Consumer Federation of America

October 7, 2013

Docket Clerk
U.S. Department of Agriculture
Food Safety and Inspection Service (FSIS)
Patriots Plaza 3, 1400 Independence Avenue SW.
Mailstop 3782, Room 8– 163B
Washington, DC 20250–3700

Re: Docket No. FSIS– 2008-0017

To Whom It May Concern:

The Consumer Federation of America (CFA) appreciates the opportunity to comment on the Proposed Rule "Descriptive Designation for Needle- or Blade-Tenderized (Mechanically Tenderized) Beef Products" (Docket No. FSIS–2008-0017). CFA strongly supports the labeling of mechanically tenderized beef.

The Risk of Mechanically Tenderized Beef

Beef is mechanically tenderized through a process of piercing the product with a set of needles or blades, which break up muscle fiber and tough connective tissue, resulting in increased tenderness. These needles or blades pierce the surface of the product increasing the risk that any pathogens, such as *E. coli* or *Salmonella*, located on the surface of the product can be transferred to the interior.[1]

Mechanical tenderization is a common practice in the beef industry, although estimates of the extent of the practice vary. According to FSIS's 2008 *E. coli* Checklist, 37 percent of establishments (850 0f 2323) indicated that they had a mechanical tenderization operation.[2] More than 80 percent of the establishments surveyed indicated they did not test source materials or finished product for *E. coli* O157:H7. Based on the survey, FSIS estimated that over 50 million pounds of mechanically tenderized beef products were being produced each month.[3] More recently, a 2012 report by RTI International estimates that there are 555 official establishments

[1] Luchansky JB, Phebus RK, Thippareddi H, Call JE. Translocation of surface-inoculated Escherichia coli O157:H7 into beef subprimals following blade tenderization. *J Food Prot.* 2008 Nov; 71(11):2190-7..
[2] FSIS Checklist and Reassessment of Control of *E. coli* O157:H7 in Beef Operations, Available at: http://www.fsis.usda.gov/wps/wcm/connect/9ce5ce22-f609-4990-bd9a-ce2c323d229b/Ecoli_Reassement___Checklist.pdf?MOD=AJPERES.
[3] U.S. Department of Agriculture. 2008. Results of Checklist and Reassessment of Control for *Escherichia coli* O157:H7 in Beef Operations, p. 35. Available at: www.fsis.usda.gov/PDF/Ecoli_Reassement_&_Checklist.pdf.

that produce blade, needle, and both blade and needle mechanically tenderized beef products.[4] RTI further estimated that 10.5% of raw beef products are mechanically tenderized, and 15.8% are mechanically tenderized and enhanced.[5] Additionally, RTI estimates that the food service industry market share for mechanically tenderized beef (including beef containing added solution) is 53 percent and the market share for retail is 47 percent. In its proposed rule, FSIS estimates that mechanically tenderized beef accounts for 6.2 billion servings annually.

Currently, consumers, food service and retail outlets which purchase beef products are unable to distinguish between mechanically tenderized beef and non-mechanically tenderized, intact beef. Mechanically tenderized products typically have no visible signs of mechanical tenderization and processors provide no information indicating that the products have undergone such a process. This is important because research has demonstrated that pathogens that may be on the surface of a steak or roast can be translocated into the center of the product thru the process of mechanical tenderization.[6] [7] [8] Thus mechanically tenderized products must be cooked more thoroughly than intact beef in which pathogens are only present on the surface of the product.

Since 2003, the CDC has identified five outbreaks attributable to mechanically tenderized beef products prepared in restaurants and consumers' homes. Among these outbreaks, there were a total of 157 *E. coli* O157:H7 cases that resulted in 34 hospitalizations and 4 cases of hemolytic uremic syndrome (HUS). Failure to thoroughly cook a mechanically tenderized raw or partially cooked beef product was a significant contributing factor in all of these outbreaks.[9]

Outbreaks linked to tenderized/marinated steaks in the United States:

- 2009 recall of blade tenderized steaks, vacuum tumbled with marinade (25 illnesses, 10 hospitalizations)[10]
- April-May 2007 recall of needle injected and marinated steaks (8 illnesses, 6 hospitalizations)[11]

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[4] Muth MK, BallM, Coglaiti MC. "RTI International Final Report—Expert Elicitation on the Market Shares for Raw Meat and Poultry Products Containing Added Solutions and Mechanically Tenderized Raw Meat and Poultry Products." February 2012. Table 3–11 on p. 3–17.

[5] Based on slaughter volumes multiplied by average carcass weights in the "Expert Elicitation on the Market Shares for Raw Meat and Poultry Products Containing Added Solutions and Mechanically Tenderized Meat and Poultry Products," RTI International, February 2012.

[6] Gill CO, McGinnis JC, "Factors Affecting the Microbiological Condition of the Deep Tissues of Mechanically Tenderized Beef." *Journal of Food Protection* 68:4 (796-800), 2005.

