October 8, 2013

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

Re: Docket No. FSIS-2008-0017: Descriptive Designation for Needle- or Blade-Tenderized (Mechanically Tenderized) Beef Products; 78 Fed. Reg. 34589; (June 10, 2013)

To Whom It May Concern:

The American Meat Institute (AMI) is the nation's oldest and largest meat packing and processing industry trade association. AMI members slaughter and process more than 90 percent of the nation's beef, pork, lamb, veal, and a majority of the turkey produced in the United States. In addition, some AMI members operate beef facilities in Brazil, Australia, and Canada, and many members import beef. Finally, approximately 80 percent of AMI member companies are small or very small based on Small Business Administration standards.

The safety of the meat and poultry products AMI members produce is their top priority and to that end, the industry shares a common goal with the Food Safety and Inspection Service (FSIS or the agency) of ensuring the safety and wholesomeness of meat and poultry products. AMI members have implemented many food safety processes and procedures that go beyond current FSIS regulations and continue to ensure that the meat and poultry products they produce are safe, wholesome, affordable, and available.
The existing labeling scheme for products that have been needle injected or blade tenderized, with appropriate qualifying statements or other label information, provides open and transparent information based on recognizable common and usual product names and should be kept.\(^1\) Rather than mandate labeling that will not enhance food safety, the agency should focus on two concepts. First, the agency’s priority should be encouraging the industry, to the maximum extent possible, to use prevention technologies and Good Manufacturing Practices to render non-intact products as safe as possible. Second, any contemplated labeling changes should focus on providing useful information to consumers that can add an additional margin of safety, such as examining the effectiveness of current safe handling labels as well as handling and cooking instructions that can inform consumers.

To assist the agency as it examines the plethora of issues presented, AMI submits the following comments regarding the proposed rule and in doing so respectfully requests that FSIS withdraw the proposal.

**The Food Safety Risk Associated with Mechanically Tenderized Beef Products is Very Low and Does Not Warrant the Proposed Labeling**

In considering this rulemaking the agency should begin at the beginning. In March 2002, FSIS conducted a risk assessment with respect to mechanically tenderized (MT) products. From that risk assessment the agency concluded that MT products did not represent an increased concern relative to intact meat cuts. Indeed, that risk assessment predicted one illness per 15.9 million servings of intact beef and a similar risk, one illness in 14.2 million servings, for MT steaks. The agency concluded that “… there is almost no difference in the risk of illness from intact (not tenderized) versus non-intact (tenderized) steaks, …” and the probability of *E. coli* O157:H7 surviving typical cooking practices in either tenderized or non-tenderized steaks, is miniscule.”\(^2\)

According to FSIS, there have been six incidents involving MT products since 2000, the most recent almost four years ago in December 2009. Those foodborne illness outbreaks prompted the agency in 2010 to “update” the risk assessment done in 2002. Although the agency provided some preliminary results from its 2010 work the final updated risk assessment has never been published or made publically available for review or discussion. Indeed, neither the 2002 risk assessment

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\(^1\) The agency should clarify that vacuum tumbled products would not be subject to any of the contemplated labeling if FSIS elects to move forward in some fashion with the proposed rulemaking.

\(^2\) (Attachment A)
performed by FSIS nor the 2010 updated version are referenced anywhere in the preamble to the proposed rule.³

That the agency is 1) ignoring the 2002 risk assessment and 2) not making publicly available the updated version of that risk assessment is not only unacceptable but inconsistent with the Administrative Procedure Act (APA) and the direction from the President of the United States. Early in his administration President Obama issued a memorandum, “Transparency and Open Government,” in which the President stated that government, and his administration in particular, needed to be transparent, participatory, and collaborative.⁴ FSIS has not repudiated the conclusions of the 2002 risk assessment and the agency’s failure to provide as part of the rulemaking record the updated version denies affected entities an opportunity to comment in a meaningful fashion. The failure even to acknowledge this work cannot be seen to comply with President Obama’s direction to be transparent, participatory, and collaborative.

The preamble also fails to acknowledge a May 2013 risk assessment done in Canada that is consistent with the conclusions of the agency’s 2002 risk assessment and the preliminary information provided by FSIS concerning its 2010 work.⁵ The Canadian Risk Assessment (CRA) stated that “although there is a potential for difference in risk between MTB [mechanically tenderized beef] and intact beef cuts, this difference is small, and exposure to E. coli O157:H7 appears to be low at this time.”⁶ Moreover, the CRA found that “MTB products produced under GMP’s and with interventions applied prior to tenderization, are not perceived to present a significantly increased risk relative to similar produced non-tenderized products in the Canadian marketplace.”⁷ The CRA concluded that the risk relative to baseline (baseline being an intact beef products value of 1) associated with MTB cuts is 5, or 265 million servings to cause one (1) illness.⁸ In comparison, however, the risk relative to baseline for ground beef is 7300 or 176,000 servings to cause one (1) illness. (Emphasis added.)

³ See 78 Fed. Reg. 34589 (June 10, 2013). PowerPoint presentation of updated risk assessment (Attachment B). On February 1, 2010 AMI requested that FSIS specifically address the fact that the risk assessment should address marinated products to which FSIS responded. (Attachment C) The risk assessment completed in 2002 combined the two types of products, marinated and blade tenderized, together rather than using a more detailed approach for each. The updated risk assessment compares marinated to mechanically (NT/BT) tenderized products and identified differences between the two product categories.

⁴ http://www.whitehouse.gov/the_press_office/TransparencyandOpenGovernment


⁶ Id. Key Findings and Preliminary Opinion, at 7.

⁷ Id.

⁸ Id. The Canadian study estimate is that it would take 1.29 billion servings to cause one (1) illness, which, although technically not zero, is practically nil.
Interestingly, also included in the preliminary results is the relative risk of mechanically tenderized beef (MTB US) and Chemically Injected Beef (CIB) to intact beef (risk again at 1). The FSIS analysis yielded the relative risk for MTB US at 1.8 and for CIB at 6.9. In short, these analyses support the conclusion that the risk associated with mechanically tenderized products is extremely low.9

An additional consideration offered by the CRA is the impact an intervention’s use has on the relative risk of MTB. More specifically, the CRA found that when an intervention is applied with the efficacy found in some of the published literature, the relative risk is reduced to 2.7.10 The CRA also analyzed circumstances in which the intervention is less effective, with the expected slight increase in relative risk, i.e., 3.6.11

The Canadian consideration of intervention use in its analysis is significant for two related reasons. First, nowhere in the proposed rule does FSIS appear to consider the impact that using interventions has on the risk associated with MT products. Second, similarly, nowhere in the proposed rule does the agency acknowledge that the meat industry moved toward using interventions directly before tenderization, as well as following other best practices in the last few years.12 In response to the FSIS-directed reassessment the industry went to work and developed, and continues to develop, good manufacturing practices that have lowered the risk dramatically since the first outbreaks.13 In other words, as it has done in the past to address food safety challenges in the wake of the outbreaks of the type the agency cites as the basis for the proposal, the industry has embraced the use of various interventions and other best practices to reduce the risk associated with MT products.

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9 Blade tenderized beef product should be treated as a different product category than intact beef products or enhanced/marinated products. Adding a “mechanically tenderized” descriptor to the product name for blade tenderized products is neither warranted nor necessary. Although mechanical tenderization is a process that may be disclosed on the label because the product has potentially different eating characteristics than intact beef products, such labeling cannot and will not improve food safety. In fact, no foodborne illness outbreaks have been definitively linked to this category of product.
10 Id.
11 Id.
12 Indeed, the proposed rule references the agency’s May 2005 Federal Register publication (70 Fed. Reg. 30331, May 26, 2005), in which FSIS directed establishments to reassess their HACCP plans to account for outbreaks associated with MT products. That mandate required establishments that produce MT beef products to consider those outbreaks in reassessing their HACCP plans to ensure those plans adequately address E. coli O157:H7 and other biological hazards.
13 See Attachment E.
Indeed, it is telling that there has not been a single foodborne illness outbreak in the U.S. attributable to MT beef cuts in almost four years. That fact is directly related to the significant shift by the affected industry to more aggressively utilize a variety of effective interventions and processing practices when producing MT products.

Provided below is a list of industry actions and accomplishments that have occurred during the last few years:

- Process monitoring of beef harvest has become routine;
- High event programs that address abnormally high rates of positive \textit{E. coli} have become the norm based on the volume of beef produced;
- Brine recirculation conditioning systems are a recent innovation and are used in marinated and enhanced solution processing;
- Mechanical tenderizing equipment has been redesigned to improve cleaning during and at the end of production;
- Most primals subject to tenderization now are also subjected to an intervention treatment prior to steak cutting;
- Best practices for manufacturing marinated and mechanically tenderized products are routinely updated by industry experts; and
- FSIS has required, through Notices and Directives, the beef industry address the threat of contamination through mandatory reassessments of HACCP plans, supplier/customer knowledge of internal customer specifications, and more focused and rigorous food safety assessments.

These practices have become commonplace in the industry and likely have contributed significantly to the fact that there have been no foodborne illness outbreaks identified with MT products in almost four years.

Moreover, research supports the use of these practices. Specifically, recent research from Texas Tech University indicates that applying an antimicrobial treatment to the subprimal prior to mechanical tenderization is an effective hurdle in a multiple-hurdle food safety process management program. The Texas Tech researchers found that beef subprimals inoculated to $10^3$ log CFU/cm$^2$ level of \textit{E. coli} O157:H7 and treated with 5% lactic acid spray treatment demonstrated a “reduction in surface pathogen load leads to subsequent reduction in pathogen internalization. \textit{E. coli} O157:H7 was not detected in the internal portions of low inoculum–treated steaks cooked to internal temperatures of 55, 60, 65, 70, or 75°C (data not presented). These data suggest that when pathogen translocation (as influenced by total pathogen load) is reduced, cooking to an internal temperature of 55°C or greater reduces the number of internalized \textit{E. coli} O157:H7 cells to a level that is undetectable using the methodology described...” The researchers also stated “...[T]hese data validate the evaluation of additional subprimal intervention
strategies to further reduce, eliminate, and/or injure *E. coli* O157:H7 cells present on the surface of subprimals intended for mechanical tenderization....” Finally, given the lactic acid treatment and other realistic beef industry practices, the “...reduction of pathogens on subprimals exposed to typical industry contamination levels (10^4 CFU/cm²) reduces the risk of pathogen translocation and subsequent survival after cooking.”

For the foregoing reasons the agency must conclude that the risk associated with MT products is very low, making the proposed rule unnecessary.

**The Proposed Rule does not articulate a Credible Reason why the Term “Mechanically Tenderized” must be included in the Product Name**

The proposed rule would require that the product name of MT beef products “include the descriptive designation ‘mechanically tenderized’ and an accurate description of the beef component” and FSIS asserts that by “including this descriptive designation consumers will be informed that this product is non-intact.” What FSIS does not explain, as it must, is why the term “mechanically tenderized” must be part of the product name.

More specifically, in the proposed rule the agency states that it

... has concluded that without specific labeling, raw or partially cooked mechanically tenderized beef products could be mistakenly perceived by consumers to be whole, intact muscle cuts. The fact that a cut of beef has been needle- or blade-tenderized is a characterizing feature of the product and, as such, a material fact that is likely to affect

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15 Admittedly, not all processors may use the latest methods to produce mechanically tenderized or marinated products in a manner that eliminates or minimizes the likelihood of *E. coli* O157:H7 being present. For that reason, as it does for addressing certain other pathogens, e.g. *Listeria monocytogenes*, the agency could consider a labeling option for processors that are not able to state that *E. coli* is not reasonably likely to occur because they do not utilize some effective combination of the practices identified above, e.g., no high event program, no fabrication intervention, continued use of processes or procedures associated with recalls.

16 78 Fed. Reg. 34589. Adding the term “mechanically tenderized” to the product name would cause needled injected, marinated products to be mislabeled because adding solutions via needle injection does not mechanically tenderize the product. Only blade tenderizing equipment is specifically designed to mechanically tenderize the product.
consumers’ purchase decisions and that should affect their preparation of the product.\textsuperscript{17}

Through these conclusory comments the agency seems to suggest by its reference to the “characterizing feature” of mechanical tenderization that this proposal is not solely about food safety. Indeed, from a food safety standpoint there is no reason why the term “mechanically tenderized” must be incorporated into the product name.

There are several examples of agency labeling requirements that are intended to enhance food safety by providing additional information to consumers and none of them affect the product name. Most obvious among those examples are the agency's mandatory safe food handling instructions, which can often be found not on the principal display panel (PDP) of a product’s packaging but on the back. Similarly, ingredients that are allergens, which present a risk to the health of a person allergic to a particular substance continue to be in the ingredient statement but may be highlighted to raise consumer awareness. Such allergens are included as part of the ingredient declaration and would only be part of the product name if the particular ingredient at issue is a significant component of the product. In short, other significant, mandatory food safety labeling requirements do not intrude into the product name as this proposal would if finalized.

Conveying the fact that a product has been subject to mechanical tenderization and therefore consumers should prepare the product differently than if it is intact can be accomplished just as easily through means other than requiring that term’s inclusion in the product name. Meat and poultry labels are replete with useful and often necessary information that is found on a product’s labeling, either on the PDP or elsewhere. Nutrition labeling information which, although health related is not directly related to food safety, is typically on the back panel of a product’s labeling. The mark of inspection is on the PDP, but is relatively small in size. Indeed, increasingly the official establishment number is found on the back panel of many products. So to, in the case of claims such as all natural or the use of certain flavorings, \textit{e.g.} smoke flavor, the agency requires a qualifier directly under the product name advising consumers about the use of that flavoring. These are just a few examples in which the agency conveys important food safety or other necessary information to consumers through labeling without intruding into the product name.

\textsuperscript{17} \textit{Id.} at 34592.
Moreover, neither entity that petitioned FSIS for labeling that would distinguish intact from MT products even asked for the intrusive labeling proposed. The 2009 Safe Food Coalition petition requested that the agency take action to require that the labels of mechanically tenderized beef products disclose the fact that the products have been mechanically tenderized and the reasons offered by that coalition all involve food safety:

- consumers and restaurants do not have sufficient information to ensure that these products are cooked safely because FSIS does not provide recommended cooking temperatures for mechanically tenderized products;
- the recommended cooking temperatures for intact products are not appropriate for non-intact, mechanically tenderized products; and
- a labeling requirement for mechanically tenderized products is critical for consumers and retail outlets so that they have the information necessary to safely prepare these products.

Likewise the 2010 petition submitted by the Conference for Food Protection (CFP) asked FSIS to issue a mandatory labeling provision for mechanically tenderized beef that would require labels to specify that a cut has been mechanically tenderized. Again, the CFP petition focused on food safety and consumer and foodservice preparation of MT products. Neither petition stated or even suggested that consumers were or are being misled or deceived because the term “mechanically tenderized” is not in the product name.

The APA requires the agency to have some basis to impose a regulatory requirement. Here, the agency has not explained, as it is obligated to do, why a less intrusive yet still conspicuous labeling scheme, such as a statement next to the safe handling instruction, somewhere on the principal display panel, or elsewhere on the packaging, that the product is mechanically tenderized would not be effective in conveying that “product attribute” to consumers. As demonstrated above, FSIS routinely uses qualifying statements that are adjacent to or near the product name to convey information to consumers or elsewhere on the PDP to convey necessary information. The agency has offered no data or other information to suggest that consumers have historically been misled because the term “mechanically tenderized” has not been in the product name.
Because FSIS intends to “conduct a public education campaign to explain the significance of the term ‘mechanically tenderized’ to consumers” AMI submits that requiring MT product labels to convey in a conspicuous fashion somewhere on the labeling other than in the product name will be just as effective as the proposed rule.18 Such an approach is consistent with the agency’s stated goal of “clearly and completely” identifying “the preparation process that the product underwent” while achieving another FSIS “goal” – “to choose a term that will not affect consumers’ perception of the quality, or cost, of the product.”19

Cooking Instructions should be Developed in Conjunction with Updating Safe Handling Instructions to Aid Consumers in the Proper Cooking of Marinated and Mechanically Tenderized Beef Products

The proposal also would require MT product labels to bear validated cooking instructions. Specifically, FSIS proposed to require validated cooking instructions that include, “at a minimum: (1) the method of cooking; (2) a minimum internal temperature validated to ensure that potential pathogens are destroyed throughout the product; (3) whether the product needs to be held for a specified time at that temperature or higher before consumption; and (4) instruction that the internal temperature should be measured by the use of a thermometer.”20 Moreover, the agency stated that

To validate the cooking instructions, ..., the establishment would be required to obtain scientific or technical support for the judgments made in designing the cooking instructions, and in-plant data to demonstrate that it is, in fact, achieving the critical operational parameters documented in the scientific or technical support.21

The agency seems to offer the possibility of a “safe harbor” for those facilities who elect to use and whose products qualify under the agency’s guidance documents for validated cooking instructions. The elephant in the room with respect to validated cooking instructions, however, is the fact that for many, if not virtually all, MT products there are multiple methods of preparation utilized by consumers

18 Id. at 34593. Indeed, the agency could consider adding the phrase “See back panel for cooking instructions,” or a similar phrase, adjacent to the “mechanically tenderized” qualifier to enhance consumer awareness of the cooking instructions. See discussion infra, p. 9.
19 Id. During the conference call the agency held to announce this proposed rule agency officials stated that data does not exist via focus groups or other research to support a conclusion that using the term “mechanically tenderized” will not affect consumers’ perception of the quality, or cost, of the product.
20 Id. at 34594
21 Id.
and likely numerous, if not countless, variations for each method.\textsuperscript{22} Rather than require the four steps proposed it would be better to require companies to inform consumers that they should cook the product to ensure the product reaches the necessary temperature, \textit{e.g.} 145 degrees Fahrenheit with a three minute rest period or its equivalent and to do so using a meat thermometer. Such an approach reduces the likelihood that consumers will be confused, not to mention displeased and disappointed, when provided cooking instructions using a method that is other than how they prefer to prepare the product.\textsuperscript{23}

In addition, although the FSIS validation compliance guideline provides useful information regarding validating cooking methods, a more rewarding use of industry and stakeholder resources would be to review the effectiveness of the safe handling label with the goal of improving consumer handling and preparation of meat and poultry products. In that regard, the agency should consider amending the instructions to state specifically that beef, veal, pork and lamb whole muscle roasts, steak and chops, which include marinated or needle tenderized beef products, to be cooked to 145 degrees Fahrenheit with a three minute rest period; ground meat to be cooked to 160 degrees Fahrenheit; and all poultry products, including ground poultry, to be cooked to 165 degrees Fahrenheit.

