

required, at the discretion of CCC, to provide evidence that the eligible commodity was produced in accordance with paragraphs (e), (f), and (g) of this section and other provisions of this part.

Signed in Washington, DC, on September 20, 2002.

James R. Little,

Executive Vice President, Commodity Credit Corporation.

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DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Part 417

[Docket No. 00-022N]

E. coli O157:H7 Contamination of Beef Products

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Compliance with the HACCP system regulations and request for comment.

SUMMARY: The Food Safety and Inspection Service (FSIS) is publishing this document to inform manufacturers of beef products of the Agency's views about the application of the hazard analysis and critical control point (HACCP) system regulations to contamination with *Escherichia coli* (*E. coli*) O157:H7.

FSIS believes that the availability of certain scientific data on *E. coli* O157:H7 constitutes a change that could affect an establishment's hazard analysis or alter its HACCP plans for raw beef products. Therefore, under the HACCP regulations, if establishments have not already reassessed their HACCP plans for raw beef products in light of this data, they must do so now.

Establishments that have not already reassessed their HACCP plans in light of this data must reassess their HACCP plans to determine whether *E. coli* O157:H7 contamination is a hazard reasonably likely to occur in their production process. This requirement applies to HACCP plans for all raw beef products, including ground beef, other non-intact beef products, and intact beef products. If reassessment results in a determination that *E. coli* O157:H7 contamination is a food safety hazard reasonably likely to occur in the establishment's production process, then it must be addressed in a HACCP plan.

All establishments producing raw beef products are required to reassess their HACCP plans. However,

establishments receiving product for grinding may have purchase specifications requiring all their suppliers to have one or more critical control points (CCPs) validated to eliminate or to reduce *E. coli* O157:H7 below detectable levels. Such establishments may determine that no additional steps to address this pathogen are necessary in their production process. Establishments adopting this approach should incorporate these purchase specifications and their means of ensuring that their specifications are met in their HACCP plans, in their Sanitation SOPs, which FSIS has recognized as prerequisites for HACCP, or in other prerequisite programs.

In addition, FSIS is issuing new guidance material related to the control of *E. coli* O157:H7 and is making available the Agency's draft comparative risk assessment of intact and non-intact (blade tenderized) steaks. (See **ADDRESSES.**) Additionally, FSIS will be issuing a revised *E. coli* O157:H7 sampling and testing Directive and this notice discusses the revisions expected to be made.

FSIS invites comments on the matters presented in this notice, on its guidance material, and on the draft comparative risk assessment.

DATES: Comments may be submitted by December 6, 2002. Establishments that produce raw beef products, and that have not already reassessed their HACCP plans for those products in light of the scientific data on *E. coli* O157:H7 discussed in this notice, are to reassess their HACCP plans by the following dates according to plant size: December 6, 2002 for large plants (all establishments with 500 or more employees); February 4, 2003 for small plants (all establishments with 10 or more employees but fewer than 500); and April 7, 2003 for very small plants (all establishments with fewer than 10 employees or annual sales of less than \$2.5 million).

See the **SUPPLEMENTARY INFORMATION** for FSIS verification dates.

ADDRESSES: Submit one original and two copies of written comments to FSIS Docket Clerk, Docket No. 00-022N, 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 document and the guidance material 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. The draft comparative risk assessment of intact and non-intact

(blade tenderized) steaks is also available on the Internet at: <http://www.fsis.usda.gov/OPPDE/rdad/publications.htm>. FSIS is making the guidance material available today at the same Internet address.

FOR FURTHER INFORMATION CONTACT: Dr. Daniel Engeljohn, Director, Regulations and Directives Development Staff, Food Safety and Inspection Service, U.S. Department of Agriculture (202) 720-5627.

SUPPLEMENTARY INFORMATION:

HACCP

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.*) and the Poultry Products Inspection Act (PPIA) (21 U.S.C. 451 *et seq.*) to protect the health and welfare of consumers by preventing the distribution of meat and poultry products that are unwholesome, adulterated, or misbranded. To further the goal of reducing the risk of foodborne illness from meat and poultry products to the maximum extent possible, FSIS issued final regulations on July 25, 1996, mandating Pathogen Reduction-Hazard Analysis and Critical Control Point (HACCP) Systems for 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.

Part 417, the regulations on HACCP systems, requires a hazard analysis to determine the food safety hazards reasonably likely to occur in the production process and to identify the preventive measures an establishment can apply to control those hazards in the production of particular products (§ 417.2(a)). Ten potential hazard areas, including microbiological contamination, are listed to guide establishments in this analysis (§ 417.2(a)(3)). Whenever a hazard analysis reveals one or more such hazards are reasonably likely to occur in the production process, the regulations require that the establishment develop and implement a written HACCP plan, for each product, that includes specified control measures for each hazard so identified (§ 417.2(b)(1) and (c)).

Section 417.2(a)(1) provides that a food safety hazard is reasonably likely to occur if a prudent establishment would establish control measures because the hazard 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.

The likelihood that a food safety hazard will occur in the production process for a particular product at a given location, and the identification and adequacy of preventive measures to control a likely hazard, must be determined by each establishment. Obviously, conditions that affect such determinations may change over time. For this reason, the HACCP system regulations require that every establishment reassess the adequacy of its HACCP plans at least annually and whenever any changes occur that could affect the underlying hazard analysis or alter the HACCP plans (§ 417.4(a)(3)). New information regarding the fact that *E. coli* O157:H7 is more prevalent than was previously thought is such a change. When reassessment reveals that a plan no longer meets the requirements for the contents of a HACCP plan, the establishment must modify the plan immediately (§ 417.4(a)(3)).

E. coli O157:H7 Policy

In 1994, FSIS notified the public that raw ground beef contaminated with *E. coli* O157:H7 is adulterated under the FMIA unless the ground beef is further processed to destroy this pathogen. Also in 1994, FSIS began sampling and testing ground beef for *E. coli* O157:H7. (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, available on the Internet at <http://www.fsis.usda.gov/oppde/rdad/publications.htm> and in the Docket Clerk's office.)

On January 19, 1999, FSIS published a policy statement, "Beef Products Contaminated with *E. coli* O157:H7" (64 FR 2803). This statement explained the Agency's policy governing beef products that contain *E. coli* O157:H7. The Agency stated that, in evaluating beef products contaminated with *E. coli* O157:H7, it would distinguish intact cuts of muscle (e.g., steaks and roasts) distributed for consumption from non-intact products (e.g., beef that has been mechanically tenderized by needling or cubing) and from intact cuts of muscle that are to be further processed into non-intact product prior to distribution for consumption (e.g., manufacturing trimmings for use in production of ground beef). This statement explained that intact cuts of beef that are to be further processed into non-intact product prior to distribution for consumption must be treated in the same manner as non-intact cuts of beef

because 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 product.

The Agency stated that if non-intact products or intact products that are to be further processed into non-intact product prior to distribution for consumption are found to be contaminated with *E. coli* O157:H7, they must be processed into ready-to-eat product, or they would be deemed to be adulterated (64 FR 2804). FSIS explained that pathogens, including *E. coli* O157:H7, may be introduced below the surfaces of non-intact products as the result of the processes by which they are made. As a result, customary cooking of these products may not be adequate to kill the pathogens. In contrast, the meat interior of intact products remains protected from pathogens migrating below the exterior. Consequently, customary cooking of these products will destroy any *E. coli* O157:H7. Finally, in this **Federal Register** notice, FSIS requested comments and recommendations relevant to the Agency's policy and to any regulatory requirements that might be appropriate to prevent the distribution of beef products adulterated with this pathogen.

