Programs commences on October 1 of each calendar year. The rate for laboratory services is $60.00 per hour in fiscal year 2007, $63.00 per hour in fiscal year 2008, and $67.00 per hour in fiscal year 2009.

(b) Printed updated schedules of the laboratory testing fees for processed fruits and vegetables (7 CFR part 93), poultry and egg products (7 CFR part 94), and meat and meat products (7 CFR part 98) will be available for distribution to Science and Technology's constituents and stakeholders by the individual Laboratory Managers of Science and Technology laboratories listed in § 91.5. These single test laboratory fee schedules are based upon the applicable hourly fee rate stated in § 91.37(a).

(c) Except as otherwise provided in this section, charges will be made at the applicable hourly rate stated in § 91.37(a) for the time required to perform the service. A charge will be made for service pursuant to each request or certificate issued.

(d) When a laboratory test service is provided for AMS by a commercial or State government laboratory, the applicant will be assessed a fee which covers the costs to the Science and Technology program for the service provided.

(e) When Science and Technology staff provides applied and developmental research and training activities for microbiological, physical, chemical, and biomolecular analyses on agricultural commodities the applicant will be charged a fee on a reimbursable cost to AMS basis.

■ 4. Section 91.38 is revised to read as follows:

§ 91.38 Additional fees for appeal of analysis.

(a) The applicant for appeal sample testing will be charged a fee at the hourly rate for laboratory service that appears in this paragraph. The new fiscal year for Science and Technology Programs commences on October 1 of each calendar year. The appeal rate for laboratory service is $71.00 per hour in fiscal year 2007, $74.00 per hour in fiscal year 2008, and $78.00 per hour in fiscal year 2009.

(b) The appeal fee will not be waived for any reason if analytical testing was completed in addition to the original analysis.

■ 5. Section 91.39 is revised to read as follows:

§ 91.39 Premium hourly fee rates for overtime and legal holiday service.

(a) When analytical testing in a Science and Technology facility requires the services of laboratory personnel beyond their regularly assigned tour of duty on any day or on a day outside the established schedule, such services are considered as overtime work. When analytical testing in a Science and Technology facility requires the services of laboratory personnel on a Federal holiday or a day designated in lieu of such a holiday, such services are considered holiday work. Laboratory analyses initiated at the request of the applicant to be rendered on Federal holidays, and on an overtime basis will be charged fees at hourly rates for laboratory service that appear in this paragraph. The new fiscal year for Science and Technology Programs commences on October 1 of each calendar year. The laboratory analysis rate for overtime service is $71.00 per hour in fiscal year 2007, $74.00 per hour in fiscal year 2008, and $78.00 per hour in fiscal year 2009. The laboratory analysis rate for Federal holiday or designed holiday service is $82.00 per hour in fiscal year 2007, $85.00 per hour in fiscal year 2008, and $89.00 per hour in fiscal year 2009.

(b) Information on legal holidays or what constitutes overtime service at a particular Science and Technology laboratory is available from the Laboratory Manager or facility supervisor.

■ 6. Section 91.42 is revised to read as follows:

§ 91.42 Billing.

(a) Each billing cycle will end on the 25th of the month. The applicant will be billed by the National Finance Center (NFC) using the Foundation Financial Information System (FFIS) on the 1st day, following the end of the billing cycle in which voluntary laboratory services and other services were rendered at a particular Science and Technology laboratory or office.

(b) The total charge or fee shall normally be stated directly on the analysis report or on a standardized official certificate form for the laboratory analysis of a specific agricultural commodity and related commodity products.

(c) The actual bill for collection will be issued by the USDA, National Finance Center Billings and Collection Branch, (Mail: P.O. Box 60075), 13800 Old Gentilly Road, New Orleans, Louisiana 70160–0001.

PART 92—[REMOVED AND RESERVED]

■ 7. Part 92 is removed and reserved.

Dated: March 23, 2007.

Lloyd C. Day,

Administrator, Agricultural Marketing Service.

[FR Doc. E7–5787 Filed 3–29–07; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 981

[Docket No. FV06–981–1 FR]

Almonds Grown in California; Outgoing Quality Control Requirements

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: This rule adds 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 rule provides for a mandatory program under the order to reduce the potential for *Salmonella* bacteria in almonds. This action will help ensure that quality almonds are available for human consumption.

DATES: This rule is effective on March 31, 2007. Handler treatment plans for the 2007–08 crop year must be submitted by May 31, 2007. Mandatory compliance with this rule begins September 1, 2007.

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,* or *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.*

SUPPLEMENTARY INFORMATION: This final 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 final rule adds 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 will 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.

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 products, 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 (GAPs), Good Manufacturing Practices (GMPs), and Sanitation Standard Operating Procedures (SSOPs). GAPs provide guidelines to growers on how to minimize potential biological hazards during the production and harvesting of almonds. GMPs define procedures to be used by handlers to allow almonds to be processed, packed, and sold under sanitary conditions. SSOPs 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 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 must subject their almonds to a process that achieves a minimum 4-log reduction in *Salmonella* bacteria prior to shipment. The program provides 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 also provides 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 must be prominently identified with the term ''unpasteurized.''

Specific Parameters of Mandatory Program

Under the program, handlers must 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 rule only affects 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 achieves a minimum 4-log reduction may be used, or a combination of different treatments may 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.[1] The risk assessment model demonstrated that a minimum 4-log reduction provides an appropriate level of consumer protection. Thus, the Board concluded that a 4-log reduction was an appropriate standard for almonds.

Treatment Processes

Treatment processes for handlers must 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 will 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 will not ''recommend'' or ''approve'' technologies, its review will 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 must be provided to the TERP (by a company pursuing TERP acceptance for its technology) for review to ensure that the technologies are consistently achieving the minimum 4-log reduction.

[1] Journal of Food Protection, Vol. 69, No. 7, 2006, Pages 1594–1599.

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 must be approved annually by the Board prior to the beginning of each crop year, or more frequently if needed during the crop year, for example, to fill a vacancy on the panel.

On-Site Versus Off-Site Treatment

Under the program, unless handlers ship their almonds to a Board-approved DV user (described later in this document), or ship their almonds to locations outside of the U.S., Canada, or Mexico, handlers must 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 will not be considered a shipment.

