

Dated: December 11, 2018.

Bruce Summers,

Administrator, Agricultural Marketing Service.

[FR Doc. 2018-27140 Filed 12-13-18; 8:45 am]

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DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 956

[Doc. No. AMS-SC-18-0028; SC-18-956-1]

Sweet Onions Grown in the Walla Walla Valley of Southeast Washington and Northeast Oregon; Proposed Amendments to Marketing Order 956 and Referendum Order

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Proposed rule and referendum order.

SUMMARY: This document proposes amendments to Marketing Order No. 956, which regulates the handling of sweet onions grown in the Walla Walla Valley of Southeast Washington and Northeast Oregon. The Walla Walla Sweet Onion Marketing Committee (Committee) recommended changing the Committee's size, quorum, and voting requirements. The Committee also recommended changing the term of office and staggered term limits so that the term of office for producers and handlers would be two fiscal periods instead of three fiscal periods, and one-half instead of one-third of the producer and handler member terms would expire every year.

DATES: The referendum will be conducted from December 17, 2018, through December 31, 2018. The representative period for the referendum is June 1, 2017, through May 31, 2018.

FOR FURTHER INFORMATION CONTACT: Geronimo Quinones, Marketing Specialist, or Patty Bennett, Director, 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: Geronimo.Quinones@usda.gov or Patty.Bennett@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@usda.gov.

SUPPLEMENTARY INFORMATION: This proposal, pursuant to 5 U.S.C. 553, proposes amendments to regulations issued to carry out a marketing order as defined in 7 CFR 900.2(j). This proposal is issued under Marketing Order No. 956, as amended (7 CFR part 956), regulating the handling of sweet onions grown in the Walla Walla Valley of Southeast Washington and Northeast Oregon. Part 956 (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 sweet onion producers and handlers operating within the area of production and a public member.

Section 608c(17) of the Act and the applicable rules of practice and procedure governing the formulation of marketing agreements and orders (7 CFR part 900) authorizes amendment of the Order through this informal rulemaking action.

The Department of Agriculture (USDA) is issuing this rule in conformance with Executive Orders 13563 and 13175. This action 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 proposal has been reviewed under Executive Order 12988, Civil Justice Reform. This rule is not intended to have retroactive effect. This rule shall not be deemed to preclude, preempt, or supersede any State program covering sweet onions grown in the Walla Walla Valley of Southeast Washington and Northeast Oregon.

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. A 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 no later than 20 days after the date of entry of the ruling.

Section 1504 of the Food, Conservation, and Energy Act of 2008 (2008 Farm Bill) (Pub. L. 110-246) amended section 608c(17) of the Act, which in turn required the addition of supplemental rules of practice to 7 CFR part 900 (73 FR 49307; August 21, 2008). The amendment of section 608c(17) of the Act and the supplemental rules of practice authorize the use of informal rulemaking (5 U.S.C. 553) to amend Federal fruit, vegetable, and nut marketing agreements and orders. USDA may use informal rulemaking to amend marketing orders based on the nature and complexity of the proposed amendments, the potential regulatory and economic impacts on affected entities, and any other relevant matters.

AMS has considered these factors and has determined that the amendments proposed are not unduly complex and the nature of the proposed amendments is appropriate for utilizing the informal rulemaking process to amend the Order.

The proposed amendments were unanimously recommended by the Committee following deliberations at two public meetings held on November 14, 2017, and March 3, 2018. The proposals would amend the Order by changing the Committee's size, quorum, and voting requirements. This action would also change the term of office and staggered term limits so that the term of office for producers and handlers would be two fiscal periods instead of three fiscal periods, and one-half instead of one-third of the producer and handler member terms would expire every year. If the proposed amendments are finalized, the Committee would hold nominations for producer and handler member and alternate positions. All the Committee's producer and handler positions would be filled by new nominations. Members and alternates who are currently serving could be nominated to serve on the new Committee.

A proposed rule soliciting comments on the proposed amendments was issued on July 19, 2018, and published in the **Federal Register** on July 24, 2018 (83 FR 34953). One comment in support of the amendments was received. AMS will conduct a producer referendum to determine support for the proposed

amendments. If appropriate, a final rule will then be issued to effectuate the amendments favored by producers in the referendum.

Proposal 1—Reduce Committee Size

Section 956.20 provides that the Committee consists of ten members, six of whom shall be producers, three of whom shall be handlers, and one public member. This proposal would amend § 956.20 by reducing the size of the Committee from ten to seven members, four of whom shall be producers, two of whom shall be handlers, and one public member. The requirement that each member have an alternate with the same qualifications as the member would remain unchanged.

