

United States Department of Agriculture
Food Safety and Inspection Service
1400 Independence Avenue, SW
Room 1175, South Building
Washington, D.C. 20250

[Docket No. FSIS-2008-0017]

Re: Descriptive Designation for Needle- or Blade- Tenderized (Mechanically Tenderized) Beef Products

Founded in 2006 to help America create innovative, science-based solutions for the food safety challenges of the 21st century, the Center for Foodborne Illness & Research (CFI) is a national non-profit dedicated to advancing a stronger, more science based food safety system that prevents foodborne illness and protects public health. CFI appreciates the opportunity to comment on USDA's Food Safety and Inspection Service (FSIS) proposal, *Descriptive Designation for Needle or Blade Tenderized (Mechanically Tenderized) Beef Products* [Docket No. FSIS –2008—0017]. ***CFI applauds FSIS for proposing this new labeling requirement because it will protect public health by providing food preparers, including restaurant, institutional and household cooks, with important information that can prevent foodborne illness.***

Background

Protecting public health is the major objective of FSIS. According to the Centers for Disease Control and Prevention (CDC), there are an estimated 73,000 *E. coli* O157:H7 infections each year, causing significant morbidity and mortality, with disease severity ranging from mild symptoms to severe diarrhea to death. Approximately 15% of *E. coli* O157:H7 patients will develop HUS, a condition that consists of acute kidney failure, anemia and decreased platelet counts.¹ Further, *E. coli* O157:H7 infections, especially those that develop HUS or TTP, have been associated with secondary long-term health outcomes, including chronic kidney disease and neurological dysfunction.²

In 1994, following the Jack-in-the-Box outbreak, FSIS recognized *E. coli* O157:H7 as a significant public health risk and declared it an adulterant in raw ground beef. Later, FSIS required cooking instruction labels for raw ground beef product and expanded its *E. coli* testing program to include raw beef trim. Most recently, FSIS has declared six additional non-O157 STECs as adulterants in ground beef.

Since 2003, CDC has identified five outbreaks associated with needle or blade-tenderized beef prepared in restaurants and consumers' homes. These outbreaks caused a total of 157 *E. coli* O157:H7 cases that resulted in 34 hospitalizations and 4 cases of hemolytic syndrome (HUS). Insufficient cooking of non-

¹ Roberts T, Kowalczyk B and Buck, P. 2009. The long-term health outcomes of selected foodborne pathogens. White paper, Center for Foodborne Illness Research & Prevention. Accessed 7/20/13 at: http://www.foodborneillness.org/images/stories/cfi_pdfs/CFI_LTHO_PSP_report_Nov2009_050812.pdf.

² Batz MB, Henke E, Kowalczyk B. 2013. Long-term consequences of foodborne infections. *Infect. Dis. Clin. North Am.* (3) 599-616.

intact, mechanically tenderized (MT) beef product was cited as a significant factor in all of these outbreaks.³

Much research has been conducted on the translocation of pathogens, like *E. coli* O157:H7 and *Salmonella*, from the surface to the interior of non-intact MT beef products.^{4 5 6} Further, given the preferences that consumers have for lightly cooked beef (but not for undercooked pork or poultry), it is critical that food preparers be able to identify MT beef product and have explicit cooking instructions to reduce the risk of disease. Without a label and cooking instructions, the public's health is compromised because MT beef appears the same as intact beef steaks and roasts – there is no visual clue (except with cubed beef) that would alert food preparers that complete cooking is necessary to ensure safety.

In 2007, due to an increase in *E. coli* O157:H7 positive test results and recalls involving USDA beef products, FSIS issued Notice 65-07 instructing FSIS inspection personnel to notify establishments of these trends. The Notice also called for a re-evaluation of establishments' hazard analysis, which could impact on their Hazard Analysis and Critical Control Points plans (Reassessment), and included a checklist to collect information about the practices at several types of raw beef operations (Checklist). FSIS received 2,002 Reassessment responses and 2,323 Checklist responses, more than a 90% response rate.⁷ Based on this Reassessment and the Checklist, FSIS determined that 37% of beef establishments (850 of 2323) had a mechanical tenderization operation, resulting in over 50 million pounds of MT beef products being produced each month. In addition, of the establishments reporting about their MT beef production, 80% indicated that they did not test source materials or finished product for *E. coli* O157:H7.⁸

Similarly, in 2012 an expert elicitation was conducted by RTI International to determine the size of the market and the size distribution of the firms producing enhanced and/or mechanically tenderized meat and poultry products. The RTI report found that 10.5% of raw beef products are mechanically tenderized and that 15.8% are mechanically tenderized and enhanced.⁹ Of this treated product, it was estimated that the food service industry market share for mechanically tenderized beef (including beef containing added solution) is 53% and the market share for retail is 47%.