Process Authorities

Handlers may 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 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 include 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. 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 TERP. Should the applicant disagree with the TERP's decision concerning approval, it may appeal the decision in writing to the Board, and ultimately to USDA. Additionally, the TERP may revoke any approval for cause. The TERP must notify the process authority in writing of the reasons for revoking the approval. If the process authority disagrees with the TERP's decision, he/she may appeal the decision in writing to the Board, and ultimately to USDA. A process authority whose approval has been revoked must submit a new application to the TERP and await approval.

As explained later in this document, process authorities may also ''establish'' treatment processes for manufacturers under the DV program. The procedures and criteria for process authorities who establish treatment processes are identical to those for process authorities who validate such processes. ''Establish'' means that the treatment processes and protocols have been evaluated to ensure the technology's ability to deliver a lethal treatment for *Salmonella* in almonds to achieve a minimum 4-log reduction.

Compliance and Verification Program

Treatment Plans

To ensure compliance with the mandatory program, handlers will be subject to verification by the Federal or Federal-State Inspection Service (inspection agency) and review by Board staff. Handlers may use either an on-site (traditional) or an audit-based verification program. Each handler must decide which verification program will be the most cost-effective for his or her operation. All handlers must 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. The plan will be reviewed by the Board in conjunction with the inspection agency to ensure such plans are complete and auditable. The plan will be approved by the Board and must address specific parameters for the handler to ship almonds. Such parameters include, but are not 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 will be exported; (6) a statement whether the handler will 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 will be used on the almonds (including, for example, number of blanching lines, etc.); (9) a description of how treated product will be differentiated and segregated from untreated product to ensure maintenance of treated product integrity; (10) a list of procedures regarding how interhandler transfers will 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 will be subject to the approved treatment plan utilized at that off-site facility. Handlers must follow their own approved treatment plans for almonds sent to an off-site facility that is not affiliated with another handler.

Additionally, an off-site treatment facility that does not handle almonds, pursuant to § 981.16, must provide access to the inspection agency and Board staff for verification of treatment and review of treatment records. A treatment process at an off-site facility that has been validated by a Board-approved process authority is deemed to be approved by the Board for handler use. The Board may revoke any such approval for cause. The Board must notify the off-site treatment facility of the reasons for revoking the approval. Should the off-site facility disagree with the Board's decision, it may appeal the decision in writing to USDA. Handlers may treat their almonds only at off-site treatment facilities that have been deemed to be approved by the Board.

On-Site Verification Program

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

Audit-Based Verification Program

Under an audit-based verification program, handlers will be subject to periodic audits conducted by the inspection agency. The inspection agency will verify that handlers were following the treatment parameters and protocols specified in their approved treatment plans. Audit frequency will be tied to handler performance. Handlers will be provided with written audit reports specifying deficiencies. Handlers who do not comply with an audit-based verification program will be required to revert to an on-site verification program. Audit reports will 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 will 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, it will be the responsibility of the receiving handler to ensure that the almonds are treated prior to shipment and to maintain documentation to that effect. As provided in § 981.455, handlers must submit an ABC Form No. 7, ''Interhandler Transfer of Almonds,'' to the Board when they are involved in interhandler transfers.

Records

Handlers will be required to maintain records and documentation that will 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 must be maintained for 2 full years following the end of a crop year. Such records must identify lots from the point of treatment forward to the point of shipment by the handler. Lot identification must also provide the ability to differentiate treated from untreated product. Additionally, off-site treatment facilities located within the production area that provide the service of treating almonds for handlers, but are not handlers themselves, must maintain treatment records for 2 full years following the end of a crop year and make such records available to the Board.

Exemptions

Direct Verifiable Program

Handlers may ship untreated almonds directly to Board-approved manufacturers (DV users) within the U.S., Canada, or Mexico for further processing under the Direct Verifiable or DV program. The Board will issue a DV user code to an approved manufacturer. Handlers must reference this code on all documentation accompanying the lot. This will help the Board track DV shipments and facilitate compliance with the program. Handlers must also 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 directly to the approved DV user. While a third party may be involved in such transactions, shipments to a third party and then to a manufacturing location are not permitted under the DV program. Almonds under the DV program must be shipped directly from handlers to approved manufacturing locations.

Manufacturers wanting to participate in the DV program must submit an application 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 TERP. Should the applicant disagree with the TERP's decision concerning approval, it may appeal the decision in writing to the Board, and ultimately to USDA. Additionally, the TERP may revoke any approval for cause. The TERP must notify the manufacturer in writing of the reasons for revoking the approval. If the manufacturer disagrees with the TERP's decision, it may appeal the decision in writing to the Board, and ultimately to USDA. A manufacturer whose approval has been revoked must submit a new application to the TERP and await approval.

Similar to handlers, manufacturers must 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 may use treatment processes that have been ''established'' by a Board-approved process authority. As previously stated, ''established'' means that the process authority has evaluated the treatment processes and protocols to ensure the technology's ability to deliver a lethal treatment for *Salmonella* in almonds to 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). DV users must submit with their application to the TERP documentation to verify that their treatment technology and equipment have been validated by a Board-approved process authority. Such documentation may include, but not be limited to, a letter from a process authority certifying the validation. The documentation must be sufficient to demonstrate that the treatment processes and equipment achieve a 4-log reduction in *Salmonella* bacteria.

Manufacturers must also do the following: (1) Identify the manufacturing locations where treatment will 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 will be audited by a Board-approved auditor within 1–2 months after the start of treatments, and at least once every 12 months thereafter. The cost of the DV audit shall be borne by the manufacturer. Such audits will 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 will be sent to the Board within 10 days of the audit. DV user 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 TERP. Should the applicant disagree with the TERP's decision concerning approval, it may appeal the decision in writing to the Board, and ultimately to USDA. Additionally, the TERP may revoke any approval for cause. The TERP must notify the DV auditor in writing of the reasons for revoking the approval. If the DV auditor disagrees with the TERP's decision, it may appeal the decision in writing to the Board, and ultimately to USDA. A DV auditor whose approval has been revoked must submit a new application to the TERP and await approval.

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 may 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 directly 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 added to § 981.442 of the order's administrative rules and regulations.

Final 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 final regulatory flexibility analysis. Comments concerning the impact of the rule on small entities are discussed in the **Analysis of Comments** section below.

