

were previously approved by OMB and assigned OMB No. 0581-0178, Vegetable and Specialty Crops. Termination of the reporting requirements under the Order would reduce the reporting and recordkeeping burden on Irish potato handlers in Southeastern states and should further reduce industry expenses.

Because handlers would no longer be required to file forms with the Committee, this proposed rule would not impose any additional reporting or recordkeeping requirements on either small or large entities.

In addition, USDA has not identified any relevant Federal rules that duplicate, overlap, or conflict with this 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.

Additionally, interested persons are invited to submit information on the regulatory and information collection impacts of this action on small businesses.

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.

This proposal invites comments on the termination of Marketing Order No. 953, which regulates the handling of Irish potatoes grown in Southeastern states. All written comments received within the 60-day comment period will be considered before a final determination is made in this matter.

Based on the foregoing, and pursuant to section 608c(16)(A) of the Act and § 953.66 of the Order, USDA is considering termination of the Order. If USDA decides to terminate the Order, trustees would be appointed to conclude and liquidate the affairs of the Committee and would continue in that capacity until discharged by USDA. In addition, USDA would notify Congress 60 days in advance of termination pursuant to section 608c(16)(A) of the Act.

#### List of Subjects in 7 CFR Part 953

Marketing agreements, Potatoes, Reporting and recordkeeping requirements.

#### PART 953—[REMOVED]

■ For the reasons set forth in the preamble, under the authority of 7 U.S.C. 601-674, AMS proposes that 7 CFR part 953 be removed.

Dated: July 19, 2018.

**Bruce Summers,**

*Administrator, Agricultural Marketing Service.*

[FR Doc. 2018-15890 Filed 7-24-18; 8:45 am]

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#### DEPARTMENT OF AGRICULTURE

#### Agricultural Marketing Service

#### 7 CFR Part 1208

[Document No. AMS-SC-18-0041]

#### Processed Raspberry Promotion, Research and Information Order; Continuance Referendum

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

**ACTION:** Notification of referendum order.

**SUMMARY:** This document directs that a referendum be conducted among eligible producers of raspberries for processing and importers of processed raspberries to determine whether they favor continuance of the Agricultural Marketing Service's (AMS) regulations regarding a national processed raspberry research and promotion program.

**DATES:** The referendum will be conducted from September 10 through October 5, 2018. The Department will provide the option for ballots to be returned electronically. Further details will be provided in the ballot instructions. Mail ballots must be postmarked by October 5. Ballots delivered via express mail or email must show proof of delivery by no later than 11:59 p.m. Eastern Time (ET) on October 5, 2018, to be counted.

**ADDRESSES:** Copies of the processed raspberry program may be obtained from: Referendum Agent, Promotion and Economics Division, Specialty Crops 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 contact Hakim Fobia at (202) 720-4835 or via electronic mail: [Hakim.Fobia@ams.usda.gov](mailto:Hakim.Fobia@ams.usda.gov).

**FOR FURTHER INFORMATION CONTACT:** Hakim Fobia, Marketing Specialist, Promotion and Economics Division, Specialty Crops Program, AMS, USDA, 1400 Independence Avenue SW, Room

1406-S, Stop 0244, Washington, DC 20250-0244; telephone: (202) 720-9915, (202) 720-4835 (direct line); facsimile: (202) 205-2800; or electronic mail: [Hakim.Fobia@ams.usda.gov](mailto:Hakim.Fobia@ams.usda.gov).

**SUPPLEMENTARY INFORMATION:** Pursuant to the Commodity Promotion, Research, and Information Act of 1996 (7 U.S.C. 7411-7425) (1996 Act), it is hereby directed that a referendum be conducted to ascertain whether continuance of the Processed Raspberry Promotion, Research and Information Order (7 CFR part 1208) is favored by eligible producers of raspberries for processing and importers of processed raspberries. The program is authorized under the 1996 Act.

