

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 1208

[Document Number AMS-FV-14-0042]

Processed Raspberry Promotion, Research, and Information Order; Late Payment and Interest Charges on Past Due Assessments

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Proposed rule.

SUMMARY: This proposal invites comments on prescribing late payment and interest charges on past due assessments under the Processed Raspberry Promotion, Research, and Information Order (Order). The Order is administered by the National Processed Raspberry Council (Council) with oversight by the U.S. Department of Agriculture (USDA). Under the Order, assessments are collected from domestic producers and importers and used for research and promotion projects designed to maintain and expand the market for processed raspberries. This proposal would implement authority contained in the Order that allows the Council to collect late payment and interest charges on past due assessments. Three additional changes are proposed to reflect current practices and update the Order and regulations. This action would contribute to effective administration of the program.

DATES: Comments must be received by December 12, 2014.

ADDRESSES: Interested persons are invited to submit written comments concerning this proposal. Comments may be submitted on the Internet at: <http://www.regulations.gov> or to the Promotion and Economics Division, Fruit and Vegetable Program, AMS, USDA, 1400 Independence Avenue SW., Room 1406-S, Stop 0244, Washington, DC 20250-0244; facsimile: (202) 205-2800. All comments should reference the document number and the

date and page number of this issue of the **Federal Register** and will be made available for public inspection, including name and address, if provided, in the above office during regular business hours or it can be viewed at <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT:

Tarun Harit, Program Management Specialist, Promotion and Economics Division, Fruit and Vegetable Program, AMS, USDA, 1400 Independence Avenue SW., Room 1406-S, Stop 0244, Washington, DC 20250-0244; telephone: (202) 720-9915; facsimile (202) 205-2800; or electronic mail: Tarun.Harit@ams.usda.gov.

SUPPLEMENTARY INFORMATION: This proposal is issued under the Order (7 CFR part 1208). The Order is authorized under the Commodity Promotion, Research, and Information Act of 1996 (1996 Act) (7 U.S.C. 7411-7425).

Executive Order 12866 and Executive Order 13563

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules and promoting flexibility. This action has been designated as a "non-significant regulatory action" under section 3(f) of Executive Order 12866. Accordingly, the Office of Management and Budget (OMB) has waived the review process.

Executive Order 13175

This action has been reviewed in accordance with the requirements of Executive Order 13175, Consultation and Coordination with Indian Tribal Governments. The review reveals that this regulation would not have substantial and direct effects on Tribal governments and would not have significant Tribal implications.

Executive Order 12988

This proposal has been reviewed under Executive Order 12988, Civil Justice Reform. It is not intended to have retroactive effect. Section 524 of

the 1996 Act (7 U.S.C. 7423) provides that it shall not affect or preempt any other Federal or State law authorizing promotion or research relating to an agricultural commodity.

Under section 519 of the 1996 Act (7 U.S.C. 7418), a person subject to an order may file a written petition with USDA stating that an order, any provision of an order, or any obligation imposed in connection with an order, is not established in accordance with the law, and request a modification of an order or an exemption from an order. Any petition filed challenging an order, any provision of an order, or any obligation imposed in connection with an order, shall be filed within two years after the effective date of an order, provision, or obligation subject to challenge in the petition. The petitioner will have the opportunity for a hearing on the petition. Thereafter, USDA will issue a ruling on the petition. The 1996 Act provides that the district court of the United States for any district in which the petitioner resides or conducts business shall have the jurisdiction to review a final ruling on the petition, if the petitioner files a complaint for that purpose not later than 20 days after the date of the entry of USDA's final ruling.

Background

This proposal invites comments on prescribing late payment and interest charges on past due assessments under the Order. The Order is administered by the Council with oversight by USDA. Under the Order, assessments are collected from domestic producers and importers and used for research and promotion projects designed to maintain and expand markets for processed raspberries. Processed raspberries include raspberries that have been frozen, dried, pureed, made into juice, or altered by mechanical processes. This proposal would implement authority contained in the Order and the 1996 Act that allows the Council to collect late payment and interest charges on past due assessments. This action was unanimously recommended by the Council and would contribute to effective administration of the program.

Section 1208.52(a) of the Order specifies that the funds to cover the Council's expenses shall be paid from assessments on producers and importers, donations from persons not subject to assessments, and from other

funds available to the Council. Paragraph (b) specifies that the collection of assessments on domestic processed raspberries is the responsibility of the first receiving handler of the raspberries for processing. Section 1208.52 (6)(e) specifies that “a late payment charge shall be imposed on any handler or importer who fails to remit to the Council, the total amount for which any such first handler or importer is liable on or before the due date established by the Council. In addition to the late payment charge, an interest charge shall be imposed on the outstanding amount for which the first handler or importer is liable. The rate of interest shall be prescribed in regulations issued by the Secretary.”