\textbf{The Cost/Benefit Analysis Lacks Specificity and does not Satisfy Executive Order 12866}

The preamble discusses several benefits, and costs, attendant to the proposed rule. Significantly, however, the agency failed to assign dollar values to many of those purported benefits and costs. For example, the preamble does not assign a “value” to several factors that certainly will result in some sector of the chain incurring a cost, \textit{e.g.}, the cost to validate cooking instructions, the loss to producers who sell MT products, the loss to consumers when cooking the product to a higher temperature and in turn are dissatisfied with the product, substituting products that consumers may like less, the loss to food service providers that change their processes.

\textsuperscript{22} Indeed, similar considerations exist for the tens of thousands of foodservice operators who, because of the negligible risk discussed above, have preparation procedures they have used for many years, if not longer and yet are likely to be inconsistent with the cooking instructions accompanying the product.

\textsuperscript{23} We note that, notwithstanding the agency’s assertion that MT products should be cooked differently than intact products, the time and temperature cooking and dwell times recommended by FSIS have not changed.
Executive Order 12866 (EO) mandates that the agency conduct a cost benefit analysis such as the instant one and in order to comply with the EO it is incumbent upon the agency to identify real numbers with the costs and the benefits. Mere recognition that there will be some cost without attempting to ascertain those values does not satisfy the EO command. In short, the agency is supposed to have some reasonable idea of the costs and benefits that a rule would impose/enjoy before it proposes a rule. Here, the process is stood on its head and inconsistent with both the APA and the EO when the agency proposes a rule, acknowledges it does not have adequate cost/benefit information, and attempts to address that infirmity through an invitation to comment.

* * * * *

For the foregoing reasons AMI respectfully requests that the agency withdraw the proposed rule. Adopting such a rule would add unnecessary and unwanted costs to the production of MT products while offering little, if any, benefit to the consumer; including food safety. If you have any questions regarding these comments or anything else regarding this matter, please contact me at (202) 587-4229 or mdopp@meatami.com.

Respectfully submitted,

Mark Dopp
Senior Vice President
& General Counsel

cc: Patrick Boyle  
    Jim Hodges  
    Janet Riley  
    Dr. Betsy Booren  
    Scott Goltry  
    Susan Backus  
    Dr. Elisabeth Hagen  
    Al Almanza  
    Rachel Edelstein  
    Rosalyn Murphy-Jenkins
ATTACHMENT A
Mr. Scott Goltry, Vice President
Food Safety and Inspection Service
American Meat Institute
1150 Connecticut Ave., NW, 12th Floor
Washington, D.C. 20036

Dear Scott:

Thank you for your February 1, 2010, letter regarding the American Meat Institute’s (AMI) review of illness-related recalls linked to mechanically tenderized beef products. I appreciate hearing from you, and I apologize for the delay in responding.

As an initial response to your letter, the Food Safety and Inspection Service (FSIS) delivered a presentation at an April 14, 2010, meeting of AMI’s Inspection Policy Committee and Scientific Affairs Advisory Committee (copy enclosed). This presentation outlined FSIS’ efforts to update FSIS’ 2002 Comparative Risk Assessment of \textit{E. coli} O157:H7 in intact and mechanically tenderized steaks based on new cooking data and research methodology.

In addition to sharing the Agency’s data needs and next steps, FSIS released preliminary results from the updated risk assessment, which suggested higher risk from mechanically tenderized beef, and considerably higher risk from chemically injected beef, a product category not delineated in the 2002 assessment. Further research is needed to evaluate the impact of cooking \textit{E. coli} O157:H7 present in tumbled beef, marinated beef, marinated mechanically tenderized beef, and fabricated steaks. FSIS has made gathering data on marinated meat and poultry products a research priority. To that end, we appreciate the data outlined in your letter. The Centers for Disease Control and Prevention provided FSIS data on outbreaks related to tenderized/marinated steaks, and this data was used in the risk assessment.

Since the April 2010 meeting, FSIS has continued to develop and refine the updated risk assessment based on independent peer review comments, and following a thorough Agency review, the risk assessment will be posted on the FSIS Web site. The final results of the risk assessment may be used to inform future policy development at the Agency as well. FSIS is currently developing new labeling requirements for mechanically tenderized meat and poultry products, which have been processed in a manner that changes the basic nature of the product and is not readily observable by consumers. When the new requirements are released, we will invite all interested stakeholders, including AMI, to provide comments and feedback.
Thank you again for your letter. We appreciate your input and your commitment to food safety.

Sincerely,

[Signature]

David P. Goldman, M.D., M.P.H.
Assistant Administrator
Office of Public Health Science
Risk Assessment Update for *E. coli* O157:H7 in non-intact beef

Risk Assessment Division
Office of Public Health Science
Food Safety and Inspection Service

Objective

- To estimate comparative risks between intact and tenderized steaks that are either mechanically tenderized or chemically injected.
- To be used to guide FSIS labeling requirements that would mitigate the risk of *E. coli* O157:H7 illness from the consumption of tenderized steaks.
Background

- 2002 FSIS Comparative Risk Assessment of E. coli O157:H7 in intact and mechanically tenderized steaks
- Six outbreaks since 2003
- New data from ARS study (2010)
- Update of the 2002 FSIS RA

<table>
<thead>
<tr>
<th></th>
<th>2002 Model</th>
<th>2010 Model</th>
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<tbody>
<tr>
<td>Product Type</td>
<td>Intact vs. MTB</td>
<td>Intact vs. MTB vs. CIB</td>
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<tr>
<td>Cooking Data Source</td>
<td>Sporing et al.</td>
<td>Sporing et al. and ARS</td>
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<tr>
<td>Cooking Method</td>
<td>Grilling, Broiling, and Frying</td>
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<td>Thickness of steaks</td>
<td>Differentiated</td>
<td>Combined</td>
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<td>Cooking Lethality Model</td>
<td>Exponential</td>
<td>Log-linear</td>
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<tr>
<td>Model Outputs</td>
<td>Risk per serving</td>
<td>Number of illness</td>
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Model Inputs (1)

- 3 Scenarios based on product type
  - Intact
  - Mechanically Tenderized Beef (MTB)
  - Chemically Injected Beef (CIB)
- Initial Contamination
- Cooking temperature:
  - 120, 130, 140, 150, and 160 °F
- Cooking Effects

Model Inputs (2)

- Growth Effects
- Health Effect
  - Dose-response model: beta-Poisson model
  - Population:
    - General population
    - Susceptible population
- Consumption data
  - FSIS product volume data, ERS, and NHANES

Total # of illness in the US

\[ \text{# of Illness} = \left( \text{Risk / serving} \right) \times \text{total # of serving in the US} \]

\[ \begin{align*}
5 \times 10^{-4} \ (\text{Illness/serving}) \times \\
1,000,000 \text{ servings} &= 500 \text{ illness}
\end{align*} \]
Preliminary Results (1):
Log_{10}-Reductions for 3 Scenarios with Trend Lines
### Preliminary Results (2):

#### Predicted Outcomes

(assuming 10 billion servings steaks)

<table>
<thead>
<tr>
<th></th>
<th>Intact</th>
<th>MTB</th>
<th>CIB</th>
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<tbody>
<tr>
<td>P (I/S)</td>
<td>$4.39 \times 10^{-7}$</td>
<td>$8.04 \times 10^{-7}$</td>
<td>$3.04 \times 10^{-6}$</td>
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<tr>
<td>Illness</td>
<td>4,390</td>
<td>8,044</td>
<td>30,402</td>
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<tr>
<td>Hosp. (21.6%)</td>
<td>949</td>
<td>1,739</td>
<td>6,572</td>
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<tr>
<td>HUS (5.1%)</td>
<td>223</td>
<td>410</td>
<td>1,548</td>
</tr>
<tr>
<td>Death (0.6%)</td>
<td>27</td>
<td>50</td>
<td>190</td>
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<tr>
<td>Relative Risk</td>
<td>1</td>
<td>1.8</td>
<td>6.9</td>
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Assumes all serving are Intact, MTB, or CIB

Conclusion

- Risks from MTB and CIB are higher than that from Intact Beef by ~2 and ~7 fold, respectively.

- This preliminary estimation only provides information on cooking effect and the relative risks for 3 different scenarios.
Data Needs

- Cooking effect for tumbling and/or marinated steaks vs. intact steaks

- Comparative study on thermal resistance cooking lethality of *E. coli* O157:H7 in ground vs. whole muscle (Data available for *Salmonella*)
# Next Steps

| February – March, 2010 | - Consumption Analysis  
- The 1st version of risk assessment model  
- Work with FSIS/OPPD on Preamble for labeling |
|-----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| April – May, 2010     | - Populate the model with RA data  
- Run and Test the model  
- Scenario Analysis |
| June – July, 2010     | - Risk assessment Report to OPPD  
- Presentations and Briefing  
- Development of Statement of Work for Independent Peer Review |

## Next Steps

| August – September, 2010 | - Peer Review  
- Response to peer review comments  
- Make report 508-compliant  
- Publish on FSIS website |
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<td>September – November, 2010</td>
<td>- Submit manuscript for publication</td>
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Comparative Risk Assessment for Intact (Non-Tenderized) and Non-Intact (Tenderized) Beef: Executive Summary

Prepared by:

Risk Assessment Division
Office of Public Health Science
Food Safety and Inspection Service
United States Department of Agriculture

March, 2002
1. RISK MANAGEMENT REQUESTS AND OBJECTIVES

In October 2001, the Office of Policy, Program Evaluation and Development (OPPDE) requested the following types of risk assessments to support policy decision-making regarding *E. coli* O157:H7 in non-intact beef:

(1) a farm-to-table risk assessment to evaluate the effectiveness of interventions in reducing the occurrence and extent of *E. coli* O157:H7 contamination on carcasses and reduce the subsequent risk of illness; and

(2) a comparative risk assessment to evaluate the risk of illness per serving from intact versus non-intact (e.g., tenderized) beef steaks and roasts prepared using traditional cooking practices (grilling, broiling, and frying).

The requested farm-to-table risk assessment for non-intact (tenderized) beef could not be developed because of the lack of sufficient data on the prevalence and level of *E. coli* O157:H7 on specific locations of the carcass (see the *Risk Assessment Plan for Non-Intact Beef*, FSIS 2001). There was, however, sufficient data to assess the risk of illness from non-intact (tenderized) beef compared to intact (non-tenderized) beef.

The comparative risk assessment, including modeling approach, data inputs and underlying assumptions, as well as the resulting risk estimates are summarized below. For additional technical detail, see the *Technical Report: Comparative Risk Assessment for Intact (Non-Tenderized) and Non-Intact (Tenderized) Beef* (FSIS, March 2002).

2. PUBLIC HEALTH REGULATORY CONTEXT

2.1. Public Health Background

*E. coli* O157:H7 was first recognized as a foodborne pathogen with major public health consequences in 1982, when it was associated with two outbreaks of bloody diarrhea in Oregon and Michigan. An estimated 62,000 cases of symptomatic *E. coli* O157:H7 infections occur annually in the United States due to foodborne exposures, resulting in approximately 1,800 hospitalizations and 52 deaths. As many as 3,000 cases may develop hemolytic uremic syndrome annually. Surveillance data indicate that the highest incidence of illness from *E. coli* O157:H7 occurs in children under 5 years of age (Mead 1999).

While epidemiological evidence indicates that ground beef is the primary foodborne source of exposure to *E. coli* O157:H7, a recent study of the survival of *E. coli* O157:H7 in tenderized beef under customary cooking practices suggests that these sources of non-intact beef may also pose a public health risk (Sporing 1999, KSU 2001). Non-intact beef has also been implicated as the source of *E. coli* O157:H7-related illnesses in recent foodborne outbreaks in the U.S. and Canada (Michigan Department of Community Health 2000, Wisconsin Department of Health and Family Services 2000, and Health Canada 2002).1 In two of these outbreaks, undercooked non-intact beef (e.g., beef tournedos and beef roasts)

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1 These *E. coli* O157:H7 outbreaks did not provide sufficient quantitative data for use in this risk assessment.
was implicated as the most likely vehicle for E. coli O157:H7 (Michigan Department of Community Health 2000, Health Canada 2002). In the third outbreak, illnesses may have resulted from the consumption of food that was cross-contaminated with E. coli O157:H7 from non-intact beef (Wisconsin Department of Health and Family Services 2000).

2.2. Regulatory Background

To protect public health, FSIS declared raw non-intact beef, including ground beef, adulterated if it contains E. coli O157:H7. This policy is based on the premise that E. coli O157:H7, an extremely virulent organism, may survive after cooking non-intact beef products and cause serious illness in consumers. In contrast, FSIS does not consider intact beef containing E. coli O157:H7 to be adulterated because it is assumed that any E. coli O157:H7 on the surface of these products would be destroyed during cooking.

The regulatory history for E. coli O157:H7 in beef is provided below:

Ground beef. In 1994, FSIS notified the public that raw ground beef contaminated with E. coli O157:H7 is adulterated under the Federal Meat Inspection Act (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.

Non-Intact beef. On January 19, 1999, FSIS published a Federal Register notice explaining that all raw non-intact beef products (e.g., those that have been mechanically tenderized by needling or cubing), in addition to ground beef, that are found to be contaminated with E. coli O157:H7 must be processed into ready-to-eat product, or they would be deemed to be adulterated.

Intact beef. The January 1999 notice also explained that if intact cuts of beef that are to be further processed into non-intact product prior to distribution for consumption (e.g., manufacturing trimmings) 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. FSIS would also consider it acceptable to irradiate these products prior to distribution for consumption, if they are found contaminated with E. coli O57:H7.

Justification of the 1999 policy. FSIS explained that: (1) E. coli O157:H7 is an extremely virulent organism; and (2) E. coli O157:H7 may survive cooking in non-intact beef and cause illness among consumers. FSIS explained that pathogens, including E. coli O157:H7, may be introduced below the surfaces of non-intact products (e.g., tenderized beef) 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 essentially protected from pathogens migrating below the exterior. Consequently, customary cooking of intact products will destroy any E. coli O157:H7.

3. SCIENTIFIC GUIDANCE

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2 FSIS believes that there is ample anecdotal evidence that consumers frequently eat blade tenderized meat, particularly steaks, cooked "rare" or "medium. The Agency thought that this method of preparation would be insufficient to destroy E. coli O157:H7 in the interior of the meat and, as a result, may render the product injurious to health.
A subcommittee of the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) was asked to answer several questions with regard to the potential public health risk posed by *E. coli* O157:H7 in blade-tenderized, non-intact beef (e.g., steaks and roasts) (NACMCF 2002). The following questions were addressed:

Q1: Do non-intact, blade tenderized beef steaks present a greater risk to the consumer from *E. coli* O157:H7 compared to intact beef steaks if prepared similarly to intact beef steaks?

Q2: Do non-intact, blade tenderized beef roasts present a greater risk to the consumer from *E. coli* O157:H7 compared to intact beef roasts if prepared similarly to intact beef roasts?

Q3: Is the available information on non-intact products adequate to answer questions 2 and 3? If not, are there other reasons to conclude that the translocation of *E. coli* O157:H7 that occurs with the blade tenderization or similar processes renders traditional cooking (consider the traditional cooking process for these products to be very rare or rare) of these products inadequate to kill the pathogen?

Q4: Does the available scientific evidence support the need for a labeling requirement to distinguish between intact and non-intact products in order to enhance public health protection?

NACMCF considered several sources of information in addressing these questions, including epidemiologic data, FSIS microbiological baseline data, the Kansas State University study (Sporing 1999), data on the predictive microbiology of *E. coli* O157:H7 under various cooking conditions, consumer cooking behavior data for steaks and roasts, and data on the processing of non-intact steaks and roasts. There were several data gaps identified by NACMCF in addressing its charge (see Research Needs).

In January 2002, based on the available data, NACMCF concluded that “non-intact, blade tenderized beef steaks do not present a greater risk to consumers if the meat is oven broiled and cooked to an internal temperature of 140 °F or above” (question #1). NACMCF also concluded that “blade tenderized beef steaks would present a greater risk when compared to intact beef steaks if they are cooked to an internal temperature below 140 °F.” (question #1). A primary resource for these conclusions was the Kansas State University study (Sporing 1999). Since the KSU study considered only beef steaks and not beef roasts, NACMCF concluded that there was insufficient data to determine if non-intact beef roasts presented a greater risk than intact beef roasts (question #2). In addition, NACMCF concluded that there was insufficient consumer behavior data to determine if traditional cooking methods are adequate to destroy *E. coli* O157:H7 translocated to the interior of blade tenderized beef

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3 These NACMCF statements are based primarily on data published by Kansas State University (Sporing 1999). Following inoculation of the surface of intact beef steaks (1/2", ¾" or 1¼" in thickness) with a five-strain cocktail of *E. coli* O157:H7 to approximately 10⁷ cfu/cm², single-pass blade tenderization resulted in internalization of approximately 3 x 10⁷ cfu/gm or approximately 3-4% of the initial inoculum. It was assumed that the surface of intact beef (subprimals) steaks would typically harbor less than 10⁵ coliforms/cm² when produced under good manufacturing practices. A worst case scenario is that all of the coliforms may be *E. coli* O157:H7 and that their total numbers may exceed 10⁷/cm².
steaks and roasts (question #3). There was also insufficient data for the subcommittee to respond to the issue of labeling non-intact beef products (question #4).

4. RISK ASSESSMENT

2.1. Problem Statement

The majority of steaks and roasts destined for hotel, restaurant, and institutional use in the United States may be subjected to “mechanical tenderization.” This is a process in which large pieces of meat are penetrated, usually in several directions, by sets of needles, or double-edged blades, and then cut into steaks and roasts. Sometimes the needles used are hollow, allowing meat to be injected with solution containing flavorings and/or digestive agents such as papain. The purpose of the process is to make lower grade cuts of beef more tender.

During tenderization, transfer of *E. coli* O157:H7 may occur in two ways: (1) from the surface to the interior of contaminated meat; and (2) from contaminated meat to previously non-contaminated pieces of meat (e.g., cross-contamination via blade tenderization needles and/or recycling of injection fluid). Subsequently, *E. coli* O157:H7 in these non-intact servings may survive cooking and cause illness among consumers.

Taking these issues into consideration and using currently available data, the comparative risk of illness from non-intact (tenderized) beef relative to intact (non-tenderized) beef was quantitatively assessed.

