for the almond industry, and to date, the TERP has accepted steam and moist heat treatments as acceptable for achieving the Board's *Salmonella* reduction goals. Membership on the TERP would be approved annually by the Board prior to the beginning of each crop year, or more frequently if needed during the crop

<sup>1</sup> Journal of Food Protection, Vol. 69, No. 7, 2006, Pages 1594–1599.

year, for example, to fill a vacancy on the panel.

#### *On-Site Versus Off-Site Treatment*

Under the Board's proposal, unless handlers shipped their almonds to a Board-approved DV user (described later in this document), or shipped their almonds to locations outside of the U.S., Canada, or Mexico, handlers would have to subject their almonds to a treatment process or processes prior to shipment either at their handling facility (on-site), or at an off-site treatment facility located within the production area (California). An off-site facility may or may not be affiliated with another handler. Transportation of almonds by a handler to an off-site treatment facility would not be considered a shipment.

#### *Validation by Process Authorities*

Handlers could only use, or transport their almonds to off-site treatment facilities that use treatment processes that have been "validated" by a Board-approved process authority. Validation means that the treatment technology and equipment utilized have been demonstrated to achieve the minimum 4-log reduction. The use of process authorities is modeled after process authorities as cited in the "Guide to Inspections of Low Acid Canned Food Manufacturers" (Guide) (<http://www.fda.gov>). Treatment technology and equipment that have been modified to the point where operating parameters such as time, temperature, or volume, change must be revalidated.

For purposes of this document, a process authority is a person or an organization that has expert knowledge of appropriate processes for the treatment of almonds as described above, and meets other criteria as specified by the Board. Such criteria would include, but not be limited to, the following: (1) Knowledge about the equipment used for the treatment process; (2) experience in conducting appropriate studies to determine the ability of the equipment to deliver the appropriate treatment (such as heat penetration or heat distribution studies); and (3) the ability to determine that sufficient data has been gathered to identify the critical factors needed to ensure the quality of the final product. On an annual basis, process authorities would have to submit an application to the Board on ABC Form No. 51, "Application for Process Authority for Almonds," and be approved by the Board's TERP. Should the applicant disagree with the TERP's decision, it could appeal the decision in writing to the Board, and ultimately to USDA.

#### *Compliance and Verification Program Treatment Plans*

To ensure compliance with the mandatory program, handlers would be subject to verification by the Federal or Federal-State Inspection Service (inspection agency). Handlers could use either an on-site (traditional) or an audit-based verification program. Each handler would decide which verification program would be the most cost-effective for his or her operation. All handlers would be required to submit a treatment plan to the Board for the upcoming crop year by May 31. The crop year runs from August 1 through July 31 of the subsequent year. However, for the 2007–08 crop year, which would be the first year that the mandatory program was in effect, handlers would have to submit their treatment plans by May 1, 2007. The plan would be reviewed by the Board in conjunction with the inspection agency to ensure such plans were complete and auditable. The plan would be approved by the Board and must address specific parameters for the handler to ship almonds. Such parameters would include, but not be limited to, the following: (1) The location of treatment plant; (2) the name and address of off-site treatment facility (custom processor), if appropriate; (3) a statement regarding whether treatment processes have been accepted by the TERP and/or "determined" by the FDA; (4) a statement regarding validation of treatment technology and equipment by a Board-approved process authority; (5) a statement whether untreated almonds would be exported; (6) a statement whether the handler would use the DV program; (7) a description or flow chart explaining how raw, untreated almonds enter and flow through the handler facility, and how the product would flow through the treatment process, including post treatment, packing, and/or storage; (8) a list of all treatments that would be used on the almonds (including, for example, number of blanching lines, etc.); (9) a description of how treated product would be differentiated and segregated from untreated product to ensure maintenance of treated product integrity; (10) a list of procedures regarding how interhandler transfers would be tracked; and (11) an explanation by handlers using a combination of processes to achieve a minimum 4-log reduction, that the processes occur in an appropriate sequence in sufficiently close proximity to ensure that the integrity of the treated product is maintained between processes.

Almonds sent by a handler for treatment to an off-site facility affiliated with another handler would be subject to the approved treatment plan utilized at that off-site facility. Handlers would have to follow their own approved treatment plans for almonds sent to an off-site facility that is not affiliated with another handler.

#### *On-Site Verification Program*

Under an on-site verification program, handlers would cause the inspection agency to verify that their almonds had been subjected to an acceptable treatment process that had been validated by a Board-approved process authority. Such handlers would have to submit, or cause to be submitted, a verification report to the Board. The inspection agency would have to physically observe the treatment process to issue such a report. It would be the handler's responsibility to arrange for inspection agency verification. An on-site program would be comparable to a traditional in-line or lot inspection program.

#### *Audit-Based Verification Program*

Under an audit-based verification program, handlers would be subject to periodic audits conducted by the inspection agency. The inspection agency would verify that handlers were following their approved treatment plans. Audit frequency would be tied to handler performance. Handlers would be provided with written audit reports specifying deficiencies. Handlers who do not comply with an audit-based verification program would be required to revert to an on-site verification program. Audit reports would be provided to the Board to facilitate program compliance.

#### *Interhandler Transfers*

Interhandler transfers of almonds may or may not be treated prior to transfer. Handlers receiving untreated almonds from another handler would be responsible for treating the product. Handlers receiving treated almonds from another handler would need to have procedures outlined in their treatment plan addressing how the integrity of the treated almonds would be maintained. In all instances involving interhandler transfers, it would be the responsibility of the receiving handler to ensure that the almonds are treated prior to shipment and to maintain documentation to that effect.