On March 8, 1999, FSIS held a public meeting to discuss the policy addressed in its January 19, 1999, **Federal Register** notice. On February 11, 2000, FSIS announced that it would hold a public meeting on February 29, 2000, to discuss recent developments concerning *E. coli* O157:H7 (65 FR 6881). In the February 11, 2000, **Federal Register** notice, FSIS also responded to comments received concerning the Agency's *E. coli* O157:H7 policy and again requested comments. On February 29, 2000, FSIS held the public meeting on *E. coli* O157:H7. At the meeting, numerous organizations presented information on *E. coli* O157:H7. FSIS presented information on the new testing procedures that it is using for *E. coli* O157:H7 and on the FSIS risk assessment on *E. coli* O157:H7. The Agricultural Research Service (ARS) presented information on research concerning the incidence of *E. coli* O157:H7 in animals entering the slaughter plant and at various stages in the slaughter process. Also, the Centers for Disease Control and Prevention (CDC) presented information concerning

its increased estimates for illnesses associated with *E. coli* O157:H7. A complete transcript of the February 29, 2000, public meeting is available on the Internet at <http://www.fsis.usda.gov/oppde/rdad/frpubs/ecolimtg.pdf>.

On November 5, 2001, FSIS announced the availability of and requested comments on its draft risk assessment for *E. coli* O157:H7 in ground beef (66 FR 55912). At this time, FSIS also made the interpretive summary of the risk assessment and draft risk assessment available on the Internet. The draft risk assessment discusses and cites the studies discussed below. As stated below, under "Relevant Data Requiring Reassessment," the data from some of these studies and FSIS surveillance data provided evidence that *E. coli* O157:H7 is more prevalent than was thought before these data became available.

Risk of E. coli O157:H7 Contamination

Exposure to *E. coli* O157:H7 has been linked to serious, life-threatening human illnesses (hemorrhagic colitis and hemolytic uremic syndrome). At the February 29, 2000, public meeting, a representative from the CDC presented its national estimates for foodborne illnesses associated with *E. coli* O157:H7. These estimates showed an increase from previous CDC estimates of illnesses associated with *E. coli* O157:H7. At that time, CDC increased its estimates for illnesses associated with *E. coli* O157:H7 because surveillance data allowed a more detailed estimation of mild illnesses not resulting in physician consultation.¹ As FSIS stated in the February 11, 2000, meeting notice, although not all these illnesses were attributable to beef, the increase in illness associated with *E. coli* O157:H7 indicated that this pathogen occurred more frequently than was previously thought (65 FR 6882). CDC continues to collect data on the incidence of reported cases. Based on recent preliminary FoodNet data, there does not appear to be a sustained decrease in disease associated with *E. coli* O157:H7.²

Also at the public meeting, an FSIS representative presented information on the new *E. coli* O157:H7 testing procedures that the Agency began using on September 3, 1999. This method is approximately four times more sensitive

¹ For information on the estimates, see Mead, Paul S., et al., "Food-Related Illness and Death in the United States," *Journal of Emerging Infectious Diseases*, Vol. 5, No. 5, 1999.

² Morbidity and Mortality Weekly Report. 2002. Preliminary FoodNet Data on the Incidence of Foodborne Illnesses—Selected Sites, United States, 2001. Vol. 51, Number 15: 325–329.

than the previous method. Prior to the introduction of the new FSIS testing method, the prevalence of *E. coli* O157:H7 in raw ground beef samples tested was 0.149 percent. Using the new method between September 3, 1999, and September 8, 2002, the prevalence of *E. coli* O157:H7 in raw, ground beef samples tested was 0.797 percent. This increase in *E. coli* O157:H7 prevalence in raw ground beef samples suggests that the low rate of positive findings in the past may have had more to do with the sensitivity of the method and size of the sample being used than with the rarity of the pathogen.

Also at the February 29, 2000, public meeting, a representative from ARS presented information concerning a recent *E. coli* O157:H7 prevalence study (hereinafter referred to as the Elder study).³ In this study of fed cattle, 28 percent (91 of 327) of fecal samples were positive for *E. coli* O157:H7. Previous studies of fed cattle had found a fecal prevalence of 2 percent (188 of 11,881 samples),⁴ 4 percent (38 of 1046 samples),⁵ 6 percent (14 of 240 samples),⁶ and, for the study hereinafter referred to as the Smith study, 23 percent (707 of 3054 samples).⁷

Three multistate studies reported the apparent prevalence of feedlots containing one or more infected cattle. Even if one animal in a herd was found positive for *E. coli* O157:H7 the herd was considered positive for *E. coli* O157:H7. These estimates were 63 percent (63 of 100 feedlots),⁸ 100 percent (6 of 6 feedlots),⁹ and 100 percent (5 of 5 feedlots).¹⁰ Although all

the studies cited in the preceding sentence found a high proportion of herds to contain at least one animal that was positive for *E. coli* O157:H7, except for the Smith study, these studies did not find many animals within a specific herd to be positive for *E. coli* O157:H7. The Smith and Elder studies found higher within herd *E. coli* O157:H7 prevalence than all the other studies cited. That is, these studies found more animals within a specific herd to be positive for *E. coli* O157:H7 than the other studies did.

The study from ARS mentioned above (Elder 2000) also addressed the prevalence of *E. coli* O157:H7 on carcasses at preevisceration, at postevisceration, and at postprocessing. *E. coli* O157:H7 was found on 43 percent (148 of 341) of the preevisceration carcasses, 18 percent (59 of 332) of the postevisceration carcasses, and 2 percent (6 of 330) of the postprocessing carcasses.

In addition to fed cattle, culled breeding cattle (dairy and beef cows and bulls) are an important source of beef products. Four studies provided fecal prevalence evidence of *E. coli* O157:H7 of 1 percent (10 of 1412 samples),¹¹ 1 percent (52 of 4361 samples),¹² 2 percent (89 of 4031 samples),¹³ and 3 percent (7 of 205 samples).¹⁴

Five multistate studies reported the apparent prevalence of breeding herds containing one or more infected cattle. These estimates were 24 percent (22 of 91 herds),¹⁵ 61 percent (8 of 13 herds),¹⁶ 75 percent (27 of 36 herds),¹⁷ 87 percent

(13 of 15 herds),¹⁸ and 100 percent (6 of 6 herds).¹⁹

At the February 29, 2000, public meeting, FSIS presented preliminary results from the FSIS draft risk assessment for *E. coli* O157:H7 in ground beef. These preliminary results did not incorporate the evidence presented at this meeting from the ARS (Elder 2000). The best estimate of the prevalence of *E. coli* O157:H7 in live cattle destined for ground beef production was given as just over 10 percent. The bounds of uncertainty depended upon the class of animal considered, fed or culled, and ranged from less than 5 percent to greater than 15 percent. For plants that slaughter culled cattle, the estimated prevalence of *E. coli* O157:H7-contaminated 2000 pound combo-bins was given as 15 percent, with a range from greater than 5 percent to less than 30 percent. For steers and heifers, the estimated combo bin prevalence was over 40 percent, with a lower bound greater than 20 percent and an upper bound less than 60 percent.

Trim from bins is mixed together and ground to achieve product with specific fat content. The mixing of the contents of several combo bins disperses the *E. coli* O157:H7 organisms and results in ground product with a lower concentration, but higher prevalence, of contamination than in the original bins. Preliminary risk assessment estimates suggested that nearly 90 percent of grinder loads had at least one *E. coli* O157:H7 organism present with a lower bound greater than 70 percent and an upper bound greater than 95 percent.

