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Guidance Document on *E. coli* O157:H7 and *E. coli* O157:NM in Raw Beef

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1. Summary

The Canadian "Guidance Document on *Escherichia coli* O157:H7 and *E. coli* O157: NM in Raw Beef" (hereafter referred to as the *E. coli* O157 guidance document) is based on Good Manufacturing Practices[1] (GMPs) and the principles of Hazard Analysis and Critical Control Point (HACCP). This guidance document relies on a combination of application of GMPs and HACCP system, inspection and product testing to verify control of *E. coli* O157 in raw beef. This guidance document applies to all raw beef sold in Canada, produced both domestically and imported. The present guidance document revises and replaces Guideline 10: "Guidelines for Raw Ground Beef products found positive for *Escherichia coli* O157:H7" dated March 8, 1999.

The current guidance document differs from the 1999 guidelines in the following:

(1) Health Canada's strong recommendation to implement a testing program for *E. coli* O157 in Precursor Materials (PM) used for the production of Finished Raw Ground Beef Products (FRGBP) (hereafter also referred to as finished ground beef) as well as in Beef Products Processed for Raw Consumption (BPPRC) (hereafter also referred to as products for raw consumption).

(2) Microbiological testing for indicator organisms is retained as an element for determining the effectiveness of process controls and sanitation.

(3) More specific guidance is given regarding the determination of implicated and suspect product lot(s) following an *E. coli* O157 positive finding.

In response to an *E. coli* O157 positive test result in either PM, finished raw ground beef products or beef products processed for raw consumption, the following rationale is applied to determine both implicated product and suspect lot(s):

- As a minimum, all product produced from the lot from which the sample units were collected would be considered implicated.
- When processors test their raw beef products according to the "regular" lot definition of the present document (see 3.19), product additional to the lot that generated the positive result may be implicated or considered suspect.

[1] 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.

- When processors test product under a redefined lot, per section 3.19.1, and GMPs are in place, only the tested lot may be implicated. This constitutes a strong incentive for processors to use a redefined lot with an acceptable sampling protocol.

Section 7.2 provides additional information for each group of high-risk products (PM, FRGBP or BPPRC) and outlines situations where the scope of implicated product or suspect lot(s) needs to be reconsidered.

(4) New guidance addressing High-Event Periods (HEP) and products manufactured during these periods has also been developed.

Following the recommendations found in the revised guidance document should lead to an enhancement of the verification and control of *E. coli* O157 in raw beef and provide an increased ability to identify and control *E. coli* O157 contamination of precursor material and finished products. These risk management actions will provide an early warning and permit the appropriate interventions to protect consumers.

2. Purpose and Scope

This document is intended to protect the health of Canadian consumers by providing guidance to industry to reduce the potential contamination of finished raw ground beef products (FRGBP) as well as beef products processed for raw consumption (BPPRC) with *Escherichia coli* O157:H7 and O157:NM (non-motile) bacteria (collectively referred to hereafter as *E. coli* O157). It provides guidance on intervention strategies to minimize the prevalence of *E. coli* O157 in finished raw ground beef products and beef products processed for raw consumption. It is recognized that the elimination of *E. coli* O157 in raw ground beef is not currently possible. Therefore, this document also provides guidance on risk assessment and risk management approaches to reduce the risk of foodborne illness due to products that test positive for *E. coli* O157.

Food safety enforcement bodies at the federal, provincial and territorial level may also use this guidance document as a reference to assess adherence to GMPs by beef processors, distributors, retailers, importers, and others. Thus, this guidance may be used to assess compliance with general requirements of food safety legislation or regulations, in particular, compliance with Sections 4 and 7 of the *Food and Drugs Act*.

3. Definitions

In the context and for the purpose of this guidance document, the following definitions apply:

3.1 **Beef products processed for raw consumption (BPPRC)** (hereafter also referred to as products for raw consumption) are prepared in establishments and may be pre-packaged as products that are either intended or likely to be consumed in an uncooked state, as may be the case by custom or tradition (e.g., carpaccio and steak tartare).

3.2 **Beef trim,** generally, is a precursor material consisting of portions of beef carcasses obtained during boning and preparation of various meat cuts, such as primal cuts as well as all subsequently obtained cuts.

3.3 **Comminuted meat** is equivalent to ground meat.

3.4 **Combos or combo bins** are large containers that hold approximately 900 kg (2000 lb) of boneless meat that has been removed from carcasses.

3.5 ***E. coli* O157** comprises all non-sorbitol-fermenting *E. coli* O157:H7 and O157:NM, that are confirmed by biotyping, serotyping and/or other accepted methods as typical *E. coli* O157 (see Appendix 1 A).

3.6 **Epidemiologically linked** refers to the relationship between a food product and ill persons as determined by the study of the frequency, distribution, and determinants of the particular outbreak in question.

3.7 **Establishment,** means any building, room, basement, vehicle of transportation, cellar, or open or enclosed area occupied or used for handling, processing or preparing raw beef products and includes places of slaughter of meat animals or processing of meat food products. A further definition is any building or geographically contiguous buildings and associated premises where there is slaughter of meat animals or processing of meat products.

Note: The terms ‘establishment’ and ‘plant’ are considered interchangeable herein.

3.8 **Finely textured beef is** the meat obtained by removing muscle tissue attached to bones by the means of mechanical meat/bone separation equipment and that contains:

- no skin;
- no more than 0.15% of calcium;

- no bone particles larger than 1.5 mm in size and a maximum of 20% of the bone particles larger than 1 mm in size; and
- a minimum protein content of 10%; or if destined for retail sale, 14% (CFIA, 2013)

3.9 **Finished raw ground beef products (FRGBP)** (hereafter also referred to as finished ground beef) include all raw ground beef products that will be sold to consumers in that state, as well as raw meat products that contain comminuted and formed beef (for example, patties, burgers, steakettes, etc.). It also includes prepackaged product as well as bulk product that will be repackaged, either by processors or retailers, for consumer use. It does not include ground beef that will be used for further processing into different products (for example, sausages).

3.10 **Ground beef** includes any raw comminuted beef and veal product including ground, chopped, flaked or minced product, as well as finely-textured beef.

3.11 **Hazard Analysis and Critical Control Point (HACCP):**
A system that identifies, evaluates and controls hazards that are significant for food safety (CAC, 2003).

3.12 **Health Risk 1:** A situation where there is a reasonable probability that the consumption/exposure to a food will lead to adverse health consequences which are serious or life-threatening, or that the probability of a foodborne outbreak situation is considered high.

3.13 **Health Canada advice for health risk 1 situations:**
Appropriate actions should be taken immediately to prevent exposure of the population to the product, including product at the consumer level. Follow-up action should aim to determine the cause of the problem and determine if appropriate and timely corrective measures have been taken.

3.14 **Hurdle approach** refers to a combination of interventions applied to food aimed at preserving its safety and quality throughout its shelf-life.

3.15 **Implicated product** consists of, as a minimum, the raw beef product that generated a positive result when tested for *E. coli* O157. Additional product may be implicated due to various circumstances as outlined in section 7.2.

3.16 **Indicator organisms** are commonly used to measure potential fecal contamination of samples. The presence of coliform bacteria, such as *E. coli* or other enteric organisms, is a commonly used indicator (Appendix 1 B and 1 C). Indicator organisms can be assessed rapidly and quantitatively. Testing for indicator organisms, which are not pathogenic,

can be an important component of process control and is useful for assessing hygiene; but it cannot be relied upon to control the risk of illness from *E. coli* O157.

3.17 **Intact raw beef** is a piece of meat whose internal structure has not been modified. This category includes: dressed carcasses in whole/half or quarter format, primal cuts, trimmings removed from the aforementioned parts, head meat, cheek meat, diaphragm, and intercostal muscle. Intact beef muscle cuts include steaks, roasts, briskets, and stew beef. Pathogens that may be present on the external surface would not likely migrate below the surface.

3.18 **A lot when defined in terms of carcasses** is considered to be both sides of a single carcass.