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 will be about 25 process authorities, 53 almond manufacturers, 50 DV program auditors, and 20 off-site California treatment facilities (non-handlers) 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 process authorities, almond manufacturers, DV program auditors, and off-site treatment facilities (non-handlers) is not available, it may be assumed that some process authorities, almond manufacturers, DV program auditors, and off-site California treatment facilities (non-handlers) 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 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 adds 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 will be implemented under the order. Specifically, handlers must subject their almonds to a treatment process that achieves a minimum 4-log reduction in *Salmonella* bacteria prior to shipment. The program exempts 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 also exempts handlers who ship untreated almonds to locations outside of the U.S., Canada, or Mexico. All containers of untreated almonds shipped under the exemptions must be prominently identified with the term ''unpasteurized.'' 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 will vary considerably depending on their markets and treatment method(s) chosen. Handlers may: (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 will 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 will 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 will 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 will 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
20,000–30,000	525,000–800,000
Over 30,000	600,000–1,000,000

While treatment equipment costs will be the most significant outlay, there will 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 will 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 mandatory treatment program 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 Handler annual capacity (Pounds)	B Total equipment cost*	C Annual use cost of equipment, 5 year life**	D Unit Cost of Equipment at: 50% of capacity (C/50% of A)	E Unit Cost of Equipment at: Full capacity (C/A)	F Average operating cost	G Equipment plus operating cost at: 50% of capacity (D + F)	H Equipment plus operating cost at: 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 will 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 will 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 will likely have to invest approximately 40–80 person-hours to develop their treatment plan. However, once this document has been created, it will be updated on an annual basis, which will 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. Validation costs are expected to be borne by handlers, as well as DV users and off-site treatment facilities (non-handler). DV audit costs will be borne by DV users.

Handler verification costs may vary, depending on whether the handler is under an on-site program or an audit-based program. The fee for an on-site program will 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 will be a minimum $78.00 per hour. Travel time for both programs will be charged at $44.00 per hour and $0.34 per mile. Verification costs may also be charged to off-site treatment facilities (non-handler); however, such costs may be passed on to the respective handlers using the facility.

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 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 was 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 imposes additional reporting and recordkeeping burden on California almond handlers, process authorities, almond manufacturers, DV program auditors, and off-site treatment facilities. Process authorities, manufacturers, and DV auditors must submit respective applications to the Board. Almond handlers must submit treatment plans to the Board. In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), these new forms and a sample ''Handler Treatment Plan'' were submitted to the Office of Management and Budget (OMB) and have been approved under OMB Control No. 0581–0242, Almonds Grown in California. Specific burdens for the three new applications and handler treatment plan are addressed in the section below titled **Paperwork Reduction Act**. ABC Form No. 7, ''Interhandler Transfer of Almonds,'' has previously been approved by OMB under OMB Control No. 0581–0178, ''Vegetable and Specialty Crop Marketing Orders. 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.

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.

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.

Analysis of Comments

A proposed rule concerning this action was published in the **Federal Register** on December 6, 2006 (71 FR 70683). Copies of the rule were also mailed or sent via facsimile to all almond handlers. Finally, the proposal was made available through the Internet by USDA and the Office of the Federal Register. A 45-day comment period ending January 22, 2007, was provided for interested persons to respond to the proposal. Eighteen comments were received. Of the 18 comments, 3 supported the rule with no changes, 7 supported the rule with modification, 3 were opposed, and the remaining 5 comments raised other issues. The comments are addressed in the following paragraphs.

Comments in Full Support

The three comments which supported the rule with no changes were submitted by a grower cooperative/handler/marketer; a grower/handler; and a trade association representing almond hullers and shellers. One commenter believes the rule is necessary to prevent *Salmonella* from reaching the consuming public via California almonds. Another of the commenters summarized his company's experience in a *Salmonella* outbreak and recall. He contends that, based on his company's experience with treatments, there has been no noticeable impact on product shelf-life, roasting, or flavor to consumers. He added that his raw almond business has increased since implementing 100 percent treatment with no increase in quality complaints. The third commenter believes that the livelihood of the industry is at risk if it does not proceed immediately to mitigate the presence of *Salmonella* in its product. All of the commenters supported implementation of the rule as soon as possible.

Comments in Support, With Modification

The seven comments which supported the rule with modification were submitted by the Board; a trade association representing food, beverage, and consumer product companies; a trade association representing confectionary manufacturers, suppliers, buyers, and brokers; a chocolate and confectionary manufacturer; a processor/marketer of nut products; a handler; and a grower/handler.

Four of the commenters addressed the proposed reporting requirements. Three of these comments expressed concern with an annual submission of an application for DV users. Two suggested that, once the DV user has been approved by the Board and is on an approved list, there is no reason to remove the entity except for cause, or at the request of the DV user. Another suggested that, if a DV user does not change its treatment technology, and if a problem has not been identified by the DV auditor, there is no reason for DV users to reapply annually to the Board. Two commenters suggested that the initial approval for process authorities and DV auditors should be sufficient, adding that agency approval is not required under regulations governing production of low-acid canned foods, which is the source of the process authority concept.

The Board commented that the DV user and auditor applications were designed so that once the entity is originally approved, it would only have to reconfirm participation in subsequent years. A new or modified application would only be necessary in cases where new procedures, equipment, or processing locations have been introduced.

Based on the comments received, USDA has determined that modifications to the proposed rule regarding reporting requirements are warranted. Process authorities, DV users, and DV auditors must submit an initial application to the Board. For subsequent crop years, such approved entities with changes in the information contained in their initial application must submit a new, revised application to the Board for review and approval prior to the start of the crop year. Approved applicants with no changes to their initial application must send the Board a letter, signed and dated, indicating that there are no changes to the application the Board has on file. In the new § 981.442(b)(3) regarding the application for process authorities, § 981.442(b)(6)(i) regarding the application for DV users, and

§ 981.442(b)(6)(i)(D) regarding the application for DV auditors are revised accordingly. The revised reporting burdens are addressed in the section below titled **Paperwork Reduction Act**.