The estimates presented at the public meeting were preliminary and were premised on the assumption that slaughter plants were achieving an average of about 1.5 log₁₀ reduction of *E. coli* O157:H7 as a result of decontamination measures taken after dehiding and after carcass splitting. At this time, FSIS does not have information about the level of log reduction for *E. coli* O157:H7 being achieved in specific slaughter operations or thereafter, or about whether the 1.5 log₁₀ reduction modeled in the risk assessment is comparable to what industry is achieving today. If validated interventions being used today result in more than a 1.5 log₁₀ reduction, and

³ Robert. O. Elder, *et al.* Correlation of Enterohemorrhagic *Escherichia coli* O157 Prevalence in Feces, Hides, and Carcasses of Beef Cattle During Processing. Proc Natl Acad Sci USA. Mar 2000. 97(7): 2999–3003.

⁴ Dargatz DA, Wells SJ, Thomas LA, *et al.* Factors associated with the presence of *Escherichia coli* O157 in feces of feedlot cattle. J. Food Prot. 1997; 60(5): 466–470.

⁵ Hancock DD, Besser TE, Rice DH, *et al.* Multiple sources of *Escherichia coli* O157 in feedlots and dairy farms in the Northwestern USA. Prev. Vet. Med. 1998; 35: 11–19.

⁶ Hancock DD, Rice DH, and Besser TE. 1999. Prevalence of *E. coli* O157:H7 in feedlot cattle at slaughter plants. Study funded by National Cattlemen's Beef Association. Washington State University.

⁷ Smith, D, Blackford M, Younts S, *et al.* 2001. Ecological relationships between the prevalence of cattle shedding *E. coli* O157:H7 and characteristics of the cattle or conditions of the feedlot pen. J. Food Prot. 64(12): 1899–1903.

⁸ Dargatz DA, Wells SJ, Thomas LA, *et al.* Factors associated with the presence of *Escherichia coli* O157 in feces of feedlot cattle. J. Food Prot. 1997; 60(5): 466–470.

⁹ Hancock DD, Besser TE, Rice DH, *et al.* Multiple sources of *Escherichia coli* O157 in feedlots and dairy farms in the Northwestern USA. Prev. Vet. Med. 1998; 35: 11–19.

¹⁰ Smith, D, Blackford M, Younts S, *et al.* 2001. Ecological relationships between the prevalence of

cattle shedding *E. coli* O157:H7 and characteristics of the cattle or conditions of the feedlot pen. J. Food Prot. 64(12): 1899–1903.

¹¹ Hancock DD, Besser TE, Kinsel ML, Tarr PI, Rice DH, and Paros MG. The prevalence of *Escherichia coli* O157 in dairy and beef cattle in Washington State. Epidemiol. Infect. 1994; 113: 199–207.

¹² Garber L, Wells S, Schroeder-Tucker L, *et al.* Factors associated with fecal shedding of verotoxin-producing *Escherichia coli* O157 on dairy farms. J. Food Prot. 1999; 62(4): 307–312.

¹³ Besser TE, Hancock DD, Pritchett LC, *et al.* Duration of detection of fecal excretion of *Escherichia coli* O157:H7 in cattle. J Infect. Dis. 1997; 175: 726–729.

¹⁴ Rice DH, Ebel ED, Hancock DD, *et al.* *Escherichia coli* O157 in cull dairy cows on farm and at slaughter. J. Food Prot. 1997; 60(11): 1386–1387.

¹⁵ Garber L, Wells S, Schroeder-Tucker L, *et al.* Factors associated with fecal shedding of verotoxin-producing *Escherichia coli* O157 on dairy farms. J. Food Prot. 1999; 62(4): 307–312.

¹⁶ Hancock DD, Besser TE, Rice DH, *et al.* A longitudinal study of *Escherichia coli* O157 in fourteen cattle herds. Epidemiol. Infect. 1997; 118: 193–195.

¹⁷ Hancock DD, Rice DH, Herriot DE, *et al.* Effects of farm manure handling practices on *Escherichia coli* O157 prevalence in cattle. J. Food Prot. 1997; 60(4): 363–366.

¹⁸ Lagreid WW, Elder RO, and Keen JE. Prevalence of *Escherichia coli* O157:H7 in range beef calves. Epidemiol. Infect. 1999; 123(2): 291–298.

¹⁹ Hancock DD, Besser TE, Rice DH, *et al.* Multiple sources of *Escherichia coli* O157 in feedlots and dairy farms in the Northwestern USA. Prev. Vet. Med. 1998; 35: 11–19.

other factors remain the same, then the prevalence of *E. coli* O157:H7 would be a lower percentage than that reflected in the preliminary risk assessment estimates. FSIS requests comment and data on these issues. FSIS is still reviewing the draft risk assessment and may further modify its estimates in the future.

As noted above, on November 5, 2001, FSIS announced the availability of, and requested comments on, its draft risk assessment for *E. coli* O157:H7 in ground beef (66 FR 55912). At that time, FSIS also submitted the draft risk assessment to the National Academies of Science (NAS) for scientific peer review. FSIS received 6 comments in response to its request for comments in the **Federal Register**. FSIS is currently reviewing those comments. FSIS expects to receive NAS' comments concerning the risk assessment shortly and may revise the risk assessment based on NAS' comments and the public comments received.

Relevant Data Requiring Reassessment

Studies before those of Smith and Elder suggested that *E. coli* O157:H7 prevalence rates within herds were low. A 1992–1993 FSIS baseline survey of steer and heifer carcasses found 4 (0.2%) of these carcasses *E. coli* O157:H7–positive, and a 1993–1994 FSIS baseline survey of cow and bull carcasses found none of the carcasses positive for *E. coli* O157:H7. The USDA's Animal and Plant Health Inspection Service-Veterinary Services-National Animal Health Monitoring System also completed on-farm surveys of dairy cattle in 1992 and feedlot cattle in 1994. These national surveys found *E. coli* O157:H7 in 0.4 percent of dairy calves sampled and 1.6 percent of feedlot cattle sampled. Thus, these results suggested that *E. coli* O157:H7 occurred in cattle at a prevalence level that would require substantial numbers of samples to detect the organism in a population.

The results from FSIS' *E. coli* O157:H7 testing program since FSIS began using its new testing method and certain research studies discussed above provide evidence that *E. coli* O157:H7 is more prevalent than was thought before these data became available, and that this pathogen may be a hazard that is reasonably likely to occur at all stages of handling raw beef products. The specific studies cited above that suggest that *E. coli* O157:H7 is more prevalent than previously thought in live cattle and carcasses are the study by Elder *et al.* and the study by Smith *et al.* (both cited above).

FSIS is publishing this document to advise federally inspected establishments of the Agency's position on one aspect of its public health strategy to deal with *E. coli* O157:H7 contamination and to provide an opportunity for comment on that position, as FSIS continues to develop a comprehensive strategy. As explained under the HACCP discussion above, the regulations require that establishments reassess their HACCP plans whenever any changes occur that would affect their hazard analysis or alter their HACCP plans. The availability of FSIS testing data since FSIS began using the new testing method and the information from the Smith and Elder studies presented above is a change that requires establishments to reassess their HACCP plans because these data provided evidence that *E. coli* O157:H7 is more prevalent than was thought before this data became available.

The Elder and Smith studies were completed in 2000 and 1999, respectively, and published thereafter, and FSIS surveillance data from its new testing method became available in 1999. FSIS has not previously informed manufacturers of beef products that it believes that the availability of these data constitutes a change that could affect an establishment's hazard analysis and alter its HACCP plans for raw beef products. The preliminary results of the draft risk assessment on *E. coli* O157:H7 support FSIS' position. No more recent data have become available that would affect FSIS' conclusions regarding the prevalence of *E. coli* O157:H7.

