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 945

[Docket No. FV04–945–1]

Irish Potatoes Grown in Certain Designated Counties in Idaho, and Malheur County, OR; Continuance Referendum

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Referendum order.

SUMMARY: This document directs that a referendum be conducted among eligible growers of Irish potatoes in certain designated counties in Idaho, and Malheur County, Oregon, to determine whether they favor continuance of the marketing order regulating the handling of Irish potatoes grown in the production area.

DATES: The referendum will be conducted from January 14 through January 31, 2005. To vote in this referendum, growers must have produced Irish potatoes for the fresh market within the designated production area in Idaho or Malheur County, Oregon, during the period August 1, 2003, through July 31, 2004.

ADDRESSES: Copies of the marketing order may be obtained from the office of the referendum agents at 1220 SW. Third Avenue, Suite 385, Portland, Oregon 97204–2807, or the Office of the Docket Clerk, Marketing Order Administration Branch, Fruit and Vegetable Programs, Agricultural Marketing Service, U.S. Department of Agriculture, 1400 Independence Avenue, SW., Stop 0237, Washington, DC 20250–0237.

FOR FURTHER INFORMATION CONTACT: Barry Broadbent, Marketing Specialist, Northwest Marketing Field Office, Marketing Order Administration Branch, Fruit and Vegetable Programs, AMS, USDA, 1220 SW. Third Avenue, Suite 385, Portland, Oregon 97204–2807; telephone (503) 326–2724; fax (503) 326–7440; or Kathy Finn, Acting Rulemaking Team Leader, Marketing Order Administration Branch, Fruit and Vegetable Programs, Agricultural Marketing Service, U.S. Department of Agriculture, 1400 Independence Avenue, SW., Stop 0237, Washington, DC 20250–0237; telephone (202) 720–2491; fax (202) 720–8938.

SUPPLEMENTARY INFORMATION: Pursuant to Marketing Order No. 945 (7 CFR part 945), 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 growers. The referendum shall be conducted during the period January 14 through January 31, 2005, among Irish potato growers in the production area. Only growers that were engaged in the production of Irish potatoes for the fresh market in Idaho and Malheur County, Oregon, during the period of August 1, 2003, through July 31, 2004, may participate in the continuance referendum.

USDA has determined that continuance referenda are an effective means for determining whether growers favor continuation of marketing order programs. The Department would consider termination of the order if less than two-thirds of the growers voting in the referendum and growers of less than two-thirds of the volume of Irish potatoes represented in the referendum favor continuance. In evaluating the merits of continuance versus termination, the USDA will not only consider the results of the continuance referendum. The USDA will also consider all other relevant information concerning the operation of the order and the relative benefits and disadvantages to growers, handlers, and consumers in order to determine whether continued operation of the order would tend to effectuate the declared policy of the Act.

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the ballot materials to be 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. 0581–0178. It has been estimated that it will take an average of 20 minutes for each of the approximately 1,135 growers of Irish potatoes in Idaho and Malheur County, Oregon, to cast a ballot. Participation is voluntary. Ballots postmarked after January 31, 2005, will not be included in the vote tabulation.

Gary D. Olson and Barry Broadbent of the Northwest Marketing Field Office, Fruit and Vegetable Programs, Agricultural Marketing Service, USDA, are hereby designated as the referendum agents of the Department 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 growers of record and may also be obtained from the referendum agents, or from their appointees.

List of Subjects in 7 CFR Part 945

Irish potatoes, Marketing agreements, Reporting and recordkeeping requirements.

Authority: 7 U.S.C. 601–674.

Dated: December 17, 2004.

A.J. Yates,

Administrator, Agricultural Marketing Service.

[FR Doc. 04–28055 Filed 12–22–04; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Part 417

[Docket No. 04–017N]

HACCP Reassessment for Slaughterers of Young Calves

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Notice of proposed rule; request for comments.

SUMMARY: The Food Safety and Inspection Service (FSIS) is publishing this document to inform slaughterers of young calves, including those marketed, slaughtered, and labeled as ''veal,'' of the need for such firms to reassess their Hazard Analysis and Critical Control Point (HACCP) System, including prerequisite programs, with respect to

animal drug residues and the use of unapproved new animal drugs. FSIS is concerned about the widespread, illegal use of drug implants in young calves that was discovered in 2004. The discovery of this illegal use represents a change that would affect the hazard analysis and could alter the HACCP plans, of establishments that slaughter young calves. Therefore, under the HACCP regulations, any establishment that slaughters young calves, including those marketed, slaughtered, and labeled as veal, must, as part of its calendar year 2005 annual reassessment of its HACCP plans, determine whether unapproved new animal drugs are hazards reasonably likely to occur in its process if it has not previously done so. If the reassessment results in a determination that animal drug residues, including unapproved new animal drugs, are food safety hazards reasonably likely to occur, these hazards must be addressed in the establishment's HACCP plan.

FSIS invites comments on the matters presented in this document. The comments will be used by FSIS to inform further policy development on animal drug residues.

DATES: The Agency must receive comments by February 22, 2005.