2.2. Methodology

This risk assessment begins with an estimation of the occurrence and extent of *E. coli* O157:H7 contamination in raw intact beef steaks prior to tenderization, models the transfer of *E. coli* O157:H7 during tenderization, the growth and decline in the number of *E. coli* O157:H7 on beef steaks due to storage and handling conditions prior to cooking, the survival of *E. coli* O157:H7 contamination on intact and non-intact beef steaks during cooking, and the subsequent probability of illness (Figure 1). Each of these steps (1-5) along with the data inputs and underlying assumptions are discussed in more detail below.

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6 It was assumed that the risk estimates apply to roasts as well as steaks. This assumption was made because data was available only for steaks (e.g., Sporing 1999). In general, roasts are thicker than steaks. Kansas State University found that the longer cooking time required to achieve the same internal temperature in thicker cuts of meat resulted in a greater reduction in the number of *E. coli* O157:H7 (Sporing 1999). As a result, it may be expected that roasts are cooked longer than steaks and there would be a greater reduction in the number of *E. coli* O157:H7. Further research is needed to evaluate the effectiveness of cooking in reducing *E. coli* O157:H7 in roasts compared to steaks.
Figure 1. Conceptual process for the production, preparation and consumption of intact (non-tenderized) and non-intact beef (tenderized).

**Step 1. Estimation of the Level of E. coli O157:H7 Contamination in Raw Steaks.**
Currently, there is no sampling data available on the prevalence and levels of *E. coli O157:H7* on, or in, steaks. As a result, the occurrence and extent of *E. coli O157:H7* contamination on servings of steak had to be estimated based on: (1) the proportion of the carcass that becomes intact or non-intact cuts of beef versus ground beef; and (2) the predicted prevalence and levels of *E. coli O157:H7* in ground beef servings (Table 1).²

Table 1 indicates that of the approximately 0.3% contaminated ground beef servings produced annually, most contain about one *E. coli O157:H7* organism.

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² The risk assessment for ground beef (FSIS August 2001) estimated the levels of *E. coli O157:H7* in ground beef based on data from the FSIS (1994) national baseline survey of slaughter plants. In the 1994 FSIS survey, a 60-cm² surface area was sampled from each of 2,081 chilled carcasses originating from feedlots. Four (0.2%) carcasses were *E. coli O157:H7*-positive, and enumerated densities were reported (50% were <0.030 cfu/cm² and 50% were between 0.301 and 3.000 cfu/cm²). Based on a study using more sensitive detection methods, the actual prevalence of carcasses contaminated with at least 0.03 cfu/cm² would be about 5% (Elder 2000). Modeling was used to estimate the fraction of contaminated ground beef servings with various levels of *E. coli O157:H7* (FSIS August 2001).
Table 1. *E. coli* O157:H7 levels predicted in ground beef servings (FSIS August 2001).

<table>
<thead>
<tr>
<th><em>E. coli</em> O157:H7 per serving</th>
<th>Fraction of servings</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>June-September</td>
</tr>
<tr>
<td>0</td>
<td>99.5%</td>
</tr>
<tr>
<td>1</td>
<td>0.46%</td>
</tr>
<tr>
<td>3</td>
<td>0.038%</td>
</tr>
<tr>
<td>10</td>
<td>0.0035%</td>
</tr>
<tr>
<td>31</td>
<td>0.0000027%</td>
</tr>
<tr>
<td>100</td>
<td>0%</td>
</tr>
</tbody>
</table>


The ground beef risk assessment (FSIS, August 2001) also estimated the proportion of beef processed into prime cuts versus ground beef as follows:

- 75% of a steer/heifer carcasses' original surface area becomes beef trim used to make ground beef;
- 25% of the original surface area's *E. coli* O157:H7 remain to contaminate primal cuts of beef (e.g., steaks and roasts);
- the remaining surface *E. coli* O157:H7 on primal cuts are distributed across about 82% of the weight of the original carcass (i.e., 500 lbs. of beef per carcass and about 18% is trim).

Adjusting the prevalence of *E. coli* O157:H7 in ground beef based on the proportion of carcass that become primary cuts of meat (e.g., steaks and roasts) rather than trim, an estimated 0.02% of steaks produced annually contain *E. coli* O157:H7. Assuming that the *E. coli* O157:H7 organisms are evenly distributed on the surface of carcasses, servings of steaks are estimated to have the same distribution of *E. coli* O157:H7 organisms as in Table 1. To simplify the modeling, it was assumed that steak/roast servings contain either:

- no *E. coli* O157:H7 organisms (99.98% of the time); or
- one *E. coli* O157:H7 organism (0.02% of the time).

**Step 2. Transfer of *E. coli* O157:H7 During Tenderization.** Mechanical tenderization is performed using a series of stainless steel, double-edged blades or needles. The needles or blades penetrate the meat by cutting through muscle tissues and fibers, rather than

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6 Such an assumption is necessary to derive the estimates from the ground beef risk assessment since both mapped carcasses contamination data or the availability of *E. coli* O157:H7 contamination data for steaks and roasts are lacking. A serving of ground beef is a mixture of trim from many carcasses, while a single serving of steak or roast is from a single carcass. As a result, *E. coli* O157:H7 in ground beef may not be a reasonable surrogate to estimate *E. coli* O157:H7 contamination in steaks. The National Cattlemen's Beef Association has conducted additional research on *E. coli* O157:H7 contamination in steaks and plans to make this data available to the FSIS Risk Assessment Division (Bo Regan, personal communication, February 2002).

7 This assumption did not have much effect on the risk estimates for steak/roast servings since there are > 10 times as many servings with only 1 *E. coli* O157:H7 organism.
tearing the tissue or punching holes. It is estimated that large pieces of meat are pierced three times with about 0.8 needles per cm² of meat surface each time the needle head strikes. During this process, *E. coli* O157:H7 can be transferred from the surface to the interior of contaminated meat and/or to meat previously not contaminated (e.g., cross-contamination).

The Kansas State University study indicated that about 3-4% of *E. coli* O157:H7 on the surface of intact steaks is transferred to the interior during single-pass blade tenderization (Sporing 1999). The risk assessment assumed that this data (e.g., 3-4% translocation of surface *E. coli* O157:H7) is reasonably indicative of the results of commercial tenderization. The Kansas State University data also suggests that multiple-pass tenderization may not result in significantly more *E. coli* O157:H7 being translocated from the surface to the interior of meat (see below).

The Kansas State University study also indicated that the amount of *E. coli* O157:H7 translocated into the interior of steaks decreased with increasing depth of penetration. This suggests that most *E. coli* O157:H7 is deposited near the surface of a meat during single-pass blade tenderization and that there are few organisms remaining on a blade to be transferred to greater depths of contaminated meat or to meat that was previously not contaminated. Also, given the very low prevalence and levels of *E. coli* O157:H7 contamination (e.g., 0.02% of steaks with most having only 1 *E. coli* O157:H7 organism), cross-contamination may not be a significant factor in the risk of illness from *E. coli* O157:H7 in non-intact beef when compared to steaks contaminated internally through translocation of *E. coli* O157:H7 during tenderization. As a result, cross-contamination was not modeled in this risk assessment and only single-pass tenderization was considered.

**Step 3. Estimation of growth and decline of *E. coli* O157:H7 during distribution, storage and handling prior to cooking.** Large pieces of meat (subprimals), either tenderized or left intact, are then cut into standard pieces (e.g., steaks and roasts) and sold to retail for consumption. Consideration was given to the amount of growth and decline in the level of *E. coli* O157:H7 in intact and non-intact beef products during distribution and storage prior to cooking. Assuming that the growth of *E. coli* O157:H7 is the same in steaks as in ground beef (FSIS August 2001), the risk assessment estimated the following:

- about 50% of steaks have no change in the number of *E. coli* O157:H7 during storage and handling;

- about 49% (range: 20-80%) of steaks have a reduction in the levels of *E. coli* O157:H7 resulting from freezing the product; and

- about 1% of steaks have some growth of *E. coli* O157:H7 during storage and handling.

To simplify the modeling, it was assumed that freezing eliminates *E. coli* O157:H7. Since all contaminated steaks (only 0.02% of all steaks) are modeled as having only 1 *E. coli* O157:H7 organism, freezing would leave, at most, 0.1 *E. coli* O157:H7 organism. This
assumption does not significantly change the risk estimates for non-intact and intact steaks. The fraction of steaks estimated with various levels of *E. coli* O157:H7 contamination (e.g., “bugs per serving” (BPS)) are shown in Figure 1.

![Figure 1. Fraction of steaks contaminated with various levels of *E. coli* O157:H7 organisms prior to cooking (“BPS” = “bugs per serving”).](image)

It is assumed that levels of *E. coli* O157:H7 are the same for non-intact (tenderized) and intact (not tenderized) beef prior to cooking. Figure 1 shows that 99.99% (range: 99.8% to 99.998%) of steaks are not contaminated with *E. coli* O157:H7 after taking into consideration the potential for growth and decline in the number of organisms as a result of storage and handling of these products. Only about 0.01% (range: 0.2% to 0.002%) of steaks contain *E. coli* O157:H7 and most of these contaminated servings contain only 1 *E. coli* O157:H7 organism.

**Step 4. Estimation of the Level of *E. coli* O157:H7 Contamination After Cooking.** After storage, steaks are prepared by a variety of cooking methods (e.g., broiling, grilling, and frying) prior to consumption. A recent analysis of the USDA Continuing Survey of Food Intakes by Individuals indicates that about 40% of consumers fry steaks, and an equal percent (30%) grill or broil these products (Bogen 2001). This information along with data from the FDA/Audits International Home Cooking Interactive Database$^8$ was used to estimate the temperatures to which steaks are cooked in the U.S. (FDA 2000) (Figure 3).

$^8$ The data from the FDA/Audits International Home Cooking Temperature Database do not differentiate between observations for beef, pork or lamb. The lower temperatures in the database were used to represent cooking temperatures for beef since it is likely that pork and lamb are more thoroughly cooked. This more conservative estimate can be adjusted with consumer and retail behavior data as it becomes available.
Figure 3: Internal temperature (°C) to which steaks are cooked in the U.S. based on data from the FDA/Audits International Home Cooking Interactive Database.

The Kansas State University study also provided data on the effects of cooking in reducing *E. coli* O157:H7 in non-intact (tenderized) and intact (tenderized) steaks as a function of cooking method (broiling, grilling, and frying), internal temperature, and steak/roast thickness (Sporing 1999). The Kansas State University data indicated significant uncontrolled variability in the experiment and a noticeable leveling out, or "plateauing," effect at the higher temperatures, which is probably due to the limitation in the experiment of inoculating steaks to about $10^6$ *E. coli* O157:H7. The best fit to this data was drawn taking into consideration the fact that at some temperature all *E. coli* O157:H7 would be destroyed (Figure 4).

The differences in best fit curves for the cooking methods (Figure 4) suggests that the same "internal cooking temperature" in the three cooking methods does not correspond to the same killing conditions in/on the meat. This suggests that there may be another confounding factor not controlled in the Kansas State University study. The movement of curves to the right suggest that *E. coli* O157:H7 is slightly shielded from the effects of cooking in non-intact (tenderized) steaks compared to intact (tenderized) steaks.
Figure 4: Best fit curves to Sporing (1999) data for broiling, grilling, and frying 3.2 cm thick intact (not tenderized) and non-intact (tenderized steaks). Not shown: data for 1.3 and 1.9 cm thick steaks.

Combining this information, the risk assessment estimates that 0.000026% (i.e., 2.6 of every 10 million servings) of intact steaks contain one or more *E. coli* O157:H7. For non-intact (tenderized) steaks, 0.00037% (i.e., 3.7 of every 10 million servings) contain one or more *E. coli* O157:H7. See Figure 6 for a full range of exposure doses of *E. coli* O157:H7 in intact and non-intact beef.

**Step 5. Dose-Response.** The *E. coli* O157:H7 dose-response relationship shown in Figure 5 was adapted from the ground beef risk assessment (FSIS August 2001) using data from five Japanese foodborne outbreaks (Nauta 2001, Shingawa 1997, Uchimura 1997)*. The dashed curve is intended to apply to the general population. A dose-response curve for susceptible individuals (e.g., children < 5 years old) would be shifted to the left of this curve (i.e., closer to the Japan 2 young children data point).

This dose-response relationship suggests, for example, that if 100 individuals from the general population each consumed servings containing, say, 10,000 *E. coli* O157:H7 (i.e., 4 logs), about 60 would become ill.

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*Translated by Dr. Fumiko Kasuga, National Institute of Infectious Diseases, Japan.*
Figure 5. Expected *E. coli* O157:H7 dose-response curve for the general population.

2.2. Risk Assessment Results

The probability of *E. coli* O157:H7 surviving typical cooking practices in either tenderized or not-tenderized steaks, is minuscule. As can be seen in Figure 6, 0.000026 percent (i.e., 2.6 of every 10 million servings) of steaks that are intact (not tenderized) contain one or more *E. coli* O157:H7. For non-intact (tenderized) steaks, 0.000037 percent (i.e., 3.7 of every 10 million servings) contain one or more *E. coli* O157:H7. There is almost no difference in exposure to *E. coli* O157:H7 in cooked intact (not tenderized) versus non-intact (tenderized) steaks (see almost overlapping lines in Figure 6).

Figure 6 suggests that illness seldom occurs at doses less than 10 *E. coli* O157:H7 per serving of intact or non-intact beef. At a dose of 100 *E. coli* O157:H7, approximately 16 percent of those exposed will become ill. The fraction of intact (not tenderized) steaks with exposure doses of 100 or more *E. coli* O157:H7 is about 1.4 in 10 million, while the fraction of non-intact (tenderized) servings with exposure doses ≥100 *E. coli* O157:H7 is about 1.5 in 10 million.
Figure 6. Model output showing predicted bacteria per serving after cooking (exposure dose) and corresponding frequency of illness (response).

Moreover, there is almost no difference in the risk of illness from intact (not tenderized) versus non-intact (tenderized) steaks:

- 1 illness per 15.9 million servings of intact steaks;
- 1 illness per 14.2 million serving of non-intact (tenderized) steaks.

This implies that there would be about seven additional illnesses due to tenderization for every billion steak servings.

3. Comparison of Risk Assessment Results to NACMCF Findings

The risk assessment and NACMCF found had somewhat similar findings:

- NACMCF found that non-intact (tenderized) beef does not pose a greater risk of illness than intact beef it is oven broiled and cooked to an internal temperature of 140°F (45.8°C) or more.

- The risk assessment found almost no difference in the risk of illness from intact versus non-intact (tenderized) steaks regardless of cooking temperature [1 illness out of 15.9 for intact steaks compared to 1 illness out of 14.2 millions non-intact steaks].

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10 The risk assessment indicates 80% confidence that the predicted probability of illness from E. coli O157:H7 for both intact and non-intact (tenderized) steaks is between $4.5 \times 10^{-6}$ and $1.0 \times 10^{-5}$. 

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4. Research Needs

The following research needs have been identified in order to obtain more information about the microbiological profile, cooking practices, industry practices for blade tenderizing, and the proportion of blade tenderized beef marketed in the U.S.. Data is also needed regarding the exposure dose of *E. coli* O157:H7 likely to cause illness in susceptible populations.

1. A lack of quantitative (variable) baseline data for *E. coli* O157:H7, or appropriate indicator organisms such as *E. coli* biotype 1, coliforms, and/or *Salmonella*, on primal and subprimal cuts of beef immediately prior to blade tenderization was identified. Ideally, mapped carcass prevalence and level of *E. coli* O157:H7 data should be collected.

2. Data on the type of tenderization, processing conditions, and establishment production volume should be gathered along with baseline data as risk factors useful in as a profile to target Agency inspection resources for HACCP verification activities.

3. Survival of *E. coli* O157:H7 in core beef samples following cooking to specified temperatures, including data on the survival of *E. coli* O157:H7 in beef roasts compared to beef steaks.

4. Industry and consumer practices for cooking various cooking methods (e.g., grill vs. broil).

5. Industry practices for blade tenderization; such as the type of machine, number of passes through the tenderizer, sanitation of equipment, through put, temperature of the processing room, and the temperature of the primal cuts.

6. Proportion and quantity of blade-tenderized beef distributed to retail and food service establishments.

7. Better understanding of the heat and mass transfer characteristics of blade-tenderized meats cooked by various means.

8. Quantify the heat resistance (e.g., D and z values) of the individual strains of *E. coli* O157:H7 used in the Sporing (1999) study. Individual strains should be identified and characterized.

9. Dose-response relationship for susceptible populations (e.g., children < 5 years old). Exposure dose data could be collected during outbreak investigations.
5. References


Health Canada (March 2002). Reported cases of illness associated with tenderized beef. One page of summary information from the Quebec Center of Food Inspection and Animal Health provided by Dr. Anna Lammerding.


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ERRATA

COMPARATIVE RISK ASSESSMENT FOR INTACT (NON-TENDERIZED) AND NON-INTACT (TENDERIZED) BEEF

Below is a list of errors found in the Interpretive Summary Comparative Risk Assessment for Intact (Non-Tenderized) and Non-Intact (Tenderized) Beef. The date of discovery of the error is indicated. The list will be updated when and if other errors are discovered. Last updated 3/20/2006.

Page 12, the statement in section 2.2. Risk Assessment Results,

- 1 illness per 14.2 million servings of intact steaks;
- 1 illness per 15.9 million serving of non-intact (tenderized) steaks.

should be stated as

- 1 illness per 15.9 million servings of intact steaks;
- 1 illness per 14.2 million serving of non-intact (tenderized) steaks.

(Discovery date: November, 2004)
February 1, 2010

David Goldman, M.D.
Assistant Administrator, Office of Public Health Science
Food Safety and Inspection Service
United States Department of Agriculture
Jamie Whitten Building
Room 341-E
Washington, DC 20250

RE: Risk assessment for non-intact beef steaks

Dear Dr. Goldman:

On December 24, 2009, the Food Safety and Inspection Service (FSIS or the agency) initiated a recall (FSIS-RC-067-2009) of ca. 248,000 pounds of mechanically tenderized beef steak associated with illnesses caused by Escherichia coli O157:H7. The American Meat Institute (AMI) treats each recall very seriously because of the adverse health risks they present for consumers. Recalls also can serve as a vehicle for the industry to learn more about a foodborne illness outbreak and the cause or causes of that outbreak. That information, in turn, can assist the meat and poultry industry and other stakeholders in implementing better processes or procedures that can help eliminate further outbreaks.

In the above-referenced recall, as in some other recalls, the underlying cause of the illness is unclear. Were the products that caused the illnesses mechanically tenderized only, mechanically tenderized and then marinated by a solution in a tumbler or by needle injection? Gleaning the correct information from this, and other, recalls can be very helpful in developing strategies and procedure to prevent future outbreaks.