Three of the comments raised various issues regarding process authorities. One issue concerned the release of proprietary information regarding manufacturers' processes. Two commenters suggested adding language to the regulatory text that clarifies, as the preamble does, the role of process authorities in establishing technologies for manufacturers, in particular, the protection this option provides regarding proprietary data under the DV program. The commenters want to ensure that disclosure of data on manufacturers' proprietary processes is not required for determination of acceptance by the TERP of manufacturers' treatment processes. The Board commented that process authorities for DV users must provide reports to the Board that contain sufficient content to describe the verification methodologies that were used to establish that the treatment processes and technologies achieve a minimum 4-log reduction in *Salmonella* bacteria. The Board contends that the TERP would not require information regarding manufacturers' proprietary manufacturing processes.

As previously stated, manufacturers' use of treatment processes established by process authorities was included in the regulation to address concerns regarding the release of data on manufacturers' proprietary processes to the TERP. Modification of the regulatory text to address this is not warranted. However, USDA concurs that the Board needs documentation to ensure that processes established by process authorities achieve a 4-log reduction in *Salmonella* bacteria. Accordingly, § 981.442(b)(6)(i)(C) is revised to specify that DV users must provide documentation with their DV application to the TERP to verify that their treatment technology and equipment have been validated by a Board-approved process authority. Such documentation may include, but not be limited to, a letter from such process authority certifying the validation. Finally, such documentation must be sufficient to demonstrate that the treatment processes and equipment achieve a 4-log reduction in *Salmonella* bacteria. The revised reporting burden regarding DV users is addressed in the section below titled **Paperwork Reduction Act**.

Two commenters requested that the rule be clarified to specify that process authorities may be employees of a manufacturer, which is similar to process authorities for low-acid canned foods. USDA concurs, but notes that it is essential to ensure that process authorities act in a neutral, unbiased manner for both manufacturers and handlers. Accordingly, paragraph (b)(3) in § 981.442 has been modified to specify that process authorities may be employees of the entity for which they are conducting validation.

The rule has also been clarified to specify that DV auditors may not be employees of manufacturers they are auditing. It is important that a third party perform the audit to ensure the integrity of the DV program. Accordingly, paragraph (b)(6)(i)(D) in § 981.442 has been modified to specify that DV auditors may not be employees of the entity for which they are conducting an audit.

Two commenters also suggested adding language to the regulatory text that clarifies, as the preamble does, the criteria that process authorities must meet in order to be approved by the TERP. This criteria includes 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); and (3) able to determine that sufficient data has been gathered to identify the critical factors needed to ensure the quality of the final product. Accordingly, paragraph (3) in the new § 981.442(b) has been modified accordingly.

The Board commented that the rule be clarified to specify that persons, not an organization, must submit applications for approval as process authorities. It is the Board's intent that persons, not organizations, be approved process authorities. The Board wants to ensure that persons conducting validation are qualified to do so. USDA concurs with the comment. Paragraph (3) in the new § 981.442(b) has been modified accordingly.

The Board also commented that the rule be clarified to specify that, under the DV program, almonds must be shipped by handlers directly to approved manufacturer locations where such almonds will be treated. The Board contends that, without direct shipment, it would be impossible to ensure that almonds were being shipped to a facility where treatment would occur. Indirect shipments to third parties could lose identity and be difficult to track. USDA concurs with the comment. While a third party may be involved in the transaction, shipments to a third party and then to a manufacturing location are not permitted under the DV program. Paragraph (b)(6)(i) of § 981.442 has been modified accordingly.

Related to the issue of direct DV shipments, one commenter stated that two small roasters indicated to him they would like to see the rule revised to allow use of a custom vendor under the DV program. USDA assumes this means that the almonds would be shipped outside the production area to a non-manufacturing entity or third party for treatment. Based on the reasons stated in the preceding paragraph regarding the need to track shipments to approved manufacturer locations, the comment is denied.

Two commenters provided recommendations regarding the frequency of USDA audits for handlers under the audit-based verification program. In its comment, the Board agreed that audit frequency be tied to handler performance, and suggested that, during the first year, audits be conducted during month 1, 3, 6, and 12. If all procedures are in place and documentation is accurate, in the second year, audits should only be conducted once every 6 months. Another commenter suggested that two audits be conducted for the first year, but less frequently in subsequent years when the program is ongoing unless equipment changes are made to the technology used by the handler; the commenter suggested audits every 24 months in subsequent years.

USDA has taken these suggestions under consideration in development of its handler audit plan. However, handler audit frequency is not a part of the regulatory text of this rule. Accordingly, no changes have been made to the proposed rule based on these comments.

One commenter requested that the Board (TERP) provide process authorities critical ranges, or minimum standards, for variables and conditions that are critical to PPO and other treatment processes. USDA understands that it is the Board's intent to make this information available to process authorities and other interested parties (*i.e.*, equipment manufacturers, handlers, or scientists). Paragraph (b)(3) of § 981.442 is modified accordingly.

Related to validation, one commenter stated that, to-date, there is no surrogate organism for validating dry roasting processes. This is correct. USDA understands that the Board continues to fund research for non-pathogenic surrogates that could be used for validating both moist and dry heat treatment processes. Until these are available, validation for moist and dry heat processes must be done with

Salmonella bacteria. Validation with live *Salmonella* is not necessary for PPO, blanching, or oil roasting because the Board has developed specific protocols and parameters for these processes.

Two commenters suggested that the rule be modified to specify time frames for the approval of process authorities; one suggested a 45-day time frame for approval, and one suggested a 30-day time frame for approval, and 2 weeks for appeals. One of the commenters also suggested time frames for approval of applications for DV users and DV auditors—30 day time frame for approval, and 2 weeks for appeals.

Timely review of these applications is important. USDA will work with the Board to ensure quick review and response. However, it is not necessary to specify time frames within the regulation. Thus, these comments are denied.

One commenter suggested that DV users be audited no more than once every 2 years. Although not specified in the regulatory language, the preamble indicates that DV users will be audited within 1–2 months after the start of treatments, and at least once every 12 months thereafter. An annual audit of DV users is appropriate to maintain the integrity of the mandatory program. Thus, the comment is denied.

Three commenters expressed concern with the impact of treatments on the quality, shelf-life, and/or sensory characteristics of almonds. One contends that the Board's quality research is still ongoing. Another contends that treated and untreated almonds should be comparable in terms of taste, nutritional composition, product performance, color, appearance, and shelf-life; the commenter requested that the Board or TERP require extensive product testing of any potential new technology to assure the consuming public that such almonds are materially unchanged in regard to their eating quality.