ADDRESSES: FSIS invites interested persons to submit comments on this notice. Comments may be submitted by any of the following methods:

- Mail, including floppy disks or CD–ROM's, and hand- or courier-delivered items: Send to Docket Clerk, U.S. Department of Agriculture, Food Safety and Inspection Service, 300 12th Street, SW., Room 102, Cotton Annex, Washington, DC, 20250.

All submissions received must include the Agency name and docket number 04–017N.

All comments submitted in response to this notice, as well as research and background information used by FSIS in developing this document, will be available for public inspection in the FSIS Docket Room at the address listed above between 8:30 a.m. and 4:30 p.m., Monday through Friday. The comments also will be posted on the Agency's Web site at *http://www.fsis.usda.gov/OPPDE/rdad/FRDockets.htm.*

FOR FURTHER INFORMATION CONTACT: Carole Thomas, Technical Analysis Staff, Office of Policy, Program, and Employee Development, FSIS, U.S. Department of Agriculture, 1400 Independence Avenue, SW., Room 405, Cotton Annex, Washington, DC, 20250–3700, (202) 205–0210.

SUPPLEMENTARY INFORMATION:

Background

FSIS administers a regulatory program under the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 *et seq.*) to protect the health and welfare of consumers by preventing the processing and distribution of meat products that are unwholesome, adulterated, or misbranded or otherwise unfit for human food. In pursuit of its goal of reducing the risk of foodborne illness from meat products to the maximum extent possible, FSIS issued final regulations on July 25, 1996, mandating the development and implementation of Pathogen Reduction and Hazard Analysis and Critical Control Point (HACCP) Systems by Federally inspected establishments (61 FR 38806). These regulations require that federally inspected establishments take preventive and corrective measures at each stage of the food production process where food safety hazards occur.

During routine ante-mortem and post-mortem inspections in late March 2004, FSIS inspection program personnel discovered drug implants in animals that were presented for slaughter as veal. For the purpose of this notice, FSIS considers young calves to be bovine food animals, weighing 400 pounds or less (carcass weight, hide-on) with characteristics of immature cattle, and ''veal'' to be young calves with a non-functioning rumen. (FSIS is aware that the Agricultural Marketing Service, USDA, has specific characterizations of what type of animal can be marketed as veal and calf. While FSIS intends to engage in rulemaking to establish a regulatory definition for veal, FSIS believes that it is in the best interest of public health to issue this reassessment notice now.)

Subsequently, FSIS learned that the use of growth promoting implants was a widespread practice within the veal industry. However, the Food and Drug Administration (FDA) has not approved growth promoting implants for use in food animals presented for slaughter as veal and considers their use to be a violation of the Federal Food, Drug, and Cosmetic Act (FFDCA).

On April 2, 2004, FDA made publicly available on its Web site, *http://www.fda.gov/cvm/guidance/guide172.doc,* ''Guidance for Industry—Use of Unapproved Hormone Implants in Veal Calves.'' This document provided guidance on the appropriate disposition of veal calves that had been implanted with unapproved new animal drugs and made clear that such use is illegal.[1] On April 5, 2004, FSIS, in the interest of public health, issued FSIS Notice 23–04, ''FSIS Verification of Veal Calves with Implants.'' This notice informed FSIS inspection program personnel of FDA's determination that the use of growth promoting implants in non-ruminating veal calves is a violation of the FFDCA and advised that veal calves could be passed for food only if they met the criteria specified in the notice.

The criteria set forth in FSIS Notice 23–04 expired on June 6, 2004. Therefore, on June 3, 2004, FSIS issued FSIS Notice 31–04, ''Verification of Implant Usage in Non-Ruminating Calves.'' This notice provides instructions for inspection program personnel to use when they suspect the use of growth promoting implants in non-ruminating veal calves. On July 16, 2004, FDA and FSIS jointly issued a letter to the American Veal Industry, as well as to other trade associations, reiterating that the practice of implanting food animals that are to be marketed as ''veal'' with growth promoting implants is illegal, and that those animals and their parts are subject to not being granted the mark of inspection.[2]

Under the FMIA, the term ''adulterated'' (21 U.S.C. 601(m)) applies to any carcass, part thereof, meat or meat food product if it bears or contains (by reason of administration of any substance to the live animal or otherwise) any added poisonous or added deleterious substance which may make such product unfit for food (*see* 601(m)(2)(A)). An unapproved new animal drug may be considered a deleterious substance. If administered to a live animal, the presence of that substance could render the product in which it is found, that is, the edible tissues of the animal, unfit for human food and thus adulterated.

Under the authority of the FFDCA, FDA determines whether or not new animal drugs proposed for use in food animals by the drug sponsor are safe for use. This determination includes consideration of whether there will be unsafe residues of the drug in the tissues that are used for human food. To ensure that there are not unsafe residues, FDA establishes and codifies tolerance levels for residues of such drugs. If FDA has not received a new

[1] U.S. Department of Health and Human Services, Food and Drug Administration, Center for Veterinary Medicine. April 2, 2004. Guidance for Industry—Use of Unapproved Hormone Implants in Veal Calves.