#### *Handler Records*

Handlers would be required to maintain records and documentation

that would be subject to audit by the inspection agency and the Board for the purpose of verifying compliance with the regulation. Consistent with § 981.70 of the order regarding handler records and verification, records would have to be maintained for 2 full years following the end of a crop year. Such records would identify lots from the point of treatment forward to the point of shipment by the handler. Lot identification would also provide the ability to differentiate treated from untreated product.

#### Exemptions

##### *Direct Verifiable Program*

Handlers could ship untreated almonds directly to Board-approved manufacturers within the U.S., Canada, or Mexico for further processing under the Direct Verifiable or DV program. The Board would issue a DV user code to an approved manufacturer. Handlers would have to reference this code on all documentation accompanying the lot. This would help the Board track DV shipments and facilitate compliance with the program. Handlers would also have to identify each container of such almonds with the term "unpasteurized." Container means a box, bin, bag, carton, or any other type of receptacle used in the packaging or handling of bulk almonds. The lettering must be on one outside principal display panel, at least ½ inch in height, clear and legible. If a third party is involved in the transaction, the handler must provide sufficient documentation to the Board to track the shipment from the handler's facility to the approved DV user.

Manufacturers wanting to participate in the DV program would have to submit an application annually to the Board on ABC Form No. 52, "Application for Direct Verifiable (DV) Program for Further Processing of Untreated Almonds," and be approved by the Board's TERP. Should the applicant disagree with the TERP's decision, it could appeal the decision in writing to the Board, and ultimately to USDA.

Similar to handlers, manufacturers would have to subject the almonds to a treatment process or processes using technologies that achieve in total a minimum 4-log reduction of *Salmonella* bacteria as determined by the FDA or accepted by the TERP. Additionally, manufacturers could use treatment processes that have been "established" by a Board-approved process authority. "Established" means that that the process authority would evaluate treatment processes and protocols to ensure the technology's ability to

deliver a lethal treatment for *Salmonella* in almonds and achieve a minimum 4-log reduction. The Board recommended this option to address manufacturers' concern regarding the process to seek TERP acceptance of their treatments, which could involve providing data on their proprietary processes to the TERP (i.e., specific time and temperature data for special equipment).

Manufacturers must also do the following: (1) Identify the manufacturing locations where treatment would occur; (2) have their treatment technology and equipment validated by a Board-approved process authority. Treatment technology and equipment that have been modified to the point where operating parameters such as time, temperature, or volume, change must be revalidated; (3) maintain all records regarding validation and verification of treatment methods, processing, and product traceability for 2 years, and make such records available for review by the Board; and (4) ship untreated almonds (due, for example, to a manufacturer overbuying) to a handler, to another approved DV user, to locations outside the U.S., Canada, or Mexico (containers must remain identified with the term unpasteurized), or dispose of such almonds in non-edible channels.

Further, DV users would be audited by a Board-approved auditor within 1–2 months after the start of treatments, and at least once every 12 months thereafter. Such audits would determine if: (1) The DV user utilized appropriate treatment processes; (2) the DV user has a letter issued by a Board-approved process authority that validated that the treatment achieves a 4-log reduction of *Salmonella*; (3) personnel and procedures used at the facility ensure that treatment parameters were followed; and (4) records are retained for two years that document the treatment of almonds, or that any untreated almonds were properly disposed of as outlined above. A summary audit report of the DV user would be sent to the Board within 10 days of the audit. On an annual basis, DV user auditors would have to submit an application to the Board on ABC Form No. 53, "Application for Direct Verifiable (DV) Program Auditors," and be approved by the Board's TERP. Should the applicant disagree with the TERP's decision, it could appeal the decision in writing to the Board, and ultimately to USDA.

The Board recommended including Mexico and Canada as part of the DV program for compliance purposes. The Board was concerned that handlers could circumvent the regulation by

shipping untreated almonds to Mexico or Canada, then, bring them back into the U.S. and sell them in normal market channels.

#### **Shipments Outside of the U.S., Canada, or Mexico**

Handlers could also ship untreated almonds directly to locations outside the U.S., Canada, or Mexico, provided that each container of such almonds is prominently identified with the term unpasteurized. The lettering must be on one outside principal display panel, at least ½ inch in height, clear and legible. Again, if a third party is involved in the transaction, the handler must provide sufficient documentation to the Board to track the shipment from the handler's facility to the importer in the foreign country.

Accordingly, a new paragraph (b) regarding outgoing quality control and a mandatory program to reduce the potential for *Salmonella* bacteria contamination in almonds is proposed to be added to § 981.442 of the order's administrative rules and regulations.

#### **Initial Regulatory Flexibility Analysis**

Pursuant to requirements set forth in the Regulatory Flexibility Act (RFA), the Agricultural Marketing Service (AMS) has considered the economic impact of this rule on small entities. Accordingly, AMS has prepared this initial regulatory flexibility analysis.

The purpose of the RFA is to fit regulatory actions to the scale of business subject to such actions in order that small businesses will not be unduly or disproportionately burdened. Marketing orders issued pursuant to the Act, and the rules issued thereunder, are unique in that they are brought about through group action of essentially small entities acting on their own behalf. Thus, both statutes have small entity orientation and compatibility.

There are approximately 6,000 producers of almonds in the production area and approximately 115 handlers subject to regulation under the marketing order. Additionally, the Board estimates there would be about 25 process authorities, 53 almond manufacturers, and 50 DV program auditors impacted by this rule. Small agricultural producers are defined by the Small Business Administration (13 CFR 121.201) as those having annual receipts of less than \$750,000, and small agricultural service firms are defined as those whose annual receipts are less than \$6,500,000.

