43



97-068N
97-068N-43
The Humane Society Of
The United States



# 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.

THE HUMANE SOCIETY OF THE UNITED STATES
2100 L Street, NW
Washington, DC 20037

March 22, 1999

The Humane Society of the United States, on behalf of our more than seven million members and constituents, appreciates this opportunity to offer comments on the January 19, 1999 Federal Register notice, "Beef Products Contaminated With Escherichia Coli O157:H7." This is an issue of great concern to us, as are all issues concerning farmed animals and human health.

Human Morbidity and Mortality

E. coli O157:H7 is a very serious problem, which appears to be on the increase. Based on the findings of the Foodborne Diseases Active Surveillance Network, human E. coli O157:H7 infections increased 22 percent from 1997 to 1998. The Centers for Disease Control and Prevention (CDC) has recently doubled its calculation of the number of people sickened every year by this potentially deadly pathogen, now warning that up to 40,000 may be. In addition, it is believed that a milder strain of E. coli O157:H7 may exist which makes people sick but not to the extent that they seek professional medical attention.

Approximately 25 percent of E. coli O157:H7 patients are hospitalized, and hemolytic uremic syndrome (HUS), strikes between 2 and 8 percent of those infected. HUS results in the destruction of red blood cells, blood-clotting cells, and the lining of blood vessel walls. About 80 percent of all HUS cases in the U.S. are attributed to E. coli infections. Kidney failure may also result, with 75 percent of HSUS patients requiring at least one blood transfusion and half requiring kidney dialysis. Even with intensive care, 3 to 5 percent of HUS patients die. Clotting caused by E. coli O157:H7 can damage the heart, the lungs and even the central nerve system. Thrombotic thrombocytopenic purpura, a failure of the blood vessels which feed nerve cells, is another possible complication which can result in encephalitis-like disease, with psychosis, comas or seizures. Death can and does also occur, though a definitive figure is difficult to calculate since the bacteria may leave a person's body prior to a diagnosis being made.

E. coli O157:H7 has developed resistance to tetracycline, streptomycin, and sulpha drugs. Treatment with antibiotics can actually worsen a patients condition. Research has, in fact, suggested that the use of antibiotics, specifically ionophores, may have allowed or enhanced the ability of E. coli O157:H7 to become established in the intestinal microflora of cattle.

Testing, Sampling and Adulteration

With such alarming morbidity and mortality rates, and the extreme pain and suffering which accompanies the disease, we cannot understand why any product known to be contaminated with such a dangerous pathogen would be allowed to be distributed. The notice states, "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." This does not take into account the very real possibility of cross-contamination, and the tendency to undercook these products. This statement is especially troubling coupled with the understanding that the infectious dose of E. coli O157:H7 is as few as ten, possibly one, organism. *Any* product contaminated with E. coli O157:H7 should be considered adulterated.

The notice also states that intermediate products, such as beef derived from advanced meat/bone separation machinery and recovery systems will be excluded from the sampling and testing program "since these products are generally further processed to formulate products such as hamburger, but they are not themselves distributed to consumers." By stating that these products are "generally further processed," does this mean that not all product is further processed, and if not what becomes of that product which is not further processed? Will the formulated products which the intermediate products are further processed into be included in the sampling and testing program? Since they will ultimately be distributed to consumers, they certainly should be. And will the beef contained in multi-ingredient products be tested prior to its inclusion in these products? We cannot imagine any justifiable rationale why it would not be since the form of beef used for these products and amount of processing it is likely to undergo make the probability of it being contaminated higher than for product that is to be sampled and tested. Since there is a significant possibility that any beef could be contaminated with E. coli O157:H7, all beef should be included in the sampling and testing program.

The Need for Prevention

Two large studies have indicated that two percent of cattle used for beef and three percent of cattle used for dairy production carry E. coli O157:H7 which they shed in their feces. Studies using greater accuracy have shown the prevalence rates of the organism to often be as high as three percent in cattle. Levels of E. coli O157:H7 of 1% in the feedlot generally translate into a 2% level in holding pens and close to 3% post-mortem. In other words, E. coli O157:H7 levels in the feedlot triple by post-mortem.