The Order was implemented in May 2012. Assessment collection began in September 2012. Domestic assessments are due to the Council once annually by October 31. Import assessments are collected monthly by the U.S. Customs and Border Protection (Customs). If Customs does not collect the assessment, the importer must pay the assessment directly to the Council. Entities that produce less than 20,000 pounds of raspberries for processing annually or import less than 20,000 pounds of processed raspberries annually are exempt from assessment.

Assessment funds are used by the Council for activities designed to benefit all industry members. Thus, it is important that all assessed entities pay their assessments in a timely manner. Entities who fail to pay their assessments on time would be able to reap the benefits of Council programs at the expense of others. In addition, they would be able to utilize funds for their own use that should otherwise be paid to the Council to finance Council programs.

Council Recommendation

Thus, the Council met on January 15, 2014, and unanimously recommended specifying rates of late payment charges and interest on past due assessments in the Order's regulations. Specifically, the Council recommended that a late payment charge be imposed on any handler or importer who fails to make timely remittance to the Council of the total assessments for which the handler or importer is liable. The late payment would be imposed on any assessments not received within 30 calendar days of the date they are due. This would be a one-time late payment charge equal to 10 percent of the assessments due before interest charges have accrued. The Council also recommended that 1 percent per month interest on the

outstanding balance, including any late payment and accrued interest, be added to any accounts for which payment has not been received within 30 calendar days after the date assessments are due. Interest would continue to accrue monthly until the unpaid balance was paid to the Council.

This action would help facilitate program administration by providing an incentive for entities to remit assessments in a timely manner, with the intent of creating a fair and equitable process among all assessed entities. Accordingly, a new subpart C would be added to the Order for rules and regulations, and a new § 1208.520 would be added to subpart C.

This proposal would also make three additional changes to the Order. This proposed rule would revise the terms crop and fiscal years as defined in §§ 1208.3 and 1208.7, respectively. The crop and fiscal years are changed in the Order from the 12-month period April 1 through March 31 to October 1 through September 30. The new time frames help facilitate program operations because domestic assessments are due by October 31, so those funds can be used to support current year activities. Revising the terms would bring the Order in line with current practices.

This proposal would also change the OMB control numbers in §§ 1208.78 and 1208.108. In § 1208.78, the OMB control number 0581-0257 would be omitted because it is no longer relevant. In § 1208.108, the OMB control number would be changed from 0581-NEW to 0581-0093, the control number assigned by the OMB.

Initial Regulatory Flexibility Act Analysis

In accordance with the Regulatory Flexibility Act (RFA) (5 U.S.C. 601-612), AMS is required to examine the impact of the proposed rule on small entities. Accordingly, AMS has considered the economic impact of this action on small entities.

The purpose of the RFA is to fit regulatory actions to the scale of businesses subject to such actions so that small businesses will not be disproportionately burdened. The Small Business Administration defines, in 13 CFR part 121, small agricultural producers as those having annual receipts of no more than \$750,000 and small agricultural service firms (first handlers and importers) as those having annual receipts of no more than \$7.0 million.

According to the Council, it is estimated that there are 160 producers of raspberries for processing and 30 first handlers of processed raspberries in the

United States. Dividing the processed raspberry crop value for 2013 reported by the National Agricultural Statistics Service (NASS) of \$60,883,000¹ by the number of producers yields an average, annual producer revenue of \$380,520. It is estimated that in 2013, 75 percent of the first handlers shipped under \$7.0 million worth of processed raspberries.

Likewise, based on Customs data, it is estimated there are 140 importers of processed raspberries. Using 2013 Customs data, nearly all importers, or 99 percent, import less than \$7.0 million worth of processed raspberries annually. Thus, the majority of domestic producers, first handlers and importers of processed raspberries would be considered small entities.

Regarding the value of the commodity, as mentioned above, based on 2013 NASS data, the value of the domestic processed raspberry crop was about \$61 million. According to Customs data, the value of 2013 imports was about \$65 million.

This proposal invites comments on prescribing late payment and interest charges on past due assessments under the Order. The Order is administered by the Council with oversight by USDA. Under the Order, assessments are collected from domestic producers of raspberries for processing and importers of processed raspberries. Processed raspberries include raspberries that have been frozen, dried, pureed, made into juice, or altered by mechanical processes. This proposed rule would add a new § 1208.520 that would specify a late payment charge of 10 percent of the assessments due and interest at a rate of 1 percent per month on the outstanding balance, including any late payment and accrued interest. This section would be included in a new Subpart C—Rules and Regulations. This action was unanimously recommended by the Council and is authorized under section 1208.52(e) of the Order and section 517(e) of the 1996 Act.

