Annex O: Policy on the Control of *E. coli* O157:H7/NM Contamination in Raw Beef Products

1.0 Effective Date

This policy is effective on the date of publication.

2.0 Purpose

The purpose of this policy is:

1. To provide clear guidance to industry and inspection staff on the measures required to control *Escherichia coli* O157:H7/NM in raw beef products; and
2. To reflect the risk-based approach taken by the Canadian Food Inspection Agency (CFIA) to address the risk posed by this pathogen.

3.0 Definitions

In the context of this policy, the following definitions apply.

3.1 Accredited laboratory

A laboratory that is formally recognized by the Standards Council of Canada (SCC), the Canadian Association for Laboratory Accreditation (CALA), or another accreditation body that is a signatory to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Agreement (MRA) as conforming to the requirements of ISO/IEC 17025:2005.

3.2 *E. coli* O157:H7/NM

Escherichia coli O157:H7/NM are enterohaemorrhagic, Shiga toxin producing strains of *Escherichia coli* (*E. coli*). Reference to *E. coli* O157 in this document includes both H7 (flagellar antigen) and NM (non-motile) bacteria.

The presumptive positive and confirmed positive results of *E. coli* O157 are defined as follows:

3.2.1 Presumptive positive

A sample that gives a positive test result for potential presence of *E. coli* serotype O157 from an enrichment broth is referred to as a presumptive positive (i.e. causes a positive reaction with a CFIA recognized screening test presented in E. coli O157">Appendix 2 of this policy).

An operator may choose to treat presumptive positive results as positive results unless otherwise specified with the policy (see section section 5.5). In such instances, these samples will be presumed to be positive samples for the purpose of this policy.

3.2.2 Confirmed positive

To be confirmed positive, a pure isolate from the original enrichment broth must exhibit typical appearance on selective agar media and:

1. is serologically and biochemically determined to be *E. coli* O157, and/or
2. is genetically determined to be *E. coli* O157.

Additionally, to be a confirmed positive, one of the following criteria must be met:

1. positive for Shiga toxin (ST) production; and/or
2. positive for Shiga toxin gene(s) (stx).

3.3 Epidemiological evidence

Epidemiological evidence refers to data (descriptive or analytical in nature) demonstrating an association between a food product and human illness as determined by the study of the frequency, distribution and determinants of the particular outbreak.

3.4 Full lethality treatment

A beef product is considered to have received a full lethality treatment for *E. coli* O157 when the manufacturing process has been scientifically validated to achieve a five log reduction of *E. coli* O157.

3.5 Implicated product

Implicated product consists of, at a minimum, the lot of raw beef product that generated a positive result when tested for *E. coli* O157. Additional products may be implicated due to various circumstances as outlined in section 7.2 and 9.0.

3.6 Raw beef

Raw beef includes beef and veal, as well as their hearts, head meat, cheek meat, oesophagus, etc. Raw beef products include intact beef products, non-intact beef products and comminuted beef products.

Note: Beef tails and tongues are excluded from the raw beef product definition since they are customarily fully cooked and have not been linked to human illnesses.

3.6.1 Intact raw beef

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 and sub-primal cuts, steaks, roasts, briskets, diced beef and stew beef, trimmings removed from the aforementioned parts, head meat, cheek meat, diaphragm, and intercostal muscle.

3.6.2 Non-intact raw beef

Non intact raw beef is beef that has been either:

1. mechanically tenderized with blades or needles; or
2. injected.

3.6.3 Comminuted beef

Comminuted beef includes ground, finely textured, chopped, mechanically separated, flaked and minced beef.

3.6.4 Precursor material (PM)

Precursor material includes any raw beef products intended to be used for production of finished raw ground beef product (FRGBP). This includes, but is not limited to, trims, bench trims, boneless beef, finely textured beef, hearts, head meat, cheek meat, tongue roots and weasand meat. It includes primal cuts, such as chucks, if intended to be used for production of FRGBP.

3.6.5 Finished raw ground beef products (FRGBP)

FRGBP includes all raw ground beef products that will be sold to consumers in that state, as well as raw beef products that contain comminuted and formed beef (e.g., patties, burgers, steakettes, etc.). It includes pre-packaged product as well as bulk product that will be repackaged, either by processors or retailers, for consumer use.

FRGBP does not include ground beef that will be used for further processing into sausages and for products which are subjected to full lethality treatment to produce Ready-to-Eat (RTE) products in federally registered establishments.

3.7 Suspect product

Suspect product 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.

4.0 Risk Posed by *E. coli* O157

Based on currently available information, *E. coli* O157 contamination of raw beef is a health hazard likely to occur. Human infections with *E. coli* O157 may occur through consumption of contaminated uncooked or partially cooked beef products resulting in disease conditions such as haemorrhagic colitis, bloody diarrhea and abdominal pain. Some patients may develop hemolytic uremic syndrome (HUS) with kidney failure. Children, elderly and immuno-compromised individuals are more likely to experience serious forms of illness when compared to the general population.

Cattle are the primary source of *E. coli* O157 that infects humans. The shedding of *E. coli* O157 in cattle feces is intermittent and increases during summer and fall season. Contamination of beef carcasses with *E. coli* O157 occurs during slaughtering and dressing procedures, especially during the de-hiding and evisceration processes. The subsequent use of any meat components derived from a contaminated carcass in FRGBP would be considered a risk to human health.

5.0 Control Measures/Interventions

To minimize the risks posed by *E. coli* O157, operators of federally registered establishments handling raw beef products must include the following measures in their Hazard Analysis and Critical Control Points (HACCP) system:

1. Food Safety Enhancement Program (FSEP) forms (or equivalent) on product identification and intended use are complete and accurate with regards to the *E. coli* O157 hazard and controls;

2. the *E. coli* O157 hazard is clearly identified on the FSEP form (form # 5 or equivalent) and has been passed through the decision tree (FSEP form # 8 or equivalent);
3. the operator has to determine how the hazard will be controlled, for example, through Critical Control Points (CCPs), pre-requisite programs or process controls.

The HACCP system must be validated to demonstrate that the level of *E. coli* O157 in raw beef products is below the detectable level i.e., no *E. coli* O157 is detected in a sample when tested with one of the approved methods (refer to Appendix 2 of this policy for the relevant information).

Establishments handling raw beef (beef slaughter operations, further processors and grinding operations) must implement appropriate control measures to ensure the safety of beef products.

5.1 Beef Slaughter Establishments

In the case of a slaughter establishment, the operator must:

1. Use at least one pathogen reduction intervention, such as steam/hot water pasteurization, organic acid sprays, etc. This intervention must be validated according to FSEP principles and those presented in Appendix 1 of this policy, to reduce *E. coli* O157 contamination to below detectable level. The operator must develop, implement and maintain written control programs within their HACCP system to ensure that the selected pathogen reduction intervention is functioning as intended, and that the critical parameters (e.g., critical limits, operating standards) are met. The monitoring methods and frequency shall be designed to detect any loss of control. This would allow the affected product to be identified before it leaves the control of the slaughter establishment and to be segregated accordingly. The operator should also ensure the selected antimicrobial control intervention complies with the corresponding requirements of Meat Hygiene Manual of Procedures (MHMOP), Chapter 17 for microbial controls including the assurance that all chemicals used for antimicrobial interventions are used in accordance with Health Canada's assent.
2. Develop, implement, and maintain a written control program within their HACCP system to ensure that the dressing procedures are followed and implemented in a manner to prevent the contamination of carcasses and other raw meat products with biological hazards.
3. Develop, implement, and maintain a written control program within their HACCP system to prevent airborne contamination of the meat products, especially carcasses.
4. Develop, implement, and maintain a written control program within their HACCP system to ensure that the Good Manufacturing and Personnel Hygiene Practices are followed and implemented in a manner to prevent the contamination of carcasses/raw meat products with biological hazards.
5. Develop, implement, and maintain a written control program within their HACCP system to ensure that conditions under which the carcasses are stored and transported are satisfactory. Operators must comply with carcass cooling performance requirements found in the MHMOP, Chapter 17.

Additionally, operators may choose to:

1. collaborate with producers and transporters on pre-harvest management practices aimed at reducing *E. coli* O157 load in live animals presented for slaughter;
2. assess the cleanliness of animals (e.g., mud scoring) at live animal receiving and use this information to establish appropriate control procedures such as, implementing appropriate sequencing of the affected lot or animals during slaughter, implementing reduced line speeds, adding more trimmers on the production line and /or enhancing the monitoring of control measures designed to reduce the hazard to below detectable levels, to ensure the control over biological hazards;
3. utilize a hide-on carcass wash to remove excess organic matter and reduce airborne particles; and
4. use additional intervention steps, as part of a multi-hurdle approach, contributing to the reduction of *E. coli* O157 contamination of raw meat product to below detectable level. If such interventions are added, operators must, as part of their HACCP system, define the critical operating parameters and the appropriate monitoring frequencies to demonstrate that the process is being executed effectively and to ensure that the additional interventions are functioning as intended. These interventions must also be validated as necessary, as per FSEP requirements.

In cases where carcasses are sampled for *E. coli* O157 as part of the operator's verification activities, each sampled carcass, as well as one carcass preceding and following the tested carcass, must be held pending the receipt of results. In the event of positive *E. coli* O157 results, all three carcasses will be considered contaminated and must be disposed of as per the options presented in section 7.3. Alternatively, the operator may choose to conduct a laboratory analysis on the two adjacent untested carcasses to demonstrate that cross contamination has not occurred and that *E. coli* O157 is below detectable levels using a methodology listed in Appendix 2.

