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

DEPARTMENT OF AGRICULTURE
Agricultural Marketing Service

7 CFR Part 205
[Docket Number TM–04–07]

National Organic Program, Sunset Review

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Advance notice of proposed rulemaking with request for comments.

SUMMARY: As required by the Organic Foods Production Act of 1990 (OFPA), the allowed use of 165 synthetic and non-synthetic substances in organic production and handling will expire on October 21, 2007. In addition, prohibitions on the use of 9 non-synthetic substances will expire in organic production on October 21, 2007. The Agricultural Marketing Service (AMS) is publishing this advance notice of proposed rulemaking (ANPR) to make the public aware of this OFPA requirement. AMS believes that public comment is essential in the review process to determine whether these substances should continue to be allowed or prohibited in the production and handling of organic agricultural products.

DATES: Comments must be submitted on or before August 16, 2005.

ADDRESSES: Interested persons may submit written comments on this ANPR using the following addresses:

• E-mail: National.List@usda.gov.
• Fax: (202) 205–7808.

Written comments responding to this ANPR should be identified with the docket number TM–04–07. You should clearly indicate your position to continue or not continue the allowance or prohibition of the substances identified in this ANPR and the reasons for your position. You should include relevant information and data to support your position (e.g., scientific, environmental, manufacturing, industry impact information, etc.). You should also supply information on alternative substances or alternative management practices, where applicable, that support a change from the current exemption or prohibition of the substance. Only the supporting material relevant to your position will be considered.

It is our intention to have all comments concerning this ANPR, whether submitted by mail, E-mail, or fax, available for viewing on the National Organic Program (NOP) homepage (http://www.ams.usda.gov/nop). Comments submitted in response to this ANPR will also be available for viewing in person at USDA–AMS, Transportation and Marketing Programs, Room 4008–South Building, 1400 Independence Ave., SW., Washington, DC 20250, from 9 a.m. to 12 noon and from 1 p.m. to 4 p.m., Monday through Friday (except official Federal holidays). Persons wanting to visit the USDA South Building to view comments received in response to this ANPR are requested to make an appointment in advance by calling (202) 720–3252.

FOR FURTHER INFORMATION CONTACT:
Arthur Neal, Director, Program Administration, National Organic Program, USDA–AMS—TMP—NOP, 1400 Independence Ave., SW., Room 4008–So. Bldg., Ag Stop 0268, Washington, DC 20250. Telephone: (202) 720–3252; Fax: (202) 205–7808. E-mail: arthur.neal@usda.gov.

SUPPLEMENTARY INFORMATION:
Background
The Organic Foods Production Act (OFPA), 7 U.S.C. 6501 et seq., authorizes the establishment of the National List of exempted and prohibited substances. The National List identifies synthetic substances (synthetics) that are exempted (allowed) and non-synthetic substances (nonsynthetics) that are prohibited in organic crop and livestock production. The National List also identifies nonsynthetics and synthetics that are exempted for use in organic handling. The exemptions and prohibitions granted under the OFPA are required to be reviewed every 5 years by the National Organic Standards Board (NOSB). The Secretary of Agriculture has authority under the OFPA to renew such exemptions and prohibitions. If they are not reviewed by the NOSB and renewed by the Secretary within 5 years of their inclusion on the National List, their authorized use or prohibition expires. This means that a synthetic substance currently allowed for use in organic production will no longer be allowed for use after October 21, 2007; a non-synthetic substance currently prohibited from use in organic production will be allowed after October 21, 2007; and a synthetic or nonsynthetic substance currently allowed for use in organic handling will be prohibited after October 21, 2007.

Expiration of the exempted or prohibited use of substances is provided for under the OFPA’s sunset provision. This ANPR announces the sunset of 165 exempted and 9 prohibited substances currently on the National List, which became effective October 21, 2002. This ANPR establishes October 21, 2007, as the date by which the sunset review and renewal process must be concluded and also begins the public comment process on whether the existing specific exemptions or prohibitions on the National List should be continued. This ANPR discusses how the NOP will manage the sunset review and renewal process.

Because these substances may be critical to the production and handling of a wide array of raw and processed organic agricultural products, their expiration could cause disruption of well-established and accepted organic production, handling, and processing systems. Therefore, the NOP is initiating the sunset review and renewal process now, in order to provide ample opportunity for you to make your views known.