Since promulgation of the Order in 1995, the number of Walla Walla sweet onion producers and handlers operating in the industry has decreased, which makes it difficult to find enough members and alternates to fill all positions on the Committee. Decreasing the Committee's size from ten members to seven members would make it more reflective of today's industry. Reducing the size of the Committee would enable it to more effectively fulfill membership and quorum requirements. These changes should help the Committee streamline its operations and increase its effectiveness.

Proposal 2—Revise Term of Office and Staggered Term Limits

Section 956.21 requires Committee members and their alternates to serve for three fiscal periods in staggered terms with one-third of the terms expiring each year.

This proposal would change § 956.21 by revising the terms of office for the producer and handler members from three fiscal periods to two fiscal periods beginning on June 1 so that one-half of the Committee membership changes every year. The staggered terms would also change so that one-half instead of one-third of the producer and handler member terms expire every year. The proposed term limit changes would only apply to producer and handler members; the public member term would remain at three years.

Proposal 3—Revise Quorum and Voting Requirements

Currently, Section 956.28(a) states that six members of the Committee shall constitute a quorum, and six concurring votes shall be required to pass any motion or approve any Committee action, except that recommendations made pursuant to § 956.61 shall require seven concurring votes.

The proposed changes would modify § 956.28 to state that four rather than six members would constitute a quorum, and four rather than six concurring votes would be required to pass any motion or approve any Committee action, except for recommendations made pursuant to § 956.61, which would require five rather than seven concurring votes. These changes would help streamline the Committee's operations and increase its effectiveness.

Final Regulatory Flexibility Analysis

Pursuant to the requirements set forth in the Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612), AMS has considered the economic impact of this action on small entities. Accordingly, AMS has prepared this final 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 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 eight handlers of Walla Walla sweet onions subject to regulation under the Order and approximately 15 producers in the regulated production area. Small agricultural service firms are defined by the Small Business Administration (SBA) as those having annual receipts of less than \$7,500,000, and small agricultural producers are defined as those having annual receipts of less than \$750,000 (13 CFR 121.201).

The Committee reported that approximately 390,000 50-pound bags or equivalents of Walla Walla sweet onions were shipped into the fresh market in 2017. Based on information reported by USDA's Market News Service, the average 2017 marketing year f.o.b. shipping point price for the Walla Walla sweet onions was \$14.90 per 50-pound equivalent. Multiplying the \$14.90 average price by the shipment quantity of 390,000 50-pound equivalents yields an annual crop revenue estimate of \$5,811,000. The average annual revenue for each of the eight handlers is therefore calculated to be \$726,375 (\$5,811,000 divided by eight), which is less than the SBA threshold of \$7,500,000. Consequently, all the Walla Walla sweet onion handlers could be classified as small entities.

In addition, based on information provided by the National Agricultural Statistics Service (NASS), the average

producer price for Walla Walla sweet onions for the 2012 through 2016 marketing years is \$15.27 per 50-pound equivalent. NASS has not released data regarding the 2017 marketing year at this time. Multiplying the 2012–2016 marketing year average price of \$15.27 by the 2017 marketing year shipments of 390,000 50-pound equivalents yields an annual crop revenue estimate of \$5,955,300. The estimated average annual revenue for each of the 15 producers is therefore calculated to be approximately \$397,020 (\$5,955,300 divided by 15), which is less than the SBA threshold of \$750,000. In view of the foregoing, the majority of Walla Walla sweet onion producers and all of the Walla Walla sweet onion handlers may be classified as small entities.

The proposed amendments would change the Committee's size, quorum, and voting requirements. The proposed amendments would also change the term of office and staggered term limits so that the term of office for producers and handlers would be two fiscal periods instead of three fiscal periods, and one-half instead of one-third of the producer and handler member terms would expire every year.

The Committee's proposed amendments were unanimously recommended at two public meetings on November 14, 2017, and March 3, 2018. If these proposals are approved in a referendum, there would be no direct financial effects on producers or handlers. The number of producers and handlers operating in the industry has decreased, which makes it difficult to find enough members to fill positions on the Committee. Decreasing the Committee's size would make it more reflective of today's industry.

If the proposed amendments are finalized, the Committee would hold nominations for producer and handler member and alternate positions. All the Committee's producer and handler positions would be filled by new nominations. Members and alternates who are currently serving could be nominated to serve on the new Committee.

The Committee believes these changes will serve the needs of the Committee and the industry. No economic impact is expected if the proposed amendments are approved because they would not establish any new regulatory requirements on handlers nor would they have any assessment or funding implications. There would be no change in financial costs, reporting, or recordkeeping requirements if the proposals are approved.