5.2 Further beef processing operations that receive carcasses for processing

The following requirements apply to federally registered further beef processing operations (e.g., beef boning, cutting, grinding operations) with or without on-site slaughter activities:

1. The storage prerequisite program must indicate that conditions under which the carcasses are kept until being boned/cut are satisfactory. This includes, but is not limited to, storage temperature as well as potential for cross-contamination;
2. Conditions under which the carcasses are further processed (cutting/boning) must be satisfactory and meet the HACCP system specifications; and
3. If any of the raw beef products obtained from the boning/cutting processes tests positive for *E. coli* O157, the investigation must also include the evaluation of all parameters of the slaughter process that have an impact on the presence and potential spread of *E. coli* O157.

5.3 Mandated testing of PM that are used for the production of FRGBP

Products subject to operator's mandated testing include beef trim, bench trim, head meat, cheek meat, tongue roots, weasand meat, hearts, coarse ground beef and finely textured beef because they are commonly used in production of FRGBP. Additionally, if other raw beef components such as primal or sub-primal cuts (e.g., chucks, top round, sirloin cuts, etc.) are destined for use in the FRGBP, these components must be tested. As such, operators who generate these PM will be required to test these products for *E. coli* O157. Unless demonstrated otherwise by the operators (through documented evidence and controls), the PM will be considered as potential input material for the production of FRGBP and must be tested as described below.

When the use of common PM cannot be verified by the CFIA (e.g., product is sold outside of the federally registered sector), it will be considered as a potential input for the production of FRGBP and must be tested. Exemptions from mandatory testing will only be permitted if the operator has requested and provided an alternative control program, acceptable to the CFIA, that will ensure untested precursor materials will not be used for FRGBP at any level of distribution. The operators alternative control program must be documented in their HACCP system and must include procedures to verify the end use. The control program will be subject to CFIA *E. coli* compliance verification activities. Operators must keep this information current, accurate and available to the CFIA.

5.3.1 Sampling procedures

Operators must implement a robust testing protocol for each production lot of any type of PM that is destined for use in FRGBP. The tests used must satisfy the conditions set out in Appendix 2 of this policy document.

A minimum of 60 sub-samples must be examined per lot.

A lot cannot exceed five combos and cannot weigh more than approximately 4,500 kg. An alternate unit to a combo may be defined and used by the operator (e.g., a pallet of boxes or a tote, buggy, vat, tub, etc.), provided the weight of the lot does not exceed approximately 4,500 kg.

All combos/units must be equally represented in the sample. For example, a minimum of 12 individual pieces would be taken from each combo of a five combo lot. For alternate units, a minimum of 60 equally distributed pieces must be collected across the lot (e.g., a 10 vat lot of trim could be sampled by collecting six pieces per vat, a five pallet lot could be sampled by collecting 12 pieces per pallet, etc.).

A minimum of 325 g of material from each lot shall be collected and submitted for testing. At least 65 g of material (12 pieces weighing 5 or 6 g each) would be collected from each combo in a five-combo lot. For alternate units the amount of material collected from each unit would depend on the number of units in the lot but would still be made up of 5 or 6 g pieces collected

equally from each unit, adding up to a minimum total of 325 g for the lot. The material collected for testing should represent the outside surface of the product (e.g., carcass surface for sampled trim, exposed surfaces of the heart muscle, external aspect of the diaphragm muscle, etc.). In other words, it must not be taken from inner meat tissue unless the normal production process has left only inner tissue to sample.

Notes:

1. In the N-60 sampling procedure, 60 represents the minimum number of sub-samples required, regardless of the size (number of combos/units) and weight of the lot. Whether the lot weighs 4,500 kg, 2,000 kg or 100 kg, 60 sub-samples must be collected from the lot.
2. Alternate parameters may be used to define robust testing provided they have been evaluated by the CFIA (the Meat Hygene Division and Food Safety Division) and provide an equivalent or increased level of confidence.
3. For PM not amenable to excision sampling (e.g., finely textured beef), a minimum of five sample units of approximately 65 g each must be collected from a lot which cannot exceed approximately 4,500 kg. Sample units must be representative of the whole lot. Alternate parameters may be used to define robust testing according to note 2 above.

5.3.2 Lot considerations for PM

The operator must define the lot in their written program for the purpose of sampling PM for *E. coli* O157 using the following guidelines:

1. A lot is defined as comprising all cartons, packages or containers either:
    1. Produced under the same conditions at one establishment from one effective clean-up and sanitation to the next effective clean-up and sanitation provided the volume of production does not exceed approximately 4500 kg; or
    2. Determined by the operator when implementing a statistically based sampling program (robust testing or alternate sampling protocol accepted by the CFIA). The operator must have an acceptable rationale that supports the alternative lot definition. Such lots will be referred to as redefined lots. A lot cannot exceed five combos or an alternate unit (approx. 900 kg each) and cannot weigh more than approximately 4,500 kg (refer to section 5.3.1 for more information); or
    3. Establishments producing less than 4,500 kg of each type of PM (e.g., trim, bench trim, cheek meat, hearts, finely textured beef etc.) per day may consider more than one day of production as one lot for that type of PM provided that they meet the following conditions:
        1. Perform full sanitation and cleaning at the end of each production day,
        2. The product lot does not exceed five consecutive calendar days of production and does not exceed approximately 4500 kg,

3. The entire lot is evenly sampled for testing and in the event of a positive test result, the whole lot is considered to be positive and the source materials subjected to investigation in accordance with section 7.4.

2. Before taking a sample for *E. coli* O157 testing, the operator must isolate and clearly identify the lot according to their written program and to the satisfaction of the CFIA inspector. It is strongly recommended that the lot, and any raw product manufactured from the lot, be held pending receipt of laboratory results. The operator must further identify the supplying establishment number (if product received from another establishment), the production date, production lot number and any other relevant data available about the lot;
3. In cases where no satisfactory scientific basis is provided by the operator for lot definition, the default lot considered by the CFIA will be the product produced under the same conditions at one establishment from one effective clean-up and sanitation to the next effective clean-up and sanitation;
4. It should be noted that if an operator has an acceptable rationale that supports an alternate lot definition and regularly tests specific lots of product for *E. coli* O157, this information could possibly be a basis for determining whether one *E. coli* O157-positive lot will implicate other lots produced on the same day.

5.3.3 Raw intact primal and sub-primal cuts

Intact primal and sub-primal cuts used for purposes other than the manufacture of FRGBP do not pose the same level of risk as FRGBP and, therefore, do not require testing for *E. coli* O157. In contrast to FRGBP, the interior of these intact raw beef products is considered free of pathogens. Consequently, customary cooking of these products is expected to inactivate any *E. coli* O157 that might be present on surfaces. An establishment producing and distributing pre-packaged intact steaks is not required to test these products for *E. coli* O157.

Trims generated during the manufacturing of primal and sub-primal cuts are commonly used for the production of FRGBP and they must be tested as prescribed under section 5.3 of this policy. Trim testing is not required when they are used to produce products that are subjected to a full lethality treatment to produce RTE products in a federally registered establishment.

Should any part of beef cuts such as primal and sub primal cuts, including boneless chucks that are generally not destined for the production of FRGBP, be used by an operator to produce FRGBP they must be subjected to robust testing applicable to PM. This testing may be done by the operator producing these products (at their buyer's request) in accordance with section 5.3 of this policy, or by the operator receiving these products in accordance with section 5.5 of this policy.

5.3.4 Bench trims

Beef trimmings are beef manufacturing trims produced in slaughter establishments from cattle slaughtered on-site and are intended for use in FRGBP.

Bench trims are beef trimmings which are produced in establishments which do not have on-site slaughter operations but perform further beef processing activities, for example, beef cutting, boning and grinding, etc. Establishments producing bench trims for the production of FRGBP either at the same facility or at another facility are required to perform robust testing in accordance with Section 5.3 of this policy.

Operators are encouraged to segregate source materials received from different suppliers. Where source material is received from multiple suppliers and segregation of bench trims is not possible, it becomes difficult to perform trace back investigations in the event of the positive test result. When *E. coli* O157 is detected, operators must verify the status of CCP compliance and test results at all supplying establishments as per the purchase specification agreement to identify any deviation, unusual trends or high event period (HEP) on the day the source material was produced and must inform the inspector accordingly.

When bench trims are produced from source material(s) which have been tested under a robust testing protocol in accordance with section 5.3, it is not required to test the subsequent bench trims. These lots need to be clearly identified and segregated from other untested materials.

Presumptive positive results for bench trims may be considered as positive results by the operator. The operator is required to have a prior purchase specification agreement with the suppliers of the source material as to whether a presumptive positive is accepted as a positive result or a complete laboratory confirmation will be performed. This information must be documented in the HACCP system and purchase specification.

5.4 CFIA risk-based verification sampling of PM intended for use in production of FRGBP (M218)

This sampling plan reflects a risk-based approach based on factors such as seasonality (April to September), production volume, historical testing and inspection data. It has been designed to verify the effectiveness of control measures for *E. coli* O157 in place at establishments that produce PM.

Products targeted for sampling under this plan are all types of PM. If on a given sampling day an establishment is also producing PM other than the beef trimmings (e.g., head meat, cheek meat, tongue roots, hearts etc.), CFIA inspection staff will collect alternate PM so that a maximum number of different types of PM are collected during one year sampling period. PM intended to be used in further processing into RTE products are not to be sampled under this plan. The inspector should sample only PM produced at the establishment. If the operator commingles PM from different suppliers, the sample is to be collected before the operator commingles PM whenever possible.

Establishments have been divided into four categories based on their production volume: extra large, large, medium and small. Current sampling frequencies for establishments have been outlined in the National Microbiological Sampling Guidelines and Assessment Criteria.

