DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Part 417

[Docket No. 04–042N]

HACCP Plan Reassessment for Mechanically Tenderized Beef Products

AGENCY: Food Safety and Inspection Service, USDA.

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

SUMMARY: The Food Safety and Inspection Service (FSIS) is publishing this notice to inform establishments that produce mechanically tenderized beef products that their next annual HACCP plan reassessment for these products must take into account the fact that there have been three relatively recent *Escherichia coli* (*E. coli*) O157:H7 outbreaks associated with consumption of mechanically tenderized beef. This requirement applies to HACCP plan reassessments for raw and cooked mechanically tenderized beef products, including such products that are injected with marinade (or ''enhanced'' products). One outbreak that was associated with consumption of mechanically tenderized beef occurred in August 2000, one in June 2003, and one in August 2004.

The occurrence of these outbreaks represents a change that would affect the hazard analysis and could alter the HACCP plans of establishments that produce mechanically tenderized beef products. Therefore, establishments that produce such products should consider the significance of the outbreaks and ensure that their HACCP plans adequately address relevant biological hazards, particularly *E. coli* O157:H7. If an establishment that produces mechanically tenderized beef products has already considered the significance of the three outbreaks as part of a HACCP plan reassessment, it need not repeat this effort. An establishment that has already conducted its 2005 reassessment for mechanically tenderized beef products and has not yet considered the significance of the three outbreaks as part of a HACCP plan reassessment should do so as part of its 2006 annual HACCP plan reassessment. FSIS invites comments on this notice.

DATES: The Agency must receive comments by July 25, 2005.

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

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

All submissions received must include the Agency name and docket number 04–042N.

All comments submitted in response to this notice, as well as research and background information used by FSIS in developing this document, will be available for public inspection in the FSIS Docket Room at the address listed above between 8:30 a.m. and 4:30 p.m., Monday through Friday. The comments also will be posted on the Agency's Web site at *http://www.fsis.usda.gov/regulations_&_policies/2005_Notices_Index/index.asp.*

FOR FURTHER INFORMATION CONTACT: Lynn Dickey, Director, Regulations and Petitions Policy Staff, Office of Policy, Program, and Employee Development, FSIS, U.S. Department of Agriculture, 1400 Independence Avenue, SW., Room 405, Cotton Annex, Washington, DC 20250–3700, (202) 720–5627.

SUPPLEMENTARY INFORMATION:

Background

FSIS administers a regulatory program under the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 *et seq.*) to protect the health and welfare of consumers by preventing the distribution in commerce of meat products that are adulterated or misbranded. In pursuit of its goal of reducing the risk of foodborne illness from meat products to the maximum extent possible, FSIS issued final regulations on July 25, 1996, that mandated the development and implementation of Pathogen Reduction and Hazard Analysis and Critical Control Point (HACCP) Systems by federally inspected establishments (61 FR 38806). These regulations require that federally inspected establishments take preventive and corrective measures at each stage of the food production process where food safety hazards occur. The HACCP regulations (9 CFR 417.2(a)) require establishments to conduct a hazard analysis to determine what food safety hazards are reasonably likely to occur in the production process of particular products and to identify the preventive measures that the establishment can apply to control those hazards.

Section 417.2(a)(1) of the HACCP regulations states that a food safety hazard that is reasonably likely to occur is one for which 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. Whenever a hazard analysis reveals that one or more hazards are reasonably likely to occur in the production process, the regulations require that the establishment develop and implement a written HACCP plan that includes specific control measures for each hazard identified (9 CFR 417.2(b)(1) and (c)).

Section 417.4(a)(3) of the regulations requires that every establishment reassess the adequacy of its HACCP plan at least annually and whenever any changes occur that could affect the hazard analysis or alter the HACCP plan. Because the outbreaks discussed in this notice are the first known outbreaks associated with consumption of mechanically tenderized beef products, and because there have been three outbreaks, the occurrence of these *E. coli* O157:H7 outbreaks is a change that could affect the hazard analysis or alter the HACCP plans for such products.

FSIS' Actions To Address E. coli O157:H7

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 (21 U.S.C. 601(m)(1)) unless the ground beef is further processed to destroy this pathogen. The public health risk presented by beef products contaminated with *E. coli* O157:H7 is not limited, however, to raw ground beef products. In the January 19, 1999, **Federal Register**, FSIS explained that if non-intact beef products, including beef that has been mechanically tenderized by needling or cubing, 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 2803).

