Paperwork Reduction Act

The **Federal Register** information collection notice was published in the proposed rule on September 29, 1998 (63 FR 51864). A revised information collections package was submitted to the Office of Management and Budget and approved under OMB control number 0560–0148.

Discussion of Comments

Five comments, all in favor of the proposed change, were received from tobacco importers and brokers in response to the proposed rule which was published in the **Federal Register** at 63 FR 51864 (September 29, 1998). There were no unfavorable comments. Accordingly, for the reasons given when the proposed rule was published, it has been determined to adopt the proposed rule as a final rule.

List of Subjects in 7 CFR Part 1464

Imports, Loan programs—agriculture, Tobacco.

For the reasons set forth in the preamble, 7 CFR 1464 is amended as follows:

PART 1464—TOBACCO [Amended]

1. The authority citation for 7 CFR 1464 continues to read as follows:

Authority: 7 U.S.C. 1421, 1423, 1441, 1445, 1445–1 and 1445–2; 15 U.S.C. 714b, 714c.

2. Section 1464.101(b) is amended by revising the definition of ''de minimis special entries'' to read as follows:

§ 1464.101 Definitions.

* * * * *

(b) Terms. * * *

De minimis special entries. Imports of unmanufactured tobacco when the total importation at any time or on any date is 100 kilograms or less and such tobacco is imported segregated from other tobacco for use as samples, for research, or other use approved by the Director.

* * * * *

Signed at Washington, DC, on January 11, 1999.

Keith Kelly,

Executive Vice President, Commodity Credit Corporation.

[FR Doc. 99–1134 Filed 1–15–99; 8:45 am]

BILLING CODE 3410–05–P

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Chapter III

[Docket No. 97–068N]

Beef Products Contaminated With *Escherichia Coli* O157:H7

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Policy on beef products contaminated with E. coli O157:H7.

SUMMARY: In 1994, the Food Safety and Inspection Service (FSIS) notified the public that raw ground beef products contaminated with the pathogen *Escherichia coli* O157:H7 are adulterated under the Federal Meat Inspection Act unless the ground beef is further processed to destroy this pathogen. FSIS is publishing this notice to provide the public with information about its policy regarding beef products contaminated with *Escherichia coli* O157:H7 and to afford the public an opportunity to submit comments and recommendations relevant to the Agency's policy, and any regulatory requirements that may be appropriate to prevent the distribution of beef products adulterated with this pathogen.

DATES: Comments must be received by March 22, 1999.

ADDRESSES: Submit one original and two copies of written comments to FSIS Docket Clerk, Docket No. 97–068N, U.S. Department of Agriculture, Food Safety and Inspection Service, Room 102, Cotton Annex, 300 12th Street, SW, Washington, DC 20250–3700. All comments submitted in response to this notice will be available for public inspection in the Docket Clerk's office between 8:30 a.m. and 4:30 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Patricia F. Stolfa, Assistant Deputy Administrator, Regulations and Inspection Methods, Food Safety and Inspection Service, Washington, DC 20250–3700; (202) 205–0699.

SUPPLEMENTARY INFORMATION:

Introduction

The Food Safety and Inspection Service (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 distribution of meat and meat food products that are unwholesome, adulterated, or misbranded. This notice explains the Agency's policy governing beef products that contain the pathogen *Escherichia coli* O157:H7 (*E. coli* O157:H7). Interested parties are encouraged to submit their views, relevant information, and suggestions regarding this policy or any regulatory requirements that the commenters believe may be appropriate to prevent the distribution of products contaminated with *E. coli* O157:H7.

Beef Products of Concern

In 1994, FSIS notified the public that raw ground beef products contaminated with *E. coli* O157:H7 are adulterated within the meaning of the FMIA unless the ground beef is further processed to destroy this pathogen. Exposure to *E. coli* O157:H7 has been linked with serious, life-threatening human illnesses (hemorrhagic colitis and hemolytic uremic syndrome). Raw ground beef products present a significant public health risk because they are frequently consumed after preparation (*e.g.*, cooking hamburger to a rare or medium rare state) that does not destroy *E. coli* O157:H7 organisms that have been introduced below the product's surface by chopping or grinding (*e.g.*, ground beef, veal patties, and beef pattie mix).