3.19 **A lot of finished raw ground beef product, ground beef precursor material (**for example, **trims) or beef products processed for raw consumption** is all the finished raw ground beef product, ground beef precursor material or beef products processed for raw consumption produced under the same conditions at one establishment from one effective clean-up and sanitation to the next effective clean-up and sanitation.

In situations where segregated lines of production (see 3.28) are in place for the production of finished raw ground beef products, the product from each line becomes a specific lot (refer to the definition of segregated lines for the production of finished raw ground beef products) [2].

3.19.1 Other definitions of a lot, in other words a **redefined lot**, may be assessed on a case-by-case basis by the regulatory authority, provided that:

i) the processor is following a HACCP system[3] or a HACCP-based approach, that includes an acceptable recall procedure; AND

ii) the processor has an acceptable rationale that supports an alternative lot definition; AND

iii) each lot is tested using a sampling protocol that meets or exceeds the requirements defined in Appendix 1 D (precursor material), 1 E (finished raw ground beef products) or 1 F (beef products processed for raw consumption), AND

[2] Processors should maintain records to document all sanitation practices.

[3]The HACCP system should meet specified requirements, as expressed and evaluated by the competent regulatory authority.

iv) a proper lot identification system is in place to distinguish one 'tested' lot from another.

3.20 **Non-intact raw beef** is meat that has been ground, tenderized, injected, subjected to a process that incorporates a solution (e.g., massaging, tumbling), or cubed. This includes comminuted beef products (e.g., ground beef, finely textured beef and mechanically separated beef).

3.21 **Prepared meat product** means an edible meat product that has been cooked or dehydrated or to which has been added any substance other than meat, a meat by-product or mechanically separated meat.

3.22 **Presumptive or confirmed positive lot of product for *E. coli* O157:H7**

3.22.1 A lot reported as presumptive positive for *E. coli* O157:H7 is:
the product represented by a sample that causes a positive reaction with an acceptable screening test (see Appendix 1 G).

3.22.2 A lot reported as confirmed positive for *E. coli* O157:H7 is:
the product represented by a sample in which is found a biochemically-identified *E. coli* isolate that is serologically or genetically determined to be "O157" that meets at least one of the following criteria:

- positive for verotoxin production; and/or
- positive for verotoxin gene(s);

Note: Any presumptive positive lots found through industry testing programs that were not subjected to confirmatory testing steps, will be considered positive.

3.23 **Precursor material (PM)** includes any raw beef product used to make finished raw ground beef products including, but not limited to trims, boneless beef, coarse ground beef, hearts, head meat, cheek meat, weasand meat, and may include some primal cuts such as chucks, if they are intended to be used for ground beef.

3.24 **Primal cuts of beef** include a number of basic cuts which are typically produced when processing a beef carcass. These cuts include the following: chuck, hip, rib, short loin, sirloin, brisket and shank, plate, flank and round. These are generally used to produce smaller cuts like steaks and roasts. When any of these cuts are used or intended to be used in the manufacture of finished raw ground beef products they should be regarded as precursor materials and subjected to the same control and verification measures as other precursor materials

3.25 **Processors** include both abattoir and further-processing operations.

3.26 **Retailers** refer to businesses which sell goods to the consumer, as opposed to suppliers that normally sell their goods to another business. Retailers include large businesses and also smaller, non-chain locations run independently such as family-run butcher shops.

3.27 **Sampling protocols** applicable to precursor material, finished raw ground beef products and beef products processed for raw consumption are defined in Appendix 1 D, 1 E and 1 F respectively.

3.28 **Segregated lines for the production of finished raw ground beef products**
Processors may have more than one grinding line in their facility. The following conditions must be met for processors to consider that their finished raw ground beef products production lines are **segregated**, thus limiting the size of the lot to a specific production line:

i) The entire lot of any precursor material that is used for the production of finished raw ground beef products must be processed on a single line (in other words, a given lot of precursor material cannot be split between two grinding lines); AND

ii) Each grinding line must be clearly defined with regard to its equipment and the product flow; AND

iii) Process controls must be in place to prevent cross-contamination between the different production lines, for example, from product, equipment or employees.

iv) The lot from a segregated line for the production of finished raw ground beef products may be further defined when the requirements found under 3.19.1 are met.

3.29 **Suspect lot** is a lot of untested product or product for which testing results were reported as "not detected" (i.e., negative), but that is associated (e.g., origin or processing time and space) with product which tested positive for *E. coli* O157:H7. Suspect lot(s) should be tested according to the appropriate protocol from Appendix 1 (in other words, per Appendix 1 D, 1 E or 1 F protocols). When tested, product generating a positive result for *E. coli* O157:H7 becomes implicated.

4. Roles and Responsibilities

This guidance document, developed jointly by Health Canada, the Canadian Food Inspection Agency (CFIA) and the Public Health Agency of Canada (PHAC), takes into account the roles and responsibilities of industry, government and consumers.

4.1 Industry

It is industry's role and responsibility to comply with all applicable legislative and regulatory requirements in Canada which include Sections 4 and 7 of the *Food and Drugs Act* (Government of Canada, 2008). Industry is expected to develop and implement GMPs and controls that lead to the production of safe beef products. *E. coli* O157 generally originates from the contaminated hide or intestinal contents of healthy cattle (healthy carrier). Therefore, beef processors should have an effective GMPs and/or HACCP system to prevent transfer of the pathogen to edible parts of carcasses during the slaughter and dressing process. Effective control procedures are also needed to prevent cross-contamination when the carcasses are being cut up. Processors are encouraged to use antimicrobial treatments, such as steam or hot water pasteurization and organic acid rinses, to reduce or eliminate residual contamination from carcasses and their parts. Sampling protocols applied at strategic points in the process and the use of microbiological testing as a verification tool to demonstrate the efficacy of the control measures put in place to address *E. coli* O157 are recommended. Food distributors and retailers are responsible for controlling the temperature of meat products during transport and storage to suppress or limit bacterial growth.

4.2 Government

Health Canada has a responsibility for developing and setting food safety standards and guidelines to help minimize the risk of foodborne illness. Health Canada consults and works with the CFIA and provincial/territorial governments to ensure that public health actions are appropriate and effective. It is the role of the CFIA and provincial/territorial governments to oversee the food industry to ensure that it meets its food safety responsibilities, including the application of effective and timely management strategies appropriate to the risk, when required. The role of the PHAC is to promote and protect the health of Canadians through leadership, partnership, innovation and action in public health (PHAC, 2007). The PHAC, the CFIA and Health Canada work together with public health officials and provincial/territorial ministries of health to investigate the source of any *E. coli* O157 related illnesses when an outbreak is suspected. The PHAC takes an active role in illness surveillance across the country, e.g., C-EnterNet, a multi-partner program designed to detect changes in trends in human enteric disease and in levels of pathogen exposure from food, animal and water sources in Canada (PHAC, 2009). In addition, the three federal departments provide reference laboratory services, conduct food safety investigations, Health Risk Assessment (HRA) and recall actions.

It is also the role of the government of Canada to brief the medical community, public health officials, the food industry and consumers on many issues related to *E. coli* O157. With regards to consumers, Health Canada, the CFIA and the PHAC (and other provincial/territorial bodies)

have in the past, and will continue in the future, to develop and deliver science-based educational material to inform consumers and health care providers about the hazards associated with *E. coli* O157 and how to minimize the risks of foodborne disease, with a particular focus on vulnerable populations and their families, as well as their care providers.

4.3 Consumers

In addition to government agencies and food industries working diligently to minimize the exposure to *E. coli* O157, consumers also have an important role to play. That role calls for Canadians to learn and adopt safe food handling, responsible food selection and safe preparation practices (Health Canada, 2013b). Caterers and care providers for the elderly and other vulnerable populations (e.g., young children) have a higher level of responsibility in this regard.