FSIS estimates that the expected number of *E. coli* O157:H7 illnesses caused by MT beef products could range from 587 to 4,657 per year and suggests that 133 to 1,497 illnesses could be averted by labeling

³ Culpepper W, Ihry T, Medus C and et al. 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.

⁴ Gill CO and McGinnis JC. 2005. Factors affecting the microbiological condition of the deep tissues of mechanically tenderized beef. *J of Food Protect*, 68(4): 796-800.

⁵ Luchansky JB, Phebus RK, Thippareddi H and Call JE. 2008. Translocation of surface-inoculated *Escherichia coli* O157:H7 into beef subprimals following blade tenderization. *J of Food Protect* 71(11): 2190-97.

⁶ Luchansky JB, Porto-Fett, AC, Shoyer BA et al. 2010. Inactivation of shiga toxin-producing O157:H7 and non-O157 shiga toxin-producing *Escherichia coli* in brine-injected, gas-grilled steaks. *J of Food Protect* 74(7): 1054-64.

⁷ US Department of Agriculture. 2008. Results of checklist and reassessment of control for *Escherichia coli* O157:H7 in beef operations. Accessed 9/28/13 at: http://www.fsis.usda.gov/wps/wcm/connect/9ce5ce22-f609-4990-bd9a-ce2c323d229b/Ecoli_Reassessment_Checklist.pdf?MOD=AJPERES.

⁸ ---- Ibid.

⁹ Muth MK, Bali M, Coglaiti MC. 2012. Expert elicitation on the market shares for raw meat and poultry products containing added solutions and mechanically tenderized meat and poultry products. RTI International Final Report, No. 0211740.012, February, 2012. Accessed 9/28/13 at: http://www.fsis.usda.gov/wps/wcm/connect/3a97f0b5-b523-4225-8387-c56a1eeee189/Market_Shares_MTB_0212.pdf?MOD=AJPERES.

MT beef products.¹⁰ The average cost for an *E. coli* O157:H7 infection is estimated to be \$3,281 (in 2010 dollars) – however, this estimate is likely to be conservative since it does not include the costs of pain and suffering of the acute illness and the long-term health complications of an *E. coli* O157:H7 infection. FSIS anticipates that the economic benefits could range from \$436,000 to \$4,911,000.¹¹ Further, the industry cost and the budgetary impact on the Agency for implementing this proposed rule is expected to be low.¹²

FSIS should label mechanically tenderized beef product that is destined for restaurants/institutions, as well as product that is destined for consumer retail outlets. In 2009, the Safe Food Coalition (SFC) submitted a petition to USDA/FSIS to label all MT meat and poultry products. Over the past four years, SFC has maintained the position that the mechanical tenderization process presents a serious health risk because MT meat and poultry products need complete cooking to kill internal pathogens. The proposed MT beef label is an effective method for providing consumers with important information about products so that they can make informed choices. CFI is pleased that FSIS is now proposing this type of a label for MT beef products and plans to work with FSIS to expand this requirement to all MT meat and poultry products.

Label Placement and Characteristics

The purpose of the label is to draw attention to MT product. CFI supports a label to identify MT beef, regardless of where or when the product is mechanically tenderized. Included in the MT beef category are products that have been needle or blade tenderized; vacuum marinated; injected with marinade or water; mechanically cubed; enzyme formed.

The new requirements for MT beef identification and safe cooking instructions should not be added to the current “safe food handling” label. Instead, FSIS should develop a standardized, separate label that can be easily recognized as an identifying marker of a unique product that requires specific cooking and handling instructions. In the case of MT beef product destined to undergo full lethality at a FSIS facility, that product does not need to be labeled since all cooked products are required to reach full lethality before leaving a FSIS facility.

With regard to the label stipulations related to font and size, some modification should be allowed in order to create an eye-appealing label. However, the font for the product’s name and the term “mechanically tenderized” should be prominent and in the same font and size, while the cooking instructions could be one font size smaller. The text color should be easily distinguishable from a single color background.

Designation of “Mechanically Tenderized”

CFI supports the use of “mechanically tenderized” as an accurate term to describe needle and blade tenderized product and indicate that the surface of the product has been pierced or cut. Consumers and restaurant/institutional cooks will likely find “mechanically tenderized” more understandable than the regulatory term “nonintact.” Finally, “mechanically tenderized” is a term that has been used by both industry and government regulators for many years, so its meaning is clear to these stakeholders.

¹⁰ US Department of Agriculture. 2013. Proposed rule: Descriptive designation for needle or blade-tenderized (mechanically tenderized) beef products [Docket No. FSIS—2008—0017]. Federal Register, 78(111): p. 34599. Accessed 7/21/13 at: <http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/2008-0017.pdf>.

¹¹ ---- Ibid., p. 34601.

¹² ----Ibid., pp. 34596-34602.