AMI has conducted a review of available information regarding illness-related recalls linked to mechanically tenderized beef products. From this review AMI has determined that all of the recalls due to outbreaks were related to the consumption of marinated or enhanced steak products. (See Table 1 below.) Because of potential cross contamination issues, the recalled product may include more than just the implicated product.
Table 1. Analysis of Mechanically Tenderized and/or Marinated Beef Products Associated
Recalls

<table>
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<th>Year</th>
<th>Recall Number</th>
<th>Product</th>
<th>Illnesses</th>
<th>Marinated</th>
<th>Mechanically Tenderized</th>
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</thead>
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<td>2000</td>
<td>NA</td>
<td>Beef steak</td>
<td>2</td>
<td>Unknown</td>
<td>Yes</td>
</tr>
<tr>
<td>2003</td>
<td>FSIS-RC-028-2003</td>
<td>Bacon-wrapped beef steaks</td>
<td>10</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>2004</td>
<td>FSIS-RC-033-2004</td>
<td>Beef steaks</td>
<td>4</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>2007</td>
<td>FSIS-RC-019-2007</td>
<td>Beef steaks</td>
<td>5</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>2007</td>
<td>FSIS-RC-023-2007</td>
<td>Ground Beef and steaks&lt;sup&gt;a&lt;/sup&gt;</td>
<td>NA</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>2007</td>
<td>NA</td>
<td>Beef Steak (Cooked tri-tip)</td>
<td>27</td>
<td>Unknown</td>
<td>Unknown</td>
</tr>
<tr>
<td>2007</td>
<td>NA</td>
<td>Beef Steak (Tri-tip)</td>
<td>&lt;i&gt;ca 24&lt;/i&gt;</td>
<td>Unknown</td>
<td>Unknown</td>
</tr>
<tr>
<td>2009</td>
<td>FSIS-RC-067-2009</td>
<td>Beef steaks</td>
<td>7&lt;sup&gt;b&lt;/sup&gt;</td>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
</table>

<sup>a</sup>Recall was initiated due to ground beef illness and expanded to include mechanically tenderized products. No illnesses were associated with mechanically tenderized steaks. Communication with FSIS and recalling company.

<sup>b</sup>Illnesses associated with recalled product. The Centers for Disease Control and Prevention report 14 additional illnesses associated with the outbreak strain, but no link to recalled product, for a total of 21 illnesses. FSIS confirmed that all of the steak exposures for ill people were due to product that was first mechanically tenderized and then marinated.

Based on the data presented in Table 1, AMI requests that the agency use this information to revise the agency’s “Comparative Risk Assessment for Intact (Non-Tenderized) and Non-Intact (Tenderized) Beef, March 2002”. Marinated or enhancement solution-added products were not differentiated in the 2002 risk assessment. That is, the types of steak products that have caused illnesses have not been addressed in the agency’s risk assessment. Additionally, on June 12, 2009, a letter submitted to Secretary Vilsack by the Safe Food Coalition had no mention of this marinated category of steak products.

It is an imperative that the process of manufacturing beef steaks be understood so that the risk assessment of mechanically tenderized beef steaks is meaningful and both benefits public health and provides useful information to the regulated industry. Because the marinated or enhanced mechanically tenderized products are a small portion of the entire beef steak production volume, a more focused approach will more likely help the agency and the industry as we collectively work to prevent illnesses associated with mechanically tenderized and marinated steak products.

Thank you for your consideration and timely response to this request. If AMI can be of further assistance, please contact me either by email at SGoltry@meatami.com or 202-587-4254.

Sincerely,

Scott Goltry
Vice President
Food Safety and Inspection Service

cc: Al Almanza  
Phil Derfler  
Kenneth Petersen
ATTACHMENT D
Findings of the Health Risk Assessment of *Escherichia coli* O157 in Mechanically Tenderized Beef Products in Canada

Regular Paper

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Abstract In late 2012, a total of 16 cases of foodborne illness caused by *Escherichia coli* O157 were reported as part of a Canadian outbreak related to contaminated beef. During the food safety investigation associated with the outbreak, it was determined that a few cases were likely associated with the consumption of mechanically tenderized beef (MTB) which had been tenderized at the retail level. Details of this investigation and its follow-up are available online on the Canadian Food Inspection Agency (CFIA) website. This event raised awareness of the Canadian public and the scientific community regarding the practice of mechanical tenderization of beef. Furthermore, four relatively recent *E. coli* O157 outbreaks in the United States have highlighted the fact that non-intact products, other than ground beef, such as tenderized roasts and steaks, may represent an increased risk of illness relative to intact muscle cuts (USDA-FSIS, 2008; Laine et al., 2008; CDC, 2010). In order to evaluate this risk, Health Canada (HC) and the Public Health Agency of Canada (PHAC) have developed a plan to gather information and communicate any potential risks to Canadians associated with the practice of mechanical tenderization of beef products. The Bureau of Microbial Hazards, Food Directorate, HC, in partnership with The Public Health Risk Sciences Division, Laboratory for Foodborne Zoonoses, PHAC and in collaboration with other food safety partners have developed a health risk assessment on the potential health risks associated with MTB products in Canada. This document summarizes the initial findings of the assessment and updates the relative risk estimates for Canada using the structure of the 2013 model published by PHAC (Smith et al., 2013), while taking into account new information. The model demonstrated that the consumption of MTB is approximately 5 times riskier than consumption of an
intact beef cut. In contrast, ground beef is 1500 and 7300 times riskier than MTB and intact beef cuts, respectively. Additionally, model investigations of an intervention, applied directly prior to tenderization demonstrated that the calculated risk associated with MTB can potentially be reduced to a level of risk nearing that of an intact beef cut. A more fulsome assessment document accounting for data submitted to HC most recently (April – May 2013) and including detailed characterizations of mathematical modeling of the various scenarios envisaged is currently under preparation and will be published subsequently.

1. Background

Human foodborne illness caused by E. coli O157 appears to have declined over the past years as judged by the number of cases reported through the National Notifiable Diseases Database and National Enteric Surveillance Program (NESF), Public Health Agency of Canada (PHAC, 2013a), Table 1. However, foodborne infection with E. coli O157 remains a significant cause of gastroenteritis in Canada and this pathogen continues to be implicated in numerous outbreaks worldwide (Pennington, 2010). Symptomatic E. coli O157:H7 infections are typically characterized by diarrheas and haemorrhagic colitis, and can progress to haemolytic uraemic syndrome (HUS), a life-threatening sequelea that usually requires blood transfusions and dialysis. Symptoms of HUS vary and typically occur in about 5 to 10 % of people who get sick from E. coli O157:H7 overall and about 15 % of young children and the elderly develop haemolytic uraemic syndrome (HUS), which can be fatal. Other sequelae such as permanent kidney damage can also occur (PHAC, 2013b).

Although E. coli O157 has been isolated from various animal species (domestic and wildlife), healthy cattle are considered to be the most important animal reservoir associated with its transmission into the food chain and with human infection (Yoon and Hovde, 2008). During the processes of slaughtering, dressing and fabrication of beef, E. coli O157, if present on the hide and/or in the intestinal contents, can be transferred to the surface of the dressed carcass and onto subsequent cuts of meat, e.g., primal and sub-primal cuts.

Contamination of structurally intact beef cuts or steaks by E. coli O157 is generally limited to the surface of the meat and the bacteria can be inactivated by common cooking practices. However, when beef contaminated with the bacteria is ground (i.e., non-intact beef), the contamination can be spread throughout the product. The consumption of contaminated ground beef cooked to an end-point internal temperature of less than 71°C has been a major cause of E. coli O157 infection, as illustrated by numerous outbreaks (Huang and Sheen, 2011). It is frequently found that contaminated product associated with illness outbreaks is mishandled in some manner, e.g., cross-contamination, inadequate cooking temperature, lack of verification of internal temperature, etc. As such, attention by industry and regulators to the control of E. coli O157 in beef has been targeted in great part to ground beef products, as they are considered to represent the greatest concern for public health.

One E. coli O157 outbreak in Canada and four outbreaks in the US (Table 2) have highlighted the fact that aside from ground beef, non-intact products such as tenderized roasts and steaks may represent a risk of illness which could be addressed through risk management action.

In addition to the attention on mechanically-tenderized beef (MTB) as a result of these outbreaks, research on mechanically-tenderized products has been published in the scientific literature over the past decade. These studies have demonstrated that MTB products may not be evenly cooked and/or cooked to an end-point internal temperature which is sufficient to ensure safety. This is because bacteria, including pathogens such as E. coli O157 and Salmonella spp., can be transferred into the interior of meat cuts by mechanical tenderization, with or without the injection of marinades and brines (Echeverry et al., 2009; Echeverry et al., 2010; Gill and McGinnis, 2004; Gill and McGinnis, 2005; Gill et al., 2005a; Gill et al., 2005b; Graumann and Holley, 2007; Huang and Sheen, 2011; Luchansky et al., 2008; Luchansky et al., 2009; Luchansky et al., 2011; Luchansky et al., 2012).

<table>
<thead>
<tr>
<th>Pathogen / Group</th>
<th>2006</th>
<th>2007</th>
<th>2008</th>
<th>2009</th>
<th>2010</th>
<th>2011</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Total</td>
<td>Rate</td>
<td>Total</td>
<td>Rate</td>
<td>Total</td>
<td>Rate</td>
</tr>
<tr>
<td>E. coli O157‡</td>
<td>978</td>
<td>2.99</td>
<td>934</td>
<td>2.83</td>
<td>661</td>
<td>1.98</td>
</tr>
<tr>
<td></td>
<td>529</td>
<td>1.56</td>
<td>404</td>
<td>1.18</td>
<td>452</td>
<td>1.39</td>
</tr>
</tbody>
</table>

Table 1. Excerpted annual totals and rates (per 100,000) for E. coli O157 reported to NESF, 2006 to 2011:

* Rates calculated using the population estimates for Canada as of July 1 for years 2006 to 2011 as reported by Statistics Canada.
+ Only cases of E. coli O157 are included in this table, as E. coli non-O157 is not consistently reported by provinces.
‡ Full table available at: http://www.phac-aspc.gc.ca/fs-sa/fs/recoll-eng.php#fig1
Federal food safety authorities have undertaken several initiatives with the goal of understanding how non-intact products may present a risk of illness, and how this risk could be addressed through management action. For example, one assessment is the United States Department of Agriculture (USDA) Food Safety and Inspection Service (FSIS) "Comparative Risk Assessment for Intact and Non-intact (Tenderized) Beef" that was published in March 2002 (USDA-FSIS, 2002). At the time, the USDA-FSIS reached the conclusion that MTB products did not represent an increased concern relative to intact meat cuts. Specifically, the USDA-FSIS risk assessment predicted 1 illness per 15.9 million servings for intact steaks, and 1 illness per 14.2 million servings for non-intact (tenderized) steaks. Additionally, it was stated that, "...there is almost no difference in the risk of illness from intact (not tenderized) versus non-intact (tenderized) steaks," and "the probability of E. coli O157:H7 surviving typical cooking practices in either tenderized or not-tenderized steaks, is minuscule." However, in light of illnesses associated with E. coli O157 in MTB since the release of the 2002 assessment, the USDA-FSIS announced an update to their risk assessment. This update has not yet been published; however, until a revised assessment is available, their previous work was thoroughly conducted and the findings remain relevant.

In Canada, a team from the Public Health Agency of Canada (PHAC) published a stochastic, quantitative risk assessment model to evaluate the effects of interventions at several stages in pre-harvest and processing, prior to final fabrication of beef (Smith et al., 2013) as a refinement of a previous Canadian risk assessment model published in 1998.

Table 2. North American outbreaks linked to whole muscle cuts of beef, adequately reported to determine non-intact status (i.e., that tenderization has occurred).

<table>
<thead>
<tr>
<th>Year</th>
<th>Type of meat</th>
<th>Location</th>
<th>Cases</th>
<th>Publication source</th>
</tr>
</thead>
<tbody>
<tr>
<td>2000</td>
<td>needle tenderized sirloin steaks</td>
<td>USA</td>
<td>2</td>
<td>USDA-FSIS, 2005 FR70-30331-30334</td>
</tr>
<tr>
<td>2003</td>
<td>boneless beef filet bacon-wrapped steak product injected with marinade</td>
<td>USA</td>
<td>11</td>
<td>Laube et al., 2003 J. Food Prot. 2003, 66(6):1198</td>
</tr>
<tr>
<td>2004</td>
<td>tenderized, marinated beef steak product</td>
<td>USA</td>
<td>4</td>
<td>USDA-FSIS, 2005 FR70-30331-30334</td>
</tr>
<tr>
<td>2009</td>
<td>blade tenderized steaks</td>
<td>USA</td>
<td>21</td>
<td>CDC, 2010 Published online</td>
</tr>
<tr>
<td>2012</td>
<td>needle tenderized steaks</td>
<td>Canada</td>
<td>5</td>
<td>PHAC, 2013 Internal communications</td>
</tr>
</tbody>
</table>

Scope

The following factors outline the scope of this assessment:

Pathogen of concern:
- *E. coli* O157:H7 and *E. coli* O157:NM (E. coli O157)

Food(s) of concern:
- Mechanically tenderized beef produced in Canada (i.e., non-intact products where the meat surface is penetrated by the use of blades or needles and/or is injected or massaged/tumbled with a solution)
  - Excludes diced, cubed, and reformatted products
  - Excludes imported products (data on key characteristics of these products is not available)

Population of interest:
- Canadian population

Endpoint(s) of concern:
- Illnesses of any severity caused by *E. coli* O157

Steps in the production, processing, distribution, preparation and consumption:
- All steps from farm to fork are included

Control measures and mitigations:
- Change in tenderization conditions
- Influencing consumer behaviour (i.e., introduction of labeling, consumer education, etc.), specifically, through the introduction of a cooking temperature recommendation (as per risk managers charge)
  - Based on the effects of the above control measures and mitigations, the potential development and implementation of policy instruments (i.e., guidance documents, guidelines, etc.) may be better informed

Data included:
- Scientific and published literature
- Unpublished data supplied by other governmental departments, agencies, and stakeholders

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* It should be noted that Health Canada did not analyse the USDA-FSIS report with the purpose of determining its applicability in Canada, using the newly available Canadian data, or to suggest areas where refinements could be made by the USDA-FSIS.
Objectives

The principal objectives of this assessment are to:

- Characterize the risk that could be associated with MTB specific to post- or late-fabrication practices, using a measure of risk per serving.
  - Characterization of the risks that could be associated with MTB in comparison to ground beef and intact beef cuts.
- Examine mitigation or control strategies which could be applied by various stakeholders along the food chain (e.g., processors, retailers, regulators, consumers), and analyse their effects on the potential risk.

In order to meet the objectives, the following questions will be considered in this risk assessment:

**Question 1:**
What is the risk per serving from MTB to which consumers may be exposed via Canadian beef? How does this risk compare to the risk per serving from consuming other intact and non-intact beef products (including ground beef and brine injected beef and whole steaks)?

- Would there be large effects on the risk per serving depending on adherence to a recommended cooking temperature?

**Question 2:**
Based on the specific charge requested by risk managers, one particular control measure to be investigated is the effect of cooking temperature. Based on the outputs of the risk assessment, should a cooking temperature be recommended to consumers and/or food service operators, specific to MTB?

2. Approach

Health Canada has undertaken a risk assessment on the potential health risks associated with *E. coli* O157 in MTB using elements of the health risk assessment framework developed by the FAO/WHO Codex Alimentarius Commission - Principles and Guidelines for the Conduct of Microbiological Risk Assessment CAC/GL 30 (WHO, 1999).

As part of this work, a review of the scientific literature around the issue of MTB was done. HC has also issued a public request for data* aiming to obtain information specific to the Canadian context.

Additionally, through collaboration and partnership with stakeholders, and the incorporation of newly available data, the stochastic quantitative risk assessment model published by the PHAC (Smith et al., 2013) was updated and used to evaluate the comparative level of risk between ground beef, intact beef cuts and MTB posed to the Canadian public, resulting in a semi-quantitative risk assessment.

The current investigation aims to update the relative risk estimates for Canada using the structure of the 2013 model published by PHAC, while taking into account new information. This includes consideration of the complexity of the beef production continuum in Canada and the possibility that tenderization may occur at various stages, including at the producer, the retailer and/or in the consumer home (Figure 1). An understanding of the extent of tenderization is important to understand the potential risks that could be associated with MTB consumption in Canada.

*HRI: Hotel, restaurant, institution

Figure 1. Simplified exposure pathway

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As well, Health Canada is using this work as an opportunity to examine mitigation or control strategies that could be implemented along the beef production continuum and play a role in decreasing the risk to the Canadian population. In particular, the potential implementation of a cooking temperature recommendation was investigated.

2.1 Overview of the model

The PHAC model is a stochastic, quantitative risk assessment model used to characterize risks from the consumption of E. coli O157:H7 in beef products (Smith et al., 2013). The model was developed considering two core objectives, including: 1) evaluation of the relative efficacies of pre-harvest and processing-level interventions, and 2) determination of risks to Canadians from consumption of E. coli O157:H7 in ground beef, non-intact beef cuts (i.e., MTB), and intact beef cuts at that time. The model outputs identified reductions in public health risk ranging from 30.99-99.95% depending on the combination and application of a number of interventions. Risks from consumption of non-intact beef cuts that had been tenderized by either blades or injection of brine were estimated to be an order of magnitude greater than those for intact cuts.

The PHAC model is a large “farm-to-fork” model and was adopted for use in the current assessment, with minor modifications and consideration of additional data. The model uses Monte Carlo simulations with Latin Hypercube Sampling and is constructed in Microsoft Excel 2010 coupled with @Risk (version 5.5.0, Palisade Corporation, New York, USA). For each scenario explored using the model, 25,000 iterations were performed.

The model structure is described in detail elsewhere (Smith et al., 2013), and basic components are briefly summarized herein. Canadian data describing prevalence and concentration of E. coli O157 in cattle feedlots at farms and feedlots were used as initiating parameters for the assessment. Using transfer ratios and factors derived from observational studies, E. coli O157 occurrence on cattle hides and subsequently, carcasses, at processing were calculated. The prevalence, concentration and behavior of E. coli O157 was modeled throughout various processing steps leading to the production of ground beef, non-intact beef cuts, and intact beef cuts using information and relationships gleaned from the scientific literature and government reports. The scenario reflecting current processing practices considered in the PHAC model used data from systematic review and meta-analyses to evaluate the impacts of interventions used by Canadian processors. The Smith et al. (2013) “current practices” intervention scenario was used to represent the baseline scenario described in the current assessment, with modifications to reflect increased use of processing-level interventions in Canada.