Data for the most recently completed crop year indicate that about 52 percent of the handlers shipped under \$6,500,000 worth of almonds. Dividing

average almond crop value for 2003–2005 reported by the National Agricultural Statistics Service (NASS) (\$2.043 billion) by the number of producers (6,000) yields an average annual producer revenue estimate of about \$340,000. Based on the foregoing, about half of the handlers and a majority of almond producers may be classified as small entities. While data regarding the size of the process authorities is not available, it may be assumed that some

process authorities, almond manufacturers, and DV program auditors may be classified as small entities.

The almond industry’s 6,000 growers produce approximately 1 billion pounds annually (kernel weight basis). Industry members expect production to increase by 50 percent in the next 3–5 years, due to a significant amount of newly planted acreage that will come into production.

Although the Board currently projects that there are about 115 handlers, handler number estimates can vary over time. Recent surveys have yielded estimates ranging from 112 (see Table 1) to 117 (see Table 2). Handlers ultimately market their almonds to customers in the U.S. and abroad. As shown in Table 1, the Board estimates that about 27 of 112 handlers handle more than 10 million pounds each, and cumulatively handle 82 percent of the crop.

TABLE 1.—NUMBER OF HANDLERS CATEGORIZED BY SIZE

|                               | Less than 1 million lbs. | Between 1 and 5 million lbs. | Between 5 and 10 million lbs. | More than 10 million lbs. |
|-------------------------------|--------------------------|------------------------------|-------------------------------|---------------------------|
| No. of handlers .....         | 41                       | 28                           | 16                            | 27                        |
| Percent of crop handled ..... | 1                        | 6                            | 11                            | 82                        |

According to data provided by the Board, about 30 percent of California almonds are sold domestically (about 300 million pounds). An estimated 20 percent of the domestic shipments are in the form of manufactured product—blanched, sliced, diced, or otherwise further processed using thermal treatments. About 70 percent of

California almond production is exported to more than 80 countries worldwide. Mexico and Canada account for approximately 5 percent of export shipments. The quantities shipped by companies handling almonds vary considerably. However, a limited number of handlers are responsible for the majority of domestic and export

shipments as shown in Table 2 below. Table 2 shows that 16 handlers are responsible for 90 percent of domestic shipments. Many of the same handlers are among the 38 that are responsible for 90 percent of exports. About 79 of an estimated 117 handlers are responsible for the remaining 10 percent of export shipments.

TABLE 2.—HANDLER SHIPMENT SUMMARY

|   | Domestic (U.S.) 300,000,000 pounds | Export to Canada and Mexico 37,600,000 pounds | All export (includes Canada and Mexico) 700,000,000 pounds |
|---|------------------------------------|---|--|
| No. of handlers responsible for 50 percent of shipments ..... | 3                                  | 4   | 9  |
| No. of handlers responsible for 80 percent of shipments ..... | 12                                 | 16  | 26   |
| No. of handlers responsible for 90 percent of shipments ..... | 16                                 | 26  | 38   |

This rule would add a new paragraph (b) for outgoing quality control under § 981.442 of the order’s administrative rules and regulations, whereby a mandatory program to reduce the potential for *Salmonella* bacteria in almonds would be implemented under the order. Specifically, handlers would have to subject their almonds to a treatment process that achieves a minimum 4-log reduction in *Salmonella* bacteria prior to shipment. The program would exempt handlers who ship untreated almonds under a direct verifiable (DV) program to manufacturers within the U.S., Canada, or Mexico who agree to treat the almonds accordingly. The program would also exempt handlers who ship untreated almonds to locations outside of the U.S., Canada, or Mexico. All containers of untreated almonds shipped under the exemptions would have to be prominently identified with the term “unpasteurized.” The program would take effect for the 2007–08 crop

year which 25 begins on August 1, 2007. Authority for the program is provided in § 981.42(b) of the order.

According to the Board, the costs to individual handlers to comply with the program would vary considerably depending on their markets and treatment method(s) chosen. Handlers could: (1) Install new equipment in their processing lines to treat the almonds prior to shipment into commercial channels; (2) outsource to another handler or an off-site facility within California for treatment; (3) transfer their untreated product to another handler who would treat the almonds prior to shipment; (4) ship their untreated almonds to Board-approved DV users or to locations outside of the U.S., Canada, or Mexico; or (5) use a combination of these approaches.

In a handler survey conducted by the Board in March 2005 (to which 116 handlers handling almonds at that time responded), 86 handlers (74 percent) have their own facilities and/or

equipment to process almonds; the remainder have almonds processed on their behalf. Of those handlers with their own facilities and/or equipment, 66 (77 percent of 86) indicated they planned to install equipment to treat almonds while the remaining 20 indicated they would outsource to a third party, or custom processor. Again, the overall economic impact of the program would vary based on the approach selected. Smaller handlers may choose to defer purchasing equipment and send their almonds to an off-site facility for treatment until more cost effective technologies are available.

Costs would also vary by treatment method. Some handlers may choose to install PPO chambers at their facilities. Handler sources estimate that typical installation costs for a PPO chamber range from \$500,000 to \$1,250,000. As with other technologies, overall cost would depend upon how much infrastructure is in place in the processing facility as well as the desired

capacity of the chambers. Actual treatment cost for handlers treating their own product is approximately \$0.03 per pound, varying with volume and efficiencies. PPO treatment is currently available in the industry on a contract basis at \$0.04–\$0.05 per pound (including transportation to the facility).