The public health risk presented by beef products contaminated with *E. coli* O157:H7 is not limited, however, to raw ground beef products. Given the low infectious dose of *E. coli* O157:H7 associated with foodborne disease outbreaks and the very severe consequences of an *E. coli* O157:H7 infection, the Agency believes that the status under the FMIA of beef products contaminated with *E. coli* O157:H7 must depend on whether there is adequate assurance that subsequent handling of the product will result in food that is not contaminated when consumed.

In evaluating the public health risk presented by *E. coli* O157:H7-contaminated beef products, FSIS has carefully considered the deliberations of the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) and its Meat and Poultry Subcommittee. Last year, the Food and Drug Administration (FDA) requested recommendations, for use in the 1999 edition of its Food Code, on appropriate cooking temperatures for, among other foods, intact beef steaks for the control of vegetative enteric pathogens. In discussing intact product, the Committee stated that:

Due to a low probability of pathogenic bacteria being present in or migrating from the external surface to the interior of beef muscle, cuts of intact muscle (steaks) should be safe if the external surfaces are exposed

to temperatures sufficient to effect a cooked color change. In addition, the cut (exposed) surfaces must receive additional heat to effect a complete sear across the cut surfaces. . . .

The Committee's definition of ''Intact Beef Steak'' limited the applicability of this conclusion to ''[a] cut of whole muscle(s) that has not been injected, mechanically tenderized, or reconstructed.'' [1] For purposes of FDA's current Food Code (1997, Subpart 1–201.10(B)(41)), ''injected'' means:

manipulating a MEAT so that infectious or toxigenic microorganisms may be introduced from its surface to its interior through tenderizing with deep penetration or injecting the MEAT such as with juices which may be referred to as ''injecting,'' ''pinning,'' or ''stitch pumping.'' [2]

FSIS believes that in evaluating beef products contaminated with *E. coli* O157:H7, intact cuts of muscle that are to be distributed for consumption as intact cuts should be distinguished from non-intact products, as well as from intact cuts of muscle that are to be further processed into non-intact product prior to distribution for consumption. Intact beef cuts of muscle include steaks, roasts, and other intact cuts (*e.g.*, briskets, stew beef, and beef ''cubes for stew,'' [3] as well as thin-sliced strips of beef for stir-frying) in which the meat interior remains protected from pathogens migrating below the exterior surface).

Non-intact beef products include beef that has been injected with solutions, mechanically tenderized by needling, cubing,[4] Frenching, or pounding devices, or reconstructed into formed entrees (*e.g.*, beef that has been scored to incorporate a marinade, beef that has a solution of proteolytic enzymes applied to or injected into the cut of meat, or a formed and shaped product such as beef gyros). Pathogens may be introduced below the surface of these products as a result of the processes by which they are made. In addition, non-intact beef products include those beef products in which pathogens may be introduced below the surface by a comminution process such as chopping, grinding, flaking, or mincing (*e.g.*, fresh veal sausage and fabricated beef steak).

Intact cuts of beef that are to be further processed into non-intact cuts prior to distribution for consumption must be treated in the same manner as non-intact cuts of beef, since pathogens may be introduced below the surface of these products when they are further processed into non-intact products. Manufacturing trimmings (*i.e.*, pieces of meat remaining after steaks, roasts, and other intact cuts are removed) are an example of this type of product. Although manufacturing trimmings may be intact, they are generally further processed into non-intact products.

The Agency believes that with the exception of beef products that are intact cuts of muscle that are to be distributed for consumption as intact cuts, an *E. coli* O157:H7-contaminated beef product must not be distributed until it has been processed into a ready-to-eat product—*i.e.*, a food product that may be consumed safely without any further cooking or other preparation. Otherwise, such products (*i.e.*, non-intact products and intact cuts of muscle that are to be further processed into non-intact products prior to distribution for consumption) must be deemed adulterated. Intact steaks and roasts and other intact cuts of muscle with surface contamination are customarily cooked in a manner that ensures that these products are not contaminated with *E. coli* O157:H7 when consumed. Consequently, such intact products that are to be distributed for consumption as intact cuts are not deemed adulterated.

E. coli O157:H7 Sampling and Testing Program

FSIS currently samples and tests various raw ground beef products (including veal products) for *E. coli* O157:H7.[5] The program sampling is done at inspected establishments and retail stores. The Agency has limited the sampling and testing program to beef products because foodborne illness from *E. coli* O157:H7 has not been associated, to date, with other types of livestock or poultry subject to federal inspection.