5. Background

Foods of animal origin are generally safe to consume when farmers, processors, and retailers have followed good production and manufacturing practices, and when consumers properly handle and cook the product. However, there is always a risk of contamination at the farm or during slaughter, processing or packaging. *E. coli* O157, which is pathogenic, can be found on the hides and in the intestinal contents of beef animals. Upon harvesting, there is a possibility that these parts of the animal may contaminate the meat, the equipment and the working environment. Consumer illnesses can arise when these pathogenic microorganisms survive inadequate cooking of the meat, when ready-to-eat foods become cross-contaminated and/or when a contaminated beef product is eaten raw.

Raw beef products that have been subjected to a grinding process such as comminuting, chopping, flaking, mincing or fine texturing pose a higher risk than whole muscle cuts of meat that have been subjected to minimal processing. Grinding distributes pathogens from the meat's surface into the ground product, which increases the risk to consumers if the product is not properly handled and cooked.

While all raw foods of animal origin may contain pathogens such as *Salmonella*, *Campylobacter* or *Listeria monocytogenes*, *E. coli* O157 is a particular concern in finished raw ground beef products because healthy cattle frequently carry this pathogen. If it is transmitted to consumers via contaminated food, *E. coli* O157 can cause outbreaks and sporadic cases of serious illness. Human infection with *E. coli* O157 may result in hæmorrhagic colitis, an acute form of bloody diarrhœa with abdominal pain. In about 10% of patients, hæmorrhagic colitis may be followed by the hæmolytic uremic syndrome (HUS), with kidney failure, and/or thrombotic thrombocytopenic purpura, a condition like HUS, but with neurological complications that can

persist for many years. Children, the elderly and immuno-compromised individuals are most at risk from these serious forms of illness. Non-pathogenic ("generic") strains of *E. coli* may serve as indicators of fecal contamination. These strains are generally associated with the status of GMPs in a facility and are only indirectly linked to the presence of *E. coli* O157.

E. coli O157 is a member of the VTEC (verotoxin producing *Escherichia coli*) group of *E. coli.* This group is distinguished from other *E. coli* by the production of one or more verotoxins (VT), also known as shiga toxins (ST). The terms shiga-toxin producing *E. coli* (STEC) and enterohemorrhagic *E. coli* (EHEC) are also used for this group of bacteria.

E. coli isolates can be subdivided into various serotypes (O groups) based upon the possession of one of 180 O-antigens. Certain O groups of VTEC have a greater association with outbreaks and serious human illness than others. In Canada and the USA, O157 has been identified as the predominant serotype found in clinical isolates.

Although verotoxin-producing *E. coli* other than O157 strains have caused illness and could become more of a concern in the future, *E. coli* O157 is presently the most commonly identified pathogenic *E. coli* associated with severe human illness in Canada. Thus, the focus of the present guidance document is on *E. coli* O157 which is a significant threat to public health. In Canada, the incidence per 100,000 people of *E. coli* O157 infection from 2004 to 2009 was 3.7, 2.49, 3.32, 3.25, 2.29 and 1.9, respectively. From 2004 to 2007, there was an average of 1000 cases per year. However, beginning in 2008, there has been a substantial decrease in the number of reported cases, with only 661 and 529 cases being reported in 2008 and 2009, respectively (PHAC, 2009). It is estimated that about 63,153 cases of *E. coli* O157 occur annually in the USA (Scallan *et al*., 2011), with approximately 20 deaths.

Several high profile outbreaks of *E. coli* O157 associated with the consumption of undercooked ground beef resulted in the illness initially being called "hamburger disease". It should be noted that illness from this pathogen may also occur due to cross-contamination after the handling and preparation of contaminated finished raw ground beef products or beef products processed for raw consumption. Besides ground beef products, other foods such as leafy greens, sprouts, fermented meats, unpasteurized cider and fruit juices have also been implicated in *E. coli* O157 outbreaks. Waterborne transmission of *E. coli* O157, through contaminated drinking water supplies or public pools, may also occur. Therefore, public health officials should consider all possible sources when investigating outbreaks of *E. coli* O157 illness.

Quantitative risk assessments of *E. coli* O157 have been conducted for ground beef (Cassin *et al.*, 1998; Smith *et al.*, 2013). As improved pathogen reduction interventions are introduced at the farm, harvest plant and processing levels, the level of risk to the consumer estimated by these risk assessments will need updating.

Steam or hot water pasteurization and antimicrobial carcass treatments can substantially reduce contamination. Treatments applied early in the manufacturing process may reduce the number of bacteria to a low level, thus decreasing the level present when the product is used. However, some *E. coli* O157 may survive decontamination interventions and remain on the carcass and its parts during subsequent processing. There is also a possibility that the meat may be subject to cross-contamination during processing if controls are not in place or are inadequate. Therefore, additional interventions on carcasses or their parts (for example, lactic acid treatment of trim implemented as late as possible in the manufacturing process) may be necessary. Multiple controls or treatments (hurdles) are generally required to achieve adequate control, including carcass treatments and treatment of parts just before packaging or use. Effective temperature controls during transport and storage at retail (for example, refrigerated product kept at ≤4°C) can help to minimize the potential for pathogen growth.

Ground beef represents a significant source of protein in the diet of most Canadians, with the average consumption being estimated at approximately 5 kg per capita per year[4]. Considering both the risk posed by *E. coli* O157 and the amount of beef consumed, steps should be taken to ensure that this hazard has been properly addressed when raw ground beef products (whether fresh or frozen) are sold to consumers or to foodservice establishments. Steps should also be taken to ensure that the *E. coli* O157 hazard is addressed in products for raw consumption, even though these products represent a lesser portion of the Canadian diet.

While elimination of *E. coli* O157 in raw ground beef is not currently possible, reducing the prevalence of this pathogen in finished ground beef can result in a corresponding reduction in the number of *E. coli* O157 illnesses transmitted by ground beef.

[4] Based on Statistics Canada data (2009) total consumption of beef and veal (boneless carcass weight) was 12 kg per capita per year. Ground beef is generally estimated to represent about 40 % the amount of beef consumed annually.

6. Guidance to reduce the prevalence of *E. coli* O157 in raw beef

Principle #1

Finished raw ground beef products and beef products processed for raw consumption should not contain detectable levels of *E. coli* O157.

Recommendation

All processors supplying retailers or food service providers with finished raw ground beef products and/or beef products processed for raw consumption should take steps to address *E. coli* O157 as a hazard likely to occur, by developing and implementing documented and validated processes.

The industry should aim to produce finished ground beef and products for raw consumption that are free of *E. coli* O157. A combination of interventions as well as sanitation measures may be used, as applicable, throughout the whole process chain. As an approach to reduce the prevalence of *E. coli* O157 in finished ground beef and products for raw consumption, Health Canada strongly recommends:

i) Implementation of microbial sampling protocols for PM and finished ground beef as described in Appendix 1 D and 1 E, respectively.

ii) Implementation of a microbial sampling protocol for products for raw consumption as described in Appendix 1 F.

iii) That processors require their suppliers of PM to have tested each lot for *E. coli* O157 in order to receive only product that has been determined to be below detectable levels.

When contamination occurs or is reported in those products, the source should be determined where possible, and appropriate corrective action should be taken to prevent a recurrence of the problem or a similar situation. Specific measures are discussed for each product type in sections 6.1.1 and 6.1.2.

Processors of federally-registered establishments should consult the CFIA's "Policy on the Control of *E. coli* O157 Contamination in Raw Beef Products" in the Meat Hygiene Manual of Procedures, Chapter 4, Annex O.

Processors of non-federally registered establishments may also find it useful to consult the CFIA document. Processors may also consult the best practice documents published by the Beef Industry Food Safety Council.

Principle #2

A proactive approach to data collection and analysis should be adopted to identify any major issues before they develop.

Recommendation

Processors should summarize and analyze all data on a "real–time" basis to verify process controls and use this information as part of the company's out-of-control action plan (OCAP). Monitoring programs should include a system to record data and their evaluation, (**e.g., performing trend analyses). A continual review of the data is important to revise and adjust monitoring programs.**

Beef processing establishments cannot rely solely on product testing to verify and control *E. coli* O157. Process controls are an essential part of a processor's food safety program and should include steps for the control of *E. coli* O157.