Inclusion of Cooking Instructions

Providing consumer and restaurant/institutional cooks with instructions about cooking MT beef in order to decrease the risk of illness is an important aspect of FSIS' proposed rule. The MT beef label should include cooking instructions. This information will alert food preparers that MT beef product is significantly different from other beef products (even if it looks the same) and requires complete cooking.

FSIS Recommended Cooking Instructions

FSIS has suggested that a combined time and temperature method could be used to ensure lethality of internal pathogens in MT beef products. In FSIS' *Compliance Guideline for Validating Cooking Instructions for Mechanically Tenderized Beef Products*, the Agency provides two options for validating cooking instructions for MT beef products. Option 1 allows a producer to use FSIS documents (attached to the *Compliance Guideline*) to validate cooking instructions. Option 2 provides information to those producers who decide to validate cooking instructions without using those documents.

Option 1

For MT beef products, FSIS supports an internal cooking temperature of 145°F with a 3 minute rest time and provides documents that allow for other time/temperature combinations.¹³ In 2009, FSIS introduced a time/temperature combination of 145°F with a 3 minute rest time as its new cooking recommendation for meat (chops, steaks, roasts), but notes that consumers, for personal reasons, may choose to cook to higher temperatures.¹⁴ While validated in several studies, this new cooking recommendation is problematic. First, studies on consumer cooking practices show that only a small portion of consumers use a thermometer to check for doneness¹⁵ ¹⁶ and that many consumers do not associate "rest time" with complete cooking, i.e. food safety.¹⁷ Given this, it is unlikely that consumers will follow FSIS's requirements for a time/temperature cooking recommendation on MT beef products. Second, FSIS does not explain the importance of the "state of the product" (refrigerated, frozen, frozen-then-thawed) for meat, including MT beef product. However, research has shown that if MT beef product is not completely thawed prior to cooking, then uneven heating can result, allowing harmful pathogens to survive.¹⁸ Third, given the variance in product (1" thickness vs. 3" thickness) and cooking surfaces (range, oven, open-flame gas grill, electric clam grill), FSIS needs to provide more information to producers and food preparers about how these factors can affect complete cooking of the product's interior. Finally, USDA's time/temperature plus rest time cooking instruction in Attachment 1 suggests

¹³ US Department of Agriculture. 2013. FSIS compliance guideline for validating cooking Instructions for mechanically tenderized beef products, p. 4. Accessed 10/01/13: http://www.fsis.usda.gov/wps/wcm/connect/606919b6-5192-40bd-a32b-99a41c75eeb6/Comp_Guide_MTB.pdf?MOD=AJPERES.

¹⁴ USDA/FSIS. Safe Minimum Internal Temperature Chart. Accessed 10/04/2013 at: http://www.fsis.usda.gov/wps/portal/fsis/topics/food-safety-education/get-answers/food-safety-fact-sheets/safe-food-handling/safe-minimum-internal-temperature-chart/ct_index.

¹⁵ National Cattlemen's Beef Association. 2010. Consumer perceptions of beef safety research overview. Funded by The Beef Checkoff, Fig.7, p.5

¹⁶ RTI International. 2007. What surveys say about food handling in the home and at retail. Presented by S.Cates at the 94th Annual International Association of Food Protection Meeting, Lake Buena Vista, FL, July 8-11, 2007. Accessed 10/02/13: http://www.rti.org/pubs/cates_iafp.pdf.

¹⁷ Partnership for Food Safety Education. 2009. PFSE New Cook Time Messaging Focus Groups Final Report. Brand Amplitude, LLC, September 2, 2009.

¹⁸ Luchansky JB, Porto-Fett AC, Shoyer BA, Phillips, J 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. 2013. *J of Food Protect* 76 (9): 1500-1512.

turning the product one time during cooking, while recent research shows that MT beef product should be turned at least twice during cooking to increase uniform internal heating of product.¹⁹

Option 2

In FSIS' guidance document for cooking MT beef products, the Agency is clear that if an establishment wants to provide cooking instructions for unique products, then the establishment must consider specific product and testing variables in their supporting documentation. One of the testing variables is the state of the product at the start of cooking, e.g., frozen v. refrigerated or room temperature. In the guidance document, FSIS states that producers developing their own cooking instructions must assume *the lowest expected temperature at the start of cooking*.²⁰ However, for Option 1, FSIS seems to be willing to allow MT beef producers to select "refrigerated" as the state of product because the product is refrigerated at the point of sale. Given that consumer and restaurant/institutional cooks frequently freeze product after purchase, this seems to ignore the directions given in Option 2, e.g., that the producer must assume the lowest expected temperature at the start of cooking. FSIS should amend Option 1 to include "state of product" in its validated cooking instructions for the MT beef label.