In early 2006, the Board allocated $1 million towards a project to ensure that appropriate treatment resulted in no significant degradation of the almonds. The Board formed a team comprised of manufacturers, handlers, technical experts, and Board staff to develop the parameters of the research project and evaluate the results. Control almonds were compared with almonds that were subjected to PPO and two different moist heat treatments. Control and treated almonds were also roasted. The Board indicated it its comments that the team met in January 2007 and reviewed the following findings. There were no indications to-date of significant degradation or product deterioration when comparing treated samples with control samples. Data presented by a confectionary manufacturer regarding a pilot trial with treated, consumer ready product indicated that the product chemistry does not present any evidence of degradation in raw or roasted almonds. Also, as mentioned earlier, one commenter who was involved in a recall contends that, based on his company's experience with treatments, there has been no noticeable impact on product shelf-life, roasting, or flavor to consumers. No changes have been made to the proposed rule based on these comments.

One commenter expressed concern with the treatment cost estimates in the proposed rule. Costs for steam and PPO treatments were estimated between $0.02—$0.07 per pound. The commenter represents confectionary companies and contends that costs to its members would be slightly higher, depending on broker fees and the volume of almonds purchased. The commenter estimates that there could be an additional cost of $0.05 to $0.10 per pound for treated almonds purchased by small and medium confectionary companies that purchase lesser volumes of almonds through brokers.

While costs to these buyers could be slightly higher if they purchased treated almonds, the benefits of this rulemaking action outweigh the costs. Additionally, confectionary companies will still be able to purchase untreated almonds. No changes have been made to the proposed rule based on this comment.

Several of the comments addressed PPO. One commenter contends that PPO is not permitted to-date in Canada, the European Union (EU), or Mexico. While it is true that PPO is not permitted in the EU and Canada, it is permitted in Mexico. Regarding shipments to the EU, under the mandatory program, handlers may ship almonds untreated to the EU, provided such almonds are labeled ''unpasteurized.'' Almonds shipped to Canada can be treated with one of the other available technologies, or can be shipped untreated to DV users in that country. No changes have been made to the proposed rule based on these comments.

One of the commenters stated that they support pasteurization, but believe it should not be at the handler level, and questioned the authority to impose such a requirement through this rulemaking. The commenter contends that the safety of almond-containing products can be assured by treating almonds after they leave control of the handler, and that later treatment furthers food safety objectives by affording less opportunity for re-contamination of almonds. The commenter argues that only treated almonds should be sold to those who plan to sell them to consumers as raw or natural almonds.

USDA is implementing this rulemaking action under the quality control authority contained in the almond marketing order. Under the Act, the authorizing statute for all marketing orders, regulations may only be implemented at the handler level. Thus, no changes have been made to the proposed rule based on this comment.

One of the commenters indicated his support for 100 percent pasteurization for all almonds. He stated that, given the food safety risks, available control technologies and protocols, he strongly encourages USDA to make almond pasteurization mandatory for all almonds.

As stated earlier in this rule, the Board's initial proposal to USDA in February 2006 would have ultimately required handlers to treat all almonds prior to shipment. 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.''

Although this rule does not mandate treatment for all California almonds, it will help to ensure consumers receive a good quality product, while at the same time addressing global customer needs. No changes will be made to the rule based on this comment.

One commenter asked for USDA's assistance in getting PPO approved for use in all export markets. The commenter also asked USDA to pursue avenues to provide $3–$5 million to the almond industry over the next 5 years for research to continue development of additional food safety issues, including aflatoxin and pasteurization. These requests are outside the scope of this rulemaking action. Thus, no changes have been made to the proposed rule based on this comment.

Comments Opposed or Raising Other Issues

The three comments opposed to the rule were submitted by small handlers and one was submitted by an agricultural consultant. All of the

commenters contend that the rule will put small handlers out of business. One small handler said that 40 percent of his shipments are brown skin, and 60 percent are manufacturered. Almost all of his sales are domestic, with some product shipped to Canada and Mexico. Two commenters said that their businesses were geared toward providing product to buyers and consumers quickly. Both of these commenters contend that the technologies are too expensive for small handlers. Both also expressed concern with the cost of contracting out for treatment. One stated that having product treated ahead of time is problematic because one may not know the container-size that buyers want prior to treatment. Concern was also expressed with the quality of treated almonds, stating that there are only two methods of treatment to-date—PPO and steam (moist heat). One commenter also contends that consumers should have a choice to buy raw or processed almonds, and that labeling almonds as non-pasteurized would be acceptable to many.

USDA has evaluated the impact of this rulemaking action on small handlers. There is an added expense for handlers who ship primarily domestic to entities that are not DV users. Their almonds must be treated prior to shipment. Such handlers must evaluate their own business situation to determine the merits of investing in treatment equipment or contracting out for treatment. As previously stated, PPO treatment is currently available on a contract basis at $0.04–$0.05 per pound (including transportation to the facility). Also, the Board continues to fund research projects to develop additional treatment methods. USDA understands the challenges facing small handlers; however, USDA is also concerned about the impact of another *Salmonella* outbreak linked to almonds on the industry as a whole. USDA supports the Board's proposal for a mandatory treatment program for almonds.

The concern raised regarding the impact of treatments on the quality of almonds was addressed earlier in this document. Preliminary results of a comprehensive study conducted by the Board in conjunction with manufacturers and handlers, has shown no significant degradation in the quality or shelf-life of almonds. Again, no changes have been made to the proposed rule based on concerns regarding quality.

In response to the comment that consumers should have a choice to buy raw or processed almonds, and the suggestion that almonds be labeled as non-pasteurized, USDA assumes that the commenter means labeling at the consumer level. The Act provides authority for requirements under a marketing order at the handler level, not the consumer level. Thus, no changes have been made to the proposed rule based on this comment.

Two comments were submitted by a small handler and a collective group of three handlers/growers requesting delayed implementation of the rule. The proposed rule stated that the mandatory program would take effect on August 1, 2007, the start of the 2007–08 crop year, with handlers submitting their treatment plans for 2007–08 by May 1, 2007. The three growers/handlers raised concerns about available treatment capacity, and contend that it is logistically impossible to implement the program by August 1, 2007. They expressed concern with potentially only a 3-month lag between publication of the final rule and implementation of the program. The small handler requested delayed implementation until issues for small handlers are addressed guaranteeing that they will not be forced out of business.