Alternatives to the proposals, including making no changes at this

time, were considered by the Committee. Due to changes in the industry, AMS believes the proposals are justified and necessary to ensure the Committee's ability to locally administer the program. Reducing the size of the Committee would enable it to fulfill membership and quorum requirements fully, thereby ensuring a more efficient and orderly flow of business.

Paperwork Reduction Act

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. 0581-0178 (Vegetable and Specialty Crops). No changes in those requirements are necessary because of this action. 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 Walla Walla Valley sweet onion 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.

The Committee's meetings were widely publicized throughout the production area. All interested persons were invited to attend the meetings and encouraged to participate in Committee deliberations on all issues. Like all Committee meetings, the November 14, 2017, and March 3, 2018, meetings were public, and all entities, both large and small, were encouraged to express their views on the proposals.

A proposed rule concerning this action was published in the **Federal Register** on July 24, 2018 (83 FR 34953). A copy of the proposed rule was sent via email to the Committee manager for dispersal to all Committee members and interested parties. The rule was also made available through the internet by USDA and the Office of the Federal Register. A 60-day comment period ending September 24, 2018, was provided to allow interested persons to respond to the proposal. One comment

was received in support of the amendments.

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.

Findings and Conclusions

The findings and conclusions and general findings and determinations included in the proposed rule set forth in the July 24, 2018, issue of the **Federal Register** are hereby approved and adopted.

Marketing Order

Annexed hereto and made a part hereof is the document entitled "Order Amending the Order Regulating the Handling of Sweet Onions Grown in the Walla Walla Valley of Southeast Washington and Northeast Oregon." This document has been decided upon as the detailed and appropriate means of effectuating the foregoing findings and conclusions. It is hereby ordered that this entire rule be published in the **Federal Register**.

Referendum Order

It is hereby directed that a producer referendum be conducted in accordance with the procedure for the conduct of referenda (7 CFR 900.400-407) to determine whether the annexed Order Amending the Order Regulating the Handling of Sweet Onions Grown in the Walla Walla Valley of Southeast Washington and Northeast Oregon is approved by producers who have engaged in the production of sweet onions within the production area during the representative period. The representative period for the conduct of such referendum is hereby determined to be June 1, 2017, to May 31, 2018.

The agents of the Secretary to conduct such referendum are designated to be Dale Novotny and Barry Broadbent, 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@usda.gov and Barry.Broadbent@usda.gov, respectively.

Order Amending the Order Regulating the Handling of Sweet Onions Grown in the Walla Walla Valley of Southeast Washington and Northeast Oregon¹

Findings and Determinations

The findings hereinafter set forth are supplementary to the findings and determinations which were previously made in connection with the issuance of the Order; and all said previous findings and determinations are hereby ratified and affirmed, except insofar as such findings and determinations may be in conflict with the findings and determinations set forth herein.

1. The Order, as amended, and as hereby proposed to be further amended, and all the terms and conditions thereof, would tend to effectuate the declared policy of the Act;

2. The Order, as amended, and as hereby proposed to be further amended, regulates the handling of sweet onions grown in the Walla Walla Valley of Southeast Washington and Northeast Oregon and is applicable only to persons in the respective classes of commercial and industrial activity specified in the Order;

3. The Order, as amended, and as hereby proposed to be further amended, is limited in application to the smallest regional production area which is practicable, consistent with carrying out the declared policy of the Act, and the issuance of several marketing orders applicable to subdivisions of the production area would not effectively carry out the declared policy of the Act;

4. The Order, as amended, and as hereby proposed to be further amended, prescribes, insofar as practicable, such different terms applicable to different parts of the production area as are necessary to give due recognition to the differences in the production and marketing of onions produced or packed in the production area; and

5. All handling of onions produced or packed in the production area as defined in the Order is in the current of interstate or foreign commerce or directly burdens, obstructs, or affects such commerce.

Order Relative to Handling

It is therefore ordered, that on and after the effective date hereof, all handling of sweet onions grown in the Walla Walla Valley of Southeast Washington and Northeast Oregon shall be in conformity to, and in compliance with, the terms and conditions of the

¹ This order shall not become effective unless and until the requirements of § 900.14 of the rules of practice and procedure governing proceedings to formulate marketing agreements and marketing orders have been met.

said Order as hereby proposed to be amended as follows:

The provisions of the proposed marketing order amending the Order contained in the proposed rule issued by the Administrator on July 19, 2018, and published in the **Federal Register** (83 FR 34953) on July 24, 2018, will be and are the terms and provisions of this order amending the Order and are set forth in full herein.

List of Subjects in 7 CFR Part 956

Onions, Marketing agreements, Reporting and recordkeeping requirements.

Dated: December 11, 2018.