Based on anecdotal information from its inspection program personnel and from In-Depth Verification Reviews (IDVs), FSIS believes that most establishments have not taken the data discussed above into account in their hazard analysis, and that establishments might not have addressed *E. coli* O157:H7 in their HACCP plans or, for grinding establishments, in programs that serve as prerequisites to HACCP plans. Therefore, the Agency is issuing this notice informing the public of its views concerning the implications of the *E. coli* O157:H7 data discussed above.

According to the data from the studies discussed above, the fecal prevalence of *E. coli* O157:H7 in fed cattle is significantly higher than the fecal prevalence of *E. coli* O157:H7 in culled breeding cattle (dairy, beef cows, and bulls). However, FSIS believes that all establishments producing raw beef products, including those slaughtering culled breeding cattle or using meat from culled breeding cattle in processing, need to reassess their

HACCP plans because the data show that *E. coli* O157:H7 is present in culled breeding cattle, because most slaughter establishments slaughter both fed and culled breeding cattle, and because most beef processing establishments use meat from both fed and culled breeding cattle. FSIS believes that establishments that slaughter both types of cattle or use both types of meat in processing would not develop different HACCP plans for slaughtering fed versus culled breeding cattle or for processing meat from fed versus culled breeding cattle.

Prior Reassessments Based on Relevant *E. coli* O157:H7 Data

Because all establishments are required to reassess their HACCP plans at least annually according to § 417.4(a)(3), all establishments should have reassessed their HACCP plans at least once, and possibly twice, since the February 29, 2000, public meeting. As noted above, at that public meeting, FSIS, ARS, and the CDC presented some of the data that provided evidence that *E. coli* O157:H7 was more prevalent than previously thought at that time, and that this pathogen may be a hazard that is reasonably likely to occur at all stages of handling raw beef products. In addition, FSIS placed the transcript from the public meeting on its web site shortly after the meeting. Finally, FSIS released the draft risk assessment, which discussed the published data that provide evidence that *E. coli* O157:H7 is more prevalent than previously thought, on its web page in November 2001.

Because FSIS made some of the data discussed above available in 2000 and released the draft risk assessment in 2001, establishments that produce raw beef products already may have reassessed their HACCP plans based on this data to determine whether *E. coli* O157:H7 is a hazard reasonably likely to occur in their production of these products, and, if so, whether their HACCP plans appropriately address this hazard. Establishments that already have taken the relevant *E. coli* O157:H7 data into account in a reassessment are not required to conduct another reassessment of their HACCP plans, provided these establishments have evidence of their reassessment based on this data that is available to FSIS inspection program personnel in their hazard analysis, HACCP plans, or record of reassessment. Establishments should have taken into account all of the data discussed above that suggest that *E. coli* O157:H7 is more prevalent than previously thought: the FSIS testing data and the data from the Smith and Elder studies.

Outcomes of Reassessments Based on Relevant *E. coli* O157:H7 Data

Establishments that produce raw beef products that have not conducted a reassessment of their HACCP plans based on the relevant *E. coli* O157:H7 data discussed above to determine whether *E. coli* O157:H7 is a hazard reasonably likely to occur in their production of these products, and, if so, whether their HACCP plans appropriately address this hazard, are required to conduct a reassessment. If this pathogen is a hazard reasonably likely to occur, then it must be addressed in a HACCP plan through one or more CCPs designed to control the pathogen.

Even establishments that produce intact product will need to reassess their HACCP plans based on the new *E. coli* O157:H7 data. These establishments are required to reassess their HACCP plans because much intact beef product may be used to make non-intact product, such as ground beef. According to § 417.2(a)(2), establishments are required to identify the intended use or consumers of the finished product. Therefore, to be able to determine the adequacy of their HACCP plans, establishments that produce intact beef products need to determine whether their products will be used to produce raw, non-intact product.

This document addresses only the need for HACCP plan reassessment. FSIS cannot predict the likelihood that an establishment producing raw beef products will need to incorporate, or alter, controls to prevent, eliminate, or reduce *E. coli* O157:H7 to an acceptable level (i.e., a level that would not be detectable using the FSIS testing method or a method with a sensitivity at least equivalent to FSIS' method) in one or more HACCP plans as a result of plan reassessment. FSIS does believe, however, that given the FSIS testing data and the data from the Elder and Smith studies discussed above, establishments should strongly consider the possibility that *E. coli* O157:H7 contamination is a hazard reasonably likely to occur in their production of beef products, especially if an establishment produces non-intact product that has been or could be adulterated with *E. coli* O157:H7 or produces intact product that is to be used for non-intact product, and this non-intact product has been or could be found to be adulterated with *E. coli* O157:H7.

In determining whether *E. coli* O157:H7 is a hazard reasonably likely to occur in the production process for their raw beef products, establishments

should take into account whether their raw beef products have tested positive for *E. coli* O157:H7 in either FSIS or industry testing. They should also consider whether there is a reasonable likelihood of *E. coli* O157:H7 contamination of their raw beef products in the absence of controls (see § 417.2(a)(1)).

Although all establishments producing raw beef products are required to reassess their HACCP plans, some establishments may determine that they do not need to change their HACCP plans. For example, some establishments may already address *E. coli* O157:H7 in their HACCP plans. Even if these establishments did not take the FSIS testing data and the Smith and Elder data into account in their prior hazard analysis, they may determine that their HACCP plans are still adequate to prevent, eliminate, or reduce *E. coli* O157:H7 to an undetectable level in light of the data, and that these data do not affect their hazard analysis. Similarly, establishments that produce raw intact product that will not be further processed into raw, non-intact product may determine that these data do not affect their hazard analysis, and that their HACCP plans do not need to be changed.

Critical Control Points and Sanitation SOPs and Other Prerequisite Programs

The regulations require that establishments develop HACCP plans that include critical control points (CCPs): points, steps, or procedures in a food process at which a control can be applied, and, as a result, a food safety hazard can be prevented, eliminated, or reduced to acceptable levels. FSIS considers an acceptable reduction for *E. coli* O157:H7 to be a reduction to an undetectable level.

Because controls to reduce the risk of *E. coli* O157:H7 contamination when the product is still intact may be the best means of controlling the hazard, FSIS believes that slaughter establishments and deboning establishments should strongly consider putting in place one or more validated CCPs that are designed to eliminate or reduce *E. coli* O157:H7 and other pathogens. If such establishments have controls in place to address *E. coli* O157:H7 specifically, they cannot conclude that the pathogen is *not* a hazard reasonably likely to occur in the absence of those controls. FSIS believes that any interventions that slaughter and deboning establishments use to address *E. coli* O157:H7 should be incorporated into their HACCP plans. At this time, FSIS is not aware of any prerequisite programs that are

appropriate for use in slaughter and deboning establishments to address *E. coli* O157:H7. FSIS advises that it intends to scrutinize very closely the hazard analyses and HACCP plans of those slaughter or deboning establishments that conduct, or have conducted, a reassessment and decide that an intervention for *E. coli* O157:H7 is not necessary.

According to the requirements of § 417.4(a)(1), establishments must validate CCPs to ensure that they can successfully apply a scientifically appropriate CCP to prevent, eliminate, or reduce *E. coli* O157:H7 under their commercial operating conditions (see 61 FR 38826–38827). Until establishments demonstrate that the CCP achieves the anticipated effect under actual in-plant conditions, effectiveness of the CCP is theoretical, and the plan is not validated. Based on information from inspection program personnel and IDVs, FSIS believes that many establishments have not validated their CCPs based on actual in-plant conditions.