Retail and consumer storage practices, for both refrigeration and freezing conditions, were used alongside growth or inactivation models to determine the levels of E. coli O157 in beef products prior to cooking. Distributions of internal temperatures achieved during cooking of ground beef, non-intact beef cuts, and intact beef cuts and serving sizes were used to calculate the dose of E. coli O157 consumed. The modeled dose was incorporated into a Beta-Binomial dose-response model to determine the primary outputs of the model; the probabilities of illness per serving of each beef product.

For the current assessment, the process model and mathematical equations remained identical to Smith et al. (2013), aside from the following: the parameter describing the proportion of beef cuts that are subjected to a tenderization process, used to calculate PAS in the Smith et al. (2013) study, was not considered. This proportion is unknown, and given the objectives of the current assessment, it is preferable to compare the inherent risks associated with each product without consideration of the likelihood of consuming each product. This parameter could be used in future modeling efforts alongside incorporation of consumption volume data to determine number of illnesses per year, etc. Also, the current assessment expresses risks as the mean number of servings resulting in a single illness: this is the inverse of the mean probability of illness per serving.

3. Hazard Identification and Characterization

The hazard of concern is E. coli O157:H7 and E. coli O157:NM (E. coli O157). The biological characteristics, species specificities, virulence traits, as well as conditions for growth, inhibition and inactivation of this pathogen are well described elsewhere (ICMSF, 1996; NZPSA, 2001; Meng et al., 2007). Additionally, the severity of the illness associated with E. coli O157 infection and the potential sequelae associated with the illness and outcomes are also well documented (Pennington, 2010).

The minimum infectious dose of enterohaemorrhagic E. coli has been estimated as 100-200 cells, and possibly as low as 10 cells based on retrospective analyses of ground beef and salami associated with outbreaks (Meng et al., 2007). The dose-response model used in the updated quantitative work supporting this assessment was the Beta-binomial model developed by Cassin et al. (1998), which also estimates a very low infectious dose. Currently, there are no dose-response models for E. coli O157:H7 illness based on outbreak data linked to the consumption of MTB or steaks.

4. Exposure Assessment

The exposure assessment focuses on:

- the process of mechanical tenderization and its effects on the prevalence and concentration of E. coli O157, if present;
• possible interventions that could be applied to beef directly prior to tenderization and;
• the extent of tenderization along the production/distribution continuum, as well as in the consumer home.

In considering the above, the following are the main factors affecting this exposure assessment:

1. According to current industry practices, it is assumed that primary processing has a significant effect on absolute risk. Processors operating under normal conditions and with GMPs should effectively decrease contamination to low levels. However, in this investigation, it is assumed that a carcass is not labeled as destined to produce beef cuts that will be tenderized. Thus all cuts would be treated with the same primary process and interventions, regardless of whether they were going to be tenderized or not. Based on these key assumptions, it is understood that primary processing will not have a significant influence on the relative risk determination presented here.

2. Data collected and reported in the published literature at various points of processing from broken carcasses to beef cuts at retail, suggest a low prevalence and low concentration of E. coli O157.

3. A number of tenderization processes are available for use by beef processors. These can be broadly categorized as blade tenderization, needle tenderization with or without injection of marinades or brines (also called “deep basting,” “injection marination,” “enhancement,” or “moisture enhancement”), high pressure needleless injection, and massaging/tumbling with solution.

a. In instances where bacteria are vertically transferred (pushed from the surface of a beef cut inwards), data suggest that the bulk of the microflora will remain near the top 1 cm of the meat surface. However, depending on the method of tenderization, this can vary (Sporing, 1999; Gill and McGinnis, 2005; Luchansky et al., 2008: Luchansky et al., 2009; Huang and Sheen, 2011; Johns et al., 2011.)

b. Data suggest mechanical tenderizers have the ability to horizontally transfer bacteria (spread bacteria from one uncontaminated individual steak to another) (Sporing, 1999; Gill et al., 2005a; Gill et al., 2005b; Luchansky et al., 2008; Adler et al., 2012; Jeremiah et al., 1999). Horizontal transfer can occur from a single contamination event forward to at least 4 additional beef cuts (Huang and Sheen, 2011). Information is lacking for steaks beyond this stage, so the maximum number of additional cuts that would be contaminated is not known.

c. Several data sources suggest that tenderization methods have different effects on the spread of contamination, and, in particular, tenderization with the injection of brine appears to increase the distribution depth and amount of bacteria within a beef cut. The re-use of brine for injection can also contribute to the horizontal spread of contamination (Gill et al., 2005a; Heller et al., 2007; Uttaro and Aalhus, 2007). Data suggest that needleless injection can also transfer bacteria from the surface to the interior of the meat (Ray et al., 2010; Jeffries et al., 2012).

4. There is a relatively large body of work studying interventions on carcasses, trimmings and other beef cuts which report variation in efficacy depending on the treatment (Geormaras et al., 2011, Pittman et al., 2012). There have been a few studies which have investigated the efficacy of interventions in the specific context of MTB (Heller et al., 2007; Echeverry et al., 2009). Data reported in the published literature suggest that interventions immediately prior to mechanical tenderization can reduce the internalization of surface pathogens (Heller et al., 2007; Echeverry et al., 2009) Echeverry et al., 2010). Heller et al. (2007) reported a reduction of 0.9-1.1 logs in concentration of E. coli O157 as a result of such an intervention.

5. The maintenance and sanitation of tenderizing equipment is key to limiting the horizontal spread (Sporing, 1999; Gill and McGinnis, 2005; Luchansky et al., 2008; Sofos and Geormaras 2010; Huang and Sheen, 2011).

6. The exact extent of the practice of mechanically tenderizing beef in Canada is not known.

a. Data for federally-registered establishments has been collected, and provides an estimate of the practice at the processor level. Based on these data, MTB represents at most 25% of the total production volume. However, it is possible that this fraction is significantly smaller.

7. Data for retail establishments has also been collected, and demonstrates that the capacity for tenderization at the retailer may be three times greater than at the processor level (based on potential volume through tenderizing equipment available at retailers). Data provided by stakeholders to Health Canada from January to March 2013, revealed that needle and injected tenderization is in fact, practiced much less
frequently than blade tenderization at a ratio of 1 injected tenderized product to 11 blade tenderized products. In considering recommendations for cooking temperature, it is important to also factor in the method of cooking, type of beef cut, thickness and brine ingredients if applicable, as these will influence the effectiveness of the cooking temperature in the inactivation of the pathogen (Sporing, 1999; Luchansky et al., 2009; Luchansky et al., 2011; Porto-Fett et al., 2013; Mukherjee et al., 2008; Gill et al., 2009; Yoon et al., 2009; Shen et al., 2010; Adler et al., 2012).

5. Labeling of some MTB products at retail is a fairly recent occurrence in Canada and changes in consumer behavior with respect to adherence to cooking guidance provided on the label is not known.

6. Key Findings & Preliminary Opinion

In the present risk assessment, previous scientific knowledge on the identification and characterization of E. coli O157 were reviewed and are still applicable. Additionally, a number of the qualitative factors presented in the exposure assessment demonstrate that although there is a potential for a difference in risk between MTB and intact beef cuts, this difference is likely small, and the exposure to E. coli O157 appears to be low at this time.

MTB products produced under GMPs and with interventions applied prior to tenderization, are not perceived to represent a significantly increased risk relative to similarly produced non-tenderized intact meat products in the Canadian marketplace.

These findings are supported by the quantitative analysis detailed below in the "Preliminary Response to Guiding Questions."

6. Preliminary Response to Guiding Questions

Question 1:

What is the risk per serving from MTB to which consumers may be exposed via Canadian beef? How does this risk compare to the risk per serving from consuming other intact and non-intact beef products (including ground beef and brine injected beef and whole steaks)?

Would there be large effects on the risk per serving depending on adherence to a recommended cooking temperature?

<table>
<thead>
<tr>
<th>Scenario</th>
<th>Meat cut</th>
<th>Number of servings to cause 1 illness</th>
<th>Risk relative to baseline</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Intact</td>
<td>1.29 billion</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td></td>
<td>MTB</td>
<td>265 million</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Ground beef</td>
<td>176,000</td>
<td>7300</td>
<td></td>
</tr>
<tr>
<td>2*</td>
<td>MTB, 0.4-0.6 log reduction intervention</td>
<td>397 million</td>
<td>3.6</td>
<td>HC (2013) risk assessment / PHAC updated model</td>
</tr>
<tr>
<td></td>
<td>MTB, 0.9-1.1 log reduction intervention</td>
<td>487 million</td>
<td>2.7</td>
<td></td>
</tr>
<tr>
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<td>MTB, 1.4-1.6 log reduction intervention</td>
<td>1.19 billion</td>
<td>1.1</td>
<td></td>
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<tr>
<td>3*</td>
<td>Intact</td>
<td>35.9 million</td>
<td>1</td>
<td>USDA-APHIS (2002) risk assessment (not updated)</td>
</tr>
<tr>
<td></td>
<td>MTB</td>
<td>14.2 million</td>
<td>1.1</td>
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</tbody>
</table>

Table 3. Summary of Modeling Results

* A difference of 1 represents the baseline risk chosen for the given modeling scenario. Numbers greater than 1 indicate a risk increase relative to baseline (example, "3" represents a result which is "3 times riskier").

* The PHAC risk model uses the Monte Carlo numerical technique for performing risk calculations. This allows the incorporation of a distribution of possible input values, for any single parameter. In presenting a prediction for the number of servings required to cause one illness, it is the inverse value (mean probability of illness given a serving) which is calculated by the model. In the model, calculations include the variation implicit in the input parameter distributions, the boundaries of which are not presented here.

* Log reductions of E. coli O157 as a result of interventions tested by Heller et al., (2007), are expected to fall within the range of 0.9-1.1 log. Alternate reductions (i.e., 0.4-0.6 and 1.4-1.6 log) were informed using different data (Pitman et al., 2012; Georrou et al., 2011 and Echeverry et al., 2009). It was assumed that the described interventions were performed directly prior to tenderization, and the log reduction refers to the concentration of E. coli O157 on the surface of the beef cut.

* The 2002 US risk assessment model does not have the same construction or inputs as the PHAC risk assessment model, and therefore the results should not be compared. However, these results do provide an idea of the magnitude of other risk predictions of this nature.

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Updates to the PHAC (Smith et al., 2013) model, modeling outputs and discussion

Along with updated data regarding the baseline model scenario for interventions in processing, since the 2013 publication, another significant change to the PHAC model examined the potential exposure more specifically attributable to the ratio of blade tenderized to brine injected tenderized beef (point 6c in the Exposure Assessment Section).

The updated PHAC model predicted the mean number of servings which would result in one E. coli O157 illness after consuming an MTB steak, intact steak and ground beef. For a summary of this analysis, see Table 3. The analysis predicted that the mean number of servings which would result in one E. coli O157 illness after consuming MTB steak is 265 million. In comparison, the mean number of servings of ground beef which may cause one E. coli O157 illness was 176,000. Finally, the mean number of servings of intact beef cuts (steak) which may cause one E. coli O157 illness was 1.29 billion. Relatively speaking, the results of the model predict that the consumption of MTB is approximately 5 times riskier than consumption of an intact cut. In contrast, ground beef is 1500 and 7300 times riskier than MTB and intact cuts, respectively.

The difference between the calculated risk from ground beef, MTB and intact cuts could be due to numerous factors. One of the most important effects on the difference in risk between ground beef and beef cuts is the higher probability that ground beef source material is contaminated (i.e., beef trimmings). Trimmings are generally derived from the surface of a carcass where contamination is more likely and trimmings are typically packaged in large, 1,000 kg containers (combos) where cross-contamination can occur with relative ease.

The PHAC risk model uses the Monte Carlo numerical technique for performing risk calculations. This allows the incorporation of a distribution of possible input values, for any single parameter. In the model, calculations include the variation implicit in the input parameter distributions. It is these variations that allow the consideration of changes in the risk estimate resulting from, for example: the differences in tenderization methods, differences in treatments on the beef cuts (i.e., interventions) and differences in cooking temperatures, among other factors.

In addition, the PHAC model operates based on literature data which show that the level and variability of inactivation during cooking can be different depending on whether a steak is intact (Sporing, 1999), needle tenderized/injected (Luchansky et al., 2011) or blade tenderized (Luchansky et al., 2009; Luchansky et al., 2012; Sporing, 1999). These authors mainly compared similar cooking methods and steak thicknesses to determine these differences.

In the case of injection, reductions in the concentration of E. coli O157 due to cooking ranged from 0.3 - 4.1 log CFU/g (Luchansky et al., 2011), whereas blade tenderized steaks experienced reductions due to cooking ranging from 0.5 - 6.3 log CFU/g (Luchansky et al., 2009; Luchansky et al., 2012; Sporing, 1999). To illustrate the incorporation of this data into the PHAC risk model, if steaks are cooked to 63 or 71°C, the average reductions in the concentration of E. coli O157 calculated for injected steaks, blade tenderized steaks and intact steaks was 2.7, 3.8 and 4.5 log CFU/g at 63°C, and 3.3, 4.4 and 5.2 log CFU/g at 71°C. This is not to say that the only temperatures considered in the model were 63 and 71°C, because the model uses a distribution of values for this particular input*, but at either 63 or 71°C, if either value is randomly selected for a given simulation, the log reductions would be calculated as stated above.

6.1 Additional simulations

6.1.1 A possible scenario regarding the application of an antimicrobial intervention prior to tenderization

In addition to the PHAC model baseline scenario, three alternative beef treatments incorporating an intervention directly prior to tenderization were also explored (Table 3, scenario 2). The original model did not include the possibility of an intervention directly prior to tenderization, but it is known that producers performing tenderization can apply a treatment such as a hot water or lactic acid wash to the surface of a beef cut, before passing it through the tenderization equipment. In the scenario where an intervention is applied with an efficacy similar to the range reported by Heller et al., (2007) for a variety of intervention types, the mean probability of E. coli O157 illness per serving of MTB steak is reduced so that the consumption of MTB is approximately 2.7 times riskier than consumption of an intact cut.

In the case that an intervention applied directly before tenderization has an efficacy similar to the ranges published in the literature (ranging from no effect to 1.6 log reduction), then the effect on the calculated risk will vary. For example, steaks treated directly prior to tenderization with an intervention causing a 0.4-0.6 log reduction are approximately 3.6 times riskier than an intact cut. If a more effective intervention is applied (e.g.,

*Informed by the EcoSure (2008) consumer survey, details are the same as in Smith et al., (2013).
The modeling output of the risk assessment model used suggests that the level of risk associated with MTB is 5 times higher relative to intact beef cuts if all are produced under GMPs and normal circumstances. However, as noted in the response to question 1, if an intervention is applied directly prior to tenderization, the calculated risk associated with MTB can be reduced to a level nearing that of intact cuts. It follows that, if the risks posed by MTB and intact cuts are equivalent, then the usefulness of recommending a cooking temperature to consumers would be of limited value.

In considering recommendations on what cooking temperature would successfully reduce exposure to E. coli O157, it is important to also factor in the method of cooking, type of beef cut, thickness, and brine ingredients (if applicable). Currently, there is no consensus in the scientific literature and there are uncertainties as to consumer response and resulting behaviours to labeled packages of MTB products. More data is therefore needed to better document and inform the advice for a specific cooking temperature if it were to be adopted.

7. Major Challenges and Data Gaps

1. Throughout this risk assessment, the findings reported do not take into account, for example, circumstances where a processor may have experienced some failure in their process, or may have received inputs with levels of contamination to such an extreme that even a well-designed process would be overwhelmed, etc. It is important to note that these failures are considered as extraordinary circumstances that would occur rarely, and that no data are available to estimate how often they might take place.

2. An important part of risk assessment is the identification of areas where knowledge is incomplete (uncertainty) to such an extent where the application of the risk assessment findings are too limited to satisfy the "charge" laid out for the assessment team. Equally important is the identification of areas where variability of a parameter or process is so great that it may have the same effect. The Monte Carlo technique used in the quantitative portion of this assessment allows some analysis of these effects. However, in this risk assessment, that quantitative analysis was not the focus and final risk estimates were presented only as mean values, not distributions. In a qualitative sense, however, it should be highlighted that the amount of uncertainty in parameters involving consumer behaviour, particularly with respect to implementation of cooking recommendations, is high. The incorporation of consumer behaviour in any risk assessment, however, will be a great challenge.

3. With respect to the quantitative analysis, any data gaps found in the Smith et al. (2013) risk assessment would apply to the conclusions drawn for the purpose of this assessment. However, certain data
gaps were filled since the latter publication and the model was tested with this new data.

a. New cooking data from Luchansky et al. (2012) were used to expand the distribution of log reductions due to cooking used in the model.

b. New data on the ratio of blade to needle and injected tenderized beef were used to strengthen the overall risk calculation.

c. New data regarding the baseline model scenario (pre and early processing intervention regimes) were used to strengthen the overall risk calculation.

d. The extent of the difference between methods and temperatures that may be used to cook different cuts of beef is not known. Although the survey used to inform cooking times for the modeling portion of this assessment is specific to either ground beef or “beef” – there is no distinction between roasts and steaks for example.

4. The interventions evaluated in the Smith et al. (2013) risk assessment were quantified using systematic review and meta-analyses data. The additional antimicrobial intervention evaluated (i.e., one that could be applied directly prior to tenderization) was informed by a narrative review.

5. With respect to any microbiological or molecular testing data, there is always some inherent variability and uncertainty. The detail required from published data to incorporate variability and uncertainty into the quantitative analysis was not available from the data sources used in the current risk assessment. Additionally, the ability of the PHAC model structure to handle these analyses was not tested.

a. One particular challenge is the use of experimental studies that produce an estimate of log reduction. These studies generally use levels of inoculum (e.g., 10^4 - 10^6 CFU/ml or CFU/g) which are much higher than expected on beef cuts based on surveillance data, thus, they may overestimate actual log reductions.

6. With respect to any microbiological or molecular testing data, there is also a challenge with interpreting the behaviour, presence and concentration of indicator organisms in relation to E. coli O157:H7, where no data regarding the pathogen is readily available. No investigation of additional quantitative adjustments to the PHAC model was undertaken with respect to the inclusion of indicator organism data.