Bruce Summers,

Administrator, Agricultural Marketing Service.

For the reasons discussed in the preamble, 7 CFR part 956 is proposed to be amended as follows.

PART 956—SWEET ONIONS GROWN IN THE WALLA WALLA VALLEY OF SOUTHEAST WASHINGTON AND NORTHEAST OREGON

■ 1. The authority citation for 7 CFR part 956 continues to read as follows:

Authority: 7 U.S.C. 601–674.

■ 2. Amend § 956.20 by revising paragraph (a) to read as follows:

§ 956.20 Establishment and membership.

(a) The Walla Walla Sweet Onion Marketing Committee, consisting of seven members, is hereby established. The Committee shall consist of four producer members, two handler members, and one public member. Each member shall have an alternate who shall have the same qualifications as the member.

* * * * *

■ 3. Revise § 956.21 to read as follows:

§ 956.21 Term of office.

(a) Except as otherwise provided in paragraph (b) of this section, the term of office of grower and handler Committee members and their respective alternates shall be two fiscal periods beginning on June 1 or such other date as recommended by the Committee and approved by the Secretary. The terms shall be determined so that one-half of the grower membership and one-half of the handler membership shall terminate each year. Members and alternates shall serve during the term of office for which they are selected and have been qualified, or during that portion thereof beginning on the date on which they qualify during such term of office and continuing until the end thereof, or

until their successors are selected and have qualified.

(b) The term of office of the initial members and alternates shall begin as soon as possible after the effective date of this subpart. One-half of the initial industry grower and handler members and alternates shall serve for a one-year term and one-half shall serve for a two-year term. The initial as well as all successive terms of office of the public member and alternate member shall be for three years.

(c) The consecutive terms of office for all grower and handler members shall be limited to two two-year terms. There shall be no such limitation for alternate members.

■ 4. Amend § 956.28 by revising paragraph (a) to read as follows:

§ 956.28 Procedure.

(a) Four members of the Committee shall constitute a quorum, and four concurring votes shall be required to pass any motion or approve any Committee action, except that recommendations made pursuant to § 956.61 shall require five concurring votes.

* * * * *

[FR Doc. 2018–27143 Filed 12–13–18; 8:45 am]

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DEPARTMENT OF COMMERCE

Bureau of Industry and Security

15 CFR Part 744

[Docket No. 180712626–8840–01]

RIN 0694–AH61

Review of Controls for Certain Emerging Technologies

AGENCY: Bureau of Industry and Security, Commerce.

ACTION: Advance notice of proposed rulemaking (ANPRM), Extension of comment period.

SUMMARY: The Bureau of Industry and Security (BIS) is extending the comment period for its November 19, 2018, advanced notice of proposed rulemaking (ANPRM), “Review of Controls for Certain Emerging Technologies” until January 10, 2019. In response to requests received from members of the public, BIS believes it is appropriate to extend the comment period to provide interested parties additional time to submit their responses to the ANPRM.

DATES: The comment period announced in the notice that was published on November 19, 2018 (83 FR 58201) is

extended. Comments on the ANPRM must now be received by BIS on or before January 10, 2019.

ADDRESSES: You may submit comments through either of the following:

• *Federal eRulemaking Portal:* <http://www.regulations.gov>. The identification number for this rulemaking is BIS 2018–0024.

• *Address:* By mail or delivery to Regulatory Policy Division, Bureau of Industry and Security, U.S. Department of Commerce, Room 2099B, 14th Street and Pennsylvania Avenue NW, Washington, DC 20230. Refer to RIN 0694–AH61.

FOR FURTHER INFORMATION CONTACT:

Kirsten Mortimer, Office of National Security and Technology Transfer Controls, Bureau of Industry and Security, Department of Commerce, Phone: (202) 482–0092; Fax (202) 482–3355; Email: Kirsten.Mortimer@bis.doc.gov.

SUPPLEMENTARY INFORMATION:

Background

On November 19, 2018 (83 FR 58201), the Bureau of Industry and Security (BIS) published an advanced notice of proposed rulemaking, “Review of Controls for Certain Emerging Technologies,” which included a comment period deadline of December 19, 2018. Since publication, BIS has received requests for additional time to submit comments. In response to those requests, BIS is extending the public comment period until January 10, 2019. A description of the specific topics and issues that BIS would like addressed is outlined in the November 19, 2018 **Federal Register** ANPRM.

Dated: December 10, 2018.

Matthew S. Borman,

Deputy Assistant Secretary for Export Administration.

[FR Doc. 2018–27148 Filed 12–13–18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 314 and 601

[Docket No. FDA–2013–N–0500]

Withdrawal of Proposed Rule on Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; withdrawal.