Published scientific studies have demonstrated that there are effective decontamination methods that can be used for preventing, eliminating, or reducing *E. coli* O157:H7. Establishments can validate their CCPs for *E. coli* O157:H7 by ensuring that the operation of the CCP in their plant can meet the parameters of these studies, and by challenge studies using an appropriate surrogate for *E. coli* O157:H7 that could include, but not be limited to, *E. coli* and coliforms. There are no situations in which inspection program personnel will ask that establishments introduce pathogenic or harmful bacteria into the establishments to validate the effectiveness of CCPs. Establishments can ensure the effectiveness of their CCPs through monitoring, verification, and corrective action procedures in their written HACCP plans.

FSIS believes that establishments that receive product for grinding also should address *E. coli* O157:H7. These establishments can employ validated CCPs in their HACCP plans to address *E. coli* O157:H7. Interventions are becoming available to grinders. These establishments can also establish and require that specifications for the raw material that they purchase be met by suppliers. FSIS believes that grinders that have purchase specifications that require that all of their suppliers have one or more CCPs in their HACCP plans that are validated to eliminate or reduce *E. coli* O157:H7 below detectable levels and that ensure that these specifications are met may determine that no additional steps to address *E. coli*

O157:H7 are necessary in their production process for ground beef. However, given the nature of the pathogen, FSIS strongly recommends that grinders that have purchase specifications addressing *E. coli* O157:H7 determine whether CCPs preventing *E. coli* O157:H7 growth or contamination after product receipt are necessary.

Grinders could incorporate purchase specifications to prevent *E. coli* O157:H7-contaminated product from entering their establishment in their HACCP plans. However, the Agency also recognizes that some may argue that purchase specifications addressing *E. coli* O157:H7 do not lend themselves to a point, step, or procedure in a food process at which control can be applied (see definition of "critical control point" in § 417.1). Also, if grinding establishments have purchase specifications addressing *E. coli* O157:H7 that require that incoming product has been treated to eliminate or reduce *E. coli* O157:H7 to an undetectable level, and if they ensure that these specifications are met, these establishments may determine that they do not need a separate CCP to eliminate or reduce *E. coli* O157:H7 after receipt of product. In recognition of these arguments, FSIS advises that grinders may choose not to include purchase specifications addressing *E. coli* O157:H7 as CCPs in their HACCP plans. If they do not include these purchase specifications as CCPs in their HACCP plans, however, establishments should incorporate them in their Sanitation SOPs, which FSIS has recognized as prerequisites for HACCP (61 FR 38834), or in other programs that are prerequisites for HACCP (prerequisite programs).

Current regulations do not include specific requirements for prerequisite programs other than Sanitation SOPs. However, under § 417.5(a)(1), establishments must maintain records of their hazard analysis, including all supporting documentation. According to the regulations, the hazard analysis must include the food safety hazards that can occur before, during, and after entry into the establishment (§ 417.2(a)). If an establishment has determined in its hazard analysis that *E. coli* O157:H7 is a hazard that can occur at one of these points but is *not* reasonably likely to occur in the establishment's processing because the establishment has a prerequisite program with purchase specifications addressing *E. coli* O157:H7, information concerning the prerequisite program is supporting documentation that must be maintained under § 417.5(a)(1). All documentation

supporting the hazard analysis must be made available to FSIS upon request (§ 417.5(f)).

FSIS expects the supporting documentation concerning prerequisite programs other than Sanitation SOPs to include the programs' procedures and operational controls in writing. In addition, FSIS expects the documentation to include records that document that the program is effective, and that *E. coli* O157:H7 is not reasonably likely to occur. Without this documentation, FSIS would question the adequacy of the establishment's HACCP system and hazard analysis.

Establishments should revise their prerequisite programs, as necessary, to ensure their effectiveness and should take appropriate corrective actions when they determine that their prerequisite programs may have failed to prevent contamination or adulteration of product. If establishments that address *E. coli* O157:H7 in their prerequisite programs and not in their HACCP plans produce *E. coli* O157:H7-positive product, this occurrence would be considered a "deviation not covered by a specified corrective action" or an "unforeseen hazard" (§ 417.3(b)). Therefore, these establishments would be required to take the corrective actions, including reassessment, set forth in § 417.3(b).

As with other prerequisite programs that include purchase specifications addressing *E. coli* O157:H7, establishments with Sanitation SOPs that include purchase specifications addressing *E. coli* O157:H7 may conclude that the pathogen is not reasonably likely to occur in the establishments' processing because of the Sanitation SOPs. However, unlike other prerequisite programs, current regulations provide requirements for Sanitation SOPs and ensure that FSIS has access to establishments' records documenting the implementation and monitoring of the Sanitation SOPs. According to the Sanitation SOP regulations, establishments that include purchase specifications addressing *E. coli* O157:H7 in their Sanitation SOPs will need to evaluate routinely the effectiveness of these purchase specifications in preventing the adulteration of their products. They will also need to revise these purchase specifications as necessary to keep them effective (see § 416.14). Moreover, they will need to maintain records to document the implementation, monitoring, and correction of their purchase specifications (see §§ 416.15 and 416.16).

Under § 416.15, establishments are required to conduct corrective actions

when they determine that their Sanitation SOP may have failed to prevent direct contamination or adulteration of product; however, under § 416.15, establishments are not required to reassess their Sanitation SOPs when they determine that their Sanitation SOPs may have failed to prevent direct contamination or adulteration of product. If establishments that address *E. coli* O157:H7 in their Sanitation SOPs and not in their HACCP plans produce *E. coli* O157:H7-positive product, this occurrence would be considered a "deviation not covered by a specified corrective action" or an "unforeseen hazard" (§ 417.3(b)). Therefore, these establishments would be required to take the corrective actions, including reassessment, set forth in § 417.3(b).

FSIS received a petition dated December 30, 1999, signed by numerous meat and poultry trade organizations (see 65 FR 30952 for information on this petition and the text of this petition). The petition stated that a HACCP plan is only one part of a plant's overall food safety system, and that other integral components of that system include Sanitation SOPs, various good manufacturing practices, and other prerequisite programs that are needed to form the foundation for the HACCP system. The petition stated that FSIS should recognize these other components of establishments' food safety systems when determining whether HACCP plans are adequate.

In this notice, FSIS is recognizing that establishments receiving raw beef product for grinding can effectively include purchase specifications addressing *E. coli* O157:H7 in Sanitation SOPs and other prerequisite programs. FSIS has made no general determinations concerning food safety hazards other than *E. coli* O157:H7 and no general determinations concerning what circumstances other than grinders' receiving product that meets purchase specifications can be addressed through prerequisite programs, rather than HACCP. If establishments, other than grinders, address any food safety hazard in a prerequisite program, and if grinders include more than purchase specifications addressing *E. coli* O157:H7 in their prerequisite programs, FSIS will review the establishments' supporting documentation for these programs and will make a determination concerning the adequacy of these programs, applicable HACCP plans, and hazard analyses on a case-by-case basis.

FSIS does not believe that establishments receiving raw beef product for grinding will be able to substitute Sanitation SOPs or other

prerequisite programs addressing *E. coli* O157:H7 for their HACCP plans in their entirety because the Agency does not believe that *E. coli* O157:H7 contaminated product from outside sources would be the only food safety hazard reasonably likely to occur in the production of ground beef in the absence of controls. For establishments receiving raw beef product for grinding, FSIS believes that Sanitation SOPs or other prerequisite programs together with HACCP plans function as food safety HACCP systems that effectively produce safe, unadulterated product.

Verification

All establishments are required to conduct on-going verification activities to ensure that their HACCP plans are effectively implemented (§ 417.4(a)(2)). Whether the establishment has CCPs addressing *E. coli* O157:H7 in their HACCP plans or has concluded the pathogen is not reasonably likely to occur because it has purchase specifications that prevent the pathogen from entering the facility, the establishment is required to conduct on-going verification activities to ensure that any CCP is adequately addressing *E. coli* O157:H7, or that the purchase specifications continue to prevent the pathogen from entering the facility. FSIS recommends that establishments' verification activities include testing for *E. coli* O157:H7.