In the October 7, 2002, **Federal Register**, FSIS informed manufacturers of raw beef products, including manufacturers of mechanically tenderized raw beef products, that they were required to reassess their HACCP plans, in light of certain scientific data on *E. coli* O157:H7, to determine whether *E. coli* O157:H7 contamination was a hazard reasonably likely to occur in their production process (67 FR 62325). The data discussed in that **Federal Register** provided evidence that *E. coli* O157:H7 was more prevalent than was thought before the data became available, and that this pathogen may be a hazard reasonably likely to

occur at all stages of handling raw beef products (67 FR 62328).

Although FSIS previously informed establishments producing mechanically tenderized raw beef products that they were required to reassess their HACCP plans based on the availability of specific scientific data related to the prevalence of *E. coli* O157:H7, only one outbreak (the 2000 outbreak discussed below) associated with such product had occurred at the time these establishments conducted their HACCP plan reassessments. In addition, FSIS has not previously required establishments that produce cooked mechanically tenderized beef products to reassess their HACCP plans to ensure that these HACCP plans adequately address biological hazards, particularly *E. coli* O157:H7.

E. coli O157:H7 Outbreaks Associated With Mechanically Tenderized Beef

In August 2004, the Colorado Department of Public Health and Environment (CDPHE) confirmed by culture tests four *E. coli* O157:H7 cases with matching Pulse-Field Gel Electrophoresis (PFGE) patterns in the Denver, Colorado, metropolitan area. The CDPHE determined that the individuals who became ill in this outbreak ate a tenderized, marinated beef steak product at four separate locations of a national restaurant chain. The CDPHE conducted an age and sex-matched case-control study that showed that consumption of this particular steak product was the only commonality of those who became ill. Although the CDPHE did not test product for *E. coli* O157:H7, the case-control study provided strong evidence that consumption of this product was associated with the outbreak. The producing establishment voluntarily recalled approximately 406,000 pounds of product. Information on this recall can be found on the FSIS web page (*http://www.fsis.usda.gov*), through the ''FSIS Recalls'' link, under recall case number 033–2004.

In June 2003, State health departments confirmed by culture tests eleven *E. coli* O157:H7 cases in five States: Seven cases in Minnesota, one case in Michigan, one case in Kansas, one case in Iowa, and one case in North Dakota. The cases were a two-enzyme PFGE pattern match. Based on the food intake histories of the persons who became ill, the State health departments epidemiologically linked all cases to a tenderized beef steak product (a boneless beef filet bacon-wrapped steak product injected with marinade). The Michigan Department of Agriculture Laboratory analyzed one sample of product associated with the outbreak and found it positive for *E. coli* O157:H7. The Minnesota Departments of Agriculture and Health Laboratories analyzed five samples of the product associated with the outbreak and found them positive for *E. coli* O157:H7. The product samples analyzed matched the two-enzyme PFGE pattern of the outbreak cases. The food histories of the persons who became ill, and the fact that the PFGE patterns in the product samples analyzed matched the outbreak cases, provided strong evidence that consumption of the tenderized steak product was associated with the outbreak.

At the time of the outbreak, the establishment that produced the tenderized beef steak product was thoroughly breaking down, cleaning, and sanitizing its injectors only once per week. The establishment subsequently documented a revised plan in its Sanitation Standard Operating Procedures (SOPs) to break down, clean, and sanitize its injection needles, tenderizing needles, and associated processing equipment on a daily basis. Also, after changing its Sanitation SOPs, the establishment incorporated in its production process an antimicrobial treatment of the product prior to the tenderizing and marinating process.

The establishment that had produced the product linked to the 2003 outbreak voluntarily recalled approximately 739,000 pounds of product. Information on this recall can be found on the FSIS web page (*http://www.fsis.usda.gov*), through the ''FSIS Recalls'' link, under recall case number 028–2003.

From information obtained from the Centers for Disease Control and Prevention and State health departments, FSIS identified another outbreak that was associated with the consumption of mechanically tenderized steaks. In August 2000, the Michigan Department of Community Health (MDCH) laboratory identified two human isolates of a distinct strain of *E. coli* O157:H7 with matching PFGE patterns. This strain had not been previously found in Michigan.