Generally, products will be sampled at all establishments at a normal frequency. A compliance history including a positive *E. coli* O157 result from M218 testing of PM or M201 testing of the product downstream will be taken into account when placing an establishment on enhanced frequency of testing for the next 120 days. Such a decision will be taken by the Area Program Specialist.

The samples are analyzed forthe presence of *E. coli* O157 and generic *E. coli* enumeration. Refer to the "National Microbiological Sampling Guidelines and Assessment Criteria" for current information.

CFIA strongly recommends holding the entire lot pending the result of analysis. In order to provide the establishment enough time to hold the lot, the CFIA inspector will notify the operator in advance (24 hours notice) about the planned sampling. The inspector will collect the sample using the N-60 method described in table 1 below according to the operator's lot definition and section 5.3.2 of this policy.

For PM not amenable to excision sampling (e.g., finely textured beef), a minimum of five sample units of approximately 200 g each must be collected from a lot that has been assembled according to the operator's lot definition and section 5.3.2 of this policy. Sample units must be representative of the whole lot.

5.4.1 N-60 method of sample collection

If a specific production lot is composed of more than five containers, pallets, boxes or other units of PM, the CFIA inspector will randomly select five units for sampling. The number of pieces to be collected per unit is as follows:

Table 1: Number of sample pieces to be collected per unit

Number of containers in a specific production lot	**Number of sample pieces to be collected from each unit**
More than 5 (randomly select 5)	12
5	12
4	15
3	20
2	30
1	60

Using aseptic techniques, the inspector will cut off a thin piece that is approximately 50 cm^2 for each of the 60 pieces [e.g., 10 cm (4") x 5 cm (2") x 0.3 cm (1/8")]. The priority is to collect samples from the outer surface of PM. The inspector will place the sampled pieces into the sterile plastic sample bag and weigh it to ensure that the sample weighing approximately 1 kg (2 lb) was collected.

5.4.2 Follow-up on *E. coli* O157 positive results under the M218 sampling plan

When *E. coli* O157 is detected in a sample, as a minimum, the sampled lot is adulterated. The inspector will verify whether the establishment has held or shipped the positive lot. If the lot has been shipped outside of the federal system, the CFIA inspection staff will notify the Area Recall Coordinator immediately.

CFIA will verify that the positive product is transported and disposed of in an appropriate manner and an investigation is performed by the operator in accordance with this policy.

CFIA will determine the number of follow-up samples that will be collected at the establishment producing PM based on the results of the investigation. The same type of PM which tested positive under M218 must be collected during follow-up sampling.

In circumstances where the same product lot is sampled by the CFIA and the operator or any third party, the lot cannot be released into commerce if there are conflicting test results (i.e., CFIA test result is positive and the operator or third party test result is "not detected" for *E. coli* O157 and vice versa).

5.5 Specific controls for suppliers of PM

Operators of establishments supplying raw PM for the production of FRGBP must review their HACCP system to ensure compliance with the purchase specifications. The purchase specification agreement between the operator, or a designated person, of the supplying establishment (beef slaughter or further processing establishments) and by the operator or designated person of the receiving establishment (cutting or deboning or grinding or intermediary establishment or broker), as a minimum, must reflect the following controls:

1. The Letter of Guarantee (LOG) must be signed and dated by the operator, or a designated person, of the supplying establishment. The LOG must identify the validated intervention(s) (including CCPs) as well as other measures used to reduce, prevent or eliminate the hazard associated with *E. coli* O157 for all beef products produced by the supplying slaughter establishment. As part of the annual HACCP validation activities, the LOG will be reviewed in consultation with the receiving establishment.
2. The supplier must have a written program to verify and monitor that only products that tested "not detected" are supplied for the production of FRGBP. The shipped product must be accompanied with test results for each lot or part of a lot of PM. Testing results can be communicated through a Certificate of Analysis (COA), electronic copy of COA, summary sheet or Product Notification Document (PND) with COA codes and production dates or an accepted alternative for each lot or part of a lot that tested "not detected." Alternatively, agreements may be made between the supplier and receiver to identify lot(s) that tested "not detected" with appropriate labels or identification marks for verification purposes. The selected option must provide confidence that only PM that tested "not detected" will be used in the production of FRGBP and must be acceptable to

the local CFIA inspection staff and documented in the purchase specification agreement and/or LOG.

3. In situations where receiving establishments choose to perform verification testing of PM, including the testing of bench trim, the supplying and receiving establishments must have a prior agreement as to whether a presumptive positive is accepted as a positive result or if a cultural confirmation will be pursued to determine either a confirmed positive or a negative result (Appendix 2 of this policy) and the supplying establishments will be informed accordingly. The receiving establishment must maintain the integrity of the lot received from the supplier pending laboratory test results.
4. Establishments shipping product pending test result(s) must provide a statement as to whether a presumptive positive test result will be accepted as a positive result, or if cultural confirmation will be pursued to determine whether the presumptive positive is a confirmed positive or a confirmed negative (reported as a "not detected") result. The purchase specification agreement and LOG must also include a statement to the effect that when the supplier obtains a positive result, the receiving establishment, as well as the supplier's local CFIA inspection staff will be notified. When tested product is shipped pending reception of test results, the shipping establishment must:
    1. have a written protocol in place;
    2. identify the product in an appropriate way;
    3. maintain complete records identifying the type of product, as well as the quantity, being shipped;
    4. control product while it is in transit - the use of company seals is mandatory;
    5. get confirmation from the receiver that the product (specifying the type and quantity) was received; and
    6. notify the recipient that the product cannot be used before they are notified that *E. coli* O157 was not detected.

When PM is shipped through intermediary establishment(s) or broker(s), the immediate seller of the PM must provide the test results for all lots or part of a lot to the receiving beef grinding establishment or must make an alternate arrangement to ensure that the grinding establishment has access to test results for all lots or parts of a lot of PM before grinding. This is to verify that only PM which tested "not detected" is used in the production of FRGBP.

For shipping of confirmed positive or presumptive positive products to other federally registered establishments, refer to section 7.0.

Notes:

1. Suppliers cannot ship PM outside of the federally registered system pending test results.
2. Suppliers cannot export PM pending test results.

5.6 Beef grinding establishments producing FRGBP

Beef grinding establishments producing FRGBP must develop, implement and monitor a program to verify that only PM that tested "not detected" is received for the production of

FRGBP. This may be achieved by appropriate CCPs or prerequisite programs (B 2.1) to ensure controls at receiving.

Beef grinding establishments must have a copy of the LOG signed and dated by the supplier of PM, or a designated person or intermediary establishment or broker, as applicable according to section 5.5. Beef grinding establishments must ensure that all PM received are accompanied with test results for each lot or part of a lot. The control and verification procedures must be established as per the purchase specification agreement between the supplier and receiver. This may be accomplished by a COA, electronic copy of COA, summary sheet or PND with COA codes and production dates or an accepted alternative for each lot or part of a lot that tested "not detected." Alternatively, the supplier and receiver may agree to identify lot(s) that tested "not detected" with appropriate labels or identification marks for verification purposes. The selected option must provide confidence that only PM that tested "not detected" will be used in the production of FRGBP and must be acceptable to the local CFIA inspection staff and documented in the purchase specification agreement and/or LOG.

If operators are receiving PM pending test results they must maintain control over such products until results are obtained. For operators receiving product pending result, the purchase specification agreement and LOG must include a statement indicating that when the supplier obtains a positive result, the operator(s) of the receiving establishment(s) will receive the information and will notify the local CFIA inspection staff. When tested product is received pending test results, the receiving establishment must:

1. have a written protocol in place;
2. maintain complete and accurate records of all products received under these conditions; and
3. keep the product segregated in a designated area until the final laboratory results are obtained.

The PM cannot be used before test results are obtained. Beef grinding establishments that use in-house generated PM (e.g., bench trims) in the production of FRGBP must test such PM to ensure that only PM that tested "not detected" is used for grinding.

When a product has been distributed prior to its testing results being known and the test results indicate a presumptive or confirmed *E. coli* O157 result, the CFIA must be immediately notified and the incident treated as a potential recall situation. The CFIA strongly advises against this procedure.

5.7 CFIA verification sampling of FRGBP (M201)

This sampling plan has been designed for all federally registered establishments that produce FRGBP. The samples are analyzed forthe presence of *E. coli* O157 and generic *E. coli* enumeration.

Before collecting the sample, the inspector must ensure that the lot meets the operator's lot definition (minimum 900 kg or whole day production if the total volume is < 900 kg/day). When a combo of PM is selected for grinding, the whole combo must be used for the sampled lot.

From a selected lot of FRGBP, the inspector will randomly select and collect a sample, preferably at the grinding stage. The inspector will collect five sub-samples of 200 grams each, such that they are representative of the entire lot. The inspector will prepare the sample for shipping according to CFIA standards using a sufficient number of ice packs and insulated packaging material.

If establishments producing FRGBP have more than one production line, sampling of FRGBP should be alternated to ensure that all production lines are covered in one year of sampling period. The following conditions must be met to consider that the operator's FRGBP production lines are segregated, thus limiting the size of the lot to a specific line:

1. The entire lot of any PM that is used for the production of FRGBP must be processed on a single line (in other words, a given lot of PM cannot be split between two production lines);
2. Each production line must be clearly defined with regard to its equipment and the product flow;
3. Process controls must be in place to prevent cross-contamination between different production lines.

Note:

If any non-beef ingredients are added to beef at the grinding stage along with the PM, the inspector should consult with the CFIA receiving laboratory to determine the expected turnaround time for results. Ground beef/veal samples containing spices cannot be analyzed using a rapid screening method(s) that are routinely used by CFIA laboratories but must be analyzed using a cultural method. As such, test results for these types of products will not be available for 4-5 days and the operator will be required to hold the sampled lot for this period of time.