[2] U.S. Department of Agriculture, Food Safety and Inspection Service; Food and Drug Administration, Center for Veterinary Medicine. July 16, 2004.

drug application from the drug sponsor, and has not established and codified a tolerance level for the drug, the use of such drugs is illegal.

FDA has not evaluated the safety of growth promoting implants in non-ruminating young calves. Therefore, FSIS cannot determine when the edible tissues from animals to whom such substances have been administered are not unfit for human food. If FSIS cannot make this determination, it cannot determine when the edible product from those animals that have been administered the unapproved new animal drug are not adulterated, and thus it cannot apply the mark of inspection to such products.

HACCP Systems

9 CFR 417.2(a) requires establishments to conduct a hazard analysis to determine what food safety hazards are reasonably likely to occur in their process and to identify the preventive measures that the establishment can apply to control those hazards. The hazards may occur before, during, or after entry into the establishment. FSIS has identified drug residues as possible food safety hazards (9 CFR 417.2(a)(3)).

Section 417.2(a)(1) states that a food safety hazard that is reasonably likely to occur is one for which a prudent establishment would establish control measures because it historically has occurred, or because there is a reasonable possibility that it will occur in the particular type of product being processed, in the absence of those controls. Whenever a hazard analysis reveals that one or more hazards are reasonably likely to occur in the production process, the regulations require that the establishment develop and implement a written HACCP plan that includes specific control measures for each hazard so identified (417.2(b)(1) and (c)).

Requirement and Basis for Reassessment

Section 417.4(a)(3) states that every establishment shall reassess the adequacy of its HACCP plan at least annually and whenever any changes occur that could affect the hazard analysis or alter the HACCP plan. The finding that new animal drugs have been knowingly administered, on a widespread basis, to a production class of animals in which their use is not approved, represents information that could alter the hazard analysis, and ultimately the HACCP plan, of any establishment that slaughters animals of that class, in this case young calves, for human food. Therefore, establishments that slaughter young calves, including those young calves marketed, slaughtered, and labeled as ''veal,'' need to consider the hazard presented by the illegal use of animal drugs in the animals they slaughter, and what actions they should take to control it if they determine that it is reasonably likely to occur, as a result of their reassessments.

If reassessment results in a determination by the establishment that a residue of an unapproved new animal drug is a food safety hazard that is reasonably likely to occur, this hazard must be addressed in the establishment's HACCP plan. However, FSIS recognizes that some slaughterers employ measures to ensure that they do not purchase food animals for slaughter with violative animal drug residues. These slaughterers should consider incorporating these measures into their HACCP plans or prerequisite programs.

FSIS Actions To Enforce and Facilitate Compliance With the Reassessment

The Agency intends to instruct inspection program personnel to verify, as part of the Agency's verification of the 2005 hazard analysis reassessment, that establishments that slaughter young calves have considered the hazard of illegal residues. Before performing that verification, inspection program personnel will ensure that all establishments that slaughter young calves are aware that the Agency has issued this notice. They will also ensure that those establishments that have not yet reassessed their HACCP plans, based on the relevant FSIS findings discussed earlier, begin their reassessment. By looking into establishments' reassessment actions before the time that the establishments are required to complete their reassessments, FSIS will ensure that all establishments slaughtering young calves, including establishments that are considered small and very small businesses, and those that may not belong to a trade association, are aware of this notice.

Paperwork Reduction Act

FSIS has reviewed the paperwork and recordkeeping requirements in this notice in accordance with the Paperwork Reduction Act and has determined that the paperwork requirements for the regulations that require establishments that slaughter calves to reassess their HACCP Plans have already been accounted for in the Pathogen Reduction/HACCP Systems information collection approved by the Office of Management Budget (OMB). The OMB approval number for the Pathogen Reduction/HACCP Systems information collection is 0583–0103.

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, in an effort to ensure that the public and in particular minorities, women, and persons with disabilities, are aware of this notice, FSIS will announce it on-line through the FSIS Web page located at *http://www.fsis.usda.gov.*

FSIS also will make copies of this **Federal Register** publication available through the FSIS Constituent Update, which is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, recalls, and other types of information that could affect or would be of interest to our constituents and stakeholders. The update is communicated via Listserv, a free e-mail subscription service consisting of industry, trade, and farm groups, consumer interest groups, allied health professionals, scientific professionals, and other individuals who have requested to be included. The update also is available on the FSIS Web page.

Through Listserv and the Web page, FSIS is able to provide information to a much broader, more diverse audience.

Done at Washington, DC, on December 20, 2004.

Barbara J. Masters,

Acting Administrator.

[FR Doc. 04–28083 Filed 12–22–04; 8:45 am]

BILLING CODE 3410–DM–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[R05–OAR–2004–MI–0002; FRL–7849–2]

Approval and Promulgation of Implementation Plans: Michigan: Oxides of Nitrogen

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The EPA is approving a revision to the plan prepared by Michigan that will limit the emissions of oxides of nitrogen (NO_X) from large stationary sources (*i.e.* power plants, industrial boilers and cement kilns). This plan meets all of the requirements contained in an EPA rule that was published in the **Federal Register** on April 16, 2004. This rule, otherwise known as the NO_X SIP Call Phase I provides for NO_X reductions from