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

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Food Directorate
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Canada

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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 Critical Control Point (HACCP). This guidance document was developed using as its foundation a combination of inspection and end-product testing to verify control of *E. coli* O157 in raw beef. This guidance document applies to 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 Fresh Raw Ground Beef Products (FRGBF) as well as in Beef Products Processed for Raw Consumption (BPPRC).

(2) Microbiological testing for indicator organisms (see 3.15) in PM, FRGBP, BPPRC and the processing environment 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 product lots following an *E. coli* O157 positive finding.

In response to an *E. coli* O157 positive result for either PM, FRGBP or BPPRC, 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 as per the regular lot definition of the present document (see 3.18), product additional to the lot that generated the positive result may be implicated or considered suspect. Only high-risk products (for example, PM, FRGBP and BPPRC), would be considered implicated or 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 the product under a redefined lot as per 3.18.1, and GMP 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 lots needs to be reconsidered.

This revised guidance document should lead to an enhancement of the verification and control of *E. coli* O157 and provide an increased ability to identify and control *E. coli* O157 contamination of precursor material and finished products. These 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 and to provide 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 FRGBP and BPPRC. 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 of beef processors, distributors, retailers, importers, and others to GMPs. 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)** are products that are prepared in establishments and may be pre-packaged as products that are either intended to be consumed or are likely to be consumed in an uncooked state, as may be the case by cultural custom or tradition, for example, 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 cuts, that includes 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 ~900 Kg (~2000 lb) of boneless meat that has been removed from carcasses.

3.5 ***E. coli* O157** comprises all sorbitol non-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 the implicated product(s) 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. NOTE: The terms 'establishment' and 'plant' are interchangeable. 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.

3.8 **Finished raw ground beef products (FRGBP)** 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).

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

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

3.11 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.

3.12 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 try to determine the cause of the problem, and determine if appropriate and timely corrective measures have been taken.

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

3.14 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 7.2.

3.15 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). Indicators 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.

3.16 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.

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

3.18 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 beef 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 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].

3.18.1 Other definitions of a lot (i.e., 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

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

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

3.19.1 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).

3.19.2 A lot reported as confirmed positive for *E. coli* O157:H7 is:
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); and/or
- genetically determined to be "H7" (See Appendix 1 A).

[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.

3.20 **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.

3.21 **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

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

3.23 **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.

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

3.25 **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. The lot from a segregated line for the production of finished raw ground beef products may be further defined when the requirements found under 3.18.1 are met.

3.26 **Suspect lot** is a lot that could be implicated in *E. coli* O157:H7 contamination. Suspect lots should be tested as per the appropriate protocol from Appendix 1 (in other words, as

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 as a joint effort between 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 which include Sections 4 and 7 of the *Food and Drugs Act* (Government of Canada, 2008) and to develop and implement GMPs and controls that are conducive 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 GMP 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 that identify the nature and assess the level of risk associated with the consumption of contaminated food products and develops guidance documents to help minimize the risk of foodborne illnesses. Health Canada consults and works with the CFIA and provincial/territorial governments on the above to ensure that public health responses 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 (Health Canada, 2010a) 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 has already begun to play a more active role in food 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.

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, 2010a). Caterers, parents of young children and care providers for the elderly and other vulnerable populations have a higher level of responsibility in this regard. To this end, 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.

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. Sources of disease-causing (or pathogenic) *E. coli* O157 include the hides and intestinal contents of beef animals. Upon harvesting, there is a possibility that these sources may contaminate the meat, the equipment and the working environment. Consumer illnesses 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 FRGBP 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 haemorrhagic colitis, an acute form of bloody diarrhoea with abdominal pain. In about 10% of patients, haemorrhagic colitis may be followed by the haemolytic 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,* when present at higher levels in the meat, may serve as indicators of fecal contamination but are only indirectly linked to the presence of *E. coli* O157*,* being more generally associated with the status of GMP in a facility.

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 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 2008 was 3.7, 2.49, 3.32, 3.25 and 2.29, respectively. During this same time period, there was an average of around 1000 cases per year. However, starting in 2008, there has been a substantial decrease in the number of reported cases, with only 702 and 613 cases being reported in 2008 and 2009, respectively (PHAC 2010, unpublished results). 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 annually.