Refer to the "National Microbiological Sampling Guidelines and Assessment Criteria" for current information.

5.7.1 Operator's follow-up to *E. coli* O157 positive test results under sampling plan M201 for the verification of FRGBP

In response to a positive *E. coli* O157 result reported under this CFIA verification sampling plan, operators must conduct follow up sampling at their own expense at the frequency described below. These samples are to be collected under CFIA supervision and are to be tested in an accredited laboratory using a CFIA recognized testing method. Recognised methods can be found in Appendix 2 of the policy.

Table 2: Sampling frequency for follow-up to *E. coli* O157 positives test results		
Establishment Size	**Production Volume (kg/yr)**	**Total Number of Follow-up Samples**
Small	<25,000	8
Medium	25,000 - 400,000	8
Large	400,000 - 40,000, 000	12
Extra Large	>40,000,000	16

The following maximum and minimum sampling limits must be respected:

1. a maximum of two follow-up samples per shift per day.
2. a minimum of three follow-up samples per week. If an establishment produces the product in question less than three times per week, CFIA inspector can recommend sampling frequency on case-by-case basis.

The operator will randomly select a lot and collect five sample units of 200 g each in a sanitary manner. The operator will prepare the sample for shipping according to CFIA standards using sufficient ice packs and insulated packaging material.

If there is a positive sample during the follow up testing, the operator is required to continue sampling until 8, 12 or 16 consecutive samples that test "not detected" have been collected (see Table 2, above).

Accredited laboratories must report results to the operator as well as Food Safety Division, CFIA at the following e-mail address: GB-DBH@inspection.gc.ca.

Product must be held pending test results when follow-up testing is conducted. The operator must notify IIC upon the receipt of test results.

5.8 Non-intact raw beef products and Mechanically Tenderized Beef (MTB)

When manufacturing non-intact raw beef products, the equipment used may transfer bacteria from the surface of a contaminated cut of meat to its interior, as well as cross contaminate subsequent portions processed by the same equipment.

Testing for *E. coli* O157 is not mandatory for non-intact raw beef products. However, operators of federally registered establishments producing or handling non-intact raw beef products must identify *E. coli* O157 as a hazard likely to occur in these products and demonstrate that their HACCP system effectively manages this hazard. The HACCP plan(s) must include control measures according to "industry best practices". These may include an agreement with the supplier, assessment of the sanitation process, verification of the sanitation process by equipment sampling (i.e., swabbing), the use of antimicrobials and labelling with cooking instructions. If non-intact raw beef products are found to be associated with a positive *E. coli* O157 result, the operator must notify CFIA immediately and take appropriate corrective and preventative measures. CFIA will assess these events on a case-by-case basis.

5.8.1 Labelling requirements for MTB

Mechanically tenderized beef products include products which are tenderized with blades or needles, including needle injected products and cubed steaks (e.g., fast fry/minute steaks). In addition to the basic labelling requirements, mechanically tenderized beef intended to be sold in Canada must be identified as "mechanically tenderized" on the label. The products must be labeled throughout the production and the distribution chain from the processor to the purchaser (i.e., end-user, consumer). As per the *Food and Drug Regulations*, Article B.14.022, the following statement(s) must be included on the product's principal display panel:

1. Identification as "Mechanically tenderized" in the common name or elsewhere on the principal display panel,
2. Safe cooking instructions indicating "Cook to a minimum internal temperature of 63°C (145°F), and
3. In the case of steaks, an additional safe cooking instruction indicating "Turn steak over at least twice during cooking" to help achieve a consistent temperature throughout.

These requirements apply to both fresh and frozen uncooked MTB, as well as both pre-packaged and non-packaged products. For more information on mechanically tenderized beef labelling requirements, including manner of declaring, please refer to the meat section of the Food Labelling for Industry website.

5.9 Beef products processed for raw consumption (BPPRC)

BPPRC are the 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 raw. Examples are carpaccio and steak tartare.

Operators producing or intending to produce BPPRC must develop, implement and maintain a CFIA accepted control program including N-60 (or N-5 for products not amenable to excision sampling) testing of PM and/or finished product. PM should be tested according to section 5.3.

Sample units must be representative of the whole lot which cannot exceed approximately 4,500 kg. A total of 325 g per lot should be analyzed for *E. coli* O157. Alternative sampling protocols may be used, provided that they are as/or more rigorous and have been accepted by CFIA.

6.0 Untested Raw Beef Products

The following control measures must be implemented while handling untested raw beef products:

6.1 Untested raw beef destined for full lethality treatment

During hazard analysis, the operator may determine that the hazard related to *E. coli* O157 is likely to occur, but that no new CCP(s) is/are required in the establishment because all products (which otherwise are considered to be PM) are subjected to a full lethality treatment on-site or are shipped directly to another federally registered establishment where similar steps are taken to control the hazard.

Whenever untested precursor materials are shipped directly to another establishment for cooking, both establishments must identify the hazard of *E. coli* O157:H7 and have control programs in place for labelling untested product, segregation, inventory and traceability. They must have a purchase specification/agreement to ensure that all untested product received will be subject to full lethality treatment and will not be diverted elsewhere. In addition, the receiving establishment must maintain thermal lethality records.

The CFIA will evaluate the request of an operator for approval of a control program for movement of untested product to an intermediary establishment (storage or other processing establishment) prior to being shipped to an establishment that will provide the full lethality treatment. In addition to requirements mentioned above for the original shipping establishment and for the final receiving establishment, any written request for movement of untested precursor materials through an intermediate establishment shall

1. identify the hazard of *E. coli* in untested precursor materials received and shipped and provide control programs for maintaining product identification (labelling), segregation, inventory and traceability at the intermediary establishment
2. include a purchase specification agreement that includes all establishments involved to document their commitment to maintaining the required control programs that will result in untested product receiving the full lethality treatment.

All products must be labelled as "untested"-for cooking only" or similar statements that convey the same meaning and are acceptable to the local inspection staff until the lethality treatment is completed. It is not required to have an LOG when untested beef products are shipped to other federally registered establishments or to establishment (s) approved by other competent authority in consultation with the CFIA.

The request for movement to an establishment outside of the federal system shall be evaluated on a case-by-case basis and would need to demonstrate an equivalent level of control as this policy.

At all establishments involved, the CFIA can verify that operators are following their control programs using appropriate CVS tasks.

For product sent for a full lethality treatment after it has been tested and found positive for *E. coli* O157, or product that the operator has chosen to treat as positive based on presumptive positive results, refer to section 7.0 of this policy.

6.2 Product segregation

When operators are handling both raw beef products that have tested "not detected" for *E. coli* O157 and beef products which have not been tested for *E. coli* O157, the operator must develop and implement a written segregation program. This program must ensure that raw beef products received for cooking or other full lethality treatment are not used in the production of FRGBP and that cross-contamination is prevented.

The appropriate information must be noted on FSEP forms (potential cross-contamination). The segregation procedures must include monitoring, verification and deviation procedures as well as record keeping, and be auditable and effective.

7.0 Positive Test Results for *E. coli* O157

Unless otherwise specified within this policy presumptive positive results may be considered as positive results by the operator. When this is the case, the measures that apply are the same as if the laboratory result had been a confirmed positive. When this presumptive positive result impacts on another establishment (e.g., product tested at the receiving step was a presumptive positive), the operator performing the test must have a prior agreement with the supplier as to whether a presumptive positive is accepted as a positive result or if cultural confirmation will be pursued to determine either a positive or a "not detected" result (please refer to Appendix 2 of this policy). All registered establishments that supply or receive PM for FRGBP production must document prior agreements in their purchase specifications (section 5.5). This ensures that product disposition and follow-up for both the supplying establishment and purchasing establishment can proceed expediently when a presumptive positive result is obtained.

When obtaining positive results for *E. coli* O157, whether confirmed or considered as positive, the operator must take immediate action, in accordance with the following subsections of this policy.

7.1 Notification requirements

Any raw beef product that is presumed to be positive (presumptive positive as per section 3.2.1) or confirmed positive for *E. coli* O157 is adulterated and the operator must inform the CFIA and any establishment that receives beef products pending test results. Additionally, any raw beef product that is presumptive positive pending confirmation is considered potentially adulterated by the CFIA and the operator must also inform the CFIA and any establishment that receives beef products pending test results. In such situations, the CFIA and any receiving establishments must be notified as soon as final results are available (either confirmed positive or reported as "not detected" by cultural method). For auditing purposes, the information must be presented to the CFIA in written form.

7.2 Scope of implicated product

1. When an operator is implementing a sampling protocol under a statistically based sampling program according to section 5.3:

   PM: The redefined lot of PM that tested positive and 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 will be considered implicated. Additionally, CFIA expects operators to consider whether any other products or lots should be designated as suspect products or lots based on factors such as the source of PM, time of production, production line and high event period (refer to section 9.0). CFIA recognizes that the rationale and decision in which the operator determines potentially implicated or suspect products can be complex. However, the basic principles of this activity must be a part of the written program and be made available to CFIA staff upon request.

   FRGBP: The lot of FRGBP that tested positive will be considered implicated. Any lot of FRGBP or of a further processed product that contains a portion of the redefined lot that tested positive will be considered implicated.

2. When an operator is using the regular lot definition or is not implementing a robust sampling protocol according to this policy:

   PM: All PM representing a lot that has been produced under the same conditions as the tested product at one establishment. For example, all PM produced from one effective clean-up and sanitation to the next effective clean-up and sanitation would be implicated when one full day production is considered as a lot.

