

# 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 955

[Docket No. FV-95-955-1]

#### Vidalia Onions Grown in Georgia; Order Directing That a Referendum be Conducted

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

**ACTION:** Referendum order.

**SUMMARY:** This document directs that a referendum be conducted among eligible producers of Vidalia onions to determine whether they favor continuance of the marketing order regulating the handling of Vidalia onions grown in the production area.

**DATES:** The referendum will be conducted from March 1 through March 31, 1995. To vote in this referendum, growers must have been producing Vidalia onions during the period January 1 through August 15, 1994.

**ADDRESSES:** Copies of the marketing order may be obtained from the office of the referendum agent at P.O. Box 2276, Winter Haven, Florida, 33883-2276, or the Office of the Docket Clerk, Marketing Order Administration Branch, Fruit and Vegetable Division, AMS, USDA, P.O. Box 96456, Room 2525-S, Washington, DC 20090-6456.

**FOR FURTHER INFORMATION CONTACT:** William J. Pimental, Southeast Marketing Field Office, Marketing Order Administration Branch, Fruit and Vegetable Division, Agricultural Marketing Service, U.S. Department of Agriculture, P.O. Box 2276, Winter Haven, Florida, 33881-2276; telephone: (813) 299-4770, or Shoshana Avrishon, Marketing Order Administration Branch, Fruit and Vegetable Division, Agricultural Marketing Service, U.S. Department of Agriculture, Room 2536-S, P.O. Box 96456, Washington, DC 20090-6456; telephone: (202) 720-3610.

**SUPPLEMENTARY INFORMATION:** Pursuant to Marketing Order No. 955 [7 CFR Part

955], hereinafter referred to as the "order," and the applicable provisions of the Agricultural Marketing Agreement Act of 1937, as amended [7 U.S.C. 601-674], hereinafter referred to as the "Act," it is hereby directed that a referendum be conducted to ascertain whether continuance of the order is favored by the producers. The referendum shall be conducted during the period March 1 through March 31, 1995, among Vidalia onion producers in the production area. Only producers that were engaged in the production of Vidalia onions during the period of January 1 through August 15, 1994, may participate in the continuance referendum.

The Secretary of Agriculture has determined that continuance referenda are an effective means for ascertaining whether producers favor continuation of marketing order programs. The Secretary would consider termination of the order if less than two-thirds of the producers voting in the referendum and producers of less than two-thirds of the volume of Vidalia onions represented in the referendum favor continuance. In evaluating the merits of continuance versus termination, the Secretary will not only consider the results of the continuance referendum. The Secretary will also consider other relevant information concerning the operation of the order; the order's relative benefits and disadvantages to producers, handlers, and consumers; and whether continued operation of the order would tend to effectuate the declared policy of the Act.

In any event, section 8c(16)(B) of the Act requires the Secretary to terminate an order whenever the Secretary finds that a majority of all producers affected by the order favor termination, and such majority produced for market more than 50 percent of the commodity covered under such order.

In accordance with the Paperwork Reduction Act of 1980 (44 U.S.C. chapter 35), the ballot materials used in the referendum herein ordered have been submitted to and approved by the Office of Management and Budget (OMB) and have been assigned OMB No. 0581-0160 for Vidalia onions. It has been estimated that it will take an average of 10 minutes for each of the approximately 250 producers of Vidalia onions to cast a ballot. Participation is voluntary. Ballots postmarked after

March 31, 1995, will not be included in the vote tabulation.

William J. Pimental and Christian D. Nissen of the Southeast Marketing Field Office, Fruit and Vegetable Division, Agricultural Marketing Service, USDA, are hereby designated as the referendum agents of the Secretary of Agriculture to conduct such referendum. The procedure applicable to the referendum shall be the "Procedure for the Conduct of Referenda in Connection With Marketing Orders for Fruits, Vegetables, and Nuts Pursuant to the Agricultural Marketing Agreement Act of 1937, as Amended" (7 CFR part 900.400 *et seq.*).

Ballots will be mailed to all producers of record and may also be obtained from the referendum agents.

#### List of Subjects in 7 CFR Part 955

Marketing agreements, Onions, Reporting and recordkeeping requirements.

Authority: 7 U.S.C. 601-674.

Dated: February 21, 1995.

Patricia Jensen,

*Acting Assistant Secretary, Marketing and Regulatory Programs.*

[FR Doc. 95-4740 Filed 2-24-95; 8:45 am]

BILLING CODE 3410-02-P

## DEPARTMENT OF AGRICULTURE

### Food Safety and Inspection Service

#### 9 CFR Parts 308, 310, 318, 320, 325, 326, 327, and 381

[Docket No. 95-005N]

#### Information Briefings: Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems

**AGENCY:** Food Safety and Inspection Service, USDA.

**ACTION:** Announcement of outreach activities.

**SUMMARY:** The Food Safety and Inspection Service (FSIS) is announcing a series of public outreach activities to provide information on the proposed rule titled "Pathogen Reduction; Hazard Analysis and Critical Control Points (HACCP) Systems" that was published on February 3, 1995. These activities consist of six briefings on the proposal; three scientific/technical conferences; and one two-day public hearing. These

activities are intended to assist the public in understanding the proposed rule and in providing comments on the proposed rule.

