

Proposed Rules

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 920

[Docket No. FV02-920-4 PR]

Kiwifruit 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 Kiwifruit Administrative Committee (Committee) for the 2002-03 and subsequent fiscal periods from \$0.03 to \$0.045 per 22-pound volume fill container or equivalent of kiwifruit. Expenses for 2002-03 are higher than last fiscal period and the current assessment rate would not generate enough funds to cover the expenses. The Committee locally administers the marketing order which regulates the handling of kiwifruit grown in California. Authorization to assess kiwifruit handlers enables the Committee to incur expenses that are reasonable and necessary to administer the program. The fiscal period begins August 1 and ends July 31. The assessment rate would remain in effect indefinitely unless modified, suspended, or terminated.

DATES: Comments must be received by September 16, 2002.

ADDRESSES: Interested persons are invited to submit written comments concerning this rule. Comments must be sent to the Docket Clerk, Marketing Order Administration Branch, Fruit and Vegetable Programs, AMS, USDA, 1400 Independence Avenue SW., STOP 0237, Washington, DC 20250-0237; Fax: (202) 720-8938, e-mail:

moab.docketclerk@usda.gov. Comments should reference the docket number and the date and page number of this issue of the **Federal Register** and will be available for public inspection in the Office of the Docket Clerk during regular

business hours, or can be viewed at: <http://www.ams.usda.gov/fv/moab.html>.

FOR FURTHER INFORMATION CONTACT: Toni Sasselli, Marketing Assistant, or Rose M. Aguayo, Marketing Specialist, California Marketing Field Office, 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. 920, as amended (7 CFR part 920), regulating the handling of kiwifruit 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 kiwifruit 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 kiwifruit beginning on August 1, 2002, 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

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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 would increase the assessment rate established for the Committee for the 2002-03 and subsequent fiscal periods from \$0.03 to \$0.045 per 22-pound volume fill container or equivalent of kiwifruit.

The California kiwifruit marketing 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 of California kiwifruit. They are familiar with the Committee's needs and 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 at a public meeting. Thus, all directly affected persons have an opportunity to participate and provide input.

For the 2000-01 and subsequent fiscal periods, the Committee recommended, and USDA approved, an assessment rate that would continue in effect from fiscal period to fiscal period unless modified, suspended, or terminated by USDA upon recommendation and information submitted by the Committee or other information available to USDA.

The Committee met on July 10, 2002, and unanimously recommended 2002-03 expenditures of \$80,760 and an assessment rate of \$0.045 per 22-pound volume fill container or equivalent of kiwifruit. In comparison, last year's budgeted expenditures were \$78,000. The assessment rate of \$0.045 is \$0.015 higher than the rate currently in effect. The higher assessment rate is needed to offset the 2002-03 increase in salaries

and vehicle expenses, and to keep the operating reserve at an adequate level.

The following table compares major budget expenditures recommended by the Committee for the 2002–03 and 2001–02 fiscal periods:

Budget expense categories	2002–03	2001–02
Administrative Staff & Field Salaries	\$55,500	\$50,000
Travel	5,000	9,500
Office Costs/Annual Audit	14,500	14,500
Vehicle Expense Account	5,760	4,000

The assessment rate recommended by the Committee was derived by the following formula: Anticipated expenses (\$80,760), plus the desired 2003 ending reserve (\$36,287), minus the 2002 beginning reserve (\$23,979), divided by the total estimated 2002–03 shipments (2,068,182 22-pound volume fill containers). This calculation resulted in the \$0.045 assessment rate. This rate would provide sufficient funds to meet the anticipated expenses of \$80,760 and result in a July 2003 ending reserve of \$36,287, which is acceptable to the Committee. The July 2003 ending reserve funds (estimated to be \$36,287) would be kept within the maximum permitted by the order, approximately one fiscal period's expenses (\$ 920.41).

The proposed assessment rate would 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 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 Committee 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 2002–03 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), the

Agricultural Marketing Service (AMS) has considered the economic impact of this rule on small entities. Accordingly, AMS has prepared this initial regulatory flexibility analysis.