Information on quality and process control verification steps and results from the various microbiological verification sampling protocols implemented in the plant (e.g., indicator testing of dressed carcasses, trim testing, finished product testing, etc.) should be monitored closely and be subjected to "real-time" analysis. These results should provide information on the efficacy of process control steps used along the manufacturing process of beef products. These data should be used to gain an in-depth understanding of the effectiveness of the overall control measures put in place in a plant resulting in enhanced process awareness and improved control over time. As each processor gains experience in controlling *E. coli* O157, within their context, they will be able to make appropriate adjustments.

Data which support a comprehensive knowledge of the manufacturing process can help processors determine the appropriate course of action when events that may overwhelm normal process controls occur (e.g., inputs with a higher than normal contamination rate, etc.). Data analysis to determine patterns (or "trends") can be useful in determining situations where a potential loss of control is likely to occur (e.g., upward shift of recorded values, etc.) or has occurred in the plant's day-to-day operations. This analysis can also identify places in their

processes where controls are lacking and where corrective action can be applied. However, in the case of a pathogen such as *E. coli* O157, this ability may be limited due to the nature of the contamination in beef products (i.e., sporadic or low level contamination). Nonetheless, the timely analysis of all data gathered at process control steps or elsewhere in the manufacturing process is strongly encouraged.

Data collected, along with the analysis, should be accessible to those in the processing plant responsible for managing the food safety program, including the *E. coli* O157 control program. At least one or more individuals within the establishment (e.g., quality assurance, food safety and/or HACCP coordinators) should have the responsibility for updating, monitoring and acting upon the data.

It is important to continually strive for enhanced control by responding to each potential food safety issue, including the detection of *E. coli* O157 contamination, with appropriate corrective actions in a timely manner. Processors should establish appropriate criteria (i.e., limit) indicative of out-of-control situations and take preventative action before this limit is exceeded. The use of up-to-date technologies can help in providing immediate notification when the established criterion is approached or breached.

An out-of-control action plan (OCAP) should be developed to guide company actions when high rates of positive for *E. coli* O157 are observed. Data analysis should be used with a company OCAP as part of the overall food safety system. Additionally, identified patterns can be used by regulatory authorities to model and estimate risk and better target oversight activities.

6.1 Testing raw beef products for *E. coli* O157

At present, the HACCP programs and various interventions in the beef slaughter process can significantly reduce, but not completely eliminate, *E. coli* O157 in finished ground beef. This is due to the fact that, as with other raw meats, there is no definitive kill step in the finished ground beef production process. Instead a "hurdle" approach is relied upon, in which multiple barriers are implemented, each contributing in varying degrees to reducing pathogen levels in the finished product.

In late 2002, many North American beef processors began testing trim and/or finished ground beef for the presence of *E. coli* O157. Product that tested positive was either cooked or destroyed. Since that time, *E. coli* O157 levels in finished ground beef as well as *E. coli* O157 illnesses have decreased. For instance, the USDA's Food Safety and Inspection Service (FSIS) testing indicated that *E. coli* O157 prevalence rates in finished ground beef were reduced from 0.87% and 0.73% in 2001 and 2002, respectively to 0.18-0.17% from 2004 to 2006 and then

increased slightly to 0.24% and 0.30% in 2007 and 2009, with a peak at 0.47% in 2008. Prevalence was reduced again in subsequent years with 0.32% in 2009, 0.24% in 2010 to reach its lowest in 2011 with 0.07% and slightly up in 2012 with 0.16% (FSIS, 2013a).

Along with the implementation of sampling protocols, many North American beef processors also refocused their HACCP programs to address *E. coli* O157 and began implementing new and improved interventions. It has been reported that approximately 68.2 million kg (150 million pounds) of beef trim (0.8% of the total annual USA trim production), testing positive for *E. coli* O157 as part of industry testing programs, are currently diverted from use in the production of raw ground product each year in the United States. In 2009, Canadian beef establishments, representing more than 90% of beef production in Canada, reported the diversion of approximately 2.1 million kilograms of beef trim from the production of ground beef because of known or potential contamination with *E. coli* O157 detected by industry test results.

Most of the industry testing programs for *E. coli* O157 in trims, using the stringent sampling protocol, n = 60, c = 0, are able to screen out trims with a 5% or higher prevalence rate of the organism in tested lots on about 19 occasions out of 20 (Pa = 0.95). Since this represents a relatively high prevalence of contamination, it can be inferred that much of the trim currently being diverted would have resulted in the production of contaminated finished ground beef and significant consumer exposure to *E. coli* O157, if not removed from distribution. A strong argument can be made that testing has had a direct role in the observed decreases in *E. coli* O157 in finished ground beef contamination rates and illnesses.

Health Canada has concluded that the implementation of improved interventions, supported by testing, could play a significant role in decreasing *E. coli* O157 contamination rates in finished ground beef, which could be related to the reduction of illnesses caused by this pathogen. Furthermore, testing also plays an indirect role in improving safety, as it identifies opportunities for plants to improve their processes. When positive lots are reported, the processor is expected to review the control measures in place and make corrections or enhancements as necessary, to reduce the probability of future contamination.

E. coli O157 sampling can be complemented by testing for indicator organisms, which is recommended (see 6.2) as a means of monitoring process control, effectiveness of interventions applied and adherence to GMPs on a day-to-day basis. This type of testing allows plants to establish long term performance trends.

Finally, the use of the suggested sampling protocols outlined in Appendix 1 for PM, finished ground beef and products for raw consumption, when combined with the other requirements, allows processors to redefine their production lot (see 3.19.1).

6.1.1 Testing for *E. coli* O157 in PM

Principle #3

Precursor materials used to produce raw beef products, particularly finished raw ground beef and beef products processed for raw consumption should not contain detectable levels of *E. coli* O157.

Recommendation

Processors producing precursor material for further processing into finished raw ground beef products and beef products processed for raw consumption are strongly encouraged to implement a sampling protocol as described in Appendix 1D.

For the purpose of directly reducing *E. coli* O157 contamination rates in retail ground beef, establishing meaningful long-term performance trends and promoting continuous process improvement, Health Canada strongly recommends that processors producing PM for further processing into finished raw ground beef products and products for raw consumption implement a sampling protocol, as described in Appendix 1 D and 1F respectively.

If PM tests positive for *E. coli* O157, it:

- should not be used to produce raw beef products, including finished ground beef and products for raw consumption, AND
- should either be destroyed or treated as indicated in section 7.4.2.

The PM testing program should include feedback to the dressing process when *E. coli* O157 is detected in PM. Each positive result should be investigated in an effort to determine the source of the contamination and to guide corrective actions to prevent a recurrence or a similar situation.

6.1.1.1 High-Event Periods (HEP)

From time to time, processors may experience periods in which a high number or rate of positives for *E. coli* O157 (i.e., “hot spots”, “hot day(s)” or “high-event periods”) is detected through their testing regimes. Those situations can be indicative of either:

- a localized “out-of-control” situation that can affect part or all of one day’s production (i.e., a lot, if not redefined or certain redefined lots), that may indicate an isolated

problem during processing (for example, equipment malfunction for the application of an antimicrobial) or

- a systemic break-down situation (e.g., failure to prevent contamination) where more than one product and/or more than one day of production may be affected.

Processors should develop a plan to identify when a High-Event Period (HEP) occurs, including the determination of appropriate criteria for the identification of a HEP (e.g., threshold or limit), which may reflect a weakness in control or a loss of control over the dressing process. When a HEP is suspected (including situations where the predetermined threshold level is approached), processors should determine whether the positive lots are related in time (time of processing) and/or space (source area of a carcass or carcasses). Confirmed HEPs demand a more intensive investigation to identify the source of the problem and implementation of timely corrective actions. The actions taken need to reflect the findings of the investigation.

When a HEP is identified, processors need to consider if products other than those reported positive (i.e., untested products and/or lots for which testing results were reported as "not detected") might be suspect. For example, processors may determine that production lots of trimmings reported as "not detected" and manufactured from the same source materials at the same time as lots reported positive for *E. coli* O157, are suspect. If the establishment makes that determination, products:

- should not be used in the production of finished ground beef or products for raw consumption, AND
- should be treated as indicated in section 7.4
- untested products may be tested to determine disposition, in consultation with the responsible regulatory authority.