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 FRGBP or BPPRC. 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. As improved pathogen reduction interventions are introduced at farm, slaughter plant and processing levels, the level of risk to the consumer estimated by these 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 from the start, thus decreasing the level present when the product is used. However, some *E. coli* O157 may survive the decontamination interventions and the meat may also be subject to cross-contamination when cut up. Therefore, additional treatment(s) of carcasses or their parts (for example, lactic acid washing of trim implemented as late as possible in the manufacturing process) may be necessary. Multiple 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 risk.

Ground beef represents a significant source of protein in the diet of most Canadians, with the average consumption being approximately 15 kg per capita per year[4]. Considering both the risk posed by *E. coli* O157 and the amount 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 BPPRC, 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 FRGBP can result in a corresponding reduction in the number of *E. coli* O157 illnesses transmitted by ground beef.

[4] Based on Statistics Canada data showing a total beef consumption of about 30 kg beef carcass weight per capita per year. Ground beef represents about half 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 (FRGBP) and beef products processed for raw consumption (BPPRC) should not contain detectable levels of *E. coli* O157.

Recommendation

All processors supplying retailers or food service providers with finished raw ground beef products (FRGBP) and/or beef products processed for raw consumption (BPPRC) 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 FRGBP and BPPRC 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 FRGBP, Health Canada strongly recommends:

i) Implementation of microbial sampling protocols for PMs and/or FRGBP as described in Appendix 1 D and 1 E, respectively.

ii) Implementation of a microbial sampling protocol for BPPRC 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.

PM which tests positive should not be used for manufacturing FRGBP or any raw product containing beef (see 6.1.1). Where possible, the source of the contamination should be determined and appropriate corrective action should be taken to prevent a recurrence of the problem or a similar situation. Processors of federally-registered establishments should consult the CFIA *Policy on the Control of* E. coli *O157 Contamination in Raw Beef Products* in the *Meat Hygiene Manual of Procedures*, Chapter 4, Annex O available at: http://www.inspection.gc.ca/english/fssa/meavia/man/ch4/annexoe.shtml. Processors of non-federally registered establishments may also find it useful to consult the CFIA document. Processors may also consult the Best Practices documents published by the Beef Industry Food Safety Council available at: http://www.bifsco.org/technicalresources.aspx.

Principle #2

Variations in trends and other signs of potential problems should be identified before any major issues develop.

Recommendation

Processors are encouraged to summarize and analyze all data on a regular basis to determine trends.

Processors who have implemented a sampling protocol as a process control are encouraged to conduct a trend analysis on their results by summarizing and analyzing all data on a regular basis. When possible, quality control and statistical methods should include modern graphical techniques (for example, control charts) as well as appropriate descriptive and analytical statistical methods. Review of the data will provide information on the prevalence of *E. coli* O157, the fluctuation over time (seasonal incidence) and identify issues to be addressed in a timely manner. Trend analysis should be used to achieve improved control over time as each processor gains experience in controlling *E. coli* O157 and makes appropriate adjustments. In addition, identified trends can be used by regulatory authorities to model and estimate risk and thus 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 FRGBP. This is due to the fact that, as with other raw meats, there is no definitive kill step in the FRGBP production process. Instead a "hurdle" approach is relied upon, in which multiple pathogen barriers are implemented, each contributing in varying degrees to reduce pathogen levels in the finished product.

In late 2002, many North American beef processors began testing trim and/or FRGBP for the presence of *E. coli* O157. Product that tested positive was either cooked or destroyed. Since that time, *E. coli* O157 levels in FRGBP 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 FRGBP 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 0.298% in 2007 and 2009, with a peak at 0.47% in 2008.

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 US 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 FRGBP 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 FRGBP 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 FRGBP, which could be directly 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 found, 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.

Sampling for *E. coli* O157 in PM, FRGBP and BPPRC is also highly beneficial, in that it allows plants to establish long term performance trends that are more meaningful than those established through, for instance, generic *E. coli* testing, which does not directly correlate with product safety. *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 and adherence to GMPs on a day-to-day basis.

Finally, the use of the suggested sampling protocols outlined in Appendix 1 for PM, FRGBP and BPPRC, when combined with the other requirements, allows processors to redefine their production lot (see 3.18.1).

6.1.1 Testing for *E. coli* O157 in precursor material

Principle #3

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

Recommendation

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

For the purposes 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 products implement a sampling protocol, as described in Appendix 1 D.