7. With respect to the determination of exposure to MTB, there is a challenging hurdle presented by the number of potential routes any particular piece of beef takes before being tenderized and then consumed. As stated, the exact amount of beef being tenderized in Canada is not known. Thus, it was necessary to make assumptions about where tenderization may be occurring (i.e., at processor, retailer, or consumer home), and this presented an impediment to determining the population risk. A general schematic which communicates these assumptions is included in Figure 1.

a. As stated in the exposure assessment, estimates of the volumes of MTB produced in federally-registered establishments, as well as retail, have been collected. More data for both of these types of establishments may be forthcoming.

b. Data is lacking for the non-federally registered sector (i.e., provincially-licensed establishments).

8. There are more sources of data, particularly microbiological or molecular testing data (e.g., prevalence and concentration of E. coli O157 at various points in the beef production continuum), for the US beef industry. Where Canadian data are not available, the true applicability of the US data in the Canadian context is unknown. It was assumed that the representativeness of the US data was adequate for use in determining the risk of MTB in Canada.

9. The low prevalence of E. coli O157 in beef provides a number of challenges. For example, microbiological sampling schemes and testing methods may have limits of detection which do not allow the risk assessor to make inferences about the actual bacterial population present on beef primal/sub-primal cuts.

8. Acknowledgements

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9. References


Pathogen Control During Tenderizing/
Enhancing of Whole Muscle Cuts

Prepared by: National Cattlemen's Beef Association, American Meat
Institute, National Meat Association, Southwest Meat Association

Why Best Practices?
Best Practices for tenderizing or enhancing operation reduce the likelihood that contamination with potential pathogens (specifically \textit{E. coli} O157:H7) will occur.

What is the Issue?
Tenderized and enhanced products may pose a risk if potential pathogens are moved from the meat surface to the interior portions of the meat products and the product is not cooked adequately to destroy the pathogens inside the meat product. If equipment used in the operation is contaminated somehow, and not cleaned and sanitized, the tenderizing or enhancing equipment, and perhaps the solution to be injected, may become the vehicle of the contamination.

Although the likelihood that subprimals or other intact cuts of meat are contaminated with \textit{E. coli} O157: H7 is very low, because tenderizing and enhancing operations are raw meat processing operations, consideration should be given to \textit{E. coli} O157: H7 as a potential, sporadic contaminate that could find its way into the processing environment and specific tenderizing or enhancing processing systems. Additionally, FSIS gave notice that all processors must reassess their HACCP systems to consider \textit{E. coli} O157:H7 in their hazard analysis.

Analysis of outbreaks has suggested that insufficient sanitation of equipment was the biggest issue in the three \textit{E. coli} O157:H7 outbreaks possibly linked to enhanced/tendered beef steaks. The agency believes proper sanitation to be the single most important control measure available to processors of mechanically tenderized and enhanced products to prevent foodborne outbreaks.

As the tenderizers/injectors pass through the product they may introduce biological hazards to the interior or the product. Inadequate injection needle sanitation poses the greatest risk to spread any microbial contaminants present on the incoming raw materials, thus needle sanitation is critical. All needles must be removed at least daily and soaked in a sanitation solution before inspection and reassembly of the needle injector. Ideally, two sets of needles could be rotated to allow for maximum soaking time and potentially greater sanitation efficacy.

Validation and verification of sanitation practices are always challenging, however the nature of small diameter hollow injection needles further compounds this issue. To validate the efficacy of the sanitation system needles can be sacrificed (broken) to determine if the cleaning and sanitizing procedures are adequate. Likewise, routine verification of sanitation practices for needles can be determined by sacrificing and sampling needles at some frequency.
Best Practices: Pathogen Control During Tenderizing/Enhancing of Whole Muscle Cuts

Supported by:

National Cattlemen’s Beef Association
American Meat Institute
National Meat Association
Southwest Meat Association

Revised February 2006
Industry Best Practices for Pathogen Control During Tenderizing/Enhancing of Whole Muscle Cuts

Purpose
This document is designed to discuss Best Practices that can be implemented throughout the tenderizing or enhancing operation, as well as during cleaning and sanitizing operations, to reduce the likelihood that contamination with potential pathogens (specifically \textit{E. coli} O157:H7) will occur. There are multiple ways to reach the optimal end-result, and each operator must be able to apply the practices and procedures that best fit an individual operation. This document is not designed to mandate the use of any specific system or technology, but rather, to stress the importance of validating that the tenderizing or enhancing system is optimized to reduce the risk of contamination.

Introduction
FSIS defines non-intact beef products as ground beef; beef injected with solution, beef that has been mechanically tenderized by needling, cubing, frenching, or pounding devices, and beef that has been reconstructed into formed entrees. Whole muscle cuts (e.g., chucks, ribs, tenderloins, strip loins, top sirloin butts, rounds) may be treated to increase tenderness or to add ingredients for quality purposes, a practice that often occurs before subsequent fabrication at the same or external location. Treatments may include solid-needle tenderizing or hollow-needle tenderizing where a solution is pumped into the whole muscle. In the latter case, the solution typically is recirculated, refrigerated and treated to ensure the quality of the pumping solution. It is important that the management of these operations be such that the equipment, refrigeration, solutions and product are optimized for quality and safety.

Producers of raw non-intact beef products recognize that these products may pose a risk if potential pathogens are moved to the interior portions of the meat products (Krizner, 1999; Phebus et al., 2000; Lambert et al., 2001; Hajmeer et al., 2002), and the product is not cooked adequately to destroy the pathogens inside the meat product. As is discussed below, the likelihood of potential pathogens being transferred to the inside from the outside of the product is extremely low because of a very low prevalence of pathogens on meat portions being tenderized or enhanced (Ransom et al., 2002; Warren et al., 2003). If equipment used in the operation is contaminated somehow, and not cleaned and sanitized, the tenderizing or enhancing equipment, and perhaps the solution to be injected, may become the vehicle of the contamination. To reduce the risk, it is extremely important that processors implement Best Practices by focusing on cleaning and sanitation practices for tenderizing and enhancing operations.

One of the primary considerations in assessing the likelihood of contamination of products that are tenderized or enhanced is whether or not contamination, especially with \textit{E. coli} O157:H7, is a hazard reasonably likely to occur on the surface of intact meat portions before the tenderizing or enhancing operation. Several studies indicate that \textit{E. coli} O157:H7 is not a hazard reasonably likely to occur on the surface of intact meat portions. A study was conducted by Warren et al. (2003) where sponge samples were taken of 1,014 subprimal cuts from six beef processing plants.
(at least annually). An example letter from a harvest/fabrication facility to meet the processor’s prerequisite program requirements has been provided and is included in Best Practices: Appendix A.

Another important criterion for supplier selection is the ability and demonstrated maintenance of cold chain management. This includes rapid chilling of hot carcasses to control microbial growth and proper carcass rotation within the cooler to ensure timely fabrication.

Lastly, it is important for non-intact beef processors to have specific data on E. coli O157:H7 incidence to support the position taken during the hazard analysis as “not reasonably likely to occur.” These data must relate to the raw materials and/or finished product(s). Routine microbiological testing may include sampling and testing for E. coli O157:H7. Other microbiological testing includes analyses for Salmonella, Aerobic Plate Count (APC), Total Plate Count (TPC), coliforms, and generic E. coli. For all microbiological testing, it is important that there be a written protocol for sample collection, lab analysis and proficiency testing, as well as the procedures for reporting the results. It is important to establish how the results will be used before the data are collected. Most of these microbiological tests are used for tracking supplier trends over time; however, each establishment must clearly define how they are going to use the information and the consequences of failing to meet internal microbiological guidelines.

**Supplier Evaluations**

Raw material suppliers are critical to both food safety and quality aspects of producing tenderized and enhanced products. In addition to well-defined requirements it is important that there are procedures established to evaluate the raw material supply whether from an internal or external vendor source. Guidelines developed for the Raw Ground Products Best Practices can be used to help design a system for evaluating supply sources for other non-intact raw materials. A more detailed discussion of supplier evaluations can be found in the *Best Practices for Raw Ground Products* document (NMA et al., 2003b; [www.bifsco.org/BestPractices.htm](http://www.bifsco.org/BestPractices.htm)).

**Temperature Control**

Cold chain management is a continuum from the time a carcass leaves the slaughter process and enters the chilling process through processing, packaging, storage and distribution. The goal is to achieve and maintain the temperature that will inhibit the growth of foodborne pathogens and slow the growth of spoilage microflora. The minimum growth temperatures for the pathogens of most concern are 44.6°F (7°C) for salmonellae and 44.6-46.4°F (7-8°C) for pathogenic E. coli (ICMSF, 1996). If cold chain control is violated at any point in the chain, product safety and quality may be compromised.

Cold chain management is especially important at the tenderizing or enhancing operation. Specific points where temperature should be controlled, other control points related to temperature control, and examples of operating limits in tenderizing or enhancing operations include:

- Receiving and storage of raw materials at 40°F or less
- Processing raw materials using a “First In First Out” (FIFO) rotation
- Monitoring raw materials and finished products using a process room/cooler control program

5
• Traceability program is in place for all finished products
• Food Defense program exists to prevent tampering with operational equipment, raw materials and pickle solutions

**Meat Protein Suspension Injection Products**

• Letters of guarantee and certificates of analysis exist for ingredients used in the processing of the suspension solution (to include all meat and nonmeat ingredients in the brine or pickle solution, as well as documentation on “supplier evaluation” on the sources the trim raw material used)
• Documented GMPs (including needle integrity checks) exist for injecting operations
• Chilled water feeding system is preferable to complete chilling of brine following mixing and as the suspension is generated from it
• Maximum age is established for reuse brine (pickle) solutions (e.g., 24 hours), with a mandatory break in the use cycle (e.g., every 24 hours)
• Maximum age is established for reuse suspension solutions (e.g., 8 hours), with a mandatory break in the use cycle (e.g., every 16-20 hours)
• Use of an antimicrobial intervention (e.g., UV) for re-circulating pickle solution is implemented if needed as determined by the hazard analysis
• Use of bacterostatic ingredients in the brine solution (e.g. lactate, diacetate, sodium metasilicate) if needed as determined by the hazard analysis
• If possible, inject the product from the side opposite of the external surface to minimize any bacterial translocation
• Daily needle removal and soaking in sanitation solution is conducted
• Established protocol exists for managing rework, including traceability and a time frame for incorporation into manufacturing
• Traceability program is in place for all finished products
• Food Defense program exists to prevent tampering with operational equipment, raw materials and pickle solutions

**Lotting**

All non-intact processors should have a lotting mechanism for coding and recording all products to allow trace back and trace forward of products throughout the manufacturing and distribution system. FSIS recognizes that the establishment will define a lot and expects scientific or other supportive basis for defining the lot. Lotting systems can range from very simplistic, e.g., handwritten numbering, to very elaborate, e.g., computerized, automated bar coding. Lotting is often based on some unit of time (e.g., hour, shift, day); however lotting can be driven by other factors including raw material source, production line or processing room. Some processors may choose to further divide lots of product into sublots. By creating smaller lot units, process control can be demonstrated and documented more frequently; and there is a potential to minimize the

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1 Cozzini’s SUSPENTEC™ system is a patented method of reducing meat, poultry or fish trimmings to micron size and incorporating them in traditional brines to create a suspension; the suspensions can then be injected into whole-muscle products. The use of this equipment is governed by FSIS Policy Memo PM041B. At the time this document was put together, Cozzini’s SUSPENTEC™ system was the only such technology available for Beef, Pork and Poultry. These practices may or may not be applicable to other suspension technologies when they become available.
for growth of *E. coli* O157:H7 if present as a process contaminant or as a highly unlikely contaminant of subprimals. These strategies typically involve prevention of harborsages and niches through cleaning and sanitation of equipment, maintaining cold temperatures and using antimicrobial interventions on the subprimals prior to processing and during recirculation of enhancement solutions. Occasional verification that *E. coli* O157:H7 is not being harbored in the plant environment by swabbing equipment is recommended.

**Sanitation and Facilities**

Production of tenderized and enhanced products must occur in facilities that meet all Federal regulations (9 CFR 307, 310, 313, 314, 317, 318, 320, and 416) and the equipment used must meet sanitary operating guidelines. Establishments should meet all regulatory requirements of the Sanitation Standard Operating Procedures and should consider the guidelines presented in the Sanitation Performance Standards.

For optimal operation, the entire system should be process engineered. The idea of process engineering encompasses facility design, equipment design, product movement, supply movement and employee movement to create an environment that minimizes microbial contamination. The American Meat Institute’s *Sanitary Design of Equipment and Facilities* (AMI, 2003) serves as a good reference. A checklist and a fact sheet, can be accessed at the following Web sites:

(http://www.meatami.com/Content/ContentGroups/Food_Safety_Inspection/Inspection1/Sanitation1/AMIEquipmentDesignChecklist.xls)


FSIS personnel (Engeljohn, 2005) have suggested that insufficient sanitation of equipment was the biggest issue in the three *E. coli* O157:H7 outbreaks possibly linked to enhanced/tenderized beef steaks. The agency believes proper sanitation to be the single most important control measure available to processors of mechanically tenderized and enhanced products to prevent foodborne outbreaks.

Specifically, enhanced and mechanically tenderized processors should follow sanitation practices much like those adhered to by ready to eat (RTE) operations. A comprehensive review of RTE sanitation and practices are found in the *Guidelines for Developing Good Manufacturing Practices (GMPs), Standard Operating Procedures (SOPs) and Environmental Sampling/Testing Recommendations (ESTRs) in Ready to Eat (RTE) Products* (NMA, 1999).

As the tenderizers/injectors pass through the product they may introduce biological hazards to the interior or the product. Inadequate injection needle sanitation poses the greatest risk to spread any microbial contaminants present on the incoming raw materials, thus needle sanitation is critical. All needles must be removed at least daily and soaked in a sanitation solution prior to inspection and reassembly of the needle injector. Ideally, two sets of needles could be rotated to allow for maximum soaking time and potentially greater sanitation efficacy. Injection systems should be cleaned in place (CIP) using a validated sanitation process of cleaning followed by
Packaging and Labeling
Packaging of non-intact beef cuts must occur in a manner to minimize the likelihood of contamination from packaging equipment, the environment, or food contact surfaces. Routine microbiological audit sampling and testing may be used to verify the efficacy of cleaning and sanitation, both on a routine basis and following equipment maintenance or relocation (AMI et al., 2003).

It is the belief of FSIS that consumers do not understand or expect whole muscle steaks and roasts to have been needle. Thus, the agency has suggested that processors consider voluntary labeling of enhanced and mechanically tenderized products to identify them as non-intact and to include cooking instructions. At least one large processor currently includes cooking instructions (145°F for three minutes) on such products.

Integrated Approach to Control
One way to evaluate the overall safety of a product is by calculating the integrated control measures, which is an evaluation of the baseline incidence and the bacteriostatic / bacteriocidal effects of all the variables which contribute to the safety of the end product. The integrated approach to control includes, but is not limited to the following factors:

- Organism incidence rates in live animals
- Interventions applied at harvest and fabrication
- Raw material incidence rates
- Application of industry recognized best practices
- Interventions (including knife trimming) applied prior to injection/mechanical tenderization
- Organism translocation rates due to injection/mechanical tenderization
- Antimicrobial effects of an enhancement brine
- Ingredients affecting the heat liability of the organism
- Temperature control to minimize microbial amplification
- Cooking practices applied to the products
- Integrated time-temperature processing (integrated lethality)—incorporates all heat treatments, i.e. the increase in temperature as the product heats and the temperature levels as the product cools. Microbial destruction takes place during the entire heating and cooling process, not just at the minimum internal temperature.
- Relationship between depth of possible translocation, cooking time and temperature to effectively destroy microorganisms

By considering all of these variables, the true safety of the product can be determined.


Testing for *E. coli* O157:H7
Carcasses — Daily validation testing for *E. coli* O157:H7 is conducted at each beef slaughter plant. This has been in place and effect since 2000. Carcasses are sampled at the same sites as listed in 9CFR 310.25 for *E. coli* Biotype I and are retained pending results.

**Beef Materials Destined For Non-Company Name Grinding**
In accordance with the intended use described in the plants’ Raw Not Ground HACCP plans (including trim and some variety meats harvested in slaughter), all materials destined for raw ground use are subjected to a statistically based sampling plan\(^1\) for *E. coli* O157:H7. All boxed materials that are “Lot tested and found to be negative for *E. coli* O157:H7” are labeled with that statement. Combo’d trim does not carry this on the label as combo’d trim materials are tested per customer order and a Certificate of Analysis (COA), specific to those combos is provided to the contracted end user. Since boxes may be broken down into smaller ship units by a primary (or secondary or tertiary, etc.) distributor, we deemed it necessary to label the individual box so the ultimate end user is aware that the materials were part of sampling lot that tested negative for *E. coli* O157:H7.

These labeling components are addressed in our HACCP plan as they are an integral part of the intended use.

**Ground Beef**
- All raw materials destined for grinding in the plants listed in this document are pre-tested\(^1\) and negative for *E. coli* O157:H7 prior to grinding.
- External sources of trim raw material must have a validated carcass intervention for *E. coli* O157:H7 in place and a copy of that compliance is maintained on file at the receiving establishment.
- External sources of raw material must meet Company Name requirements for outside vendors including but not limited to: validated HACCP systems, 3rd party food safety/GMP audits, *E. coli* O157:H7 testing programs that meet or exceed 95% confidence for detection capability.
- Certificate of Analysis (COA’s) received for all outside materials sent to grind.

**Laboratory Verification Testing**
- Verification of *E. coli* O157:H7 lab methods is routinely performed at each Company Name Laboratory in conjunction with the American Proficiency Institute Microbiological Performance Evaluation Program.
Verification
- In accordance with the facilities' HACCP plans, all CCP's have been validated and are verified at the specified frequencies in the HACCP plan in accordance with 9CFR 417.4.
- Company Name is audited on an annual basis by an independent third party auditor. That audit encompasses both regulatory compliance (HACCP, SSOP, 10,010.1, etc.) and good manufacturing practices. A summary matrix of audit scores is available upon request.

Customer Notification
- Company Name plants have a recall plan on file that includes notification to affected customers of any product that may be adulterated or misbranded.

Last, the Company Name plants listed below are federal establishments and operate under the regulatory requirements promulgated in Title 9 of the Code of Federal Regulations. By dint of the Mark of Inspection, we are obligated to adhere to all applicable requirements contained therein.

COMPANY NAME BEEF PLANTS

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Standard Operating Procedure Clean In Place System Cleaning: Example II

PURPOSE: To minimize bacterial growth.