The Sunset Process
As the first step in this process, we invite public comment on the specific exemptions or prohibitions currently on the National List that are described in this document. All substances currently on the National List have been previously evaluated and determined by the NOSB for consistency with OFPA and its implementing regulations. According to section 6517(e) of the OFPA, these substances must be reviewed by the NOSB and renewed by the Secretary for their use or prohibition.
The NOP understands that supportive technical or scientific information for synthetic alternatives not currently on the National List may not be easily available to organic producers and handlers. Such information may, however, be available from the research community including universities, or other sources, including international organic programs.

Comments that DO NOT Support Continuing an Existing Prohibition
If you provide comments against the continuation of a prohibition contained on the National List, you should specify how the prohibited substance is now consistent with the criteria in the OFPA and the NOP regulations. When these prohibitions were originally recommended by the NOSB, they were accepted because the evidence available to the NOSB at the time of review demonstrated that the substances were...
found to be harmful to human health or the environment and were inconsistent and not compatible with organic practices. Therefore, any comments against the continuation of an existing prohibited substance that is currently on the National List should provide new information, including a copy of the specific source of any supportive literatures showing that the currently prohibited substance is no longer harmful to human health or the environment and is consistent and compatible with organic practices.

An Appendix to this ANPR contains worksheets to assist you in gathering relevant information concerning these issues. These worksheets are not required for you to submit a comment. These worksheets are used by the NOSB to develop their recommendations to the Secretary to include an exempted or prohibited substance on the National List. You do not have to answer the questions on the worksheets; they are intended to help you provide substantive comments to the NOSB when you provide comments on the specific substance.

Request for Comments

The NOP requests that you comment whether the NOSB should continue to recommend the following exemptions and prohibitions on the National List of Allowed and Prohibited Substances for organic agricultural production and handling:

§ 205.601 Synthetic substances allowed for use in organic crop production.

(a) As algicide, disinfectants, and sanitizer, including irrigation system cleaning systems.
   (1) Alcohols.
   (i) Ethanol.
   (ii) Isopropanol.
   (2) Chlorine materials—Except, That, residual chlorine levels in the water shall not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act.
      (i) Calcium hypochlorite.
      (ii) Chlorine dioxide.
      (iii) Sodium hypochlorite.
   (4) Hydrogen peroxide.
   (7) Soap-based algicide/demossers.
   (b) As herbicides, weed barriers, as applicable.
      (1) Herbicides, soap-based—for use in farmstead maintenance (roadways, ditches, right of ways, building perimeters) and ornamental crops.
      (2) Mulches.
         (i) Newspaper or other recycled paper—without glossy or colored inks.
         (ii) Plastic mulch and covers (petroleum-based other than polyvinyl chloride (PVC)).
   (c) As compost feedstocks—Newspapers or other recycled paper—without glossy or colored inks.
   (d) As animal repellents—Soaps, ammonium—for use as a large animal repellant only, no direct contact with soil or edible portion of crop.
   (e) As insecticides (including acaricides or mite control).
      (1) Ammonium carbonate—for use as bait in insect traps only, no direct contact with crop or soil.
      (2) Boric acid—structural pest control, no direct contact with organic food or crops.
      (4) Elemental sulfur.
      (5) Lime sulfur—including calcium polysulfide.
         (6) Oils, horticultural—narrow range oils as dormant, suffocating, and summer oils.
      (7) Soaps, insectical.
      (8) Sticky traps/barriers.
   (f) As insect management.
      (1) Coppers, fixed—copper hydroxide, copper oxide, copper oxychloride, includes products exempted from EPA classification by the Environmental Protection Agency (EPA), for use with nonsynthetic substances available for use on the National List. Provided, That, copper-based materials must be used in a manner that minimizes accumulation in the soil and shall not be used as herbicides.
      (2) Copper sulfate—Substance must be used in a manner that minimizes accumulation of copper in the soil.
         (3) Hydroxypropyl gallate.
         (4) Hydrogen peroxide.
         (5) Lime sulfur.
         (6) Oils, horticultural, narrow range oils as dormant, suffocating, and summer oils.
      (8) Sodium nitrate
      (9) Elemental sulfur.
      (10) Streptomycin, for fire blight control in apples and pears only.
      (11) Tetracycline (oxytetracycline calcium complex), for fire blight control only.
   (j) As plant or soil amendments.
      (1) Aquatic plant extracts (other than hydrolyzed)—Extraction process is limited to the use of potassium hydroxide or sodium hydroxide; solvent amount used is limited to that amount necessary for extraction.
      (2) Elemental sulfur.
      (3) Humic acids—naturally occurring deposits, water and alkali extracts only.
      (4) Lignin sulfonate—chelating agent, dust suppressant, floatation agent.
      (5) Magnesium sulfate—allowed with a documented soil deficiency.
      (6) Micronutrients—not to be used as a defoliant, herbicide, or desiccant.