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

There are approximately 326 producers of kiwifruit in the production area and approximately 52 handlers subject to regulation under the marketing order. Small agricultural producers are defined by the Small Business Administration (13 CFR 121.201) as those having annual receipts less than \$750,000, and small agricultural service firms are defined as those whose annual receipts are less than \$5,000,000.

None of the 52 handlers subject to regulation have annual kiwifruit sales of at least \$5,000,000. Two of the 326 producers subject to regulation have annual sales of at least \$750,000. Thus, the majority of handlers and producers of kiwifruit may be classified as small entities.

This rule would increase the assessment rate established for the Committee and collected from handlers for the 2002–03 and subsequent fiscal periods from \$0.03 to \$0.045 per 22-pound volume fill container or equivalent of kiwifruit. The Committee unanimously recommended 2002–03 expenditures of \$80,760 and an assessment rate of \$0.045 per 22-pound volume fill container or equivalent of kiwifruit. The proposed assessment rate of \$0.045 is \$0.015 higher than the 2001–02 rate. The quantity of assessable kiwifruit for the 2002–03 fiscal period is estimated at 2,068,182 22-pound volume fill container or equivalent of kiwifruit. Thus, the \$0.045 rate should provide \$93,068 in assessment income and be adequate to meet this year's expenses.

The following table compares major budget expenditures recommended by the Committee for the 2002–03 and 2001–02 fiscal years:

Budget expense categories	2002–03	2001–02
Administrative Staff & Field Salaries	\$55,500	\$50,000
Travel	5,000	9,500

Budget expense categories	2002–03	2001–02
Office Costs/Annual Audit	14,500	14,500
Vehicle Expense Account	5,760	4,000

The Committee reviewed and unanimously recommended 2002–03 expenditures of \$80,760, which included increases in administrative salaries and vehicle expenses. Prior to arriving at this budget, the Committee considered alternative expenditure levels, but ultimately decided that the recommended levels were reasonable to properly administer the order. The assessment rate recommended by the Committee was derived by the following formula: Anticipated expenses (\$80,760), plus the desired 2003 ending reserve (\$36,287), minus the 2002 beginning reserve (\$23,979), divided by the total estimated 2002–03 shipments (2,068,182 22-pound volume fill containers). This calculation resulted in the \$0.045 assessment rate. This rate would provide sufficient funds to meet the anticipated expenses of \$80,760 and result in a July 2003 ending reserve of \$36,287, which is acceptable to the Committee. The July 2003 ending reserve funds (estimated to be \$36,287) would be kept within the maximum permitted by the order, approximately one fiscal period's expenses (\$ 920.41).

A review of historical information and preliminary information pertaining to the upcoming fiscal period indicates that the grower price for the 2002–03 season could range between \$9.50 and \$13.00 per 22-pound volume fill container or equivalent of kiwifruit. Therefore, the estimated assessment revenue for the 2002–03 fiscal period as a percentage of total grower revenue could range between 0.5 and 0.3 percent.

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. Some of the additional costs may be passed on to producers. However, these costs would be offset by the benefits derived by the operation of the marketing order. In addition, the Committee's meeting was widely publicized throughout the California kiwifruit industry and all interested persons were invited to attend the meeting and participate in Committee deliberations on all issues. Like all Committee meetings, the July 10, 2002, 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 information on the regulatory and informational impacts of this action on small businesses.

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

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: <http://www.ams.usda.gov/fv/moab.html>. Any questions about the compliance guide should be sent to Jay Guerber at the previously mentioned address in the **FOR FURTHER INFORMATION CONTACT** section.

A 30-day comment period is provided to allow interested persons to respond to this proposed rule. Thirty days is deemed appropriate because: (1) The 2002–03 fiscal period begins on August 1, 2002, and the marketing order requires that the rate of assessment for each fiscal period apply to all assessable kiwifruit 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 920

Kiwifruit, Marketing agreements.