Regarding steam technologies, handler sources estimate the following equipment costs for in-line steam systems designed to treat almonds at varying capacities from 1,000 pounds to over 30,000 pounds of almonds per hour:

TABLE 3.—ESTIMATED EQUIPMENT COSTS FOR STEAM UNITS FOR DIFFERING LEVELS OF TREATMENT CAPACITY

| Capacity (pounds per hour) | Equipment costs     |
|----------------------------|---------------------|
| 1,000 .....                | \$100,000–\$200,000 |
| 5,000 .....                | 300,000–325,000     |
| 7,500–15,000 .....         | 370,000–470,000     |

TABLE 3.—ESTIMATED EQUIPMENT COSTS FOR STEAM UNITS FOR DIFFERING LEVELS OF TREATMENT CAPACITY—Continued

| Capacity (pounds per hour) | Equipment costs   |
|----------------------------|-------------------|
| 20,000–30,000 .....        | 525,000–800,000   |
| Over 30,000 .....          | 600,000–1,000,000 |

While treatment equipment costs would be the most significant outlay, there would also be capital expenditures associated with additional conveyance equipment, boilers, cooling systems, bins, and possible expansion or construction of new buildings. Handler sources estimate these costs to be an additional 50 percent of the treatment equipment costs cited in Table 3, depending on capacity needs, and assuming maximum throughput.

A typical system of 10 million pound annual capacity would be equivalent to 22,000 pounds per hour, which falls in

the 20,000 to 30,000 pound per hour range in Table 3. The treatment equipment costs for that capacity range from \$525,000 to \$800,000. With an additional 50 percent for cost of other related equipment and facility expansion, the costs range from \$787,500 to \$1,200,000. Handler sources suggest that a figure near the upper end of that range, \$1,125,000, is a good point estimate of the cost for a 10,000,000 pound per year treatment line.

An important step in assessing the financial impact of the proposed mandatory treatment on handlers is to estimate the annualized equipment cost and operating cost of treating the almonds to prevent *Salmonella* contamination. This can be illustrated by additional computations, with 10,000,000 pounds per year serving as a representative level of treatment capacity, as shown in Table 4, third line of column A. Table 4 also shows a range of costs across different levels of handler treatment capacity.

TABLE 4.—ESTIMATE OF AVERAGE ANNUAL EQUIPMENT AND OPERATING COSTS AT VARYING LEVELS OF HANDLER TREATMENT CAPACITY

| A<br>Handler annual capacity<br><br>(Pounds) | B<br>Total equipment cost * | C<br>Annual use cost of equipment, 5 year life ** | D E<br>Unit cost of equipment at |                     | F<br>Average operating cost | G H<br>Equipment plus operating cost at |                     |  |
|--|-----------------------------|---|----------------------------------|---------------------|-----------------------------|---|---------------------|--|
|  |                             |   | 50% of capacity (c/50% of A)     | Full capacity (C/A) |                             | 50% of capacity (D+F)                   | Full capacity (E+F) |  |
|  |                             |   | Cents per pound                  |                     |                             |   |                     |  |
| 2,000,000 .....                              | \$300,000                   | \$69,292  | \$0.069                          | \$0.035             | \$0.0035                    | \$0.0725                                | \$0.0385            |  |
| 5,000,000 .....                              | 487,500                     | 112,600   | 0.045                            | 0.023               | 0.0035                      | 0.0485                                  | 0.0265              |  |
| 10,000,000 .....                             | 1,125,000                   | 259,845   | 0.052                            | 0.026               | 0.0035                      | 0.0555                                  | 0.0295              |  |
| 15,000,000 .....                             | 1,500,000                   | 346,460   | 0.046                            | 0.023               | 0.0035                      | 0.0495                                  | 0.0265              |  |
| 20,000,000 .....                             | 1,650,000                   | 381,106   | 0.038                            | 0.019               | 0.0035                      | 0.0415                                  | 0.0225              |  |

\* Equipment cost estimates at varying capacity levels, including treatment chambers, plus an additional 50 percent for conveyors, other equipment and extension of facilities.

\*\* Annualized equipment cost is computed by dividing the equipment purchase cost by 4.3295, which is the Present Value of a \$1 annuity for 5 Years (estimated life of the equipment) at a 5 percent interest rate (estimated cost of capital).

Source for equipment and operating costs: Almond handlers.

To obtain the annual unit cost for installing a 10 million pound capacity treatment line (an expenditure of \$1,125,000 in column B), the first step is to obtain the annualized equipment cost. The parameters recommended by the handlers were a 5 year equipment life and a 5 percent cost of capital. The annual equipment use factor (4.3295) is the present value of a \$1 annuity for 5 years at 5 percent. Dividing the total equipment expenditure of \$1,125,000 by 4.3295 yields an annualized equipment cost estimate of \$259,845 (column C). Dividing this figure by the annual 10,000,000 pound capacity yields a cost per pound estimate of 2.6 cents (column E). If the treatment line ran at half

capacity, the equipment costs per pound would double to 5.2 cents (column D).

This method of computing annualized equipment cost does not account for the tax implications of annual equipment depreciation or for the salvage value at the end of the equipment's useful life. In addition, the useful life of many pieces of equipment may well be over 5 years.

Ongoing operational costs (electricity, etc.) are estimated by handlers to range from \$0.0027 to \$0.0043 per pound, depending on the system. The midpoint of this range (\$0.0035) appears in column F.