**DATES:** See Supplementary Information for dates of hearings.

**ADDRESSES:** See Supplementary Information for locations of hearings.

**FOR FURTHER INFORMATION CONTACT:** Dan Vitiello, Director, Planning and Analysis, Planning Office, Policy, Evaluation and Planning Staff, FSIS,

USDA, Room 6904 Franklin Court, Washington, DC 20250, (202) 501-7138.

**SUPPLEMENTARY INFORMATION:** On February 3, 1995, FSIS published a proposed rule titled "Pathogen Reduction; Hazard Analysis and Critical Control Points (HACCP) Systems" (60 FR 6774). The proposal provides a number of requirements applicable to Federal and State-inspected meat and poultry establishments. The proposed requirements are designed to reduce the occurrence and numbers of pathogenic

organisms in meat and poultry products, thereby reducing the incidence of foodborne illness associated with the consumption of these products.

**Information Briefings**

To assist the public in understanding the proposal, FSIS is holding six briefings as follows. Each briefing will run from 1:00 p.m. to 5:00 p.m. Any person who wishes to attend any of the information briefings should contact the FSIS Planning Office at (202) 501-7138.

Date	City/state	Location	Contact
Mar. 7	San Francisco, Oakland, CA	Henry J. Kaiser Convention Center, 10 Tenth Street, Oakland, CA 94607.	Linda Russell, (202) 501-7138.
Mar. 14	Dallas, TX	Dallas Grand Hotel, 1914 Commerce St., Dallas, TX 75201, (214) 747-7000; 1-800-421-0011.	Dan Vitiello (202) 501-7138.
Mar. 16	Chicago, IL	Holiday Inn O'Hare Airport, 5440 North River Rd., Rosemont, IL 60018, (708) 671-6350.	Ken Elane, (202) 501-7138.
Mar. 21	Atlanta, GA	Richard Russell Federal Building, 75 Spring St., SW., Atlanta, GA 30303.	Ron Niemeyer, (202) 501-7138.
Mar. 23	New York, NY	Federal Building, 26 Federal Plaza, Room 305, New York, NY 10278.	Ken Elane, (202) 501-7138.
Mar. 30	Washington, DC	Hyatt Regency Crystal City, 2799 Jefferson Davis Highway, Arlington, VA 22202, (703) 418-1234.	Linda Russell (202) 501-7138.

The format for each briefing will be the same:

1. A panel of subject matter specialists will explain various aspects of the proposal.
2. Attendees will submit any questions they have, in writing.
3. Panelists will answer the questions.

**Scientific/Technical Conferences**

FSIS also plans to hold three conferences, each addressing a specific scientific/technical issue. Information on each specific conference will be published separately at a later date.

The three conferences are scheduled to be held as follows:

Issue: "New Technology to Improve Food Safety"

April 12-13, Chicago, IL, Holiday Inn O'Hare Airport, 5440 North River Road, Rosemont, IL 60018, (708) 671-6350

Issue: "The Role of Microbiological Testing in Verifying Food Safety"

May 1-2, Philadelphia, PA, Holiday Inn-Independence Mall, Fourth and Arch Streets, Philadelphia, PA 19106, (215) 923-8860

Issue: "An Evaluation of the Role of Microbiological Criteria in Establishing Food Safety Performance Standards in Meat and Poultry Products"

May 18-19, Washington, DC, Georgetown University, Conference Center, 3800 Reservoir Road, Washington, DC 20007, (202) 687-3200

**Public Hearing**

Lastly, FSIS is planning to hold a two-day public hearing for those

commenters who wish to submit oral comments in response to the proposed rule. (Oral comments may also be provided to FSIS by contacting the persons listed in the proposed rule). The public hearing will be held:

May 30-31, Washington, DC, Georgetown University Conference Center, 3800 Reservoir Road, NW., Washington, DC 20007, (202) 687-3200

Done at Washington, DC, on: February 17, 1995.

Michael R. Taylor,

*Acting Under Secretary for Food Safety.*

[FR Doc. 95-4498 Filed 2-24-95; 8:45 am]

**BILLING CODE 3410-DM-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Part 211**

[Docket No. 94N-0421]

**RIN 0905-AE63**

**Current Good Manufacturing Practice for Finished Pharmaceuticals; Positron Emission Tomography**

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

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is proposing to amend its regulations to permit

manufacturers of positron emission tomography (PET) radiopharmaceuticals to apply to the agency for approval of an exception or alternative to the requirements of the current good manufacturing practice (CGMP) regulations. This action is intended to relieve PET manufacturers, nearly all of whom are small entities, from regulations that might result in unsafe handling of PET radiopharmaceuticals, that are inapplicable or inappropriate, or that otherwise do not enhance safety or quality in the manufacture of PET radiopharmaceuticals.

**DATES:** Written comments by March 29, 1995. FDA proposes that any final rule that may issue based on this proposal become effective on its date of publication in the Federal Register.

**ADDRESSES:** Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** John W. Levchuk, Center for Drug Evaluation and Research (HFD-322), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-0095.

**SUPPLEMENTARY INFORMATION:**

**I. Introduction**

PET is a diagnostic imaging modality consisting of onsite production of radionuclides that are intravenously injected into patients for diagnostic purposes. The potential usefulness of a PET radiopharmaceutical is based upon