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International Food Risk Analysis Journal

Findings of the Health Risk Assessment of *Escherichia coli* O157 in Mechanically Tenderized Beef Products in Canada

Regular Paper

Angela Catford[1,*], Marie-Claude Lavoie[1], Ben Smith[2], Enrico Buenaventura[1], Hélène Couture[1], Aamir Fazil[2], and Jeffrey M. Farber[1]

1 Bureau of Microbial Hazards, Food Directorate, Health Products and Food Branch, Health Canada
2 Public Health Risk Sciences Division, Laboratory for Foodborne Zoonoses, Public Health Agency of Canada

* Corresponding author E-mail: angela.catford@hc-sc.gc.ca

Received 14 May 2013; Accepted 28 May 2013

DOI: 10.5772/56713

Abstract In late 2012, a total of 18 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, 2005; Laine *et al.*, 2005; CDC, 2010). In order to evaluate this risk, Health Canada (HC) and the Public Health Agency of Canada (PHAC) have developed a workplan 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

* http://www.inspection.gc.ca/food/consumer-centre/food-safety-investigations/xl-foods/eng/1347937722467/1347937818275

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 (NESP), 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 diarrhoea and haemorrhagic colitis, and can progress to haemolytic ureamic syndrome (HUS), a life-threatening sequelae 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 hemolytic uremic syndrome (HUS), which can be fatal. Other sequalae 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).

Pathogen / Group	2006		2007		2008		2009		2010		2011	
	Total	Rate*	Total	Rate	Total	Rate	Total	Rate	Total	Rate	Total	Rate
E. coli O157†	978	2.99	934	2.83	661	1.98	529	1.56	404	1.18	482	1.39

Table 1. Excerpted annual totals and rates (per 100,000) for *E. coli* O157 reported to NESP, 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-fi/ecoli-eng.php#fig1

Year	Type of meat	Location	Cases	Publication source
2000	needle tenderized sirloin steaks	USA	2	USDA-FSIS, 2005 FR 70:30331-30334
2003	boneless beef filet bacon-wrapped steak product injected with marinade	USA	11	Laine *et al.*, 2005 J. Food Prot. 2005, 68(6):1198
2004	tenderized, marinated beef steak product	USA	4	USDA-FSIS, 2005 FR 70:30331-30334
2009	blade tenderized steaks	USA	21	CDC, 2010 Published online
2012	needle tenderized steaks	Canada	5	PHAC, 2013 Internal communications

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).

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.

* 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.

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 reformed 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

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?

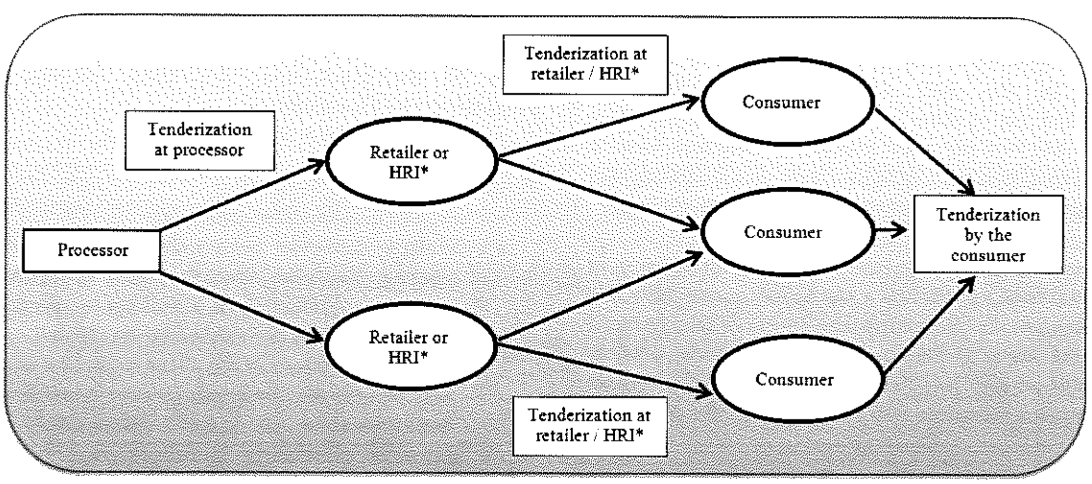
2. Approach

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

* http://www.hc-sc.gc.ca/fn-an/consult/2012-ecoli/index-eng.php

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 30.9-99.99% 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 simulation 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 faeces 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 andrelationships 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 scenariodescribed in the current assessment, withmodifications 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 P_{ibc} 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; NZFSA, 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 Aahlus, 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 (Geornaras *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 Geornaras 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