The key results from Table 4 are the cost estimates per pound of almonds treated, including both annualized

equipment costs and operating costs. The highest cost is 7.25 cents per pound for the smallest handler (2 million pounds treated annually) operating at 50 percent capacity (column G). The lowest cost estimate is 2.25 cents per pound for a handler treating 20 million pounds per year operating at full capacity (column H). These costs can be put in context by comparing them to almond grower prices as reported each year by the NASS. For 2003 to 2005, grower prices averaged \$2.07 per pound, computed by dividing the value of production for those three years by the three-year quantity of production. The treatment cost estimates per pound in Table 4

range from 3 percent to 1 percent of the 2003–2005 average grower price, and represent an even smaller proportion of the prices paid to handlers when selling to almond users further down the marketing chain.

A key aspect of handler costs is the proportion of total capacity at which a new production line would operate. Operating at higher capacity spreads the equipment cost across a wider base. For a small handler, investing in equipment with this level of capacity may only be viable economically if the costs are spread over their entire production run, rather than only applying costs to a small portion of their production run. If they do not intend to run their entire production through the treatment process, it may be more viable to outsource the treatment. Costs of contract processing (i.e., batch operations for steam processes or PPO treatment) are estimated to range from \$0.04 to \$0.05 per pound. This estimate includes additional costs associated with transporting almonds to a custom facility (\$0.01 to \$0.015 per pound). For

medium-sized and larger handlers, it may be more cost effective to construct a treatment processing line, particularly if they intend to immediately put a significant portion of their production through the process.

Handler sources estimate that the cost of setting up a new oil roast line is \$300,000 to \$600,000, with operating costs of \$0.06 to \$0.10 per pound. A blanching line may cost upward of \$1,500,000 to \$2,500,000 with an operating cost of approximately \$0.12 to \$0.22 per pound. It is unlikely that handlers would select these technologies unless they are already providing custom processed, value-added products to their customers.

Regarding compliance and oversight costs, it is anticipated that handlers who do not currently have thorough recordkeeping procedures in place would likely have to invest approximately 40–80 person-hours to develop their treatment plan. However, once this document has been created, it would be updated on an annual basis, which would likely involve less time.

Validation of treatment systems is estimated to cost from \$1,000 to \$3,000 per line, depending upon the complexity of the equipment utilized. Treatment technology and equipment that have been modified to the point where operating parameters such as time, temperature, or volume, change must be revalidated.

Handler verification costs could vary, depending on whether the handler was under an on-site program or an audit-based program. The fee for an on-site program would be a minimum charge of \$44.00 per hour (with 1 hour required to treat 44,000 pounds), or \$0.204 per hundredweight, whichever is greater. The former is equivalent to \$1.00 per thousand pounds treated. For an audit-based program, the fee would be \$78.00 per hour. Travel time for both programs would be charged at \$44.00 per hour and \$0.34 per mile.

Examples of estimated handler verification costs are provided in Tables 5 and 6 below:

TABLE 5.—ANNUAL HANDLER VERIFICATION COSTS: ON-SITE PROGRAM

| Audit cost by type     | Volume of almonds treated per year |             |              |               |               |
|------------------------|------------------------------------|-------------|--------------|---------------|---------------|
|                        | 100,000 lbs                        | 2 mill. lbs | 40 mill. lbs | 100 mill. lbs | 250 mill. lbs |
| Hourly rate* .....     | \$100                              | \$2,000     | \$40,000     | \$100,000     | \$250,000     |
| Per Cwt = \$.204 ..... | 204                                | 4,080       | 81,600       | 204,000       | 510,000       |

\* Hourly rate of \$44/hour, with 1 hour required per 44,000 lbs of volume treated (equivalent to \$1.00 per thousand pounds treated).

TABLE 6.—ANNUAL HANDLER VERIFICATION COSTS: AUDIT-BASED PROGRAM

|                                     | Audit cost by hours required to complete audit* |       |       |       |       |       |       |       |
|-------------------------------------|---|-------|-------|-------|-------|-------|-------|-------|
|                                     | 1   | 2     | 3     | 4     | 5     | 6     | 7     | 8     |
| Audit hourly cost = \$78 .....      | \$78  | \$156 | \$234 | \$312 | \$390 | \$468 | \$546 | \$624 |
| Auditor Transportation Cost** ..... | 32  | 32    | 32    | 32    | 32    | 32    | 32    | 32    |
| Cost per individual audit .....     | 110   | 188   | 266   | 344   | 422   | 500   | 578   | 656   |

\* Estimated hours per audit varies by volume treated annually: (up to 2 million pounds: 1–3 hours); (more than 2 but less than 40 million pounds: 2–5 hours); (40 million pounds or more: 3–8 hours).

\*\* Estimated auditor transportation cost to each facility is approximately \$32: \$22 for travel time (1/2 hour @ \$44/hour) plus mileage reimbursement of \$10 (30 miles @ \$0.34 per mile).

The benefits associated with the proposed mandatory program are the avoided costs of a *Salmonella* outbreak. These costs may vary depending on several factors, including the quantity of product recalled, impact on consumer sales, lost customer confidence, insurance costs, and possible litigation. Using 2003–2005 average almond crop value as the basis, a loss of 5 percent would be equal to approximately \$102 million.

The Board considered various alternatives and options to a mandatory treatment program. One option would

be to take no action. However, the Board concluded that this was not in the best interest of the industry nor consumers. The Board believes that the industry should provide consumers with a quality product. Taking no action when there are viable alternatives could be significant in terms of the financial well being of the industry should another outbreak occur that was linked to almonds.

The Board also considered continuing its voluntary action plan alone, without proposing a mandatory program. However, surveys conducted by the

Board indicate that not all handlers are implementing the action plan. Thus, the Board concluded that a mandatory program is in the best interest of the industry and consumers.