The representative period for establishing voter eligibility for the referendum shall be the period from January 1 through December 31, 2017. Persons who produced 20,000 pounds or more of raspberries for processing in the United States or imported 20,000 pounds or more of processed raspberries into the United States during the representative period and were subject to assessment during that period are eligible to vote. Persons who received an exemption from assessments pursuant to § 1208.53 for the entire representative period are ineligible to vote. The referendum will be conducted from September 10 through October 5, 2018. The Department will provide the option for ballots to be returned electronically. Further details will be provided in the ballot instructions.

Section 518 of the 1996 Act (7 U.S.C. 7417) authorizes continuance referenda. Under § 1208.71(b), the U.S. Department of Agriculture (USDA) must conduct a referendum every seven years to determine whether eligible producers of raspberries for processing and importers of processed raspberries favor continuance of the program. A referendum also may be held by a request of 10 percent or more of all the eligible producers and importers, by request of the National Processed Raspberry Council, which administers the program, or by the Secretary of Agriculture. In March 2018, USDA received a petition requesting a referendum from more than the required 10 percent of eligible entities, thus USDA will hold a referendum. The program will continue if it is favored by a majority of eligible producers and importers voting in the referendum.

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35), the referendum ballot has been approved by the Office of Management and Budget (OMB) and assigned OMB No. 0581-0093. It has

been estimated that approximately 200 entities will be eligible to vote in the referendum. It will take an average of 15 minutes for each voter to read the voting instructions and complete the referendum ballot.

### Referendum Order

Hakim Fobia, Marketing Specialist, and Heather Pichelman, Director, Promotion and Economics Division, Specialty Crops Program, AMS, USDA, Stop 0244, Room 1406-S, 1400 Independence Avenue SW, Washington, DC 20250-0244, are designated as referendum agents for this referendum. The referendum procedures at 7 CFR 1208.100 through 1208.108, issued pursuant to the 1996 Act, will be used to conduct the referendum.

The referendum agents will mail the ballots to be cast in the referendum and voting instructions to all known, eligible producers and importers prior to the first day of the voting period. Persons who produced 20,000 pounds or more of raspberries for processing in the United States or imported 20,000 pounds or more of processed raspberries into the United States during the representative period and were subject to assessment during that period are eligible to vote. Persons who received an exemption from assessments pursuant to § 1208.53 during the entire representative period are ineligible to vote. Any eligible producer of raspberries for processing or importer of processed raspberries who does not receive a ballot should contact a referendum agent no later than one week before the end of the voting period. Mail ballots must be postmarked by October 5. Ballots delivered via express mail or email must show proof of delivery by no later than 11:59 p.m. ET on October 5, 2018, to be counted.

### List of Subjects in 7 CFR Part 1208

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

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

Dated: July 20, 2018.

**Bruce Summers,**  
Administrator.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 15

[Docket No. FDA-2018-N-2689]

#### Facilitating Competition and Innovation in the Biological Products Marketplace; Public Hearing; Request for Comments

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

**ACTION:** Notification of public hearing; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA or the Agency) is announcing a public hearing on FDA's approach to enhancing competition and innovation in the biological products marketplace, including by facilitating greater availability of biosimilar and interchangeable products.

**DATES:** The public hearing will be held on Tuesday, September 4, 2018, from 9 a.m. to 5 p.m. The public hearing may be extended or may end early, depending on the level of public participation. Persons seeking to attend or to present at the public hearing must register by Tuesday, August 14, 2018. Section III provides attendance and registration information. Electronic or written comments will be accepted after the public hearing until Friday, September 21, 2018.

**ADDRESSES:** The public hearing will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503A), Silver Spring, MD 20993-0002. Entrance for public hearing participants (non-FDA employees) is through Building 1, where routine security check procedures will be performed. For parking and security information, please refer to <https://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm>.

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 Friday, September 21, 2018. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of Friday, September 21, 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 the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

### Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand delivery/Courier (for written/paper submissions):** Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked, and identified as confidential, if submitted as detailed in "Instructions."

**Instructions:** All submissions received must include the Docket No. FDA-2018-N-2689 for "Facilitating Competition and Innovation in the Biological Products Marketplace; Public Hearing; Request for Comments." Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two