State Inspection Programs and Programs Outside the United States (U.S.)

Establishments in states that have their own inspection programs that produce raw beef products and that have not already done so must reassess their HACCP plans in light of the *E. coli* O157:H7 data discussed above. Similarly, producers outside the U.S. that import raw beef product into the U.S. that have not already done so will have to reassess their HACCP systems based on the data discussed above.

FSIS Actions To Enforce and Facilitate Compliance With the Reassessment Requirement

Establishments that produce raw beef products are to reassess their HACCP plans unless they have already reassessed their HACCP plans based on the *E. coli* O157:H7 data that suggest that the pathogen may be more prevalent than previously thought, and they have evidence of this reassessment that is available to FSIS inspection program personnel in their hazard analysis, HACCP plans, or record of reassessment. Although establishments are not required to maintain a written

record of their reassessment, FSIS encourages them to do so.

The Agency intends to instruct its inspection program personnel to determine whether reassessments were conducted or are being conducted and to begin making this determination on November 6, 2002. At this time, inspection program personnel will ensure that all establishments producing raw beef products are aware that the Agency has issued this notice and will ensure that those establishments that have not yet reassessed their HACCP plans based on the relevant *E. coli* O157:H7 data discussed above begin their reassessment in time to complete it by the following date according to plant size: December 6, 2002 for large plants (all establishments with 500 or more employees); February 4, 2003 for small plants (all establishments with 10 or more employees but fewer than 500); and April 7, 2003 for very small plants (all establishments with fewer than 10 employees or annual sales of less than \$2.5 million). FSIS will not begin enforcing the required reassessment until December 6, 2002 for large plants; February 4, 2003 for small plants; and April 7, 2003 for very small plants. By looking into establishments' reassessment actions prior to the time they are required to complete their reassessments, FSIS will ensure that all establishments producing raw beef products, including those that are small and very small businesses that may not belong to a trade association, are aware of this notice. FSIS will mail this notice to all small and very small plants prior to the effective date for reassessment.

The Agency then intends to instruct its inspection program personnel to collect data concerning the outcomes of the required reassessment and to begin collecting this data on: December 23, 2002 for large plants; February 19, 2003 for small plants; and April 21, 2003 for very small plants. Inspection program personnel will collect data concerning (1) whether establishments reassessed their HACCP plans based on the relevant *E. coli* O157:H7 data prior to or after publication of this notice; (2) whether establishments changed their HACCP plans or prerequisite programs as a result of a reassessment that took this data into account; (3) if establishments changed their HACCP plans or prerequisite programs, how the plans or prerequisite programs were changed; and (4) if establishments did not change their HACCP plans or prerequisite programs, the reasons the plans or programs were not changed. If an establishment does not reassess its HACCP plans in accord with this document, FSIS will evaluate the

establishment's compliance with Part 417.

Guidance

FSIS is making available guidelines entitled, "Guidance for Beef Grinders and Suppliers of Boneless Beef and Trim Products" on the Internet (<http://www.fsis.usda.gov/oppde/rdad/publications.htm>). In this guidance material available today, FSIS is providing recommendations for reducing the occurrence of *E. coli* O157:H7 and *Salmonella* in ground beef, boneless beef, and trim products. FSIS initially made this guidance material available to the public in March 1998. FSIS has expanded this guidance material to include guidance for suppliers of boneless beef and trim and recommendations for reducing *Salmonella* in ground beef, boneless beef, and trim products.

In the guidance material, to further reduce the risk of *E. coli* O157:H7 contamination after product receipt, FSIS is recommending that grinders receiving product from more than one supplier prevent any mixing of product from different suppliers, unless they can demonstrate that the source materials from the different suppliers have been adequately treated to eliminate or reduce *E. coli* O157:H7 to an undetectable level. Keeping product from different suppliers separate will prevent any potentially *E. coli* O157:H7-contaminated source material from adulterating source materials from other suppliers. Also, by keeping product from different suppliers separate, grinders will be able to identify the potential source of any *E. coli* O157:H7-contaminated product should the pathogen be detected. If FSIS finds samples of ground beef produced from suppliers' source materials outside the grinding establishment or retail facility to be positive for *E. coli* O157:H7, FSIS intends to notify the supplying establishments that they may have supplied *E. coli* O157:H7-positive product to a grinding establishment or retail facility.

FSIS intends to gather pertinent information concerning suppliers from Federal grinding establishments and retail facilities. If FSIS confirms that ground product is positive for *E. coli* O157:H7, FSIS intends to obtain from Federal grinding establishments the following information concerning their suppliers of the source materials: the name, point of contact, and phone number for the establishments supplying the source materials for the lot of ground beef sampled; the supplier lot numbers and production dates; and any other information that would be

useful to suppliers that may have supplied *E. coli* O157:H7-positive product to Federal grinding establishments. Similarly, at the time FSIS collects samples of ground beef from retail facilities, FSIS will obtain from the retail facility the names and establishment numbers of the establishments supplying the source materials for the lot of ground beef sampled, the supplier lot numbers and production dates, and any other information that would be useful to suppliers if they are later notified of an *E. coli* O157:H7 positive finding.

Under § 320.1(b)(1), establishments and retail facilities are required to keep records of each transaction involving their purchasing or receiving any meat or meat food product. These records must show the name or description of the articles they purchase or receive (§ 320.1(b)(1)(i)) and the name and address of the seller of the articles they purchase (§ 320.1(b)(1)(iv)). Establishments and retail facilities must provide FSIS access to these records (§ 320.4, 21 U.S.C. 642). FSIS expects that supplier lot numbers and production dates are normally available at Federal grinding establishments and retail facilities. In addition, FSIS expects that establishments or retail facilities would normally obtain the contact information FSIS is collecting.

In addition, FSIS is making available on the Internet address previously listed new guidance material on reducing the occurrence of *E. coli* O157:H7 for beef slaughter establishments and for live animal producers. In the guidance material for beef slaughter establishments, FSIS has included examples of published studies of decontamination methods that can be used as critical control points addressing *E. coli* O157:H7.

The Agency invites comments on the guidance materials it is making available. In the guidance materials, FSIS is emphasizing that it is important for everyone who is involved in producing beef products to have in place measures designed to prevent, eliminate, or reduce the presence of *E. coli* O157:H7 in their products.

In both the guidance material for beef grinders and suppliers of boneless beef and trim products and the guidance material for beef slaughter establishments, FSIS is recommending that establishments consider that *E. coli* O157:H7 prevalence may be higher in April through September than during other times of the year, and that they may have to account for this increased prevalence in their HACCP systems. Several studies show that the period from June to September is a high

prevalence season.²⁰ In addition, FSIS has recently reviewed establishment testing data that show greater *E. coli* O157:H7 prevalence in April through September. To account for increased *E. coli* O157:H7 prevalence, establishments may need to conduct more frequent or more rigorous verification activities, and they may need to employ more rigorous interventions, during April through September.

Finally, at the Internet address previously listed, FSIS is making available guidance material on the procedures for joint FSIS and FDA approval of ingredients and sources of radiation, including antimicrobials, used in the production of meat and poultry products and specific guidance on the use and labeling of ingredients and sources of radiation used to reduce microorganisms, particularly *E. coli* O157:H7, on beef carcasses, ground beef, and beef trimmings. This guidance document also includes a discussion on direct and secondary direct food additives and the appropriate use of the ingredient statement on the label of treated meat.