6.1.2 Testing for *E. coli* O157 in Finished Raw Ground Beef Products

Principle #4

HACCP plans should be designed to eliminate or at least be consistently effective in reducing *E. coli* O157 prevalence in finished raw ground beef products (i.e., finished raw ground beef products should not contain detectable levels of *E. coli* O157).

Recommendation

To verify the effectiveness of control measures, processors are strongly encouraged to implement a sampling protocol appropriate to the situation (as described below and in Appendix 1). When a product is found positive for *E. coli* O157, appropriate action should be taken to eliminate the hazard.

Testing of finished raw ground beef products should be performed in the following circumstances:

- When the PM (including finely textured beef - FTB) was not tested or it cannot be confirmed that the PM used for the production of finished ground beef has been tested with an appropriate protocol, (i.e., meeting or exceeding the requirements of Appendix 1 D). In such cases, the finished ground beef should be tested as described in Appendix 1 E.

- As part of a monitoring sampling protocol implemented by regulatory authorities. Sampling procedures and methodology will be determined by the appropriate regulatory authority.

In addition, testing of finished ground beef may be performed, where appropriate, within the context of an establishment's HACCP system:

- As a process control for the production of finished ground beef where the PM has been sampled under an acceptable sampling protocol, in other words, meeting or exceeding Appendix 1 D requirements. In such cases, the finished ground beef should be tested as described in Appendix 1 E.

- As part of a verification procedure under HACCP, or to meet customer or export requirements. In such cases, processors may use a sampling protocol that is different from the one found in Appendix 1 E.

Note: Critical control points should be validated and the validation should be repeated any time there are relevant changes in the HACCP plan, for example, new interventions are introduced or existing ones are modified due to a failure.

Regardless of the reason for testing, a lot of ground beef that tests positive for *E. coli* O157 is considered to pose a potential health risk to consumers and an appropriate response should be taken to eliminate that risk.

Ground beef that tests positive for *E. coli* O157:

- Should not be released to the marketplace either as finished raw ground beef or as part of a raw product containing beef (for example, sausages).
- Should either be destroyed or treated as indicated in section 7.4.2.

Specific guidance relating to the level of risk and the type of public health action to be taken is discussed in detail in section 7.0 – Risk Assessment and Risk Management.

6.1.3 Testing for *E. coli* O157 in Beef Products Processed for Raw Consumption

Principle #5

Beef products processed for raw consumption should not contain detectable levels of *E. coli* O157.

Recommendation

Processors are encouraged to implement a sampling protocol for beef products processed for raw consumption (as described in Appendix 1F). When a product is found positive for *E. coli* O157, appropriate action should be taken to eliminate the hazard.

Products for raw consumption should be controlled by a sampling protocol that meets or exceeds the requirements of Appendix 1 F.

A lot of product for raw consumption that tests positive for *E. coli* O157 is considered to pose a health risk to consumers and an appropriate response should be taken to eliminate that risk.

Therefore,

- products for raw consumption that test positive for *E. coli* O157 should either be destroyed; or
- treated as indicated in section 7.4.2.

Specific guidance relating to the level of risk and the type of public health action to be taken is discussed in detail in section 7.0 – Risk Assessment and Risk Management.

6.2 Use of indicator organisms to verify process controls

Principle #6

Process controls (as part of a HACCP system) should be monitored.

Recommendation

Processors should document the measures they use to demonstrate the efficacy of their process controls and sanitation measures, including the sampling protocols used, the action levels of the indicator organisms being monitored and the action taken when levels are exceeded.

Verification steps can help ensure a HACCP plan is adequate and efficient. Verification procedures may include various activities (e.g., review of plans, CCP records, establishing critical limits, etc.). This should include implementation of controls at appropriate points along the production chain, for example controls on the dressing line and supplier programs for further processing.

Microbiological testing is an important tool in verifying HACCP plans and control points and in determining whether the process is under control by providing information related to the company's process controls. The HACCP plan may specify acceptable levels of an indicator or target organism at key steps in the process, such as for the dressed carcass, PM and for the finished ground beef. Additional verification steps could also be included by the processor. Interventions may also be identified and the type of corrective action to be taken when the level of the indicator or target organism(s) exceeds the acceptable level should be noted. Generic *E. coli* can be a useful indicator to verify process control since it is ubiquitous in feces, and rapid enumeration test kits are available (see Appendix 1 B). It is important that processors producing PM conduct generic *E. coli* testing at some point(s) in their operation to assess process control.

The levels of an indicator organism, such as generic *E. coli*, should be monitored at key points in beef production. This can demonstrate both the efficacy of interventions and adherence to GMPs throughout the production process. For example, the levels of generic *E. coli* in trims obtained from suppliers could be monitored to provide a potential indication of the supplier's sanitation and/or handling practices.

Between March 2001 and February 2002, the CFIA, Health Canada and the Canadian Meat Council (CMC) conducted a joint baseline study on the microbiological quality of ground beef manufactured at federally-registered establishments in Canada. This study showed that processors should be able to produce ground beef in which the level of generic *E. coli* is consistently ≤100 CFU/g. Therefore, processors should target a level of generic *E. coli* that does not exceed 100 CFU/g (preferably not exceeding 10 CFU/g) in the ground beef product, to demonstrate adequate GMPs (e.g., handling practices).

As the aforementioned study did not assess generic *E. coli* levels in precursor material, such as beef trims, nor in products for raw consumption, it will be up to the manufacturers of these materials to establish levels of generic *E. coli* that would be indicative of GMPs deficiencies.

Processors may use other indicators such as Enterobacteriaceae or total coliforms, but they should be able to provide scientific justification for their choice and acceptable level. All criteria should be based on statistically valid sampling protocols as discussed in Appendix 1.

When the number of generic *E. coli* is above the suggested level or the threshold/action level set by processors for other indicator microorganisms, processors should identify the cause, take action(s) where appropriate, and review their HACCP plan or their GMPs where a HACCP-based system is not in place.

6.3 Microbiological testing of equipment and surfaces in the processing environment

Principle #7

Sanitation systems used by processors should be effective and adherence to GMPs should be monitored.

Recommendation

To assess the effectiveness of the sanitation system, processors should conduct routine and systematic environmental testing for indicator organism(s), such as Total Aerobic Counts (TAC) or generic *E. coli*. This will also help identify and monitor equipment surfaces that are difficult to clean.

Processing equipment such as knives, saws, grinder plates, conveyer belts and wheels have the potential to spread bacteria because of build-up of organic debris during processing. This may result in in-process cross-contamination between carcasses or meat pieces with bacteria, including *E. coli* O157, if initially present on carcasses or on beef cuts being processed. To minimize this potential spread, effective sanitation procedures should be put in place by processors along with implementing routine testing and monitoring procedures (see Health Canada's Compendium of Analytical Methods (Health Canada, 2013a), to determine the appropriate method to use, as well as Appendix 1 B and 1 C) to identify equipment and surfaces that could potentially impact the microbial quality and safety of the final product. Typically, such programs monitor organisms such as TAC, generic *E. coli* or other indicators to verify the efficacy of sanitation processes.

7.0 Risk Assessment and Risk Management

Detection of *E. coli* O157 in PM, finished ground beef, or products for raw consumption require prompt action by the manufacturer of the products to control the hazard and minimize the risk to consumers, as well as to follow up with measures to prevent a recurrence. These actions should address each step of the product's manufacture, starting at the abattoir. If contaminated products are already in the marketplace, regulatory authorities should act quickly to implement public health measures to contain the risk and minimize consumer exposure. To facilitate product tracing, processors should develop and put in place good product traceability schemes (both for incoming and outgoing product) as part of their general HACCP system. Quickly identifying and regaining control of implicated product(s) is essential in minimizing continued consumer exposure to such products.