The Board also considered the effectiveness of testing for *Salmonella* prior to shipment. During the 2001 and 2004 outbreaks, significant amounts of testing occurred at the orchard level, in hulling and shelling facilities, and at retail. However, it was determined by the CDHS, University of California, Davis, and other pathogen experts that testing cannot be relied upon as the only

measure to ensure that almonds are *Salmonella* free. Thus, the Board concluded that testing alone was not a viable alternative.

The Board also explored the merits of requiring alternative log reductions. As previously mentioned, the Board initially supported a 5-log reduction, which was FDA's performance standard. However, a risk assessment model demonstrated that a minimum 4-log reduction could provide an appropriate level of consumer protection compared to a 5-log reduction. Thus, the Board concluded that a minimum 4-log reduction was an appropriate standard for almonds.

The Board also explored the merits of whether the DV program should be temporary, whereby all almonds would be treated at the handler level prior to shipment. The Board submitted an initial proposal to USDA in February 2006 that would have ultimately required handlers to treat all almonds prior to shipment, with the DV program being temporary. However, concerns were raised by various parties, including manufacturers, handlers, and foreign countries, regarding the temporary nature of the DV program, and the requirement that all exported almonds be treated prior to shipment. The Board ultimately revised its proposal to remove the proviso regarding discontinuance of the DV program, to allow untreated almonds to be shipped to locations outside the U.S., Canada, or Mexico, and to require that all containers of untreated almonds be prominently identified with the term "unpasteurized."

This action would impose additional reporting and recordkeeping burden on California almonds handlers, process authorities, almond manufacturers, and DV program auditors. Process authorities, manufacturers, and DV auditors would be required to submit respective applications to the Board annually. Almond handlers would be required to submit treatment plans to the Board annually. These new forms and a sample "Handler Treatment Plan" are being submitted to the Office of Management and Budget (OMB) for approval under OMB Control No. 0581-NEW. Specific burdens for the three applications and handler treatment plan are detailed later in this document in the section titled Paperwork Reduction Act. As with all Federal marketing order programs, reports and forms are periodically reviewed to reduce information requirements and duplication by industry and public sector agencies. Finally, USDA has not identified any relevant Federal rules

that duplicate, overlap, or conflict with this rule.

Additionally, the meetings were widely publicized throughout the California almond industry and all interested persons were invited to attend the meetings and participate in deliberations on all issues. Between the summer of 2004 and the Board's August 2006, meeting, this issue was addressed at an estimated 12 Board meetings, 18 Food Quality and Safety Committee meetings, and well over 20 task force meetings. All of these meetings were public meetings and all entities, both large and small, were able to express views on this issue. Additionally, the Board issued about 35 updates to handlers regarding its voluntary action plan and progress towards its recommended mandatory program. Finally, interested persons are invited to submit information on the regulatory and informational impacts of this action on small businesses.

A small business guide on complying with fruit, vegetable, and specialty crop marketing agreements and orders may be viewed at: <http://www.ams.usda.gov/fv/moab.html>. Any questions about the compliance guide should be sent to Jay Guerber at the previously mentioned address in the **FOR FURTHER INFORMATION CONTACT** section.

A 45-day comment period is provided for interested persons to comment on this proposal. The comment period is deemed appropriate because the Board recommended that the mandatory program be in effect for the 2007-08 crop year, which begins August 1, 2007. For that year, handlers would have to submit their treatment plans to the Board by May 1, 2006. All written comments received will be considered before a final determination is made on this matter.

#### **Paperwork Reduction Act**

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the AMS announces its intention to request approval of a new information collection under the marketing order for California almonds.

*Title:* Almonds Grown in California, Marketing Order No. 981.

*OMB No.:* 0581-NEW.

*Expiration Date of Approval:* 3 years from OMB date of approval.

*Type of Request:* New collection.

*Abstract:* The information collection requirements in this request are essential to carry out the intent of the Act, to provide the respondents the type of service they request, and to administer the California almond marketing order program, which has been operating since 1950.

On August 22, 2006, the Board unanimously recommended adding a new section to the order's administrative rules and regulations to implement a mandatory program to help reduce the potential for *Salmonella* in almonds. This document concerns the additional reporting and recordkeeping requirements regarding this mandatory program, in addition to the accompanying regulation previously discussed. Almond handlers would be required to submit annual treatment plans to the Board and inspection agency regarding how they plan to treat their almonds to reduce the potential for *Salmonella*. Entities interested in being almond process authorities that would validate technologies would have to submit an application to the Board on ABC Form No. 51, "Application for Process Authority for Almonds." Manufacturers in the U.S., Canada, and Mexico interested in being approved to accept untreated almonds, provided they agree to treat the almonds themselves under the Board's DV program, would have to submit an application to the Board on ABC Form No. 52, "Application for Direct Verifiable (DV) Program for Further Processing of Untreated Almonds." Entities interested in being approved DV user auditors would have to submit an application to the Board on ABC Form No. 53, "Application for Direct Verifiable (DV) Program Auditors." This information would be needed by the Board to properly administer the mandatory *Salmonella* treatment program for the California almond industry.

The information collected is used only by authorized representatives of USDA, including AMS, Fruit and Vegetable Programs regional and headquarters' staff, and authorized employees and agents of the Board. Authorized Board employees, agents, and the industry are the primary users of the information and AMS is the secondary user.

#### **Handler Treatment Plan**

*Estimate of Burden:* Public reporting burden for this collection of information is estimated to be no more than 27.3 hours per response (80 hours per response for the first year of regulation, and 1 hour per response each year thereafter).

*Respondents:* Almond handlers.

