

# Proposed Rules

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

## DEPARTMENT OF AGRICULTURE

### Agricultural Marketing Service

#### 7 CFR Part 925

[Doc. No. AMS–SC–15–0077; SC16–925–1 PR]

#### Grapes Grown in a Designated Area of Southeastern California; Increased Assessment Rate

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

**ACTION:** Proposed rule.

**SUMMARY:** This proposed rule would implement a recommendation from the California Desert Grape Administrative Committee (Committee) to increase the assessment rate established for the 2016 and subsequent fiscal periods from \$0.0250 to \$0.0300 per 18-pound lug of grapes handled under the marketing order (order). The Committee locally administers the order, and is comprised of producers and handlers of grapes grown in a designated area of southeastern California. Assessments upon grape handlers are used by the Committee to fund reasonable and necessary expenses of the program. The fiscal period began on January 1 and ends December 31. The assessment rate would remain in effect indefinitely unless modified, suspended, or terminated.

**DATES:** Comments must be received by March 25, 2016.

**ADDRESSES:** Interested persons are invited to submit written comments concerning this proposed rule. Comments must be sent to the Docket Clerk, Marketing Order and Agreement Division, Specialty Crops Program, AMS, USDA, 1400 Independence Avenue SW., STOP 0237, Washington, DC 20250–0237; Fax: (202) 720–8938; 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.regulations.gov>. All comments submitted in response to this proposed rule will be included in the record and will be made available to the public. Please be advised that the identity of the individuals or entities submitting the comments will be made public on the internet at the address provided above.

**FOR FURTHER INFORMATION CONTACT:** Kathie Notoro, Marketing Specialist, or Jeffrey Smutny, Regional Director, California Marketing Field Office, Marketing Order and Agreement Division, Specialty Crops Program, AMS, USDA; Telephone: (559) 487–5901, Fax: (559) 487–5906, or Email: [Kathie.Notoro@ams.usda.gov](mailto:Kathie.Notoro@ams.usda.gov) or [Jeffrey.Smutny@ams.usda.gov](mailto:Jeffrey.Smutny@ams.usda.gov).

Small businesses may request information on complying with this regulation by contacting Antoinette Carter, Marketing Order and Agreement Division, Specialty Crops Program, AMS, USDA, 1400 Independence Avenue SW., STOP 0237, Washington, DC 20250–0237; Telephone: (202) 720–2491, Fax: (202) 720–8938, or Email: [Antoinette.Carter@ams.usda.gov](mailto:Antoinette.Carter@ams.usda.gov).

**SUPPLEMENTARY INFORMATION:** This proposed rule is issued under Marketing Order No. 925, as amended (7 CFR part 925), regulating the handling of grapes grown in a designated area of southeastern California. 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 proposed rule in conformance with Executive Orders 12866, 13563, and 13175.

This proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. Under the marketing order now in effect, grape handlers in a designated area of southeastern California 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 grapes beginning on January 1, 2016, and continue until amended, suspended, or terminated.

The Act provides that administrative proceedings must be exhausted before parties may file suit in court. Under section 608c(15)(A) of the Act, any handler subject to an order may file

with USDA a petition stating that the order, any provision of the order, or any obligation imposed in connection with the order is not in accordance with law and request a modification of the order or to be exempted therefrom. Such handler is afforded the opportunity for a hearing on the petition. After the hearing, USDA would rule on the petition. The Act provides that the district court of the United States in any district in which the handler is an inhabitant, or has his or her principal place of business, has jurisdiction to review USDA’s ruling on the petition, provided an action is filed not later than 20 days after the date of the entry of the ruling.

This proposed rule would increase the assessment rate established for the Committee for the 2016 and subsequent fiscal periods from \$0.0250 to \$0.0300 per 18-pound lug of grapes handled.

The grape order provides authority for the Committee, 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 Committee are producers and handlers of grapes grown in a designated area of southeastern California. They are familiar with the Committee’s needs and with the costs of 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 2015 and subsequent fiscal periods, the Committee recommended, and the USDA approved, an assessment rate that would continue in effect from fiscal period to fiscal period unless modified, suspended, or terminated by USDA based upon recommendation and information submitted by the Committee or other information available to USDA.

The Committee met on November 12, 2015, and unanimously recommended 2016 expenditures of \$143,500, a contingency reserve fund of \$6,500, and an assessment rate of \$0.0300 per 18-pound lug of grapes handled. In comparison, last year’s budgeted expenditures were \$135,500. The Committee recommended a crop estimate of 5,000,000 18-pound lugs, which is lower than the 5,800,000 18-

pound lugs handled last year. The Committee also recommended carrying over a financial reserve of \$47,500, which would increase to \$54,000 if the contingency fund is not expended. The assessment rate of \$0.0300 per 18-pound lug of grapes handled recommended by the Committee is \$0.0050 higher than the \$0.0250 rate currently in effect. The higher assessment rate, applied to shipments of 5,000,000 18-pound lugs, would generate \$150,000 in revenue and be sufficient to cover anticipated expenses.