   Any lot of PM, FRGBP or of a prepared meat product that contains a portion of the implicated PM (as described above) will also be considered implicated.

   FRGBP: 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 further processed product that contains a portion of the implicated FRGBP (as described above) will also be considered implicated.

The scope of implicated products described in this section may be further expanded depending on the following indications in the overall context of the situation:

1. Epidemiological evidence;
2. High Event Period (HEP) situation;
3. Out-of-control process; and
4. Inadequate lot identification and sampling protocols.

Note:

Intact raw beef products linked to the same source material as PM that has tested positive, may be implicated, on a case-by-case basis, depending on their end use (e.g., FRGBP, mechanically tenderized beef or BPPRC), when there is epidemiological evidence of illness, process deviations, or HEP situation.

7.3 Product disposition

The following options are available to operators for product disposition. The product disposition must be conducted under CFIA's authorization and supervision. Whichever option is selected, the traceability component must be covered in detail in the operator's HACCP system.

7.3.1 Implicated product

7.3.1.1 Cooking

Cooking can be performed to salvage the product by further processing into a fully cooked finished product within the federally registered sector through a validated cooking process (full lethality treatment). If done in a different establishment, the adulterated product must be transferred under company seal and it must be sent directly to an establishment that provides the heat treatment. Appropriate records must be kept by all involved operators to ensure complete control over the product until the hazard has been addressed. In all cases where product is salvaged, the following requirements apply:

1. The cooking process must be validated by the operator and control programs (e.g., CCP) must be accepted by local CFIA inspection staff before being used.
2. The operator must maintain lot integrity to facilitate traceability of product(s) and must also maintain a complete and up to date inventory of all products being salvaged because it was found positive for *E. coli* O157 or because the operator has chosen to treat it as positive for *E. coli* O157. The inventory shall include the following information: initial lot numbers and test results, type of product, weights, time/date of cooking and lot numbers of finished products, etc.

When positive product is shipped to another federally registered establishment for cooking, the following conditions apply:

1. The shipping establishment must:
    1. Maintain complete records identifying the type of product, as well as the quantity, being shipped for cooking.
    2. Label the product with "For cooking only" (stamp or sticker). If the product is being stored in an off-site registered storage at the time that the *E. coli* O157 test results are known, the product can be labelled at the storage facility, with the consent of the CFIA inspector.

3. Control product while it is in transit. The use of company seals is mandatory.
4. Get confirmation from the receiving establishment that the product (specifying the type and quantity) was received. (Note: this should be stated in the operator's protocol.)

2. The receiving establishment must:
    1. Confirm the receipt of positive product with the shipping establishment.
    2. Maintain complete and accurate records of all positive products received for cooking process.
    3. Meet the above requirements applicable to this procedure (accepted cooking process and inventory of product).

Note:

1. Operators may ask the CFIA to permit the storage of positive product prior to subjecting it to the full lethality treatment (cooking). Any such request must be presented to the Area Program Specialist for evaluation. If accepted, the HACCP systems of the shipping establishment, the storage establishment and the receiving establishment must address this situation. Appropriate controls must be in place and monitored (including but not limited to product inventory, segregation procedures, company seals used for transit, etc.).
2. Products determined to be contaminated or implicated cannot be transferred outside of the federally registered system.

7.3.1.2 Denature and condemnation

Operators have the option to denature positive product with suitable denaturing agents and condemn product under the direct supervision of the CFIA.

7.3.1.3 Rejection of positive products

In the case of a product received from another registered establishment, the operator may reject the product and, providing the supplier has agreed in advance, return the product to the supplier under company seal for appropriate disposition. Records must be kept by both operators to ensure that the positive product is adequately controlled until it is subjected to either one of the two disposition options described above.

7.3.2 Suspect product at the processing level

7.3.2.1 Cooking

Product from a suspect lot as defined in Section 3.7 can be diverted at the manufacturer's discretion for further processing into a fully cooked product through a validated cooking process (full lethality treatment) at a federally registered establishment or at establishment(s) approved by other competent authority in consultation with CFIA. The shipping establishment must have a control program in place for movement of suspect products, including requirements for shipment under company seal and direct shipment to the cooking establishment. Appropriate records must

be kept by all involved operators to ensure complete control over the product until the full lethality treatment has been applied. In all cases, the following requirements apply:

1. The operator of the originating establishment must maintain a complete traceability record of whether suspect product was changed (e.g., boned, trim from combos boxed for shipping, etc.) and documentation that it was shipped to a cooking facility.
2. The cooking process must be validated by the operator of the further processing establishment and be part of the HACCP system.

When suspect product is shipped to another establishment for cooking, the following conditions apply:

1. The shipping establishment must:
    1. Maintain complete records identifying the type of product and quantity being shipped for cooking.
    2. Label the product with "For cooking only" (stamp or sticker). If the product is being stored in an off-site registered storage at the time the product is designated as suspect, the product can be labelled at the storage facility with the consent of the CFIA inspector.
    3. Control product while it is in transit. The use of company seals is mandatory.
    4. Get confirmation from the receiving establishment that the product (specifying the type and quantity) was received.
2. The receiving establishment must:
    1. Maintain records identifying the type and quantity of product received, and
    2. Confirm that all products received were subjected to the full lethality treatment.

Note: Operators may store suspect product prior to subjecting it to the full lethality treatment (cooking). Steps taken for storage will be included in the operator's control program.

7.3.2.2 Denature and condemnation

Operators have the option to denature suspect product with suitable denaturing agents and condemn product. All relevant records (e.g., product type, quantity etc.) must be maintained.

7.4 Follow-up actions by operators

7.4.1 Positive results obtained for products produced at the establishment

Operators must summarize and analyze all laboratory results (CFIA testing and industry testing) on a daily basis (see section 8.0) and develop criteria that would indicate a situation where the number of positive results exceeds what is typically expected within a certain timeframe (see section 9.0). The operator must investigate and evaluate the impact of any positive test result, investigate any potential link between positive results and take additional measures (e.g., pathogen reduction steps) to control the risk posed by *E. coli* O157, should the result of such investigation warrant it.

The operator must take positive results as evidence that their HACCP system has been ineffective in producing a product where *E. coli* O157 is below detectable levels. Consequently, the operator must immediately notify the Inspector-in-Charge (IIC)/Veterinarian-in-Charge (VIC) of the establishment, who will in turn notify their Inspection Manager and the Area Program Specialist. The operator must also take the following actions:

1. Ensure that any affected product is under control.
2. Investigate the cause of the deviation by evaluating, as appropriate:
    1. all applicable HACCP controls;
    2. sanitation procedures (Prerequisite Programs);
    3. any other pertinent documentation and procedures.

Notes:

1. This also includes beef slaughter activities, whether these take place on site or at another registered establishment.
2. While each positive must be investigated in an effort to identify the probable cause and to guide corrective measures, the scope and depth of an investigation may be adjusted according to circumstances, taking into account such factors as the frequency and number of positives being found (process awareness), and the type(s) of product(s) affected.
3. Apply corrective actions to eliminate the cause of the deviation(s).
4. Ensure that the corrective action has brought the CCP and/or Prerequisite program(s) under control.
5. Perform a food safety assessment on the affected product and determine if other products were implicated. Determine the appropriate disposition.
6. Implement measures to prevent recurrence of the deviations. Careful consideration should be given to increase the efficacy of the pathogen reduction steps used in the HACCP system.
7. Verify the effectiveness of the preventative measures. When the pathogen reduction step has been substantially modified to increase its efficacy, the intervention must be revalidated. The plant management and IIC/VIC may consult with the Area Program Specialist regarding the need to revalidate a pathogen reduction intervention.
8. For each corrective action and preventative measure, the designated employee must specify on the record: a target date for completion of corrective actions and preventative measures; the actual completion date for these corrective actions and preventative measures. Each entry must include the date, and be signed or initialled by the establishment employee making the entry.
9. Provide the inspector with the operator's action plan regarding the adulterated product explaining how the product will be handled, controlled, brought back into compliance or disposed of.

If no contamination source can be identified a report indicating this fact should be produced and made available to the CFIA. The report must mention the rationale used to reach that conclusion. The report should include:

1. documents reviewed;

2. dates reviewed;
3. evaluation of the impact of this positive result on their own testing results for this type of product; and
4. signatures of reviewer(s).

In all cases, the CFIA inspector evaluates the investigation done by the operator in collaboration with the designated Area Program Specialist, Supervisor and Regional Veterinary Officer. When the investigation's conclusion or the corrective actions taken are judged inadequate, a Corrective Action Request (CAR) will be issued under the Compliance Verification System (CVS).

7.4.2 Positive results obtained as a result of testing performed by the receiving establishment

In the case where a positive result is obtained following testing done on products received from a supplier, the following requirements apply:

1. The operator having performed the test must immediately notify the IIC and the supplying establishment of the positive result. The supplying operator will then inform the IIC/VIC at their establishment of the positive result. The IIC/VIC of the supplying establishment will inform their own Inspection Manager and Area Program Specialist of the situation;
2. The receiving operator must determine the disposition of affected product according to one of the three options presented under section 7.3 of this policy and take action accordingly;
3. The supplying establishment must treat this notification as evidence that their HACCP system may have been ineffective in producing a product where *E. coli* O157 is below the detectable level and must investigate the situation accordingly and take immediate follow-up actions according to section 7.4.1 above.

The Area Program Specialist will ensure that the necessary details are communicated to any other CFIA area staff that may need the information.