*Estimated Number of Respondents:* 115.

*Estimated Number of Responses per Respondent:* 1.

*Estimated Total Annual Burden on Respondents:* 3,143 hours per year (9,200 hours for the first year of



regulation, and 115 hours for each year thereafter).

**Application for Process Authority for Almonds—ABC Form No. 51**

*Estimate of Burden:* Public reporting burden for this collection of information is estimated to average 2 hours per response.

*Respondents:* Persons or organizations that would like to qualify to be Board-approved process authorities that validate treatments and technologies.

*Estimated Number of Respondents:* 25.

*Estimated Number of Responses per Respondent:* 1.

*Estimated Total Annual Burden on Respondents:* 50 hours.

**Application for Direct Verifiable (DV) Program for Further Processing of Untreated Almonds—ABC Form No. 52**

*Estimate of Burden:* Public reporting burden for this collection of information is estimated to average 1 hour per response.

*Respondents:* Manufacturers who would like to qualify to participate in the Board's direct verifiable program.

*Estimated Number of Respondents:* 53.

*Estimated Number of Responses per Respondent:* 1.

*Estimated Total Annual Burden on Respondents:* 53 hours.

**Application for Direct Verifiable (DV) Program Auditors—ABC Form No. 53**

*Estimate of Burden:* Public reporting burden for this collection of information is estimated to average 1 hour per response.

*Respondents:* Entities that would like to qualify as auditors under the DV program.

*Estimated Number of Respondents:* 50.

*Estimated Number of Responses per Respondent:* 1.

*Estimated Total Annual Burden on Respondents:* 50 hours.

*Comments:* Comments are invited on: (1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other

technological collection techniques or other forms of information technology.

Comments should reference OMB No. 0581-NEW and the California almond marketing order, and be sent to the USDA in care of the Docket Clerk at the address above. All comments received will be available for public inspection during regular business hours at the same address. All responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record.

The AMS is committed to complying with the E-Government Act, to promote the use of the Internet and other information technologies to provide increased opportunities for citizen access to Government information and services, and for other purposes.

It is estimated that handlers and manufacturers may spend between 20–100 hours annually maintaining records pertaining to this rule. Using a figure of \$10 per hour (a sum deemed reasonable, should handlers and manufacturers be compensated for this time), it is estimated that the recordkeeping burden would cost handlers and manufacturers between \$200–\$1,000 per year. Additionally, handler and manufacturers would have to maintain related records and documentation for two full years following the end of the crop year.

A 60-day comment period is provided to allow interested persons to comment on this proposed information collection.

**List of Subjects in 7 CFR Part 981**

Almonds, Marketing agreements, Nuts, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, 7 CFR part 981 is proposed to be amended as follows:

**PART 981—ALMONDS GROWN IN CALIFORNIA**

1. The authority citation for 7 CFR part 981 continues to read as follows:

**Authority:** 7 U.S.C. 601–674.

2. Section 981.442 is amended by adding paragraph (b) to read as follows:

**§ 981.442 Quality control.**

\* \* \* \* \*

(b) *Outgoing.* Pursuant to § 981.42(b), beginning with the 2007–08 crop year, which begins on August 1, 2007, and except as provided in § 981.13 and in paragraph (6) of this section, handlers shall subject their almonds to a treatment process or processes prior to shipment to reduce potential *Salmonella* bacteria contamination in

accordance with the provisions of this section.

(1) *Treatment process.* Acceptable treatment processes shall utilize technologies that have been determined to achieve in total a minimum 4-log reduction of *Salmonella* bacteria in almonds, pursuant to a letter of determination issued by the Food and Drug Administration (FDA), or acceptance by a scientific review panel as identified by the Board (Technical Expert Review Panel or “TERP”). Such panel shall be approved at least annually by the Board prior to the beginning of each crop year, or as needed during the crop year.

(2) *On-site versus off-site treatment.* Handlers shall subject almonds to a treatment process or processes prior to shipment either at their handling facility (on-site), or at an off-site treatment facility located within the production area. Transportation of almonds by a handler to an off-site treatment facility shall not be deemed a shipment.

(3) *Validation by process authorities.* Handlers shall only use, or transport their almonds to off-site treatment facilities that use treatment processes that have been validated by a Board-approved process authority. Validation means that the treatment technology and equipment have been demonstrated to achieve in total a minimum 4-log reduction of *Salmonella* bacteria in almonds.

A process authority is an entity that has expert knowledge of appropriate processes for the treatment of almonds as defined in paragraph (b)(1) of this section, and meets other criteria as specified by the Board. Treatment technology and equipment that have been modified to the point where operating parameters such as time, temperature, or volume, change shall be revalidated. On an annual basis, process authorities must submit an application to the Board on ABC Form No. 51, “Application for Process Authority for Almonds,” and be approved by the Board's TERP. Should the applicant disagree with the TERP's decision, it may appeal the decision in writing to the Board, and ultimately to USDA.

(4) *Compliance and verification.* In accordance with the requirements of this paragraph, handlers shall utilize either an on-site verification program (traditional), or an audit-based verification program to ensure that their almonds have been subjected to an acceptable treatment process to reduce *Salmonella* bacteria prior to shipment. Each handler may decide which verification program would be the most cost-effective for his or her operation.