The major expenditures recommended by the Committee for the 2016 fiscal period include \$28,500 for research, \$20,080 for office expenses, \$56,500 for management and compliance expenses, \$25,000 for consultation services, and \$6,500 for a contingency reserve. The \$28,500 research project is a continuation of a vine study in progress by the University of California, Riverside. In comparison, major expenditures for the 2015 fiscal period included \$15,500 for research, \$17,000 for general office expenses, \$62,750 for management and compliance expenses, \$25,000 for consultation services, and \$9,500 for a contingency reserve. Overall 2016 expenditures include a decrease in management and compliance expenses, and increases in office expenses, and research expenses.

The assessment rate recommended by the Committee was derived by evaluating several factors, including estimated shipments for the 2016 season, budgeted expenses, and the level of available financial reserves. The Committee determined that the \$0.0300 assessment rate would generate \$150,000 in revenue to cover the budgeted expenses of \$143,500, and a contingency reserve fund of \$6,500.

Reserve funds by the end of 2016 are projected to be \$47,500 if the \$6,500 added to the contingency fund is expended or \$54,000 if it is not expended. Both amounts are well within the amount authorized under the order. Section 925.41 of the order permits the Committee to maintain approximately one fiscal period's expenses in reserve.

The proposed assessment rate would continue in effect indefinitely unless modified, suspended, or terminated by USDA based upon a recommendation and information submitted by the Committee or other available information.

Although this assessment rate would be in effect for an indefinite period, the Committee would continue to meet prior to or during each fiscal period to recommend a budget of expenses and

consider recommendations for modification of the assessment rate. The dates and times of Committee meetings are available from the Committee or USDA. Committee meetings are open to the public and interested persons may express their views at these meetings. USDA would evaluate the Committee's recommendations and other available information to determine whether modification of the assessment rate is needed. Further rulemaking would be undertaken as necessary. The Committee's 2016 budget and those for subsequent fiscal periods would be reviewed and, as appropriate, approved by USDA.

#### Initial Regulatory Flexibility Analysis

Pursuant to requirements set forth in the Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612), the Agricultural Marketing Service (AMS) has considered the economic impact of this proposed rule on small entities. Accordingly, AMS has prepared this initial regulatory flexibility analysis.

The purpose of the RFA is to fit regulatory actions to the scale of businesses 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.

There are approximately 13 handlers of southeastern California grapes who are subject to regulation under the marketing order and about 41 grape producers in the production area. Small agricultural service firms are defined by the Small Business Administration (13 CFR 121.201) as those having annual receipts of less than \$7,500,000, and small agricultural producers are defined as those whose annual receipts are less than \$750,000. Ten of the 13 handlers subject to regulation have annual grape sales of less than \$7,500,000, according to USDA Market News Service and Committee data. In addition, information from the Committee and USDA's Market News indicates that at least 10 of 41 producers have annual receipts of less than \$750,000. Thus, it may be concluded that a majority of the grape handlers regulated under the order and about 10 of the producers could be classified as small entities under the Small Business Administration's definitions.

This proposed rule would increase the assessment rate established for the Committee and collected from handlers for the 2016 and subsequent fiscal periods from \$0.0250 to \$0.0300 per 18-

pound lug of grapes. The Committee unanimously recommended 2016 expenditures of \$143,500, a contingency reserve fund of \$6,500, and an assessment rate of \$0.0300 per 18-pound lug of grapes handled. The proposed assessment rate of \$0.0300 is \$0.0050 higher than the 2015 rate currently in effect. The quantity of assessable grapes for the 2016 season is estimated at 5,000,000 18-pound lugs. Thus, the \$0.0300 rate should generate \$150,000 in income. In addition, reserve funds at the end of the year are projected to be \$54,000, which is well within the order's limitation of approximately one fiscal period's expenses.

The major expenditures recommended by the Committee for the 2016 fiscal period include \$28,500 for research, \$20,080 for general office expenses, \$56,500 for management and compliance expenses, \$25,000 for consultation services and \$6,500 for the contingency reserve. In comparison, major expenditures for the 2015 fiscal period included \$15,500 for research, \$17,000 for general office expenses, \$62,750 for management and compliance expenses, \$25,000 for consultation services, and \$9,500 for a contingency reserve. Overall 2016 expenditures include a decrease in management and compliance expenses, and increases in general office expenses, and research expenses.