Regarding the economic impact of this proposed rule on affected entities, this action would impose no costs on handlers and importers who pay their assessments on time. It would merely provide an incentive for entities to remit their assessments in a timely manner. For all entities who are delinquent in paying assessments, both large and small, the charges would be applied the same. As for the impact on the industry as a whole, this action would help facilitate program administration by

¹ Noncitrus Fruits and Nuts 2013 Summary, July 2014, USDA, National Agricultural Statistics Service, p. 37.

providing an incentive for entities to remit their assessments in a timely manner, with the intent of creating a fair and equitable process among all assessed entities.

Additionally, as previously mentioned, the Order provides for an exemption for entities that produce or import less than 20,000 pounds of processed raspberries annually. About 140 producers of raspberries for processing and 80 importers of processed raspberries pay assessments under the Order.

Regarding alternatives, one option to the proposed action would be to maintain the status quo and not prescribe late payment and interest charges for past due assessments. However, the Council determined that implementing such charges would help facilitate program administration by encouraging entities to pay their assessments in a timely manner. The Council reviewed rates of late payment and interest charges prescribed in other research and promotion programs and concluded that a 10 percent late payment charge and interest at a rate of 1 percent per month on the outstanding balance would be appropriate.

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the information collection and recordkeeping requirements that are imposed by the Order have been approved under OMB control number 0581-0093. This proposed rule would not result in a change to the information collection and recordkeeping requirements previously approved and would impose no additional reporting and recordkeeping burden on domestic producers, first handlers, and importers of processed raspberries.

As with all Federal promotion 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 proposed rule.

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.

Regarding outreach efforts, the Council met on January 15, 2014, and unanimously made its recommendation. All of the Council's meetings, including meetings held via teleconference, are open to the public and interested persons are invited to participate and express their views.

We have performed this initial RFA regarding the impact of this proposed action on small entities and we invite comments concerning potential effects of this action on small businesses.

While this proposed rule set forth below has not received the approval of USDA, it has been determined that it is consistent with and would effectuate the purposes of the 1996 Act.

A 30-day comment period is provided to allow interested persons to respond to this proposal. Thirty-days is deemed appropriate because the Council would like to implement this incentive as soon as possible to facilitate the collection of assessments on a timely basis. All written comments received in response to this proposed rule by the date specified will be considered prior to finalizing this action.

List of Subjects in 7 CFR Part 1208

Administrative practice and procedure, Advertising, Consumer information, Marketing agreements, Raspberry promotion, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, 7 CFR part 1208 is proposed to be amended as follows:

PART 1208—PROCESSED RASPBERRY PROMOTION, RESEARCH, AND INFORMATION ORDER

- 1. The authority citation for 7 CFR part 1208 continues to read as follows:

Authority: 7 U.S.C. 7411-7425; 7 U.S.C. 7401.

- 2. Section 1208.3 is revised to read as follows:

§ 1208.3 Crop year.

Crop year means the 12-month period from October 1 through September 30 or such other period approved by the Secretary.

- 3. Section 1208.7 is revised to read as follows:

§ 1208.7 Fiscal period.

Fiscal period means the 12-month period from October 1 through September 30 or such other period as approved by the Secretary.

- 4. Section 1208.78 is revised to read as follows:

§ 1208.78 OMB control numbers.

The control numbers assigned to the information collection requirements by the Office of Management and Budget pursuant to the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35, are OMB control number 0505-0001, and OMB control number 0581-0093.

- 5. Section 1208.108 is revised to read as follows:

§ 1208.108 OMB control number.

The control number assigned to the information collection requirement in this subpart by the Office of Management and Budget pursuant to the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35, is OMB control number 0581-0093.

- 6. Subpart C—Rules and Regulations is added to read as follows:

Subpart C—Rules and Regulations

§ 1208.520 Late payment and interest charges for past due assessments.

(1) A late payment charge shall be imposed on any handler or importer who fails to make timely remittance to the Council of the total assessments for which such handler or importer is liable. The late payment will be imposed on any assessments not received within 30 calendar days of the date they are due. This one-time late payment charge shall be 10 percent of the assessments due before interest charges have accrued.

(2) In addition to the late payment charge, 1 percent per month interest on the outstanding balance, including any late payment and accrued interest, will be added to any accounts for which payment has not been received by the Council within 30 calendar days after the date the assessments are due. Such interest will continue to accrue monthly until the outstanding balance is paid to the Council.

Dated: November 5, 2014.

Rex A. Barnes,

Associate Administrator.

[FR Doc. 2014-26677 Filed 11-10-14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 888

[Docket No. FDA-2014-N-1205]

Orthopedic Devices; Reclassification of Thoracolumbosacral Rigid Pedicle Screw Systems; Classification and Effective Date of Requirement for Premarket Approval for Dynamic Stabilization Systems

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed order.

SUMMARY: The Food and Drug Administration (FDA) is proposing in this administrative order to reclassify rigid pedicle screw systems, a