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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 927

[Doc. No. AMS–SC–18–0049; SC18–927–2 PR]

Pears Grown in Oregon and Washington; Decreased Assessment Rate for Processed Pears

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Proposed rule.

SUMMARY: This proposed rule would implement a recommendation from the Processed Pear Committee (Committee) to decrease the assessment rate established for “summer/fall” varieties of pears for canning for the 2018–2019 and subsequent fiscal periods. The assessment rate would remain in effect indefinitely unless modified, suspended, or terminated.

DATES: Comments must be received by October 12, 2018.

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 document 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 the comments will be made public on the internet at the address provided above.

FOR FURTHER INFORMATION CONTACT: Dale Novotny, Marketing Specialist, or Gary Olson, Regional Director, Northwest Marketing Field Office, Marketing Order and Agreement Division, Specialty Crops Program, AMS, USDA; Telephone: (503) 326–2724, Fax: (503) 326–7440, or Email: DaleJ.Novotny@ams.usda.gov or GaryD.Olson@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.

SUPPLEMENTARY INFORMATION: This action, pursuant to 5 U.S.C. 553, proposes an amendment to regulations issued to carry out a marketing order as defined in 7 CFR 900.2(j). This proposed rule is issued under Marketing Order No. 927, as amended (7 CFR part 927), regulating the handling of pears grown in Oregon and Washington. Part 927, (referred to as “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 Committee locally administers the Order and is comprised of growers, handlers, and processors operating within the area of production, and a public member.

The Department of Agriculture (USDA) is issuing this proposed rule in conformance with Executive Orders 13563 and 13175. This proposed rule falls within a category of regulatory actions that the Office of Management and Budget (OMB) exempted from Executive Order 12866 review. Additionally, because this proposed rule does not meet the definition of a significant regulatory action, it does not trigger the requirements contained in Executive Order 13771. See OMB’s Memorandum titled “Interim Guidance Implementing Section 2 of the Executive Order of January 30, 2017, titled ‘Reducing Regulation and Controlling Regulatory Costs’” (February 2, 2017).

This proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. Under the Order now in effect, Oregon and Washington pear handlers are subject to assessments. Funds to administer the Order are derived from such assessments. It is

intended that the assessment rate would be applicable to all assessable “summer/fall” varieties of pears specifically used for canning for the 2018–2019 fiscal period, 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.

The 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 Committee members are familiar with the Committee’s needs and with the costs of goods and services in their local area and are in a position to formulate an appropriate budget and assessment rate. The assessment rate is formulated and discussed in a public meeting where all directly affected persons have an opportunity to participate and provide input.

This proposed rule would decrease the assessment rate from \$8.00, the rate that was established for the 2017–2018 and subsequent fiscal periods, to \$7.15 per ton of “summer/fall” varieties of pears for canning handled for the 2018–2019 and subsequent fiscal periods. The assessment rate for “winter” and “other” pears for processing would remain unchanged at \$0.00. The Committee met on May 30, 2018, and unanimously recommended 2018–2019 fiscal period expenditures of \$693,472. In comparison, last year’s budgeted expenditures were \$800,150. The Committee also unanimously recommended an assessment rate of \$7.15 per ton of “summer/fall” varieties

of pears for canning handled. The proposed assessment rate of \$7.15 per ton is \$0.85 lower than the \$8.00 per ton rate currently in effect. The Committee recommended the lower assessment rate to balance assessment revenue with its budgeted expenditures and to maintain its monetary reserve at levels authorized in the Order.

The major expenditures recommended by the Committee for the 2018–2019 fiscal period include \$495,000 for promotion and paid advertising, \$136,172 for research, \$15,000 for market access programs, \$25,000 for administrative and management services, and \$22,300 for Committee expenses. In comparison, these major expense categories for the 2017–2018 fiscal period were budgeted at \$591,030, \$147,694, \$14,576, \$25,000, and \$21,850; respectively.