Prior to arriving at this budget, the Committee considered alternative expenditures and assessment rates, to include not increasing the \$0.0250 assessment rate currently in effect. Based on a crop estimate of 5,000,000 18-pound lugs, the Committee ultimately determined that increasing the assessment rate to \$0.0300 would generate sufficient funds to cover budgeted expenses. Reserve funds at the end of the 2016 fiscal period are projected to be \$47,500 if the \$6,500 contingency fund is expended or \$54,000 if it is not expended. These amounts are well within the amount authorized under the order.

A review of historical crop and price information, as well as preliminary information pertaining to the upcoming fiscal period, indicates that the shipping point price for the 2015 season averaged about \$22.75 per 18-pound lug of California desert grapes handled. If the 2016 price is similar to the 2015 price, estimated assessment revenue as a percentage of total estimated handler revenue would be 0.13 percent for the 2016 season (\$0.0300 divided by \$22.75 per 18-pound lug).

This action would increase the assessment obligation imposed on handlers. While assessments impose

some additional costs on handlers, the costs are minimal and uniform on all handlers. However, these costs would be offset by the benefits derived from the operation of the marketing order. In addition, the Committee's meeting was widely publicized throughout the grape production area and all interested persons were invited to attend and participate in Committee deliberations on all issues. Like all Committee meetings, the November 12, 2015, meeting was a public meeting and all entities, both large and small, were able to express views on this issue. Finally, interested persons are invited to submit comments on this proposed rule, including the regulatory and informational impacts of this action on small businesses.

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the order's information collection requirements have been previously approved by the Office of Management and Budget (OMB) and assigned OMB No. 0581-0189. No changes in those requirements as a result of this action are necessary. Should any changes become necessary, they would be submitted to OMB for approval.

This proposed rule would impose no additional reporting or recordkeeping requirements on either small or large California grape handlers. 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.

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.

USDA has not identified any relevant Federal rules that duplicate, overlap, or conflict with this action.

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/rules-regulations/moa/small-businesses>. Any questions about the compliance guide should be sent to Antoinette Carter at the previously-mentioned address in the **FOR FURTHER INFORMATION CONTACT** section.

A 15-day comment period is provided to allow interested persons to respond to this proposed rule. Fifteen days is deemed appropriate because: (1) The 2016 fiscal period begins on January 1, 2016, and the order requires that the rate of assessment for each fiscal period apply to all assessable grapes handled

during such fiscal period; (2) the Committee needs to have sufficient funds to pay its expenses, which are incurred on a continuous basis; and (3) handlers are aware of this action, which was unanimously recommended by the Committee at a public meeting and is similar to other assessment rate actions issued in past years.

#### List of Subjects in 7 CFR Part 925

Grapes, Marketing agreements, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, 7 CFR part 925 is proposed to be amended as follows:

#### PART 925—GRAPES GROWN IN A DESIGNATED AREA OF SOUTHEASTERN CALIFORNIA

■ 1. The authority citation for 7 CFR part 925 continues to read as follows:

**Authority:** 7 U.S.C. 601–674.

■ 2. Section 925.215 is revised to read as follows:

##### § 925.215 Assessment rate.

On and after January 1, 2016, an assessment rate of \$0.0300 per 18-pound lug is established for grapes grown in a designated area of southeastern California.

Dated: March 3, 2016.

**Elanor Starmer,**

*Acting Administrator, Agricultural Marketing Service.*

[FR Doc. 2016–05420 Filed 3–9–16; 8:45 am]

**BILLING CODE P**

#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

##### Food and Drug Administration

##### 21 CFR Part 888

[Docket No. FDA–2015–N–3785]

##### Medical Devices; Orthopedic Devices; Classification of Posterior Cervical Screw Systems

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is proposing to classify posterior cervical screw systems into class II (special controls) and to continue to require premarket notification to provide a reasonable assurance of safety and effectiveness of the device. A posterior cervical screw system is a prescription device used to provide immobilization

and stabilization in the cervical spine as an adjunct to spinal fusion surgery. The term “posterior cervical screw systems” is used to distinguish these devices from currently classified pedicle screw spinal systems cleared for use in other spinal regions.

**DATES:** Submit either electronic or written comments by June 8, 2016. See section IV of this document for the proposed effective date of a final rule that may issue based on this proposal.

**ADDRESSES:** You may submit comments as follows:

##### Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <http://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

##### Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand delivery/Courier (for written/paper submissions):** Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

**Instructions:** All submissions received must include the Docket No. FDA–2015–N–3785 for “Medical Devices; Orthopedic Devices; Classification of Posterior Cervical Screw Systems.”