The sampling and testing program does not cover intermediate products, such as beef derived from advanced meat/bone separation machinery and recovery systems, since these products are generally further processed to formulate products such as hamburger, but they are not themselves distributed to consumers. Additionally, the sampling and testing program does not cover multi-ingredient products that contain beef, as well as other livestock or poultry ingredients (*e.g.*, sausage that contains both fresh beef and pork).

If FSIS confirms the presence of *E. coli* O157:H7 in a raw ground beef product sampled in the sampling and testing program, it takes regulatory action (coordinating with State officials for products found at retail). The action taken by FSIS is based on the facts of the particular case (*e.g.*, the quantity of product that the sample represents; whether the product is associated with an outbreak of foodborne illness), but in all cases it reflects the Agency's determination that, unless further processed in a manner that destroys this pathogen (*e.g.*, into ready-to-eat beef patties), the product involved that is contaminated with *E. coli* O157:H7 is adulterated.

At this time, FSIS is not expanding its sampling and testing program to include all types of non-intact beef products or intact cuts of muscle that are to be further processed into non-intact products prior to distribution. The Agency may reconsider its sampling and testing program, as well as the scope of products deemed adulterated, in response to any comments received on the Agency's position regarding application of the FMIA's adulteration standards.

Other FSIS Activities

FSIS's effort to reduce the risk of foodborne illness associated with beef products has included development of a guidance document to assist processors of ground beef in developing procedures to minimize the risk of *E. coli* O157:H7, and other pathogens, in their products. Draft Agency guidance, along with materials developed by two trade associations, was made available to the public and was the subject of an April 22, 1998, public meeting (63 FR 13618, March 20, 1998).[6] The Agency has reviewed the comments received on the draft materials and is publishing a notice of the availability of the revised guidance in this issue of the **Federal Register**.

FSIS is participating in a risk assessment regarding *E. coli* O157:H7. A public meeting regarding the risk assessment was announced in an earlier

[1] The NACMCF-adopted minutes of the Subcommittee on Meat and Poultry are available for viewing in the FSIS docket room.

[2] A copy of the 1997 FDA Food Code is available for viewing in the FSIS docket room. In addition, an electronic version of the Code is linked on line through the FSIS web page located at http://www.fsis.usda.gov.

[3] The phrase ''cubes for stew'' generally refers to meat hand-cut into uniform squares.

[4] The term ''cubing'' generally refers to the process of flattening and knitting together meat into cutlet size products by means of a machine.

[5] For the Agency's current sampling and testing program instructions, see FSIS Directive 10,010.1, Microbiological Testing Program for *Escherichia coli* O157:H7 in Raw Ground Beef, February 1, 1998. A copy of this document is available for viewing in the FSIS docket room.

[6] Copies of the comments received on the guidance document (Docket #98–004N), along with the transcript of the public meeting and the draft guidance document are available for viewing in the FSIS docket room. In addition, an electronic version of the FSIS and industry guidance documents are available on line through the FSIS web page located at http://www.fsis.usda.gov (see the link for HACCP guidance documents).

Federal Register notice and was held on October 28, 1998 (63 FR 4432, August 18, 1998).[7]

FSIS is now reviewing its regulations to determine what changes the Agency should make to increase consumer protection against meat and poultry products adulterated with *E. coli* O157:H7, or other pathogens. Therefore, FSIS is soliciting input from the public about regulatory requirements that may be appropriate to prevent the distribution of products adulterated with *E. coli* O157:H7. Any changes that the Agency would make in the regulations would have to be consistent with the Agency's view expressed in this notice that beef products, other than surface-contaminated intact cuts that are to be distributed for consumption as intact products, that contain *E. coli* O157:H7 are adulterated unless conditions of transportation and other handling ensure that they will not be distributed until they have been processed into ready-to-eat products.

Because FDA has amended its regulations to permit the use of ionizing radiation for refrigerated or frozen uncooked meat, meat byproducts, and certain meat food products to control foodborne pathogens (62 FR 64107, December 3, 1997), FSIS is preparing a proposed rule on procedural and labeling requirements for irradiated products. Interested persons will have the opportunity, in that rulemaking, to submit comments to the Agency on irradiation treatment of *E. coli* O157:H7-contaminated products as an option for effectively eliminating this one specific pathogen.