Those made from nitrates or chlorides are not allowed. Soil deficiency must be documented by testing.
   (i) Soluble boron products.
   (ii) Sulfates, carbonates, oxides, or silicates of zinc, copper, iron, manganese, molybdenum, selenium, and cobalt.
   (7) Liquid fish products—can be pH adjusted with sulfuric, citric or phosphoric acid. The amount of acid used shall not exceed the minimum needed to lower the pH to 3.5.
   (8) Vitamins, B1, C, and E.
   (k) As plant growth regulators.
      (1) Ethylene gas—for regulation of pineapple flowering.
         (l) As floating agents in postharvest handling.
            (1) Lignin sulfonate.
            (2) Sodium silicate—for tree fruit and fiber processing.

(m) As synthetic inert ingredients as classified by the Environmental Protection Agency (EPA), for use with nonsynthetic substances or synthetic substances listed in this section and used as an active pesticide ingredient in accordance with any limitations on the use of such substances.
   (1) EPA List 4—Inerts of Minimal Concern.

§ 205.602 Nonsynthetic substances prohibited for use in organic crop production.

(a) Ash from manure burning.
   (b) Arsenic.
   (c) As disinfectants, sanitizer, and medical treatments as applicable.
      (1) Alcohols.
      (i) Ethanol—disinfectant and sanitizer only, prohibited as a feed additive.
      (ii) Isopropanol—disinfectant only.
   (2) Aspirin—approved for health care use to reduce inflammation.
   (3) Biologics—Vaccines.
   (4) Chlorhexidine—Allowed for surgical procedures conducted by a veterinarian. Allowed for use as a teat dip when alternative germicidal agents and/or physical barriers have lost their effectiveness.
   (e) Potassium chloride—unless derived from a mined source and applied in a manner that minimizes chloride accumulation in the soil.
   (f) Sodium fluoaluminate (mined).
   (g) Sodium nitrate—unless use is restricted to no more than 20% of the crop’s total nitrogen requirement; use in spirulina production is unrestricted until October 21, 2005.
   (h) Strychnine.
   (i) Tobacco dust (nicotine sulfate).

§ 205.603 Synthetic substances allowed for use in organic livestock production.

(a) As disinfectants, sanitizer, and medical treatments as applicable.
   (1) Alcohols.
   (i) Ethanol—disinfectant and sanitizer only, prohibited as a feed additive.
   (ii) Isopropanol—disinfectant only.
   (2) Aspirin—approved for health care use to reduce inflammation.
   (3) Biologics—Vaccines.
   (4) Chlorhexidine—Allowed for surgical procedures conducted by a veterinarian. Allowed for use as a teat dip when alternative germicidal agents and/or physical barriers have lost their effectiveness.
(5) Chlorine materials—disinfecting and sanitizing facilities and equipment. Residual chlorine levels in the water shall not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act.

(i) Calcium hypochlorite.

(ii) Chlorine dioxide.

(iii) Sodium hypochlorite.

(6) Electrolytes—without antibiotics.

(7) Glucose.

(8) Glycerine—Allowed as a livestock teat dip, must be produced through the hydrolysis of fats or oils.

(9) Hydrogen peroxide.

(10) Iodine.

(11) Magnesium sulfate.

(12) Oxytocin—use in parturition therapeutic applications.

(13) Paraciticides. Ivermectin—prohibited in slaughter stock, allowed in emergency treatment for dairy and breeder stock when organic system plan-approved preventive management does not prevent infestation. Milk or milk products from a treated animal cannot be labeled as provided for in subsection D of this part for 90 days following treatment. In breeder stock, treatment cannot occur during the last third of gestation if the progeny will be sold as organic and must not be used during the lactation period for breeding stock.

(14) Phosphoric acid—allowed as an equipment cleaner. Provided, That, no direct contact with organically managed livestock or land occurs.