- PM, for example, trims, hearts, etc., that test positive for *E. coli* O157 should not be used to produce raw beef products, including FRGBP.
- Positive PM should either be destroyed or be treated as per indicated in section 7.4.2.

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 (FRGBP).

Recommendation

To verify the effectiveness of their 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 minimize or eliminate the hazard.

Testing of FRGBP should be performed in the following circumstances:

- When the PM was not tested or it has not or cannot be confirmed that the PM and/or finely textured beef (FTB) used for the production of FRGBP has been tested with an appropriate protocol, in other words, meeting or exceeding the requirements of Appendix 1 D (for example, imported raw beef products not accompanied by a Report of Analysis are used to produce the FRGBP). In such cases, the FRGBP 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 FRGBP may be performed, where appropriate, within the context of an establishment's HACCP system:

- As a process control for the production of FRGBP 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 FRGBP 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 mitigate 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).

- Ground beef that tests positive for *E. coli* O157 should either be destroyed or be treated as per 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 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 (BPPRC) 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 (BPPRC) (as described in Appendix 1F). When a product is found positive for *E. coli* O157, appropriate action should be taken to minimize or eliminate the hazard.

BPPRC should be controlled by a sampling protocol that meets or exceeds the requirements of Appendix 1 F.

A lot of BPPRC that tests positive for *E. coli* O157 is considered to pose a health risk to consumers and an appropriate response should be taken to mitigate that risk. Therefore,

- BPPRC that test positive for *E. coli* 0157 should either be destroyed; or
- be treated as per 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 7.0 – Risk Assessment and Risk Management.

6.2 Indicator organisms in finished raw ground beef products and their precursor material, as well as in beef products processed for raw consumption

Principle #6

Process controls and adherence to GMP should be monitored.

Recommendation

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

Microbiological testing is important in verifying HACCP plans and in determining whether the process is under control. The HACCP plan may specify tolerable levels of an indicator or target organism at key steps in the process, such as for each ingredient or PM and for the FRGBP, as well as for BPPRC. Intervening steps 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 tolerable level. Generic *E. coli* is a useful indicator for this purpose since it is ubiquitous in feces, and rapid enumeration test kits are available (see Appendix 1 B).

The levels of an indicator organism such as generic *E. coli* in FRGBP and their PM, as well as in BPPRC, can assist in monitoring process control and adherence to GMPs.

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 (but preferably not exceeding 10 CFU/g) in the ground beef product, to demonstrate adequate GMPs and sanitation procedures.
- It is also important that processors producing PM for FRGBP production conduct generic *E. coli* testing at some point(s) in their operation to assess process control.

As the aforementioned study did not assess generic *E. coli* levels in FRGBP precursor material, such as beef trim, nor in BPPRC, it will be incumbent on the manufacturers of these materials to establish levels of *E. coli* that would be indicative of GMP deficiencies.

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

6.3 Microbiological testing of equipment and surfaces in the processing environment

Principle #7

Sanitation systems used by processors should be effective.

Recommendation

To assess the effectiveness of the sanitation system, processors should conduct routine and systematic environmental testing for an 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.

The build-up of organic debris on equipment and surfaces such as knives, saws, conveyer belts and wheels may result in the cross-contamination of meat with *E. coli* O157 during processing. Therefore, effective sanitation should be put in place by processors who should also implement routine testing and monitoring procedures (see MFLP-41 in Health Canada's Compendium of Analytical Methods, as well as Appendix 1 B and 1 C) to identify equipment and surfaces that could impact the microbial quality and safety of the final product. Typically, such programs monitor levels of generic *E. coli,* or other indicator organisms such as TAC, to verify the efficacy of sanitation processes.

7. Risk Assessment and Risk Management

Detection of *E. coli* O157 in PM, FRGBP, or BPPRC requires 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 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.

7.1 Risk Characterization

Principle #8

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

i) contaminated (i.e., found 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 FRGBP or BPPRC is considered to pose a Health Risk to consumers when:

- The lot of FRGBP or BPPRC is confirmed positive for *E. coli* O157 by an acceptable method or is otherwise implicated as per 7.2 (Note: presumptive positive lots found in industry testing programs that were not subjected to confirmatory testing will be considered positive)

  OR

- The lot of FRGBP or BPPRC is epidemiologically linked to *E. coli* O157 illness, in other words:
  - There is an epidemiological link between the product and human illness **AND/OR**
  - There is direct laboratory evidence to link the illness and the implicated product obtained from the microbiological sub-typing, 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, FRGBP or BPPRC has tested positive for *E. coli* O157, the minimum amount of product that is implicated by this result is the lot from which the sample units were collected for analysis. Additional product will 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 the rationale to make the appropriate decisions.