During the slaughter process, approximately one animal out of every 500 is contaminated with E. coli O157:H7 due to the smearing of manure or splashing of intestinal contents during evisceration. Slowing plant line speeds down would help prevent intestines from being inadvertently cut open and contaminated material from being spread. Keith Nunes, Associate Publisher/Editor of Meat & Poultry Magazine, states: "People will scoff at this notion [slowing down line speeds], alleging a slowdown costs money, but when you compare how much the industry is spending for O157:H7 sampling, generic E. coli tests and intervention technologies, I think it would [be] a wash." One contaminated cow can infect 16 tons of meat, the equivalence of 128,000 quarter-pound hamburgers. In one day, a single Excel plant's production of over 2.5 million pounds of beef may be distributed to 32 states and 4 countries, to 87 distributors, 40 processors, 3 freezers and 9 international customers.

E. coli O157:H7 is a dauntingly resilient organism. It is remarkably acid tolerant, and can survive the processing of fermented meat products. It can survive freezing and can multiply at temperatures as low as 44 degrees F. It can develop heat resistance if exposed to sublethal doses of heat, and will not be killed in foods that are heated slowly to the final cooking temperatures normally used.

Irradiation is being touted as the best means of controlling pathogenic bacteria. Aside from the logistical feat required to irradiate the 13 billion pounds of hamburger Americans eat each year -let alone all the other beef- this highly objectionable technology will do nothing to resolve

the problems with pathogens in the roughly 1.5 billion tons of animal manure produced each year. Manure used as fertilizer is the cause of pathogenic contamination of fruits, vegetables and other crops. E. coli O157:H7 has been shown to be able to survive in manure for nearly 2 years.

Intervention measures to stop E. coli O157:H7 after the production stage are essentially a losing battle. HACCP is in no way a comprehensive means of addressing the problem, and sampling and testing is just that, a mere sampling of a tiny fraction of total product. Pathogen prevention must occur prior to the slaughterplant, with live animal management practices. This is where efforts must be focused if there is a genuine intent to prevent death and disease from E. coli O157:H7 infection.

Production Level Safeguard Measures

Management changes in the cattle industry are believed to have created a niche for E. coli O157:H7, which should be controllable at the production level. Studies by the APHIS Veterinary Services National Animal Health Monitoring System have shown that for both "beef" and "dairy" cattle, E. coli O157:H7 may be amenable to reduction through management factors. At the December 1998 Beef Safety Symposium sponsored by the National Cattlemen's Beef Association and the American Meat Science Association, research on beef production and management practices as they relate to E. coli O157:H7 incidence in cattle was agreed to be the most important issue.

Numerous production level measures to safeguard against E. coli O157:H7 have been suggested. Researchers at the American Meat Science Association conference held February 1999 agreed that on-farm sanitary practices may be the best line of defense against E. coli O157:H7. They identified open and dirty water troughs as a problem, with clean, uncontaminated water being one way to limit contamination. Recommendations included "very simple, not-too-costly measures" such as covering water tanks and cattle feed to prevent contamination, hanging fly strips, and preventing birds from entering barns.

Dale Hancock, an epidemiologist at Washington State University, has conducted research into the on-farm ecology of E. coli O157:H7 since 1990. In a study of cattle water troughs, 40 percent of the troughs he examined had not been cleaned out in a year. He inoculated troughs with the bacteria, which thrived and multiplied for four months in the trough sediment. (According to Dr. Hancock, most dairies clean water troughs in intervals exceeding six months, during which time sediment can reach an accumulation of several centimeters.)

Dr. Hancock also examined feed, and found that E. coli O157:H7 can increase 1,000 to 10,000-fold in moist feeds. He found that half of commercial feeds contain detectable E. coli, indicating widespread fecal contamination. Feeds are said to play a key role in the promotion of new E. coli strains due to the high daily intake by animals and the ability of E. coli to multiply in feeds when moisture is added.