The assessment rate recommended by the Committee was derived by considering anticipated expenses, expected shipments, and the amount of funds available in the authorized reserve. The quantity of assessable “summer/fall” pears for canning for the 2018–2019 fiscal period is estimated at 100,000 tons. Thus, the proposed \$7.15 per ton should provide handler assessments of \$715,000. This amount would be adequate to cover budgeted expenses of \$693,472, with any excess funds used to make a small contribution to the Committee’s monetary reserve. Funds in the reserve (currently \$497,565) would be kept within the maximum permitted by § 927.42(a) of approximately one fiscal period’s expenses.

The assessment rate proposed in this rule 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 budget 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 1,500 growers of pears for processing in the production area and approximately 43 handlers of processed pears subject to regulation under the Order. Small agricultural producers are defined by the Small Business Administration (SBA) as those having annual receipts less than \$750,000, and small agricultural service firms are defined as those whose annual receipts are less than \$7,500,000 (13 CFR 121.201).

According to data from USDA National Agricultural Statistics Service (NASS), the Committee, and the industry for the 2016–2017 season (the most recent complete season of record) the average f.o.b. price for Oregon–Washington processed Bartlett pears (the only variety used for canning in the production area) was approximately \$390.50 per ton. Total shipments for that period were approximately 103,020 tons. Using the number of handlers, and assuming a normal distribution, the majority of handlers would have average annual receipts of less than \$7,500,000 (\$390.50 per ton times 103,020 tons equals \$40,229,310 divided by 43 handlers equals \$935,565 per handler).

In addition, based on data from the Committee, the industry produced 103,020 tons of processed pears in the production area during the 2016–2017 season, with an average grower price of \$360 per ton. Based on the average grower price, production, and the total number of Oregon–Washington processed pear growers reported by the Committee (1,500), and assuming a normal distribution, the average annual grower revenue is below \$750,000 (\$360 per ton times 103,020 tons equals \$37,087,200 divided by 1,500 growers equals \$24,725 per grower). Thus, the majority of Oregon and Washington

processed pear handlers and growers may be classified as small entities.

This proposal would decrease the assessment rate collected from handlers for the 2018–2019 and subsequent fiscal periods from \$8.00 per ton to \$7.15 per ton of Oregon and Washington “summer/fall” pears for canning handled. The Committee unanimously recommended 2018–2019 fiscal period expenditures of \$693,472 and the \$7.15 per ton assessment rate. The proposed assessment rate of \$7.15 per ton is \$0.85 lower than the rate in effect for the 2017–2018 fiscal period. The quantity of assessable “summer/fall” pears for canning for the 2018–2019 fiscal period is estimated at 100,000 tons. Thus, the proposed \$7.15 per ton rate should provide \$715,000 in assessment income. Income derived from handler assessments should be adequate to cover budgeted expenses, with any excess funds to be carried over in the Committee’s monetary reserve to be used in subsequent years.

The major expenditures recommended by the Committee for the 2018–2019 fiscal period include \$495,000 for promotion and paid advertising, \$136,172 for research, \$15,000 for market access programs, \$25,000 for administrative and management services, and \$22,300 for Committee expenses. In comparison, these major expense categories for the 2017–2018 fiscal period were budgeted at \$591,030, \$147,694, \$14,576, \$25,000, and \$21,850, respectively.

The proposed lower assessment rate is necessary to balance assessment revenue with the Committee’s 2018–2019 fiscal period budgeted expenditures and to maintain its monetary reserve at levels authorized in the Order.