7.1 Risk Characterization

Principle #8

Consumers should not be exposed to finished raw ground beef products or beef products processed for raw consumption if they are:

i) Contaminated (i.e., reported positive) with *E. coli* O157; or
ii) Epidemiologically linked to *E. coli* O157 illness.

Recommendation

Appropriate actions should be taken immediately to prevent exposure of the population to the product(s), including product at the consumer level.

A lot of finished ground beef or product for raw consumption is considered to pose a Health Risk to consumers when:

- The lot of finished raw ground beef product or beef product processed for raw consumption is confirmed positive for *E. coli* O157 by an acceptable method or is otherwise implicated according to section 7.2 (Note: presumptive positive lot(s) found through industry testing programs that were not subjected to confirmatory testing will be considered positive)

  OR

- The lot of finished ground beef or product for raw consumption is epidemiologically linked to *E. coli* O157 illness, in other words:

  - The weight of evidence is strong and suggests an epidemiological link between the product and human illness **AND/OR**

  - There is direct laboratory evidence to link the illness and the product obtained from molecular sub-typing methods, such as pulsed-field gel electrophoresis (PFGE), when strains isolated from the human illness and from the food linked epidemiologically to the illness are indistinguishable.

7.2 Determination of Implicated Product

When a sample collected from either PM, finished ground beef or product for raw consumption has tested positive for *E. coli* O157, the minimum amount of product that is implicated should be the lot from which the sample units were collected for analysis. Additional product would be implicated when positive product was either mixed with similar product or used for the production of another raw beef product. The following sections provide rationale to make appropriate decisions.

7.2.1 PM, Finished Raw Ground Beef Product and Beef Products Processed for Raw Consumption produced and tested under the "regular" lot definition

Finished raw ground beef products and beef products processed for raw consumption represent the highest hazards among the raw beef products offered to consumers. Therefore, Health Canada strongly recommends that their production be verified using an appropriate sampling protocol.

As such, products for raw consumption should be tested according to Appendix 1 F protocol, or an alternative that meets or exceeds these specifications. In order to identify contaminated ground beef product as early as possible during its processing, all PM should be tested according to the Appendix 1 D protocol, or an alternative that meets or exceeds these specifications. Furthermore, the finished ground beef should be tested according to Appendix 1 E protocol, or an alternative that meets or exceeds these specifications, when the PM was not tested or it cannot be confirmed that the PM used in their production was adequately tested.

Alternative sampling protocols will be evaluated by the relevant regulatory authority prior to their implementation in the processing establishment.

7.2.1.1 PM, Finished Raw Ground Beef Products and Beef Products Processed for Raw Consumption produced and tested under an acceptable redefined lot

When the tested beef products were processed under an acceptable redefined lot (in other words the regulatory authority has determined that all the requirements listed under 3.19.1 are met), the lot would be redefined either according to the specifications of Appendix 1 D, for PM, Appendix 1 E for finished ground beef or Appendix 1 F for products for raw consumption OR according to the processor's HACCP plan (e.g., some processors define a lot as a single combo from which they collect 60 sample units).

When testing PM and products for raw consumption, the implicated product would be limited to the redefined lot that generated the positive result, provided that the following conditions are met:

- The sampling was done in accordance with the applicable protocol, AND
- GMPs or a recognized HACCP system were in place in the establishment when the product was manufactured, AND
- The tested redefined lot was held and kept intact pending the receipt of results.

When testing finished ground beef, providing that the above three conditions are met, the implicated product would consist of the redefined lot that generated the positive result, as defined in the establishment's prerequisite program or HACCP plan.

However, if any portion of the *E. coli* O157 positive material from the redefined lot has been:

- Mixed with other lot(s) of similar product,

  OR

- Used in the manufacture of finished ground beef or a prepared meat product (for example, sausages without a lethality process adequate to kill *E. coli* O157).

These new lots would be automatically considered implicated, regardless of the quantity of positive product they contain. This situation highlights the need to properly identify and hold tested product until the laboratory results are obtained.

Additional bracketing of implicated or suspect product may be conducted based on source of trims, time of production, production line, etc., taking into account "like product".

Please refer to section 7.2.1.3 for situations where the scope of implicated and suspect product respectively may be expanded.

7.2.1.2 PM, Finished Raw Ground Beef Products or Beef Products Processed for Raw Consumption produced when a testing protocol is not in place or when testing of these products do not meet the specifications listed in Appendix 1 D, 1 E or 1 F, respectively

Principle #9

If establishments do not follow the recommended sampling protocols for testing raw beef and/or beef products, the products that are implicated could be much broader.

Recommendation

Processors are strongly encouraged to implement sampling protocols as described in Appendix 1. When the recommended *E. coli* O157 sampling protocol (i.e., as stated in Appendix 1 D, 1 E, 1 F) is not met, the scope of implicated product based on a positive *E. coli* O157 finding could be expanded.

In the absence of a sampling protocol, or when the sampling protocol does not meet the specifications outlined in Appendix 1 D (PM), Appendix 1 E (finished ground beef) or Appendix 1 F (products for raw consumption), or the establishment does not have an acceptable redefined lot sampling protocol reviewed and accepted by regulatory authorities, the following guidance applies.

7.2.1.2.1 Precursor Material

When a PM test result is positive for *E. coli* O157:

- All the PM produced under the same conditions as the tested product at one establishment from one effective clean-up and sanitation to the next effective clean-up and sanitation is implicated (see 3.19).
- Any lot of PM containing a portion of implicated product (as described under the above bullet) also becomes implicated; in other words when implicated product is mixed with other lot(s) of PM.
- Any lot of finished ground beef or of a raw prepared meat product containing implicated PM (as described above, under the first bullet) is also considered implicated, regardless of when it was produced.
- When GMPs are adequate, there is no need to suspect additional product at the same establishment from other days.

7.2.1.2.2 Finished Raw Ground Beef Products

When a finished raw ground beef product test result is positive for *E. coli* O157:

- All the finished ground beef produced under the same conditions at one establishment from one effective clean-up and sanitation to the next effective clean-up and sanitation is implicated (see 3.19).
- Any lot of finished ground beef that contains a portion of implicated product would be implicated (as described under the above bullet), in other words, when implicated product is mixed with other lot(s) of finished ground beef.
- When the lot(s) of PM used to make this finished ground beef was not subjected to the recommended sampling protocol, this lot of PM and/or other lot(s) of ground beef produced using this PM are considered suspect, and should be subjected to sampling (according to Appendix 1 D and 1 E specifications for PM and finished ground beef, respectively). If the suspect lot(s) of PM tests negative in follow-up testing, no further product is implicated. Any lots of PM or ground beef found positive through follow-up testing, as well as ground beef products derived from any positive PM lot(s), are considered implicated.
- If the lot(s) of PM used to make this finished ground beef was subjected to the recommended minimum sampling protocol (or to a more stringent testing protocol) and generated a "not detected"/negative result, it would not be implicated.

7.2.1.2.3 Beef Products Processed for Raw Consumption

When a beef product processed for raw consumption tests positive for *E. coli* O157:

- All the products for raw consumption that were produced under the same conditions at one establishment from one effective clean-up and sanitation to the next effective clean-up and sanitation would be implicated (see 3.19).
- Any lot of product for raw consumption containing a portion of the implicated product (as described under the above bullet) also becomes implicated, in other words, when implicated product is mixed with other lot(s) of products for raw consumption or used in the manufacture of a prepared meat product.
- When GMPs are adequate, there is no need to suspect additional product at the same establishment from other days.

7.2.1.3 Expansion of product scope

7.2.1.3.1 Expansion of scope of implicated products

The scope of implicated lots may be expanded on a case-by-case basis, if one, or more, of the following circumstances is present:

- The data analysis conducted by operators suggests that the process is not under control.
- Epidemiological evidence indicates that illness may have been caused by lots in which *E. coli* O157 was not detected.
- Evidence of significant GMPs issues, along with taking into consideration the specific situation of a particular plant.
- Evidence that validated CCP(s) to control *E. coli* O157 are not in place in the establishment (for example, all implicated raw beef received is not used in the production of fully cooked product or has not been subjected to another validated lethality treatment).
- Evidence of inadequacies in either the design or implementation of the applicable sampling protocol or lot identification system.