When Dr. Hancock's planned research which may have shown the need to modify practices at the ranch or feedlot, his funding from the cattle industry dried up. He concludes,

"Farm management practices can provide a practical means to reduce the prevalence of E. coli O157:H7 in cattle on farms and in slaughter plants."

Cornell University researchers have shown that something as basic and natural as **feeding hay** to cattle, rather than the grain-based concentrate diets which they are instead commonly fed, reduces the human health risks from beef contaminated with E. coli O157:H7. The gastrointestinal tracts of cattle digest starch poorly, and undigested grain in the colon causes acid to accumulate there, making the bacteria acid resistant. Carbohydrates from hay do not ferment so readily. James B. Russell, a USDA microbiologist and faculty member of the Cornell Section of Microbiology has, in fact, attributed the evolution of acid-resistant strains of E. coli to the high-grain, growth-promoting diets used by the cattle industry for the past 40 years.

**Feed deprivation** disturbs the gastrointestinal tract, increasing an animal's susceptibility to infection by E. coli O157:H7. Feed deprivation causes normal rumen microbes to starve and cease making volatile fatty acids which suppress E. coli (and Salmonella) bacteria. During a lack of food, these acids are absorbed, allowing pathogens to increase in population. Feed deprivation has been shown to increase the susceptibility of calves to E. coli O157:H7, and the shedding of it by calves already colonized. Similarly, lightweight cattle entering feedlots have a greater chance of carrying E. coli O157:H7, and cattle subjected to feed deprivation, such as during transport, marketing, or prior to slaughter, are considered at high risk for carrying an unusually high number of O157:H7 organisms. (The incidence of the pathogen is 3-fold higher in recently shipped feedlot animals). Dairy industry feeding practices associated with increased prevalence of E. coli O157:H7 include feeding grain during the first week of a calf's life; the use of unwashed communal feeding utensils among calves; feeding oats in starter rations; and feed withdrawal.

The use of **ionophores** in the diet of feedlot cattle in the latter 1970's roughly coincides with the identification of E. coli O157:H7 as a food-borne human pathogen. Ionophores inhibit gram-positive organisms in the rumen, and so enable the increased proliferation of gram-negative organisms, including E. coli O157:H7. Antibiotic injections to young cattle destabilize the intestinal flora, causing an increased susceptibility to transient E. coli strains, including O157:H7.

**Manure on animals** is an obvious and pervasive cause of the spread of pathogens. The term, "dunglocks," has actually been coined for the manure which commonly hangs from the back legs of cattle. This results from cattle being kept crowded together in unsanitary environments. Feedlot cattle across the country regularly enter slaughter plants with mud and feces encrusted on their legs, abdomens, and tails. In contrast, in Australia, where most cattle are grass fed, the animals generally are clean upon arrival at slaughter. USDA inspectors should reject dirty animals before they enter the slaughterplant.

Funding

These are basic management practices which for far too long have gone unaddressed. The beef industry is clearly shirking its responsibility in seeking solutions to E. coli O157:H7. This was made clear in September when a $450,000 allocation earmarked for production-level E. coli research was voted down by the Beef Board, the beef industry's clearinghouse for checkoff-

sourced funding for promotion and research, which opted instead to spend the money on promoting beef consumption. This is a blatant and inexcusable disregard for the health of their customers and the public at large. In a similar vein, the beef-operating committee of the Beef Promotion & Research Board has recommended that $408,000 of a $5.652 million budget go towards studying E. coli, whereas $1.385 million would go to advertising in 1999. The $408,000 is to be spent on determining the accuracy of the industry's raw product material sampling and test procedures for E. coli O157:H7 and other pathogens, and defining the optimal sampling and testing techniques for raw materials and beef products - nothing toward preventative measures at the production stage. (The FDA, on the other hand, is to be commended for its recent provision of $850,000 for research primarily into E. coli O157:H7 and cattle production.)