[7] Stopforth JD, Lopes M, Shultz JE, Miksch RR, Samadpour M, "Microbiological Status of Fresh Beef Cuts." *Journal of Food Protection* 69:6 (1456-1459), 2006.

[8] Luchanksy JB, Phebus RK, Thippareddi H, Call JE, "Translocation of Surface-Inoculated Escherichia coli O157:H7 into Beef Subprimals following Blade Tenderization." *Journal of Food Protection* 71:11 (2190-2197), 2008.

[9] Culpepper W, Ihry T, Medus C, Ingram A, Von Stein D, Stroika S, Hyytia-Trees E, Seys S, Sotir MJ. "Multi-state outbreak of *Escherichia coli* O157:H7 infections associated with consumption of mechanically-tenderized steaks in restaurants—United States, 2009." Presented at International Association for Food Protection; August 1–4, 2010; Anaheim, CA. Swanson, L. E., Scheftel, J.M., Boxrud, D.J., Vought, K.J., Danila, R.N., Elfering, K.M., and Smith, K.E. 2005. Outbreak of *Escherichia coli* O157:H7 infections associated with nonintact blade-tenderized frozen steaks sold by door-to-door vendors. *J. Food Prot* 68:(1198–1202).

[10] FSIS News Release for Recall 067-2009

[11] FSIS News Release for Recall 019-2007

- May-Aug. 2007 no recall; outbreak related to needle tenderized, seasoned tri-tip beef (124 illnesses, 8 hospitalizations)[12]
- July-Aug. 2004 recall of blade tenderized steaks exposed to marinade in vacuum tumbler (4 illnesses, 1 hospitalization) [13]
- May-June 2003 recall of bacon wrapped steaks, mechanically tenderized, injected flavoring (13 illnesses, 7 hospitalizations) [14]

Because the transfer of pathogens from the surface to the interior of the product is a defining feature of the product, yet indistinguishable to the average consumer, labeling is essential to inform consumers that the products have been mechanically tenderized and must be handled and cooked differently.

CFA Supports Labeling of Mechanically Tenderized Beef

CFA strongly supports FSIS's decision that all mechanically tenderized beef should be labeled to identify the product as having undergone that process, regardless of where the treatment has been applied. CFA agrees that labels should be used both for products consumers purchase in the grocery store and other retail outlets, as well as on products distributed to food service establishments.

CFA further supports the use of the term "mechanically tenderized" on the label to designate beef products which have been needle- or blade-tenderized, including beef products injected with a marinade or solution. The term "mechanically tenderized" is accurate and truthful, and is more likely to be understood by the general public than a regulatory term like "non-intact." The term is also one that is generally understood by the regulated industry and has been used consistently by FSIS over the years.

FSIS is proposing that the print for all words in the descriptive designation, as well as the words in the description of the product, appear in the same font style, color, and size as the product name and on a single-color contrasting background. Labeling of mechanically tenderized beef is essential so that consumers are informed that this product is different from an intact product. Therefore the designation of the product as "mechanically tenderized" must occur in such a way to ensure that consumers will recognize it. However, CFA would be amenable to slight variations in FSIS' proposed requirements for font size. For instance, a descriptive designation that is one font size smaller will still be obvious and easily seen by the consumer. However a descriptive designation that is more than one font size smaller will more likely be passed over or ignored by a consumer. In terms of font style and color, it is important that the term "mechanically tenderized" be clearly linked to the name of the product, so that consumers are aware that the product has undergone this process. Consequently, CFA supports those elements of FSIS' proposal.

[12] CDC Foodborne Outbreak Database
[13] FSIS Notification for Recall 033-2004
[14] FSIS Notification for Recall 028-2003

Cooking Temperatures

CFA strongly supports FSIS's decision to require validated cooking instructions on the labels of mechanically tenderized beef. CFA agrees that the cooking instructions should be practical and likely to be followed. At a minimum, the cooking instructions should include the method of cooking; an internal temperature validated to ensure that potential pathogens are destroyed throughout the product; whether the product needs to be held for a specified time at that temperature or higher before consumption; how often the product should be turned (for steaks) to achieve adequate pathogen destruction; and instruction that the internal temperature should be measured by the use of a thermometer. CFA further agrees that validated cooking instructions should result in at least a 5-$\log_{10}$ reduction of *Salmonella* and shiga toxin-producing *E. coli* (STEC) organisms including *E. coli* O157:H7. Cooking instructions should also be validated based on the state of the product; i.e., whether the product will be cooked from a frozen or fresh state.