7.2.1 Testing of precursor material, finished raw ground beef products and beef products processed for raw consumption

FRGBP and BPPRC represent the highest hazards among the raw beef products offered to consumers. Therefore, Health Canada strongly recommends that their production be controlled by an appropriate sampling protocol.

As such, BPPRC should be tested as per Appendix 1 F protocol, or an alternative that meets or exceeds these specifications. For FRGBP, in order to identify contaminated product as early as possible during its processing, all PM should be tested as per the Appendix 1 D protocol, or an alternative that meets or exceeds these specifications. Furthermore, the FRGBP should be tested as per 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 Precursor material, 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 3.18.1 are met), the lot would be redefined either as per the specifications of Appendix 1 D, for PM, Appendix 1 E for FRGBP or Appendix 1 F for BPPRC; OR as per 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 BPPRC, providing that the following conditions are met, the implicated product would be limited to the redefined lot that generated the positive result:

- The sampling was done in accordance with the applicable protocol, AND
- GMPs 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 FRGBP, providing that the above three conditions are met, the implicated product would consist of the redefined lot that generated the positive result, as well as one or two of the redefined lots produced immediately before and/or immediately after the positive lot as defined in the establishment`s 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 FRGBP or of a prepared meat product (for example, sausages),

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.

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

7.2.1.2 Testing protocol(s) not in place for precursor material, finished raw ground beef products or beef products processed for raw consumption or testing protocol(s) which do(es) 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 potentially 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 (FRGBP) or Appendix 1 F (BPPRC), the following guidance applies.

7.2.1.2.1 Precursor Material

When a test result is positive for PM:

- 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 3.18).
- 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 FRGBP or of a prepared meat product containing implicated PM (as described 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 test result is positive for FRGBP:

- All the FRGBP 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 3.18).
- Any lot of FRGBP 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 FRGBP).
- When the lot(s) of PM used to make this FRGBP was not subjected to the recommended sampling protocol, this lot of PM and/or other lots of ground beef produced using this PM are considered suspect, and should be subjected to sampling (as per Appendix 1 D and 1 E specifications for PM and FRGBP 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 FRGBP was subjected to the recommended minimum sampling protocol (or to a more stringent testing protocol) and generated a negative result, it would not be implicated.

7.2.1.2.3 Beef Products Processed for Raw Consumption:

When a test result is positive for BPPRC:

- All the BPPRC that was 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.
- Any lot of BPPRC 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 BPPRC 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 scope of implicated product

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

- The trend analysis conducted by operators suggests that the process is not under control.
- Epidemiological evidence indicates that illness may have been caused by lots that tested negative.
- Evidence of systemic contamination as determined by the processors or regulatory authorities, for example, multiple lots dispersed 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 trend analysis.
- Evidence of significant GMP violations, for example, significant numbers of raw ground beef lots sampled at the processing plant demonstrate generic *E. coli* levels > 100 CFU/g.
- Evidence that validated CCP(s) are not in place in the establishment to control *E. coli* O157 (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.

7.2.1.4 Re-testing for *E. coli* O157

With regard to re-testing either PM, FRGBP or BPPRC for *E. coli* O157, the following considerations apply:

- Lots of PM, FRGBP or BPPRC 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, FRGBP or BPPRC that initially tests negative but is subsequently re-tested and found positive, is considered positive.

- Retesting of PM or FRGBP 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, the 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 GMP violations

At the discretion of the regulatory authority, PM, FRGBP or BPPRC 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 poor GMPs.

7.2.1.6 Mixing of implicated and non-implicated lots of raw beef products (precursor material, finished raw ground beef products, beef products processed for raw consumption)

When implicated PM, FRGBP or BPPRC 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 illness 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, these intact muscle cuts are not usually implicated when:

i) they are associated with the same source material as trim or ground beef found positive for *E. coli* O157, or

ii) they have been produced during the same production period (for example, between clean-ups) as trim or ground beef found positive for *E. coli* O157.

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

i) where they are intended as precursor material to ground product;

ii) when illnesses are epidemiologically linked to the product under investigation;

iii) when the particular product in question is likely to be consumed or intended to be consumed in an uncooked state, as by cultural custom or tradition, for example, carpaccio, steak tartare;

iv) when significant GMP violations have been observed and/or gross contamination is evident.