FSIS *E. coli* O157:H7 Testing Program

Currently, FSIS tests only raw ground beef products for *E. coli* O157:H7. In addition to continuing to test for *E. coli* O157:H7 in raw ground beef, FSIS is considering testing raw beef trimmings and other intact materials used in non-intact product and beef carcasses and parts (primals and subprimals) that will be processed into non-intact product. FSIS is considering testing trimmings, other source materials for non-intact product, and carcasses and parts that will be processed into non-intact product because controls to reduce the risk of *E. coli* O157:H7 when the product is still intact may be among the best ways to control the hazard. FSIS testing would verify the effectiveness of these controls. Such controls would include interventions used at slaughter, proper chilling practices, and

segregating product that has been treated with interventions from product that has not. The only treatment available to eliminate *E. coli* O157:H7 in raw, non-intact product (e.g., ground beef, blade tenderized steaks, and blade tenderized roasts) is a full bactericidal treatment, such as irradiation or cooking. However, there are also treatments that can be used that have been shown to reduce significantly the level of this pathogen. At this time, FSIS has not finalized plans to begin *E. coli* O157:H7 testing of raw beef trimmings, other intact materials used in non-intact product, and beef carcasses and parts that will be processed into non-intact product.

Although it has not finalized its plans regarding verification activities at establishments that produce intact product, FSIS intends to conduct verification activities at establishments that supply intact product to grinding establishments when the Agency determines that a supplier may be responsible for *E. coli* O157:H7-positive ground product. In this situation, FSIS intends to conduct verification activities concerning the supplier's HACCP system and Sanitation SOPs. FSIS also intends to conduct verification tests on trim when the Agency finds ground product at a grinder that receives product from outside sources positive for *E. coli* O157:H7 and is able to identify the supplier.

FSIS received a petition from the Center for Science in the Public Interest (CSPI), dated July 1, 2002, requesting that, in addition to its current testing of raw, ground beef for *E. coli* O157:H7, FSIS conduct *E. coli* O157:H7 testing of raw beef carcasses and beef trim. In their petition, CSPI also stated that slaughterhouses should be required to conduct *E. coli* O157:H7 testing of carcasses and trimmings. FSIS has posted a copy of the petition on the Internet at the address previously listed.

FSIS also received a letter from Excel Corporation, dated June 10, 2002, that included recommendations for changing FSIS' testing program. Excel Corporation stated that FSIS' sampling frequency should be based on what scientific evidence shows about the applied intervention's effectiveness in reducing *E. coli* O157:H7. Excel also stated that carcasses would need to be sampled more frequently than trim and trim more frequently than ground beef to reach the same level of statistical verification of the effectiveness of an intervention process.

Excel also recommended that FSIS provide that ground beef that has been tested and found negative for *E. coli* O157:H7 could be labeled to indicate

²⁰ Garber, L., et al., Factors associated with the shedding of verotoxin-producing *Escherichia coli* O157 on dairy farms. *J Food Prot.* 1999; 62(4): 307-312; Hancock, D.D., et al., The prevalence of *Escherichia coli* O157 in dairy and beef cattle in Washington State. *Epidemiol Infect.* 1994; 113: 199-207; Hancock D., Personal communication. Ongoing research project in collaboration with FDA-CVM. 2001; Hancock, D.D., et al., Effects of farm manure handling practices on *Escherichia coli* O157 prevalence in cattle. *J Food Prot.* 1997; 60(4): 363-366. Heuvelink, A.E., et al., Occurrence of verocytotoxin-producing *Escherichia coli* O157 on Dutch dairy farms. *J Clin. Microbiol.* 1998; Dec: 3480-3487; Van Donkersgoed, J.T., et al., The prevalence of verotoxins, *Escherichia coli* O157:H7, and *Salmonella* in the feces and rumen of cattle at processing. *Can Vet J.* 1999; 40:332-338.

this fact, so that FSIS program personnel would reduce their sampling of this product once it is at retail. Excel recommended the following statement be allowed on product that tests negative for *E. coli* O157:H7: "Product sampled and sample tested and found negative for *E. coli* O157:H7." FSIS has posted a copy of the letter on the Internet.

In modifying its verification sampling and testing program for *E. coli* O157:H7, FSIS will consider the data that its inspection program personnel collect concerning establishments' actions in response to the required HACCP plan reassessment and comments received concerning the Agency's *E. coli* O157:H7 testing program, the GSPI petition, and the letter from Excel Corporation.

FSIS Directive 10,010.1

According to the Agency's current sampling and testing program instructions in FSIS Directive 10,010.1, FSIS does not typically collect raw ground beef samples for *E. coli* O157:H7 testing at establishments that conduct activities addressing *E. coli* O157:H7 that are specified in the Directive, including testing for *E. coli* O157:H7. Recently, FSIS found that some of these establishments producing raw ground beef have had problems with *E. coli* O157:H7 contamination. Therefore, FSIS is in the process of revising the Directive so that no establishments producing raw ground beef will be exempt from FSIS *E. coli* O157:H7 sampling and testing. FSIS intends to sample and test product from all grinding establishments at this time. FSIS will also be developing a risk-based verification program that takes into account such factors as volume of production and effectiveness of interventions.

FSIS also intends to revise Directive 10,010.1 to make it consistent with HACCP. According to the existing Directive, if FSIS collects a raw ground beef sample from an establishment that tests positive for *E. coli* O157:H7, FSIS must continue to collect samples from that establishment until the Agency has obtained 15 consecutive negative test results.

FSIS intends to remove this provision from the Directive because FSIS believes that this policy is inconsistent with HACCP. Under HACCP, it is the establishment's responsibility to take appropriate corrective actions when a sample tests positive for *E. coli* O157:H7.

When FSIS has removed from the Directive the provision requiring 15 consecutive negative FSIS *E. coli*

O157:H7 test results following an FSIS *E. coli* O157:H7 positive test result, FSIS will exercise its discretion in determining the appropriate number of follow-up samples to collect and test and will make this determination based on the suspected cause of *E. coli* O157:H7 contamination and the establishment's corrective action.

The current Directive defines the "sampled lot" as all raw ground beef products produced between performance of complete cleaning and sanitization procedures for all equipment used in handling or processing a raw ground beef product. FSIS believes that this definition is too prescriptive, and that, under HACCP, establishments should be given more flexibility concerning the definition of the sampled lot. Therefore, FSIS is revising the Directive to recognize the establishment's definition of the sampled lot, provided the establishment has a scientific or other supportable basis for defining the sampled lot.

FSIS cautions, however, that an establishment's defined lot size does not relieve an establishment from its responsibility to consider whether there are connections between lots. For example, if multiple lots of raw ground product were produced from source materials from the same production lot of a single supplier, and some of this product was found positive for *E. coli* O157:H7, FSIS would expect the establishment to have a scientific basis that justifies why any raw ground product produced from those source materials should *not* be considered to be adulterated.

Finally, FSIS intends to revise the Directive to specify that the Agency will only collect samples of product that has passed pre-shipment record review in accordance with § 417.5(c).

FSIS does not intend to discontinue its *E. coli* O157:H7 testing program. By conducting its own verification sampling and testing program, FSIS will have meaningful data on the occurrence of *E. coli* O157:H7 in beef processing operations. FSIS invites comment on the issues related to FSIS Directive 10.010.1.

Comments

In response to the February 11, 2000, notice announcing the February 29, 2000, public meeting, FSIS received 294 comments, 285 of which were identical comments. Comments were from consumers, consumer groups, industry associations, a food animal concerns organization, and an FSIS employee. Comments addressed various issues including FSIS' policy concerning non-intact products announced in the

January 19, 1999, policy statement, FSIS and industry testing for *E. coli* O157:H7, and the FSIS *E. coli* O157:H7 risk assessment data that were presented at the February 29, 2000, public meeting. In addition, several commenters responded specifically to the questions for consideration that FSIS listed in the February 11, 2000, notice.