Regarding capacity, the commenters contend that more technologies are needed and believe that, once the rule becomes mandatory, more companies will likely submit protocols to TERP for review acceptance. The commenters summarized their understanding of available technologies, and contend that the mandatory program would restrict commerce due to insufficient capacity. The comment contends the following. There are three moist heat processes accepted by the TERP. The latest process (A) recently received ''approval'' for one chamber, and is operating at one facility in central California. Another process (B) has been TERP-accepted with no systems built, and the third (C) has three systems in place primarily for private use, and limited capacity for outside custom volume. Regarding PPO, the commenters contend there are limited facilities in California. The largest facility available is in Nevada, outside the production area of California. They contend that, due to capacity constraints, only a fraction of the needed PPO space is available. The comment also raises concerns regarding fees and availability for custom treatment, particularly if the time frame between publication of the final rule and implementation of the program is only 3 months. If a handler were going to build his/her own facility, the comment estimates that construction and validation could take more than 1 year.

In response to concerns regarding technology and available capacity, the comment is correct in that there are three moist heat processes accepted to-date by the TERP. However, as shown below in Table 7, moist heat capacity is estimated at a minimum 652 million pounds. The comment is correct that one chamber for Process A in central California has been validated and is in operation (100 million pound capacity). However, that machine has two other chambers to be validated. Once validation is completed, an additional 200 million pounds of capacity will be available. Regarding process B, the comment is incorrect that a machine has not yet been built. In fact, a machine has been built and is being installed (88 million pound capacity). For process C, one machine is operational, and in-plant validation is starting on two additional machines (another 176 million pounds in capacity).

TABLE 7.—MOIST HEAT CAPACITY

Moist heat process	Status	Capacity (pounds)
A	—3 chambers for one machine in one plant, 1 chamber validated and operational.	[1] 100
	—Other 2 chambers to be validated.	[1] 200
B	—1 machine being installed (validated in industrial warehouse).	[1] 88
C	—1 machine validated and operational.	[1] 88
	—2 machines in process of in-plant validation.	[1] 176

Total capacity 652 million.
[1] In millions.

Regarding PPO, the comment is correct in that handlers must treat their almonds within the production area of California. However, the comment is incorrect that PPO capacity in California is limited. Board data indicates available PPO capacity within California of at least 250 million pounds. Thus, total capacity from moist heat and PPO is estimated at over 800 million pounds. Additional machines and equipment are likely to be built in the future. Raw domestic almond shipments (240 million pounds) and shipments to Canada and Mexico (36.7 million pounds) total about 276 million pounds. Thus, there will be more than sufficient capacity to treat all of this production.

No changes have been made to the proposed rule due to concerns regarding capacity.

In response to the suggestion that implementation of the program be delayed, USDA believes this has merit. USDA concurs that sufficient time is needed between publication of the final rule and implementation of the mandatory program. Once the final rule is published, the Board must circulate applications to prospective process authorities, DV users, and DV auditors. Time is needed for application submission, review, and approval. Treatment technology and equipment must be validated by Board-approved process authorities. Handlers must develop and submit treatment plans to USDA and the Board for review and approval. Small handlers without treatment equipment must arrange for outsourcing treatment and may have to make adjustments in their business practices. For example, they may have to treat their almonds ahead of time, work with their customers to assess their needs regarding container size, etc. earlier than in the past, or perhaps try to develop new customers that could qualify as DV users.

USDA has determined that about a 5-month lag time between publication of the final rule and implementation of the program is appropriate. USDA assessed the merits of waiting another complete crop year for implementation, August 2008, and believes that such a delay would not be warranted. USDA considered a September 1, 2007, date for implementation. New crop shipments begin September 1, so this date would ensure that 2007–08 crop almonds are covered under the program. Accordingly, in the new § 981.442(b), the introductory text in paragraph (b) is modified to specify a September 1, 2007, implementation date, and paragraph (b)(4)(i) is modified to specify that, for the 2007–08 crop year, handler treatment plans must be submitted by May 31, 2007, rather than May 1, 2007.

Another commenter contends that the DV program is the only viable and rational option to adopt and maintain, and supports the labeling of untreated product shipped to approved DV users within the U.S., Canada, and Mexico, and outside these areas, provided product is labeled. The commenter does not support 100 percent treatment for all almonds when only 5 percent of almonds are consumed raw. In response, the rule provides for a DV program, labeling of untreated product, and does not require all almonds to be treated prior to shipment.

Another commenter suggested that the word ''pasteurized'' or ''unpasteurized'' on containers be both in English and in the language used by the receiving country. The Board addressed this concern in its comment. The Board contends that translating the word ''unpasteurized'' on containers is not feasible because it is not always clear what the final destination will be. The Board suggests that all markings on containers be in English for ease of translation if so required by the country into which the goods will enter. USDA concurs with the Board. Regarding the word ''pasteurized,'' the regulation does not require treated containers of almonds to be labeled. No changes have been made to the proposed rule based on this comment.

Another commenter contends that the industry's concern regarding California almonds being shipped back into the U.S. from Canada and Mexico is unfounded. He contends that freight costs and difficulties with getting the goods through customs would prohibit transshipments. The Board discussed this issue in depth prior to making its recommendation to treat Canada and Mexico similar to the U.S. under the mandatory program. The Board concluded that transshipments could be a problem. USDA concurs with the Board. The comment is denied.

Paperwork Reduction Act

The proposed rule published on December 6, 2006, provided for a 60-day comment period on the reporting requirements contained in the rule. That period ended on February 5, 2007. Four comments were received that concern reporting requirements and are addressed in the *Analysis of Comments* section above. Based on these comments, the reporting burdens were revised for the applications for process authorities, DV users, and DV program auditors. These entities must submit an initial application to the Board. For subsequent years, rather than submitting new applications, approved applicants with no changes to their initial applications must send the Board a letter, signed and dated, indicating there are no changes to the application the Board has on file. Additionally, DV users must submit with their application documentation to verify that their treatment technology and equipment were validated by a Board-approved process authority, and to demonstrate appropriate treatment processes. The revised reporting burdens are as follows.