Done at Washington, DC, on January 13, 1999.

Thomas J. Billy,

Administrator.

[FR Doc. 99–1123 Filed 1–15–99; 8:45 am]

BILLING CODE 3410–DM–P

[7] Copies of the comments received on the risk assessment process (Docket #98–037N), the transcript of the risk assessment public meeting, and a preliminary scoping document are available for viewing in the FSIS docket room. In addition, an electronic version of the preliminary scoping document is available on line through the FSIS web page located at http://www.fsis.usda.gov (see the link for the Office of Public Health and Science, *E. coli* risk).

DEPARTMENT OF THE TREASURY

Office of Thrift Supervision

12 CFR Parts 563, 563b

[No. 99–1]

RIN 1550–AA72

Capital Distributions

AGENCY: Office of Thrift Supervision, Treasury.

ACTION: Final rule.

SUMMARY: The Office of Thrift Supervision (OTS) is issuing a final rule revising its capital distribution regulation. Today's rule updates, simplifies, and streamlines this regulation to reflect OTS's implementation of the system of prompt corrective action (PCA) established under the Federal Deposit Insurance Corporation Improvement Act of 1991 (FDICIA). The final rule also conforms OTS's capital distribution requirements more closely to those of the other banking agencies.

EFFECTIVE DATE: April 1, 1999.

FOR FURTHER INFORMATION CONTACT: Edward J. O'Connell, III, Project Manager, (202) 906–5694; Evelyne Bonhomme, Counsel (Banking and Finance), (202) 906–7052; Karen Osterloh, Assistant Chief Counsel, (202) 906–6639, Regulations and Legislation Division, Chief Counsel's Office, Office of Thrift Supervision, 1700 G Street NW., Washington, D.C. 20552.

SUPPLEMENTARY INFORMATION:

I. Background

On January 7, 1998, the OTS published a proposed rule adding a new subpart E to part 563 to govern capital distributions by savings associations.[1] The proposal was intended to update, simplify, and streamline the existing capital distribution rule to reflect OTS's implementation of the system of prompt corrective action (PCA) established under the Federal Deposit Insurance Corporation Improvement Act of 1991 (FDICIA). Consistent with section 303 of the Community Development and Regulatory Improvement Act of 1994 (CDRIA), the proposed rule was also designed to conform the OTS capital distribution regulation to the rules of the other banking agencies, to the extent possible.

[1] 63 FR 1044 (Jan. 7, 1998).

II. Summary of Comments and Description of Final Rule

A. General Discussion of the Comments

The public comment period on the proposed rule closed on March 9, 1998. Four commenters responded: one federal savings bank, one savings and loan holding company, one law firm representing a federal savings bank, and one trade association. Two commenters supported the proposed rule with certain modifications and clarifications. One commenter, the savings and loan holding company, opposed the proposed changes. Another commenter addressed coverage of capital distributions by operating subsidiaries. The issues raised by the commenters are addressed in the section-by-section analysis below.

B. Section-by-Section Analysis

Proposed § 563.140—What Does this Subpart Cover?

Section 563.140 of the proposed rule described the scope of the regulation. Proposed subpart E would apply to all capital distributions by savings associations. The OTS specifically requested comment on whether the capital distribution rule should also apply to capital distributions by operating subsidiaries of savings associations. This issue is addressed below under § 563.141.

Proposed § 563.141—What is a Capital Distribution?

Proposed § 563.141 defined the term ''capital distribution'' as a distribution of cash or other property to a savings association's owners, made on account of their ownership. The proposed definition, at § 563.141(a), excluded dividends consisting only of a savings association's shares or rights to purchase shares, and excluded payments that a mutual savings association is required to make under the terms of a deposit instrument.

Capital distributions would also include a savings association's payment to repurchase, redeem, retire, or otherwise acquire any of its shares or other ownership interests, any payment to repurchase, redeem, or otherwise acquire debt instruments included in total capital, and any extension of credit to finance an affiliate's acquisition of those shares or interests. Proposed § 563.141(b). Additionally, a capital distribution would include any direct or indirect payment of cash or other property to owners or affiliates made in connection with a corporate