* The term GMPs in the text is used as a generic term and includes all key conditions and control measures necessary for manufacturers to ensure the safety and the suitability of food during manufacturing. It is understood that Canadian Federally Registered establishments operate under the Food Safety Enhancement Program (FSEP) and that is similar to a Hazard Analysis and Critical Control Point (HACCP) system, and would be included in the concept of GMPs covered in this document.

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)

8. 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.

5. 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?*

Scenario	Meat cut	Number of servings to cause 1 illness	Risk relative to baseline*	Source
1	Intact	1.29 billion	1	HC (2013) risk assessment / PHAC updated model †
	MTB	265 million	5	
	Ground beef	176,000	7300	
2‡	MTB, 0.4-0.6 log reduction intervention	357 million	3.6	
	MTB, 0.9-1.1 log reduction intervention	487 million	2.7	
	MTB, 1.4-1.6 log reduction intervention	1.19 billion	1.1	
3§	Intact	15.9 million	1	USDA-FSIS (2002) risk assessment (not updated)
	MTB	14.2 million	1.1	

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, "5" represents a result which is "5 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 (Pittman *et al.*, 2012, Geornaras *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.

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 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).

1.4-1.6 log reduction), the calculated risk from MTB steaks can be reduced to a level nearly equivalent to the risk from intact steaks.

An assumption was made that any data gaps and limitations in the model developed by PHAC would not impact the relative differences in risk between MTB, intact cuts and ground beef. Additionally, despite the fact that certain data gaps have been addressed since the publication by PHAC, the remaining data gaps and challenges with the model structure associated with the 2013 and 1998 PHAC risk assessments (discussed in the section "Major Challenges and Data gaps") would apply to the final conclusions.

6.1.2 An example scenario regarding cooking temperature and MTB

In an attempt to answer the question *"Would there be large effects on the risk per serving depending on adherence to a recommended cooking temperature?,* the updated PHAC model was used again to compare the risk per serving of MTB cooked to different temperatures at different levels of compliance. Hypothetical scenarios where adherence to a recommendation to cook MTB to a specific internal temperature varies, were then generated. The hypothetical scenarios which were tested included compliance rates ranging from 60 to 100%, and recommended temperatures ranging from 63 to 77°C.

This scenario analysis identified the following:

- The mean risk per serving of MTB which is cooked to an internal temperature of at least 63°C, 100% of the time, can be reduced to the same level as the mean risk per serving of intact steaks cooked without a temperature restriction, i.e., the range of temperatures estimated in the baseline model (27 to 138°C).
- It is not known how compliance to an internal cooking temperature recommendation may vary and what compliance levels would be expected. Values chosen for this analysis were arbitrary. However, it is anticipated that there will be a large uncertainty surrounding consumer preferences and willingness to adopt recommendations.

Other factors that would be important in an analysis of the effectiveness of a cooking temperature were not included in the scenario analysis, but will be briefly discussed in Question 2.

<u>Question 2:</u>

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? If so, what should it be?

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 anti-microbial 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., 10^6 - 10^9 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

The authors would like to acknowledge the excellent contributions of the following persons during the preparation of this document: Leanne DeWinter, Dr. Alex Gill, Dr. Colin Gill, Brian Harrison, André Jean, Dr. Maria Nazarowec-White, Loan Nguyen, Bill Slater, and Mark Smith.

Additionally, the authors would like to acknowledge the data and consultation contributions of the following people and/or associations: Dr. Rick Holley, University of Manitoba, Ministère de l'Agriculture des Pêcheries et de l'Alimentation du Québec, The Canadian Food Inspection Agency (Food Safety Division and Meat Programs), The Canadian Meat Council, The Public Health Agency of Canada (Laboratory for Foodborne Zoonoses), and The Retail Council of Canada

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