7.2.3 Tenderized beef

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

However, a 2002 USDA risk assessment indicated almost no difference in risk of illness associated with tenderized versus non-tenderized beef steaks. The study also concluded that this finding would also be applicable to tenderized beef roasts because they are thicker than steaks and thus need to be cooked longer resulting in, if anything, a greater reduction of *E. coli* O157. Furthermore, there have been relatively few *E. coli* O157 outbreaks associated with tenderized beef products. Therefore, tenderized beef will, in general, be treated the same way as non-tenderized primal cuts and would only be implicated under the circumstances mentioned in 7.2.2 (for example, evidence of illnesses, significant GMP violations and/or gross contamination). Incidents involving tenderized products will be assessed on a case-by-case basis.

7.3 Follow-up Action when an *E. coli* O157 Positive Result is Obtained 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 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 equivalent to, in other words, as stringent as, those used to test domestic product.

7.4 Disposition of Implicated Product

7.4.1 Product recalled from the consumer level

All implicated FRGBP or BPPRC which are recalled from the consumer level should not re-enter the human food chain. 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* to below detectable levels. Otherwise, the recalled product should be destroyed.

7.4.2 Implicated product at the retail or processor level

PM, FRGBP and any BPPRC 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 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.

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 for testing redefined lots (See 2.16.1).

Sampling protocol	Recommended sampling protocols[5]	Implicated products[6]	Suspect products
Testing of precursor material for *E. coli* O157	As per the sampling specifications of Appendix 1 D	The redefined lot (see 3.18.1) that tested positive Any lot of PM, FRGBP 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	As per the sampling specifications of Appendix 1 E	The redefined lot (see 3.18.1) that tested positive, as well as the one or two of the redefined lots produced immediately before the positive lot and/or the one or two produced immediately after the positive lot. Any lot of FRBG or of a prepared meat product that contains a portion of the FRGBP 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	As per the sampling specifications of Appendix 1 F	The redefined lot (see 3.18.1) that tested positive. Any lot of a prepared meat product that	Additional product may be considered suspect under specific circumstances.

[5] 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.

[6] Additional product may be implicated as per the specifications of the alternative sampling protocol

		contains a portion of the BPPRC from the redefined lot that tested positive. (See 7.2.1.1)	(See 7.2.1.3)

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, FRGBP and BPPRC, 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, FRGBP 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 FRGBP 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 FRGBP or of a prepared meat product that contains a portion of the implicated PM (as described above) also becomes implicated. The lots of PM that generated this FRGBP, when they were	Additional product is considered suspect under specific circumstances. (See 7.2.1.3).

Sampled Product	Implicated Product	Suspect Product
	not subjected to the recommended sampling protocol, should be tested as per Appendix 1 D of this guidance document. As well, any FRGBP already produced from these PM lots should be tested as per Appendix 1 E of this guidance document. Any product generating a positive result becomes implicated. PM and/or FRGBP that test negative is not implicated. 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 BPPRC 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 BPPRC containing a portion of the implicated product described above also becomes implicated (in other words, with regards to mixing different lots of BPPRC). (See 7.2.1.2.3)	Additional product is considered suspect under specific circumstances. (See 7.2.1.3)

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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):

http://www.hc-sc.gc.ca/fn-an/res-rech/analy-meth/microbio/volume3/mflp-80-eng.php

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. Sample units should not weigh less than 100 g and sample units should not be composited, especially when baseline levels are being established. Samples should be analyzed using acceptable, quantitative methodology. Examples of appropriate methods would include those found in the Compendium of Analytical Methods, such as MFHPB-19, MFHPB-26, MFHPB-27 or MFHPB-34. 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. The Compendium of Analytical Methods can be found at:

http://www.hc-sc.gc.ca/fn-an/res-rech/analy-meth/microbio/index-eng.php

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. 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 other indicator organisms 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 just above, 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. Alternative sampling protocols may be used, provided that they are as/or more rigorous than that outlined just above, and have been approved by a regulatory authority.

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. 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. A lot cannot exceed approximately 4,500 kg (10,000 pounds). 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.

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 BPPRC. Sample units should be representative of the whole lot which cannot exceed ≈4,500 kg (10,000 pounds). A total of 325g per lot should be analysed. 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).