Local health departments obtained case histories from both of the persons who had become ill. The only similar possible exposure to the pathogen for the two individuals was a steak meal consumed by each on August 12, 2000, at different locations of a local restaurant steakhouse chain. Each individual had eaten a sirloin steak cooked to order with a red or pink center. The sirloin steaks were needle tenderized. The investigation of this matter suggested that the sirloin steak eaten by each person was likely the common source of the distinct strain of *E. coli* O157:H7 associated with these individuals' illnesses. The fact that both of the ill persons consumed an identical restaurant meal on the same day and had the onset of symptoms on the same date indicated that consumption of the tenderized beef steak product was associated with the illnesses. As a result of this investigation, the supplier of the steaks agreed to procedural changes in its operations, including sanitizing the needle-piercing machine used and testing its beef for *E. coli* O157:H7.

Reassessment in Response to Outbreaks

The *E. coli* O157:H7 outbreaks discussed above that were associated with consumption of mechanically tenderized beef products are events that could alter the hazard analysis, and ultimately the HACCP plan, of any establishment that produces mechanically tenderized beef products. Therefore, as part of their next annual HACCP plan reassessment for such products, establishments that produce raw or cooked mechanically tenderized beef products (with or without marinade), hereafter referred to as mechanically tenderized beef products, must take into account the *E. coli* O157:H7 outbreaks discussed above to determine whether their HACCP plans for these products adequately address biological hazards, particularly *E. coli* O157:H7. Establishments that produce mechanically tenderized beef products that have already taken these three outbreaks into account in a HACCP plan reassessment for these products are not required to consider these outbreaks in their next annual HACCP plan reassessment, provided the establishments have evidence of their reassessment in their hazard analysis or HACCP plans, or a record of reassessment, and make this evidence available to FSIS inspection program personnel.

When conducting a reassessment that takes these outbreaks into account to determine whether HACCP plans for mechanically tenderized beef products adequately address biological hazards, *E. coli* O157:H7 in particular, establishments may need to evaluate the adequacy of any *E. coli* O157:H7 interventions applied to the products' source materials. If they have not already done so, establishments producing mechanically tenderized beef products may wish to consider implementing purchase specifications that require that incoming product has been treated to eliminate or reduce *E. coli* O157:H7 to an undetectable level. If establishments producing mechanically tenderized beef products require their

suppliers to meet such purchase specifications, they should also ensure that their suppliers actually meet these purchase specifications. Establishments could incorporate such purchase specifications in their HACCP plans, in their Sanitation SOPs, which FSIS has recognized as prerequisites for HACCP, or in other prerequisite programs.

Establishments producing mechanically tenderized beef products might also consider applying an allowed antimicrobial agent to the surface of the product prior to processing or tenderization. FSIS has made available on its web site a document entitled, ''Guidance on Ingredients and Sources of Radiation Used to Reduce Microorganisms on Carcasses, Ground Beef, and Beef Trimmings.'' This document provides guidance on the use of antimicrobials on beef products. A link to the document is found with the October 7, 2002, **Federal Register** notice entitled, ''*E. coli* O157:H7 Contamination of Beef Products,'' on the ''Interim and Final Rules'' page of FSIS' web site *http://www.fsis.usda.gov/Regulations_&_Policies/2002_Interim_&_Final_Rules_Index/index.asp*.

When conducting their reassessment, establishments producing mechanically tenderized beef products should consider the number of times tenderizers pass through the product. In addition, they should evaluate the adequacy of their sanitation procedures for mechanical tenderizers, including needles, and for associated processing equipment, including reservoirs and piping associated with the tenderizing and enhancing operations. Because tenderizers pass through the product, they may introduce biological hazards, including *E. coli* O157:H7, into the interior of the product. Therefore, sanitation procedures are particularly important in the production of mechanically tenderized beef products. Thus, Sanitation SOPs, other prerequisite programs, or HACCP plans should address procedures that ensure that all mechanical tenderizers and associated processing equipment are cleaned on a regular basis to minimize the potential for translocating *E. coli* O157:H7 from the exterior surface of the product to the interior and to minimize the potential for cross contamination within and among lots of production.