7.5 CFIA control of affected product

Any raw beef product that is presumptive positive (as per section 3.2.1) or confirmed positive for *E. coli* O157 is considered adulterated by the CFIA and must remain under company control. The operator must inform the CFIA of any positive results. For auditing purposes, the information must be presented to the CFIA in written form.

According to the *Meat Inspection Regulations, 1990* (MIR):

20. (2) *Where an adulterated meat product in a registered establishment can be made to conform to the standards prescribed by this Part for an edible meat product, the meat product shall be held by an inspector until it is made to conform to those standards by the operator.*

130.(1) *No person shall remove or alter an official seal or official tag applied by or under the authority of an inspector unless authorized to do so by an inspector. (2) Any food animal, meat product or other thing being held on the instructions of an inspector shall not be handled or used in any way without the permission of an inspector.*

The CFIA inspector will hold the product using CFIA/ACIA held tag 0093 until it is made to conform to the standards by the operators. The CFIA inspector will keep the appropriate information on file. The inspector must also indicate at the back of the held tag the sections of the MIR under which the product is held.

The inspector must be provided with the operator's action plan with regards to the adulterated product. This plan must explain how the product will be handled, controlled, brought back into compliance or disposed of. Deviation records must be kept with all the needed information (e.g., product involved quantity, lot identification and laboratory result, etc.).

If an adulterated product is sent to another federally registered establishment for cooking, the HACCP plan of the receiving establishment must also address the needed controls. In such cases, the CFIA inspector of the receiving establishment must be notified.

As per section 130 of the *MIR*, the inspector must either remove the held tag in person or authorize its removal. The action taken must be documented in both the operator's HACCP plan and the inspector's files.

Notes:

1. If the product was imported, the IIC through the Area Program Specialist will immediately notify in writing the National Specialist, Import Program in Ottawa. The National Specialist, Import Program will notify the authorities of the exporting country for a follow-up investigation.
2. If any product affected by the unsatisfactory result is in distribution, the inspection staff must inform the Area Recall Coordinator.

8.0 Process Awareness

The objective of process awareness is to identify trends of events over time which may indicate potential loss of process control. Process awareness may include actions or measures taken to control incoming material, time and temperature controls, physical, chemical and microbiological controls etc. As a part of their HACCP system, operators must develop, implement and monitor process awareness programs and must analyze the data to determine trends over time. Out of control situations or deviations determined through process awareness should be addressed through root cause analysis, appropriate corrective actions, preventative measures and annual validation programs.

Process awareness can be enhanced through routine recording of the chronology or specific times of certain operations, such as slaughter, fabrication, trim collection and grinding. This information can enable real-time or retroactive determination of relationships between source

materials and between products, which can help in assessing the significance of positive test results.

The conclusion drawn from analysis and the rationale must be made available to the CFIA. As a part of process awareness, the operator must establish criteria/limits to define periods when the analysis indicates a potential loss of control.

8.1 Process awareness for establishments producing PM

In order to meet the specific requirements of this policy, operators that produce PM (slaughter/further processing/grinding establishments) must develop process awareness program to monitor trends of *E. coli* O157 and generic *E. coli* or other target organisms. All test results obtained for PM through CFIA testing, operator's mandated and non-mandated testing and third party testing performed in the establishment must be included in the process awareness program.

8.2 Process awareness for establishments producing FRGBP

There is no mandatory requirement for establishments to test FRGBP for *E. coli* O157. Operators must develop microbiological testing programs for verification of process control which includes the following characteristics:

1. Product type: Operators may test raw ground beef or FRGBP.
2. Target organism(s): Operator may select target organisms which provide the most useful information for determining control of the process. It is recommended that operators choose generic *E. coli* or coliforms testing for this purpose; and
3. Sampling frequency: Operator may determine sampling frequency based on their specific operation and production volume. As a minimum, the following annual sampling frequencies must be followed:

Table 3: Minimum operator sampling frequency for FRGBP based on annual production volume

Establishment Size	**Production Volume (kg/yr)**	**Minimum number of samples/year** [Table Note 1]
Small	<25,000	12
Medium	25,000 - 400,000	18
Large	400,000 - 40,000, 000	24
Extra Large	>40,000,000	36

Table Notes

Table Note 1

Samples must be evenly distributed throughout the year.

Return to table note 1 referrer

Operators must justify their choice of product type, target organism and sampling frequency in their written program. They must determine and justify the criteria/limits that indicate a loss of control and follow up actions to be taken. Operators using non-beef ingredients (e.g., spices) in FRGBP must develop control programs to ensure the safety of these ingredients.

In order to meet the specific requirements of this policy, operators producing FRGBP must develop process awareness program to monitor trends of selected target organisms. All test results obtained through CFIA testing (*E. coli* O157 and generic *E. coli*), operator's mandated and non-mandated testing and third party testing performed in the establishment must be included in the process awareness program.

8.3 Follow-up actions when process awareness indicates a loss of control

Operators must notify CFIA inspection staff when there is an indication of a potential loss of control. Additionally, they are required to perform root cause analysis and take appropriate corrective actions and preventative measures according to their written program. Even if no root cause can be identified, a report indicating this fact and a rationale for this conclusion should be made available to the CFIA. The LOG may include an agreement or arrangement for the notification of suppliers and follow-up actions at their end.

8.4 CFIA verification activities

CFIA inspection staff will review and verify the establishment's written program for process awareness to ensure requirements listed in this section are met.

9.0 High Event Period (HEP)

HEP is a situation in which an establishment experiences a high number or rate of positive results for *E. coli* O157 in PM from production lots containing the same source material. That is, the PM was produced from one or more carcasses slaughtered and dressed consecutively or intermittently within a defined period of time (e.g., shift). HEP may indicate systemic breakdown of the slaughter dressing operation that may implicate other parts of the beef carcass in addition to the PM that tested positive. It may indicate an unsanitary condition during the slaughter/dressing operation which may have resulted in widespread contamination across production lots.

As such, the PM that tested "not detected" but obtained from same source materials as those which have tested positive may be considered as suspect PM.

Beef establishments producing PM and conducting robust N-60 sampling and testing programs (i.e., beef slaughter and processing establishments) must identify and document HEP criteria. This will allow for adequate identification of implicated and suspect products beyond the products that were reported positive.

For example, the demonstration of a temporal and spatial relationship between positive lots could indicate a potential loss of control over the process and a likely HEP situation. Here temporal

means the time of processing based on recorded start and stop times of relevant operations and spatial refers to the area of carcass from which different types of trim and intact cuts are derived. Demonstrating a temporal and spatial relationship between positive and other lots could be used to determine the scope of implicated products.

Based on the investigation, operators must identify whether the HEP situation is localized or systemic and, accordingly, determine the scope of implicated product(s). A localized situation may affect only a short production time or a specific product(s) due to an isolated problem while a systemic situation may affect products over a greater period of time or more products due to a broader problem.

CFIA requires establishments to take action if sampling of PM produces a positive rate which is statistically significantly greater than or equal to 5%. While developing HEP numerical criteria, establishments may opt for a 95%, 98.85% or 99.95 % confidence intervals. At a lower confidence level, the HEP will be detected at a lower observed positive rate and the chance of releasing an adulterated product into commerce is minimized. The detection of HEP may trigger corrective and preventative actions at an earlier stage. Operators must identify whether they will treat presumptive positive test results as positive or confirm all presumptive positives in their written program. Refer to Appendix 3 for suggested HEP numerical criteria.

Establishments may develop alternate proposals for defining HEP criteria based on temporal and spatial relationships between positive lots. Products must be held under control until the completion of investigation. Proposals must be presented to CFIA for approval.

Beef slaughter and further processing establishments producing less than seven lots of PM per day which includes all types of PM (e.g., trims, bench trims, boneless beef, coarse ground beef, hearts, head meat, cheek meat, weasand meat and primal cuts, such as chucks, if intended to be used for production of FRGBP) are not required to develop HEP protocol but will have to investigate every positive test result as per section 7.4.1.

9.1 Expected actions in HEP situations

In addition to actions described in section 7.4.1 operators need to conduct further investigation and present a rationale to CFIA as to whether the lots of PM that tested "not detected" and untested intact primal and sub-primal products produced from the same source material as the positive- tested PM have *E. coli* O157 below detectable level.

During a HEP situation, primal and sub-primal cuts linked in time and space to positive lots of PM may be considered adulterated because they were prepared under unsanitary conditions and therefore might be expected to have higher than normal levels of contamination. Some of the factors considered in this determination will be:

1. rate of PM *E. coli* O157 positives during the HEP;
2. magnitude of process deviations during the HEP;

3. microbial test results on primal and sub-primal cuts, if applicable, and other relevant test results;
4. interventions, for example: antimicrobials applied to primal and sub-primal cuts;
5. cross contamination controls; and
6. end use of primal and sub-primal cuts.

Suspect primal and sub-primal cuts and other intact raw beef with or without antimicrobial application may be released when subjected to a sampling and testing procedure which has been approved by CFIA inspection staff.

The actions taken in response to a HEP situation will depend upon the findings of the investigation of the positive results. As a follow-up action, the operator may consider increased testing after experiencing HEP, however if the establishment is able to find the root cause of HEP and takes corrective actions to prevent positive results from recurring, then an increase in testing would not be required. This increase in testing can be achieved by either defining smaller lots of trimmings (one combo bin instead of five combo bins) or selecting additional samples from five combo lots (e.g., N-75 instead of N-60) and should continue until the establishment has a high degree of confidence that the corrective actions are effective. Additionally, operator may increase monitoring and verification of both slaughter and dressing procedures, implement additional antimicrobial interventions and test additional products.