(i) By May 31, each handler shall submit to the Board a Treatment Plan for the upcoming crop year: *Provided*, That, for the 2007–08 crop year, which begins on August 1, 2007, each handler shall submit to the Board its Treatment Plan by May 1, 2007. A Treatment Plan shall describe how a handler plans to treat his or her almonds, and must address specific parameters as outlined by the Board for the handler to ship almonds. Such plan shall be reviewed by the Board, in conjunction with the inspection agency, to ensure it is complete and can be verified, and be approved by the Board. Almonds sent by a handler for treatment to an off-site facility affiliated with another handler shall be subject to the approved Treatment Plan utilized at that facility. Handlers shall follow their own approved Treatment Plans for almonds sent to an off-site facility that is not affiliated with another handler.

(ii) Handlers utilizing an on-site verification program shall cause the inspection agency to verify that their Treatment Plans have been followed, and that their almonds have been subjected to an acceptable treatment process that has been validated by a Board-approved process authority. Such handlers shall submit, or cause to be submitted, a verification report to the Board. The inspection agency must physically observe the treatment process to issue such report.

(iii) Handlers utilizing an audit-based verification program shall be subject to periodic audits conducted by the inspection agency. The inspection agency shall provide copies of the audit report to the Board. Handlers who do not comply with an audit-based verification program shall be required to revert to an on-site verification program.

(iv) Interhandler transfers of almonds may or may not be treated prior to transfer. Handlers receiving untreated almonds from another handler shall be responsible for treating the product. Handlers receiving treated almonds from another handler must have procedures outlined in their Treatment Plan addressing how the integrity of the treated almonds will be maintained. In all instances involving interhandler transfers, the receiving handler shall be responsible for ensuring that the almonds are treated prior to shipment and maintaining documentation to that effect.

(5) *Records.* Handlers shall maintain records and documentation that will be subject to audit by the Board for the purpose of verifying compliance with this section. Records must be maintained for two full years following the end of the crop year, and must

identify lots from the point of treatment forward to the point of shipment by the handler. Lot identification shall also provide the ability to differentiate treated from untreated product.

(6) *Exemptions.* Handlers may ship untreated almonds under the following conditions. For purposes of this section, container means a box, bin, bag, carton, or any other type of receptacle used in the packaging of bulk almonds.

(i) Handlers may ship untreated almonds for further processing directly to manufacturers located within the U.S., Canada or Mexico. This program shall be termed the Direct Verifiable (DV) program. Handlers may only ship untreated almonds to manufacturers who have submitted ABC Form No. 52, “Application for Direct Verifiable (DV) Program for Further Processing of Untreated Almonds,” and have been approved by the Board’s TERP. Such manufacturers must apply to the Board and be approved annually by the TERP. Should the applicant disagree with the TERP’s decision, it may appeal the decision in writing to the Board, and ultimately to USDA. The Board shall issue a DV User code to an approved manufacturer. Handlers must reference such code in all documentation accompanying the lot and identify each container of such almonds with the term “unpasteurized.” Such lettering shall be on one outside principal display panel, at least ½ inch in height, clear and legible. If a third party is involved in the transaction, the handler must provide sufficient documentation to the Board to track the shipment from the handler’s facility to the approved DV user. Approved DV Users shall:

(A) Subject such almonds to a treatment process or processes using technologies that achieve in total a minimum 4-log reduction of *Salmonella* bacteria as determined by the FDA, accepted by the Board’s scientific review panel, or established by a Board-approved process authority;

(B) Identify the manufacturing locations where treatment will occur;

(C) Have their treatment technology and equipment validated by a Board-approved process authority. Treatment technology and equipment that have been modified to the point where operating parameters such as time, temperature, or volume, change shall be revalidated;

(D) Have their technology and procedures verified by a Board-approved DV auditor to ensure they are being applied appropriately. On an annual basis, DV auditors must submit an application to the Board on ABC Form No. 53, “Application for Direct Verifiable (DV) Program Auditors,” and

be approved by the Board’s TERP. Should the applicant disagree with the TERP’s decision, it may appeal the decision in writing to the Board, and ultimately to USDA;

(E) Maintain all records regarding validation and verification of treatment methods, processing, and product traceability. Such records shall be retained for two years and shall be made available for review by the Board; and,

(F) Ship any almonds which will not be treated to a handler, to another approved DV User, to locations outside the U.S., Canada, and Mexico (containers must remain identified with the term “unpasteurized”), as specified in § 981.442(b)(6)(i), or dispose of such almonds in non-edible channels.

(ii) Handlers may ship untreated almonds directly or through a third party to locations outside the U.S., Canada, and Mexico, provided that each container of such almonds is identified with the term “unpasteurized.” Such lettering shall be on one outside principal display panel, at least ½ inch in height, clear and legible. If a third party is involved in the transaction, the handler must provide sufficient documentation to the Board to track the shipment from the handler’s facility to the importer in the foreign country.

(7) *Other restrictions.* The provisions of this section do not supersede any restrictions or prohibitions regarding almonds grown in California under the Federal Food, Drug and Cosmetic Act, or any other applicable laws or regulations or the need to comply with applicable food and sanitary regulations of city, county, State or Federal agencies.

Dated: December 1, 2006.

**Lloyd C. Day,**

*Administrator, Agricultural Marketing Service.*

[FR Doc. 06–9543 Filed 12–1–06; 12:43 pm]

**BILLING CODE 3410-02-M**

## **DEPARTMENT OF ENERGY**

### **Federal Energy Regulatory Commission**

#### **18 CFR Parts 2, 33, 365 and 366**

**[Docket No. AD07–2–000]**

#### **Repeal of the Public Utility Holding Company Act of 1935 and Enactment of the Public Utility Holding Company Act of 2005; Transaction Subject to FPA Section 203; Supplemental Notice of Technical Conference**

November 27, 2006.

**AGENCY:** Federal Energy Regulatory Commission, DOE.