Establishments producing raw, mechanically tenderized beef products might also consider including cooking instructions, in addition to required safe handling instructions (*e.g.*, cook to at least 140 degrees F), on packages of raw, mechanically tenderized beef products, or other labeling, to ensure that these products are cooked adequately to destroy *E. coli* O157:H7, should it be present. Such cooking instructions, or other labeling, however, cannot serve as a control or critical control point (CCP) to address *E. coli* O157:H7 in the production process of raw, mechanically tenderized beef products.

FSIS itself is considering requiring that raw, mechanically tenderized products be labeled to indicate that they have undergone mechanical tenderization, that the product is non-intact, and that it should be cooked to an adequate internal temperature to destroy any pathogens that may have been translocated from the surface of the product to the interior. Although the Federal meat and poultry products inspection regulations require that any marinade injected in a product be listed as an ingredient on the product's label, they do not require that product be labeled to indicate that it has been mechanically tenderized, and it is not possible to discern visually whether product has been mechanically tenderized.

Finally, establishments producing cooked mechanically tenderized beef products may need to consider whether their cooking procedures are adequate to destroy *E. coli* O157:H7, should it be present. Information on a study concerning the effects of cooking on *E. coli* O157:H7 in blade tenderized steaks is included in the following section of this document.

This section also includes information on published studies concerning bacteria other than *E. coli* O157:H7 in the interior of mechanically tenderized beef. In addition, it provides information on guidelines developed by industry associations regarding pathogen control in mechanically tenderized and enhanced beef products.

Research and Guidance on the Production of Mechanically Tenderized Beef Products

FSIS asked the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) to answer several questions with regard to *E. coli* O157:H7 in mechanically tenderized beef. NACMCF met on August 3, 2001, and January 23, 2002, to discuss these questions. A report on NACMCF's responses to FSIS'' questions is available on the Internet at *http://www.fsis.usda.gov/OPHS/NACMCF/2002/rep_blade1.htm*. The report is entitled, ''*Escherichia coli* O157:H7 in Blade-tenderized, Non-intact Beef'' (updated September 9, 2002).

FSIS asked NACMCF whether non-intact, blade tenderized beef steaks present a greater risk to consumers from *E. coli* O157:H7 compared to intact beef steaks, if prepared similarly to intact beef steaks. Based on information from a Master's thesis (Sporing, 1999), NACMCF concluded that non-intact, blade tenderized beef steaks do not present a greater risk to consumers from *E. coli* O157:H7 than intact beef steaks if the blade tenderized beef steak is oven broiled and cooked to an internal temperature of 140 degrees F or above. However, NACMF concluded that blade tenderized beef steaks present a greater risk from *E. coli* O157:H7 than intact beef steaks, particularly to immuno-compromised individuals, when served very rare with cold spots (less than 120 degrees F internal temperature).

FSIS also asked NACMCF whether non-intact, blade tenderized beef roasts present a greater risk to consumers from *E. coli* O157:H7 compared to intact beef roasts, if prepared similarly to intact beef roasts. NACMCF concluded that there were insufficient data to answer this question adequately.

Finally, FSIS asked NACMCF whether available evidence supports the need for a labeling requirement to distinguish between intact and non-intact products in order to enhance public health protection. Again, NACMCF concluded that there were insufficient data to make a response to this question at the time the committee met. The NACMCF report lists research needs at the end of the document.

Participants at the 2004 Conference of Food Protection discussed the handling of blade tenderized steaks at retail facilities and restaurants. Participants discussed the fact that blade tenderized products typically are not labeled to indicate that the products have been tenderized. They considered data from the Master's thesis that NACMCF reviewed (Sporing, 1999). These data showed that 3 to 4 percent of the surface bacterial load of blade tenderized beef steaks is transferred to the interior of the product. According to the thesis, among three methods of preparation—oven cooking, commercial grilling, and skillet cooking—skillet cooking provided the least effective and most variable reduction in *E. coli* O157:H7.

Participants in the 2004 Conference for Food Protection recommended that the Food and Drug Administration (FDA) and USDA work together to develop guidance for retail facilities and restaurants on the safe cooking of blade tenderized steaks and other non-intact steaks. The participants recommended that this guidance be included in the Annex of the Food Code, and that FDA and USDA submit this guidance at the 2006 Conference for Food Protection.

FDA and USDA intend to prepare this guidance.

