

# Rules and Regulations

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## DEPARTMENT OF AGRICULTURE

### Agricultural Marketing Service

#### 7 CFR Part 987

[Docket No. AMS-SC-16-0084; SC16-987-1 IR]

#### Domestic Dates Produced or Packed in Riverside County, California; Decreased Assessment Rate

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

**ACTION:** Interim rule with request for comments.

**SUMMARY:** This rule implements a recommendation from the California Date Administrative Committee (committee) for a decrease in the assessment rate established for the 2016-17 and subsequent crop years from \$0.10 to \$0.05 per hundredweight of dates handled. The committee locally administers the marketing order, which regulates the handling of dates produced or packed in Riverside County, California. Assessments upon date handlers are used by the committee to fund reasonable and necessary expenses of the program. The crop year begins October 1 and ends September 30. The assessment rate will remain in effect indefinitely unless modified, suspended, or terminated.

**DATES:** Effective September 22, 2016. Comments received by November 21, 2016, will be considered prior to issuance of a final rule.

**ADDRESSES:** Interested persons are invited to submit written comments concerning this 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 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 comments will be made public on the internet at the address provided above.

**FOR FURTHER INFORMATION CONTACT:**

Terry Vawter, Senior 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: [Terry.Vawter@ams.usda.gov](mailto:Terry.Vawter@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 Richard Lower, 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: [Richard.Lower@ams.usda.gov](mailto:Richard.Lower@ams.usda.gov).

**SUPPLEMENTARY INFORMATION:** This rule is issued under Marketing Agreement and Order No. 987, both as amended (7 CFR part 987), regulating the handling of dates produced or packed in Riverside County, 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 Orders 12866, 13563, and 13175.

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. Under the marketing order now in effect, Riverside County, California, date handlers are subject to assessments. Funds to administer the order are derived from such assessments. It is intended that the assessment rate as issued herein will be applicable to all assessable dates beginning October 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 rule decreases the assessment rate for the 2016-17 and subsequent crop years from \$0.10 to \$0.05 per hundredweight of dates.

The California date 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 date producers and handlers from Riverside County, California. They are familiar with the committee's needs and 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 2015-16 crop year, the committee recommended, and USDA approved, an assessment rate that would continue in effect from crop year to crop year unless modified, suspended, or terminated by USDA upon recommendation and information supplied by the committee or other information available to USDA.

The committee met on June 22, 2016, and unanimously recommended 2016-17 expenditures of \$52,500, and an assessment rate of \$0.05 per hundredweight of dates produced or packed in Riverside County, California. In comparison, last year's budgeted expenditures were \$59,250. The assessment rate of \$0.05 is \$0.05 lower than the rate currently in effect.

The major expenditure recommended by the committee for the 2016–17 crop year is \$52,500 for general and administrative expenses. In comparison, the major expenditure recommended by the committee for the 2015–16 crop year was \$59,250 for general and administrative expenses.

This year's crop is estimated to be similar in size to last year's crop. The income generated when applying the recommended lower assessment rate to the estimated crop, and combined with carry-in funds from the 2015–16 crop year and income from other sources, should be sufficient to cover anticipated 2016–17 expenses. The financial reserve will also be maintained within the limit specified under the order.

The assessment rate of \$0.05 per hundredweight of dates handled was recommended by the committee after considering several factors: The anticipated size of the 2016–17 crop, the committee's estimates of the incoming reserve, other income, and anticipated expenses. Date shipments for the year are estimated at 29,000,000 pounds (290,000 hundredweight) which should provide \$14,500 in assessment income. Income derived from handler assessments, funds from the committee's authorized reserve, along with other income should be adequate to cover budgeted expenses for the crop year.

Section 987.72(d) of the order states that the committee may maintain a monetary reserve not to exceed the average of one year's expenses incurred during the most recent five preceding crop years, except that an established reserve need not be reduced to conform to any recomputed average. The committee expects to utilize \$33,000 of the reserve during the year to cover expenses, leaving approximately \$39,500 in the reserve account at the end of the crop year. The remaining reserve will be below the limit specified in the order.