FSIS considered these comments when it developed plans to make the intended changes to Directive 10,010.1 discussed above. FSIS will continue to consider these comments, any comments submitted in response to this notice, the data that its inspection program personnel collect concerning establishments' actions resulting from the required reassessment, and baseline data for raw beef components of ground beef and beef patties and, possibly, baseline data for carcasses, as it determines how it will modify its *E. coli* O157:H7 testing program and as it makes any additional changes to the Directive addressing the program.

E. coli O157:H7 in Intact and Non-Intact (Tenderized) Beef

In May 2001, FSIS requested that the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) answer several questions with regard to *E. coli* O157:H7 in blade-tenderized, non-intact beef. NACMCF reviewed data from Kansas State University to respond to these questions. A February 14, 2002, report from NACMCF that includes FSIS' questions and NACMCF's response to the questions is available on the Internet at: <http://www.fsis.usda.gov/OPHS/NACMCF/index.htm>.

Based on the Kansas State data, NACMCF concluded that non-intact, blade tenderized beef steaks could potentially contain an infective dose of *E. coli* O157:H7 in their interior. NACMCF also concluded that blade tenderized steaks do not present a greater risk to consumers than intact beef steaks with regard to *E. coli* O157:H7 if the meat is oven broiled and cooked to an internal temperature of 140°F or above. However, NACMCF did not conclude that blade tenderized steaks pose no greater risk than intact steaks when cooked by other methods or when cooked to lower temperatures. The report suggested that blade-tenderized steaks may pose a risk, particularly to immunocompromised individuals, when served very rare with cold spots (that is, when cooked to an internal temperature of less than 120°F). All of NACMCF's risk estimates were based on a worst case scenario that assumed a very high concentration (3 x

10^3 cfu/gm) of *E. coli* O157:H7 in raw product.

NACMCF concluded that there is insufficient data to assess whether non-intact, blade tenderized beef roasts present a greater risk to consumers than intact beef roasts with regard to *E. coli* O157:H7 if prepared similarly to intact beef roasts.

Similarly, NACMCF concluded that there was insufficient data to respond to the question of whether scientific evidence supports the need for a labeling requirement to distinguish between intact and non-intact products to protect the public.

The NACMCF report identifies research needs for addressing *E. coli* O157:H7 in blade tenderized steaks and makes recommendations to FSIS concerning the Agency's future requests to NACMCF about this issue. In the event of an outbreak or a sporadic case of illness attributed to the consumption of beef steak, the report recommends that the CDC and FSIS gather data on cooking practices for the product that caused the illness, the processing of this product, and the purchase locations of this product.

FSIS has also conducted a comparative risk assessment of intact (nontenderized) and non-intact (blade tenderized) steaks. The results of the risk assessment are consistent with those of NACMCF. The risk assessment concluded that the risk of *E. coli* O157:H7 illness is not greater for broiled tenderized steaks than for broiled nontenderized steaks at temperatures between 110°F and less than 140°F, regardless of the initial *E. coli* O157:H7 contamination level or the susceptibility of the consumer. Also, the risk assessment concluded that the risk of illness associated with *E. coli* O157:H7 from broiled tenderized and broiled nontenderized steaks cooked to 140°F is miniscule, regardless of the initial contamination level or susceptibility of the consumer. Finally, the FSIS risk assessment concluded that the risk of illness is slightly higher for grilled or fried tenderized steaks compared to grilled or fried non-tenderized steaks at temperatures between 110°F and 140°F. The FSIS comparative risk assessment of intact and non-intact (blade tenderized) steaks is still a draft document and is available on the Internet address at: <http://www.fsis.usda.gov/oppde/rdad/publications.htm>. FSIS invites comments on this risk assessment.

FSIS also received a letter dated August 27, 2002, from the National Cattlemen's Beef Association concerning a study that evaluated the surfaces of beef sub-primal cuts for the

presence of *E. coli* O157:H7 prior to mechanical tenderization. According to this letter, the results of this study show that the incidence of *E. coli* O157:H7 on sub-primals is very low. FSIS is interested in evaluating the data from this study. The Agency may incorporate these data into its comparative risk assessment of intact and non-intact steaks. Therefore, these data may influence the comparative risk assessment.

FSIS is reviewing the NACMCF report and its draft risk assessment for *E. coli* O157:H7 in intact and non-intact (blade tenderized) steaks and will consider NACMCF's conclusions and the conclusions from the risk assessment with regard to the policy announced for non-intact products in the January 19, 1999, **Federal Register** (discussed above, under "*E. coli* O157:H7 policy"). At this time, FSIS believes that the public health hazard presented by *E. coli* O157:H7 and the prevalence of *E. coli* O157:H7 in these products continues to support application of the policy announced in the January 19, 1999, **Federal Register**. There is a lack of data on industry and consumer practices for cooking pinned, needled, and blade tenderized steaks (e.g., grilling, oven broiling, or frying) and a lack of data on the proportion of industry outlets and consumers that prepare these products according to each of these different methods. If FSIS obtains substantial and reliable data showing that industry and consumers customarily cook pinned, needled, and blade tenderized products in a manner that destroys *E. coli* O157:H7, FSIS would consider modifications to its policy concerning *E. coli* O157:H7 in these products.

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, in an effort to better ensure that minorities, women, and persons with disabilities are aware of this notice, FSIS will announce it and make copies of this **Federal Register** publication available through the FSIS Constituent Update. FSIS provides a weekly Constituent Update, which is communicated via Listserv, a free e-mail subscription service. In addition, the update is available on-line through the FSIS web page located at <http://www.fsis.usda.gov>. The update is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, recalls, and any other types of information that could affect or would be of interest to our constituents/stakeholders. The constituent Listserv

consists of industry, trade, and farm groups, consumer interest groups, allied health professionals, scientific professionals, and other individuals that have requested to be included. Through the Listserv and web page, FSIS is able to provide information to a much broader, more diverse audience.

For more information contact the Congressional and Public Affairs Office, at (202) 720-9113. To be added to the free e-mail subscription service (Listserv) go to the "Constituent Update" page on the FSIS web site at <http://www.fsis.usda.gov/oa/update/update.htm>. Click on the "Subscribe to the Constituent Update Listserv" link, then fill out and submit the form.

Done at Washington, DC, on October 3, 2002.

Garry L. McKee,
Administrator.

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SMALL BUSINESS ADMINISTRATION

13 CFR Part 121

Waiver of the Nonmanufacturer Rule

AGENCY: Small Business Administration (SBA).

ACTION: Final rule.

SUMMARY: The SBA has been made aware of the existence of small business manufacturers for Hand and Edge Tool Manufacturing, North American Industry Classification System (NAICS) 332212. Notices to waive the Nonmanufacturer Rule appeared in the **Federal Register** on August 28, 2002 (67 FR 55179) and July 27, 2002 (67 FR 47755). Comments from these notices were received from large and small business manufacturers. Our knowledge of the existence of small business manufacturers requires us to deny the waiver of the Nonmanufacturer for Hand and Edge Tool Manufacturing, NAICS 332212.

EFFECTIVE DATE: September 30, 2002.

FOR FURTHER INFORMATION CONTACT: Edith G. Butler, Program Analyst, U.S. Small Business Administration, 409 3rd Street, SW., Washington DC 20416, Tel: (202) 619-0422.

SUPPLEMENTARY INFORMATION: Public Law 100-656, enacted on November 15, 1988, incorporated into the Small Business Act the previously existing regulation that recipients of Federal contracts set aside for small businesses or SBA 8(a) Program procurement must provide the product of a small business manufacturer or processor, if the