10.0 CFIA's Actions During Extended Non-Compliance

CFIA may perform HACCP System and Design and Reassessment Tasks in cases of extended non-compliance indicated by, but not limited to recalls, port-of-entry violation, systemic HEP and open CARs related to sampling, prerequisite programs and CCPs associated with *E. coli* O157.

Appendix 1: Validation of Pathogen Reduction Step(s)

Validation of in-plant pathogen reduction step(s) must be performed as per the Food Safety Enhancement Program (FSEP) approach. FSEP defines validation as obtaining evidence that a control measure, if properly implemented, is capable of controlling the hazard to a specified outcome. In this case, this means performing the following steps (as applicable).

Pre-validation step

The operator needs to determine and clearly identify in its HACCP system the intervention or the series of interventions that will be resulting in the reduction of *E. coli* O157 contamination to below detectable level and determine which one(s) will need to be validated accordingly. As appropriate, the operator should ensure compliance of the intervention(s) used with the corresponding requirements of Chapter 17 of the MOP for microbial controls including the assurance that all chemicals used for antimicrobial interventions are used in accordance with Health Canada's assent.

Step 1 Gather scientific support documentation

The first step is to gather published scientific or technical information and literature indicating effectiveness of the intervention against *E. coli* O157. To the extent possible, the literature should also prove effectivenessof the intervention against indicator organisms. The scientific documentation should also provide relevant information with respect to critical operational parameters that need to be adhered to in order to achieve the desired food safety outcome.

Examples of critical operational parameters that may apply for the validation of a particular antimicrobial intervention include: pressure, temperature, time, chemical concentration, pH, contact time, carcass coverage by the product, spatial configuration, equipment design, settings or calibration, dwell time, water activity during drying and log reduction of targeted microorganisms.

Validation documentation gathered in another establishment can form the basis for completion of the first step of the validation process provided all the critical operating parameters are the same in both plants. Note, however, that this does not exempt from completing the subsequent step(s) necessary for validation of the selected intervention(s).

A copy of all the supporting documentation must be available on site for audit purposes. The operator must have the printed, hard copy or the actual electronic copy of any scientific literature and information used for this purpose included in the establishment validation documentation package.

Step 2 On-site validation of the pathogen reduction step

The operator must demonstrate that the intervention is effective under the establishment operating conditions. This particular step is important because often laboratory conditions described in the literature are highly controlled as compared to the actual conditions in the establishment. The data should be gathered within the initial 120 days of implementing the new intervention or series of interventions to demonstrate that pathogen reduction capability is effectively achieved. The data becomes part of the documentation in support of validation.

a. Critical Operational Parameters

The operator must first identify all the relevant critical operational parameters associated with the intervention(s) that need to be evaluated as part of the initial validation process. These are identified from the selected scientific literature gathered as part of step 1. Not all critical operational parameters described in this literature will be assigned a critical/acceptable limit and eventually be associated with on-going monitoring activities as part of the control measure and be incorporated as part of the written control program. However, all critical operational parameters cited in the scientific support documentation that apply to the design of the validation should be evaluated and documented as part of the initial validation process and thereafter reassessed only as required. For example, installation of equipment may require a specific

configuration for the intervention to be effective, however, since it is not a critical operational parameter that will be eventually associated with the control measure (i.e., the operator may not plan to implement on-going monitoring activities for such parameter as part of its HACCP system), it needs to be only documented in the operator's internal records as part of the initial validation documentation and only reassessed if and when the equipment configuration is extensively modified.

Once these critical operational parameters are identified and incorporated to the HACCP system, the operator must be able to demonstrate that these same critical operational parameters can be implemented and maintained in actual in-plant processes. The operator shall be able to demonstrate within a 120 days period of initial validation that:

- Accurate observations of these parameters can be captured on an on-going basis to ensure the equipment/intervention is capable of meeting the selected critical/acceptable limits referenced in scientific literature; and
- Such observations are effective enough to detect any loss of control at the control measure before the finished product leaves the control of the producing establishment.

These observations would include evaluation of data gathered as part of the monitoring and verification, both of which should be performed at enhanced frequencies during this validation period.

Note:

Data collection procedures for measuring the critical operational parameters should be similar to those described in the reference scientific/technical literature and, any key measurements should be taken as close to the product contact point as possible, where applicable.

As a matter of principle, it could be acceptable to have proposed critical parameters which would be greater than those listed in the literature as long as these are expected to contribute to the desired outcome. The operator should be able to provide a rationale for doing so and ensure that this practice does comply with other regulatory requirements (e.g., using a higher concentration of a chemical). CFIA may request additional validation studies on a case-by-case basis, if critical parameters are not implemented in the same or a similar manner by the operator as described in the literature. An example of additional validation requirement could be the intensified microbiological testing to be conducted and documented by the operator to ensure the modified implementation achieves the desired outcome.

b. Microbiological testing data

The operator must gather microbiological testing data, using appropriate indicator organism(s), in order to demonstrate the effectiveness of the intervention or series of interventions. The intervention(s) that the operator has chosen to implement must be capable of reducing a suitable indicator organism by "X" logs under the actual in-plant operational conditions. For example, generic *E. coli* or *Enterobacteriaceae* is expected to be reduced by "X" logs by the intervention "Y".

For the purpose of this section, a suitable indicator can be defined as an organism, if present, may indicate the possible presence of *E. coli* O157. A suitable indicator should share some characteristics with the identified pathogen (e.g., heat resistance, growth range, pH range, ability to grow on selective media, etc.). In the case of *E. coli* O157, organisms associated with the gastro-intestinal tract of food animals such as *Enterobacteriaceae*, coliforms, and generic *E. coli* are appropriate choices for suitable indicator organisms. Indicator organisms recovered by performing aerobic or total plate counts (APCs or TPCs, respectively), have also been used in the scientific literature as possible indicators where microbial counts of organisms associated with the gastro-intestinal tract of food animals are too low and make it difficult to determine statistical significance of a paired study. The operator should have supporting documentation showing that the indicator organism selected is suitable to validate the selected intervention(s). **Note that *E. coli* O157 must not be introduced for experimental or validation purpose in registered establishments.** Validation design using more than one indicator organism is strongly recommended.

Sampling Protocol

The evaluation is normally done by comparing indicator levels in a sample taken before and after the intervention(s). The operator must choose a statistically significant sample size and time-frame within a defined period (up to 120 days) to demonstrate that the intervention being validated is achieving a targeted log reduction or a statistically significant log reduction while taking into consideration of potential day-to-day variation that could occur within the slaughter and intervention process. For example, an operator of a small volume production establishment cannot sample 15 carcasses during one full day of production and expect this to be considered statistically valid. In this case, it is recommended that the carcasses be randomly distributed and sampled on a weekly basis for a total of 15 weeks.

Carcasses should be randomly selected over the validation period. Days, and hours within a day, should be determined in advance to create a sampling plan. At collection time, carcasses should be selected in a blind manner, for example, sample the 5th carcass after the selected carcass. As a principle, the selection of side A or B should be alternated from one selected carcass in the sampling plan to the next one for the indicator organism testing before the intervention step being validated. This means side A (right or left) should be sampled for the indicator organism testing before the intervention step and side B (left or right) of the same carcass should be sampled after the intervention step. Then, for the next carcass identified in the sampling plan, side B should be sampled first, before the intervention step and then side A, after the intervention step. The operator can refer to Annex T of the United-States section of Chapter 11 of the Meat Hygiene Manual of Procedures for an acceptable sampling methodology. Note that operators may choose another methodology, for example, sample a larger area, based on the information provided in the scientific literature.

Table 1 is presenting scenarios of potentially acceptable minimum sampling size based on the type of intervention for the purpose of validation testing. Group 1 represents standardized interventions for which the majority of scientific literature exists. These interventions can include automated systems in common use and requires the smallest sampling sizes because of a high degree of consistency of equipment and processes and therefore, a very low variation in the

process if managed adequately. Group 2 represents non-automated, modified systems and requires an increase in sampling size because of decreased consistency of equipment and processes when compared to Group 1 interventions. Group 3 represents novel interventions and will require the greatest sampling intensities, including possible microbial testing for the presence/absence of *E. coli* O157 on a case-by-case basis.

In some occasions, a larger number of samples may be required to establish statistical validity to assure a high level of confidence of the microbial reduction effect of the intervention being validated. An operator may elect to develop a different sampling plan as to what is proposed in this section. This approach should be reviewed and discussed with the local Veterinarian In-Charge, in consultation with the Area Program Specialist and/or the Area FSEP Coordinator.

Note:

In the context of this policy, if an operator is slaughtering cattle and other species, only data gathered from bovine species will be considered valid.

Table 1: Number (n) of beef carcasses to select for the validation of microbiological reduction interventions based on indicator counts

N	n for Group 1	n for Group 2	n for Group 3
100,000	15	133	237
50,000	15	133	236
25,000	15	133	235
10,000	15	132	231
5,000	15	130	226
1,000	15	118	192
500	15	105	161
100	13	57	71
50	12	37	41
25	10	21	23
10 or less	6 or less	9 or less	10 or less

Confidence interval +/- 0.5 log on the difference of indicator organism log counts with 95% Confidence Level

n = Number of beef carcasses to be sampled over a four-month period according to the four-month production volume (N)

N = Production volume (Total number of carcasses) over four months

Group 1 = Standardized intervention, fully automated equipment, for which significant amount of literature/science is available; the operator follows the critical parameters required as dictated by the literature references, for example, steam pasteurizers, mechanical device spraying lactic acid using a specific concentration and temperature.

Group 2 = Intervention that is not fully automated which could lead to an inconsistency in the application of the antimicrobial intervention over carcasses, for example, the application of lactic acid using an hand sprayer; or proposal of a significant modification of a particular critical parameter provided in the literature; or the use of equipment does not have monitoring devices for all critical parameters provided in the literature.