CFA acknowledges that a cooking temperature of 145°F combined with a stand time of three minutes is likely to achieve the same level of food safety as an instantaneous temperature of 160°F under normal cooking conditions. However multiple variables such as the nature of the cooking process (the type of cooking, how frequently the product is turned, whether the product is cooked from a frozen or fresh state, cold spots in the product); the nature of the steaks (thickness, amount of contamination); whether consumers understand the importance of stand time to food safety and follow the practice; and whether food thermometers are used all complicate the issue substantially.

CFA has additional concerns about inconsistencies and confusion that could arise if the validated cooking instructions on each package of meat are different. Consumers purchasing steaks from different stores or companies could be faced with different cooking recommendations for each steak. According to FSIS' proposal and based on Appendix A of the guidance, companies could label their mechanically tenderized steak as requiring an instantaneous endpoint temperature of 160°F or as requiring a temperature of 150°F plus a one minute stand time. Companies could conceivably label their steaks as requiring a temperature of 140°F plus a 9 minute stand time, based on the chart in Appendix B. These recommendations would conflict with each other as well as with FSIS' current recommended cooking temperature of 145°F and a 3 minute stand time.

Further, several of the studies cited in the proposed rule and accompanying guidance suggest that higher temperatures may be more effective in assuring the safety of mechanically tenderized products than lower temperatures. Luchansky et al notes that using different cooking appliances can have an "appreciable effect on the extent and rate that microbes are inactivated in foods" and suggests that the "potential for illness can be appreciably lessened by ensuring that all portions of each steak or piece of meat achieve the recommended end point temperature of 160 degrees Fahrenheit."[15] Sporing concludes that, "If the objective is to achieve a consistent 5 log reduction for *E. coli* O157:H7, as is the requirement for ground beef, internal steak temperatures greater

[15] Luchansky JB, Porto-Fett ACS, Shoyer BA, Call JE, Schlosser W, Shaw W, Bauer N, Latimer H, "Fate of shiga toxin-producing O157:H7 and non-O157:H7 *Escherichia coli* cells within blade-tenderized beef steaks after cooking on a commercial open-flame gas grill." *J Food Prot.* 75 (62-70), 2012.

than 60.0°C [140°F] may be required, depending on the cooking method recommended."[16] A second Luchanksy study states that given the nature of steaks and cooking processes, "it is likely that not all portions of the meat achieved the target temperature; however this would result in significant reductions in pathogen numbers (e.g., 2.5 to 5.0 log), albeit while allowing for the recovery of fortuitous survivors…Thus, it may be necessary to evaluate slightly higher endpoint cooking temperatures, with or without a holding time, to ensure total elimination of ECOH and STEC." [17] A third, and most recent, Luchansky study points to the fact that cold spots within meat products could allow for fortuitous survivors of pathogens even after cooking to the proper endpoint temperatures. While this last study focused on ground beef patties, it raises questions about whether cold spots in mechanically tenderized steaks might lead to similar results.[18]

Another study by Gill et al emphasizes the importance of turning steaks frequently (i.e., more than once) when cooking to assure that the product reaches sufficient temperatures to destroy pathogens.[19] The study found that *E. coli* O157:H7 inoculated into steaks were more likely to survive at the edges of the steaks even if the center reached the appropriate temperature, a particularly important finding for steaks cut from mechanically tenderized primals. The study concluded, "the findings clearly show that, in some circumstances at least, cooking steaks to 71°C (160°F) after turning over once could have relatively small effect on *E. coli* O157:H7 at some points in some steaks. The findings also show that turning steaks over more than once during grilling will give greater certainty of adequate heating of all parts of steak than will turning over only once. Moreover, temperature history data indicated that holding steaks after cooking when they are turned over only once during grilling will not reliably compensate for inadequate heating of some parts of the steaks during cooking. These factors should be taken into account in the formulation of instructions for safe cooking of mechanically tenderized steaks."

Considering the conclusions in the studies cited above and the importance of providing consumers with accurate and easy-to-follow recommendations, CFA believes that an endpoint temperature of 160°F is most protective of public health and labels on mechanically tenderized steaks should recommend cooking to that temperature. FSIS recommends that ground beef be cooked to 160°F due to the likelihood of pathogens spread throughout the product and mechanically tenderized beef raises a similar concern. Requiring labels with an endpoint temperature of 160°F also reduces the reliance on stand times to achieve safety.