The assessment rate established in this rule will continue in effect indefinitely unless modified, suspended, or terminated by USDA upon recommendation and information submitted by the committee or other available information.

Although this assessment rate is effective for an indefinite period, the committee will continue to meet prior to or during each crop year 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 will evaluate committee recommendations and other available information to determine whether modification of the assessment rate is needed. Further rulemaking will be undertaken as necessary. The committee's 2016–17 budget and those for subsequent crop years will 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 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 70 date producers in the production area and 11 date handlers subject to regulation under the order. The Small Business Administration defines small agricultural producers as those having annual receipts of less than \$750,000, and small agricultural service firms as those whose annual receipts are less than \$7,500,000. (13 CFR 121.201)

According to the National Agricultural Statistics Service (NASS), data for the most-recently completed crop year (2015) shows that about 4.36 tons, or 8,720 pounds, of dates were produced per acre. The 2015 producer price published by NASS was \$1,560 per ton. Thus, the value of date production per acre in 2014–15 averaged about \$6,802 (4.36 tons times \$1,560 per ton, rounded to the nearest dollar). At that average price, a producer would have to farm over 110 acres to receive an annual income from dates of \$750,000 (\$750,000 divided by \$6,802 per acre equals 110.26 acres). According to committee staff, the majority of California date producers farm less than 110 acres. Thus, it can be concluded that the majority of date producers could be considered small entities. In addition, according to data from the committee staff, the majority of California date handlers have receipts of less than \$7,500,000 and may also be considered small entities.

This rule decreases the assessment rate collected from handlers for the 2016–17 and subsequent crop years from \$0.10 to \$0.05 per hundredweight of dates handled. The committee unanimously recommended 2016–17 expenditures of \$52,500 and an assessment rate of \$0.05 per hundredweight of dates, which is \$0.05 lower than the 2015–16 rate currently in effect. The quantity of assessable dates for the 2016–17 crop year is estimated at 29,000,000 pounds (290,000 hundredweight). Thus, the \$0.05 rate should provide \$14,500 in assessment income. Income derived from handler's assessments, funds from the committee's authorized reserve, and other income should be adequate to cover expenses for the 2016–17 crop year.

The major expenditure recommended by the committee for the 2016–17 crop year is \$52,500 for general and administrative expenses. The major expenditure recommended by the committee for the 2015–16 crop year was \$59,250 for general and administrative expenses.

The committee recommended a lower assessment rate because they will fund only general and administrative expenses and use funds from the reserve to augment their assessments. The income generated from the lower assessment rate applied to the estimated crop, combined with carry-in funds from the 2015–16 crop year and income from other sources, should be sufficient to cover anticipated 2016–17 expenses and to maintain a financial reserve within the limit specified under the order.

Section 987.72(d) of the order states that the committee may maintain a monetary reserve not to exceed the average of one year's expenses incurred during the most recent five preceding crop years, except that an established reserve need not be reduced to conform to any recomputed average. The committee estimated a \$72,500 reserve carry-in for the 2016–17 crop year. It expects to utilize \$33,000 of the reserve during the year, leaving a carry-out of approximately \$39,500 at the end of the 2016–17 crop year, which is below the limit specified in the order.

The committee reviewed and unanimously recommended 2016–17 crop year expenditures of \$52,500. Prior to arriving at this budget, the Committee considered alternative expenditure levels and assessment rates, including not changing the assessment rate at all or varying the line item expenses. Ultimately, the committee recommended an assessment rate of \$0.05 per hundredweight of dates after

considering several factors including the anticipated 2016–17 crop size, the committee's estimates of the incoming reserve funds and other income, and its anticipated expenses.