Group 3 = Novel interventions, very limited literature in existence and/or intervention still to be evaluated or approved by regulatory authorities, for example, irradiation of meat products.

Notes:

- If the lot size, specifically the number of animals slaughtered falls between two values appearing in first column, the highest number should be selected in order to determine the sample size.
- It is the prerogative of each individual company to decide if they want to use an accredited laboratory or not for the testing of indicator organisms. Acceptable methods can be found in the Health Canada Compendium of Analytical Methods. The "application" section of the method chosen must be appropriate for the intended purpose.

Statistical Evaluation

To assess the efficacy of the reduction intervention beyond chance, it is recommended to use a paired t-Test. The pathway for this statistical test is available in Excel (as an Add-In) under Tools / Data Analysis / t-Test: Paired Two Samples for Means. The Input Variable 1 Range should correspond to the values of EB counts before the intervention. The Input Variable 2 Range should correspond to after EB counts. The Hypothesized Mean Difference should be set to 0, and the Level of Signification (Alpha) to 0.05. Successful interventions should result in a P value inferior to 0.05.

Step 3 Carcass Testing for *E. coli* O157 for establishments validating certain non-standardized and novel interventions.

Because of the expected variability of *E. coli* O157, and considering the low prevalence of this pathogen in raw beef products, an operator using interventions described as Group 1 or 2 may be exempted from performing carcass testing on *E. coli* O157 as part of the validation process. This exemption may be permitted as long as microbial reduction results on carcasses obtained during Step 2 (indicator organisms) are in keeping with the published scientific or technical information and there is a robust day-to-day monitoring and verification system downstream in place to support it. For example, N-60 sampling procedures and results on trims downstream may provide sufficient indication and confidence that the implemented selected intervention is reducing *E. coli* O157 below detectable levels, and as a result, is working as intended. The operator must be aware that any positive test results downstream during the validation period must be carefully analyzed as part of the HACCP system. Any non-compliance on that aspect could potentially trigger the need for revalidation of the intervention.

On a case-by-case basis, CFIA may require an operator to perform some level of validation sampling on carcasses for *E. coli* O157 for in depth evaluation of novel intervention(s) in order to demonstrate that the intervention(s) actually achieves a reduction of *E. coli* O157 to below detectable levels. Operators will be required to develop the data within the initial 120 days of implementing the new intervention or series of interventions, in conjunction with the indicator organism testing on carcasses in Step 2. Sampling protocol and methodology will need to be agreed upon with the appropriate representatives of national authorities (e.g., CFIA Meat Hygiene Division and Health Canada). Any analytic method chosen will be one of the accepted official Health Canada methodologies. See Appendix 2 of this Annex for acceptable testing methodologies. If an external accredited laboratory is to be contracted, the results, specifically laboratory tests/certificates, will have to indicate which of the approved methods was used to analyze the samples.

Re-validation

The *Guidelines for the Validation of Food Safety Control Measures* from the List of Standards proposed by the Codex Alimentarius, provides some examples of situations where revalidation must be considered.

Many factors can influence the need to revalidate an intervention or series of interventions. The need for revalidation should be identified by the operator, when required, following regular monitoring and verification activities. Any unusual trends can lead to a possible revalidation of the microbial control intervention. In addition, the review of new scientific data, substantive changes in operating conditions (e.g., change in the intervention chemical used), addition of a pathogen intervention or step to the already validated intervention(s) or modification of the intervention in a novel manner, may lead to changes to previous validation conclusions. The plant management and VIC/IIC may consult with the Area Program Specialist and/or the Area FSEP Coordinator regarding the need to revalidate a pathogen reduction step.

Appendix 2: Testing Considerations for *E. coli* O157

This appendix applies to carcass, PM and FRGBP testing.

A. Sample pick-up

The collected sample must be representative of the lot being tested and must meet the screening methodology specifications.

B. Screening methodology (optional - the laboratory may proceed directly to confirmation)

Testing with both screening and confirmation methodologies must be performed in a laboratory accredited by the Standards Council of Canada (SCC), the Canadian Association for Laboratory

Accreditation (CALA), or another accreditation body that is a signatory to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Agreement (MRA) as conforming to the requirements of ISO/IEC 17025:2005 for specific tests.

A presumptive positive result will be considered positive (i.e., to correspond to a confirmed positive test result for *E. coli* O157) unless the sample proceeds to the confirmation method as described in Section C (Confirmation Methodology Requirements).

For ground beef/pattie, five sample units of 65 g each must be tested (65 g taken from each of the five sample units submitted), representing a total of 325 g of meat product. This may be tested as a composite of 325 ± 32.5 g, unless otherwise specified in the test method used.

For beef trim or trim component samples consisting of 60 intact pieces of trim, an analytical unit must be taken from each of the 60 pieces of trim to make up a total of 325 g of meat product for analysis. This may be tested as a composite of 325 ± 32.5 g, unless otherwise specified by the test method used.

Approved methods can be obtained from the Health Canada Compendium of Analytical Methods site. Note that the most recent published version of the method should be used. The "application" section of the method chosen must be appropriate for the intended purpose.

Contact the CFIA, Food Safety Science Directorate, Executive Director, for the CFIA requirements to demonstrate equivalency of methodology not published in the Compendium of Analytical Methods.

Note:

Additional requirements may apply when testing product for export to other countries. Operators must follow MOP Chapter 11 Guidelines for testing of meat products for export to other countries, such as the United States of America.

Methods listed in MOP Chapter 11 may contain methods that are not published in the Compendium of Analytical Methods (e.g., MLG FSIS methods) or some of the same methods with alternate dilutions and/or sample sizes identified. These will be considered acceptable only for products that are exclusively exported to the United States, or other countries (as applicable). Note that not all methods published in the Compendium of Analytical Methods are accepted for exports purposes.

C. Confirmation methodology requirements

The following method or equivalent[Footnote 2] is acceptable:

- MFHPB-10 - Isolation of *Escherichia coli* O157:H7/NM from foods and environmental surface samples

The above analytical method can be obtained from the Health Canada Compendium of Analytical Methods site. Note that most recent published version of the method should be used.

The confirmation test must be done from the same broth that was tested presumptive positive by the screening test. The confirmation procedure must commence within 24 hours of the initial positive screening result.

Note:

Mandated testing, both screening and confirmation, must be performed in an accredited laboratory.

There is no requirement to perform the non-mandated testing in an accredited laboratory. However, if the laboratory reports a presumptive positive result for non-mandated testing this will be considered as either a presumptive positive result pending confirmation or a presumed to be positive result as per operator's written program. If the operator wishes to pursue cultural confirmation in order for the CFIA to consider the sample as "not detected," then confirmation testing must be performed on the original enrichment broth within 24 hours of obtaining the presumptive result, and must be performed in an accredited laboratory by the confirmation methodology described above (MFHPB-10).

Appendix 3: Suggested High Event Period (HEP) Numerical Criteria

The following table is provided to help establishments determine whether they have experienced a HEP. The table provides numbers of positive results (the first column) occurring within a specified number of samples (entries in the remaining columns), that would indicate that the percent positive of *E. coli* O157 findings would be statistically significantly greater than or equal to 5%, at the following percent confidence intervals:

- 95% confidence;
- close to 98.85% confidence; and
- close to 99.95%.

Table 1. Number of *E. coli* O157 positive lots which indicate that the positive rate is statistically significantly greater than or equal to 5% at different confidence intervals

Number of positive lots Table Note 3	**Total number of lots required to be tested at different confidence intervals 95%**	**Total number of lots required to be tested at different confidence intervals 98.85%**	**Total number of lots required to be tested at different confidence intervals 99.95%**
2	7	3	
3	16	10	4

4	28	18	8
5	40	27	14
6	53	38	21
7	67	49	30
8	81	61	38
9	95	74	48
10	110	86	58
11	125	100	68

Table Notes

Table Note 3

The test result from one composite sample is considered one positive or "not detected" result.

Return to table note 3 referrer

If there were four or more positive results within 28 samples, then there would be 95% confidence that the process positive percent was not less than 5%. If there were four or more positive results within 18 samples, then there would be 98.85% confidence that the process positive percent was not less than 5%. If there were four or more positive results within eight samples, then there is 99.95% confidence that the positive percent was not less than 5%.

At a lower confidence level, an HEP will get detected at a lower observed positive rate and the chance of releasing an adulterated product into commerce is minimized. For example:

1. At 95% confidence level, an HEP will get detected when five out of 40 lots test positive.
2. At 98.85% confidence level, an HEP will get detected when six out of 38 lots test positive.
3. At 99.95% confidence level, an HEP will get detected when eight out of 38 lots test positive.

The CFIA requires establishments to take action if sampling of PM produces a positive rate statistically significantly greater than or equal to 5%. They may wish to choose more stringent criteria, for example, an establishment may decide to declare an HEP if the percent positive exceeds 3.5%. If table above does not meet an establishment's needs for determining HEP, the establishment may develop alternate proposals. Such proposal must be presented to CFIA for approval.

Acknowledgement: The statistical confidence intervals presented in Table 1 have been excerpted from the United States Department of Agriculture - Food Safety Inspection Service (FSIS) Compliance Guideline for Establishments Sampling Beef Trimmings for Shiga Toxin-Producing *Escherichia coli* (STEC) Organisms or Virulence Markers - PDF (530 kb)

Footnotes

Footnote 2

"or equivalent" – contact the CFIA, Food Safety Science Directorate, Executive Director, for the CFIA requirements to demonstrate equivalency of methodology not listed as acceptable in this document.