Regarding ABC Form No. 51, ''Application for Process Authority for Almonds,'' it is estimated that it will take a process authority about 2 hours per response (same as proposal) for the first year of regulation, but only .25 hours per response each year thereafter (a reduction of 1.75 hours), and that 25 process authorities will respond. Thus, the total annual reporting burden for the form is estimated at 50 hours (same as proposal) for the first year of regulation, and 6.25 hours for each year thereafter (a reduction of 43.75 hours).

Regarding ABC Form No. 52, ''Application for Direct Verifiable (DV) Program for Further Processing of Untreated Almonds,'' it is estimated it will take a manufacturer about 1.5 hours per response (.5 hours more than initially proposed) for the first year of regulation. The additional .5 hours addresses the time for DV users to include documentation with their application to verify that their treatment technology and equipment were validated by a Board-approved process authority. It is estimated that it will take a manufacturer only .25 hours per response each year thereafter, and that 53 manufacturers will respond each year. Thus, the total annual reporting burden for the form is estimated at 79.5 hours (26.5 hours more than initially proposed) for the first year of regulation, and 13.25 hours for each year thereafter (a reduction of 66.25 hours).

Regarding ABC Form No. 53, ''Application for Direct Verifiable (DV) Program Auditors,'' it is estimated it will take a DV auditor about 1 hour per response for the first year of regulation, but only .25 hours per response (a reduction of .75 hours) each year thereafter, and that 50 auditors will respond. Thus, the total annual reporting burden for the form is estimated at 50 hours for the first year of regulation, and 12.5 hours for each year thereafter (a reduction of 37.5 hours).

As previously stated, in accordance with the PRA, the information collection was submitted to the OMB and was approved under OMB Control No. 0581–0242, Almonds Grown in California.

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.

After consideration of all relevant matters presented, including the information and recommendation submitted by the Board and other available information, it is hereby found that this rule, as hereinafter set forth, will tend to effectuate the declared policy of the Act.

Pursuant to 5 U.S.C. 553, it is also found and determined that good cause exists for not postponing the effective date of this rule until 30 days after publication in the **Federal Register** because handler treatment plans for the 2007–08 crop year are due to the Board and USDA by May 31, 2007, and mandatory compliance with this rule begins September 1, 2007. Handlers are aware of this action which was unanimously recommended at a public meeting. Additionally, a 45-day comment period was provided for in the proposed rule, and all comments received were addressed herein.

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 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 redesignating the undesignated text following paragraph (a)(7)(iv) as paragraph (a)(7)(v) and by adding paragraph (b) to read as follows:

§ 981.442 Quality control.

* * * * *

(b) *Outgoing.* Pursuant to § 981.42(b), beginning September 1, 2007, and except as provided in § 981.13 and in paragraph (b)(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.* 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. Treatment technology and equipment that have been modified to a point where operating parameters such as time, temperature, or volume change, shall be revalidated.

(i) 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.

(ii) A process authority is a person that has expert knowledge of appropriate processes for the treatment of almonds as defined in paragraph (b)(1) of this section, and meets the following criteria:

(A) Knowledge about the equipment used for the treatment process;

(B) Experience in conducting appropriate studies to determine the ability of the equipment to deliver the appropriate treatment (such as heat penetration or heat distribution); and

(C) Able to determine that sufficient data has been gathered to identify the critical factors needed to ensure the quality of the final product.

(iii) Process authorities may be employees of the entity for which they are conducting validation. The Board shall provide process authorities specific protocols and parameters for treatment processes that are FDA determined or TERP accepted.

(iv) Process authorities must submit an initial application to the Board on ABC Form No. 51, ''Application for Process Authority for Almonds,'' and be approved by the TERP. Should the applicant disagree with the TERP's decision concerning approval, the applicant may appeal the decision in writing to the Board, and ultimately to USDA. For subsequent crop years, approved applicants with no changes to their initial application must send the Board a letter, signed and dated, indicating that there are no changes to the application the Board has on file.

(v) The TERP may revoke any approval for cause. The TERP shall notify the process authority in writing of the reasons for revoking the approval. Should the process authority disagree with the TERP's decision, he/she may appeal the decision in writing to the Board, and ultimately to USDA. A process authority whose approval has been revoked must submit a new application to the TERP and await approval.

(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 a 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. 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 a 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.

(v) An off-site treatment facility that does not handle almonds, pursuant to § 981.16, shall provide access to the inspection agency and Board staff for verification of treatment and review of treatment records. A treatment process at an off-site treatment facility that has been validated by a Board approved process authority is deemed to be approved by the Board for handler use. The Board may revoke any such approval for cause. The Board shall notify the off-site treatment facility of the reasons for revoking the approval. Should the off-site facility disagree with the Board's decision, it may appeal the decision in writing to USDA. Handlers may treat their almonds only at off-site treatment facilities that have been deemed to be approved by the Board.

(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. Off-site treatment facilities that do not handle almonds pursuant to § 981.16, shall maintain treatment records for 2 full years following the end of a crop year and make such records available to the Board.

(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 TERP. Such almonds must be shipped directly to approved manufacturing locations, as specified on Form No. 52. Such manufacturers DV users must submit an initial Form No. 52 to the Board and be approved by the TERP. Should the applicant disagree with the TERP's decision concerning approval, it may appeal the decision in writing to the Board, and ultimately to USDA. For subsequent crop years, approved applicants with no changes to their initial application must send the Board a letter, signed and dated, indicating that there are no changes to the application the Board has on file. The TERP may revoke any approval for cause. The TERP shall notify the manufacturer in writing of the reasons for revoking the approval. Should the manufacturer disagree with the TERP's decision, it may appeal the decision in writing to the Board, and ultimately to USDA. A manufacturer whose approval has been revoked must submit a new application to the TERP and await approval. 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. While a third party may be involved in such transactions, shipments to a third party and then to a manufacturing location are not permitted under the DV program. 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 TERP, or established by a process authority approved in accordance with and subject to the provisions and procedures of paragraph (b)(6) of this section. Establish means that the treatment process and protocol have been evaluated to ensure the technology's ability to deliver a lethal treatment for *Salmonella* bacteria in almonds to achieve a minimum 4-log reduction;