Prior to arriving at this budget and assessment rate, the Committee considered the benefits and costs related to maintaining the current assessment rate of \$8.00 per ton and establishing other assessment rates. However, leaving the assessment rate unchanged would generate more revenue than required to meet the Committee’s 2018–2019 fiscal period budgeted expenses of \$693,472, and would add a large amount of excess funds to the Committee’s already sufficient monetary reserve. Based on estimated shipments, the recommended assessment rate of \$7.15 per ton should provide \$715,000 in assessment income. The Committee determined assessment revenue would be adequate to fully cover budgeted expenditures for the 2018–2019 fiscal period, with a small amount of excess funds to be added to the Committee’s monetary reserve. Reserve funds would

be kept within the amount authorized in the Order.

A review of historical information and preliminary information pertaining to the upcoming fiscal year indicates that the average grower price for the 2018–2019 season should be approximately \$296 per ton of pears for processing. Therefore, the estimated assessment revenue for the 2018–2019 fiscal period as a percentage of total grower revenue would be about 2.4 percent (\$7.15 per ton assessment divided by \$296 per ton grower price).

This proposed action would decrease the assessment obligation imposed on handlers for the 2018–2019 and subsequent fiscal periods. Assessments are applied uniformly on all handlers, and some of the costs may be passed on to producers. However, decreasing the assessment rate would reduce the burden on handlers, and may reduce the burden on producers.

The Committee's meetings were widely publicized throughout the Oregon and Washington processed pear industry. All interested persons were invited to attend the meetings and participate in Committee deliberations on all issues. Like all Committee meetings, the May 30, 2018, 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 information collection 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 OMB and assigned OMB No. 0581–0189. No changes in those requirements would be necessary because of this action. Should any changes become necessary, they would be submitted to OMB for approval.

This proposed rule would not impose any additional reporting or recordkeeping requirements on either small or large Oregon and Washington processed pear 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 proposed 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/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.

List of Subjects in 7 CFR Part 927

Marketing agreements, Pears, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, 7 CFR part 927 is proposed to be amended as follows:

PART 927—PEARS GROWN IN OREGON AND WASHINGTON

- 1. The authority citation for 7 CFR part 927 continues to read as follows:

Authority: 7 U.S.C. 601–674.

- 2. In § 927.237 revise the intro paragraph text and paragraph (a) to read as follows:

§ 927.237 Assessment rate.

On and after July 1, 2018, the following base rates of assessment for pears for processing are established for the Processed Pear Committee:

- (a) \$7.15 per ton for any or all varieties or subvarieties of pears for canning classified as “summer/fall” excluding pears for other methods of processing;

* * * * *

Dated: September 6, 2018.

Bruce Summers,

Administrator, Agricultural Marketing Service.

[FR Doc. 2018–19683 Filed 9–11–18; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 310

[Docket No. FDA–2017–N–6924]

RIN 0910–AH47

Repeal of Regulation Requiring an Approved New Drug Application for Drugs Sterilized by Irradiation

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is proposing to repeal a regulation that requires an FDA-approved new drug application (NDA) or abbreviated new drug application (ANDA) for any drug product that is sterilized by irradiation (the irradiation regulation). Repealing the irradiation regulation would mean that over-the-counter (OTC) drug products that are generally recognized as safe and effective, that are not misbranded, and that comply with all applicable regulatory requirements can be marketed legally without an NDA or ANDA, even if they are sterilized by irradiation. FDA is proposing to take this action because the irradiation regulation is out of date and unnecessary. The technology of controlled nuclear radiation for sterilization of drugs is now well understood, and our regulations require that OTC drugs be manufactured in compliance with current good manufacturing practices (CGMPs). Appropriate and effective sterilization of drugs, including by irradiation, is adequately addressed by the CGMP requirements. This action is part of FDA's implementation of Executive Orders (EOs) 13771 and 13777. Under these EOs, FDA is comprehensively reviewing existing regulations to identify opportunities for repeal, replacement, or modification that will result in meaningful burden reduction while allowing the Agency to achieve our public health mission and fulfill statutory obligations.

DATES: Submit either electronic or written comments on the proposed rule by November 13, 2018.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before November 13, 2018. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of November 13, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to