Several articles in peer-reviewed journals discuss studies on the penetration of bacteria other than *E. coli* O157:H7 into the interior of mechanically tenderized beef products. For example, one study concerning *salmonellae* inoculated in beef rounds found that mechanical tenderization increased the level of *salmonellae* in core samples by about 1 logarithm, that dripping inoculated rounds into a 50 parts per million (ppm) chlorine solution did not prevent the occurrence of *salmonellae* in core samples of mechanically tenderized units, and that *Salmonella* survived in the core and on the surface of some, but not all, inoculated rounds cooked to an internal temperature of 130 degrees F (''The Effect of Mechanical Tenderization on Beef Rounds Inoculated with *Salmonellae*,'' Johnson, R.W.; Harris, M.E., and Moran, A.B., *Journal of Food Safety*. 1978; 1(3): 201–209; 9 ref.).

In another study, samples of mechanically tenderized beef were subjected to enumeration of aerobes, coliforms, *E. coli*, and organisms that formed black or grey on Harlequin TM agar (a medium formulated for recovery of *Listeria*). The study concluded that cooking mechanically tenderized beef to a medium rare condition may be adequate for ensuring the microbiological safety of this product, provided it is devoid of excessive contamination of deep tissues (''Microbiological Conditions for Mechanically Tenderized Beef Cuts Prepared at Four Retail Stores,'' Gill, C.O.; McGinnis, J.C., *International Journal of Food Microbiology*. 2004; 95(1): 95–102).

Another study found that cleaning and sanitizing the tenderizer with an iodine-based sanitizer (25 ppm titratable iodine) decreased the bacterial levels of mechanically tenderized rounds (''Microbial Aspects of Mechanical Tenderization of Beef,'' Raccah, M.; Henrickson, R.L., *Journal of Food Protection*. 1979. 42(12): 971–973; 20 ref.).

Several industry associations (the American Meat Institute, the National Cattlemen's Beef Association, the National Meat Association, and the Southwest Meat Association) have developed guidelines to address pathogen control in mechanically tenderized beef products and enhanced beef products. These guidelines are currently available on the Internet, on the Beef Industry Food Safety Council Web site at *http://www.bifsco.org/BestPractices.aspx*. The guidelines present recommended practices throughout tenderizing or enhancing operations and during cleaning and sanitizing operations.

FSIS Actions To Enforce and Facilitate Compliance with the Reassessment Requirement

The Agency intends to instruct its inspection program personnel to determine whether establishments have considered the significance of the three outbreaks discussed in this notice as part of an annual HACCP plan reassessment for mechanically tenderized beef products. FSIS will also instruct inspection program personnel to ensure that all establishments producing mechanically tenderized beef products, including small and very small establishments that may not belong to a trade association, are aware that the Agency has issued this notice. Finally, FSIS intends to instruct its inspection program personnel to collect data concerning the outcomes of the required reassessment.

Paperwork Reduction Act

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

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, in an effort to ensure that the public and in particular minorities, women, and persons with disabilities, are aware of this notice, FSIS will announce it on-line through the FSIS web page located at *http://www.fsis.usda.gov/regulations__&__policies/2005__Notices__Index/index.asp.*

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

In addition, FSIS offers an email subscription service which provides an automatic and customized notification when popular pages are updated, including **Federal Register** publications and related documents. This service is available at *http://www.fsis.usda.gov/news_and_events/email_subscription/* and allows FSIS customers to sign up for subscription options in eight categories. Options range from recalls to export information to regulations, directives and notices. Customers can add or delete subscriptions themselves and have the option to password protect their account.

Done at Washington, DC on: May 20, 2005.

Barbara J. Masters,

Acting Administrator.

[FR Doc. 05–10471 Filed 5–25–05; 8:45 am]

BILLING CODE 3410–DM–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 1 and 602

[TD 9207]

RIN 1545–AX93

Assumption of Partner Liabilities

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final and temporary regulations; and removal of temporary regulations.

SUMMARY: This document contains final regulations relating to the definition of liabilities under section 752 of the Internal Revenue Code (Code). These regulations provide rules regarding a partnership's assumption of certain fixed and contingent obligations in connection with the issuance of a partnership interest and provide conforming changes to certain regulations. These regulations also provide rules under section 358(h) for assumptions of liabilities by corporations from partners and partnerships. Finally, this document also contains temporary regulations relating to the assumption of certain liabilities under section 358(h). The text