(b) As topical treatment, external parasiticide or local anesthetic as applicable.

(1) Copper sulfate.

(2) Iodine.

(3) Lidocaine—as a local anesthetic. Use requires a withdrawal period of 90 days after administering to livestock intended for slaughter and 7 days after administering to dairy animals.

(4) Lime, hydrated—as an external pest control, not permitted to cauterize physical alterations or deodorize animal wastes.

(5) Mineral oil—for topical use and as a lubricant.

(6) Procaine—as a local anesthetic, use requires a withdrawal period of 90 days after administering to livestock intended for slaughter and 7 days after administering to dairy animals.

(c) As feed supplements—Milk replacers without antibiotics, as emergency use only, no nonmilk products or products from BST treated animals.

(d) As feed additives.

(2) Trace minerals, used for enrichment or fortification when FDA approved.

(3) Vitamins, used for enrichment or fortification when FDA approved.

(9) Hydrogen peroxide.

(10) Iodine.

(11) Magnesium sulfate.

(12) Oxytocin—use in parturition therapeutic applications.

(13) Paraciticides. Ivermectin—prohibited in slaughter stock, allowed in emergency treatment for dairy and breeder stock when organic system plan-approved preventive management does not prevent infestation. Milk or milk products from a treated animal cannot be labeled as provided for in subsection D of this part for 90 days following treatment. In breeder stock, treatment cannot occur during the last third of gestation if the progeny will be sold as organic and must not be used during the lactation period for breeding stock.

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(5) Mineral oil—for topical use and as a lubricant.

(6) Procaine—as a local anesthetic, use requires a withdrawal period of 90 days after administering to livestock intended for slaughter and 7 days after administering to dairy animals.

(c) As feed supplements—Milk replacers without antibiotics, as emergency use only, no nonmilk products or products from BST treated animals.

(d) As feed additives.

(2) Trace minerals, used for enrichment or fortification when FDA approved.

(3) Vitamins, used for enrichment or fortification when FDA approved.
Sodium phosphates—for use only in dairy foods.

Sulfur dioxide—for use only in wine labeled “made with organic grapes,” Provided, That, total sulfite concentration does not exceed 100 ppm.

Tartaric acid.

Tocopherols—derived from vegetable oil when rosemary extracts are not a suitable alternative.

Xanthan gum.

§ 205.606 Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s)).”

(a) Cornstarch (native).

(b) Gums—water extracted only (arabic, guar, locust bean, carob bean).

(c) Kelp—for use only as a thickener and dietary supplement.

(d) Lecithin—unbleached.

(e) Pectin (high-methoxy).

All comments will be considered in the development of the NOSB’s recommendations to the Secretary.

Authority: 7 U.S.C. 6501 et seq. and 7 CFR part 205.

Dated: June 13, 2005.

Kenneth C. Clayton,
Acting Administrator, Agricultural Marketing Service.

Appendix

This Appendix contains worksheets to assist you in gathering relevant information concerning the compatibility of substances with evaluation criteria of the OFPA. These worksheets are not required to submit a comment. These worksheets are used by the NOSB to develop their recommendations to the Secretary to include an exempted or prohibited substance on the National List. You do not have to answer the questions on the worksheets; they are intended only to help you provide substantive comments to the NOSB when you provide comments on the specific substance.