A Health Risk Assessment from Health Canada can be requested in such cases by the relevant regulatory authority.

7.2.1.3.2 Expansion of scope of suspect lots

The scope of suspect lots may be expanded on a case-by-case basis, if the following circumstance is present:

- Evidence of systemic contamination as determined by the processors or regulatory authorities, for example, multiple lots spread over time test positive in the same production day, or a significantly higher percentage of lots test positive in a given time frame than would be expected based on the plant's data analysis.

7.2.1.4 Re-testing for *E. coli* O157

With regard to re-testing either PM, finished ground beef or products for raw consumption for *E. coli* O157, the following considerations apply:

- Lots of PM, finished ground beef or product for raw consumption that test positive for *E. coli* O157 should not be subjected to re-testing. However, if for some reason, these lots are re-tested and found negative, they are still considered positive.
- Any lot of PM, finished ground beef or product for raw consumption that initially tests negative but is subsequently re-tested and found positive, is considered positive.
- Retesting of PM or finished ground beef will sometimes result in a re-definition of a lot (for example, composite lots of PM could be tested by the receiving processor as part of a supplier verification program). It should be noted that testing composites of multiple lots is strongly discouraged, because it can severely compromise traceability. However, when such a newly defined lot tests positive, it is considered implicated. Health Canada will assess on a case-by-case basis the health risk posed by the balance of product from individual lots making up the newly defined lot.
- If a lot of ground beef, derived from PM that previously tested negative using the recommended sampling protocol, is tested and found positive, that lot of ground beef is considered positive while the PM is considered negative.

7.2.1.5 Follow-up testing of product linked to illnesses or gross GMPs issues

At the discretion of the regulatory authority, PM, finished ground beef or products for raw consumption may be subjected to follow-up testing protocols more stringent than the minimum sampling protocols described in Appendix 1 D, 1 E and 1 F, if it is suspected that the product(s) may be linked to illnesses, or there is evidence that it was produced under inadequate GMPs.

7.2.1.6 Mixing of implicated and non-implicated lots of raw beef products

When implicated PM, finished raw ground beef products or beef products processed for raw consumption are mixed with similar non-implicated products, the resulting mixture(s) is considered implicated regardless of the ratio of implicated to non-implicated material.

7.2.2 Intact muscle cuts of beef (for example, primal cuts, roasts and steaks)

Intact muscle cuts of beef pose a much lower risk than ground products for transmitting *E. coli* O157 because, unlike ground products, pathogens are confined to the surface of these products and thus would be killed using conventional cooking practices, even if the product is less than fully cooked.

Therefore, under normal circumstances, intact muscle cuts are not usually suspect when:

- they are associated with the same source material as trim (which is a PM) or ground beef found positive for *E. coli* O157, or
- they have been produced during the same production period (for example, between clean-ups) as trim (which is a PM) or ground beef found positive for *E. coli* O157.

Intact muscle cuts which are linked to unsatisfactory product, however, are considered suspect in situations:

- where they are intended as precursor material to ground product;
- when illnesses are epidemiologically linked to the product under investigation;
- when the particular product in question is likely to be consumed or intended to be consumed in an uncooked state, as by custom or tradition, for example, carpaccio, steak tartare;
- when significant GMPs issues have been observed and/or gross contamination is evident;
- when a HEP is identified.

7.2.3 Mechanically Tenderized Beef (MTB)

During the mechanical tenderization process, the penetration of the meat by needles or blades, including the injection of marinades or brines, may transfer *E. coli* O157 from the surface of contaminated meat to the interior, raising the possibility that *E. coli* O157 would survive in such products when subjected to customary cooking practices (in other words possibly less than fully cooked).

Since 1999, there have been at least seven (7) outbreaks of *E. coli* O157 that appear to be associated with mechanically tenderized beef in the USA and Canada (Lewis *et al.*, 2012; FSIS, 2013b). In order to minimize the potential for contamination, processors should implement and adhere to strict process controls and sanitation practices, which could include prior application of an antimicrobial solution to the products being tenderized and thorough cleaning and sanitizing of the tenderizing needle or blade assembly before each use. Routine verification protocols should be implemented to ensure that the process controls and sanitation procedures are effective. Since July 2013, the CFIA has reviewed their manual of operating procedures and

processors who tenderize cuts of meat using needles or blades, must label MTB products as such, and provide adequate cooking instructions to minimize the risk to the consumer[5] (CFIA, 2012).

Incidents involving tenderized products will be assessed on a case-by-case basis by the competent regulatory authority.

7.3 Follow-up action when an *E. coli* O157 positive result is reported in product(s)

In addition to implementing and monitoring the effectiveness of a recall, when one was needed, follow-up action by the regulatory authority is necessary to ensure that appropriate action has been taken by the processor or retailer. The type of follow-up action will depend upon which raw materials have been found positive. In general, there should be a review of both GMPs and the HACCP system or a HACCP-based food safety program. Processors are responsible for making the changes necessary to prevent further recurrence.

7.3.1 Follow-up when imported product tests positive for *E. coli* O157

When an imported beef product tests positive, it should be handled in the same way as domestic product. The exporting country will be notified by the CFIA of the follow-up measures. The sampling protocols and methods used to test imported lots should be as stringent as those used to test domestic product.

7.4 Disposition of implicated or suspect product

7.4.1 Product recalled from the consumer or retail level

All finished ground beef or product for raw consumption which is recalled from the consumer and/or the retail level should not re-enter the human food chain, as the product may have been mishandled or exposed to conditions of temperature abuse. Such raw beef products could be used for inedible rendering provided the rendering operation is validated for reducing *E. coli* O157 to below detectable levels. Otherwise, the recalled product should be destroyed.

[5] Health Canada has also announced its intention mandate MTB labeling with identification and adequate cooking instructions for the non-federally registered sector including retail.

7.4.2 Implicated product at the processor level

PM, finished ground beef and any products for raw consumption that test positive for *E. coli* O157 may be used for further processing at a registered-establishment provided that ALL of the following conditions are met:

- they originated from a registered or provincially-licensed establishment and the integrity of the product and its packaging, as applicable, was maintained (e.g., sealed boxes, stamps, etc.) and
- they are held under continuous supervision by a regulatory authority, or they have not been displayed for retail sale, and
- they have not been temperature-abused (product maintained at ≤ 4°C or frozen), and
- every portion of the product will receive a heat process sufficient to ensure microbiological safety.

If ALL of the above conditions are not met, the product should be destroyed.

7.4.3 Suspect product at the processor level

PM, finished raw ground beef products and beef products processed for raw consumption that is suspect may be used for further processing at a registered establishment, provided that ALL of the following conditions are met:

- a control plan for the distribution of the suspect product has been reviewed and pre-approved by the appropriate regulatory authority, and
- the products originated from a federally-registered or provincially-licensed establishment and the integrity of the product and its packaging as applicable was maintained (e.g., sealed, boxes, stamps, etc.), and
- they have not been temperature-abused (product maintained at ≤ 4°C or frozen), and
- every portion of the product will receive a heat process sufficient to ensure microbiological safety.

If ALL of the above conditions are not met, the product should be destroyed.

Note: Based on a precautionary risk management approach, a processor is free to take more stringent recall action on product sold to the consumer than the action recommended in this guidance document.

Table 1. The recommended sampling protocols, implicated and suspect product for redefined lots (per definition 3.19.1).