If FSIS decides to permit companies to label mechanically tenderized steaks with cooking instructions that include temperatures other than 160°F, the agency should only permit temperatures of 145°F plus a 3 minute stand time, or higher. CFA is particularly concerned that

[16] Sporing, SB. "Escherichia coli O157:H7 Risk Assessment for Production and Cooking of Blade Tenderized Beef Steak." Thesis. Kansas State University, 1999.
[17] Luchansky JB, Porto-Fett ACS, Shoyer BA, Call JE, Schlosser W, Shaw W, Bauer N, Latimer H, "Inactivation of shiga toxin-producing O157:H7 and non-O157:H7 shiga toxin-producing *Escherichia coli* in brine-injected gas-grilled steaks." *Journal of Food Protection* 74 (1054-1064), 2011.
[18] Luchansky JB, et al, "Fate of Shiga Toxin-Producing O157:H7 and Non-O157:H7 *Escherichia coli* Cells within Refrigerated, Frozen, or Frozen Then Thawed Ground Beef Patties Cooked on a Commercial Open-Flame Gas or a Clamshell Electric Grill." *Journal of Food Protection* 76:9 (1500-1512), 2013.
[19] Gill CO, Yang X, Uttaro B, Badoni M, Liu T, "Effects on Survival of Escherichia coli O157:H7 in Non-Intact Steaks of the Frequency of Turning Over Steaks During Grilling." *Journal of Food Research* Vol 2, No 5 (77-89), 2013.

temperatures below 145°F will be insufficient to destroy pathogens in the product and will be accompanied by unreasonable lengths of time that the product must stand before consuming. In addition the Gill study points to the importance of sufficient turning frequency which should be incorporated into the cooking instructions. Temperatures below 145°F with long stand times would also not be consistent with FSIS' stated intention that cooking instructions be "practical and likely to be followed by consumers." FSIS should clarify how Appendix B should be used and that companies should not be permitted to label their products with temperature/time combinations below 145°F/3 minute stand time.

Educational Outreach

CFA supports FSIS's decision to conduct a public education campaign to explain the significance of the term "mechanically tenderized" to consumers as part of the implementation of the final rule. CFA encourages the development of a public education outreach campaign to inform the public about the new labeling requirements, what mechanical tenderization means, and the proper cooking and handling procedures necessary to reduce the risk of foodborne illness from mechanically tenderized beef products. In particular, FSIS should emphasize the importance of "stand time" and the role stand times play in food safety.

FSIS should conduct outreach to food service and retail purchasers of beef products as well, although such outreach should be different and separate from a public education campaign. FSIS should conduct its education and outreach campaigns as soon as the rule is finalized, even if labeling requirements have yet to be fully implemented.

FSIS should plan ways to address the challenges inherent in public education campaigns of this nature. If FSIS chooses to allow cooking temperatures other than 160°F, the agency should consider how its messaging will address multiple cooking temperatures in the marketplace as well as possible inconsistencies with FSIS' current recommended cooking temperatures and what consumers will see on the package label.

Much information is available online to consumers about cooking temperature recommendations beyond the FSIS website. While many online recommendations reference the USDA cooking recommendations, they also provide a second set of cooking temperatures used in "professional kitchens." See the following websites for examples:

- The Reluctant Gourmet: http://reluctantgourmet.com/tips-guides/tips-facts/item/1118-meat-doneness-chart
- The Food Network: http://www.foodnetwork.com/recipes-and-cooking/meat-and-poultry-temperature-guide/index.html
- Martha Stewart: http://www.marthastewart.com/270074/meat-temperatures-chart
- Wikipedia: http://en.wikipedia.org/wiki/Temperature_%28meat%29

Some of the websites cited above provide good contextual information concerning the safety of meat products and adequate cooking temperatures. However, it will be important for these same references to include information about mechanically tenderized meat products and how to cook these products properly.

Pork, Poultry, and Other Mechanically Tenderized Meat
CFA believes that other mechanically tenderized products such as pork or poultry could raise similar food safety concerns and should also require labeling and validated cooking instructions. It is just as likely that the pathogens from the surface of a cut of pork or poultry are pushed to the interior of the product from the piercing of needles and blades, as it is for mechanically tenderized beef. However, CFA recognizes that FSIS does not have sufficient data on the risk posed by other mechanically tenderized products to make that determination at this time. CFA urges FSIS to conduct research on these other products to determine the amount of product produced and potential food safety concerns. FSIS should also consult with USDA's Agricultural Research Service to conduct research on these products.

Enzyme-Formed Product
FSIS currently requires enzyme-formed product, or product bound together with transglutaminase enzyme, to include a descriptive designation on its label, distinguishing it from other products. This is important since these products are formed from multiple pieces of beef rather than a single piece of beef and are therefore, non-intact. CFA supports the current labeling of these products and would support a requirement for validated cooking instructions as well. According to the American Meat Institute, manufacturers of transglutaminase and beef fibrin estimate that, totaled, their use would affect about 8 million pounds of meat consumed each year in the U.S.[20], primarily in the food service setting. Validated cooking instructions would help reinforce the importance of cooking these products to the appropriate temperature.

CFA appreciates the opportunity to provide comments on this important issue.

Sincerely,

Chris Waldrop
Director, Food Policy Institute

[20] American Meat Institute. "Transglutaminase and Beef Fibrin: Facts, Figures & Falsehoods." Available at: http://www.meatami.com/ht/a/GetDocumentAction/i/78448