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

(C) Have their treatment technology and equipment validated by a Board-approved process authority, and provide documentation with their DV application to verify that their treatment technology and equipment have been validated by a Board-approved process authority. Such documentation may include, but not be limited to, a letter from such process authority certifying the validation. Such documentation shall be sufficient to demonstrate that the treatment processes and equipment achieve a 4-log reduction in *Salmonella* bacteria. Treatment technology and equipment that have been modified to a 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. A DV auditor may not be an employee of the manufacturer that he/she is auditing. DV auditors must submit a report to the Board after conducting each audit. DV auditors must submit an initial application to the Board on ABC Form No. 53, ''Application for Direct Verifiable (DV) Program Auditors,'' and be approved by the TERP. Should the applicant disagree with the TERP's decision concerning approval, it may appeal the decision in writing to the Board, and ultimately to USDA. For subsequent crop years, approved DV auditors with no changes to their initial application must send the Board a letter, signed and dated, indicating that there are no changes to the application the Board has on file. The TERP may revoke any approval for cause. The TERP shall notify the DV auditor in writing of the reasons for revoking the approval. Should the DV auditor disagree with the TERP's decision, it may appeal the decision in writing to the Board, and ultimately to USDA. A DV auditor whose approval has been revoked must submit a new application to the TERP and await approval;

(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: March 26, 2007.

Lloyd C. Day,

Administrator, Agricultural Marketing Service.

[FR Doc. 07–1557 Filed 3–27–07; 10:50 am]

BILLING CODE 3410–02–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 23

[Docket No. CE255; Special Conditions No. 23–195A–SC]

Special Conditions: Aviation Technology Group (ATG), Inc., Javelin Model 100 Series Airplane; Flight Performance, Flight Characteristics, and Operating Limitations

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Amended final special conditions.

SUMMARY: These amended special conditions are issued for the Aviation Technology Group (ATG), Inc., Javelin Model 100 Series airplane. This is an amendment to special condition 23–195–SC, which was published on February 1, 2007 (72 FR 4618), for certain novel or unusual design features associated with engine location, certain performance, flight characteristics and operating limitations. The original final special conditions were more generic and contained requirement language that was not necessary for jet airplanes. This amendment also corrects several references to part 23 sections to be consistent with these special conditions.

This airplane will have a novel or unusual design feature(s) associated with engine location, certain performance, flight characteristics and operating limitations necessary for this type of airplane. The applicable airworthiness regulations do not contain adequate or appropriate safety standards for this design feature. These special conditions contain the additional safety standards that the Administrator considers necessary to establish a level of safety equivalent to airworthiness standards applicable to these airplanes.

DATES: The effective date of these special conditions is March 23, 2007.

FOR FURTHER INFORMATION CONTACT: J. Lowell Foster, Federal Aviation Administration, Aircraft Certification Service, Small Airplane Directorate, ACE–111, 901 Locust, Room 301, Kansas City, Missouri, 816–329–4125, fax 816–329–4090.

SUPPLEMENTARY INFORMATION: The final special conditions with a request for comments were published on February 1, 2007 (72 FR 4618). No comments were received. These amended final special conditions remove requirement language that is not necessary for jet airplanes.

Background

On February 15, 2005, Aviation Technology Group (ATG); 8001 South InterPort Boulevard, Suite 310; Englewood, Colorado 80112–5951, applied for a type certificate for their new Model 100 Javelin airplane in accordance with the airworthiness standards in 14 CFR, part 23. The Javelin is a two-place, twin engine, turbofan-powered light jet airplane with a planned maximum operating altitude of 45,000 feet. Part 23 regulations in effect on the date of ATG's application do not contain adequate or appropriate safety standards for a small, high performance jet airplane such as the Javelin. In accordance with Small Airplane Directorate policy, the safety standards for flight performance, flight characteristics and operational limitations that the Federal Aviation Administration (FAA) finds necessary to establish an acceptable level of safety for this type of airplane are presented in this special condition.

Final special conditions with request for comments were issued on January 24, 2007, and were published on February 1, 2007. The comment period closed March 5, 2007, and no comments were received. However, the original issue contained requirement language that is not necessary for jet airplanes, and this amendment removes that language.

Type Certification Basis

Under the provisions of 14 CFR, part 21, § 21.17, ATG must show that the Model 100 meets the applicable provisions of part 23, as amended by Amendment 23–1 through 23–55 thereto. If the Administrator finds that the applicable airworthiness regulations (i.e., 14 CFR, part 23) do not contain adequate or appropriate safety standards for the ATG Model 100 series because of a novel or unusual design feature, special conditions are prescribed under the provisions of § 21.16.

Special conditions, as appropriate, as defined in § 11.19, are issued in accordance with § 11.38, and become part of the type certification basis in accordance with § 21.17(a)(2).

Special conditions are initially applicable to the model for which they are issued. Should the type certificate for that model be amended later to include any other model that incorporates the same novel or unusual design feature, the special conditions would also apply to the other model under the provisions of § 21.101(a)(1).

In addition to the applicable airworthiness regulations and special conditions, the Model 100 must comply with the part 23 fuel vent and exhaust emission requirements of 14 CFR, part 34 and the part 23 noise certification requirements of 14 CFR, part 36; and the FAA must issue a finding of regulatory adequacy pursuant to § 611 of Public Law 92–574, the ''Noise Control Act of 1972.''

Novel or Unusual Design Features

ATG intends to certificate the Javelin in both utility and acrobatic categories. The ATG Javelin Model 100 will incorporate the following novel or unusual design features:

- Two-place, tandem configuration.
- Maximum takeoff weight of approximately 6,900 pounds.
- Design cruise speed of 500 knots calibrated airspeed.
- Two Williams FJ33–4A–18M turbofan engines with dual channel FADEC controls.
- Major airframe components constructed of carbon fiber composite materials.
- Hydraulically boosted flight control system with floor-mounted control sticks.
- Integrated avionics including Avidyne displays, autopilot, and flight management system.

Novel features on the ATG Model 100 include rear mounted turbine engines embedded in the fuselage, boosted controls, and high-speed, high-altitude acrobatic capability.

Applicability

As discussed above, these special conditions are applicable to the ATG Model 100 series. Should ATG apply at a later date for a change to the type certificate to include another model incorporating the same novel or unusual design feature, the special conditions would apply to that model as well under the provisions of § 21.101(a)(1).

Conclusion

This action affects only certain novel or unusual design features on ATG Model 100 series airplanes. It is not a rule of general applicability and affects only the applicant who applied to the FAA for approval of these features on the airplane.