A review of historical and preliminary information pertaining to the upcoming crop year indicates that the producer price for the 2015–16 crop year was approximately \$78.00 per hundredweight of dates. Utilizing that price, the estimated crop size, and the assessment rate of \$0.05 per hundredweight, the estimated assessment revenue for the 2016–17 crop year as a percentage of total producer revenue is approximately .00064 percent.

This action decreases the assessment obligation imposed on handlers. Assessments are applied uniformly on all handlers, and decreasing the assessment rate reduces the burden on handlers, and may reduce the burden on producers. In addition, the committee meeting was widely publicized throughout the California date industry, and all interested persons were invited to attend the meetings and encouraged to participate in committee deliberations on all issues. Like all committee meetings, the June 22, 2016, meeting was a public meeting and all entities, both large and small, were able to express views on this issue. Industry members also discussed the various possible assessment rates, potential crop size, and estimated expenses at this meeting. Finally, interested persons are invited to submit comments on this interim 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. 0581–0178, "Vegetable and Specialty Crop Marketing Orders." 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 action imposes no additional reporting or recordkeeping requirements on either small or large Riverside County, California date 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 rule.

A small business guide on complying with fruit, vegetable, and specialty crop marketing agreements and orders may be viewed at: <https://www.ams.usda.gov/rules-regulations/moa/small-businesses>. Any questions about the compliance guide should be sent to Richard Lower at the previously mentioned address in the **FOR FURTHER INFORMATION CONTACT** section.

After consideration of all relevant material presented, including the information and recommendation submitted by the Committee 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 upon good cause that it is impracticable, unnecessary, and contrary to the public interest to give preliminary notice prior to putting this rule into effect, and that good cause exists for not postponing the effective date of this rule until 30 days after publication in the **Federal Register** because: (1) The 2016–17 crop year begins on October 1, 2016, and the marketing order requires that the rate of assessment for each crop year apply to all assessable dates handled during such crop year; (2) the action decreases the assessment rate for assessable dates beginning with the 2016–17 crop year; (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; and (4) this interim rule provides a 60-day comment period, and all comments timely received will be considered prior to finalization of this rule.

#### List of Subjects in 7 CFR Part 987

Dates, Marketing agreements, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, 7 CFR part 987 is amended as follows:

#### **PART 987—DOMESTIC DATES PRODUCED OR PACKED IN RIVERSIDE COUNTY, CALIFORNIA**

■ 1. The authority citation for 7 CFR part 987 continues to read as follows:

**Authority:** 7 U.S.C. 601–674.

■ 2. Section 987.339 is revised to read as follows:

#### **§ 987.339 Assessment rate.**

On and after October 1, 2016, an assessment rate of \$0.05 per hundredweight is established for dates produced or packed in Riverside County, California.

Dated: September 16, 2016.

**Elanor Starmer,**

*Administrator, Agricultural Marketing Service.*

[FR Doc. 2016–22745 Filed 9–20–16; 8:45 am]

**BILLING CODE 3410–02–P**

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Food and Drug Administration**

#### **21 CFR Part 878**

[Docket No. FDA–2016–N–2562]

#### **Medical Devices; General and Plastic Surgery Devices; Classification of the Magnetic Surgical Instrument System**

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

**ACTION:** Final order.

**SUMMARY:** The Food and Drug Administration (FDA) is classifying the Magnetic Surgical Instrument System into class II (special controls). The special controls that will apply to the device are identified in this order and will be part of the codified language for the magnetic surgical instrument system's classification. The Agency is classifying the device into class II (special controls) in order to provide a reasonable assurance of safety and effectiveness of the device.

**DATES:** This order is effective September 21, 2016. The classification was applicable on June 13, 2016.

**FOR FURTHER INFORMATION CONTACT:** Varun Pattani, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G452, Silver Spring, MD, 20993–0002, 301–796–6368, [varun.pattani@fda.hhs.gov](mailto:varun.pattani@fda.hhs.gov).

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360c(f)(1)), devices that were not in commercial distribution before May 28, 1976 (the date of enactment of the Medical Device Amendments of 1976), generally referred to as postamendments devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require