Product	Recommended sampling protocols[6]	Implicated products[7]	Suspect products
Testing of precursor material for *E. coli* O157	According to the sampling specifications of Appendix 1 D.	The redefined lot (see 3.19.1) that tested positive. Any lot of PM, finished ground beef or of a prepared meat product that contains a portion of the PM from the redefined lot that tested positive. (See 7.2.1.1)	Additional product may be considered suspect under specific circumstances. (See 7.2.1.3)
Testing of finished raw ground beef products for *E. coli* O157	According to the sampling specifications of Appendix 1 E.	The redefined lot (see 3.19.1) that tested positive. Any lot of finished ground beef or of a prepared meat product that contains a portion of the finished ground beef from the redefined lot that tested positive. (See 7.2.1.1)	Additional product may be considered suspect under specific circumstances. (See 7.2.1.3)
Testing of beef products processed for raw consumption for *E. coli* O157	According to the sampling specifications of Appendix 1 F.	The redefined lot (see 3.19.1) that tested positive. Any lot of a prepared meat product that contains a portion of the product for raw consumption from the redefined lot that tested positive. (See 7.2.1.1)	Additional product may be considered suspect under specific circumstances. (See 7.2.1.3)

[6] Alternative sampling protocols may be used, provided that they are as/or more rigorous than those provided in this guidance and have been accepted by a regulatory authority.

[7] Additional product may be implicated according to the specifications of the alternative sampling protocol.

Table 2. Beef products that will be implicated or suspect when testing protocol(s) are either not in place or not meeting the specifications listed in Appendix 1 D, 1 E or 1 F for PM, finished raw ground beef products and beef products processed for raw consumption, respectively

Sampled Product	Implicated Product	Suspect Product
Precursor material tested for *E. coli* O157	All the PM produced under the same conditions as the tested product at one establishment from one effective clean-up and sanitation to the next effective clean-up and sanitation would be implicated. Any lot of PM, finished ground beef or of a prepared meat product that contains a portion of the implicated PM (as described above) also becomes implicated. (See 7.2.1.2.1)	Additional product is considered suspect under specific circumstances. (See 7.2.1.3).
Finished raw ground beef products tested for *E. coli* O157	All the finished ground beef produced under the same conditions as the tested product at one establishment from one effective clean-up and sanitation to the next effective clean-up and sanitation would be implicated. Any lot of finished ground beef or of a prepared meat product that contains a portion of the implicated finished ground beef (as described above) also becomes implicated. The lots of PM that were used to make this finished ground beef, when they were not subjected to the recommended sampling protocol, should be tested according to Appendix 1 D of this guidance document. As well, any finished ground beef already produced from these PM lots should be tested according to Appendix 1 E of this guidance document. Any product generating a positive result becomes implicated. PM and/or finished ground beef that test "not detected" (i.e., negative) is not implicated.	Additional product is considered suspect under specific circumstances. (See 7.2.1.3).

Sampled Product	Implicated Product	Suspect Product
	Note: Source PM that was subjected to the minimum sampling protocol and generated negative results is not implicated. (See 7.2.1.2.2).	
Beef products processed for raw consumption tested for *E. coli* O157	All the product(s) for raw consumption produced under the same conditions as the tested product at one establishment from one effective clean-up and sanitation to the next effective clean-up and sanitation is implicated. Any lot of product for raw consumption containing a portion of the implicated product described above also becomes implicated (in other words, with regards to mixing different lots of products for raw consumption). (See 7.2.1.2.3)	Additional product is considered suspect under specific circumstances. (See 7.2.1.3)

8. References

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Appendix 1

A) Procedure to confirm a presumptive positive for *E. coli* O157

If a positive result has been obtained by using an *E. coli* O157 screening test, the sample is considered to be a presumptive positive for *E. coli* O157. Perform confirmatory testing in accordance with a method from the Health Canada's Compendium of Analytical Methods (for example, MFLP-80):

Note: If confirmatory testing is positive, the product should be disposed of in accordance with 7.4.

B) Procedure for assessing the levels of generic *E. coli* in ground beef

It is recommended that the levels of an indicator organism such as generic *E. coli* be monitored to evaluate process control. A statistically valid sampling protocol should be followed. When testing ground beef for levels of generic *E. coli*, it is strongly recommended that sample units should not be composited when baseline levels are being established. Samples should be analyzed using acceptable, quantitative methodology. Examples of appropriate methods include MFHPB-19, MFHPB-26, MFHPB-27 or MFHPB-34 found in the Compendium of Analytical Methods. Other methods may be used provided they meet the requirements for equivalent methods as defined in the Interpretive Summary Vol. 1 of the Compendium of Analytical Methods.

C) Procedure for assessing the level of other indicator organisms

If the levels of generic *E. coli* are not monitored, some other indicator microorganism should be monitored to evaluate process control. A statistically valid sampling protocol should be followed. Samples should be analyzed using acceptable quantitative methodology. For example, if total coliforms are monitored, use a quantitative method from the Compendium of Analytical Methods such as MFHPB-17, MFHPB-19, MFHPB-31, MFHPB-34, MFHPB-35. Appropriate methodologies for indicator organisms other than total coliforms are also available from the Compendium.

D) Sampling protocol for the examination of precursor material for *E. coli* O157

A minimum of 60 sample units from a lot of precursor material should be examined.

Alternative sampling protocols may be used, provided that they are as/or more rigorous than that outlined below, and have been approved by a regulatory authority. A redefined lot should not exceed 5 combos nor weigh more than approximately 4,500 kg (10,000 pounds). An alternate unit to a combo may be defined and used by the operator (for example, one pallet of boxes of product = 1 combo), provided the number of units and weight do not exceed 5 and approximately 4,500 kg respectively. A minimum of 12 individual pieces per combo; 65 g per combo and 325 g per lot should be examined. Approximately 6 g of

material from each piece representing the meat surface (in other words, not sterile inner tissue), should be examined.

E) Sampling protocol for the testing of finished raw ground beef products for *E. coli* O157

A minimum of 5 sample units from a regular (i.e., not redefined) lot of ground beef should be examined. Sample units should be representative of the whole lot and a minimum of 325g per lot, should be examined. Alternative sampling protocols may be used provided that they are as/or more rigorous than that just outlined above, and have been accepted by a regulatory authority. For redefined lots, the number of sample units, if different from above, should be as specified in the company's sampling protocol that has been accepted by a competent regulatory authority.

F) Sampling protocol for *E. coli* O157 in beef products processed for raw consumption

A minimum of 60 sample units should be examined per lot of such beef products processed for raw consumption. Sample units should be representative of the whole lot. A total of 325g per lot should be analyzed. Approximately 6g of material from the meat surface of each piece (in other words, not sterile inner tissue) should be examined. Alternative sampling protocols may be used, provided that they are as/or more rigorous than that outlined just above, and have been accepted by a regulatory authority.

G) Screening for *E. coli* O157 in precursor material or ground beef or beef products processed for raw consumption (or their source cuts)

A rapid and sensitive method found in Health Canada's Compendium of Analytical Methods that is approved for testing beef should be used. If a positive result is obtained, the sample is considered to be a presumptive positive for *E. coli* O157. Processors may action product based solely on a presumptive positive result, or they may choose to confirm that the sample is positive, as detailed in part A of this Appendix. If plants choose not to confirm, presumptive positive samples will be assumed to be positive and implicated product should be disposed of in accordance with 7.4. (Note: If the product being tested originated from another establishment, the decision not to pursue confirmatory testing should be shared with the supplying establishment).

Appendix II

List of acronyms

BPPRC: Beef product processed for raw consumption
CAC: Codex Alimentarius Commission
CMC: Canadian Meat Council
CCP: Critical control point
CFIA: Canadian Food Inspection Agency
EHEC: Enterohemorrhagic *Escherichia. coli*
FRGBP: Finished raw ground beef product
FSIS: Food Safety Inspection Service
FTB: Finely textured beef
GMP: Good Manufacturing Practices
HACCP: Hazard Analysis and Critical Control Point
HEP: High event period
HRA: Health risk assessment
HUS: Hemolytic and uremic syndrome
MTB: Mechanically tenderized beef
PFGE: Pulsed-field gel electrophoresis
PHAC: Public Health Agency of Canada
PM: Precursor material
OCAP: Out-of-control plan
ST: Shiga Toxin
STEC: Shiga-toxin producing *Escherichia coli*
TAC: Total aerobic count
USA: United States of America
USDA: United States Department of Agriculture
VT: Verotoxin
VTEC: Verotoxin producing *Escherichia coli*