Evaluation Criteria for Substances Added to the National List

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
<th>Documentation</th>
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<tbody>
<tr>
<td><strong>Category 1. Adverse impacts on humans or the environment?</strong></td>
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<tr>
<td>1. Is there environmental contamination during manufacture, use, misuse, or disposal? [§ 6518 m.3].</td>
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<td>2. Is the substance harmful to the environment? [§ 6517c(1)(A)(i); 6517c(2)(A)(i)].</td>
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<td>3. Does the substance contain List 1, 2, or 3 inerts? [§ 6517c(1)(B)(i)].</td>
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<td>4. Is there potential for detrimental chemical interaction with other materials used? [§ 6518 m.1].</td>
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<td>5. Are there adverse biological and chemical interactions in agro-ecosystem? [§ 6518 m.5].</td>
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<td>6. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§ 6518 m.5].</td>
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<td>7. Is there a toxic or other adverse action of the material or its breakdown products? [§ 6518 m.2].</td>
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<td>8. Is there undesirable persistence or concentration of the material or breakdown products in environment? [§ 6518 m.2].</td>
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<td>9. Is there any harmful effect on human health? [§ 6517c(1)(A)(i); 6517c(2)(A)(i); § 6518 m.4].</td>
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<td><strong>Category 2. Is the substance essential for organic production?</strong></td>
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<td>1. Is the substance formulated or manufactured by a chemical process? [6502 (21)].</td>
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<td>2. Is the substance formulated or manufactured by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral, sources? [6502 (21)].</td>
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<td>3. Is the substance created by naturally occurring biological processes? [6502 (21)].</td>
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<td>4. Is there a wholly natural substitute product? [§ 6517c(1)(A)(ii)].</td>
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<td>5. Is the substance used in handling, not synthetic, but not organically produced? [§ 6517c(1)(B)(iii)].</td>
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<td>6. Is there any alternative substances? [§ 6518 m.6].</td>
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<td>7. Is there another practice that would make the substance unnecessary? [§ 6518 m.6].</td>
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<td><strong>Category 3. Is the substance compatible with organic production practices?</strong></td>
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<tr>
<td>1. Is the substance consistent with organic farming and handling? [§ 6517c(1)(A)(ii); 6517c(2)(A)(iii)].</td>
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<td>2. Is the substance compatible with a system of sustainable agriculture? [§ 6518 m.7].</td>
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<tr>
<td>3. Is the substance used in production, and does it contain an active synthetic ingredient in the following categories:</td>
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DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 981

[DOCKET NO. FV05–981–2 PR]

Almonds Grown in California; Increased Assessment Rate

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Proposed rule.

SUMMARY: This rule would increase the assessment rate established for the Almond Board of California (Board) for the 2005–06 and subsequent crop years from $0.025 to $0.030 per pound of almonds received. Of the $0.030 per pound assessment, 60 percent (or $0.018 per pound) would be available as credit-back for handlers who conduct their own promotional activities. The Board would also adjust the budget and assessment rate. The Board, in its discretion, could modify, suspend, or terminate the assessment rate.

DATES: Comments must be received by June 27, 2005.

ADDRESSES: Interested persons are invited to submit written comments concerning this rule. Comments must be sent to the Docket Clerk, Market Order Administration Branch, Fruit and Vegetable Programs, AMS, USDA, 1400 Independence Avenue SW., STOP 0237, Washington, DC 20250–0237; Fax: (202) 720–8938, E-mail: moab.docketclerk@usda.gov, or Internet: http://www.regulations.gov. Comments should reference the docket number and the date and page number of this issue of the Federal Register and will be available for public inspection in the Office of the Docket Clerk during regular business hours, or can be viewed at: http://www.ams.usda.gov/fv/maob.html.

FOR FURTHER INFORMATION CONTACT: Maureen T. Pello, Senior Marketing Specialist, California Marketing Field Office, Marketing Order Administration Branch, Fruit and Vegetable Programs, AMS, USDA, 2202 Monterey Street, suite 102B, Fresno, California 93721; telephone: (559) 487–5901, Fax: (559) 487–5906; or George Kelhart, Technical Advisor, 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.

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 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. Under the marketing order now in effect, California almond handlers are subject to assessments. Funds to administer the order are derived from such assessments. It is intended that the assessment rate as proposed herein would be applicable to all assessable almonds beginning August 1, 2005, and continue until amended, suspended, or terminated. 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 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 rule would increase the assessment rate established for the Board for the 2005–06 and subsequent crop years from $0.025 to $0.030 per pound of almonds received. Of the $0.030 per pound assessment, 60 percent (or $0.018 per pound) would be available as credit-back for handlers who conduct their own promotional activities.

The order provides authority for the Board, with the approval of USDA, to formulate an annual budget of expenses and collect assessments from handlers to administer the program. The members of the Board are producers and handlers of California almonds. They are familiar with the Board's needs and with the costs for goods and services in their local area and are thus in a position to formulate an appropriate budget and assessment rate. The assessment rate is formulated and discussed in a public meeting. Thus, all directly affected persons have an opportunity to participate and provide input.

For the 2004–05 and subsequent crop years, the Board recommended, and USDA approved, an assessment rate that would continue in effect from crop year.

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1 If the substance under review is for crops or livestock production, all of the questions from 205.600(b) are N/A—not applicable.

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