The recent attempt by the largest U.S. meat company, IBP, to require its customers to sign an agreement stating they either would not test their products for E. coli O157:H7 or would pay all of the costs associated with a recall necessitated by a positive test is indicative of the industry's lack of confidence in its product and the prioritization of economic interests over that of consumer health.

Industry needs to assume its responsibility in developing and implementing management practices at the production level which will ensure the health and well-being of the animals involved and ultimately that of consumers. The government needs to make sure that it does in order to fulfill its mandate of protecting public health. The USDA should actively and immediately seek animal production food safety regulatory authority.

Traceback

The ability to trace diseased animals back through the system will greatly facilitate understanding of E. coli O157:H7 (and other pathogen) pathways, and motivate industry efforts to safeguard against it. The USDA is to be commended for its recently stated interest in instituting a system for tracking animals from birth to slaughter. Most countries in the European Union do have mandatory identification systems in place using bar-coded eartags. The Cattle Tracing System in Britain tracks every calf, cow and bull registered there from birth to death. Northern Ireland has been using the system for several years. The system uses a bar-code reader and a recognition devise that can decipher hand-written numbers and letters. By the year 2000, the European Union will require all cattle sold in 15 countries to have lifelong identification. Several other countries are also moving toward mandatory identification systems.

E. coli O157:H7 should be treated like hoof-and-mouth disease or brucellosis, with herds tested for the presence of E. coli O157:H7 and animals testing positive not allowed to be marketed. Production-site testing of cattle herds for E. coli O157:H7 has been on-going in the Netherlands.

Conclusion

E. coli O157:H7 infection is a horrendous and potentially fatal disease affecting up to 400,000 people a year, possibly more. It cannot be taken too seriously, and all reasonable safeguards against it should be taken. Any product contaminated with E. coli O157:H7 should be considered adulterated.

We would like clarification on the handling of intermediate products: if not all of it is further processed, what becomes of that which is not further processed? And will that which is further processed be included in the sampling and testing program? We contend that any type of beef could potentially be contaminated with E. coli O157:H7, therefore all types of beef should be included in the sampling and testing program.

Up to three percent of cattle may carry E. coli O157:H7, with prevalence rates increasing from feedlot to slaughter. It is a remarkably resilient organism, and irradiation is an impractical and otherwise objectionable means of addressing it. While slowing down plant line speeds is a sensible measure that should be employed (for a host of reasons), preventative measures at the animal production level must be the focus of E. coli O157H:7 control efforts. This is professed by numerous experts and authorities. Such preventative measures include supplying animals with clean water and adequate, wholesome feed of a type for which they are metabolically designed to digest; minimizing the use of antibiotics; and providing them with adequate, clean space at all times. Providing for the health and well-being of animals used for food will translate into safer food for consumers.

The beef industry should begin to fulfill its obligation to offer a safe product by funding research at the animal production level. Since it has failed to meet this obligation, the government, in order to meet its responsibility to safeguard the public health, needs to actively seek animal production regulatory authority. The USDA is the appropriate government agent to do that, which it should immediately. Traceback capability and herd testing would be effective means of both monitoring animal health and motivating industry to begin addressing food safety problems.

Thank you for your consideration of these comments. Please contact us if clarification of any part of them is needed. We appreciate your attention to this life-and-death issue.

**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] Fronching, 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

[Billing Code 3410-DM-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 E. coli O157:H7 contaminated beef products.

**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 [insert date 60 days after date of publication in the FEDERAL REGISTER].

**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:

---

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

> 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

---

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.

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

---

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

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

---

available for viewing in the FSIS docket room.

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 Federal Register notice and was held on

---

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).

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 aculterated with E. coli 0157: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 0157: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 0157: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

---

7 Copies of the comments received on the risk assessment process (Docket #98-037N), the transcript of the risk assessment pubic 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).