For the reasons set forth in the preamble, 7 CFR part 920 is proposed to be amended as follows:

PART 920—KIWIFRUIT GROWN IN CALIFORNIA

1. The Authority citation for 7 CFR part 920 continues to read as follows:

Authority: 7 U.S.C. 601–674.

2. Section 920.213 is revised to read as follows:

§ 920.213 Assessment rate.

On and after August 1, 2002, an assessment rate of \$0.045 per 22-pound volume fill container or equivalent of kiwifruit is established for kiwifruit grown in California.

Dated: August 8, 2002.

A.J. Yates,
Administrator, Agricultural Marketing Service.
[FR Doc. 02–20688 Filed 8–14–02; 8:45 am]
BILLING CODE 3410–02–P

SUPPLEMENTARY INFORMATION:

I. Discussion

As described in the related direct final rule, FDA's procedures for a regulatory hearing are set forth in part 16 (21 CFR part 16) of the agency's regulations. "Part 16 hearings" are offered under numerous statutory and regulatory provisions. Section 16.1 provides a list of statutes and regulations in which part 16 hearings are available.

Currently, § 16.42(a) provides that an FDA employee to whom the Commissioner of Food and Drugs (the Commissioner) delegates the authority, or any other FDA employee to whom such authority is redelegated, can serve as the presiding officer at a regulatory hearing. In turn, § 5.30(c) (21 CFR 5.30(c)) delegates authority to preside at and conduct a regulatory hearing to the Director of the Office of the Ombudsman for the agency; the Directors and Deputy Directors of the Center for Food Safety and Applied Nutrition, the Center for Drug Evaluation and Research, the Center for Devices and Radiological Health, and the Center for Biologics Evaluation and Research; Regional Directors; District Directors; the Director of the St. Louis Branch; and such other FDA official as the Commissioner may designate by memorandum in the proceeding.

FDA believes that the addition of the ALJ to the list of those delegated to conduct regulatory hearings would increase the pool of qualified personnel available to preside at regulatory hearings. In addition, by virtue of the nature of an ALJ's training and experience adjudicating disputes, FDA believes that an ALJ would be appropriately suited to conduct regulatory hearings. Therefore, the agency is proposing to amend §§ 5.30(c) and 16.42(a) to permit an ALJ to preside at and conduct regulatory hearings before the agency.

The regulations pertaining to ALJs issued by the Office of Personnel Management (OPM) (5 CFR 930.209(b)) provide that an agency may assign an ALJ, by detail or otherwise, to perform duties that are not the duties of an ALJ without prior approval by OPM when the duties are not inconsistent with the duties and responsibilities of an ALJ, the assignment is not to last longer than 120 days; and the ALJ has not had an aggregate of more than 120 days of such assignments or details in the preceding year. However, OPM's regulations under 5 CFR 930.209(c) also state that on a showing that it is in the public interest, OPM may authorize a waiver from the 120-day limitation.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 5 and 16

[Docket No. 02N–0251]

Presiding Officers at Regulatory Hearings

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend its administrative regulations governing who may act as a presiding officer at a regulatory hearing. This action would amend the regulations to permit an administrative law judge (ALJ) to act as a presiding officer and provide the appropriate delegations of authority. It is intended to increase the pool of qualified personnel available as presiding officers, thereby increasing the efficiency with which the agency conducts regulatory hearings, beginning with responding to hearing requests and continuing through issuance of written hearing reports. This proposed rule is a companion document to the direct final rule published elsewhere in this issue of the **Federal Register**.

DATES: Submit written or electronic comments on the proposed rule on or before October 29, 2002. If FDA receives any significant adverse comments, the agency will publish a document withdrawing the direct final rule within 30 days after the comment period ends. FDA will then proceed to respond to comments under this proposed rule using the usual notice-and-comment procedures.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

FOR FURTHER INFORMATION CONTACT: Peter C. Beckerman, Office of the Chief Counsel (GCF–1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7144.