FSIS Guidelines for Validating Cooking Instructions

CFI is concerned that the guidance document does not reflect what is known about consumer cooking and food handling behaviors. While a two-part cooking process can result in a lethality step, it is unlikely that consumers will follow two-step cooking instructions without additional educational outreach focused on the importance of time/temperature cooking combinations. CFI is concerned that a two-step cooking instruction will be ignored by many consumers, and given current funding limitations, the Agency's proposed educational outreach program focused on MT beef will be scaled back and not achieve its goals.

CFI is further concerned that the guidance document does not incorporate recent research about safe cooking practices for MT beef products – this is especially troubling since cooking is the final barrier for preventing foodborne illnesses. Several studies on log reductions of various end-point cooking temperatures show that even at higher temperatures, infectious foodborne pathogens can survive in nonintact beef due to uneven heating.²¹ A recent study published in the *Journal of Food Protection* investigated the log reductions when cooking refrigerated, frozen or frozen-then- thawed ground beef patties on a commercial gas grill or clamshell electric grill and found variance in log reductions due to uneven heating and the presence of cold spots.²² Based on these findings, FSIS should not recommend a lower cooking temperature with a specified rest time for MT beef product until additional research determines whether or not the heat generated by "rest time" can overcome potential cold spots in MT beef that began the cooking process in the frozen or partially thawed state. CFI is concerned that FSIS' current guidance about validated cooking instructions only recommends a time/temperature combination and does not stipulate that MT beef *must be completely thawed prior to cooking*.

¹⁹ Gill CO, Yangi X, Uttaro B, Badoni M and Liu T. 2013. Effects on survival of *Escherichia coli* O157:H7 in non-intact steaks of the frequency of turning over steaks during grilling. *J of Food Research* 2(5): 77-89.

²⁰ USDA. FSIS compliance guideline for validating cooking Instructions for mechanically tenderized beef products, p. 9.

²¹ Luchansky JB, Porto-Fett AC, Shoyer BA, Call JE et al. 2011. Inactivation of shiga-toxin producing O157:H7 and non-O157:H7 shiga toxin producing *Escherichia coli* in brine-injected, gas-grilled steaks. *J of Food Protect* 74(7): p. 1063.

²² 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. 2013. *J of Food Protect* 76 (9): p. 1511.

Without a statement on the MT beef label about the state of the product prior to cooking, FSIS will not be informing food preparers that MT beef product must be completely thawed when using a specific time/temperature combination to achieve lethality. (Note: In another study, it was shown that turning MT beef steaks over more than once during grilling will give greater certainty of adequate heating of all parts of a steak than will turning it over only once – this is true, even if the steak has been held for a specified time after removal from the heat source. The study concludes that these factors should be taken into account when developing cooking instruction for MT steaks.²³ (Note: Before suggesting this as a recommendation, CFI would like additional research in this area.) CFI recommends that FSIS seek additional research on MT beef, including interventions to reduce surface contamination pre-treatment and/or to reduce internal contamination post-treatment.

CFI is also concerned with the inclusion of Attachment 2 in the guidance document as a tool for validating cooking instructions of MT beef product. Attachment 2 gives a wide range of temperature/time combinations, and while these combinations may provide lethality, they can also cause confusion. FSIS has stated on numerous occasions that it wants to provide consistency in its cooking recommendations. Allowing different temperatures than those recommended by FSIS on its website will confuse food preparers and increase the likelihood that MT beef products are not cooked to the appropriate time/temperature. FSIS needs to clarify that MT beef labeling instructions must include a minimum temperature of 145°F with a 3 minute rest time or use an instant-read temperature of 160°F.

Further, given that FSIS' guidance does not provide sufficient information about factors that could impact on full lethality of MT beef products, ***CFI recommends that MT beef products be cooked to the same temperature as ground beef (160 °F).*** For those MT beef products that are intended to begin cooking in the frozen state, the guidance document should provide additional instruction with regard to cooking times and end-point temperatures to achieve complete lethality.

Guidance Updates

CFI believes that FSIS should provide a schedule for updating its materials (including the cooking recommendations posted on its website), along with a provision that if scientific discoveries provide new insights, then FSIS will update its materials as quickly as possible.

Conclusion

CFI is encouraged that FSIS has acknowledged the importance of preventing foodborne illness by labeling MT beef products. We applaud FSIS for its work on FSIS-2008-0017 and believe that this new rule will improve the safety of beef products, which in turn, will further reduce the incidence of illness, injury and death from preventable foodborne diseases.

Sincerely,



Barbara Kowalcyk
CFI CEO and Director of Research



Patricia Buck
CFI Director of Outreach & Education

²³ Gill CO et al. 2013. Effects on survival of *Escherichia coli* O157:H7 in non-intact steaks of the frequency of turning over steaks during grilling. *J of Food Research* 2(5): 77-89.