PROGRAM: A CIP cleaning solution will be run through the injection process to ensure proper cleaning of the injection process.

PROCEDURE:

1. Drain all brine material from lines, pumps, and tanks. During the draining process production personnel will continue to rinse all six tanks with potable water until all visible brine residue has disappeared.
2. Fill the two mixing tanks (#3 & #6) with 200 Gal. of cold potable water each.
3. Flush 100 Gal. from the line 1 mixing tank (#3) to each of the rear holding tanks (#2 & #1).
4. Flush 100 Gal. from the line 2 mixing tank (#6) to each of the rear holding tanks (#5 & #4).
5. Flush all water from all holding tanks through the CIP system and a minimum of 50 Gal. through each of the injectors (line 1 and line 2).
6. Fill mixing tanks (#3) and (#6) again with 200 Gal. of cold potable water and add appropriate amount of the approved CIP cleaning solution.
7. Mix thoroughly.
8. Flush 100 Gal. of the mixed cleaning solution from the line 1 mixing tank (#3) to each of the rear holding tanks (#2 & #1).
9. Flush 100 Gal. of the mixed cleaning solution from the line 2 mixing tank (#6) to each of the rear holding tanks (#5 & #4).
10. Flush all cleaning solution from all holding tanks through the CIP system pumping from each tank a minimum of 5 minutes.
11. A minimum of 50 Gal. will be pumped from one of the holding tanks of each line through its designated injector (line 1 and line 2).
12. Fill the two mixing tanks (#3 & #6) with 200 Gal. of cold potable water each.
13. Flush 100 Gal. from the line 1 mixing tank (#3) to each of the rear holding tanks (#1 & #2).
14. Flush 100 Gal. from the line 2 mixing tank (#6) to each of the rear holding tanks (#5 & #4).
15. Flush all water from all holding tanks through the CIP system and a minimum of 50 Gal. through each of the injectors (line 1 and line 2).

The currently used cleaning solution is STERIS brand Process Klenz alkaline cleaner used at 2.5% by volume. (5 gallons Process Klenz mixed with 200 gallons potable water.)

CORRECTIVE ACTION: Production will not be allowed to start until CIP cleaning has taken place.

RELATED FORMS: CIP System Cleaning Verification Process Check

MATERIALS NEEDED: Steris brand process klenz alkaline cleaner.

FREQUENCY: Daily

MONITORED BY: QA and Production Management will routinely monitor to ensure proper compliance.

General Manager ___________________________ Date ___________________________

QA Manager ___________________________ Date ___________________________
Standard Operating Procedure Operational Cleaning of Injector Reservoir In-Line Filters: Example IV

PURPOSE: To minimize bacterial growth.

PROGRAM: Injection filters will be cleaned on a regular basis to ensure the injectors operate at an optimal level.

PROCEDURE:
1. Remove the machine side in-line final filter by rotating its holding cylinder to the vertical position where it will latch against the wall of the reservoir.
2. From this position the end cap can be threaded back and spun out of the way so the filter may be removed for cleaning.
3. Remove filter and clean with tempered water of sufficient pressure to remove any built up residue.
4. Replace filter into its holding cylinder and thread back its end cap to secure filter in the cylinder.
5. Return filter assembly to the horizontal position inside the reservoir tank.
6. Remove the off side in-line final filter by rotating its holding cylinder to the vertical position where it will latch against the wall of the reservoir.
7. From this position the end cap can be threaded back and spun out of the way so the filter may be removed for cleaning.
8. Remove filter and clean with tempered water of sufficient pressure to remove any built up residue.
9. Replace filter into its holding cylinder and thread back its end cap to secure filter in the cylinder.
10. Return filter assembly to the horizontal position inside the reservoir tank.

CORRECTIVE ACTION: NA

RELATED FORMS: NA

MATERIALS NEEDED: Tempered Water

FREQUENCY: Operational cleaning of injector reservoir filters should be conducted on the hourly basis in order to maintain consistent pump settings.

NOTE: Each employee who handles injector equipment must change gloves before and after as well as clean any additional utensils needed for the tasks. This ten-step process will be used for the reservoir tanks of both line one and line two injectors. If filters are cleaned one at a time than the injector does not need to be shut down for this SOP.

MONITORED BY: QA and Production Management will routinely monitor to ensure proper compliance.

General Manager: ___________________________ Date: ___________________________

QA Manager: ___________________________ Date: ___________________________
<table>
<thead>
<tr>
<th>Intervention</th>
<th>Effectiveness in Lab setting</th>
<th>Effectiveness in Field / Plant</th>
<th>Regulatory Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acidified Sodium Chlorite</td>
<td>Company data 2.9 log reduction of <em>E. coli</em> O157. 2.0 log reduction of <em>E. coli</em> (generic), KSU 2-3 log CFU/cm² reduction of APC. ABC Research found up to a 0.63 log reduction of <em>E. coli</em> O157 on inoculated subprimals</td>
<td>Initial trials show approximately a 2 log reduction of APC.</td>
<td>Approved, however weight gain over 0.5% must be labeled.</td>
</tr>
<tr>
<td>Lactic Acid</td>
<td>CSU data supports 2.5% LA @ 55°C resulted in 1.0 log CFU/cm², while 5.0% LA @ 55°C resulted in a 1.1 log CFU/cm² (inoculated at 3.6 and 3.5 log CFU/cm², respectively).</td>
<td>Unknown. 0.4% by weight, of a 2.5% solution was not effective.</td>
<td>Pending approval at 2.5% and 5.0% levels.</td>
</tr>
<tr>
<td>Acidified Calcium Sulfate</td>
<td>Company trials are encouraging.</td>
<td>Unknown</td>
<td>Not approved in Beef trim</td>
</tr>
<tr>
<td>CPC</td>
<td>Company trials show significant log reductions.</td>
<td>Unknown</td>
<td>Not approved in Beef trim, residual levels cited as concern.</td>
</tr>
<tr>
<td>Peroxyacetic acid</td>
<td>ABC Research data found .63 -.71 log reduction of <em>E. coli</em> O157:H7 on inoculated subprimals.</td>
<td>Unknown</td>
<td>Approved</td>
</tr>
<tr>
<td>Citric Acid</td>
<td>Laboratory trials show promise.</td>
<td>Unknown</td>
<td>Approved</td>
</tr>
</tbody>
</table>
Best Practices: Appendix D
Studies on the Antimicrobial Properties of Tenderizing Pickle Solution

Preliminary Report

September 10, 2003

Study 1

Objective: To determine antimicrobial properties of a pickle solution used in tenderizing whole muscle cuts.

Composition of pickle solution: A typical pickle solution will contain phosphate, salt and flavorings. The solution used in this study contained a proprietary formula based on in finished products, e.g., 0.5%.

Measurement of the antimicrobial effect: The antimicrobial effect of the pickle solution was measured using a micro-titer assay (i.e., providing minimum inhibitory concentrations) and traditional laboratory plating procedures.

Results: Using micro-titer assays, initial experiments determined that the pickle solution reduced the concentrations of *E. coli* O157:H7 and *Salmonella* by at least 2 logs (100-fold). In follow-up experiments, direct inoculation of pickle solution with a cocktail of 3 *E. coli* O157:H7 strains and 3 *Salmonella* strains at levels near 10⁸ per mL resulted in complete lethality for all pathogens after 30 minutes of exposure (the first measurement time interval after the zero time measurement).

In a laboratory setting using traditional microbiological techniques, the antimicrobial properties of the pickle solution were determined. Pickle solution was inoculated to 1.73 logs per mL with *E. coli* O157:H7 and stored at room temperature (~73°F) or under refrigeration (37°F). No *E. coli* O157:H7 were recovered from the pickle solution after 2 hours at room temperature and after 24 hours under refrigerated conditions.

<table>
<thead>
<tr>
<th>Time</th>
<th>Storage temp</th>
<th>Room</th>
<th>Refrigerator</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 min</td>
<td>Positive</td>
<td>Positive</td>
<td></td>
</tr>
<tr>
<td>30 min</td>
<td>Positive</td>
<td>Positive</td>
<td></td>
</tr>
<tr>
<td>1 hour</td>
<td>Positive</td>
<td>Positive</td>
<td></td>
</tr>
<tr>
<td>2 hour</td>
<td>Negative</td>
<td>Positive</td>
<td></td>
</tr>
<tr>
<td>4 hour</td>
<td>Negative</td>
<td>Positive</td>
<td></td>
</tr>
<tr>
<td>24 hour</td>
<td>Negative</td>
<td>Negative</td>
<td></td>
</tr>
</tbody>
</table>

These data represent the results of a single study using inoculated organisms, and should not be extrapolated to all situations. The storage temperature and times, while different for room temperature versus refrigerated, simply indicate that the brine solution may exhibit inhibitory properties against *E. coli* O157:H7. However, further research would be needed to confirm that this is the case, and multiple variables may be contributing to this effect.
<table>
<thead>
<tr>
<th>Date</th>
<th>Meat Cut</th>
<th><em>E. coli</em> O157:H7 Result 1</th>
<th><em>E. coli</em> O157:H7 Result 2</th>
<th><em>E. coli</em> O157:H7 Result 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>29-Jul-03</td>
<td>Flat</td>
<td>NEG</td>
<td>NEG</td>
<td>NEG</td>
</tr>
<tr>
<td>29-Jul-03</td>
<td>Flat</td>
<td>NEG</td>
<td>NEG</td>
<td>NEG</td>
</tr>
<tr>
<td>29-Jul-03</td>
<td>Ribeye</td>
<td>NEG</td>
<td>NEG</td>
<td>NEG</td>
</tr>
<tr>
<td>30-Jul-03</td>
<td>Capoff Inside</td>
<td>NEG</td>
<td>NEG</td>
<td>NEG</td>
</tr>
<tr>
<td>30-Jul-03</td>
<td>Flat</td>
<td>NEG</td>
<td>NEG</td>
<td>NEG</td>
</tr>
<tr>
<td>30-Jul-03</td>
<td>Ribeye</td>
<td>NEG</td>
<td>NEG</td>
<td>NEG</td>
</tr>
<tr>
<td>31-Jul-03</td>
<td>Ribeye</td>
<td>NEG</td>
<td>NEG</td>
<td>NEG</td>
</tr>
<tr>
<td>05-Aug-03</td>
<td>Capoff Inside</td>
<td>NEG</td>
<td>NEG</td>
<td>NEG</td>
</tr>
<tr>
<td>05-Aug-03</td>
<td>Ribeye</td>
<td>NEG</td>
<td>NEG</td>
<td>NEG</td>
</tr>
<tr>
<td>05-Aug-03</td>
<td>Capoff Inside</td>
<td>NEG</td>
<td>NEG</td>
<td>NEG</td>
</tr>
<tr>
<td>06-Aug-03</td>
<td>Ribeye</td>
<td>NEG</td>
<td>NEG</td>
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</tr>
<tr>
<td>06-Aug-03</td>
<td>Capoff Inside</td>
<td>NEG</td>
<td>NEG</td>
<td>NEG</td>
</tr>
<tr>
<td>06-Aug-03</td>
<td>Inside</td>
<td>NEG</td>
<td>NEG</td>
<td>NEG</td>
</tr>
<tr>
<td>11-Aug-03</td>
<td>Ribeye</td>
<td>NEG</td>
<td>NEG</td>
<td>NEG</td>
</tr>
<tr>
<td>13-Aug-03</td>
<td>Ribeye</td>
<td>NEG</td>
<td>NEG</td>
<td>NEG</td>
</tr>
<tr>
<td>20-Aug-03</td>
<td>Inside</td>
<td>NEG</td>
<td>NEG</td>
<td>NEG</td>
</tr>
<tr>
<td>20-Aug-03</td>
<td>Capoff Inside</td>
<td>NEG</td>
<td>NEG</td>
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<td>20-Aug-03</td>
<td>Capoff Inside</td>
<td>NEG</td>
<td>NEG</td>
<td>NEG</td>
</tr>
<tr>
<td>20-Aug-03</td>
<td>Inside</td>
<td>NEG</td>
<td>NEG</td>
<td>NEG</td>
</tr>
</tbody>
</table>
ATTACHMENT F
Research Note

Survivability of *Escherichia coli* O157:H7 in Mechanically Tenderized Beef Steaks Subjected to Lactic Acid Application and Cooking under Simulated Industry Conditions


Department of Animal and Food Sciences, Texas Tech University, Box 42141, Lubbock, Texas 79409, USA

MS 12-566; Received 27 December 2012/Accepted 18 June 2013

ABSTRACT

Mechanical tenderization improves the palatability of beef; however, it increases the risk of translocating pathogenic bacteria to the interior of beef cuts. This study investigated the efficacies of lactic acid spray (LA; 5%), storage, and cooking on the survivability of *Escherichia coli* O157:H7 in mechanically tenderized beef steaks managed under simulated industry conditions. Beef subprimals inoculated with either high (10⁵ CFU/ml) or low (10⁳ CFU/ml) levels of *E. coli* O157:H7 were treated (LA or control) and stored for 21 days prior to mechanical tenderization, steak portioning (2.54 cm), and additional storage for 7 days. Steaks were then cooked to an internal temperature of 55, 60, 65, 70, or 75°C. Samples were enumerated and analyzed using DNA-based methods. Treatment with LA immediately reduced *E. coli* O157:H7 on the lean and fat surfaces of high- and low-inoculum–treated subprimals by more than 1.0 log CFU/cm² (P < 0.05). Storage for 21 days reduced surface populations of *E. coli* O157:H7 regardless of the inoculation level; however, the populations on LA- and control-treated lean surfaces of high- and low-inoculum–treated subprimals were not different after 21 days (P > 0.05). *E. coli* O157:H7 was detected in core samples from high-inoculum–treated steaks cooked to 55, 60, or 70°C. Conversely, *E. coli* O157:H7 was not detected in core samples from low-inoculum–treated steaks, regardless of the internal cooking temperature. These data suggest that LA- and storage-mediated reduction of pathogens on subprimals exposed to typical industry contamination levels (10⁵ CFU/cm²) reduces the risk of pathogen translocation and subsequent survival after cooking.

Mechanical tenderization, which involves the disruption of muscle fibers through avenues such as blade penetration or the application of pressure, is associated with improved beef tenderness (11). In 2003, a survey conducted by the National Cattlemen’s Beef Association indicated that 95% of beef purveyors utilize mechanical tenderization to enhance beef tenderness and eating quality (13). Although this process adequately enhances meat tenderness, a primary concern regarding its use is the translocation of surface bacteria from the exterior to the interior of the product—a location once considered sterile (15).

The burden of *Escherichia coli* O157:H7 in the public food supply has been ardently addressed and researched for more than two decades. In response to this public health risk, the U.S. Department of Agriculture Food Safety and Inspection Service (FSIS) declared *E. coli* O157:H7 an adulterant in ground beef in 1994. Though not specifically excluded, mechanically tenderized beef products (also referred to as nonintact beef) were often excluded from this mandate. However, in light of safety concerns for nonintact beef, the FSIS further extended this declaration to include nonintact beef products in January of 1999 (22). The FSIS acknowledged the potential for pathogen translocation to the interior of mechanically tenderized cuts, especially when undercooked (16). A series of outbreaks from 2000 to 2004 led the FSIS to publish a notice in the Federal Register mandating the reassessment of hazard analysis and critical control point plans by establishments producing nonintact beef products in 2005 (12, 23).

Many researchers have investigated the translocation of pathogenic bacteria from a product’s surface to its interior (7, 8, 12, 18, 20). Phetus and colleagues (18) concluded that 3 to 4% of surface contamination was translocated to the center of the product, although most of the contamination occurs in the more superficial tissues. While the incidence of *E. coli* O157:H7 contamination on the subprimal surface is low, the potential for bacterial translocation and survival in a cooked product warrants further investigations (15).

Cooking is generally thought to destroy or lethally injure pathogenic bacteria; however, whole-muscle meat products are often consumed after cooking at temperatures that may allow pathogen survival. Therefore, alternative strategies to reduce the number of bacteria reaching the interior portion of the steak must be investigated. Echeverry

* Author for correspondence. Tel: 806-742-2805, Ext 230; Fax: 806-742-4003; E-mail: chancey.brooks@ttu.edu.
and colleagues (7, 8) investigated subprimal surface decontamination strategies as a method for reducing the amount of surface bacteria internalized with mechanical tenderization. In their evaluation, surface application of lactic acid (LA; 5%) and lactic acid bacteria offered a viable reduction in E. coli O157:H7. Additionally, Heller et al. (11) found that subprimal treatment with 2 or 5.0% LA reduced the surface presence and internalization of E. coli O157:H7.

Investigations regarding thermal inactivation of internalized pathogenic bacteria are limited. Shen et al. (21) illustrated that pathogen inactivation is dependent on numerous factors, including steak thickness and cooking method, when only one internal cooking temperature (65°C) is utilized. Luchansky and colleagues (14) indicated that higher cooking temperatures more effectively reduced internalization of E. coli O157:H7 and non-O157:H7 Shiga toxin–producing E. coli in a brine-enhanced beef system. Regardless, a limited number of studies have examined the effects of cold subprimal intervention and various degrees of internal doneness on the thermal inactivation of internalized pathogenic bacteria. Moreover, fewer studies have examined these effects under simulated food service procurement conditions. Therefore, the objective of this project was to examine the reduction of E. coli O157:H7 on lean and fat beef subprimal surfaces as a result of 5% LA spray intervention treatment and dark storage. Additionally, the study aimed to characterize the internal survivability and thermal destruction of the pathogen when cooked to multiple endpoint temperatures associated with consumer cooking preferences.

**MATERIALS AND METHODS**

**Preparation of inoculation cocktails.** A cocktail mixture of four strains of E. coli O157:H7 (A4 966, A5 528, 966, and A1 920), originally isolated from cattle and associated with Centers for Disease Control–documented animal outbreaks, was used to inoculate subprimals in this study. All strains were obtained from the Texas Tech University Food Microbiology Laboratory Stock Collection ( Lubbock). Two concentrations (10^5 CFU/ml, high level [trial 1], and 10^4 CFU/ml, low level [trial 2]) of E. coli O157:H7 were prepared for use in two separate trials. Inoculation cocktails were prepared by using a frozen stock culture grown individually in 200 ml of Trypticase soy broth at 37°C for 24 h and subcultured three times prior to experimental use. To prepare the high-level inoculation broth (trial 1), 6 liters of buffered peptone water (BPW) was prepared in individual 1-liter bottles. An amount of 0.1 ml of the thawed stock culture was added to each of the 1-liter bottles. For the low-level inoculation broth (trial 2), 0.1 ml of the O157:H7 cocktail was placed into 9.9 ml of BPW and vortexed. Afterward, 0.1 ml of the 1:10 cocktail:BPW solution was added to each of six bottles containing 1 liter of BPW.

**Procurement of product and inoculation.** Beef strip loins (institutional meat purchase specification code IMPS 180; 40 in total, n = 10 per replication) were obtained from a federally inspected processing facility and transported to the biosafety level 2 pathogen-processing facility at Texas Tech University (Lubbock) under refrigeration (1 to 3°C). Upon arrival, the strip loins were randomly allotted to one of two trials. Strip loins assigned to trial 1 (n = 5 per replication) were inoculated with a 10^5 CFU/ml E. coli O157:H7 cocktail, with a targeted subprimal attachment level of 10^5 CFU/cm^2. Subprimals devoted to trial 2 (n = 5 per replication) were inoculated with a 10^3 CFU/ml E. coli O157:H7 cocktail, with a targeted attachment level of 10^4 CFU/cm^2. Each trial was replicated four times (n = 40 subprimals total; 20 per trial).

To achieve the desired level of surface attachment, subprimals were submerged in 5 liters of their respective inoculation broth for approximately 30 s. The subprimals were turned over after 15 s to assure even attachment on fat and lean sides. After 30 s, the subprimals were removed and allowed to rest for 15 min on wire racks in a cold room maintained at 4°C to accommodate bacterial attachment. After attachment, strip loins were randomly and evenly assigned to either LA treatment or control (CON). In addition, samples were obtained from the lean and fat side of each subprimal using a sterile 50-cm^2 template (USDA-050 template, Biotrace International, Muncie, IN) and a sterile sponge premoistened with 9 ml of BPW. Surface swabs were processed as described below.

**LA treatment and subprimal storage.** After attachment and swab sampling, subprimals were subjected to LA spray treatment using a customized spray cabinet (Chad Co., Olathe, KS) with a wire conveyor belt (series 800, Intratex, Inc., Hanahan, LA). Prior to treatment, a 5% LA spray solution was prepared using an 88% LA stock solution (Birkco Corp., Henderson, CO) and potable water. The spray was applied in a room at ambient temperature (25°C) using six spray nozzles (20 psi, flow rate of 0.42 liter/min per nozzle) equally distributed on the top and bottom sides of a belt moving at a speed of 0.05 m/s. Subprimals were allowed to rest for 5 min following treatment application. CON subprimals were treated without the application of LA. Immediately after the rest period, swab samples were obtained from the lean and fat surfaces of CON and LA subprimals as described above. Afterward, all subprimals were vacuum packaged (model MVS 45, Minipack-Torre, Dublin, Ireland) using high-barrier bags (Sealed Air, Cryovac, Bolingbrook, IL) and stored in the dark for 21 days at 2 to 4°C.

**Mechanical tenderization.** After 21 days of storage, CON and LA strip loins from trial 1 and trial 2 were mechanically tenderized using a blade tenderization unit (model H, Jaccard, Orchard Park, NY). Surface swab samples were obtained from the lean and fat subprimal surfaces before tenderization. Afterward, strip loins were placed with the external fat side down and passed through the tenderization unit once prior to portioning into 2.54-cm steaks with a sterile knife (n = 6 steaks per subprimal). Following portioning, steaks were individually vacuum packaged (model MVS 45, Minipack-Torre) using high-barrier bags (Sealed Air, Cryovac) and stored in the dark at 2 to 4°C for 7 days.

**Cooking.** After 7 days of storage (28 days post inoculation), steaks from each subprimal were randomly allotted to one of six targeted internal cooking temperatures (n = 1 steak per subprimal per temperature) as follows: raw, 55°C (extra rare or blue), 60°C (rare), 65°C (medium rare), 70°C (medium), and 75°C (well done). Prior to cooking, swab samples (50 cm^2) were obtained from the steak surface using a sterile sponge premoistened in 9 ml of BPW. In order to accurately monitor the temperature throughout cooking, a thermocouple wire (type J, Cole Parmer, Vernon Hills, IL) connected to a data monitoring device (model OMB-DAQ-56, Personal Data, Omega Engineering, Inc., Stamford, CT) was placed in the geometric center of each steak, as recommended in research guidelines provided by the American Meat Science Association (J). Steaks were cooked on a preheated clove-button-style grill (model GRP95B, George Foreman, Salton Inc., Miramar, FL) with a surface temperature of 195°C.

Steaks were removed from the grill with sterile tongs at their targeted internal temperature and allowed to rest for 5 min to allow
for postcooking temperature rise and temperature equilibration. Temperature was monitored continuously during the resting period. Additionally, the start time of grilling, endpoint temperature, time of removal from grill, peak temperature, 5-min rest, and 5-min temperature were recorded as shown in Figure 1. After the 5-min rest period, a 50-cm² surface swab was obtained from each steak, as described above. Additionally, internal (core) samples (2 cm by 5 cm) were aseptically obtained from the center of uncooked and cooked steaks after surface swabbing using a sterile scalpel. Core samples were reserved for the detection of internalized E. coli O157:H7.

Microbial analysis of samples. All swab samples were agitated in a stomacher (model 400, Seward Stomacher, Worthing, UK) for 1 min prior to the formation of serial dilutions using BPW. Serial dilutions were plated on MacConkey agar with a Trypticase soy agar (TSA) overlay. Brashears and colleagues (2) demonstrated that the utilization of a TSA overlay allows for the recovery and growth of injured E. coli O157:H7 cells. The MacConkey agar was prepared with potassium tellurite (50 µl/liter) and novobiocin sodium salt (0.020 g/liter) to inhibit the growth of background flora. Plated samples were incubated at 37°C for 18 to 24 h before visual counting of E. coli O157:H7 colonies. If enumeration yielded zero colonies, the original samples were enriched in Difco GN broth overnight (24 h) at 37°C prior to immunomagnetic separation (IMS) and agglutination to test for the presence of viable E. coli O157:H7 cells.

After excision, core samples were homogenized in a food processor (model no. HC306, Black & Decker, Towson, MD), and 10 g was homogenized with 90 ml of Difco-EC medium (BD, Sparks, MD) enrichment broth. Samples were homogenized for 2 min and then incubated at 37°C for 18 to 24 h. After enrichment, the presence of E. coli O157:H7 was determined using the PCR-based BAX system (software version 1.85, DuPont Qualicon, Wilmington, DE) according to the manufacturer’s instructions.

Experimental design and statistical analysis. Each trial (high- and low-level inoculation) was analyzed as a completely randomized design that was replicated on four independent occasions. Subprimal served as the experimental unit to which the spray treatments (LA and CON) were randomly assigned within each trial and replication. Additionally, the internal cooking temperatures were randomly assigned to steaks from each subprimal. Across all replications, there were 10 observations per cooking temperature by spray treatment by inoculation level combination. The independent variables included the treatment, storage day, internal cooking temperature, and lean or fat surface when applicable. The average surface populations of bacteria, as assessed by swabbing, were transformed into log CFU per square centimeter; and the log count was considered the dependent variable of interest. Data were analyzed using a general linear model in a commercially available statistical analysis software package (SAS, version 9.2, SAS Institute, Cary, NC). Least squares means were separated using the PDIFF statement, and differences were considered significant using an α level of 0.05. The presence (positive/negative) of E. coli O157:H7 in internal core samples was determined using the FREQ procedure of SAS.

RESULTS AND DISCUSSION

Trial 1: high-level inoculation. (i) Subprimal surfaces. The reductions of E. coli O157:H7 as a result of LA spray treatment on the lean and fat surfaces of high-inoculum-treated subprimals are shown in Table 1. Surface swabs obtained 15 min after spray treatment indicated that LA immediately reduced E. coli O157:H7 on lean and fat surfaces by 1.13 and 1.57 log CFU/cm², respectively (P < 0.05). The reduction of O157:H7 on lean tissues is in agreement with the results of Eschevery and colleagues (7), who also noted an immediate reduction (approximately 0.6 log CFU/cm²) in E. coli O157:H7 on the surface of subprimals sprayed with LA compared with the population of E. coli on inoculated nontreated samples. The enhanced reduction of pathogens on fat tissue is supported by previous research suggesting that organic acids are more effective at reducing bacterial loads on fat tissue than on lean fascia (4, 5).

Lean tissue swabs indicated reductions of 2.06 (CON) and 1.41 (LA) log CFU/cm² in surface O157:H7 after vacuum storage, although no differences between the results of the LA and CON treatments were noted (P = 0.43). A 2.0-log CFU/cm² or greater reduction in pathogen levels on the fat surface was also observed after storage. As with the 15-min samples, fat surface swabs from LA-treated subprimals had less O157:H7 (P < 0.05) than their CON counterparts. Overall, LA spray in combination with vacuum-packaged storage for 21 days reduced O157:H7 on the external fat surface; however, the reduction in E. coli
TABLE 1. Presence of Escherichia coli O157:H7 on the lean and fat surfaces of beef strip loins inoculated with high and low levels of E. coli O157:H7

<table>
<thead>
<tr>
<th>Inoculation level</th>
<th>Sample surface</th>
<th>Least squares means of E. coli (log CFU/cm²) for each sampling time and treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Lean</td>
<td>15 min</td>
</tr>
<tr>
<td>High (10³ log CFU/cm²)</td>
<td></td>
<td>CON</td>
</tr>
<tr>
<td>Lean</td>
<td>4.05 a</td>
<td>2.92 A</td>
</tr>
<tr>
<td>Fat</td>
<td>4.40 b</td>
<td>2.83 A</td>
</tr>
<tr>
<td>Low (10³ log CFU/cm²)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lean</td>
<td>1.23 a</td>
<td>0.43 A</td>
</tr>
<tr>
<td>Fat</td>
<td>1.30 b</td>
<td>0.04 A</td>
</tr>
</tbody>
</table>

- High- and low-inoculum treatments were not compared against each other.
- Samples were obtained 15 min after application of spray treatment or from the lean and fat surfaces of subprimals after 21 days of vacuum-packaged dark storage at 2 to 4°C. CON, no application of spray treatment; LA, 5% lactic acid spray applied to subprimal surfaces prior to vacuum storage.
- SEM, standard error of the mean.
- Least squares means within a row, posttreatment application time, and inoculation level lacking a common letter differ at a P value of <0.05.

O157:H7 population on the lean surface due to LA treatment was no longer apparent after 21 days of storage. Regardless, vacuum storage for 21 days reduced the presence of E. coli O157:H7 on subprimal surfaces.

(ii) Steak surfaces pre- and postcooking. Although not presented in tabular form, the population of E. coli O157:H7 was reduced (P < 0.05) on the surface of LA-treated steaks (1.2 log CFU/cm²) compared with the population on CON-treated steaks (1.58 log CFU/cm²). The magnitude of the difference in E. coli O157:H7 populations on LA- and CON-treated steak surfaces (0.48 log CFU/cm²) was the same as the magnitude of the difference on the lean subprimal surfaces (0.48 log CFU/cm²). This supports the theory that internalization of pathogens is a function of surface contamination.

The presence of E. coli O157:H7 on steak surfaces was reduced with cooking (data not presented). A single sample obtained from a CON-treated steak cooked to an internal temperature of 55°C was BAX positive for E. coli O157:H7 after cooking; however, no positive results were obtained from any other cooking temperature and treatment combination. The survivability of E. coli O157:H7 at temperatures below the FSIS-recommended internal temperature of 65.1°C has been documented previously (9, 15).

(iii) Steak cores postcooking. The survival of E. coli O157:H7 in the internal portions of CON- and LA-treated steaks is illustrated in Table 2. LA spray treatment had no influence on the proportion of internal samples from uncooked steaks positive for E. coli O157:H7 (P > 0.05). A single positive sample was obtained from the interior of an LA-treated steak cooked to an internal temperature of 60°C, whereas E. coli O157:H7 was detected in a CON-treated steak cooked to 70°C. The detection of E. coli O157:H7 in internal cores in this trial indicates that the bacterium survived heat treatment. However, previous work suggests that cooking to 65.1°C, as recommended by the FSIS for nonintact beef products, destroys internalized E. coli O157:H7 sufficiently (22). The survival of internalized E. coli O157:H7 at 70°C is not supported by previous works (10) but could be correlated to a number of variables and warrants further investigations.

Trial 2: low-level inoculation. (i) Subprimal surfaces. The reductions of E. coli O157:H7 on the lean and fat surfaces of low-inoculum-treated subprimals due to LA treatment are shown in Table 1. LA treatment immediately reduced the presence of E. coli O157:H7 on both lean and fat subprimal surfaces (P < 0.05), by 0.8 and 1.26 logs CFU/cm², respectively. Previous research also indicates a reduction in E. coli O157:H7 on the surface of subprimals treated with 1.5 to 4% LA (3, 6). As with trial 1, a greater reduction was noted on the fat than the lean surface.

The effects of LA spray treatment on E. coli O157:H7 levels after 21 days of vacuum storage are also presented in Table 1. The presence of O157:H7 on the lean and fat subprimal surfaces was reduced after storage regardless of the spray intervention treatment. Similar to trial 1, no treatment effect was observed on the lean surface of subprimals after 21 days (P = 0.27). However, a greater cumulative reduction attributed to LA treatment was observed on fat surfaces (P < 0.05). Nonetheless, these results agree with the data from trial 1, and they indicate that a reduction of E. coli O157:H7 on subprimal surfaces is obtained after 21 days of vacuum storage and suggest an enhanced reduction on fat surfaces through the utilization of 5% LA spray.

(ii) Steak surfaces pre- and postcooking. Direct plating of raw steak swab samples yielded no viable colonies; therefore, samples were enriched in Difeo-GN broth overnight and analyzed for the presence of E. coli O157:H7 using immunomagnetic separation and agglutination. After enrichment, the presence of E. coli O157:H7 was similar on CON- and LA-treated steaks. Specifically, 50.8% of 120 surface swab samples were positive regardless of the spray treatment. The lack of treatment differences after
TABLE 2. Proportion of internal core samples positive for Escherichia coli O157:H7 following treatments including blade tenderization

<table>
<thead>
<tr>
<th>Internal temp (°C)</th>
<th>No.of samples per treatment and inoculation level</th>
<th>No. positive after indicated treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>CON</td>
<td>LA</td>
</tr>
<tr>
<td>Raw</td>
<td>10</td>
<td>4</td>
</tr>
<tr>
<td>55</td>
<td>10</td>
<td>1</td>
</tr>
<tr>
<td>60</td>
<td>10</td>
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<td>65</td>
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</tr>
<tr>
<td>70</td>
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<td>1</td>
</tr>
<tr>
<td>75</td>
<td>10</td>
<td>0</td>
</tr>
<tr>
<td>All</td>
<td>60</td>
<td>6</td>
</tr>
</tbody>
</table>

a Beef strip loin steaks originating from subprimals were inoculated with a high (10^8 log CFU/cm²) or low (10^3 log CFU/cm²) level of E. coli O157:H7, and then LA (5% lactic acid spray) or CON (no application of spray treatment) treatment was applied, followed by 21 days of vacuum storage, blade tenderization, and portioning. After portioning, steaks were stored for 7 additional days prior to cooking to one of six targeted internal temperatures using a chambell-style grill. Both periods of storage were in the dark at 2 to 4°C.

28 days of storage coincides with the subprimal surface data collected after 21 days of storage. These data imply that the typical vacuum storage length of food service meat cuts reduces the number of pathogenic bacteria on subprimal surfaces. While this suggests that storage is equally as effective as surface intervention, these results were obtained after 21 days of aging and LA treatment and may differ if alternative strategies are utilized at different storage temperatures.

(iii) Steak surfaces postcooking. E. coli O157:H7 was not detected on the cooked surfaces of steaks using either direct plating or immunomagnetic separation after enrichment (data not presented). These data suggest that cooking to an internal temperature of 55°C or greater sufficiently destroys E. coli O157:H7 that may be present on the surface of steaks inoculated at 10^5 log CFU/cm².

(iv) Steak cores postcooking. Cores from low-inoculum–treated steaks were enriched prior to PCR-based detection of E. coli O157:H7 using the BAX system. E. coli O157:H7 was detected in 20% of cores derived from uncooked CON steaks and 30% of cores obtained from uncooked LA steaks (Table 2). When compared with the internalization of pathogens in trial 1, these data indicate that a reduction in surface pathogen load leads to a subsequent reduction in pathogen internalization. E. coli O157:H7 was not detected in the internal portions of low-inoculum–treated steaks cooked to internal temperatures of 55, 60, 65, 70, or 75°C (data not presented). These data suggest that when pathogen translocation (as influenced by total pathogen load) is reduced, cooking to an internal temperature of 55°C or greater reduces the number of internalized E. coli O157:H7 cells to a level that is undetectable using the methodology described above.

In conclusion, the results from this study coincide with those of previous studies which illustrate the translocation of surface bacteria to internal portions of whole-muscle beef products. Although a significant reduction of E. coli O157:H7 was seen on the subprimal surface immediately after treatment, the LA effect was mitigated after 21 days of vacuum-packaged storage. The reduction of pathogenic bacteria during storage has not been emphasized in many research efforts; however, Eschevery and colleagues (7) noted a decrease in the amount of E. coli O157:H7 bacteria on the surface of LA-treated beef strip loins as storage progressed from 0 to 21 days. Research performed by Prasai and colleagues (19) showed a reduction of nearly 1.0 log CFU/cm² in aerobic bacteria found on beef subprimals treated with LA sprays before storage for 28 days at 20°C. However, in both treatments, the levels of aerobic bacteria stabilized as storage reached 28 days.

The reduction of pathogenic bacteria with cooking to various internal temperatures has been investigated previously (15, 19). While the surface reduction of pathogenic bacteria is advantageous, their presence in the interior of steaks which are undercooked or cooked to lower degrees of doneness is a concern. This study indicates that at a 10^5-log CFU/cm² inoculation level, the presence of pathogenic E. coli O157:H7 in cooked internal steak cores and on cooked steak surfaces was below the detectable limit. However, despite initial reductions in surface populations due to LA treatment, positive cooked internal core samples were obtained at a 10^5-log CFU/cm² inoculation. These data validate the evaluation of additional subprimal intervention strategies to further reduce, eliminate, and/or injure E. coli O157:H7 cells present on the surface of subprimals intended for mechanical tenderization. Additionally, the reduction in surface pathogen loads due to storage warrants further investigations to determine the relationship between vacuum-packaged aging and E. coli O157:H7 reduction at other storage lengths.

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REFERENCES


